RAC/M/14/2010

FINAL

21 February 2011

Minutes of the 14th meeting of the Committee for Risk Assessment (RAC) (7-10 December 2010)

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. Two advisers, three invited experts, seven stakeholder representatives (from BusinessEurope, CEFIC, ECETOC, ECPA, EMCEF, EuCheMS and Eurometaux), four observers accompanying stakeholder observers (STO), three representatives of dossier submitters and two representatives from the Commission were welcomed.

For this meeting some participants took part in substance related discussions as remote participants via the WEBEX connection. This included: representatives of Member State Competent Authorities (MSCA) from France and Norway and one adviser to a RAC member. Apologies were received from four RAC members and three regular observers (ECEAE, ETUC and OECD). 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 Agenda was adopted as proposed by the Secretariat. 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. Six members and one stakeholder observer declared potential conflicts of interest to the substance-related discussions in the agenda items 7.1a (one member), 7.1b (one member), 7.1c (one member, one observer), 7.1d (one observer), 7.1g (one member), 8.1c (two members), 8.2 (one member).

4 Adoption of the draft RAC-13 Minutes

The Chair introduced the revised minutes, incorporating the comments received from members. RAC adopted the revised minutes with some comments from RAC members.

5 Administrative issues and information items

Administrative issues and information items (a-c) were covered by a room document (RAC/14/2010/58). 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.

Concerning the item d the Secretariat informed RAC about a forthcoming Annual satisfaction survey and invited members and STOs to reply to the survey before the end of the year.

6 Renewal of RAC Membership

The Secretariat reported to RAC on the ongoing activities related to the renewal of RAC membership. It was noted that, following the nominations of the Permanent Representations of the Member States received by 15 November 2010, the Management Board is expected at their meetings in December 2010 and in March 2011, to take decisions on the appointment of the nominated new candidates for RAC membership and on a renewal of current RAC members whose 3-year term will expire by end of June 2011. RAC will be further updated on the issue at its next plenary meeting in March 2011.

In addition, as agreed at RAC-12, in accordance with document RAC/12/2010/37, RAC agreed to invite three of its members with soon expiring membership to continue their rapporteurships on the ongoing dossiers until the adoption of the RAC opinions on these proposals.

7 CLH Dossiers

7.1a Hexabromocyclododecane (HBCDD) (CAS No. 25637-99-4 and 3194-55-6)

The Chair noted that an observer accompanying the regular CEFIC observer was registered for participation in this agenda item; however, the person was not able to attend the meeting or the discussion, due to the ongoing Finnair strike.

The rapporteur presented the key elements of the revised draft opinion and its annexes, developed with the support of the ad-hoc working group, and clarified the conclusions in the draft opinion regarding the HBCDD effects on fertility, its developmental toxicity and its adverse effects on or via lactation.

RAC was also informed of the late industry comments on this draft opinion submitted the day before the meeting via the regular RAC observer from CEFIC. Following the established working approach, comments were forwarded to the rapporteurs and after their agreement they were made available to all RAC members. In this regard, the Chair reminded the RAC stakeholder observers that the submission of such late industry comments so close to the adoption of a RAC opinion on a proposal should be avoided, as it is difficult for the rapporteurs and RAC members to consider them in the final opinion documents.

Further, the observer from CEFIC presented these industry comments, highlighting their concerns on the application of the classification criteria in this particular case.

The rapporteur orally responded to all the comments, clarifying the considerations behind the proposed classification and the provided justification in the revised draft opinion.

In conclusion, RAC adopted by consensus the revised draft opinion and its annexes on the CLH proposal for this substance with minor modifications. The proposed classification is presented in table 1 of Part II of this document.

The Chair thanked the rapporteurs and the members for the fruitful work on this CLH proposal and for the consensus adoption of the RAC opinion on HBCDD.

7.1b White spirit dossiers (CAS No. 8052-41-3, 64742-82-1, 64741-92-0, 64742-48-9, 64742-88-7; EC No. 232-489-3, 265-185-4, 265-095-5, 265-150-3, 265-191-7)

The Chair welcomed two experts from the Danish Competent Authority and introduced an observer accompanying the CEFIC stakeholder observer.

Building on the RAC-12 discussion regarding the classification proposal as STOT RE 1 (neurological effects), the rapporteurs presented information received from the dossier submitter and industry and other relevant data. The composition of solvents placed on the market had evolved – from those with a higher aromatic content, to those with a lower, more aliphatic one, for example type 3 white spirit. The Committee then discussed the possible relevance in terms of exposure assessment in the epidemiological studies supporting the classification and the grouping justification. The impact of aromatic content on effects was also discussed. In a closed session the ECHA Secretariat provided information on the state of play of registration for these substances.

With the support of an ad-hoc working group meeting, RAC concluded, like IPCS[1] or SCOEL[2], that there is an association between exposure to white spirits and chronic encephalopathy. It was also clear that there are no single constituents for which a hazard can be defined. Therefore acknowledging uncertainties, RAC considered the whole UVCB substance responsible for effects observed following exposure. Such relationship between exposure to white spirit and effects is shown in epidemiological studies for Stoddard solvent, type 0 and type 1 white spirit. Therefore RAC members agreed to group these three substances into one opinion. RAC members initially supported the rapporteurs' proposal to classify these three white spirits as STOT RE 1 (neurological effects). RAC members asked the rapporteurs to describe uncertainties and confounding factors related to the epidemiological studies when assessing the relevance of data in the opinion documents.

RAC members supported the way forward to separately assess the type 2 and type 3 white spirits, either together or individually, at a later stage. Epidemiological studies did not include type 2 or type 3 white spirits and further consideration was needed to determine their classification. The Chair invited stakeholders to assist the rapporteurs by providing any further available information on the link between hazard properties and types 2 or 3 white spirit to supplement information provided during the public consultation. The Chair also invited the rapporteurs to provide revised opinion(s) and annexes for discussion at RAC-15 (see 7.1b of Part II of this document).

7.1c Metazachlor (CAS No. 67129-08-2; EC No. 266-583-0)

The Chair introduced an observer accompanying the sector-specific ECPA observer.

In the previous RAC meeting members raised the issue of possible classification for fertility and it had been decided that this should be discussed in RAC-14. The Chair invited rapporteurs to present the data on fertility and the environmental classification

[1] International Programme on Chemical Safety
[2] Scientific Committee on Occupational Exposure Limits

considering comments received from RAC members on the first draft opinion. Classification for fertility was discussed and it was agreed that classification is not justified because the fertility effects observed were secondary to the reduced food consumption and lower body weights.

RAC provisionally agreed on the environmental classification as indicated in Table 2 of Part II, conclusion and action points.

The Commission suggested adding the assessment of the skin sensitisation data with the new criteria according to the second Adaptation to Technical Progress ATP for environmental classification (see 7.1c of Part II of this document).

7.1d Flufenoxuron (CAS No. 417-680-3; EC No. 101463-69-8)

The Chair welcomed the representatives of the dossier submitter from the French Competent Authority (MSCA) who took part in the discussions as remote participants and introduced an observer accompanying the sector-specific ECPA observer.

The rapporteurs were invited to present the revised draft opinion to RAC. The discussion moved forward regarding lactation effects, developmental toxicity and repeated dose toxicity. The need for further elaboration was expressed on several issues including the effects on lactation (milk quality and/or pups exposure to the substance), mutagenicity effects and addressing concerns raised from the study in dogs.

Regarding the environmental classification, RAC assessed the information and noted that the chronic classification and M-factor according to the chronic classification criteria (2nd ATP) should be similar to the classification already agreed at RAC-13.

The Chair thanked the rapporteurs for preparing the draft documents. The rapporteurs will consider the comments received and revise the draft opinion documents if needed, and subsequently submit them to RAC as indicated in section 7.1d of Part II of this document. The substance will be further discussed and possibly adopted at RAC-15.

7.1e PHMB (CAS No. 27083-27-8 or 32289-58-0; EC No. n. a (polymer))

The Chair welcomed the representatives of the dossier submitter from the French Competent Authority who took part in the discussions as remote participants and introduced an observer accompanying the stakeholder observer from CEFIC.

The Chair informed RAC about a request from industry to ECHA to withdraw the PHMB CLH dossier and clarified that only the dossier submitter can decide to withdraw the dossier.

The rapporteur was invited to present the revised draft opinion to RAC. The discussion focused on carcinogenicity and inhalation toxicity.

The accompanying observer from CEFIC explained that the proposed classification for carcinogenicity (Carc. 2 - H351) is not justified because of the excessive doses, well above the maximum tolerated doses. The observer also stressed that the observed mode of action is not relevant for humans and that analysis of the available studies

show no statistically significant differences between treatment groups and controls, when the top dose level results are disregarded.

The discussion on carcinogenicity remains open. The Secretariat will check if the information provided during public consultation was considered in the resubmitted dossier and ask France for further available information and full study reports on cancer studies. RAC members indicated that France might not have full reports available.

Regarding inhalation toxicity, the observer explained that the sign of irritation were resolved by the end of the recovery period and that this would support the removal of the H372 classification.

RAC provisionally agreed on the classification for several hazard classes as presented in Table 2 of Part II of this document.

The Commission suggested adding the assessment of the data with the new criteria according to the second ATP on skin sensitisation.

7.1f Chloroform (CAS No. 67-66-3; EC No. 200-663-8)

The Chair welcomed an adviser to the rapporteurs who took part in the discussions as remote participant. The rapporteur was invited to present the revised draft opinion to RAC. The discussion focused on the mutagenicity endpoint.

Concerning the mutagenicity classification that had been proposed, RAC discussed the application of the CLP criteria to chloroform. Due to the unusual range of negative and positive *in vitro* and *in vivo* somatic cell results (i.e. effects only seen in kidneys), and the negative germ cell test results, some members casted some doubt on whether chloroform could interact with DNA in germ cell, and be classified as a mutagen. This view was supported by the CEFIC observer. Some members also commented that chloroform is one of the few typical examples of secondary carcinogens. Other members focussed on the fact that chloroform did appear to have mutagenic potential in some studies and be able to reach testes, and argued that this merits classification.

It was agreed that the rapporteurs would look again at the available data, especially the pivotal study by Robbiano et al. (1998), and list separately positive and negative evidences. The Chair thanked the rapporteurs for preparing the draft documents. The rapporteurs will consider the comments received and revise the draft opinion documents if needed, and subsequently submit them to RAC as indicated in section 7.1b of Part II of this document. The substance will be further discussed and possibly adopted at RAC-15.

7.1g 4-tert-butylbenzoic acid (CAS No. 98-73-7; EC No. 202-696-3)

The Chair invited the RAC rapporteur to present the first draft opinion on the CLH proposal submitted by Germany. A harmonised classification and labelling for this substance had been agreed at the Technical Committee for Classification and Labelling (TC C&L) under the previous legislation. The current classification proposal does not however cover environmental hazard classes concluded at TC C&L.

The Chair thanked the rapporteur for the presentation and invited RAC members to provide comments on the first draft opinion and its annexes by the date indicated in section 7.1g of Part II of this document.

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

Room document RAC/14/2010/67_rev1 was introduced by the Chair who explained that (co-)rapporteurs are required for seven new submissions and 21 new intentions for submissions of CLH dossiers that had been received since the last meeting. Furthermore, vacant places for 29 intentions received before RAC-13 remained to be filled. RAC agreed to appoint as (co-)rapporteurs 14 members that had volunteered during RAC-14 for (co-)rapporteurship on 35 substances. RAC members were invited to come forward for the other dossiers. RAC members mentioned that in deciding to volunteer as (co-)rapporteurs it is essential to know about the intended classification. For the purposes of planning, it is also essential to have access to dossiers as soon as they are submitted. The Chair agreed to these concerns and proposed that these issues will be directly discussed with the dossier submitters at the workshop "On the way to CLH" (see 7.3b).

7.3 General CLH issues

7.3a State of play of the submitted CLH dossiers

RAC was informed by the Secretariat on the state of play of the submitted CLH dossiers as provided in a room document (RAC/14/2010/68). Members were invited to contact the Secretariat if they needed further clarification. A member pointed out the rapporteur´s need for knowing if and when a dossier submitter will re-submit a dossier after accordance check, for planning of the workload.

7.3b Analysis of adopted CLH opinions and preparation of the workshop for presenting the guidance document on the preparation of CLH dossiers

RAC was provided by the Secretariat with an update on the state of play of the planning of the workshop "On the way to CLH" that will take place on February 16, 2011, back-to-back with an informal RAC meeting. The aim of the meeting was to facilitate the dialogue between dossier submitters of CLH proposals and RAC rapporteurs and members.

7.3c Preparation of the workshop on the classification and labelling of active substances in PPP scheduled for April 2011

The ECHA Secretariat updated RAC members on the preparations for the workshop.

They explained that the revised PPP Regulation[3] specifies strict criteria for the approval of active substances. In particular this Regulation provides that carcinogens, mutagens, endocrine disruptors, substances toxic for reproduction or which are very persistent will not be approved, unless exposure to humans is negligible. It also establishes a mechanism for the substitution of more toxic pesticides by safer (including non-chemical) alternatives. EFSA had given the German Federal Institute for Risk Assessment (BfR) a mandate to examine how the classification and labelling aspects will work in practice. Accordingly, MSCAs from both the classification and

[3] 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.

labelling and plant protection product disciplines had been invited to participate in the workshop.

The Chair noted that all RAC members were invited to attend the workshop which would be considered as a RAC activity. A representative from ECPA welcomed the event and indicated their wish to be invited as an observer. The Chair explained that since ECHA was not the only organiser, the participation of industry observers cannot be decided by ECHA.

7.3e Discussion of the application of the CLP criteria for reproductive toxicity

Following last meetings' discussions on the interpretation of the CLP and DSD criteria for reproductive toxicity, specifically for the borderline of differentiation between developmental toxicity and lactation effects, the Secretariat provided RAC with a starting point for discussion (room document RAC/14/2010/69). During the meeting the information of the room document was presented.

RAC members welcomed the overview in order to improve the discussions on these hazard classes on a case-by-case basis in the future.

The Chair thanked the presenter for their presentation and invited RAC members to provide any further comments on the room document.

7.3d Discussion of the application of the CLP criteria for germ cell mutagenicity

Following discussion at the last meeting on the interpretation of the CLP criteria of germ cell mutagenicity in comparison with the mutagenicity criteria under DSD, the Secretariat presented an overview of those criteria.

RAC members welcomed the overview of the criteria, although they mentioned that it will be important to provide examples on the application of these criteria on specific substances and test results. Hence discussions should be recorded on a case-by-case basis.

The Chair mentioned that the RAC manual of conclusions and recommendations (MoCR) is the appropriate place for recording the outcome of these future discussions.

The Chair thanked the presenter for their presentation and invited RAC members to provide any further comments on the presentation.

8 Restrictions

8.1 Restriction Annex XV dossiers

8.1a Dimethylfumarate (DMFu) – second draft opinion

The rapporteurs presented the key elements of the 2nd version of the RAC opinion on DMFu and their responses to the RAC members' comments on it. It was noted that the draft opinion had been modified according to the written comments from members. Furthermore, the rapporteurs asked for members' views on the proposed modified wording of the future restriction entry in Annex XVII with regard to the sampling.

The Commission observer clarified that the main contribution expected from RAC is to provide scientific and technical advice on the proposed restriction. In addition, RAC can suggest wording for the restriction entry. However, the final entry text will be formulated by the Commission.

One member suggested that sampling should be covered in the wording for "articles and parts thereof" with proper clarification provided in the opinion.

After a short discussion on the issue, RAC agreed to follow this suggestion and the rapporteurs were requested, taking into account the proposed approach, to prepare, the 3rd version of the DMFu opinion during the meeting. Further, it was noted that following the working procedure, the Secretariat is expected to forward to the Forum the 3rd draft RAC opinion and the rapporteurs' request for a 2nd advice on enforceability for further consultation.

The Chair thanked the rapporteurs and the other RAC members and noted that the discussion on the revised opinion documents is expected to continue at the preparatory RAC meeting in February 2011 and the adoption of this opinion is envisaged at RAC-15 in March 2011.

8.1b Lead and its compounds in jewellery – second draft opinion

The rapporteurs presented the key elements of the 2nd version of the RAC opinion on lead and its compounds and their responses to the RAC members' comments on it. It was noted that while the 2nd draft opinion was being developed, the rapporteurs considered the following main issues for discussion: determination of relevant/tolerable exposure levels, definitions of a limit value for lead concentration and a tolerable migration rate (2-step approach suggested on the basis of option 7 of the draft background document and IQ reduction calculated on the basis of the information on migration rates and the dose-response estimations presented in the EFSA opinion), as well as the differentiation between precious and fashion jewellery (the SEAC rapporteur questioned the dossier submitter's arguments that a distinction between fashion jewellery and precious jewellery as well as jewellery for children's use is not possible).

The neurological effect in children, and in particular the IQ lost, was considered the most relevant endpoint. No threshold has been established for this effect, and RAC considered the recent EFSA assessment and agreed to use as DMEL the 10% of the EFSA BMDL[4] (01). The proposed value of 0.05 μg/kg bw per day represented an estimated IQ loss of 0.1 points.

Regarding migration data, RAC noted the uncertainty associated to the Danish report data. A linear correlation at higher concentration between level of content and migration exists but it is not maintained at the lowest concentrations. Two approaches were presented, one the extrapolation of this linear correlation at the lower concentrations, assuming that measurements at low lead levels are subjected to high experimental errors. Another approach was based on the lack of correlation between lead content and migration, using an average migration value. Both approaches would be further considered in the revised opinion. Also a German report on exposure from lead would be looked into in the matter of content vs. migration.

[4] Benchmark dose level

It was highlighted that the draft opinion diverges from the original dossier submitter's proposal, where more specific values are used. Conversely, standard values are used in the 2nd draft opinion that is based on the EFSA opinion on lead. In addition, the rapporteurs expressed their views on the early comments received on this restriction proposal during the first three months of the ongoing public consultation and the lead industry comments on the 2nd draft opinion, provided by the regular RAC observer from EUROMETAUX.

In the following discussion, several members expressed concerns on the questions raised by the rapporteurs. They identified a number of issues for further clarification with regard to the development of the opinion, such as: a need for specifying the approach that should be followed, a need for clarity on the interpretation of the IQ data from the JECFA[5] report referred to in the draft RAC opinion, a need for discussion on hazards and adequately expressed exposure, and then a discussion on risk characterisation.

In addition, the importance to clarify the relevance of the distinction between precious and fashion jewellery was underlined for this restriction proposal or the differentiation between children and adult's jewellery. Following the discussion it was considered that the available information does not contain information for allowing separate risk assessments by RAC for children *versus* adult or precious *versus* fashion jewellery. These were identified as important issues for further consideration during the Commission's decision-making process.

The observer from EUROMETAUX recognised the reasoning of this approach; however, it was pointed out that it should be applicable to different material contents (lead as a pure content, lead as an impurity, or lead as an ingredient), since for alloys, linear relationships are not always applicable. Furthermore, the release from the material surface, incl. coating, and the one from material content should be considered. The Chair asked STOs to provide all available information through the ongoing public consultation.

The Chair suggested an ad-hoc working group to be convened to support the rapporteurs in risk estimations and exposure model development after the plenary discussion.

During the second plenary session on this substance, the rapporteur summarised the outcome of the ad-hoc working group discussion and presented to RAC the criteria for the exposure assessment and the criteria for risk assessment, as well as some general conclusions, as agreed by the ad-hoc working group participants for this particular proposal.

Furthermore, RAC agreed on the approach to be followed when developing the RAC opinion on this restriction dossier and requested the rapporteurs to follow it when preparing the 3rd version of the RAC opinion during the meeting.

During the third plenary session on lead, the rapporteurs introduced to RAC their 3rd draft opinion developed on the basis of the agreed approach and the RAC members' recommendations. Members were also informed of the rapporteurs' open questions to the Forum in relation to their request for a 2nd Forum advice on enforceability of the restriction proposal in the draft opinion.

[5] Joint FAO/WHO Expert Committee on Food Additives

RAC expressed its gratitude for the rapporteurs' work on the draft opinion and suggested some small editorial modifications. The Secretariat was asked to forward the 3rd version of the RAC opinion on lead to the Forum and to request 2nd Forum advice on the rapporteurs' open questions and the text of the actual restriction entry, suggested in Annex E.

Finally, the Chair thanked the rapporteurs and the members for the fruitful work done on this restriction proposal and encouraged RAC to send additional comments on the 3rd draft opinion as indicated in section 8.1b of Part II of this document.

8.1c Phenylmercury compounds – first draft opinion

The Chair welcomed the SEAC rapporteurs to the meeting.

A representative of the dossier submitter from the Norwegian Competent Authority (CA) presented the Annex XV dossier proposing restrictions on five phenyl mercury compounds and state of play. The RAC rapporteurs for the dossier presented the first draft opinion and specific key issues.

RAC discussed the scope of the restriction. Environmental degradation and common degradation pathway is pivotal to the choice of substances to be restricted. Therefore, gathering further information on these issues for the group of substances concerned was felt essential. On the question of whether the scope may be modified to include other (or all) mercury compounds the ECHA Secretariat clarified that the RAC opinion should be about the five proposed compounds and the identified risks. It can however point at the relevance of other substances and the possible need for further restrictions. It was also clarified that amounts exported from the EU were already included in the scope of the restriction by its current wording.

Then RAC discussed other key issues for the rationale of the restriction (PBT-like + LRT argument; global mercury strategy; difficulty of quantifying emissions and exposure).

Finally, some questions have been identified concerning the implementation of the restriction, such as the use of total mercury measurement, the test method, and rules for sampling and sample preparation. Concerning the delay before entry into force some RAC members also recommended investigating an alternative option (3 years delay + possibility of an extension to 5 years based on justified request).

Members were invited to provide their comments as indicated in section 8.1d of Part II of this document. On the basis of any early comments from the public consultation, the dossier submitter would draw up an early RCOM and background document in mid January 2011. A second rapporteurs' dialogue was scheduled for 25 January and a second version of the RAC opinion would be produced by mid February.

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

8.1d Mercury in measuring devices

The Chair welcomed one of the SEAC rapporteurs to the meeting.

A representative of the dossier submitter from ECHA Secretariat gave an introduction and state of play to the Annex XV dossier proposing restrictions on the placing on the market for several mercury in measuring devices for industrial and professional use.

The RAC rapporteurs for the dossier presented their appraisal of the proposal and the first draft opinion. They explained the proposed restriction was justified due to the effects of mercury and the availability and lower risks posed by the alternatives. Likewise, the widespread use of measuring devices containing mercury justified Community-wide action and the existing Community legal instruments were not adequate to reduce the risks posed by mercury in measuring devices. A restriction is already in place for measuring devices intended for sale to consumers without enforcement problems. In addition, a monitoring system for measuring devices, as part of RAPEX[6], has contributed to the successful enforcement of mercury restriction in measuring devices for consumer use.

RAC members raised a number of issues in relation to the first draft opinion. Members queried whether there would be remaining occupational health implications in relation to waste recovery if the proposed restriction went ahead and whether manufacturing for export would be covered by the proposed restriction. Members also noted that further details would be required on the alternatives such as the substances used in them and the associated occupational and waste risks.

The rapporteurs explained that occupational health implications for waste handling were likely to be addressed in the next version of the draft opinion. In addition, the waste handling aspects may be flagged as a concern to the Commission.

A representative of the dossier submitter clarified that the proposed restriction does not cover production of mercury measuring devices, and as a result possible occupational exposure from remaining production for export is not addressed. The reason was that export is covered by specific Community legislation banning the export of metallic mercury and certain mercury compounds from 15 March 2011, and this ban may be extended in the future to include devices containing mercury. It was clarified that for each step of the life-cycle, the background document will describe in more detail the risks of alternatives.

A representative from CEFIC noted that the dossier is predominantly qualitative for evident reasons since in this particular case it is clear that the risk of alternatives are several orders of magnitude lower than mercury. However, this dossier should not be a reference standard for future dossiers that might need a more quantitative approach to provide a firm basis for risk assessment.

The rapporteurs set out the timetable for the development of the RAC opinion. Members were invited to provide their comments as indicated in section 8.1d of Part II of this document. On the basis of any early comments from the public consultation, the dossier submitter would draw up an early RCOM and background document in mid January 2011. A second rapporteurs' dialogue was scheduled for late January or early February and a second version of the RAC opinion would be produced by mid February.

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

[6] RAPEX is the EU rapid alert system for all dangerous consumer products see: http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm .

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

The Chair informed RAC that four volunteers had come forward for both the rapporteur and co-rapporteur positions for the intended Annex XV dossier proposing restrictions for the following phthalates: bis(2-ethylhexyl) phthalate, benzyl butyl phthalate, dibutyl phthalate, diisobutyl phthalate (room document RAC/14/2010/70). Further, the Chair presented his recommendation and the reasoning behind it and asked RAC to appoint two of the volunteering RAC members as rapporteurs for this dossier. Finally, RAC agreed to appoint the proposed candidates as RAC rapporteurs for this restriction dossier.

8.3 General restriction issues

8.3a Update on intended restriction dossiers

RAC was informed that there are no new intentions for submission of Annex XV dossiers proposing restrictions in the Registry of Intentions.

8.3b Revision of the working procedure on conformity check

The Secretariat presented the revised draft RAC&SEAC working procedure on conformity check (document RAC/14/2010/59). It was clarified that the revision is done on the basis of the experience gained with the first four restriction dossiers, according to the agreement at RAC-11.

RAC agreed the proposed revised draft working procedure with a minor change.

8.4. Joint RAC&SEAC session

8.4a Role and scope of conformity checks of restriction dossiers

The Secretariat gave a presentation on the role and scope of the conformity check in light of the experiences gained from the first four restriction dossiers. The Committees were asked for their view on the revised templates and the explanatory documents.

The separation of the recommendations from the questions that cover the legal requirements of the conformity check was further discussed. Members pointed out that by separating the recommendations in a voluntary part, valuable input for the rest of the process would be lost. The recommendations that were made in the past four dossiers have in most cases turned out to be essential elements for the development of the opinion. They were considered to be useful in communication with the dossier submitter on further development on the dossier at an early stage in the process.

The Secretariat responded that the conformity check has its legal basis which limits what can be considered for a decision on non conformity at that stage of the process; a clear difference is needed between what is required and what is considered as desirable. Recommendations should be worked on in parallel to the conformity check; they are seen as a useful input for the work of the Committees after the conformity check.

RAC and SEAC agreed on testing the revised conformity check template (RAC/14/2010/61, SEAC/09/2010/30) and, the template for recommendations on

desired information regarding Annex XV dossiers proposing restriction (RAC/14/2010/62, SEAC/09/2010/31) and the explanatory note and guidance for the conformity check of Annex XV dossiers proposing restriction (RAC/14/2010/60, SEAC/09/2010/29) on the next restriction dossier and to adjust the documents further after this if needed.

8.4b Panel on the co-operation between RAC and SEAC – restriction dossiers for DMFu and lead and its compounds

During the joint RAC and SEAC session, the Secretariat organised a panel discussion on the issue on enhancing the opinion-making process by further improving the collaboration between the two Committees, and in particular the rapporteurs' one on the ongoing restriction dossiers. The aim was also to collect members' views on current experiences, the way practicalities are organised, the liaison with the Secretariat, the usefulness of the communication tools, as well as further needs and suggestions for improvement.

The Secretariat gave an overview of the feedback that had been collected previously concerning the collaboration between SEAC and RAC rapporteurs and the collaboration between the two Committees in general. During the discussion that followed members considered this feedback and made some general recommendations to improve the work in the Committees. It was stressed that a division of work and clear communication benefited the collaboration between rapporteur and co-rapporteur. Differences in backgrounds were in most cases thought to be an advantage as they ensure wider coverage of issues.

The Secretariat indicated the importance of commenting and discussing in the work of the Committees, stressing the need for considering the deadlines dictated by the REACH Regulation.

The Chair concluded that in general the collaboration between the Committees seems to work well. The Chair also emphasized the interest of other risk assessing bodies into the work of ECHA's Committees and the collaboration between both of them.

Finally, the Chair thanked all the participants for the interesting discussion and the good suggestions provided.

9 Authorisation

9.1 Revised draft conformity check template

Following the discussion at RAC-13 and subsequent comments (see RAC/14/2010/63), the Secretariat presented the changes to the draft template for conformity checks of authorisation applications (RAC/14/2010/64_rev1) which were editorial in nature.

One member queried whether reference could be made to risk management measures for alternatives in question 5b of the template. The Secretariat explained that the wording of the question followed the wording of the REACH Regulation and therefore the template cannot be changed. However, the importance of examining the risk management measures associated with alternatives was recognised and alternative ways of requesting clarification of this was currently being examined. The Chair

noted that the working procedure for developing an opinion (RAC/14/2010/65) provides for such information to be requested from applicants if necessary.

In the absence of any further comments, the draft template was agreed with the proviso that it may need to be modified in the light of experience with applications for authorisation.

9.2 Formulating a RAC opinion on authorisation applications

9.2a RAC working procedure for developing opinions for authorisation applications

The Secretariat introduced the revised working procedure (RAC/14/2010/65). Several minor modifications had been introduced into the procedure to take into account discussions in SEAC and in the ECHA Secretariat, in particular to provide the option for RAC members to give early comments on the authorisation application and to provide further flexibility on the number and timing of discussions in plenary sessions.

One member pointed out that additional specialist support may be needed by RAC to better assess the alternatives and therefore to process certain applications for authorisation. The Secretariat and the Chair explained that the starting point for further information on alternatives was the applicant and information that is provided during the public consultation process. In addition, the RAC stakeholder observers such as ETUC may also play an important role in this respect and RAC can enlist the support of invited experts and/or co-opted members, if necessary.

The working procedure was agreed with the proviso that it may need to be modified in the light of experience with applications for authorisation.

9.2b Format of an opinion and examples of conditions

The Secretariat presented the current state of the development of the format of an authorisation opinion (room document RAC/14/2010/71).

It was explained that the role of the RAC & SEAC opinion was to provide advice to the Commission to take the final decision in relation to applications for authorisation. The RAC opinion would be developed in close collaboration with that of SEAC and the presenter set out the possible elements to be included in the RAC opinion for seven scenarios covering both the adequate control route (Article 60(2)) and the socio economic analysis route (Article 60(4)). Key aspects for RAC in assessing the applications were for threshold substances: determining the level of *appropriateness* and *effectiveness* of the proposed risk management measures; and for non-threshold substances, deciding whether the risk management measures identified by the applicant are *sufficient* to mitigate against this/these risks or whether additional conditions should be suggested.

A discussion followed in which members focussed on the meaning of ‘sufficient’ in the context of limiting the risk of a non-threshold substance. Several members pointed out that the word *sufficient* implies making a judgement on what is an acceptable risk and, in this context, there may be a difficulty to decide whether exposure scenarios for non-threshold substances were appropriate. Another member

noted that, whilst the Commission takes the final decision, RAC members would still need guidance on what constitutes an acceptable risk. A number of editorial suggestions were also made by members to be taken up by the Secretariat.

The Chair highlighted the need to distinguish between the scientific assessment by RAC and the decision to be taken by the Commission. RAC would need to concentrate on verifying the effectiveness of the proposed risk management measures and the commensurate reduction in the risk entailed by authorising the use of a substance. The Secretariat also noted that RAC was also entitled to have a view on whatever remaining risk was foreseen with an application for authorisation and signal this to the Commission.

The Chair thanked the presenter for their presentation and invited RAC members to provide any further comments on the document as indicated in section 9.2b of Part II of this document.

10 Guidance issues

10a Feedback from guidance consultations

The Secretariat updated RAC about the reply to RAC comments received on two draft guidance documents, the draft Guidance for intermediates and the draft Guidance for exposure-based adaptation.

10b Report on other guidance activities

The Secretariat updated RAC about the ongoing guidance developments with a special emphasis on guidance documents that are relevant for the work of RAC.

11 Any other business

11a PBT workshop

RAC was informed that a PBT meeting has recently been organised by the Umweltbundesamt (UBA) in Dessau, Germany. Several Member States were represented at this forum to discuss the ongoing status of PBT evaluations as a result of test programs from the old existing substance regulation (ESR). Further discussion points were the understanding of the PBT criteria in the revised Annex XIII to the REACH Regulation, as well as specific technical information such as the interpretation of fish bio concentration data from feeding studies. More detailed information will be available in the report of the workshop that will be distributed by the organiser of the meeting shortly.

11b ECHA expert database

The Secretariat informed RAC members that they may propose experts with relevant background for the ECHA expert database.

12 Main conclusions and Action Points of RAC-14

The Secretariat presented the main conclusions and action points of the RAC-14 plenary meeting for final comments and agreement by the Committee. All suggestions 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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10 December 2010

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the 14th meeting of RAC)
(7-10 December 2010)

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/14/2010_rev.1) was adopted. Six members and one STO observer have declared a potential conflict of interest to different substance-related discussions under one Agenda item.	**SECR** to upload the adopted Agenda to the RAC CIRCA IG as a part of the RAC-14 minutes.
4. Adoption of RAC-13 Draft Minutes	
The minutes of RAC-13 (RAC/M/13/2010 final draft_rev.1) was adopted with small changes.	**SECR** to upload to the RAC CIRCA IG and the ECHA website the adopted minutes
7. CLH	
7.1 CLH Dossiers	
7.1a Hexabromocyclododecane (HBCDD)	
RAC adopted <u>by consensus</u> the opinion and its annexes on the CLH proposal for HBCDD. RAC agreed to propose HBCDD to be classified as indicated in the table below.	**SECR** to upload the adopted opinion on HBCDD and its annexes to the RAC CIRCA IG, to forward them to COM and publish them on the ECHA web site after the meeting
7.1b White spirit	
RAC initially supported the rapporteurs' proposal to classify stoddard solvent, white spirit type 0 and white spirit type 1 as STOT RE 1 (neurological effects). RAC members requested additional justification to address the uncertainties in the opinion and BD. RAC members agreed with the view of the rapporteurs that opinion(s) on white spirit type	**SECR** to request industry to provide further information. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) for **stoddard solvent, white spirit type 0 and white spirit type 1** and to provide the

2 and type 3 dossiers should be considered separately and need further elaboration.	proper justification by 14 January 2011. **Rapporteurs** to revise the draft opinion(s) documents (revised draft opinion and its annexes (BD and RCOM)) for **white spirit type 2 and/or for white spirit type 3** and to provide the proper justification before RAC-15. **SECR** to distribute the revised draft opinion(s) documents to RAC when available for further discussion and possible adoption at RAC-15.
7.1c Metazachlor	
Classification for fertility was discussed and it was agreed that classification is not justified. RAC provisionally agreed on the classification as presented in the table below. The classification proposal for carcinogenicity (Carc. 2) and skin sensitisation according to the second ATP will be discussed at RAC-15.	**Rapporteurs** to revise the draft opinion documents before RAC-15. **SECR** to distribute the revised draft opinion documents to RAC when available
7.1d Flufenoxuron	
RAC discussed the CLH proposal for health hazards based on the revised draft opinion. RAC agreed to continue the discussion on the classification for **- Lact. H362** **- Repr. 2 H361d** **- STOT RE2 (Red blood cells), H373**	**SECR** to inform the dossier submitter of the rapporteurs' request for the full study reports for developmental toxicity after the meeting. **Rapporteurs** to review the draft opinion documents before RAC-15. **SECR** to distribute the revised draft opinion documents to RAC when available
7.1e PHMB	
RAC provisionally agreed on the classification as presented in the table below. The classification proposal for carcinogenicity and potency on skin sensitisation according to the second ATP will be discussed at RAC-15.	**SECR** to check information provided during public consultation and ask the dossier submitter for further available information on carcinogenicity studies and if not available, to

	industry. **Rapporteurs** to revise accordingly the draft opinion and its annexes regarding carcinogenicity
7.1f Chloroform	
RAC discussed the revised draft opinion. RAC agreed to continue the discussion on the classification for **- Muta. 2, H341**	**Rapporteur** to revise the draft opinion documents by 15 February. **SECR** to distribute the revised draft opinion documents to RAC when available.
7.1g 4-tert-butylbenzoic acid	
RAC was presented the key elements of the first draft opinion for this substance.	**Members** to provide their comments on the draft opinion by 7 January 2011 via the respective RAC CIRCA IG newsgroup. **Rapporteurs** to consider the comments received and if needed to modify the draft opinion documents by 15 February. **SECR** to distribute the revised draft opinion documents to RAC when submitted.
7.2 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/14/2010/67_rev1).	**SECR** to upload in RAC CIRCA IG 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.
7.3 General CLH issues	
d. Discussion of the application of the CLP criteria for reproductive toxicity e. Discussion of the application of the CLP criteria for germ cell mutagenicity	**Members** to post their comments on the provided RAC-14 presentations on these issues and on the room document RAC/14/2010/69 by 1 February 2011.

8. Restrictions	
8.1 Restriction Annex XV dossiers	
8.1. a DMFu	
RAC agreed on the approach to be followed in the RAC opinion with regard to the wording of the proposed restriction for DMFu and requested the rapporteurs to follow it when preparing the 3rd draft opinion.	**Rapporteurs** to prepare the 3rd draft opinion documents on DMFu by 10 December 2010 **SECR** to submit the 3rd version of RAC draft opinion on DMFu to Forum as soon as provided **SECR** to upload the 3rd version of RAC draft opinion documents to the RAC CIRCA IG after the meeting.
8.1.b Lead and its compounds in jewellery	
RAC agreed on the approach to be followed when developing the RAC opinion on this restriction proposal for lead and its compounds and requested the rapporteurs to follow it when preparing the 3rd draft opinion.	**Rapporteurs** to prepare the 3rd draft opinion documents on lead and its compounds for submission to Forum by 10 December 2010 **SECR** to submit the 3rd version of RAC draft opinion on lead and its compounds to Forum as soon as provided **SECR** to upload the 3rd version of RAC draft opinion documents to the RAC CIRCA IG as soon as available and open a CIRCA newsgroup for members' comments **Members** to submit their further comments on the 3rd draft opinion by 24 December 2010
8.1. c Phenylmercury compounds	
RAC had the first plenary discussion on the draft opinion for the Annex XV dossier proposing restrictions for phenylmercury compounds.	**Members** to post their views on the 1st draft opinion and respond to the five questions raised by the (co-) rapporteurs in their presentation at RAC-14 via the RAC CIRCA IG Newsgroup by

	22 December 2010. **Rapporteurs** to consider the comments provided during the written consultation and at RAC-14 when revising their 1st draft opinion by mid Feb 2011.
8.1.d Mercury in measuring devices	
RAC had the first plenary discussion on the draft opinion for the Annex XV dossier proposing restrictions for mercury in measuring devices.	**Members** to post their views on the 1st draft opinion and respond to the questions raised by the (co-) rapporteurs in their presentation at RAC-14 via the RAC CIRCA IG Newsgroup by 22 December 2010. **Rapporteurs** to consider the comments provided during the written consultation and at RAC-14 when revising their 1st draft opinion mid Feb 2011.
8.2 Appointment of RAC (co-) rapporteurs for restriction dossiers	
RAC agreed to appoint two of their members as rapporteurs for the intended Annex XV dossier(s) proposing restriction(s) for the four phthalates.	**SECR** to upload in RAC CIRCA IG the updated status document to reflect RAC appointments for this restriction proposal after the meeting.
8.3 General restriction issues **b Revision of the working procedure on conformity check**	
RAC agreed with the revised WP (doc RAC/14/2010/59) subject to a minor change. RAC agreed to test the revised templates for the conformity check (documents RAC/14/2010/60, RAC/14/2010/60 and RAC/14/2010/60) with the next intended Annex XV dossier proposing restriction.	**SECR** to upload the preliminary agreed procedure and revised templates to RAC after the meeting.
9 Authorisation	
9.1 RAC conformity check of authorisation applications	
Revised draft conformity check template RAC agreed the revised template (document RAC/14/2010/64_rev.1).	**SECR** to upload the final version of the template to the RAC CIRCA IG Newsgroup after the meeting.

9.2 Formulation of RAC opinions for authorisation applications	
a. RAC working procedure for developing opinions for authorisation applications RAC agreed the working procedure (document RAC/14/2010/65).	**SECR** to upload the final version of the WP to the RAC CIRCA IG Newsgroup after the meeting.
b. Format of an opinion	**Members** invited to post their views on the document via the respective RAC CIRCA Newsgroup by 20 January 2011.
GENERAL	
RAC agreed to invite three of the members with soon expiring 3-year membership to continue their rapporteurships on the ongoing dossiers until the adoption of the RAC opinions on these proposals, according to document agreed at RAC-12.	-
-	**SECR** to upload all presentations, room documents and the RAC-14 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG without delay after the meeting.

Table 1. List of adopted classification by RAC

Proposed CLH for HBCDD in adopted RAC Opinion

	CLP Regulation	Hazard statements	DSD
Classification	Repr. 2 Lact.	H361 H362	Repr. Cat 3; R63-R64
SCL	None		None
M-factor	None		None
Labelling	GHS08 Wng H361 H362		Xn R: 63-64 S: 36/37-53
Notes	None		None

Table 2. List of provisional classification by RAC
(Agreement reached for the following endpoints)

Metazachlor	CLP Regulation	Hazard statements	DSD
Classification			
	Aquatic Acute 1	H400	N; R50/53
	Aquatic Chronic 1	H410	
SCL			N; R50/53: C ≥ 0.25 % N; R51/53: 0.025 % ≤ C < 0.25 % R52/53: 0.0025 % ≤ C < 0.025 %
M-factor	Aquatic Acute; M=100 Aquatic Chronic; M=100		Not relevant

PHMB	CLP Regulation	Hazard statements	DSD
Classification			
	Acute Tox. 1	H330	T+; R26
	STOT RE 1	H372 (respiratory tract) (inhalation)	T; R48/23
	Acute Tox. 4	H302	Xn; R22
	Eye Damage 1	H318	Xi; R41
	Skin Sens. 1	H317	Xi; R43
	Aquatic Acute 1	H400	N; R50/53
	Aquatic Chronic 1	H410	
SCL			N; R50/53: C ≥ 2.5% N, R51/53: 0.25% ≤ C ≤ 2.5% R52/53: 0.025% ≤ C ≤ 0.25%
M-factor	Aquatic Acute; M= 10 Aquatic Chronic; M = 10		Not relevant

Part III. List of Attendees of the RAC-14 meeting (7-10 December 2010)

Members		**ECHA staff**
ANDERSSON Alicja		ANFÄLT Lisa
BARANSKI Boguslaw		BARRUEL Philippe
BARRON Thomasina		DE BRUIJN Jack
BJØRGE Christine		ERICSSON Gunilla
BORGES Teresa		FUHRMANN Anna
DUNAUSKIENE Lina		JACKSON Lindsay
DUNGEY Stephen		KARHU Elina
GREIM Helmut		KARJALAINEN Antti
GRUIZ Katalin		KIVELÄ Kalle
HALKOVA Zhivka		KOKKOLA Leila
JENSEN Frank		KULJUKKA-RABB Terhi
KADIKIS Normunds		LANKOSKI Jussi
LARSEN Poul Bo		LEBSANFT Jörg
LE CURIEUX-BELFOND Olivier		LUOTAMO Marita
LEINONEN Riitta		LUSCHÜTZKY Evita
LOSERT Annemarie		MAGGIORE Angelo
LUND Bert-Ove		MATTHES Jochen
MULLOOLY Yvonne		MERKOURAKIS Spyridon
NUNES Maria do Céu		MULLER Birgit
OLTEANU Maria		NOUWEN Johan
PICHARD Annick		NYLUND Lars
POLAKOVICOVA Helena		PELTOLA Jukka
POSPISCHIL Erich		RODRIGUEZ IGLESIAS Pilar
PRONK Marja		ROGGEMAN Maarten
RUCKI Marian		RÖCKE Timo
RUPPRICH Norbert		SIHVONEN Kirsi
SCHULTE Agnes		SPJUTH Linda
SMITH Andrew		VAINIO Matti
STOLZENBERG Hans-Christian		SCHÖNING Gabriele
TADEO José L.		STOYANOVA Evgenia
Van der HAGEN Marianne		TARAZONA Jose
Van MALDEREN Karen		VASILEVA Katya

VILANOVA Eugenio		**Stakeholder observers**
		ANNYS Erwin (Cefic)
Advisers to the RAC members		LAUBER Gertraud (EMCEF)
SØRENSEN Peter (adviser to Poul Bo Larsen)		MEISTERS Marie-Louise (ECETOC)
DUTTON Sarah (adviser to Andrew Smith)		MUNARI Tomaso (EuCheMS)
		ROWE Rocky (ECPA)
Representatives of the Commission		ULRICH Kerstin (BusinessEurope)
BINTEIN Sylvain (DG ENV)		VEROUGSTRAETE Violaine (Eurometaux 8.12.2010)
WISTUBA Christine (DG ENV)		WAETERSCHOOT Hugo (Eurometaux 7, 9-10.12.2010)
SEAC Restriction (co-)rapporteurs		**Other observers**
FURLAN Janez (invited as SEAC rapporteur following AP 8.1a DMFu)		COHEN Sam (an observer acting as an expert to an observer representing CEFIC for PHMB)
GEORGIOU Stavros (invited as SEAC rapporteur following AP 8.1b Lead)		DALL´ OSTO Michela (an observer acting as an expert to an observer representing ECPA for flufenoxuron)
FOCK Lars (invited as SEAC rapporteur following AP 8.1.b Lead)		KARJALAINEN Paula (an observer acting as an expert to an observer representing Cefic for white spirit)
LUTTIKHUIZEN Cees (invited as SEAC rapporteur following AP8.1d Mercury in measuring devices)		MIKKELSEN Sigurd (dossier submitter for white spirit representing the Danish CA)
RYDLEWSKA – LISZKOWSKA, Izabela (invited as SEAC co-rapporteur following AP 8.1d Mercury in measuring devices)		MORKA Heidi (dossier submitter for Phenylmercury representing the Norwegian CA)
Remote participants		WIEMANN Christine (an observer accompanying the nominated ECPA observer for metazachlor)
CEDERBERG Håkan (adviser to Alicja Andersson following AP 7.1f chloroform and AP 7.3d CLH discussion)		ØSTERGAARD Grete (dossier submitter for white spirit representing the Danish CA)
CHARLES Sandrine (a representative of the French CA following AP 7.1d flufenoxuron)		
KOPANGEN Marit (a representative of the French CA following AP 8.1.c phenylmercury)		**Joint RAC&SEAC session – AP 8.4**
PASQUIER Elodie (a representative of the French CA following AP 7.1g PHMB)		SEAC members
		SEAC Secretariat

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-14 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-14 meeting

07 December 2010
RAC/A/14/2010

Final Agenda

14th meeting of the Committee for Risk Assessment

07 – 10 December 2010
Helsinki, Finland

07 December: starts at 9:00
10 December: ends at 13:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/14/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-13

- Adoption of the draft minutes

RAC/M/13/2010 final draft
For adoption

Item 5 – Administrative issues and information items

a. Status report on the RAC - 13 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/14/2010/58
For information

d. Annual satisfaction survey

For information

Item 6 –Renewal of RAC Membership

- State of play on the renewal of RAC Memberships

RAC/14/2010/66
ROOM DOCUMENT
For information

Item 7 – CLH

7.1 CLH Dossiers

a. HBCDD

For adoption

b. White spirit dossiers

For discussion and possible adoption

c. Metazachlor

For discussion and possible adoption

d. Flufenoxuron

For discussion and possible adoption

e. PHMB

For discussion and possible adoption

f. Chloroform

For discussion and possible adoption

g. 4-tert-butylbenzoic acid

For first discussion

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

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

RAC/14/2010/67
ROOM DOCUMENT
For agreement

7.3 General CLH issues

a. State of play of the submitted CLH dossiers

RAC/14/2010/68
ROOM DOCUMENT
For information

b. Analysis of adopted CLH opinions and preparation of the workshop for presenting the guidance document on the preparation of CLH dossiers

For information

c. Preparation of the workshop on the classification and labelling of active substances in PPP scheduled for April 2011

For information

d. Discussion of the application of the CLP criteria for reproductive toxicity

RAC/14/2010/69

ROOM DOCUMENT

For discussion

e. Discussion of the application of the CLP criteria for germ cell mutagenicity

For discussion

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a. DMFu – second draft opinion

For discussion

b. Lead and its compounds– second draft opinion

For discussion

c. Phenylmercury compounds – first draft opinion

For discussion

d. Mercury in measuring devices – first draft opinion

For discussion

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

RAC/14/2010/70

ROOM DOCUMENT

For agreement

8.3 General restriction issues

a. Update on intended restriction dossiers

For information

b. Revision of the working procedure on conformity check

RAC/14/2010/59

RAC/14/2010/60

RAC/14/2010/61

RAC/14/2010/62

For discussion

8.4 Joint RAC&SEAC session

a. Role and scope of conformity checks of restriction dossiers

For discussion

b. Panel discussion on co-operation between RAC and SEAC – restriction dossiers for DMFu and lead and its compounds

For discussion

Item 9 – Authorisation

9.1 Conformity check

- Revised draft conformity check template

RAC/14/2010/63

For information

RAC/14/2010/64_rev1

For agreement

9.2 Formulation of RAC opinions for authorisation applications

a. RAC working procedure for developing opinions for authorisation applications

RAC/14/2010/65

For agreement

b. Format of an opinion

RAC/14/2010/71

ROOM DOCUMENT

For discussion

Item 10 – Guidance issues

a. Feedback from guidance consultations

b. Report on other guidance activities

For information

Item 11 – Any other business

a. Inclusion of experts nominated by RAC members into the ECHA expert database.

b. Feedback from the PBT workshop

For information

Item 12 – Main conclusions and Action Points of RAC-14

- Table with main conclusions and action points from RAC- 14

For adoption

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ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-14 meeting.

RAC/A/14/2010	Final Draft Agenda
RAC/M/13/2010	Draft Final Minutes of RAC-13
RAC/14/2010/58	Administrative issues and information items
RAC/14/2010/59	WP on conformity check of restriction dossiers
RAC/14/2010/60	Explanatory note and guidance
RAC/14/2010/61	Template of conformity check of restriction dossiers
RAC/14/2010/62	Template on recommendations to restrictions dossiers
RAC/14/2010/63	RCOM template for conformity check authorisations
RAC/14/2010/64_rev1	Revised template for conformity check authorisations
RAC/14/2010/65	RAC WP for developing opinions for authorisation applications
RAC/14/2010/66 room doc	Update on the renewal of RAC membership
RAC/14/2010/67_rev1 room doc	Appointment of CLH rapporteurs intentions
RAC/14/2010/68 room doc	State of play of the submitted CLH dossiers
RAC/14/2010/69 room doc	Discussion paper on the application of the CLP criteria for reproductive toxicity
RAC/14/2010/70 room doc	Appointment of restriction rapporteurs intentions
RAC/14/2010/71 room doc	Format of an opinion on authorisation application

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