RAC/M/11/2010
FINAL
7 September 2010

Minutes of the 11th meeting of the Committee for Risk Assessment (RAC)

(25-27 May 2010)

Part I Summary Record of the Proceedings

1 Welcome and apologies

Dr Jose Tarazona, Chair of the Committee for Risk Assessment, ECHA, welcomed participants to the meeting and informed participants that one RAC member had resigned.

The Chair welcomed: three advisers, one invited expert and seven stakeholder representatives (from CEFIC, ECETOC, EEB, ECPA, ETUC, Eurometaux and WECF), four observers accompanying stakeholder observers, one representative of a Member State Competent Authority (MSCA), three representatives from the Commission and one replacement of a RAC member.

Apologies were received from four RAC members and one regular observer (ECEAE). Two members were absent. The list of attendees is given in Part III of these minutes.

Participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes.

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 members and their advisers whether there were any conflicts of interest to be declared specific to the meeting. Eight members and one adviser declared potential conflicts of interest to different substance-related discussions in the agenda.

4 Adoption of RAC-10 Draft Minutes

The Chair introduced the revised minutes which incorporated comments received from RAC members.

RAC adopted the revised minutes with small changes. The Secretariat was to make the final version available through the RAC CIRCA IG and publish on the ECHA website.

5 Administrative issues and information items

Administrative issues and information items (a-c) were covered by room document RAC/11/2010/32. Members were informed that they have the possibility to provide

comments under the relevant agenda item or under any other business at the end of the meeting.

A second room document, RAC/11/2010/33, covered the point related to the follow-up of the first written procedure for adoption of a RAC opinion (5d). The Chair introduced two procedural issues related to the experience gained during the adoption of the first opinion by written procedure (on borates). The issues were the need to re-consider the quorum requirements in the RAC Rules of Procedure (RoPs) and the legal obligation for counting all appointed members even if they have not become active.

After some discussions, modifications of the RoPs were not seen to be necessary. Instead, other arrangements were suggested for facilitating the participation of the RAC members in the written consultations. The Chair informed members about the possibility to notify the RAC Secretariat of an alternative email to be used for the written procedures for adopting opinions during long absences (e.g. vacation or long missions). The members may also establish internal arrangements with colleagues, advisors and assistants to be informed and to vote in these written procedures during these periods of absence.

Regarding the consideration of non active members, the Chair explained that despite the efforts from the Secretariat and from the nominating Member State Competent Authority, a member appointed by the Management Board is not responding to requests to send their declarations of commitment, interests and confidentiality and to become an active member. Therefore, the Chair proposed to initiate the process for requesting the Management Board to revoke the appointment of this RAC member according to Article 5(3)(a) of the RAC RoPs. The Committee agreed by consensus to initiate the process and requested the Chair to send a justified proposal for the consideration of the Executive Director of ECHA.

6 CLH Dossiers

6.1a Gallium arsenide (GaAs) (CAS No.1303-00-0; EC No. 215-114-8)

The (co-) rapporteurs introduced to the Committee the revised draft opinion, the key comments received during the RAC consultation that led to some modifications of the draft opinion, the draft BD and the responses provided to these comments. The rapporteur introduced the CLH proposal as follows: Carc. 1A - H350, Repr. 1B - H360F, STOT-RE 1 - H372 (under CLP Regulation). An additional element for discussion was the application of the current group entry for aquatic hazards, as the dossier did not include information on this hazard class.

One of the main elements highlighted was the improved clarity of the rationale supporting the carcinogenicity hazard class. After some discussions on the read-across approach used for supporting the severe classification Carc. 1A and the remaining uncertainties, most of the members believed that it was needed to stress the potency of the substance, especially since animals are less sensitive than humans to the carcinogenic effect of arsenic. The Committee agreed with the rapporteurs' proposal for applying a weight of evidence approach, based on read-across from other arsenic compounds listed as carcinogen category 1A in Annex VI of CLP Regulation and with reference to relevant published epidemiology studies and the IARC evaluations.

Members also appreciated the revised wording on this endpoint. Some final editorial remarks were proposed also with regard to mutagenicity.

Then, the discussion focused on which primary target organs should be cited in the STOT-RE hazard statement. Several RAC members were in favour of only citing the "main" organ affected (respiratory tract) in the hazard statement. Several other RAC members wanted to have the three organs listed (respiratory and haematopoietic system and testes). All members shared the view that most important element for this decision is to present a clear message to risk managers at work places; consistency is also essential for hazard communication. Several general issues were considered, including the need for informing that only the primary target organs for which information is available are listed in the hazard statement, avoiding the misinterpretation that all organs had been evaluated and that no other organs may be affected by GaAs. The remits of the CLH process were also discussed.

A stakeholder observer representing an industry association remarked that they were in favour of focusing on only one important affected organ (respiratory tract) as the testes effect was already covered by the reproductive toxicity hazard. Other tools like safety data sheets were considered more appropriate for risk management issues than the label. A stakeholder observer representing workers organisations expressed the view that all information on hazardous effects should be accessible from the label in addition to the safety data sheets.

The rapporteur indicated that the observed adverse effects in each of these three organs may trigger the classification when compared with the limit values. Based on this indication and the overall discussions the Committee finally agreed to propose listing the three targeted organs.

With regard to the environmental hazards, the Committee discussed the need for taking over the current classification for the group entry. RAC members and stakeholders expressed some concerns on the applicability of the group entry to GaAs, due to the low solubility in water (IARC), and additional considerations such as the need to distinguish between massive form and not massive form, and for considering using only H400 instead of H400 and H410 as recommended in the guidance document. Finally, RAC agreed not to include the environmental hazard classes in the proposal, indicating that RAC is aware of the group entry but as no information has been provided in the dossier the Committee cannot evaluate these hazard classes, which are therefore not included in the RAC CLH opinion for gallium arsenide.

RAC adopted by consensus the opinion and the background document for harmonised classification and labelling of gallium arsenide with the limited editorial comments proposed by the Committee. The Chair thanked the (co-)rapporteurs for the excellent work and the additional task conducted on behalf of the Committee related to the carcinogenicity assessment.

6.1b Tetrahydrofuran (THF) (CAS number: 109-99-9; EC Number: 203-726-8)

The Chair invited the rapporteur to present the final comments. The rapporteur explained that the minor editorial comment had been considered and reminded members that RAC-10 had already agreed with the view of the (co-) rapporteurs and supported the proposed classification for THF as Carc. 2 - H351 (under CLP Regulation) and Carc. Cat. 3; R40 (under DSD).

The Chair gave the floor to the industry expert accompanying the CEFIC stakeholder observer, who expressed his disagreement with the interpretation of the results from the Pathology Working Group (PWG) report on selected histological changes in the kidneys assigned to a 2-year inhalation carcinogenicity study of THF (NTP study No 05181-03) provided in BD and presented his point of view. He concluded, that the provided studies indicated, that the tumours observed by rats were rather species specific predispositions than proof of carcinogenicity of THF.

The rapporteur explained that the dossier submitter had incorporated the PWG data into its CLH report and clarified the relevance of the findings with regard to the proposed classification for carcinogenicity. Further the rapporteur presented his opinion concerning the comparison of hypoplasia and tumour formation and indicated that according to the evaluation conducted by the dossier submitter, THF does not exacerbate chronic progressive nethrophaty (CPN), but THF carcinogenicity potency is exacerbated by CPN. He emphasised that the dossier submitter had concluded, that there was not sufficient evidence to judge definitively that the increased adenomas observed in THF–exposed rats had been the result of CPN induction only, and that this conclusion should be supported based upon the available evidence.

The issue of recent histopathological publications was raised during the discussion. The industry expert clarified that there were no new studies presented since the PWG report (2009), and that their comments were submitted during the public consultation. These comments were evaluated by the dossier submitter during the revision of the CLH report.

RAC adopted by consensus the opinion for THF, suggesting the classification of the substance as proposed by MSCA. The Chair thanked the rapporteurs for their work.

6.1c TDCP (Tris[2-chloro-1-chloromethyl)ethyl] phosphate) (CAS Number:13674-87-8; EC Number: 237-159-2)

The rapporteur gave a presentation highlighting the changes introduced in the draft opinion and BD following the commenting round and proposed the key elements requiring additional discussion.

The TDCP classification as Carcinogen Cat. 2 – H351 (under CLP Regulation) and Carcinogen Category 3; R40 (DSD) that had already been provisionally agreed at RAC-10 was confirmed.

The proposal raised in the public consultation for classification as reproductive toxicant Cat. 2 - H361f (under CLP Regulation) and Repr. Cat 3; R62 (DSD) had

been reassessed on the basis of the received comments. The rapporteurs suggested to RAC members that the data are not sufficient to support the classification for reproductive toxicity Cat 2.

In the following discussion RAC members expressed wide support for the rapporteurs' conclusion; however, the argumentation as provided in the draft opinion and BD required additional considerations. It was suggested to make a stronger reference to the classification criteria specifically to 3.7.2.5.3 "*Adverse effects or changes, seen in short- or long-term repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant general toxicity, may be used as a basis for classification, e.g. histopathological changes in the gonads*."

It was pointed out that, in general, clear-cut testes toxicity in 28 or 90 day studies usually resulted in fertility impairment observed in one- or multi-generation studies at relatively high doses (due to the high sperm reserve in rats) and consequently could justify classification. In the case of TDCP however the concerns regarding fertility are based on the observation of testes toxicity in the carcinogenicity study at the age of 24 months and to lesser extend at 12 months. With 70% of the untreated controls showing the same effect at 24 month the significance for fertility impairment was doubtful. Further it was hard to distinguish the findings in treated animals but also controls at 12 and 24 months from normal age-related effects, as more qualitative histopathological data to judge not only incidence but also appearance (single or multifocal) and severity (e.g. size of foci) was missing in the study. Based on the incidence only, it was not possible to conclude on the relevance of these findings in terms of fertility.

The negative fertility study in rabbits presents an additional argument against a classification as highlighted by one RAC member. However, as pointed out by another RAC member, species differences were not unusual and assessment should always be based upon the most sensitive species. The available information offer some evidence related to effects on reproductive organs, especially the effects in the epididymides were of concern because the oligospermia showed a clear dose-response and might therefore not solely be attributed to age-related effects. However, when compared to the criteria, the findings are not sufficient for supporting classification for reprotoxicity. RAC considered that this assessment and the remaining uncertainty should be clearly expressed in the background document.

Further analysis of the read-across argument as already requested in RAC-10 did not seem feasible. The information on the two structurally related substances TCPP (negative) and TCEP (classified as toxic for reproduction) was considered insufficient for justifying a read-across and the opinion was based on the specific data available for TDCP.

The Chair summed up, that there was an agreement between RAC members not to propose harmonised classification of TDCP for reprotoxicity as the available information is not sufficient to support the classification. He invited RAC to take part in the further discussion in an ad-hoc working group chaired by the rapporteur after the plenary that would discuss the line of argumentation to be presented in the opinion and in the background document.

A working group consisting of the rapporteur, several RAC members and the RAC Secretariat met to continue the discussions and prepare the revised proposal. The outcome was reported to RAC by the rapporteur and presented in two room documents one including the scientific rationale of the argumentation and the other presenting the proposal to be incorporated in the opinion.

RAC agreed with the conclusion that there was not sufficient evidence to propose a classification as reproductive toxicant and supported the suggested line of argumentation. The rapporteur agreed to modify the opinion and BD accordingly verifying the consistency of opinion, BD and RCOM.

Following the request from one stakeholder observer it was clarified that the opinion and BD would include the arguments supporting the RAC proposal and that the uncertainty would be adequately reflected in the opinion.

RAC members indicated that also the justification for the carcinogenicity part of opinion deserved some further editorial work to present the scientific justification more clearly.

The Chair invited the rapporteurs to provide the revised document to the Secretariat and an editorial consultation round would be launched after the meeting. The opinion will be proposed for possible adoption in a written procedure before the next RAC meeting.

6.1d Cryolites

The representative of the dossier submitter presented the CLH proposals for synthetic and natural cryolites. It was explained that the classification proposals by Germany concerned deletion of the existing harmonised classification for acute oral toxicity because the LD_{50} was higher than 5000mg/kg bw and addition of classification for eye irritation and developmental toxicity to the existing classification. The proposal for eye irritation was based on a weight of evidence approach combining data from several animal studies with limited validity with data from human occupational settings. The proposal to classify for developmental toxicity was based on postnatal growth retardation and pup organ changes in a 2-generation reproduction study with rats, the induction of bent ribs and bent limb bones in two developmental toxicity studies with mice and occurrence of dental fluorosis in children of female cryolite workers. No changes to the existing harmonised classification for repeated dose toxicity and environmental effects were proposed. The dossier submitter also pointed out that a transitional dossier for cryolite was submitted. According to the information received during the public consultation industry is currently preparing their registration dossiers to be submitted before the first registration deadline.

The rapporteurs introduced to RAC the revised draft opinion documents and their conclusions on the proposed classification. They agreed with the dossier submitter's proposal regarding the de-classification of the substance for acute toxicity by oral route (deletion of H302, R22). However, the additional classification proposed for eye irritation was not supported due to the lack of sufficient robust data. There is no support also for the proposed classification for cryolites for developmental toxicity.

The effects in the developmental studies in mice only occurred at dose levels associated with high maternal toxicity. Although the decreased pup weights in the 2-generation study were considered as borderline effects, the rapporteurs did not support classification for reproductive toxicity because the evidence for developmental toxicity is too limited and the quality of the reporting too poor to warrant classification. It is acknowledged that dental fluorosis (hypoplasia and hypomineralisation of dental enamel and dentine) has been observed in the 1930s in children of female cryolite workers. As this adverse effect only can arise in developing children, it could be discussed in relation to developmental toxicity. However, other fluorides have not been classified in the EU as developmental toxicants based on dental fluorosis.

RAC members agreed with the view of the rapporteurs to support the proposed de-classification of cryolites for acute oral toxicity by deletion of H302 (under CLP Regulation) and of R22 (under DSD) maintaining the other hazard classes in its current CLH entry in Annex VI. In addition, RAC considered that the available evidence is insufficient for supporting the proposals for additional classification for eye irritation and toxic to reproduction. Furthermore, RAC adopted by consensus the opinion and the background document for synthetic and natural cryolites with minor editorial changes.

One RAC member commented on the importance of having a minimum data set in a CLH dossier for a substance that would allow well-justified RAC conclusions on their decisions, as it is difficult to conclude when insufficient information is provided in the dossier.

Finally, the Chair thanked the RAC rapporteurs for the excellent work done.

6.1e HBCDD

In their CLH dossier for this substance, Sweden proposed to classify HBCDD for reproductive toxicity due to its effect on fertility, development and also on lactation.

The rapporteurs for this substance presented their observations and conclusions to RAC as reflected in the revised draft opinion documents for HBCDD supporting the dossier submitter's proposal, which was: Repr. 2 - H361fd (Suspected of damaging fertility. Suspected of damaging the unborn child.), Lact. H362 (May cause harm to breast-fed children) (under CLP Regulation) and Repr Cat 3; R62-63, R64 (under DSD).

The industry expert accompanying the stakeholder observer expressed the view that the provided fertility studies did not justify the fertility classification and that the proposed classification due to lactation effects was not well-justified, as the doses were very high during lactation.

The Chair reminded the stakeholder observers and their experts that available information and their statements on the interpretation of the data in the CLH report should be submitted during the public consultation, as then the dossier submitter will be able to respond to the comments and revise the CLH report, if needed. Also the rapporteurs will have sufficient time to consider the comments from the public consultation and dossier submitter's response in their draft opinion documents.

The rapporteurs further confirmed that the fertility data was used in a typical and classical way. They regarded the effects on primordial follicles as supportive evidence. Hormone disrupting activities having effect on fertility could not be ignored. Although only a cross-fostering study (which had not been performed) would be able to distinguish whether the pup mortality observed during lactation was caused by pre- or post-natal exposure of the pups, the developmental toxic effect was considered specific and relevant to humans. There was clear evidence available demonstrating accumulation of HBCDD in the human breast milk. Therefore, the rapporteur considers the dossier submitter's proposal as justified. Furthermore, it could be noted that HBCDD is highly bioaccumulative and identified as a PBT substance by the MSC (Member State Committee).

Related to the dose levels, RAC recognised that most studies involved suspended HBCDD particles with a typical size of 0.1 mm, that were mixed in the food, with an exception of the Van der Ven *et al* study (2009) in which the substance was dissolved completely before mixed in the food and where a few effects were noted at 30-100 mg/kg/day.

Furthermore, RAC members suggested that the rapporteurs consider strengthening the scientific justification in the opinion documents, focusing on the strongest and clear evidence.

RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification and labelling for this substance, as follows: Repr. 2 - H361fd (Suspected of damaging fertility. Suspected of damaging the unborn child.), Lact. H362 (May cause harm to breast-fed children) (under CLP Regulation) and Repr. Cat. 3; R62-63, R64 (under DSD).

The Chair explained that following the discussion at the meeting, the rapporteurs will be requested to revise the draft opinion documents to be in line with the proposed modifications during the plenary discussion. Subsequently an editorial commenting round will be organised and the final draft opinion and its annexes should go for adoption either by written procedure, or at the next RAC plenary meeting.

6.1f Fuberidazole (CAS Number: 3878-19-1; EC Number: 223-404-0)

For the Fuberidazole presentation the Chair invited the representative from the UK Competent Authority (MSCA) as dossier submitter to introduce the rationale of the CLH proposal for Fuberidazole.

The current harmonised classification entry in Annex VI of CLP Regulation is Acute tox. 4, Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410 (Xn; R22, N; R50-53 under DSD). UK MSCA proposed the additional classification: Skin sensitisation Category 1- H317 (≥ 50% of animals positive in a GPMT) and STOT-RE 2 (heart) - H373 (CLP Regulation) and Xi; R43 and Xn; R48/22 (DSD).

The Chair invited the RAC rapporteur to present his view on the proposal from the dossier submitter. The first opinion and BD were not yet available and the main points raised by the rapporteur for attention were: developmental toxicity, repeated dose toxicity and carcinogenicity.

The developmental toxicity focused on the two generations oral rat study. The results showed some adverse effects via lactation and there was no consistency in the results within and between generations. Similarly, the microphthalmia study showed only isolated incidences and therefore no developmental toxicity classification was proposed by the rapporteur.

Repeated dose toxicity was based on a dog oral one-year study and, according to the rapporteur, it seemed to support the classification as STOT-RE 2 with some considerations of STOT-RE 1.

Carcinogenicity was based on two tests with statistically significant increases of tumours conducted on Wistar rats and Mice NMRI. The main issues were the use of historical controls, mode of action for thyroid tumours and the mechanistic differences between humans and animals. The rapporteur supported the UK proposal for non-classification for carcinogenicity.

The Chair thanked the rapporteur and participants for their comments. The first draft opinion and BD will be prepared by the rapporteur and distributed to RAC shortly after the meeting.

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

Room document RAC/11/2010/34 was introduced by the Chair who explained that new intentions for CLH dossiers had been received and therefore, (co-) rapporteurs were required. During the meeting, several members had volunteered to act as (co-) rapporteurs for the intended CLH dossiers. RAC agreed to appoint these members as (co-)rapporteurs. A total of 17 positions were filled. Furthermore, RAC members were invited to come forward for the other vacant places. The revised status document was to be uploaded to the RAC CIRCA IG after the meeting to reflect the changes.

6.3 General CLH issues

6.3a State of play of the submitted CLH dossiers

RAC was informed that an update of the state of play of the submitted CLH dossiers is provided in room document RAC/11/2010/35. Members were invited to contact the Secretariat if they need further clarification.

6.3b Revision of the working procedures on accordance check and on processing of dossiers for harmonised classification and labelling

The Secretariat presented to RAC the revised draft working procedure on accordance check (document RAC/11/2010/24) and the revised draft working procedure on processing of dossiers for harmonised classification and labelling (RAC/11/2010/25_rev). It was further explained that the revision is needed in order to reflect the key elements coming from the RAC practical experience with the CLH dossiers according to the Committee's working procedures, in particular those related to the procedural timelines.

Furthermore, RAC agreed the proposed revised draft procedures including some additional changes.

6.3c Feedback from the Commission on adopted CLH opinions and follow-up actions

The Chair introduced the request from the Commission services related to the adopted opinion on indium phosphide and gave the floor to the rapporteurs for the CLH proposal for this dossier to present the room document RAC/11/2010/36.

The Chair asked RAC to agree on the document. The document RAC/11/2010/36 was agreed. The Chair thanked the (co)rapporteurs for the additional effort.

7 Restrictions

7.1 Restriction Annex XV dossiers

7.1a DMF – conformity check

The Secretariat presented a brief overview of the Annex XV dossier proposing a restriction for DMFu in consumer articles. This proposal submitted by the French MSCA aims to restrict the use of DMFu in articles in concentrations greater than 0.1 mg/kg, as well as to restrict the placing on the market of articles containing DMFu in concentrations greater than 0.1 mg/kg. It was also clarified that DMFu was used to protect consumer articles from mould during their storage and transportation. The Biocide Directive restricts the use of DMFu for biocidal purposes within EU. However, the import of DMFu-treated articles from non-EU countries and their placing on the market are not covered by this directive. Due to the human health effects of DMFu, mostly related to its potential to provoke severe skin irritation and sensitisation problems, a temporary ban with largely the same content as the proposed restriction, has been put into place at the EU level. This proposal aims to make the temporary ban permanent.

Furthermore, the rapporteur introduced to RAC the key elements of the draft conformity report. It was pointed out that the desirable information listed in the conformity report is not crucial for conformity, but may enhance the opinion forming process. Although robust study summaries (RSSs) for this dossier have not been submitted, the rapporteurs proposed to RAC to accept this omission for the conformity check. The rapporteur indicated that due to the limited amount of DMFu produced and in use it is doubtful if a registration dossier for DMFu will be submitted by registrants. It was suggested that the dossier submitter may still provide Robust Study Summaries (RSS) during the process – and the omission is not crucial at this stage. In the discussion that followed the presentation, it was mentioned that most of the information that would be necessary for the RSS is in any case already included in the proposal.

The rapporteur also presented some observations on the procedural aspect of the conformity check procedure (one longer RAC consultation, instead of the preliminary and final consultations included in the current procedure); after some initial reactions RAC agreed to keep for the time being the preliminary commenting rounds, as the

early members' comments might be very useful for the rapporteurs, but to stress that members should focus their attention on the final commenting round of the draft conformity report.

Finally, RAC agreed with the rapporteurs' proposal and took a decision that the Annex XV dossier proposing restriction for DMFu in consumer articles conformed with the requirements of Annex XV, in accordance with Article 69 (4) of the REACH Regulation.

The Chair thanked the rapporteurs and the Committee's members for the fruitful discussion.

7.1b Lead and its compounds in jewellery – conformity check

The Secretariat presented a brief overview of the Annex XV dossier proposing a restriction of lead and its compounds in jewellery. This proposal submitted by the French MSCA aims to restrict the use of lead and its compounds in jewellery articles if the lead migration rate is greater than 0.09 µg/cm2/hr, as well as to ban the placing on the market of such articles. The proposal further specifies that the EN 71-3 standard could be used for the migration rate measures although several adaptations to the standard are proposed. Children are the targeted population group, as they may be exposed to lead due to unintentional mouthing or swallowing of the lead-containing jewellery. The human health hazards relate to acute toxicity (due to lead poisoning) and to repeated dose toxicity (due to e.g. severe neurological brain effects with permanent impairment of the IQ).

Furthermore, the rapporteurs introduced to RAC the key elements of their draft conformity report, as well as their observations on this restriction proposal that need further clarification/action from the dossier submitter, such as clear conclusion about the different approaches for RA (e.g. N(L)OAELs, BMDLs), consideration of other routes of lead exposure, better description of the risks of the proposed alternatives, evaluation of other options e.g. limitation of lead content in jewellery. Although robust study summaries (RSSs) for this dossier have not been submitted, the rapporteurs proposed to RAC to accept this omission, as this hazard information is publicly available (via the Voluntary Risk Assessment (VRA) of Lead assessed under the ESR programme, the opinions of SCHER, TC NES and EFSA). Furthermore, it was clarified that the lead industry is expected to transfer the hazard information from the VRA in IUCLID 5 format in the context of the foreseen registration dossiers. Hence, requesting the submitting Member State to provide robust study summaries would most likely duplicate this (extensive) work. Although the rapporteurs suggested to RAC to take a decision that the dossier is in conformity with the requirements of the REACH Regulation, they confirmed their intention to specify to the dossier submitter that taking into account the desirable information in the report, together with the comments received during the public consultation, would benefit future work.

After a short discussion on the borderline between the required and desirable information and the consequences for the rapporteurs and RAC if the desirable information is not provided, RAC agreed that there is a need to explore in more detail these issues with the next set of expected restriction dossiers. The experience with these first dossiers has identified some limitations in the agreed template and

procedures, when more experience is collected, the revision of the Committees' procedures should be considered. In the mean time, some useful points learned from the experience gained with the CLH accordance check process can be applied here and suggestions for possible improvements of the conformity check report template were also proposed.

In conclusion, RAC took a decision that the Annex XV dossier proposing restriction for lead and its compounds conformed to the requirements of Annex XV, in accordance with Article 69 (4) of the REACH Regulation.

The Chair thanked the rapporteurs and the members for the fruitful discussion.

7.2 General restriction issues

The Secretariat informed RAC that both dossier submitters, Norway (for the Annex XV restriction dossier on phenyl-mercury compounds) and ECHA (for the Annex XV restriction dossier for metal mercury in measuring devises), have confirmed their plans to submit these dossiers on 15 June 2010.

8 Authorisation

8a Discussion note on the content of final Commission decisions and their effect on the format of the RAC and SEAC opinions

The Secretariat presented the discussion note on the content of final Commission decisions and their effect on the format of RAC and SEAC opinions on the applications for authorisation (document RAC/11/2010/26). The starting point of the presentation was that the opinions of RAC and SEAC need to underpin the overall decision making by the Commission. Thus, it was suggested that during the opinion making process, the Committees should include in their opinions all elements that are needed for decision-making. These are: i) whether the conditions for granting authorisation have been established, ii) what the possible (additional) conditions and monitoring arrangements would be and iii) what the duration of the review period might be; obviously the opinions should include the rationale and justifications supporting the RAC views. It was proposed that RAC would take the lead in ii) while SEAC in iii). It was also highlighted that irrespective of the legal base (Art 60(2), i.e. the "adequate control" route, or Art 60(4), i.e. the "socio-economic route") both committees would need to give an opinion.

Some specific questions were raised. The Secretariat pointed out that even if the applicant considers that the risks can be adequately controlled it would be in their interest to give further information on possible socio-economic benefits of granting an authorisation which is not strictly speaking required for a decision in accordance with Article 60(2). This is because by that the Committees would have a possibility to give an opinion and the Commission to decide whether the decision criteria of Article 60(4) are fulfilled if the criteria in Article 60(2) turn out not to be fulfilled. Furthermore, such information is also necessary e.g. when establishing the duration of the review period. The Secretariat clarified some other procedural, technical and legal issues related to the authorisation process.

The Chair thanked members for their initial comments and indicated that a written commenting round would start after the meeting.

8b Elements of the RAC and SEAC working procedure for developing opinions on the applications for authorisation

The Secretariat presented the elements of RAC and SEAC working procedure for developing opinions on the applications for authorisation (document RAC/11/2010/27). Based on these elements, the detailed working procedure will be elaborated for the September 2010 meetings of RAC and SEAC, emphasising the strict timelines and the need for close co-operation between both Committees.

During the discussion, the role of the public consultation which is based on Art 64(2) through the Agency web-site (broad information on uses for which applications have been received and for reviews of authorisations), and the specific consultation of the draft opinions with the applicant were clarified.

Comments on the participation of the applicants during the opinion development, including how (co-)rapporteurs would be in contact with the applicants, were raised. The Chair indicated that these should be covered by the RAC Rules of Procedures and the procedure for the participation of stakeholders and their accompanying experts. As all applicants need to be treated equally the general conditions for their participation should be discussed by RAC.

The Chair thanked members for their initial comments and indicated that a written commenting round would start after the meeting.

8c Discussion paper on the scope and content of conformity check of authorisation applications

The Secretariat presented to RAC the discussion paper on the scope and content of the conformity check of authorisation applications (document RAC/11/2010/28). This document incorporates the comments received from SEAC after the first discussion and is provided to RAC for discussion.

One member expressed support for the proposed narrow scope of the conformity check. The tight timelines for processing the applications were noted.

After a short discussion, the Chair thanked members for their input and indicated that a written commenting round would start after the meeting.

8d Working procedure on the conformity check of authorisation applications

The Secretariat presented the draft working procedure on the conformity check of authorisation applications (document RAC/11/2010/29). The purpose of this document was to outline the procedure for checking the conformity of authorisation

applications. It describes the main roles and tasks of the Secretariat, (co-) rapporteurs and members of RAC and SEAC, and gives the timelines for different tasks.

The Chair invited RAC members to comment on the document.

A question was raised regarding the Secretariat's strategy to support the national helpdesks as applicants will be likely to use the national helpdesks to gather support for their applications. The Secretariat responded that it will make available for authorisation all support systems that are available for other REACH processes (such as registration): guidance documents, manuals, communication and dissemination strategy, training to helpdesks, etc.

The discussion focused on how to deal with applications that do not conform and the request to the applicant to put the application in conformity. A question was raised regarding the need to formulate an opinion even if the application is not in conformity. The Secretariat replied that in their discussion with the Commission it had become clear that the Commission cannot do anything with an opinion that is based on a non-conforming application.

The Secretariat noted that the Committees shall in all cases prepare a draft opinion, send it to the applicant, address the comments if received and adopt the final opinion. Therefore, the Committee will need to balance the effective use of resources and the possibility of the applicant to put the application in conformity when commenting on the draft opinion at a very late stage. An additional difficulty is that an application might be in conformity for some uses but not in conformity for the whole application.

The Chair thanked the presenter and member for their comments and indicated that a written commenting round would start after the meeting.

8e Terms of reference for authorisation (co-) rapporteurs

The Secretariat introduced the draft terms of reference (ToR) for the (co-) rapporteurs of RAC and SEAC for authorisation applications (document RAC/11/2010/30). The purpose of this document was to initiate discussions in RAC and SEAC on the role and the tasks of the authorisation (co-) rapporteurs and to provide input to the ECHA Management Board for its decision on the remuneration of (co-)rapporteurs. The Secretariat clarified that the draft ToR will be revised in the future to be in line with the other RAC and SEAC procedures for authorisation process (as soon as they have been agreed). Additional sections addressing subsequent applications and reviews of authorisations may have to be included in the text of the ToR.

The Chair thanked members for their comments and indicated that a written commenting round would start after the meeting. In order to facilitate the discussion it was agreed to open two newsgroups on the five authorisation related documents, one for the general issues (documents under Agenda Points 8.a; 8.b and 8.e) and one for the conformity check (documents under Agenda Points 8.c and 8.d).

9 Guidance issues

9a Feedback from the guidance consultations

The Secretariat gave feedback from recent consultation on guidance documents and informed members that the revised "Guidance on the preparation of dossiers for harmonised classification and labelling" is available on the ECHA webpage. The Secretariat reported the changes made to the CLH Guidance during the CARACAL consultation period. The main revisions concerned the substance identification (SID) by adding the reference to the CLP Regulation Annex VI Part I (1.1.1.4.): '*Impurities, additives and minor components are normally not mentioned unless they contribute significantly to the classification of the substance. CLP Regulation, Annex VI, point 1.1.1.4.'* This has also been reflected in the CLH Report format, where the MSCA/IND consideration on the final entry to the Annex VI, can be dealt in the Part A and the more detailed SID in Part B of the CLH report format.

The Secretariat thanked RAC members for their valuable discussions and comments during the preparation of this guidance document.

9b Report on other guidance activities

The Secretariat presented a short overview of the key issues on the Guidance on exposure scenarios for the waste life stage, which were under consultation with RAC, the deadline for comments was 4 June 2010.

The Secretariat also gave an overview of the guidance update activities. These included updates of the Guidance on registration (Annex V–final published on 1 April 2010 and waste & recovered substances published on 12 May**),** Requirements for substances in articles (CARACAL consultation ongoing), Guidance on Risk Communication (PEG consultation ongoing), CLP Regulation - CLP guidance (first draft would be prepared for PEG consultation to be launched in September). Of particular relevance for RAC, were updates dealing with the Guidance on IR & CSA which includes the exposure scenario format (to be published before the end of May); tier 1 exposure estimates (to be published before the end of May); the scope of exposure assessment (ongoing); exposure scenarios describing strictly controlled conditions and conditions controlling releases from article matrices (ongoing PEG consultation); use descriptor system (final guidance was published on 26 March 2010); derivation of DNELs/DMELs from human data (draft for CARACAL under preparation) and CLP Regulation CLH guidance (was published on 18 May 2010).

The importance was raised of translations of the guidance, particularly for SMEs and of the validation/checking of the translations by MSCAs. The Secretariatconfirmed that it undertakes substantial efforts to make relevant guidance documents available in the official EU languages in order to improve the accessibility of the guidance for SMEs and confirmed that some MSCAs assist ECHA in the validation of translated documents.

10 Any other business

10a RAC meeting calendar for 2011

The Chair presented to RAC the RAC meeting calendar (document RAC/11/2010/31). It was also highlighted that although the duration of the scheduled six meetings may be shorter than 5 full days, in the light of the expected workload, members were recommended to provisionally reserve a week for each of the meetings.

Furthermore, three members commented on the practical arrangements related to their meeting participation, as well as the overlapping of some of the provisional meeting dates with their national holidays or meetings of other EU bodies.

10b Renewal of RAC membership

The Chair informed members that the term of office of most of the RAC members expires at the end of 2010. With regard to the renewal of their membership, members were encouraged to contact their nominating MSCAs in order to discuss their re-nominations. Further, the Secretariat informed members of the ongoing and planned activities in this regard.

Considering the increasing workload of the Committee, one member suggested encouraging all MSCAs to appoint two members and to actively support them, as this could help for a more equal distribution of the work among RAC members. The Chair informed RAC of the preparation of a letter from ECHA to MSCAs informing them of the workload of RAC members and their required support as requested at the previous meeting and offered again the possibility of discussing specific situations if requested by the members.

10c Workshop on evaluation of two organic siloxane compounds

One member informed RAC of the ongoing PBT evaluation of siloxanes (D4 and D5) done by his MSCA and the workshop that was being organised with industry in this regard to be hosted by ECHA in Helsinki on 11 June 2010. He also suggested that RAC members contact their MSC colleagues representing the individual MSCAs to ensuring that experts with the right expertise are available to participate as their advisers in the event.

10d Presentation on Extended One Generation Reproductive Toxicity Studies (EOGRTS)

The Secretariat introduced the extended one generation reproductive toxicity studies and their possible applications in regulatory risk assessment. One of the issues discussed was whether EOGRTS have the capacity to provide relevant information for classification on reproductive toxicity and especially to differentiate between category 1B and 2. The Secretariat informed members about current developments in this field. Draft guidelines from OECD for testing chemicals will be posted for information on a CIRCA Newsgroup, as well as other relevant technical document prepared by ECHA.

11 Main conclusions and Action Points of RAC-11

The Secretariat presented the main conclusions and action points of the RAC-11 plenary meeting for final comments and agreement by the Committee. All suggestions were reflected accordingly and RAC agreed the document. The main conclusions and action points are attached as Part II of these meeting minutes.

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Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the 11th meeting of RAC)
(25-27 May 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/11/2010_rev.1) was adopted. Eight members and one adviser have declared 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-11 minutes.
4. Adoption of RAC-10 Draft Minutes	
The minutes of RAC-10 (RAC/M/10/2010 draft final) was adopted with small changes.	**SECR** to upload to the RAC CIRCA IG and the ECHA website the adopted minutes
5. Administrative issues and information items	
5d. Follow-up of the 1st written procedure for adoption of a RAC opinion	
RAC agreed to ask the RAC Chair to send a justified proposal to the Executive Director of ECHA for his request to the Management Board to revoke the appointment of a person as a member of RAC. It was agreed not to modify the quorum but explore alternatives for facilitating the voting process by members. Members may notify the SECR an alternative email address for receiving requests for adopting opinions during fixed periods, e.g. vacations, missions, etc.	**Chair** to send the justified proposal and to report back to RAC on the outcome of this procedural case when solved. **SECR** to consider the members' request when launching written consultations.
6. CLH	
6.1 CLH Dossiers	
6.1a Gallium arsenide	

RAC adopted by consensus the opinion for gallium arsenide subject to some editorial changes in the opinion and its annexes. RAC members agreed with the view of the rapporteurs on the harmonised classification: **Carc. 1A - H350, Repr. 1B - H360F, STOT RE 1 - H372** (under CLP Regulation) and **Carc. Cat. 1 T; R45, Repr. Cat. 2; R60, T; R48/23** (under Dir 67/548/EEC).	**SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site after the meeting. **SECR** then to forward the adopted opinion and its annexes to COM without delay.
6.1b Tetrahydrofuran	
RAC adopted by consensus the opinion and the background document for tetrahydrofuran. RAC members agreed with the view of the rapporteurs to support the proposed classification for this substance, as follows: **Carc. 2, H351** (under CLP Regulation) and **Carc. Cat 3, R40** (under Dir 67/548/EEC).	**SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site after the meeting. **SECR** to forward to COM the adopted opinion and its annexes after the meeting.
6.1c TDCP	
RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification for this substance, as follows: **Carc. 2, H351** (under CLP Regulation) and **Carc. Cat 3, R40** (under Dir 67/548/EEC). Further RAC agreed with the view of the rapporteurs that the available evidence is not sufficient to justify classification for reproductive toxicity. Furthermore, the members suggested for rapporteurs' consideration some editorial changes for strengthening the scientific justification in the opinion documents.	**Rapporteur** to revise the draft opinion and its annexes according to the plenary comments as soon as possible and to provide it to SECR. **SECR** to circulate the revised draft opinion and its annexes for editorial comments and adoption by written procedure.
6.1d Cryolites	
RAC adopted by consensus the opinion and the background document for cryolite, synthetic and natural. RAC members agreed with the view of the rapporteurs to support the proposed de-classification for this substance for acute oral toxicity (entry revised by deletion of **Acute Tox. 4 – H302** (under CLP Regulation) and by deletion of **R22** (under Directive 67/548/EEC)) maintaining the other hazard classes in its current CLH entry in	**SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site after the meeting. **SECR** to forward to COM the adopted opinion and its annexes after the meeting.

Annex VI. In addition, RAC considered that the available evidence is insufficient for supporting the proposals for additional classification for eye irritation and reproductive toxicity.	
6.1e Hexabromocyclododecane (HBCDD) (CAS No. 25637-99-4 and **3194-55-6)**	
RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification for this substance, as follows: **Repr. 2; H361fd** (Suspected of damaging fertility. Suspected of damaging the unborn child.), **Lact. Effects H362** (May cause harm to breast-fed children) (under CLP Regulation) and **Repr Cat 3; R62, Repr Cat 3; R63, R64** (under Dir 67/548/EEC). Furthermore, the members suggested for rapporteurs' consideration some editorial changes for strengthening the scientific justification in the opinion documents.	**Rapporteurs** to revise the draft opinion and its annexes according to the RAC-11 proposed modifications by 30 June 2010. **SECR** to distribute the revised draft opinion and its annexes to RAC members for further editorial comments and possible adoption at RAC-12 or earlier by written procedure.
6.1f Fuberidazole	
-	**Rapporteur** to provide the Secretariat with the 1st draft opinion and its annexes by 07 June 2010 **SECR** to organise the RAC commenting round immediately after receiving the rapporteur's draft opinion documents.
6.2 Appointment of (co-) rapporteurs for CLH dossiers	
RAC agreed to appoint the volunteers as (co-) rapporteurs for the newly registered CLH intentions (see room document RAC/11/2010/34).	**SECR** to upload in RAC CIRCA IG the updated status document to reflect RAC appointments for CLH proposals after the meeting. **Members** are requested to come forward for the remaining positions. **SECR** to identify potential (co-)rapporteurs and encourage them to fill the vacant positions.
6.3 General CLH Issues	
6.3b Revisions of the working procedures on accordance check and on processing of dossiers for harmonised classification and labelling	

RAC agreed with the proposed revisions in the working procedures on accordance check and on processing of dossiers for harmonised classification and labelling with some editorial changes.	**SECR** to upload the agreed revised working procedures to RAC CIRCA IG after the meeting.
6.3c Feedback from the Commission on adopted CLH opinions and follow-up actions	
Following the Commission's request related to the additional justification to the RAC opinion on indium phosphide, RAC agreed on the justification proposed by the RAC (co-)rapporteurs for this substance.	**SECR** to forward to the Commission the agreed additional justification to the RAC opinion on indium phosphide after the meeting.
7 Restrictions	
7.1 Restriction Annex XV dossiers	
7.1.a DMFu – conformity check	
RAC took a decision that the Annex XV dossier proposing restriction for DMFu in consumer articles conformed with the requirements of Annex XV, in accordance with Article 69 (4) of the REACH Regulation.	**SECR** to communicate to the dossier submitter the RAC outcome of the conformity check of the DMFu dossier, together with the SEAC one by 3 June 2010 **SECR** to launch a public consultation on the Annex XV report, if the decision of SEAC is also for dossier in conformity after 3 June 2010
7.1.b Lead and its compounds in jewellery – conformity check	
RAC took a decision that the Annex XV dossier proposing restriction for Lead and its compounds conformed with the requirements of Annex XV, in accordance with Article 69 (4) of the REACH Regulation.	**SECR** to communicate to the dossier submitter the RAC outcome of the conformity check of the Lead and its compounds dossier, together with the SEAC one by 3 June 2010 **SECR** to launch a public consultation on the Annex XV report, if the decision of SEAC is also for dossier in conformity after 3 June 2010
8. Authorisation	
RAC took note on the Discussion note on the content of final Commission decisions and their effect on the format of the RAC and SEAC opinions (RAC/11/2010/26), the	**SECR** to open a CIRCA Newsgroup for members' comments on the documents RAC/11/2010/26, RAC/11/2010/27 and

elements of RAC and SEAC working procedure for developing opinions on the applications for authorisation (RAC/11/2010/27) and Draft Terms of reference for authorisation (co-) rapporteurs (RAC/11/2010/30). RAC also took note on the Discussion paper on the scope and content of conformity check of authorisation applications (RAC/11/2010/28) and draft WP on conformity check of authorisation applications (RAC/11/2010/29).	RAC/11/2010/30 after the meeting **SECR** to open a CIRCA Newsgroup for members' comments on the documents RAC/11/2010/28 and RAC/11/2010/29 after the meeting
10 Any other business	
10b Renewal of RAC membership	
-	**SECR** to keep RAC members informed of the ongoing activities
GENERAL	
-	**SECR** to upload all presentations, room documents and the RAC-11 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG by 3 June 2010.

Part III. List of Attendees

2. List of Attendees of the RAC-11 meeting (25-27 May 2010)

Members		**ECHA staff**
		BARRUEL Philippe
ANDERSSON Alicja		DE BRUIJN Jack
BARANSKI Boguslaw		ERICSSON Gunilla
BARRON Thomasina		FOTAKIS George
DI PROSPERO FANGHELLA Paola		FUHRMANN Anna
DUNAUSKIENE Lina		HONKANEN Jani
DUNGEY Stephen		HUUSKONEN Hannele
GREIM Helmut		KARHU Elina
GRUIZ Katalin		KOKKOLA Leila
HALKOVA Zhivka		KULJUKKA-RABB Terhi
KADIKIS Normunds		LANKOSKI Jussi
LARSEN Poul Bo		LEBSANFT Jörg
LE CURIEUX-BELFOND Olivier		LEFEVRE Rémi
LEINONEN Riitta		LUOTAMO Marita
LOSERT Annemarie		LUSCHÜTZKY Evita
LUND Bert-Ove		MATTHES Jochen
MULLOOLY Yvonne		MERKOURAKIS Spyridon
NAKOPOULOU Chrysanthi		NOUWEN Johan
NUNES Céu		PELTOLA Jukka
ORPHANOU Maria		SADAM Diana
PICHARD Annick		SIHVONEN Kirsi
POLAKOVICOVA Helena		VAINIO Matti
POSPISCHIL Erich		SCHÖNING Gabriele
PRONK Marja		STOYANOVA Evgenia
RUCKI Marian		TARAZONA Jose
RUPPRICH Norbert		VASILEVA Katya
SCHULTE Agnes		YLÄ-MONONEN Leena
SMITH Andrew		**Representatives of the Commission**
STOLZENBERG Hans-Christian		GRODZKI Karola (DG ENTR)
SULG Helen		ROZWADOWSKI Jacek (DG ENTR)
TADEO LLUCH José L.		WISTUBA Christine (DG ENV)
Van der HAGEN Marianne		
		Stakeholder observers
Replacements		ANNYS Erwin (CEFIC)
MYÖHÄNEN Kirsi (replacing Paul Kreuzer)		MEISTERS Marie-Louise (ECETOC)
		SANTOS Tatiana (ETUC)
Advisers to the RAC members		THEODORI Demi (WECF)
ALESSANDRELLI Maria (adviser to Paola DI PROSPERO)		VEROUGSTRAETE Violaine (Eurometaux)
CRACZYK Anna (adviser to Boguslaw Baranski)		WEFERS Heribert (EEB)
MC GARRY Helen (adviser to Andrew Smith)		

		Other observers
		EICHLER Jens Olaf (an observer accompanying the nominated CEFIC observer for THF)
		HENNINGER Kerstin (an observer acting as an expert to an observer representing ECPA for fuberidazole)
		HERBST Uta (the representative of the German CA, the dossier submitter for cryolites)
		JACOBI Sylvia (an observer accompanying the nominated CEFIC observer for HBCDD and TDCP)
		ROWE Rocky (an observer representing the nominated ECPA observer for fuberidazole)
		WAETERSCHOOT Hugo (an observer accompanying the nominated Eurometaux observer)
		Invited experts
		GEORGIOUS Stavros (invited as SEAC co-rapporteur for the conformity check for the lead restriction dossier)

Part IV. LIST OF ANNEXES

ANNEX I. Final Agenda of the RAC-11 meeting

ANNEX II. List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-11 meeting

25 May 2010
RAC/A/11/2010

Final Agenda

Eleventh meeting of the Committee for Risk Assessment

25 – 27 May 2010

Helsinki, Finland

25 May: starts at 9:00
27 May: ends at 12.30

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/11/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-10

- Adoption of the draft minutes

RAC/M/10/2010 draft final
For adoption

Item 5 – Administrative issues and information items

a. Status report on the RAC - 10 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/11/2010/32
ROOM DOCUMENT
For information

d. Follow-up of the 1st written procedure for adoption of a RAC opinion

RAC/11/2010/33
ROOM DOCUMENT

For agreement

Item 6 – CLH

6.1 CLH Dossiers

a. Gallium arsenide

For discussion and possible adoption

b. Tetrahydrofuran

For discussion and possible adoption

c. TDCP

For discussion and possible adoption

d. Cryolites (CAS13775-53-6 and CAS15096-52-3)

For discussion and possible adoption

e. HBCDD

For discussion and possible adoption

f. Fuberidazole

For initial discussion

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

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

RAC/11/2010/34
ROOM DOCUMENT
For agreement

6.3 General CLH issues

a. State of play of the submitted CLH dossiers

RAC/11/2010/35
ROOM DOCUMENT
For information

b. Revision of the working procedures on accordance check and on processing of dossiers for harmonised classification and labeling

RAC/11/2010/24
RAC/11/2010/25
For agreement

c. Feedback from the Commission on adopted CLH opinions and follow-up actions

RAC/11/2010/36
ROOM DOCUMENT
For agreement

Item 7 – Restrictions

7.1 Restriction Annex XV dossiers

a. DMF – conformity check

For decision

b. Lead and its compounds in jewellery – conformity check

For decision

7.2 General restriction issues

- Update on intended restriction dossiers

For information

Item 8 – Authorisation

a. Discussion note on the content of final Commission decisions and their effect on the format of the RAC and SEAC opinions

RAC/11/2010/26
For discussion

b. Elements of RAC and SEAC working procedure for developing opinions on the applications for authorisation

RAC/11/2010/27
For discussion

c. Discussion paper on the scope and content of conformity check of authorisation applications

RAC/11/2010/28
For discussion

d. WP on conformity check of authorisation applications

RAC/11/2010/29
For discussion and possible agreement

e. Terms of reference for authorisation (co-) rapporteurs

RAC/11/2010/30
For discussion

Item 9 – Guidance issues

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

For information

Item 10 – Any other business

a. RAC meeting calendar for 2011

RAC/11/2010/31

For information

b. Renewal of RAC membership

For information

c. Workshop on evaluation of two organic siloxane compounds

For information

d. Presentation on Extended One Generation Reproductive Toxicity Studies (EOGRTS)

For information

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

- Table with main conclusions and action points from RAC- 11

For adoption

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ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-11 meeting.

RAC/A/11/2010_rev1	Revised Draft Agenda – Eleventh meeting of the Committee for Risk Assessment
RAC/M/10/2010	Minutes of the 10th meeting of the Committee for Risk Assessment – draft final
RAC/11/2010/24	Revision of the working procedures on accordance check for harmonised classification and labelling
RAC/11/2010/25_rev	Revision of the working procedures on processing of dossiers for harmonised classification and labelling
RAC/11/2010/26	Discussion note on the content of final Commission decisions and their effect on the format of the RAC and SEAC opinions
RAC/11/2010/27	Elements of RAC and SEAC working procedures for developing opinions on the applications for authorisation
RAC/11/2010/28	Discussion paper on the scope and content of conformity check of authorisation applications
RAC/11/2010/29	WP on conformity check of authorisation applications
RAC/11/2010/30	Terms of reference for authorisation (co-) rapporteurs
RAC/11/2010/31	RAC meeting calendar for 2011
RAC/11/2010/32 (room document)	Administrative issues and information items
RAC/11/2010/33 (room document)	Follow-up of the 1st written procedure for adoption of a RAC opinion
RAC/11/2010/34 (room document)	Appointment of RAC (co-) rapporteurs for CLH dossiers
RAC/11/2010/35 (room document)	State of play of the submitted CLH dossiers
RAC/11/2010/36 (room document)	Feedback from the Commission on adopted CLH opinions and follow-up actions

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