

**Minutes of the 12th meeting  
of the Committee for Risk Assessment (RAC)  
(7-9 September 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 them that following the resignation of one RAC member Mariana-Elena Zglobiu, Maria Olteanu has been appointed as a new RAC member nominated by Romania. On behalf of RAC, the Chair welcomed the newly appointed member. The Chair also noted that Milan Paulovic is no longer a member of RAC after the decision of the ECHA Management Board (MB) to revoke his appointment. Moreover, a new nomination for RAC membership of Christine Bjørge, currently acting as an adviser of Marianne van der Hagen, has been submitted by Norway.

Ten advisers, one invited expert and nine stakeholder representatives (from Business Europe, CEFIC, ECEAE, ECETOC, EEB, ECPA, ETUC and Eurometaux), five observers accompanying stakeholder observers, three representatives from the Commission, two representatives of Member State Competent Authorities (MSCA) were welcomed.

For this meeting some participants took part, for the first time, in substance related discussions as remote participants via the WEBEX connection. The list of attendees is attached to these minutes.

Apologies were received from four RAC members and one regular observer (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 meeting. Nine members and one adviser declared potential conflicts of interest to different substance-related discussions in the agenda.

### **4 Adoption of RAC-11 Draft Minutes**

The Chair introduced the revised minutes, incorporating the comments received from members.

RAC adopted the revised minutes without changes. The Secretariat was to make the final version available through the RAC CIRCA IG and publish it on the ECHA website.

## **5 Administrative issues and information items**

Administrative issues and information items (a-c) were covered by the room document RAC/12/2010/45. 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.

## **6 MSCA support to RAC and Renewal of RAC Membership**

### **6a Update of the letters sent to MSCA and on the preparations for renewal of RAC membership**

The Secretariat informed participants about personalised letters in support of RAC members that were sent to MSCA by the Executive Director during this summer. The letters describe the RAC members increasing workload and the support they require. It calls upon MSCA to increase, wherever possible, the support to members and to nominate two candidates for RAC in the future. The MSCA were asked to contact their respective MB members, as they are to report on the topic at their next meeting in September. MSCA are informed in the letters about the mandate ending of most of the RAC members at the end of this year and that consequently they will be asked to nominate candidates for the next three years.

The Management Board will appoint members from the list of nominees for RAC at the MB meeting in December 2010.

### **6b Role of (co-)rapporteurs if their RAC Membership is not renewed**

RAC agreed to the proposal of the Secretariat of the role of (co-)rapporteurs if their membership is not renewed at the end of their term of office and the general approach to be followed. The proposal is outlined in the meeting document (RAC/12/2010/37).

## **7 CLH Dossiers**

### **7.1a Tris[2-chloro-1-chloromethyl]ethyl] phosphate (TDCP)(CAS No. 13674-87-8; EC No. 237-159-2)**

The Chair informed RAC about adoption of opinion on TDCP by consensus by written procedure and thanked the members for voting and adoption of this opinion and the (co-)rapporteurs for their work.

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

The Chair provided RAC with a brief procedural overview of this substance reminding the members that the classification of HBCDD was preliminary agreed at RAC-11; a second written consultation for members' commenting was further organised; the revised draft opinion was launched for adoption by written procedure. According to the Rules of Procedure, the written procedure for adoption of this substance's opinion was terminated with a RAC Chair's decision in agreement with the rapporteurs for HBCDD, due to major objections concerning the justification for the proposed classification for fertility, submitted by a RAC member. Therefore, the members would now be given an opportunity for further discussion and clarification

on the opinion documents. The classification proposals for developmental toxicity and lactation were considered agreed.

Furthermore, the Chair also mentioned that, industry had submitted additional comments for HBCDD received during the written procedure period (i.e. outside the public consultation). The comments were forwarded to the rapporteurs, according to the agreed working practices, and in agreement with the rapporteurs were uploaded to the confidential section of the RAC CIRCA IG for members' information.

The CEFIC expert clarified that the late industry comments contain e.g. a new statistical evaluation of data presented in the proposal.

In this regard, the Chair informed RAC that at a future plenary meeting, the Secretariat will present a proposal for members' consideration on a general approach for handling late information submitted by industry after the public consultation period.

Further, the rapporteur for HBCDD pointed out that the line of argumentation for the proposed classification for fertility will be reconsidered taking into account the comments made by the RAC member and provided at this meeting. A new draft argumentation will be prepared and presented at RAC-13. In addition, in accordance with the RAC procedures, the rapporteur requested several RAC members with reprotoxicity expertise to support the rapporteurs in the preparation of the revised argumentation in the draft opinion documents.

The member who expressed his major objections clarified that the classification for fertility endpoint should remain as agreed at RAC-11; however, the arguments for such classification should be further straightened for supporting adequately the opinion.

Furthermore, several members expressed their views on the need to generally discuss the issue of limit dose, as in this case, a very high dose had been used. One member noted however, that the substance had been administered as a powder in the diet in the Ema-study, thus making the actual dose lower than if it had been dissolved in a vehicle as in the van der Ven-study. The member also noted that the effects on the primordial follicles as shown in figure 3 in the Ema-study were significant in the two highest dose groups and relevant for assessing fertility. According to one member the data on ovarian toxicity did not match the fertility. They gave further recommendations to the rapporteurs on the proper focus of the argumentation in the opinion document for fertility.

Acknowledging the need for re-consideration of the opinion argumentation and the rapporteurs' request, RAC took a decision to establish an Ad Hoc WG for HBCDD rapporteurs' support according to Article 17 (5) of RAC Rules of procedure.

In conclusion, the Chair summed up that the discussion and the possible adoption of the CLH opinion for HBCDD will be postponed to RAC-13 and encouraged the members to provide their comments in support of the rapporteurs via the respective RAC CIRCA newsgroup.

### **7.1c Fuberidazole (CAS No. 3878-19-1; EC No. 223-404-0)**

The Chair invited the RAC rapporteur to present the second revision of the draft opinion.

The rapporteur presented their arguments and explained the options for classification for repeated dose toxicity, developmental toxicity and carcinogenicity as main elements for discussion.

The rapporteur's proposal to classify fuberidazole for repeated dose toxicity as STOT RE 2 (heart) was discussed and supported by the members.

The rapporteur's view on the validity of the 2-generation rat study for classification was discussed. The rapporteur's proposal not to classify for developmental toxicity was supported by the members.

RAC members agreed by consensus with the view of the rapporteur to support the classification, as follows: Acute Tox. 4 - H302, Skin Sens. 1 - H317; STOT RE 2 (heart) - H373, Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410 with M-factor 1 (under CLP Regulation) and Xn; R22, Xi; R43, Xn; R48/22, N; R50/53 (under Dir 67/548/EEC). RAC also agreed by consensus not to classify the substance for developmental toxicity.

Moving to carcinogenicity, the rapporteur presented an overview of the data from Wistar rats and Mice NMRI tests and requested members' comments. The members expressed views either for or against the classification for carcinogenicity. Concern on tumour incidences only at high doses and its relevancy for potential dosing and effect in humans was brought up in the discussion. On the other hand, some members stated that there was enough evidence to classify Fuberidazole for Category 2 carcinogen (suspected human carcinogen).

The Chair thanked the rapporteur and participants for their comments. The Chair requested all members to provide their view on the provided information and whether it supports classification of fuberidazole for Cat. 2 carcinogen. He suggested that members may consider consulting specialised experts in Member States if needed. Members were invited to express their views on carcinogenicity after the meeting (by 30 September) and passed the discussion to the RAC-13 meeting.

#### **7.1d White Spirit dossiers**

The Chair invited the representative from the Danish Competent Authority (MSCA) as dossier submitter to introduce the rationale of the CLH proposal for white spirit to RAC. The experts from the Danish Competent Authority provided an insight into the background to this proposal, focusing on the perspective of epidemiological research in occupational health (painters) and animal studies. The classification proposed by the dossier submitter was: STOT RE 1 - H372 (CLP Regulation) and Xn; R 48/20 (Directive 67/548/EEC).

The rapporteurs introduced to the Committee the first draft opinion, the key comments received during the RAC consultation and responses to these comments. The rapporteurs supported the classification proposed by the dossier submitter.

RAC members agreed with the view of the rapporteurs that the dossiers need further elaboration with regard to identity/composition of the solvent concerned as well as dose-response relationship and possible mode of action.

The dossier submitter explained that adverse neurological effects had been observed in painters from studies spanning the 1960- 1970s. However, an industry stakeholder representative noted that since this time, there had been a change in the composition of solvents that were marketed – from those with a higher aromatic content, to those with a lower, more aliphatic one, for example type 3 white spirit.

The stakeholder representative also proposed that the improvement of the types of solvent used since the time the clinical studies were performed, may explain the reduction of unfavourable effects in published studies.

Several members agreed that the CAS number for white spirit has a broad range and should be more closely examined. They invited the stakeholder representative to provide further information about trends in white spirit composition and respective sales volume for the period 1960-2010. CONCAWE<sup>1</sup> informed that they will provide information on the white spirit products (e.g. the grouping) which were on the market at the time when the references used in the CLH report were done.

Nevertheless, the dossier submitter noted that IPCS<sup>2</sup> and SCOEL<sup>3</sup> had already favoured grouping the white spirit substances together. In addition, the occupational health expert indicated that awareness among workers, rather than improved solvent composition, might explain the current positive trend observed in occupational health.

RAC members agreed with the view of the rapporteurs of the difficulties to identify differences in toxic responses between the various types of white spirit and that further information on the dose-response relationship for the various types of white spirit would be very useful.

The Chair invited stakeholders and the dossier submitter to assist the rapporteurs by providing any further available information on the composition of solvents marketed in the period 1960-2010 and on the link between hazard properties and types of white spirit to supplement information provided during the public consultation.

The Chair invited RAC members to provide any further comments on the rapporteurs' draft opinion by 30 September 2010 in the RAC CIRCA IG newsgroup that had been established. The Chair also invited the rapporteurs to provide a revised opinion and annexes for discussion at RAC-14.

#### **7.1e Acequinocyl (CAS No. 57960-19-7; EC No. 611-595-7)**

A representative of the Dutch Competent Authority introduced the CLH proposal which was as follows: Skin Sens. 1 - H317 (CLP Regulation) and R43 (Directive 67/548/EEC), STOT SE 1 - H370 (lung) and Xi; R37 (Directive 67/548/EEC), STOT RE 2 - H373 (blood system) (CLP Regulation); Aquatic Acute 1 - H400 and N; R50/53 (Directive 67/548/EEC); M-factor = 1000 (CLP Regulation)). Further to the original proposal the dossier submitter supported rapporteurs' suggestion and one RAC member's comment for adding Aquatic Chronic 1 (H410) to the original classification proposal because the substance cannot be considered as readily biodegradable, as one of the major metabolites is still very toxic to invertebrates (EC50 < 1 mg/L), corresponding to classification H410 (CLP Regulation)). Further to the original proposal the dossier submitter also supported several RAC members' comments for combining STOT SE 1- H370 (lung) with R39/23 instead of with Xi; R37, considering the nature of the effect, its severity and possible irreversibility.

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<sup>1</sup> The oil companies' European association for environment, health and safety in refining and distribution

<sup>2</sup> International Programme on Chemical Safety

<sup>3</sup> Scientific Committee on Occupational Exposure Limits

The dossier submitter also explained that the information provided in the current proposal is sufficient for assessing the reproductive toxicity. The data from the two generation and a teratogenicity rat study, as well as from the teratogenicity study in rabbit do not support the classification for fertility, nor for developmental toxicity. Regarding the discussion on developmental toxicity of warfarin and other coumarines and the possibility to read-across to acequinocyl, the Dutch representative clarified that depending on the outcome of that discussions, a new dossier may possibly be submitted at a later stage (by the Netherlands or any other interested Member States) but not within the group of coumarines to be discussed by RAC.

The (co-)rapporteurs for acequinocyl introduced to RAC the first draft opinion and the draft BD. They proposed to add the classification of Aquatic Chronic 1, as already supported by the dossier submitter.

RAC agreed with the view of the (co-)rapporteurs to classify this substance as follows to: Skin Sens. 1 - H317 (CLP Regulation) and Xi; R43 (Dir 67/548/EEC); STOT SE 1 – H370 (lung) (CLP Regulation); STOT RE 2 – H373 (blood system) (CLP Regulation) and no classification proposed for this endpoint under Directive 67/548/EEC; Aquatic Acute 1 – H400 with M-factor of 1000 (CLP Regulation) and N; R50/53 (Directive 67/548/EEC) with specific concentration limits N; R50/53, Cn  $\geq$  0.025%, N; R51/53, Cn  $\geq$  0.0025% and R52/53, Cn  $\geq$  0.00025%. RAC agreed to support the rapporteurs' proposal for additional classification of this substance for Aquatic Chronic 1 – H410 (CLP Regulation).

RAC further agreed that the submitted data do not support the classification for reproductive toxicity.

RAC members suggested to the rapporteurs to further consider the proposed classification R39/23 instead of Xi; R37 (Directive 67/548/EEC) considering the nature of the effect, its severity and reversibility, and as already supported by the dossier submitter.

The Chair invited the rapporteurs to provide the revised opinion documents to the Secretariat, clarifying that an editorial consultation would be launched after the meeting. Depending on the comments, the draft opinion may be proposed for adoption by written procedure before the next RAC plenary meeting.

#### **7.1f Tris(nonylphenyl)phosphite (TNPP) (CAS No. 26523-78-4; EC No. 247-759-6)**

The representative of the dossier submitter from the French Competent Authorities, who participated in the RAC meeting as a remote participant, introduced to RAC their CLH proposal as follows: Skin Sens. 1 – H317 (CLP Regulation) and Xi; R43 (Directive 67/548/EEC), Aquatic Chronic 4 – H413 and R53 (Directive 67/548/EEC).

It was clarified also that on the basis of the comments received during the public consultation, the dossier submitter decided to modify their original environmental proposal, as follows: Aquatic Acute 1 – H400, Aquatic Chronic 1 – H410, M-factor: 100 (CLP Regulation) and N; R50/53, with SCLs (Directive 67/548/EEC).

Further, the Chair invited the RAC (co-)rapporteurs to introduce to RAC their first draft opinion, the draft BD and the provisional responses to the members' comments.

The dossier submitter also indicated that other human health hazard classes had not been proposed, as the Technical Committee on Classification and Labelling under the previous legislation had already concluded on them and no new data had been submitted since then.

The rapporteur presented the draft opinion and explained that the reprotoxicity data have been provided by the dossier submitter only as supporting background information for potential discussions of nonylphenol (NP) as impurity and that he intends to indicate this very clearly in the BD and RCOM documents. The Chair confirmed that the rapporteur may revise the information in the opinion documents as appropriate. The rapporteur pointed out that TNPP may have impurities of 1-5 % of NP depending on its technical grade. As NP is classified as Repr. 2 - H361fd, Acute Tox. 4 - H302, Skin Corr. 1B- H314, Aquatic Acute 1; Aquatic Chronic 1, the manufacturers and importers should consider the impurities in their TNPP self-classification.

In addition, NP is formed by TNPP hydrolysis. The hydrolysis rate and relevance are key factors for classifying the substance TNPP. Due to the low solubility of TNPP in water, measurements are close to the detection limit and therefore study reports require careful consideration, e.g. regarding actually solubilised TNPP, or NP as relevant transformation product *versus* impurity.

The adviser to the co-rapporteur presented the rationale for providing an M-factor of 1 based on the estimated hydrolysis of TNPP into NP. Several RAC members expressed different views regarding the selection of the M-factor.

RAC agreed with the view of the rapporteurs to support the proposed classification for this substance, as follows: Skin Sens. 1- H317 (CLP Regulation) and Xi; R43 (Directive 67/548/EEC), as well as Aquatic Acute 1 – H400 (CLP Regulation), Aquatic Chronic 1 – H410 (CLP Regulation) and N; R50/53 (Directive 67/548/EEC).

Furthermore RAC invited the rapporteurs to further consider the proposed M-factor for aquatic hazard classification in consultation with members with environmental expertise and to prepare a common proposal to be further considered by RAC.

The Chair invited the rapporteurs to provide the revised opinion documents to the Secretariat that will be followed by an editorial consultation with RAC. Depending on the members' comments, the draft opinion may be proposed for adoption by written procedure before the next RAC plenary meeting.

### **7.1g Bifenthrin (CAS No. 82657-04-3; EC No. n. a.)**

A representative of the dossier submitter from the French Competent Authorities (CA) presented to RAC this CLH proposal for bifenthrin. The proposal was: Carc.Cat. 2 – H351 (CLP Regulation); Carc.Cat.3; R40 (Directive 67/548/EEC); STOT RE 1 – H372 (nervous system) (CLP Regulation); Xn; R48/22 (Directive 67/548/EEC); Acute Tox. 3 – H331 (CLP Regulation) and T; R23 (Directive 67/548/EEC); Acute Tox. 2 – H300 (CLP Regulation) and T; R25 (Directive 67/548/EEC); Skin Sens. 1 - H317 (CLP Regulation) and Xi; R43 (Directive 67/548/EEC); Aquatic Acute 1 – H400 (M-factor = 10 000); Aquatic Chronic 1 – H410 (CLP Regulation) and N; R50/53 (Directive 67/548/EEC). It was mentioned that bifenthrin is used as wood preservative, insecticide and plant protection product. Currently this substance has no harmonised classification and labelling at EU level.



The (co-) rapporteurs introduced to the Committee the first draft opinion and the key comments received during the RAC consultation and responses to these comments. They explained their preliminary conclusions concerning the proposed harmonised classification and supported the proposal from the dossier submitter for the following hazard classes: Acute Tox. 3 – H331 (under CLP Regulation) and R23 (under Dir 67/548/EEC); Acute Tox. 2 – H300 (under CLP Regulation) and T; R25 (under Dir 67/548/EEC); Skin Sens. 1 – H317 (under CLP Regulation) and Xi; R43 (under Dir 67/548/EEC); Aquatic Acute 1 – H400; Aquatic Chronic 1 – H410 (under CLP Regulation) and N; R50/53 (under Dir 67/548/EEC) with specific concentration limits N; R50/53,  $C_n \geq 0.0025\%$ , N; R51/53,  $0.00025\% \leq C_n < 0.0025\%$  and R52/53,  $0.000025\% \leq C_n < 0.00025\%$ . After discussion, RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification for this substance.

RAC further agreed on setting M-factor = 10 000 (under CLP Regulation) for the classification of Bifenthrin as hazardous to the aquatic environment. RAC also agreed on recommending a second M-factor of 100 000 based on the aquatic chronic data, as with the implementation of the 3<sup>rd</sup> revised edition of the GHS Purple book via the 2<sup>nd</sup> ATP to the CLP Regulation it will be possible to derive M-factors from 'true' chronic toxicity values. Since the 2<sup>nd</sup> ATP is still under discussion RAC agreed after some clarifications from the Commission observers that the second M-factor based on chronic toxicity data will not be listed in the table proposing the harmonised classification, but included as a recommendation in the opinion document. Furthermore, RAC agreed to follow the same approach for other substances whenever appropriate.

Concerning the French proposal for STOT RE 1 - H372, RAC discussed if the chronic effects (tremor) seen in the studies might reflect delayed acute toxicity of the substance and that the acute toxicity classification was sufficiently informative to indicate the hazardous properties of bifenthrin. Favouring a more systematic approach by adding STOT RE 1 - H372 as a further warning signal it was agreed to also support this proposal.

As proposed by the rapporteur, RAC agreed that the discussion on the proposed carcinogenicity hazard class will take place when further information is made available to the rapporteurs, possibly by RAC-13. The Secretariat will provide the rapporteurs and dossier submitter with further data on carcinogenicity (as referenced in the comments of the public consultation) when received from industry.

The Chair invited the (co-)rapporteurs to provide a revised version of the opinion in due course for further consultation with members.

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

Room documents RAC/12/2010/46 and RAC/12/2010/47 were introduced by the Chair who explained that ten new intentions for submission of CLH dossiers for active substances in plant protection products had been received. Before the meeting, six members had volunteered to act as (co-)rapporteurs for five intentions and 2 recent submissions. RAC agreed to appoint as (co-) rapporteurs the members who had volunteered for (co-) rapporteurship before or during RAC-12.

Furthermore, RAC members were invited to come forward for the other 16 vacant positions. The revised status document was to be uploaded to the RAC CIRCA IG after the meeting to reflect the changes.

### **7.3 General CLH issues**

#### **7.3a 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/12/2010/48. Members were invited to contact the Secretariat if they need further clarification.

#### **7.3b Report from the discussions at the ad hoc meeting held after RAC-11 on criteria for assessing the reliability and relevance of the studies which support the RAC opinions**

One member reported on the discussions at the Ad Hoc meeting held after RAC-11 on the criteria for assessing the reliability and relevance of the studies which support the RAC opinions and on how to deal with situations where further information is needed to assess a dossier. RAC was informed that a report is provided for information in room document RAC/12/2010/49. Members were invited to contact the Secretariat if they need further clarification.

#### **7.3c ECHA-EFSA co-operation on the classification and labelling of active substances in Plant Protection Products**

The Chair informed RAC that ECHA and EFSA are cooperating in order to facilitate the identification and classification of pesticides as carcinogens, mutagens or reproductive toxicants (CMRs) as required in the new Regulation on Plant Protection Products. The German CA has volunteered to organise a workshop in spring 2011 for facilitating the discussion. RAC members will be informed on the process, invited to participate in the workshop, and consulted on the follow up.

## **8 Restrictions**

### **8.1 Restriction Annex XV dossiers**

#### **8.1a Dimethylfumarate (DMFu) – first draft opinion**

The dossier submitter representative from the French Competent Authorities, who participated in the RAC meeting as a remote participant, presented the background information and the key elements for their Annex XV dossier proposing restriction for DMFu, as well as the main updates on the Annex XV report following the rapporteurs' recommendations and the initial comments from the public consultation.

The RAC rapporteurs introduced to RAC members the key elements of their first draft opinion on this restriction proposal and asked for RAC members' views on some other points for clarification.

Referring to the 1<sup>st</sup> Forum advice on the Annex XV restriction proposal for DMFu, the Secretariat, supported by clarifications from the Commission observers, explained that the advice covers also other issues than those related to RAC and that no RAC

response is expected. Only the elements relevant for the RAC opinion should be further addressed. Members expressed their views on the need to specify in the wording of the future restriction entry considering that the concentration limit applies not only to the article as such, but also to the individual parts thereof. It was also discussed whether the current proposal covers the imported sachets containing DMFu and whether the packaging should be considered as part of the restriction proposal.

Members discussed on the hazards to be considered in the RAC opinion and agreed that the most important endpoint is the skin sensitisation, the irritation endpoints were also seen significant.

Furthermore, the members agreed to support the preferred rapporteurs' approach for deriving a 'tentative elicitation-DNEL' based on the NOAELs in the dossier, due to the lack of data provided in the proposal for establishing an induction level.

RAC discussed also the difficulty to estimate the incidence of risk and the frequency of cases where people are sensitised after the DMFu exposure and suggested the rapporteurs to focus their attention on the number of cases that have been reported via different systems (like e.g. RAPEX) as an indication for the exposed population.

It was mentioned that in theory all 109 substances in PT 9 (preservatives) in the Biocide directive (98/8/EEC) could be regarded as alternatives to DMFu. Following the discussion on the theoretical alternatives for DMFu, the members concluded that there is no need for more information of the health and environmental risk assessment of the theoretical alternatives to be included by the dossier submitter and further considered by RAC for this particular dossier.

Finally, the Chair thanked to the rapporteurs, the members and the dossier submitters for their contributions, encouraged RAC to post their comments within ongoing written consultation via the relevant CIRCA newsgroup and concluded that further revision on first draft opinion will be done in line with the suggested modifications.

### **8.1b Lead and its compounds in jewellery – first draft opinion**

The dossier submitter representative from the French Competent Authorities, who participated in the RAC meeting as a remote participant, presented the background information and the key elements for their Annex XV dossier proposing restriction for lead and its compounds in jewellery, as well as the main updates on the Annex XV report following the rapporteurs' recommendations and the initial comments from the public consultation.

The RAC rapporteurs introduced RAC members with the key elements to be included in their first draft opinion. It was pointed out that no threshold for lead has been identified for its adverse effects regarding impairment of the IQ. Thus any relevant additional exposure to lead should be avoided. Furthermore, it was explained that after the submission of this restriction dossier, new scientific documentation from EFSA and JECFA become available and therefore, the dossier submitter should take these into account when preparing the background document.

Key issues for the following discussion were the relative contribution of the lead exposure to children from jewellery exposure compared to the background exposure (this requires information on the background exposure via food and other possible sources) and the need for more information of alternatives (comparison of TDIs and possible migration rates).

During the discussion, some members argued that the risks are not clearly described in the report. In addition, several members raised the issue on the use of lead in jewels and its possible replacement with alternatives. They pointed out that the issue of alternatives is quite relevant for the potential justification of the proposed restriction in the RAC opinion.

The rapporteurs agreed with the remarks and clarified that lead is intentionally used to increase the weight of the jewels; for light reflection and for surface filling. However, it was indicated that it would be difficult to evaluate this restriction proposal without additional information on the relative contribution of the lead exposure from jewellery under realistic conditions and sufficient information on the alternatives to allow comparison to lead.

The dossier submitter's proposal focuses on lead migration rate to be used for estimating the theoretical risks; several members asked the rapporteurs to consider a more pragmatic option based on the content of lead; taking into account that existing standard methods for testing the lead migration should be elaborated. A tiered approach (lead content as screening tool and migration rate for confirmation) was suggested.

The rapporteurs recalled that this issue, as well as the clarification of the meaning of "placing on the market" in this restriction proposal, are key elements from the 1<sup>st</sup> Forum advice to be included in the opinion of RAC. It was indicated that the dossier submitter is currently working on the evaluation of lead content in jewellery when revising their proposal and this would allow better evaluation of different options.

The observer from EUROMETAUX notified RAC that the lead industry's comments are to be submitted on the dossier during the ongoing public consultation and clarified that normally when alloys are assessed, the risk is addressed via the migration rate.

Some members also stressed in their views on the importance of the good cooperation in the ongoing dialogue between the rapporteurs and the dossier submitter. As RAC should assess the assumed risk, the members supported the rapporteurs' approach and agreed that background information for the exposure to children that demonstrates toxic effects is needed.

In conclusion, the Chair thanked to the rapporteurs, the members and the dossier submitter for their contributions and encouraged RAC to post their comments within ongoing written consultation via the relevant CIRCA newsgroup.

### **8.1c Phenylmercury compounds – conformity check**

The Secretariat presented a brief overview of the Annex XV dossier proposing restrictions at Community level to the following phenyl mercury compounds: phenylmercury acetate (CAS No. 62-38-4, EC No. 200-532-5); phenylmercury propionate (CAS No. 103-27-5, EC No. 203-094-3); phenylmercury 2-ethylhexanoate (CAS No. 13302-00-6, EC No. 236-326-7); phenylmercuric octanoate (CAS No. 13864-38-5, EC No. n.a.); and phenylmercury neodecanoate (CAS No. 26545-49-3, EC No. 247-783-7). The proposal submitted by the Norwegian CA aims to restrict the manufacture, placing on the market or use of the substances or their use(s) in mixtures in a concentration above 0.01 % weight by weight (w/w) after 5 years<sup>4</sup> of the entry

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<sup>4</sup> The proposal has the time period in square brackets.

into force. Articles or homogenous parts of articles, containing the substance(s) in a concentration above 0.01 % weight by weight (w/w) are not to be placed on the market 5 years<sup>5</sup> after the entry into force.

The Secretariat explained the proposal had been received by RAC on 16 August 2010 and it was expected that RAC should take a decision whether the Annex XV dossier was in conformity with the requirements of Annex XV at the current meeting. The justifications for the proposed restriction was that the substances degrade to mercury which is considered to be globally persistent causing transboundary effects; and it would strengthen the EU efforts in reducing mercury pollution at a global level.

The (co-) rapporteurs presented their draft conformity report for the dossier and explained that in their understanding the dossier is generally good, but some information appeared to be missing or not well presented. RAC members had an in-depth discussion over two sessions in plenary and in an ad hoc session to decide whether the Annex XV report was in conformity with the requirements of Annex XV. After discussion, RAC members decided that there was sufficient information in the dossier and RAC concluded that the report was in conformity with the requirements of Annex XV.

The dossier should be still strengthened with additional information (not formally related to the conformity check process that was finalised with the above-mentioned conclusion) to provide a good basis for RAC to formulate its opinion. The (co-) rapporteurs were invited to work with the dossier submitter and the Secretariat to obtain the additional information and present it in a clear manner. The conformity report was amended to reflect the identified desired additional information. The finalised report was to be sent to the dossier submitter once any final editorial changes had been made and SEAC had agreed its own conformity report.

RAC members also queried the basis for selecting the five phenyl mercury substances in the dossier. A RAC member working for the MSCA with the preparation of the dossier commented that the five substances had been selected for the proposed restriction on the basis of their application area (as catalysts in polyurethane systems), but grouped regarding to properties on the basis of their structural similarity. A RAC member queried whether the finalised conformity report could be published for transparency. The Chair noted the ECHA's Legal Affairs Unit will be consulted, and the publication of the conformity report will depend on the legal advice.

The Chair thanked the (co-) rapporteurs and RAC members for their work.

### **8.1d Mercury in measuring devices – conformity check**

A Commission observer presented a brief overview of the Annex XV dossier proposing restrictions at Community level for mercury (CAS number 7439-97-6, EC number 231-106-7) in measuring devices. The Commission explained that entry 18a of Annex XVII contains a review clause that requires a review of the availability of reliable safer alternatives that are technically and economically feasible for mercury-containing sphygmomanometers and other measuring devices used in healthcare and other professional and industrial uses. On the basis of this review, the Commission

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<sup>5</sup> The proposal has the time period in square brackets.

has to present a legislative proposal to extend the 18a restriction to these devices. Accordingly, it had requested ECHA to prepare an Annex XV dossier.

Fever thermometers and other measuring devices intended for sale to the general public are already restricted by the entry 18a. However, existing restrictions do not apply to antiques and to measuring devices that were already in use.

RAC had received the Annex XV dossier on 16 August 2010 which proposed restrictions on placing on the market of several mercury measuring devices.

The rapporteurs presented their draft conformity report, reminding members that RAC was expected to take a decision whether the Annex XV dossier was in conformity with the requirements of Annex XV at the current meeting.

RAC members held a discussion on the draft conformity report along similar lines to that for the proposed restriction for phenyl mercury compounds. Namely, whether the absence of data, or the presentation of data in the dossier was such that it should be considered not to be in conformity. RAC concluded that the dossier was in conformity with the requirements of Annex XV.

The dossier should be strengthened with additional information (not formally related to the conformity process) and in part re-structured to provide a better basis for RAC to formulate its opinion. The (co-) rapporteurs were invited to work with the dossier submitter and the Secretariat to obtain the additional information and present it in a clear manner. The conformity report had been amended before the meeting based on the received comments. The finalised report was to be sent to the dossier submitter once any final editorial changes had been made and SEAC had agreed its own conformity report.

The Chair thanked the (co-) rapporteurs and RAC members for their work

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

RAC was informed that there is no information of new intended Annex XV dossier proposing restriction. Therefore, the appointment of rapporteurs is not needed.

## **8.3 General restriction issues**

### **Update on intended restriction dossiers**

RAC was informed that there is no information of new intended Annex XV dossier proposing restriction.

## **9 Authorisation**

### **9.1 Content of an authorisation application**

The Secretariat presented a brief overview of the preliminary thinking of the content and structure of authorisation applications. The presentation was accompanied by room document RAC/12/2010/50. It was highlighted that an authorisation may be granted to an applicant under certain conditions for the specific use of an Annex XIV substance. The purpose of the application is to provide decision-makers with the required information to facilitate the formulation of the RAC and SEAC opinions and the Commission's decision on the granting of an authorisation. Further detail was presented about the information requirements as well as the activities currently being

undertaken by the Secretariat and the Commission to guide the preparation and submission of applications.

A brief discussion took place on what information will be released to the public (broad information on uses, as per Article 64(2)) to begin consultation with third parties on alternatives.

One stakeholder mentioned that broad information on uses could be misinterpreted when not considering all information related to uses. Then, it may not be sufficient for third parties to identify the most appropriate alternatives. Additional information, such as information on the function of the Annex XIV substance for the use applied for, will also be important. The Secretariat mentioned that the need for clarity will have to be balanced out with the need to respect confidentiality of the information submitted by the applicant. The Chair thanked the stakeholder for its contribution and suggested that the stakeholder and Secretariat remain in contact over the issue.

## **9.2 Conformity check**

### **9.2a Scope discussion on the working procedure for conformity check of authorisation applications**

The Secretariat presented its revised discussion paper (RAC/12/2010/38) on the scope and content of conformity checks on applications for authorisation following discussion at RAC-11 and subsequent comments. The presentation responded to comments made by RAC members, which were summarised in document RAC/12/2010/39\_rev1. It was explained that the modifications had been made to the discussion paper to take into account the comments made by RAC and SEAC members.

### **9.2b Second discussion on the WP on conformity check of authorisation applications**

The Secretariat presented the revised draft working procedure on the conformity check of authorisation applications (document RAC/12/2010/40) which had been modified to take into account comments from RAC and SEAC members (RAC comments summarised and responded in the document RAC/12/2010/41).

There followed a brief discussion in which several points were raised and clarified by the Secretariat.

The Chair thanked members for their comments and requested any additional comments by 1 October 2010 in the RAC CIRCA IG newsgroup that would be set up after the meeting. The Committee was to be requested to agree the working procedure at its October meeting.

## **9.3 Working procedure for developing opinions for authorisation applications**

The Secretariat presented for the first time a draft working procedure for developing opinions on applications for authorisation (documents RAC/12/2010/42, 43 & 44) which were based upon discussions at RAC-11 on the elements paper and comments from RAC and SEAC members.

One member noted that because of the wording of REACH, RAC would need to be ready to deal with applications whenever they arrived. The Secretariat explained that it was considering whether submission dates windows could be established for authorisation applications. The Secretariat further pointed out that it is also in the interest of applicants that the regulatory process is run smoothly and all applicants are treated equally.

The Secretariat clarified that the Committees' 10 month period for opinion making, including the conformity check, starts once the fee payment for the application has been received.

The Chair thanked members for their comments and requested any additional comments by 8 October 2010 in the RAC CIRCA IG newsgroup that would be set up after the meeting.

#### **9.4 Questions on alternatives**

The Secretariat presented the ongoing work on a tool that was being developed to assist rapporteurs to assess the information from applicants on alternatives. At its core was a list of questions based on the draft guidance documents. It was intended that the tool would enable the rapporteurs to identify information gaps, begin to formulate an opinion on the suitability and availability of alternatives, focus the consultation with third parties and identify points to clarify with applicants.

A short discussion followed in which members and stakeholders agreed on the usefulness of having such a tool. One stakeholder enquired whether the list of questions would be made public during the drafting stage. The Chair noted that the draft will be uploaded to the RAC CIRCA IG and, according to the ECHA Code of Conduct for stakeholders; they would be entitled to consult with their constituencies.

The Chair thanked participants for their comments.

### **10 Guidance issues**

#### **10a Feedback from guidance consultations**

The Secretariat informed RAC about the moratorium ECHA has placed on the publication of ten guidance documents until the first registration deadline of 1 December 2010. Of the ten guidance documents, five are relevant for the RAC work, and two of these have already been consulted with RAC (DNELs/DMELs and exposure scenarios for waste life cycle stage). RAC will be further consulted on the other RAC-relevant guidance documents that are currently under development on due course.

#### **10b Report on other guidance activities**

The Chair invited RAC to provide comments on the draft Guidance on Risk Communication via the respective RAC CIRCA newsgroup.

The Chair informed participants that a workshop on the CLP guidance on the preparation of dossiers for harmonised classification and labelling is foreseen to take place in the beginning of next year. The aim of the workshop will be to present the guidance document and to discuss its practical application by dossier submitters and RAC members.



## **11 Any other business**

### **11a Workshop on non-testing methods**

The Chair informed RAC that ECHA is going to organise a workshop on non-testing methods on 23-24 September 2010. Following the Secretariat's invitation five RAC members have been invited to take part in this workshop.

### **11b Revision of the RAC meeting calendar for 2011**

The revised RAC meeting calendar for 2011 (Room doc. RAC/12/2010/51) was presented to RAC.

### **11c 2<sup>nd</sup> International Conference on Risk Assessment**

The Chair informed also that DG SANCO will organise the 2<sup>nd</sup> International Conference on Risk Assessment in January 2011. DG SANCO has informed ECHA that RAC members will be welcomed. Interested RAC Members are invited to contact the RAC Secretariat and express their interests in attending that Conference.

### **11d Initial considerations on the use of the results of the draft test guideline on Extended One Generation Reproductive Toxicity Study (EOGRTS) in C&L and risk assessment processes**

The Secretariat presented to RAC the consultation on the use of information from EOGRTS for classification on reproductive toxicity and on risk assessment.

Following comments from some participants, the Secretariat clarified that the aim of the consultation was not to influence the OECD process, members had been requested to focus their comments on the use of the test results for classification and risk assessment. For specific comments on the guideline members were requested to contact their national coordinators for OECD guidelines.

The Secretariat underlined the importance to include the views of RAC members, since RAC is the ECHA body that should provide the best scientific and technical input on such issues.

Some members welcomed the opportunity for submitting comments, while others expressed concerns related to the additional work load for RAC members and question if this type of work can be considered as part of RAC tasks. Some members also indicated their involvement in the process at the national level, expressing concerns for a potential duplication of the work.

The Chair clarified that members could send general comments instead of responding the specific questions, and that members already involved in the discussions at the national/OECD level may consider informing ECHA on their involvement.

## **12 Main conclusions and Action Points of RAC-12**

The Secretariat presented the main conclusions and action points of the RAC-12 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 12<sup>th</sup> meeting of RAC)****(7-9 September 2010)**

<b>Agenda point</b>	
<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>2 Adoption of the Agenda</b>	
The final draft Agenda (RAC/A/12/2010) was adopted.  Nine members and three advisers have declared potential conflict of interest to different substance-related discussions under one Agenda item.	<b>SECR</b> to upload the adopted Agenda to the RAC CIRCA IG as a part of the RAC-12 minutes.
<b>4. Adoption of RAC-11 Draft Minutes</b>	
The minutes of RAC-11 (RAC/M/11/2010 draft final) was adopted without changes.	<b>SECR</b> to upload to the RAC CIRCA IG and the ECHA website the adopted minutes
<b>6. MSCA support to RAC and Renewal of RAC Membership</b>	
<b>6b Role of (co-)rapporteurs if their RAC Membership is not renewed</b>	
RAC agreed to the Secretariat's proposal on the role of RAC (co-) rapporteurs if their membership in not renewed in the end of their term of office and the general approach to be followed.	<b>SECR</b> to upload to the RAC CIRCA IG the agreed document and follow the agreed approach, when relevant.
<b>7. CLH</b>	
<b>7.1 CLH Dossiers</b>	
<b>7.1a. TDCP (adopted by written procedure prior RAC-12)</b>	
RAC was informed of the outcome of the written procedure for adoption of the opinion for TDCP. It was clarified that this RAC opinion (and its annexes) was adopted <u>by consensus</u> . The agreed harmonised classification in the final opinion is, as follows: <b>Carc. 2 - H351</b> (under CLP Regulation) and <b>Carc. Cat 3; R40</b> (under Dir 67/548/EEC).	<b>SECR</b> to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site by end of the week.  <b>SECR</b> to forward the adopted opinion and its annexes to COM by 15 September 2010.

<b>7.1b. Hexabromocyclododecane (HBCDD) (CAS No. 25637-99-4 and 3194-55-6)</b>	
<p>RAC members agreed with the rapporteurs' proposal to re-consider the argumentation for justification regarding the preliminary agreed classification proposed for fertility endpoint (<b>Repr. 2 - H361fd</b> (Suspected of damaging fertility. Suspected of damaging the unborn child.)).</p> <p>RAC members agreed to establish an Ad Hoc working group to support HBCDD rapporteurs in the preparation of draft opinion documents for HBCDD, according to Article 17 (5) of RAC Rules of procedure.</p>	<p><b>SECR</b> to create a CIRCA newsgroup for further RAC comments in support of the rapporteurs' revision after the meeting</p> <p><b>Members</b> to post their comments and suggestions aiming straightening of the justification in the HBCDD opinion documents for rapporteurs' further uptake by 1 October 2010</p> <p><b>Rapporteurs</b> to revise the argumentation in the justification of the draft opinion documents, based on the RAC comments and in consultation with the Ad Hoc working group before RAC-13</p> <p><b>SECR</b> to distribute the revised draft opinion and its annexes to RAC members when submitted for further discussion and possible adoption at RAC-13.</p>
<b>7.1c. Fuberidazole</b>	
<p>RAC members agreed <u>by consensus</u> with the view of the rapporteur to support the classification, as follows: <b>Acute Tox. 4 - H302, Skin Sens. 1 - H317; STOT RE 2 (heart) - H373, Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410 with M-factor 1</b> (under CLP Regulation) and <b>Xn; R22, Xi; R43, Xn; R48/22, N; R50/53</b> (under Dir 67/548/EEC).</p> <p>RAC also agreed <u>by consensus</u> not to classify the substance for developmental toxicity.</p> <p>RAC agreed that the discussion on the classification for carcinogenicity should be continued at RAC-13.</p>	<p><b>SECR</b> to create a CIRCA newsgroup for further RAC comments in support of the rapporteur's revision regarding carcinogenicity after the meeting</p> <p><b>Members</b> to post their views on the issue by 30 September 2010</p> <p><b>Rapporteur</b> to consider the comments received and if needed to modify the draft opinion documents before RAC-13</p> <p><b>SECR</b> to distribute the revised draft opinion documents to RAC when submitted for further discussion and possible adoption at RAC-13.</p>
<b>7.1d. White spirit dossiers</b>	
<p>In the 1<sup>st</sup> draft opinion of the rapporteurs the classification for STOT RE 1 and R 48/20 was supported.</p> <p>RAC members agreed with the view of the rapporteurs that the dossiers need further elaboration with regard to identity/composition of the solvent concerned as well as dose-response</p>	<p><b>SECR</b> to create a CIRCA newsgroup for further RAC comments in support of the rapporteur's revision after the meeting</p> <p><b>Members</b> to post their views on the issue by 30 September 2010</p> <p><b>SECR</b> to channel any further information</p>

<p>relationship and possible mode of action.</p>	<p>to be provided by stakeholders, industry or the dossier submitter.</p> <p><b>Rapporteurs</b> to revise the draft opinion and its annexes according to the plenary comments and to provide them to SECR.</p> <p><b>SECR</b> to circulate the revised draft opinion and its annexes for further consideration.</p>
<p><b>7.1e. Acequinocyl</b></p>	
<p>RAC members agreed <u>by consensus</u> with the view of the rapporteurs to support the proposed classification for this substance, as follows: <b>Skin Sens. 1 - H317</b> (under CLP Regulation) and <b>Xi; R43</b> (under Dir 67/548/EEC); <b>STOT SE 1 – H370 (lung)</b> (under CLP Regulation); <b>STOT RE 2-H373 (blood system)</b> (under CLP Regulation) and <b>no classification</b> (under Dir 67/548/EEC); <b>Aquatic Acute 1 - H400 with M-factor of 1000</b> (under CLP Regulation) and <b>N; R50/53</b> (under Dir 67/548/EEC).</p> <p>Furthermore, the members suggested to the rapporteurs to further consider the proposed classification <b>R39/23</b> instead of <b>Xi; R37</b> (under Dir 67/548/EEC) considering the nature of the effect, severity and reversibility.</p> <p>RAC also agreed <u>by consensus</u> that the submitted data do not support the classification for reproductive toxicity.</p> <p>RAC also agreed <u>by consensus</u> to support the rapporteurs' proposal for additional classification of this substance for <b>Aquatic Chronic 1 - H410</b> (under CLP Regulation).</p>	<p><b>Rapporteurs</b> to revise the draft opinion and its annexes according to the plenary comments as soon as possible and to provide it to SECR.</p> <p><b>SECR</b> to circulate the revised draft opinion and its annexes for further consideration and adoption by written procedure.</p> <p><b>Members</b> to consider the information on acequinocyl in the general discussion on coumarines.</p>
<p><b>7.1f TNPP</b></p>	
<p>RAC members agreed <u>by consensus</u> with the view of the rapporteurs to support the proposed classification for this substance, as follows: <b>Skin Sens. 1 - H317</b> (under CLP Regulation) and <b>Xi; R43</b> (under Dir 67/548/EEC), as well as <b>Aquatic Acute 1 - H400</b> (under CLP Regulation), <b>Aquatic Chronic 1 - H410</b> (CLP) and <b>R50/53</b> (under Dir 67/548/EEC).</p> <p>Furthermore, RAC suggested to the rapporteurs to</p>	<p><b>Rapporteurs</b> to provide the Secretariat with the revised draft opinion and its annexes by 20 September 2010.</p> <p><b>SECR</b> to organise the RAC commenting round immediately after receiving the rapporteur's revised draft opinion documents.</p>

<p>further consider the proposed <b>M-factor</b> for aquatic hazard classification in consultation with some RAC members with environmental expertise and to prepare a common proposal to be further considered by RAC.</p>	
<p><b>7.1g. Bifenthrin</b></p>	
<p>RAC members agreed <u>by consensus</u> with the view of the rapporteurs to support the proposed classification for this substance, as follows: <b>Acute Tox. 3 – H331</b> (under CLP Regulation) and <b>R23</b> (under Dir 67/548/EEC); <b>Acute Tox. 2 – H300</b> (under CLP Regulation) and <b>T; R25</b> (under Dir 67/548/EEC); <b>Skin Sens. 1 - H317</b> (under CLP Regulation) and <b>Xi; R43</b> (under Dir 67/548/EEC); <b>Aquatic Acute 1 – H400 (M-factor = 10 000); Aquatic Chronic 1 – H410</b> (under CLP Regulation) and <b>N; R50/53</b> (under Dir 67/548/EEC).</p> <p>RAC also agreed on a potential M-factor of 100 000 to be used based on the chronic data.</p> <p>RAC members also agreed to additionally classify bifenthrin as <b>STOT RE 1- H372</b> (under CLP Regulation).</p> <p>RAC agreed that the discussion on the classification on carcinogenicity will take place at RAC-13.</p>	<p><b>SECR</b> to provide the rapporteurs and dossier submitter with further data on carcinogenicity (as referenced in the comments of the public consultation) when received</p> <p><b>Rapporteurs</b> to provide the Secretariat with the revised draft opinion and its annexes in due course</p> <p><b>SECR</b> to organise the RAC commenting round immediately after receiving the rapporteur’s revised draft opinion documents.</p>
<p><b>7.2 Appointment of (co-) rapporteurs for CLH dossiers</b></p>	
<p>RAC agreed to appoint the volunteers as (co-) rapporteurs for the intended or submitted CLH proposals (listed in room documents RAC/12/2010/46 and RAC/12/2010/47).</p>	<p><b>SECR</b> to upload in RAC CIRCA IG the updated status document to reflect RAC appointments for CLH proposals after the meeting.</p> <p><b>Members</b> are requested to come forward for the remaining positions.</p> <p><b>SECR</b> to identify potential (co-)rapporteurs and encourage them to fill the vacant positions.</p>
<p><b>8 Restrictions</b></p>	
<p><b>8.1 Restriction Annex XV dossiers</b></p>	

<b>8.1. a DMFu – first draft opinion</b>	
RAC had the first plenary discussion on the rapporteurs' first draft opinion on the Annex XV dossier proposing restriction for DMFu in articles and on the identified items for further consideration.	<p><b>Members</b> to post their views on the 1<sup>st</sup> draft opinion within the ongoing written consultation via the respective RAC CIRCA Newsgroup by 17 September 2010</p> <p><b>Rapporteurs</b> to consider the comments provided during the written consultation and at RAC-12 when revising their 1<sup>st</sup> draft opinion according to the dossier-related calendar for this substance</p>
<b>8.1.b Lead and its compounds in jewellery – first draft opinion</b>	
RAC had the first plenary discussion on the rapporteurs' key elements for the first draft opinion on the Annex XV dossier proposing restriction for Lead and its compounds in jewellery and on the identified items for further consideration.	<p><b>Members</b> to post their views on the key elements for the 1<sup>st</sup> draft opinion within the ongoing written consultation via the respective RAC CIRCA Newsgroup by 17 September 2010</p> <p><b>Rapporteurs</b> to consider the comments provided during the written consultation and at RAC-12 when revising their 1<sup>st</sup> draft opinion according to the dossier-related calendar for this substance</p>
<b>8.1. c Phenylmercury compounds – conformity check</b>	
RAC decided that the Annex XV dossier proposing restriction for phenylmercury compounds is in conformity with the requirements of Annex XV for the relevant parts for RAC, in accordance with Article 69 (4) of the REACH Regulation.	<p><b>SECR</b> to communicate to the dossier submitter the RAC outcome of the conformity check of the phenylmercury compounds dossier, together with the SEAC one by 16 September 2010</p> <p><b>SECR</b> to launch a public consultation on the Annex XV report, if the decision of SEAC is also for dossier in conformity after 16 September 2010</p>
<b>8.1.d Mercury in measuring devices – conformity check</b>	
RAC decided that the Annex XV dossier proposing restriction for Mercury in measuring devices is in conformity with the requirements of Annex XV for the relevant parts for RAC, in accordance with Article 69 (4) of the REACH Regulation.	<p><b>SECR</b> to communicate to the dossier submitter the RAC outcome of the conformity check of the Mercury in measuring devices dossier, together with the SEAC one by 16 September 2010</p> <p><b>SECR</b> to launch a public consultation on the Annex XV report, if the decision of SEAC is also for dossier in conformity after 16 September 2010</p>

<b>9 Authorisation</b>	
<b>9.2 Working procedure on conformity check of authorisation applications</b>	
-	<p><b>SECR</b> to open a CIRCA Newsgroup for members' comments on the draft working procedure on conformity check of authorisation applications after the meeting</p> <p><b>Members</b> to post their comments on the draft by 1 October 2010</p>
<b>9.3 Working procedure for developing opinions for authorisation applications</b>	
-	<p><b>SECR</b> to open a CIRCA Newsgroup for members' comments on the draft working procedure for developing opinions for authorisation applications after the meeting</p> <p><b>Members</b> to post their comments on the draft by 8 October 2010</p>
<b>GENERAL</b>	
-	<p><b>SECR</b> to upload all presentations, room documents and the RAC-12 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG by 10 September 2010.</p>



### Part III. List of Attendees

#### 2. List of Attendees of the RAC-12 meeting (7-9 September 2010)

<u>Members</u>	<u>ECHA staff</u>
	ANFÄLT Lisa
ANDERSSON Alicja	BARRUEL Philippe
BARANSKI Boguslaw	DE BRUIJN Jack
BARRON Thomasina	ERICSSON Gunilla
BORGES Teresa	FOTAKIS George
DI PROSPERO FANGHELLA Paola	FUHRMANN Anna
DUNAUŠKIENE Lina	HONKANEN Jani
DUNGEY Stephen	HUUSKONEN Hannele
GREIM Helmut	KARHU Elina
GRUIZ Katalin	KOKKOLA Leila
HALKOVA Zhivka	KULJUKKA-RABB Terhi
KADIKIS Normunds	LUOTAMO Marita
KREUZER Paul	LUSCHÜTZKY Evita
LARSEN Poul Bo	MATTHES Jochen
LE CURIEUX-BELFOND Olivier	MERKOURAKIS Spyridon
LEINONEN Riitta	NYLUND Lars
LOSERT Annemarie	PELTOLA Jukka
LUND Bert-Ove	RÖCKE Timo
MULLOOLY Yvonne	SADAM Diana
NUNES Céu	SIHVONEN Kirsi
OLTEANU Maria	VAINIO Matti
PICHARD Annick	SCHÖNING Gabriele
POLAKOVICOVA Helena	STOYANOVA Evgenia
POSPISCHIL Erich	TARAZONA Jose
PRONK Marja	VASILEVA Katya
RUCKI Marian	YLÄ-MONONEN Leena
RUPPRICH Norbert	
SCHULTE Agnes	<b><u>Stakeholder observers</u></b>
SMITH Andrew	ANNYS Erwin (CEFIC)
STOLZENBERG Hans-Christian	CASALEGNO Carlotta (ECEAE)
SULG Helen	MEISTERS Marie-Louise (ECETOC)
Van der HAGEN Marianne	ROWE Rocky (ECPA)
Van MALDEREN Karen	SANTOS Tatiana (ETUC)
VILANOVA Eugenio	ULRICH Kerstin (BusinessEurope)
	WAETERSCHOOT Hugo (Eurometaux)
	VEROUGSTRAETE Violaine (Eurometaux)
	WEFERS Heribert (EEB)

<b><u>Advisers to the RAC members</u></b>	<b><u>Other observers</u></b>
ALESSANDRELLI Maria (adviser to Paola di Prospero)	FRANKE Kristian (an observer acting as an expert to an observer representing ECPA for acequinocyl)
BJØRGE Christine (adviser to Marianne van der Hagen)	HENNINGER Kerstin (an observer acting as an expert to an observer representing ECPA for fuberidazole)
CRACZYK Anna (adviser to Boguslaw Baranski)	JACOBI Sylvia (an observer accompanying the nominated CEFIC observer for HBCDD)
MC GARRY Helen (adviser to Andrew Smith)	McKEE Richard (an observer accompanying the nominated CEFIC observer for white spirit)
HAKKERT Betty (adviser to Marja Pronk)	MIKKELSEN Sigurd (a representative of the Danish CA, the dossier submitter for white spirit)
HÖGLUND Lena Marianne (adviser to Poul Bo Larsen)	ORTH Ann B (an observer accompanying the nominated ECPA observer for bifenthrin)
KLEIN Anita (adviser to Hans-Christian Stolzenberg)	ØSTERGÅRD Grete (a representative of the Danish CA, the dossier submitter for white spirit)
KORATI Safia (adviser to Karen van Malderen)	
KRAMER Helena (adviser to Alicja Andersson)	<b><u>Invited experts</u></b>
VEGA Milagros (adviser to Céu Nunes)	FURLAN Janez (invited as SEAC rapporteur following AP 8.1)
<b><u>Representatives of the Commission</u></b>	<b><u>Remote participants</u></b>
GIRAL Anne (DG ENTR)	BAILLY Guillaume (a representative of the French CA following AP 8.1a&b)
GRODZKI Karola (DG ENTR)	BASTOS Henri (a SEAC rapporteur for phenylmercury dossier following AP 8.1)
WISTUBA Christine (DG ENV)	FANKHAUSER Simone (a SEAC rapporteur for phenylmercury dossier following AP 8.)
	FIGLIORE Karine (a representative of the French CA following AP 8.1a&b)
	GEORGIOUS Stavros (a SEAC rapporteur for lead dossier following AP 8.1)
	PASQUIER Elodie (a representative of the French CA following AP 7.1f&g)
	RIBEIRO Lucie (a representative of the French CA following AP 7.1f)
	VERMANDE Emilie (a representative of the French CA following AP 8.1a&b))

**Part IV. LIST OF ANNEXES**

**ANNEX I.** Final Agenda of the RAC-12 meeting

**ANNEX II.** List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-12 meeting

7 September 2010  
**RAC/A/12/2010**

## **Final Agenda**

### **Twelfth meeting of the Committee for Risk Assessment**

**7 – 9 September 2010**

**Helsinki, Finland**

**7 September: starts at 9:00**

**9 September: ends at 16:00**

Preceded by a Presentation to RAC of the results of the EU Project PHIME to be held on 6 September from 15:30 to 18:30

#### **Item 1 – Welcome & Apologies**

#### **Item 2 – Adoption of the Agenda**

**RAC/A/12/2010**  
*For adoption*

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

#### **Item 4 – Adoption of the draft minutes of RAC-11**

- Adoption of the draft minutes

**RAC/M/11/2010 draft final**  
*For adoption*

#### **Item 5 – Administrative issues and information items**

- a. Status report on the RAC - 11 action points
- b. Outcome of written procedures
- c. Report from other ECHA bodies and activities

**RAC/12/2010/45**  
**ROOM DOCUMENT**  
*For information*

## **Item 6 – MSCA support to RAC and Renewal of RAC Membership**

a. Update on the letters sent to MSCA and on the preparations for renewal of RAC Membership

*For information*

b. Role of (co-)rapporteurs if their RAC Membership is not renewed

**RAC/12/2010/37**

*For discussion and possible agreement*

## **Item 7 – CLH**

### **7.1 CLH Dossiers**

a. TDCP (adopted by written procedure before RAC-12)

*For information*

b. HBCDD

*For adoption*

c. Fuberidazole

*For adoption*

d. White spirit dossiers

*For first discussion and possible adoption*

e. Acequinocyl

*For first discussion and possible adoption*

f. TNPP

*For first discussion and possible adoption*

g. Bifenthrin

*For first discussion*

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

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

**RAC/12/2010/46**  
**ROOM DOCUMENT**

*For decision*

**RAC/12/2010/47**  
**ROOM DOCUMENT**

*For information*

### **7.3 General CLH issues**

a. State of play of the submitted CLH dossiers

**RAC/12/2010/48**

**ROOM DOCUMENT**

*For information*

- b. Report from the discussions at the ad hoc meeting held after RAC-11 on criteria for assessing the reliability and relevance of the studies which support the RAC opinions

**RAC/12/2010/49**

**ROOM DOCUMENT**

*For information*

- c. ECHA-EFSA cooperation on the classification and labelling of active substances in Plant Protection Products.

*For information*

**Item 8 – Restrictions**

**8.1 Restriction Annex XV dossiers**

- a. DMFu – first draft opinion

*For first discussion*

- b. Lead and its compounds in jewellery – first draft opinion

*For first discussion*

- c. Phenylmercury compounds – conformity check

*For decision*

- d. Mercury in measuring devices – conformity check

*For decision*

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

*For agreement*

**8.3 General restriction issues**

- Update on intended restriction dossiers

*For information*

**Item 9 – Authorisation**

**9.1 Content of an authorisation application**

**RAC/12/2010/50**

**ROOM DOCUMENT**

*For information*

**9.2 Conformity check**

- a. Scope and content of conformity check

**RAC/12/2010/38**

(Response to comments table) **RAC/12/2010/39**  
*For discussion*

- b. Second discussion on the working procedure for conformity check of authorisation applications

**RAC/12/2010/40**  
(Response to comments table) **RAC/12/2010/41**  
*For discussion*

**9.3 Working procedure for developing opinions for authorisation applications**

**RAC/12/2010/42**  
(Response to comments table) **RAC/12/2010/43**  
(Response to comments table) **RAC/12/2010/44**  
*For first discussion*

**9.4 Questions on alternatives**

*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. Workshop on non-testing methods  
b. Revision of the RAC Meeting calendar for 2011

*For information*

**RAC/12/2010/51**  
**ROOM DOCUMENT**

*For information*

- c. 2<sup>nd</sup> International Conference on Risk Assessment

*For information*

- d. Initial considerations on the use of the results of the Extended One Generation Reproductive Toxicity Studies (EOGRTS) in C&L and risk assessment processes

*For information*

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

- Table with main conclusions and action points from RAC- 12

*For adoption*





## ANNEX II

### Documents submitted to the members of the Committee for Risk Assessment for the RAC-12 meeting.

RAC/A/12/2010_rev1	Revised Draft Agenda – Twelfth meeting of the Committee for Risk Assessment
RAC/M/11/2010	Minutes of the 11 <sup>th</sup> meeting of the Committee for Risk Assessment – draft final
RAC/12/2010/45 (room document)	Administrative issues and information items
RAC/12/2010/37	Discussion note on the role of (co-) rapporteurs if their RAC Membership is not renewed
RAC/12/2010/46 (room document)	Appointment of RAC (co-) rapporteurs for CLH dossiers – for decision
RAC/12/2010/47 (room document)	Appointment of RAC (co-) rapporteurs for CLH dossiers – for consideration
RAC/12/2010/48 (room document)	State of play of the submitted CLH dossiers
RAC/12/2010/49_rev1 (room document)	Report from the discussions at the ad hoc meeting held after RAC-11 on criteria for assessing the reliability and relevance of the studies which support the RAC opinions
RAC/12/2010/50 (room document)	Content of an authorisation application
RAC/12/2010/38	Scope and content of conformity check
RAC/12/2010/39	Scope and content of conformity check – response to comments table
RAC/12/2010/40	Second discussion on the working procedure for conformity check of authorisation applications
RAC/12/2010/41	Second discussion on the working procedure for conformity check of authorisation applications – response to comments table
RAC/12/2010/42	Working procedure for developing opinions for authorisation applications
RAC/12/2010/43	Working procedure for developing opinions for authorisation applications – response to comments table
RAC/12/2010/44	Working procedure for developing opinions for authorisation applications – response to comments table
RAC/12/2010/51_rev1 (room document)	Revision of the RAC meeting calendar for 2011

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