

**RAC/M/13/2010**  
FINAL  
21 December 2010

**Minutes of the 13th meeting  
of the Committee for Risk Assessment (RAC)  
(26-28 October 2010)**

## **Part I Summary Record of the Proceedings**

### **1 Welcome and apologies**

Dr Jose Tarazona, Chair of the Committee for Risk Assessment (RAC), ECHA, welcomed participants to the meeting and introduced and welcomed the new RAC member Christine Bjørge nominated by Norway. The Chair also informed participants at the meeting that after RAC-12, the resignation of Paul Kreuzer as a member of RAC was submitted to the Secretariat. Six advisers, three invited experts and six stakeholder representatives (from BusinessEurope, CEFIC, ECEAE, ECETOC, ECPA and Eurometaux), eight observers accompanying stakeholder observers and three representatives from the Commission were welcomed.

For this meeting some participants, representatives of Member State Competent Authorities (MSCA) or rapporteurs of the Committee for Socio-Economic Analysis (SEAC), took part 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 agenda items. Six members declared potential conflicts of interest to different substance-related discussions in the agenda.

### **4 Adoption of draft RAC-12 Minutes**

The Chair introduced the revised minutes, incorporating the comments received from members and one stakeholder observer (STO).

RAC adopted the revised minutes incorporating comments from RAC members and one stakeholder observer.

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

Administrative issues and information items (a-c) were covered by the room document RAC/13/2010/55. Members were informed of the possibility to provide comments under the relevant agenda item or under any other business at the end of the meeting.

The Chair reported on the discussion at the Management Board on the workload of RAC and indicated that the MB document has been distributed to RAC members for information.

The Chair explained in particular the request from some Management Board members for increasing the support from the ECHA Secretariat to the harmonised classification and labelling (CLH) rapporteurs in order to facilitate their work. RAC welcomed the proposal.

## **6 Renewal of RAC Membership**

The Secretariat reported to RAC on the ongoing actions related to the renewal of RAC membership. It was clarified that the nomination letters confirming the renewal of current members and/or proposing new candidates for RAC membership are expected to be submitted to ECHA via the Permanent Representations of Member States by 15 November 2010. RAC will be further updated on the issue at its next plenary meeting in December.

## **7 Stakeholder participation in the work of RAC (Closed Session)**

The Secretariat reported to RAC on the STO participation in the work of RAC for the period October 2009-October 2010, in accordance with the requirements of the RAC working procedure for admission to the work of RAC of regular and sector-specific STO observers and their advisers (RAC STO WP). RAC was requested to consider several proposals: the admission of a new STO; a request from the European Crop Protection Association (ECPA) concerning their observer status; and the practical aspects related to maintaining the balance of STO representation at RAC meetings, according to the principles laid down in the above-mentioned RAC STO WP. It was also clarified that although ECPA does not fulfil the eligibility criteria for a regular observer and its potential role in authorisation and restriction processes cannot be determined yet, ECPA could nevertheless contribute in the CLH process and other general discussions. RAC discussions on CLH process may benefit from the valuable contributions of ECPA observers.

In the following discussion, it was pointed out that the admission of new STO as RAC observers should be considered in parallel with thorough considerations regarding an appropriate balance of STO representation. STO should represent manufacturers, downstream users and NGOs. In addition, participation of the active RAC STOs which make valuable contributions to the work of RAC should be recognised in case not all STO that expressed interest could be invited due to the limitation in numbers.

Further, RAC agreed to admit the European Association for Chemical and Molecular Sciences (EuCheMS) to participate in the work of RAC as a regular RAC observer.

RAC decided to keep ECPA's sector-specific observer status, but to invite ECPA on a regular basis to participate in procedural and dossier-specific discussions in relation to CLH. Furthermore, ECPA will be granted broader access to RAC CIRCA IG.

RAC agreed to mandate the RAC Secretariat to ensure that the STO participation in the RAC work is in accordance with the general principles laid down in section 3.1 of the RAC STO WP and, if this is not the case, to undertake the necessary actions without delay.

Further, RAC agreed for the report on STO participation to be uploaded to the non-confidential RAC CIRCA IG for RAC observers' information.

Finally, RAC agreed to minute the closed session outcome in these minutes.

## 8 CLH Dossiers<sup>1</sup>

### 8.1a Hexabromocyclododecane (HBCDD) (CAS No. 25637-99-4 and 3194-55-6)

The Chair noted an observer accompanying the regular CEFIC observer.

The rapporteurs presented a revised version of the draft opinion documents (draft opinion and its annexes) for this substance focusing on the evidence providing justification for the proposed classification of HBCDD in relation to the CLH criteria for reproductive toxicity. The rapporteurs also explained the different views that had been shared between the members of the HBCDD *ad hoc* working group during the consultation period.

In the following discussion, it was concluded that the data in the submitted CLH dossier are sufficient to justify the classification for reproductive toxicity due to the clear effects on F2 pup viability during the lactation period and with consideration of the recognised bioaccumulation effects of HBCDD. However, the members had differing views when a possible classification on development is to be considered on the basis of the influence of the different exposure periods (pre-natal and/or post-natal) in the causation of the effects. The difficulty in interpreting the data, especially in relation to effects on development or via lactation, was mainly related to the lack of essential information as would have been provided in a cross-fostering study, and lack of data on mode of action and levels in breast milk in the rats.

Also, there were different interpretations of the fertility data e.g. concerning the decreased number of primordial follicles observed in the ovaries of F1 females.

Furthermore, it was noted that RAC should consider separately the proposed classification for HBCDD under CLP and DSD on the basis of a comparison of the data provided in the dossier with the CLP criteria and with the DSD criteria, respectively.

The issues were discussed in an ad hoc breakout group which made a proposal to RAC on the way forward. The rapporteurs made the relevant modifications in their draft opinion documents and presented this to RAC for agreement. In consideration of the criteria in CLP, RAC reached a preliminary agreement that HBCDD should be classified in Category 2 (with H361, without specifying the effect) for reproductive toxicity and for effects on or via lactation (with H362). RAC also agreed with the rapporteur that the available data were not sufficient to support the complete classification for HBCDD originally proposed according to the DSD criteria. Instead, RAC reached preliminary agreement that HBCDD should be classified with Repr. Cat.3; R63 and R64.

The Chair thanked the rapporteurs and the members for the fruitful discussion and explained that following the rapporteurs' revision of the draft opinion documentation in line with the above-mentioned agreements, the Secretariat will organise an editorial

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<sup>1</sup> Abbreviations in relation to harmonised classification and labelling: CLP refers to EC Regulation No. 1272/2008; and DSD refers to Directive 67/548/EEC.

consultation for possible adoption of the opinion at RAC-14 or beforehand, if feasible, by written procedure.

On a more general level, the discussion raised an issue concerning the way in which the CLP Annex I criteria for adverse effects on development of the offspring (Section 3.7.1.4) should be interpreted. This was addressed further under Agenda point 8.3.

#### **8.1b Fuberidazole (CAS No. 3878-19-1; EC No. 223-404-0)**

The Chair noted a stakeholder observer from the European Crop Protection Association (ECPA) and his adviser from Bayer to the meeting.

Further the chair reminded that at the previous meeting, RAC agreed on proposed classification for most of the hazard classes. The remaining discussion for this meeting was in relation to the carcinogenicity hazard class.

The Chair invited the RAC rapporteur to give a presentation on the carcinogenicity proposal following comments submitted by members after the discussion in RAC-12. The rapporteur explained the dossier submitter had presented the carcinogenicity data in the CLH report with the conclusion not to recommend a harmonised classification for carcinogenicity. During the public consultation, two MSCAs were in favour of a classification for carcinogenicity. RAC considered the classification of fuberidazole for carcinogenicity as a borderline case already at RAC-12. The rapporteur presented a proposal taking into account the comments received meanwhile. All written argumentations received from RAC members after RAC-12 were in favour of classification Carc. 2 (CLP). Consequently, the rapporteur presented a draft opinion describing how fuberidazole should be classified in Category 2 for carcinogenicity (CLP). The rapporteur also provided an opinion that fuberidazole should not be classified for developmental toxicity.

RAC adopted by consensus the opinion document and its annexes for fuberidazole. The proposed harmonised classification for this substance is as follows:

Acute Tox. 4 - H302, Skin Sens. 1 - H317, STOT RE 2 (heart) - H373, Carc. 2 - H351, Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410 with M-factor 1 (CLP) and Xn, R22, R48/22, R40 Carc Cat 3; R43, N; R50/53, with specific concentration limits: N; R50/53:  $C \geq 25\%$  ; N; R51/53:  $2.5\% \leq C < 25\%$  ; R52/53:  $0.25\% < C < 2.5\%$  (DSD).

The Chair thanked the rapporteur and participants for their comments and adoption of opinion.

#### **8.1c Acequinocyl (CAS No. 57960-19-7; EC No. 611-595-7)**

The Chair invited the rapporteurs to make any final remarks in relation to their revised draft opinion document, BD, and response to comments on the draft opinion.

The rapporteur provided RAC with a brief overview of the development of the draft opinion on the proposed classification of the substance on which preliminary agreement was reached at RAC-12.

Following RAC-12, a written consultation for members' comments on the revised draft opinion and its annexes had been organised. The rapporteurs presented the changes that had been made in the documents in response to the comments received.

At the meeting the formulation of the justifications for not classifying for developmental toxicity was discussed and a revised text was agreed by RAC.

The following text was deleted from the draft opinion to be recorded in the minutes: "it should be noted that RAC will discuss in the near future the justification of a read-across for developmental toxicity between warfarin and several coumarine based rodenticides. Like acequinocyl, these are all structural analogues of vitamin K. The future RAC conclusion on the coumarines may possibly trigger the need for submitting a new classification proposal for acequinocyl at a later stage."

RAC adopted by consensus the opinion document and its annexes for acequinocyl. The proposed harmonised classification for this substance is as follows:

Skin Sens. 1 - H317, STOT SE 1 – H370 (lung), STOT RE 2 – H373 (blood system), Aquatic Acute 1 – H400 and Aquatic Chronic 1 – H410 with M-factor of 1000 (CLP) and T; R39/23, R43, N; R50/53 with specific concentration limits N; R50/53, C  $\geq$  0.025%, N; R51/53,  $0.0025\% \leq C < 0.025\%$ , and R52/53,  $0.00025\% \leq C < 0.0025\%$  (DSD).

The Chair thanked the rapporteurs and participants for their comments and adoption of opinion.

#### **8.1d TNPP (Tris(nonylphenyl)phosphite) (CAS No. 26523-78-4; EC No. 247-759-6)**

The Chair welcomed the representatives of the dossier submitter from the French Competent Authority (MSCA) who took part in the discussions as remote participants and noted an observer accompanying the regular CEFIC observer.

The Chair invited the rapporteurs to make any final remarks in relation to their revised draft opinion document, BD, and response to comments on the draft opinion.

The rapporteur reminded members that preliminary agreement had been reached on the proposal for classification at RAC-12 as follows: Skin Sens. 1 – H317, Aquatic Acute 1 – H400, Aquatic Chronic 1 – H410 (CLP).

Following RAC-12 a written consultation for collecting members' comments on the M-factor was organised. An *ad hoc* working group consisting of RAC members and their advisers discussed the issue in more detail. The rapporteur presented the outcome of that discussion.

The working group came to the conclusion that due to the specific TNPP properties and flaws of key information there is insufficient data for deriving an appropriate M-factor. The main issues were the poor description of undissolved TNPP loadings and truly solubilised TNPP; the unclear rate of hydrolysis, relevant uncertainties regarding resulting concentrations of nonylphenol (NP) and other potential transformation products. On these grounds, classification of TNPP in analogy to NP was dismissed and in addition, no other line of justification was found that could provide arguments for an M-factor of 10.

RAC adopted by consensus the opinion document and its annexes. The proposed harmonised classification for this substance is as follows:

Skin Sens. 1 - H317, Aquatic Acute 1 - H400, Aquatic Chronic 1 - H410 (CLP) and Xi; R43, N; R50/53 (DSD).

The Chair thanked the rapporteurs and participants for their comments and adoption of opinion.

### **8.1e Lucirin (Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide) (CAS No. 75980-60-8; EC No. 278-355-8)**

The Chair invited the rapporteurs to introduce the dossier.

The RAC rapporteurs presented the first draft opinion. They agreed with the proposal from the dossier submitter to classify the substance as follows: Repr. 2 - H361f (CLP) and Repr. Cat. 3; R62 (DSD).

Following the rapporteurs' presentation, RAC discussed if the evidence for this classification was sufficiently robust. Some members of RAC noted that the boundary between classification categories 1B and 2 (CLP), or categories 2 and 3 (DSD) was not always clear to define. They requested clarification on the criteria for this endpoint (see also 8.3 General CLH issues).

There was common understanding that the absence of a multi generation study does not automatically exclude the consideration of Category 1B classification, since there are other ways in which such a significant hazard can be defined. One RAC member suggested that the severity of the effects would justify the classification in category 1B. However others replied that the guidance does not define the categories 1B and 2 by severity. The guidance on the CLP criteria uses the words "clear evidence" for category 1B and "some evidence... where evidence is not sufficiently convincing" as category 2.

Repeated dose toxicity studies were available reporting toxicity of lucirin on the testes. However, no effects on testes had been observed in a 28-days study, in which rats were dosed at 1000 mg/kg bw/day, and the effects in a 90-days study were minimal. This data directed the rapporteurs towards Category 2 (CLP), rather than category 1B. The data were inconclusive regarding toxicokinetics and/or strain differences. Several RAC members provided their reasoning why the evidence is not sufficiently convincing to place the substance in Category 1B for reproductive toxicity.

RAC adopted by consensus the opinion document and its annexes for lucirin. The proposed harmonised classification for this substance is as follows:

Repr. 2 - H361f (CLP) and Repr. Cat. 3; R62 (DSD).

The Chair thanked the rapporteurs and participants for their comments and adoption of opinion.

### **8.1f Metazachlor (CAS No. 67129-08-2; EC No. 266-583-0)**

The Chair noted an observer accompanying the sector specific ECPA observer. The Chair invited the rapporteurs to introduce the dossier.

RAC members discussed the classification proposal that had been presented by the rapporteurs, which was as follows: Carc. 2 - H351; Skin Sens. 1 - H317; Aquatic Acute 1 - H400; Aquatic Chronic 1 - H410; M-factor 100 (CLP) and Carc. Cat. 3: R40, R43, N; R50/53, with specific concentration limits: N; R50/53,  $C \geq 0.25\%$ , N; R51/53,  $0.025\% \leq C < 0.25\%$ , R52/53,  $0.0025\% \leq C < 0.025\%$  (DSD).

Several RAC members supported the proposed classification. As the draft opinion is still under consultation, no conclusion was reached. Members were asked to provide their comments on the draft opinion by 9 November, particularly on the carcinogenicity and the mode of action. One RAC member raised the issue of classification for reproductive toxicity. The rapporteur agreed to have a further look at the data, and it was decided that RAC members would be invited to provide their views on this aspect to the RAC CIRCA IG news group. The Chair reminded that in the case of metazachlor, all endpoints should be specified in the opinion since it is an active substance of plant protection products.

The Chair also suggested minor editorial changes and to include also M factor based on chronic data.

### **8.1g Flufenoxuron (CAS No. 417-680-3; EC No. 101463-69-8)**

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

The CLH proposal on flufenoxuron from the dossier submitter was presented to RAC through a recorded presentation prepared by a representative of the dossier submitter prior to the meeting. The current proposal was: Lact. – H362; STOT Rep. 2 – H373 (red blood cells); Aquatic Acute 1 – H400, Aquatic Chronic 1 – H410; with M-factor of 10 000 (CLP) and Xn; R48/22, R64, N; R50/53, 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,  $0.000025\% \leq C_n < 0.00025\%$  (DSD).

It was mentioned that flufenoxuron is an active substance in plant protection and biocidal products used as wood preservative and insecticide. A harmonized classification of all hazard classes is therefore required. Currently this substance has no harmonised classification and labelling at EU level. The dossier submitter confirmed that the CLH dossier contains all information available under the plant protection product and biocides processes and that they were not aware of any further (on-going) studies relevant for the CLH proposal.

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.



On the proposal for Lact.–H362, RAC discussed the mechanism of lactation effects. Some members proposed that bioaccumulation and exposure patterns might explain the differences observed between the cross-fostering and other studies

Concerning the proposal for STOT Rep 2 - H373(red blood cells), RAC discussed the interpretation of the criteria, specifically the severity of the lesions. Some members considered that effects were transient (present only at week 9) or not severe enough (pigment deposition but no lesions). Other members considered that deposition was permanent in macrophages and some organs (kidneys) and, more generally, typical of molecules with similar structure which are capable of attacking cells.

The observer accompanying the sector-specific ECPA observer noted that classification for repeated dose effects (i.e. with R48) was intended to address serious organ dysfunction. Deposition (immunocirrosis) was “mild” and not “marked” as requested by the guidance. Finally some acute effects at low dose should not infer the classification of a substance tolerated on the long term at high dose.

RAC members agreed by consensus on the environmental classification as proposed: Aquatic Acute 1 – H400, Aquatic Chronic 1 – H410 (CLP) and N; R50/53 (DSD) 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,  $0.00025\% \leq C_n < 0.00025\%$ . RAC further agreed on setting M-factor = 10 000 (CLP) for the classification of flufenoxuron as hazardous to the aquatic environment.

RAC agreed to continue the discussion on the classification for the other hazard classes particularly regarding the severity of hemolytical effects, the basis for specific target organ toxicity, the mechanism of lactation effects and to assess the potential chronic classification and M-factor according to the chronic classification criteria (2nd ATP).

The Chair informed RAC members that a RAC CIRCA IG newsgroup will be opened and invited the RAC members to provide further comments on the first draft opinion and its annexes by 11 November 2010 and thanked the rapporteurs for preparing the draft documents. The rapporteurs will consider the comments received and revise the draft opinion documents if needed, and subsequently submit them to RAC. The substance will be further discussed and possibly adopted at RAC-14.

### **8.1h PHMB (EC No. n. a (polymer); CAS No. 27083-27-8 or 32289-58-0)**

The Chair welcomed the representatives of the dossier submitter from the French Competent Authority (MSCA) who took part in the discussions as remote participants.

The CLH proposal of the dossier submitter was provided to RAC in a pre-recorded presentation. It was noted that the substance has no harmonised classification and labelling at the EU level and is an active ingredient used in biocides. The classification proposed by the dossier submitter was: Carc. 2 - H351, Acute Tox. 1- H330, STOT RE 1- H372 (“Causes damage to the respiratory tract through prolonged and repeated exposure by inhalation”), Acute Tox. 4 - H302, Eye Dam. 1 - H318, Skin Sens. 1 - H317, Aquatic Acute 1- H400, Aquatic Chronic 1- H410 with M-factor

of 10 (CLP) and Carc. Cat.3;R40, T+;R26, T;R48/23, Xn; R22, Xi; R41, R43, N; R50/53 (DSD).

Further, the Chair invited the rapporteurs to introduce the first draft opinion of PHMB dossier and the underlying scientific argumentation. The rapporteurs supported the classification as proposed by the dossier submitter.

The Chair gave the floor to the accompanying observer from CEFIC, who considered that the data did not support the proposed classification for carcinogenicity based on a new statistical analysis and did not support the classification for acute and repeated toxicity by inhalation. The Chair clarified that the late comments received the day before the RAC meeting from the STO observer, will be made available for RAC members in the RAC CIRCA IG, for information and commenting if needed. It was also clarified that the documents contained expert assessments and statistical analysis of information already submitted during the public consultation and considered by the rapporteurs, but not new data.

There were no objections from RAC members to the proposal given in the draft opinion.

The Chair reminded RAC members that a RAC CIRCA IG newsgroup had been opened and invited members to provide comments on the first draft opinion and its annexes by 3 November 2010 and thanked the rapporteurs for preparing the draft documents. The rapporteurs will consider the comments received and revise the draft opinion documents if needed, which subsequently will be submitted to RAC. The substance will be further discussed and possibly adopted at RAC-14.

### **8.1i Chloroform (CAS No. 67-66-3; EC No. 200-663-8)**

The Chair welcomed the representatives of the dossier submitter from the French Competent Authority (MSCA) who took part in the discussions as remote participants and noted an observer accompanying the regular CEFIC observer.

The CLH proposal on chloroform from the dossier submitter was provided to RAC through a pre-recorded presentation prepared by the dossier submitter. The proposal was: Acute Tox. 3 – H331, Acute Tox. 4 – H 302, STOT RE 1 – H 372, STOT Single 3 – H336, Eye Irrit. 2 – H319, Skin Irrit. 2 – H315, Muta. 2 – H341, Carc. 2 – H351; Repr. 2 – H361d (CLP) and Carc. Cat. 3; R40, Muta Cat. 3; R68, Repr. Cat. 3, R63, Xn; R20/R22-R48/20, Xi; R36/38 (DSD).

Chloroform had been on the 2<sup>nd</sup> priority list of the Existing Substances Regulation (Council Regulation (EEC) No. 793/93) and its classification had been reviewed in the context of the risk assessment procedure as it was a requirement to harmonise classification for all endpoints. In September 2007, the Technical Committee for Classification and Labelling (TC C&L) had reached agreement on all the hazard classes proposed, apart from that of mutagenicity. RAC needed to focus on the mutagenicity endpoint.

The RAC (co-) rapporteurs and their adviser introduced the first draft opinion and the key comments received during the RAC consultation and responses to these comments.

Concerning the mutagenicity classification that had been proposed, RAC discussed the application of the CLP criteria to chloroform. Some members noted that the endpoint to be addressed under CLP was “germ cell mutagenicity”, whereas under the DSD the endpoint had less specifically been given as “mutagenicity”. Normally, substances showing somatic cell mutagenicity will be covered under this endpoint, since it is widely accepted that somatic cell mutagens will have the potential to act as germ cell mutagens. However, since the focus was now on heritable mutation, when substances have been shown to lack this hazard they should not be classified. For chloroform, given the data presented, it seemed appropriate to question whether there was sufficient evidence to show the absence of this hazard potential. In particular, the unusual range of negative and positive *in vitro* and *in vivo* somatic cell results, the proposed indirect mechanism of action, and the negative germ cell test results, all seemed to cast some doubt on whether chloroform realistically could be viewed as a germ cell mutagen.

Some members focussed on the fact that chloroform did appear to have mutagenic potential, at least under certain conditions, and argued that this seemed to merit classification.

It was agreed that the rapporteur would look again at the available data and consider whether, the normal assumption that a somatic cell mutagen will have the potential to be a germ cell mutagen can be applied to chloroform. For example, there might be data on epithelium damage in the testes or useful toxicokinetic data.

Finally, it was noted by some members that there could be different classifications under CLP and DSD for any substances found unusually to be somatic cell mutagens and germ cell non-mutagens. Other members were uncertain about this.

Some members commented that chloroform is one of the few typical examples of secondary mutagenicity. The mutagenic profile seen with chloroform was considered to be of relevance to its carcinogenicity

The Chair gave the floor to the expert accompanying the CEFIC observer, who did not support the proposed classification for mutagenicity based on different interpretation of the results of the studies.

Finally, the Chair asked the (co-) rapporteurs to elaborate in the assessment the interpretation of the CLP criteria for this hazard class, offering the support of the SECR if needed. As noted by one member, regardless of how chloroform should be classified, it may be helpful for RAC to think some more about the CLP criteria and how they should be applied to those relatively unusual mutagenic substances that do not pose a germ cell hazard (e.g due toxicokinetic factors, mechanisms of action, etc.).

The Chair reminded RAC members that a RAC CIRCA IG newsgroup had been opened and invited members to provide comments on the first draft opinion and its annexes by 11 November 2010 and thanked the (co-) rapporteurs for preparing the draft documents. The (co-) rapporteurs will consider the comments received and revise the draft opinion documents if needed, which subsequently will be submitted to the RAC. The substance will be further discussed and possibly adopted at RAC-14.

### **8.1j Leucomalachite green (CAS No. 129-73-7; EC No. 204-961-9)**

The Chair invited the RAC rapporteur to present the first draft opinion on the CLH proposal submitted by the UK as Carc. 2 - H351, Muta. 2 - H341 (CLP) and Carc. Cat. 3; R40, Muta. Cat 3; R68 (DSD).

A harmonised classification and labelling for this substance had been agreed at TC C&L. However, the current classification proposal did not cover all the hazard classes that have been discussed and decided upon at TC C&L. The submitted dossier proposed classification for mutagenicity and carcinogenicity and therefore the RAC opinion should only cover these hazard classes. As the proposed classification for these hazard classes is similar to that agreed by the TC C&L, the RAC views previously agreed for handling these “TC C&L agreed substances” should be considered.

The rapporteur pointed out that there is some experimental evidence of *in vivo* mutagenicity in liver cells and some weak evidence of carcinogenicity in the liver of female mice. The data justifies the classification in category 2 (CLP) for mutagenicity and carcinogenicity .

All comments received on the first draft opinion supported the current draft opinion.

RAC agreed to support the proposed classification for this substance, as follows: Carc. 2 - H351, Muta. 2 - H341, (CLP) and Carc. Cat. 3; R40, Muta. Cat. 3; R68, (DSD).

It was requested that the S-phrases be checked. The rapporteur will make final editorial changes to the draft opinion with support from SECR without delay. A short editorial commenting round will be initiated with a deadline of 11 November for possible adoption of the opinion at RAC-14 or beforehand, if feasible, by written procedure.

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

Room document RAC/13/2010/53\_rev1 was introduced by the Chair who explained that one new submission and 40 new intentions for submissions of CLH dossiers for active substances in plant protection products had been received. Before the meeting, two members had been appointed to act as (co-)rapporteurs for two recent submissions. Three members had resigned from their appointment as (co-) rapporteurs for two submitted substances and one intention. RAC agreed to appoint as (co-) rapporteurs the 20 members that had volunteered during RAC-13 for (co-) rapporteurship on 30 substances.

Furthermore, RAC members were invited to come forward for the other dossiers.

### **8.3 General CLH issues**

#### **8.3a State of play of the submitted CLH dossiers**

RAC was informed by the Secretariat on the state of play of the submitted CLH dossiers as provided in room document RAC/13/2010/56. Members were invited to contact the Secretariat if they need further clarification.

#### **8.3b Other issues**

A Commission observer updated RAC members on the content of the next adaptation to technical progress (ATP) of the CLP Regulation that is currently envisaged by the Commission. The hazard classification for sensitisation would be divided into subcategories, 1A and 1B. The classification criteria for the aquatic chronic hazards based on NOECs from long-term studies would be included. The new hazard class of hazardous to the ozone layer would also be used and ECHA was likely to be requested to draw up guidance for this. In addition, note H was to be removed from tables 3.1 and 3.2 of the CLP Regulation. The ATP was currently being consulted with the European Parliament and adoption by the Commission was envisaged for March 2011.

He also requested, in a similar manner as currently done by RAC for the new environmental classification criteria, that RAC could provide in their opinion the classification for sensitisation on the basis of the current criteria and on the new ones.

The Commission observer also noted the RAC opinion on the CLH proposal for epoxiconazole (CAS No: 133855-98-8; EC No: 406-850-2) was currently being considered for inclusion into the next ATP. In advance of this the Commission was considering requesting ECHA to provide an opinion as to whether it is possible that the results of the ongoing studies requested under the plant protection products legislation could have an impact on RAC's opinion related to the classification of the substance as toxic for reproduction category 1B (CLP).

Following the discussions for HBCDD and lucirin, RAC requested the ECHA Secretariat to draft a proposal for facilitating the discussion on the application of the criteria for reproductive toxicity under the CLP, when associating some observed effects with fertility, developmental and/or lactation hazards, with the view to discuss the best way to move forward at RAC 14.

## **9 Restrictions**

### **9.1 Restriction Annex XV dossiers**

#### **9.1a Dimethylfumarate (DMFu) – state of play**

The rapporteurs provided feedback from the 2<sup>nd</sup> rapporteurs' dialogue that took place the day before the plenary session and their initial views on the early public consultation comments and dossier submitter's responses, as well as on the revised Annex XV restriction report (in the format of the background document (BD)). Furthermore, the rapporteurs presented the outstanding issues related to the conditions for DMFu restriction and the precise wording of this restriction.

After a short discussion on the issue, RAC acknowledged the need for further discussion on the wording of the proposed restriction for DMFu in articles, as well as a clear definition of the interpretation of the term "an article" in the context of this

restriction dossier. The Secretariat was requested to clarify this issue and to inform RAC accordingly.

In addition, the Secretariat was asked to analyse whether the restriction entries in Annex XVII can be used as assistance when designing the wording for the current proposed restriction and to provide their recommendation on the issue.

The Chair thanked the rapporteurs and the other RAC members and noted that the discussion on the revised opinion documents is expected to continue at the next meeting of RAC in December 2010.

### **9.1b Lead and its compounds in jewellery – state of play**

The Secretariat provided RAC with an update on a set of procedural issues related to this restriction dossier. The following was suggested: the key element paper for the 1<sup>st</sup> draft opinion (developed on the basis of the original restriction dossier which did not allow the rapporteurs to formulate a 1<sup>st</sup> draft opinion using the agreed template) to be considered from procedural point of view as a replacement for the 1<sup>st</sup> draft opinion; 5-day prolongation of the rapporteurs' deadline for the preparation of the 2<sup>nd</sup> draft opinion documents (due to the 5-day delay in the submission of the dossier submitter's responses to the early public consultation comments); informal written consultation on the 2<sup>nd</sup> draft opinion documents to be organised prior RAC-14 (in order to facilitate the rapporteurs' preparation for the next plenary discussion in December).

RAC agreed with the proposed procedural suggestions acknowledging that these minor adaptations of the agreed RAC procedure are relevant in this case.

Further, the rapporteurs were requested to present their feedback from the 2<sup>nd</sup> rapporteurs' dialogue that took place the day before and their initial views on the dossier submitter's responses on the early public consultation comments and on the revised Annex XV restriction report (in the format of the background document(BD)). It was clarified that the background document has been significantly improved from the original Annex XV report in response of the request for providing additional information and clarifications on the basis of the adopted EFSA opinion and JEFCA reports. It was mentioned also that TDIs of different alternatives are included in the revised report. In addition a restriction option 7 has been introduced. This option is based on a two step approach, where both lead content and lead migration rate have been assessed. However, several outstanding issues have been identified, such as, e.g. the absence of clear conclusions drawn from the information provided.

The Chair informed RAC of the received hearing request of the French Federations of Jewellery, Plate, Gifts and Craft Industry and the Federation of Crystal and Glassware. Following consultation with the rapporteurs, the Chair noted that at this stage there is no need for such a hearing; however, if a hearing is needed, this will be considered later in the process and the federations may be contacted.

The RAC regular observer from EUROMETAUX raised the issue of the importance of providing the update documentation from the dossier submitter on this restriction dossier, as the concerned industry has not seen the new data set. This would allow them to make further contributions to the opinion-forming process by February 2011.

The Chair clarified that although the main discussions on the draft opinions on the restriction proposals for lead and DMFu (including discussions on comments received

so far) are expected in the beginning of December, the 6-month public consultation period will only end on 21 December 2010. Thus, the Secretariat has considered an informal meeting to be organised in mid-February 2011, back-to-back to the Workshop on CLH guidance documents, as this would provide RAC with an opportunity for additional discussion on these two dossiers before the final adoption of the two opinions in March 2011. RAC agreed with this proposal.

### **9.1c Phenylmercury compounds state of play**

The Chair welcomed, the representatives of the dossier submitter from the Norwegian Competent Authority (CA) and one of the SEAC rapporteurs who followed the discussions as remote participants.

A RAC member presented on behalf of the dossier submitter a short overview of the structure of this restriction dossier to assist RAC members in their consideration of the proposed restrictions at Community level for five phenyl mercury compounds.

The dossier submitter explained that the five 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)) had been selected for the proposed restriction on the basis of their application area (as catalysts in polyurethane systems) and on the basis of their structural similarity.

The rapporteurs explained to RAC that the dossier had been published for public consultation on 24 September. The key elements that had arisen from the first rapporteurs' dialogue that had taken place on 7 October at ECHA were presented. During the dialogue, all of the issues flagged for attention in the RAC conformity report had been discussed and some issues had already been addressed by the dossier submitter. Agreement had been reached on the way forward for most of the remaining points. For example, the environmental behavior of the 5 substances as well as a comparison of the restriction proposed with other risk management options or alternatives were two issues to be considered further by the dossier submitter. Some questions had been identified concerning the enforceability which had been directed to the Forum.

The next steps were for members to provide comments on the dossier by 12 November in the RAC CIRCA IG newsgroup that had been established; and the rapporteurs to draw up the first draft of the opinion by 26 November in order for a discussion on the first draft to take place at RAC-14. The second rapporteurs' dialogue had been scheduled for January 2011.

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

### **9.1d Mercury in measuring devices**

The Chair welcomed one of the SEAC rapporteurs who followed the discussion remotely.

A representative of the dossier submitter from ECHA Secretariat 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 presentation was intended to assist RAC members in their review of the dossier. The dossier submitter provided an overview of the structure of the dossier, highlighting that the information on hazard is presented as a summary, the amount of mercury placed on the market is used as a qualitative estimate of the maximum emission potential and, based on the recommendation of RAC, the dossier will be strengthened in relation to the account of the risk of alternatives.

The rapporteurs presented the key elements that had arisen from the first rapporteurs' dialogue that had taken place on 5 October at ECHA. The dossier had been published for public consultation on 24 September. During the dialogue, all issues flagged in the RAC conformity report had been discussed and some issues had already been addressed by the dossier submitter. Agreement had been reached on the way forward for all of the remaining points, including the comparison between the risks of mercury with the alternatives which was to be considered further by the dossier submitter. Some questions concerning the enforceability had been directed to the Forum.

The next steps were for members to provide comments on the dossier by 12 November in the RAC CIRCA IG newsgroup that had been established; and the rapporteurs to draw up the first draft of the opinion by 26 November in order for a discussion on the first draft to take place at RAC-14. The second rapporteurs' dialogue had been scheduled for January 2011.

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

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

RAC was informed that Denmark registered a new intention to submit an Annex XV dossier proposing restriction for four phthalates. The procedure for appointment of RAC rapporteurs will be initiated after the meeting.

### **9.3 General restriction issues**

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

RAC was informed that there is a new intended Annex XV dossier proposing restriction for four phthalates.



## **10 Authorisation**

### **10.1 RAC Conformity check of authorisation applications**

#### **10.1a Working procedure for conformity check of authorisation applications**

The Chair explained that following the presentation and discussion at RAC-12 no additional comments had been received on the working procedure (RAC/12/2010/40). On this basis the working procedure was agreed and the Secretariat was to upload the final version of the working procedure to the RAC CIRCA IG.

#### **10.1b Conformity check template**

The Secretariat presented an overview of the outcome of conformity checks of authorisation applications making reference to the draft template for conformity check that had been provided (RAC/13/2010/54).

It was explained that according to the REACH Regulation, in preparing its opinion each Committee (RAC & SEAC) shall first check that the application includes all the information specified in Article 62, relevant to its remit. An authorisation shall be granted by the Commission only if the application is made in conformity with the requirements of Article 62. The draft template is divided into conformity check questions, corresponding to the mandatory information that an application for authorisation shall contain in accordance with Article 62 of the REACH Regulation. These questions cover and identify the responsibilities of both Committees. Each question is applicable to each use applied for by the applicant. It was indicated that the template may be revised in the light of experience from first applications.

A discussion took place in which RAC members raised a number of issues to clarify the way in which the format would be used and filled in.

One member queried whether Article 62(5)(b) & (6) would need to be addressed at the conformity stage. The Secretariat explained that it will be up to the applicant to decide whether to include a justification for not considering risks to human health and the environment as Article 62(5) states that “the application may include...”. Therefore, it will be inappropriate to include a mandatory conformity check question on this specific issue. The Secretariat also explained that it may be difficult to assess at the conformity check stage whether the use of the substance is in a medical device (as per Article 62(6)) however, the uses applied for should be checked under question 3. Another member noted that it was unclear whether the areas covered in the conformity check template would enable RAC to decide whether a risk assessment was provided for a particular application. The Secretariat confirmed that a check is required of whether a chemical safety assessment had been provided (question 4a) and that the assessment carried out by the applicant and to be reviewed by RAC would be based on the assessment of the risks. One of the stakeholders confirmed that industry considers the risk assessment aspect for each use to be important.

A RAC member also enquired whether the Secretariat would support RAC in relation to the information provided on the identity of the substance (question 1). The Chair confirmed that this aspect will be considered further by the Secretariat, but that a similar approach to that of the CLH and restriction processes would be likely to apply. A further member also queried what would be included in the ‘justification’ column

of the template – the justification from industry or that of the RAC (co-) rapporteurs. The Secretariat advised that according to the working procedure for the conformity check of applications for authorisation, the template is intended to be completed in two stages. In the first stage, the application will be assessed by the (co-)rapporteurs for missing information and, where information is absent, the text to be cut and pasted into the letter that goes to the applicant will be included in the proper column. In the second stage, if the information remains absent or insufficient, the justification indicating why the application does not conform will be included to be presented for the consideration and agreement of the entire Committee. The justification will be based on the legal text.

The Chair thanked participants for their contributions and invited any further comments on the template by 11 November in the newsgroup that would be created in the RAC CIRCA IG.

## **10.2 Formulating a RAC opinion on authorisation applications**

### **10.2a&b Format of an opinion and examples of conditions in the authorisation procedure**

The Secretariat gave a brief presentation on the current state of the development of the elements that may appear in the format of an authorisation opinion, but time did not allow the examples of conditions to be elaborated.

The grounds for granting authorisations were recalled with reference to the two routes set out in the REACH Regulation: adequate control (Article 60(2)) or the socioeconomic analysis (SEA) (Article 60(4)) route. Two scenarios were then presented if the SEA route is followed: a straightforward case in which RAC confirms the exposure scenarios in the application are appropriate to limit the remaining risk; and a complicated case where the exposure scenarios are not considered by RAC to adequately control the risk(s) from the uses applied for. In the latter scenario conditions and monitoring arrangements would need to be recommended for the authorisation to be granted by the European Commission. In addition, it was noted that a review period for the use could be attached to the Commission decision.

A brief discussion followed, in which one member queried the meaning of ‘limit the remaining risk’. The Secretariat explained that RAC should base its assessment of the application upon the wording of Article 60(4) (b) of REACH, namely the ‘...appropriateness and effectiveness of the risk management measures proposed’.

## **11 Guidance issues**

### **11a Feedback from guidance consultations**

The Secretariat informed RAC about the two draft guidance documents that have been submitted to RAC for comments, the draft Guidance for intermediates and the draft Guidance for exposure based adaptation. RAC members were requested to provide comments via the RAC CIRCA IG newsgroup by 11 November 2010.

### **11b Report on other guidance activities**

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

### **11c Update on the ECHA Workshop for presenting the Guidance Document on the preparation of CLH dossiers**

The Secretariat presented to RAC the outline of the workshop “on the way to CLH” to take place on 16 February 2011 in Helsinki. The workshop aims to support the improvement of the preparation and processing of CLH dossiers.

The outline of the workshop has been provided in the form of the room document (RAC/13/2010/57). RAC members were requested to provide comments via the RAC CIRCA IG newsgroup by 11 November 2010.

## **12 Any other business**

### **12a Presentation on the Extended One Generation Reproductive Toxicity Study (EOGRTS) working group**

The Chair gave the floor to Dr. Aldert Piersma to present the discussion and progress made by the OECD working group on the extended one generation reproductive toxicity studies (EOGRTS).

After presenting the protocol and main advantages (fewer animals; more power and sensitivity) of EOGRTS, he informed RAC that the main conclusion of a retrospective analysis performed by this group was that development studies and not the two-generation studies appeared to be crucial to make decisions on reprotoxicity classification. A total of 498 multi-generation studies (438 substances) were gathered in a representative database. Only 24 P1/F2 showed effects not observed at an earlier phase. He concluded that there were no single examples where a two-generation study determined the final classification. Potentially this may affect future allocation of resources.

RAC members exchanged views on these results and discussed the final conclusion. Key issues were raised such as: cross fostering and impact on classification; which thresholds trigger 2<sup>nd</sup> generation studies; assumptions about animal numbers that could be saved.

Finally the Chair thanked the presentation and comments and clarified that the aim of this discussion was not to influence the OECD process. For specific comments on the protocol members were requested to contact their national coordinators for OECD guidelines.

### **12b Update on the ECHA-EFSA cooperation on active substances in PPP and on the workshop scheduled for 2011**

The Chair reported to RAC of the meeting of the ECHA-EFSA organising committee held on 21 October.

In the context of the new regulation on PPP, ECHA (RAC) and EFSA (PRAPeR) have an obvious need to coordinate their respective procedures. This is especially important for CMR substances due to the new regulatory requirements.

A workshop will be organised in Berlin on 12-13 April 2011 to discuss these issues further. RAC members, but not advisers, are invited to this event. Two main objectives have been identified. The first objective has a regulatory nature aiming to explore cooperation routes and get common understanding among the MSCAs

responsible for C&L and PPP processes and both Agencies including their respective Committees, on the procedures and timelines associated to both regulations. The second objective has a scientific nature aiming to facilitate a common understanding among the experts of both Committees in the identification of CMR properties.

Following comments from some RAC members, the Chair clarified that the workshop is not intended to cover the additional evaluation of the PBT and POP properties of the PPP active substances, as this identification is not part of the regular tasks assigned to RAC by the REACH and CLP Regulations and the involvement of RAC would require a specific mandate.

#### **12c Workshop on identification of SVHC with endocrine disruptor properties**

One member informed RAC of the workshop that was being organised by his agency (German Federal Environment Agency UBA, Dessau) in Berlin on 6-7 December 2010. He also suggested RAC members to offer their interested colleagues to participate in the event. The focus of the event is on how to identify SVHC, especially endocrine disruptors, from an environmental perspective, without excluding human health issues, as well as how to interpret REACH Article 77(f).

#### **13 Main conclusions and Action Points of RAC-13**

The Secretariat presented the main conclusions and action points of the RAC-13 plenary meeting for final comments and agreement by the Committee. All suggestions were reflected accordingly and RAC agreed to the document. The main conclusions and action points are attached as Part II of these meeting minutes.

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## Part II. Conclusions and action points

### MAIN CONCLUSIONS & ACTION POINTS (Adopted at the 13<sup>th</sup> meeting of RAC) (26-28 October 2010)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
<b>2 Adoption of the Agenda</b>	
<p>The final draft Agenda (RAC/A/13/2010) was adopted.</p> <p>Six members have declared potential conflict of interest to different substance-related discussions under different agenda items.</p>	<p><b>SECR</b> to upload the adopted agenda to the RAC CIRCA IG as a part of the RAC-13 minutes after the meeting.</p>

#### 4. Adoption of RAC-12 Draft Minutes

<p>The minutes of RAC-12 (RAC/M/12/2010 draft final) were adopted with minor modifications.</p>	<p><b>SECR</b> to upload to the RAC CIRCA IG and the ECHA website the adopted minutes after the meeting.</p>
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#### 7. Stakeholder participation in the work of RAC (Closed session)

<p>RAC agreed to admit the European Association for Chemical and Molecular Sciences (EuCheMS) to participate in the work of RAC as a regular RAC observer.</p> <p>RAC took the following decisions on the ECPA request regarding their RAC observer status:</p> <ul style="list-style-type: none"> <li>– ECPA to keep their sector-specific observer status, but to be invited on a regular basis to participate in all procedural and dossier-specific C&amp;L discussions</li> <li>– ECPA representative to be granted with a CIRCA access to the relevant general folders in the non-confidential section of RAC CIRCA IG, as well as to the CLH section under the “Processes &amp;</li> </ul>	<p><b>SECR</b> to invite EuCheMS to nominate a representative as a regular RAC observer after the meeting</p> <p><b>RAC Chair</b> to answer to the formal ECPA request following the RAC decisions taken after the meeting.</p> <p><b>SECR</b> to grant the ECPA representative with the access to the relevant sections in the RAC CIRCA IG, as agreed, after the meeting.</p> <p><b>SECR</b> to ensure that the general principles, regarding the balanced STO participation in the RAC work, are met at any point in time and if</p>
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<p>Substances” folder.</p> <p>RAC agreed to mandate the RAC Secretariat to ensure that the STO participation in the RAC work is in accordance with the general principles laid down in section 3.1 of the RAC STO procedure and, if this is not the case, undertake without delay the necessary actions.</p> <p>Further, RAC agreed sections 1-3 concerning the report on STO participation to be extracted from document <b>RAC/13/2010/52</b> and uploaded in a separate document to the non-confidential RAC CIRCA IG for RAC observers’ information.</p> <p>Finally, RAC agreed to minute the closed session outcome in the general minutes.</p>	<p>not, to undertake the necessary actions without delay, when needed.</p> <p><b>SECR</b> to prepare a document with the extracted information from sections 1-3 of document <b>RAC/13/2010/52</b> and to upload it to the non-confidential RAC CIRCA IG after the meeting.</p> <p><b>SECR</b> to minute the outcome of the closed session discussions in the general minutes from this plenary meeting.</p>				
<h2>8. CLH</h2>					
<h3>8.1 CLH Dossiers</h3>					
<h4>8.1a. Hexabromocyclododecane (HBCDD) (CAS No. 25637-99-4 and 3194-55-6)</h4>					
<p>RAC provisionally agreed with the rapporteurs’ proposal to classify HBCDD to the reproductive toxicity category 2 under the CLP Regulation with the hazard statement H361.</p> <p>Furthermore, RAC agreed that the provided data in this CLH proposal are not sufficient for supporting the originally proposed classification for HBCDD under Directive 67/548/EEC. Therefore, RAC provisionally agreed to propose HBCDD to be classified for Repr. Cat 3; R63, R64 under DSD.</p> <table border="1" data-bbox="191 1381 810 1522"> <tr> <td>CLP Regulation (EC) No 1272/2008 (CLP)</td> <td>Directive 67/548/EEC (DSD)</td> </tr> <tr> <td><b>Repr. 2 - H361</b> <b>Lact. - H362</b></td> <td><b>Repr. Cat 3; R63</b> <b>R64</b></td> </tr> </table>	CLP Regulation (EC) No 1272/2008 (CLP)	Directive 67/548/EEC (DSD)	<b>Repr. 2 - H361</b> <b>Lact. - H362</b>	<b>Repr. Cat 3; R63</b> <b>R64</b>	<p><b>Rapporteurs</b> to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) and to provide the proper justification to be in line with the agreed RAC proposals by 15 November 2010.</p> <p><b>SECR</b> to organise editorial consultation on the revised draft opinion documents, as soon as they are received and either to propose the final draft opinion and its annexes for HBCDD to be adopted at RAC-14 or, if feasible, earlier by urgent written procedure.</p>
CLP Regulation (EC) No 1272/2008 (CLP)	Directive 67/548/EEC (DSD)				
<b>Repr. 2 - H361</b> <b>Lact. - H362</b>	<b>Repr. Cat 3; R63</b> <b>R64</b>				
<h4>8.1b. Fuberidazole</h4>					
<p>RAC adopted <u>by consensus</u> the opinion and its annexes for fuberidazole. RAC members agreed with the view of the rapporteurs on the harmonised classification for this substance as follows:</p> <table border="1" data-bbox="191 1808 810 1877"> <tr> <td>CLP Regulation (EC) No 1272/2008</td> <td>Directive 67/548/EEC</td> </tr> </table>	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC	<p><b>Rapporteur</b> to send the revised final version to the SECR by 15 November.</p> <p><b>SECR</b> to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA website when received.</p> <p><b>SECR</b> to forward the adopted opinion and its</p>		
CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC				

<p><b>Acute Tox. 4 - H302</b> <b>Skin Sens. 1 - H317</b> <b>STOT RE 2 (heart)</b> <b>H373</b> <b>Carc. Cat. 2 - H351</b></p> <p><b>Aquatic Acute 1 - H400</b> <b>Aquatic Chronic 1 - H410</b> <b>M- factor = 1 based on 0.1 &lt;L(E)C<sub>50</sub> ≤1 mg/l</b></p>	<p><b>Xn; R22,</b> <b>Xi; R43,</b> <b>Xn; R48/22,</b> <b>Xn; R40 (Carc. Cat.3)</b></p> <p><b>N; R50/53</b> <b>Specific concentration limits:</b> <b>N; R50/53: C ≥ 25%</b> <b>N; R51/53: 2.5% ≤ C &lt; 25%</b> <b>R52/53: 0.25% ≤ C &lt; 2.5%</b></p>	<p>annexes to COM without delay.</p>
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### 8.1c. Acequinocyl

RAC adopted by consensus the opinion and its annexes for acequinocyl. RAC members agreed with the view of the rapporteurs on the harmonised classification for this substance as follows:

<p>CLP Regulation (EC) No 1272/2008</p>	<p>Directive 67/548/EEC</p>
<p><b>Skin. Sens. 1 – H317</b> <b>STOT SE 1 – H370 (lung)</b> <b>STOT RE 2 – H373 (blood system)</b> <b>Aquatic Acute 1 – H400</b> <b>Aquatic Chronic 1 – H410</b> <b>M-factor = 1000</b></p>	<p><b>T; R39/23;</b> <b>Xi; 43</b></p> <p><b>N; R50/53</b> <b>Specific concentration limits:</b> <b>N; R50/53, C ≥ 0.025%</b> <b>N; R51/53, 0.0025% ≤ C &lt; 0.025%</b> <b>R52/53, 0.00025% ≤ C &lt; 0.0025%</b></p>

**SECR** to upload the opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site without delay.

**SECR** to forward the adopted opinion and its annexes to COM without delay.

### 8.1.d TNPP

RAC adopted by consensus the opinion and its annexes on TNPP. RAC members agreed with the view of the rapporteurs on the harmonised classification of this substance as follows:

<p>CLP Regulation (EC) No 1272/2008</p>	<p>Directive 67/548/EEC</p>
<p><b>Skin Sens. 1; H317</b></p>	<p><b>Xi; R43</b></p>

**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 the adopted opinion and its annexes to COM without delay.

<p><b>Aquatic Acute 1; H400</b> <b>Aquatic Chronic 1; H410</b></p>	<p><b>N; R50-53</b></p>					
<p><b>8.1.e Lucirin (Diphenyl(2,4,6-trimethylbenzoyl) phosphine oxide)</b></p>						
<p>RAC adopted <u>by consensus</u> the opinion and its annexes on lucirin. RAC members agreed with the view of the rapporteurs on the harmonised classification of this substance as follows:</p>		<p><b>Rapporteurs</b> to update BD according to the agreed changes to the draft opinion documents.</p> <p><b>SECR</b> to upload the adopted opinion and its annexes to RAC CIRCA IG and publish them on the ECHA website when received.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM without delay.</p>				
<table border="1"> <tr> <td>CLP Regulation (EC) No 1272/2008</td> <td>Directive 67/548/EEC</td> </tr> </table>	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC	<table border="1"> <tr> <td><b>Repr. 2 - H361f</b></td> <td><b>Repr. Cat. 3; R62</b></td> </tr> </table>	<b>Repr. 2 - H361f</b>	<b>Repr. Cat. 3; R62</b>	
CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC					
<b>Repr. 2 - H361f</b>	<b>Repr. Cat. 3; R62</b>					
<p><b>8.1.f. Metazachlor</b></p>						
<p>RAC discussed the first draft opinion.</p>		<p><b>Members</b> to provide their comments on the draft opinion by 9 November 2010 using the RAC CIRCA IG newsgroup.</p> <p><b>Rapporteur</b> to consider the comments received and if needed to modify the draft opinion documents before RAC-14.</p> <p><b>SECR</b> to distribute the revised draft opinion documents to RAC when submitted for further discussion and possible adoption at RAC-14.</p>				
<p><b>8.1.g Flufenoxuron</b></p>						
<p>RAC members agreed <u>by consensus</u> with the view of the rapporteur to support the environmental classification, as follows:</p>		<p><b>SECR</b> to inform the dossier submitter of the rapporteurs' request of the full study reports for the repeated dose toxicity and reproductive toxicity studies after the meeting.</p> <p><b>SECR</b> to create a RAC CIRCA IG newsgroup to collect any further RAC comments on the draft opinion documents.</p> <p><b>Members</b> to post their views on the issue by 11 November 2010.</p> <p><b>Rapporteur</b> to review the draft opinion documents before RAC-14.</p>				
<table border="1"> <tr> <td>CLP Regulation (EC) No 1272/2008</td> <td>Directive 67/548/EEC</td> </tr> </table>	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC	<table border="1"> <tr> <td>Directive 67/548/EEC</td> <td></td> </tr> </table>	Directive 67/548/EEC		
CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC					
Directive 67/548/EEC						



<p><b>Aquatic. Acute 1 - H400</b>  <b>Aquatic. Chronic 1 - H410</b>  <b>M-factor = 10 000</b></p>	<p><b>N; R50/53</b></p> <p><b>Specific concentration limits:</b>  <b>N; R50/53, <math>C \geq 0.0025\%</math></b>  <b>N; R51/53, <math>0.00025\% \leq C &lt; 0.0025\%</math></b>  <b>R52/53, <math>0.000025\% \leq C &lt; 0.00025\%</math></b></p>	<p><b>SECR</b> to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption at RAC-14.</p> <p>RAC agreed to continue the discussion on the classification for the other hazard classes particularly regarding severity of hemolytical effects, the basis for specific target organ toxicity, the mechanism of lactation effects, assess the potential chronic classification and M-factor according to the chronic classification criteria (2<sup>nd</sup> ATP).</p>
<p><b>8.1.h PHMB</b></p>		
<p>RAC discussed the first draft opinion.</p>	<p><b>Members</b> to provide their comments on the draft opinion by 3 November 2010 using the CIRCA newsgroup.</p> <p><b>Rapporteur</b> to consider the comments received and if needed to modify the draft opinion documents before RAC-14.</p> <p><b>SECR</b> to distribute the revised draft opinion documents to RAC when submitted for further discussion and possible adoption at RAC-14.</p>	
<p><b>8.1.i Chloroform</b></p>		
<p>RAC discussed the first draft opinion.</p>	<p><b>Members</b> to post their comments on the opinion documents by 11 November 2010.</p> <p><b>Rapporteur</b> to consider the comments received and if needed to modify the draft opinion documents before RAC-14.</p> <p><b>SECR</b> to distribute the revised draft opinion documents to RAC when submitted for further discussion and possible adoption at RAC-14.</p>	
<p><b>8.1.j Leucomalachite green</b></p>		
<p>RAC members agreed <u>by consensus</u> with the view</p>	<p><b>Rapporteur</b> to make final editorial changes to</p>	

<p>of the rapporteur to support the classification as follows:</p>	<p>the draft opinion with support from SECR without delay.</p>						
<table border="1"> <tr> <td data-bbox="188 289 500 352">CLP Regulation (EC) No 1272/2008</td> <td data-bbox="500 289 805 352">Directive 67/548/EEC</td> </tr> <tr> <td data-bbox="188 352 500 415"><b>Muta. 2 - H341</b></td> <td data-bbox="500 352 805 415"><b>Muta. Cat. 3; R68</b></td> </tr> <tr> <td data-bbox="188 415 500 457"><b>Carc. 2 - H351</b></td> <td data-bbox="500 415 805 457"><b>Carc. Cat. 3; R40</b></td> </tr> </table>	CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC	<b>Muta. 2 - H341</b>	<b>Muta. Cat. 3; R68</b>	<b>Carc. 2 - H351</b>	<b>Carc. Cat. 3; R40</b>	<p><b>SECR</b> to distribute the draft opinion and its annexes to RAC members for final comments when received.</p> <p><b>Members</b> to post their final comments by 11 November 2010.</p>
CLP Regulation (EC) No 1272/2008	Directive 67/548/EEC						
<b>Muta. 2 - H341</b>	<b>Muta. Cat. 3; R68</b>						
<b>Carc. 2 - H351</b>	<b>Carc. Cat. 3; R40</b>						
	<p><b>Rapporteur</b> to consider the comments received and if needed to modify the draft opinion documents.</p> <p><b>SECR</b> to organise possible adoption by written procedure.</p>						
<p><b>8.2 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 document RAC/13/2010/53_rev2).</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 vacant positions.</p> <p><b>SECR</b> to identify potential (co-)rapporteurs and encourage them to fill the vacant positions.</p>						
<p><b>8.3 General CLH issues</b></p>							
<p>RAC agreed that if the Executive Director following the request from COM gives RAC a mandate related to the proposed harmonised classification and labelling of epoxiconazole, the previous rapporteur for this substance will be appointed as the rapporteur.</p>	<p>-</p>						
<p>-</p>	<p><b>SECR</b> to draft a proposal for facilitating the discussion on the application of the criteria for reproductive toxicity under the CLP and to open a newsgroup for collecting comments.</p> <p><b>Members</b> to provide comments before RAC-14.</p>						
<p><b>9 Restrictions</b></p>							
<p><b>9.1 Restriction Annex XV dossiers</b></p>							
<p><b>9.1. a DMFu</b></p>							
<p>RAC was informed of the outcome of the 2<sup>nd</sup> rapporteurs' dialogue held the day before the start</p>	<p><b>SECR</b> to clarify the effect of the definition of an "article" on the wording in the proposed</p>						

<p>of this plenary meeting and of the views of the rapporteurs regarding the updates in the revised Annex XV report (used as a basis for the 1<sup>st</sup> draft Background document) made by the dossier submitter.</p> <p>In the discussion on the conditions for the DMFu restriction, RAC acknowledged the need for further discussion on the wording of the proposed restriction for DMFu in articles.</p>	<p>restriction and to inform the rapporteurs and the members after the meeting.</p> <p><b>SECR</b> to analyse whether the restriction entries in Annex XVII can be used when designing the wording for the proposed restriction.</p> <p><b>Rapporteurs</b> to prepare the 2<sup>nd</sup> draft opinion documents on this restriction proposal and to submit them to SECR by 19 November 2010 at the latest.</p> <p><b>SECR</b> to upload the draft opinion documents to the RAC CIRCA IG as soon as received and to open a newsgroup for members' initial comments.</p> <p><b>Members</b> to post their views on the 2<sup>nd</sup> draft opinion documents via the respective CIRCA newsgroup by 1<sup>st</sup> December 2010 in order to facilitate the rapporteurs' preparation for the plenary discussion.</p>
<p><b>9.1.b Lead and its compounds in jewellery</b></p>	
<p>RAC agreed with the following suggestions of the Secretariat for the opinion development on this restriction proposal:</p> <ul style="list-style-type: none"> <li>• key elements of the 1<sup>st</sup> draft opinion to be considered as equivalent to the 1<sup>st</sup> draft opinion,</li> <li>• the rapporteurs' deadline for the preparation of the 2<sup>nd</sup> draft opinion documents will be 24 November 2010,</li> <li>• early RAC comments on the 2<sup>nd</sup> draft opinion documents to be provided via the relevant CIRCA IG newsgroup prior to RAC-14 in order to facilitate the rapporteurs' preparation for the plenary discussion in December.</li> </ul> <p>RAC was informed of the outcome of the 2<sup>nd</sup> rapporteurs' dialogue held the day before this plenary meeting and of the views of the rapporteurs regarding the updates in the revised Annex XV report (used as a basis for the 1<sup>st</sup> draft Background document) made by the dossier submitter.</p>	<p><b>Rapporteurs</b> to prepare the 2<sup>nd</sup> draft opinion documents on this restriction proposal and to submit them to the SECR by 24 November 2010 at the latest.</p> <p><b>SECR</b> to upload the draft opinion documents to the RAC CIRCA IG as soon as received and to open a newsgroup for members' initial comments.</p> <p><b>Members</b> to post their views on the 2<sup>nd</sup> draft opinion documents via the respective CIRCA IG Newsgroup prior to RAC-14 in order to facilitate the rapporteurs' preparation for the plenary discussion.</p>
<p><b>9.1. c Phenylmercury compounds</b></p>	

RAC was informed of the outcome of the 1 <sup>st</sup> rapporteurs' dialogue held before this plenary meeting.	<b>Members</b> were invited to make any comments on the dossier by 12 November in the RAC CIRCA IG newsgroup.
<b>9.1.d Mercury in measuring devices</b>	
RAC was informed of the outcome of the 1 <sup>st</sup> rapporteurs' dialogue held before this plenary meeting.	<b>Members</b> were invited to make any comments on the dossier by 12 November in the RAC CIRCA IG newsgroup.
<b>9.2 Appointment of RAC (co-) rapporteurs for restriction dossiers</b>	
<b>9.3 General restriction issues - update on intended restriction dossiers</b>	
-	<b>SECR</b> to initiate the process for appointment of rapporteurs for the intended Annex XV dossier(s) proposing restriction(s) for the four phthalates after the meeting.
<b>10 Authorisation</b>	
<b>10.1 RAC conformity check of authorisation applications</b>	
<b>Working procedure for conformity check of authorisation applications.</b> RAC agreed the working procedure (RAC/12/2010/40).	<b>SECR</b> to upload the agreed working procedure to the RAC CIRCA IG after the meeting.
<b>Template for conformity check</b>	<b>SECR</b> to open a CIRCA Newsgroup to collect member comments on the template for the conformity check of authorisation applications after the meeting  <b>Members</b> to post their comments on the draft by 11 November 2010.
<b>GENERAL</b>	
-	<b>SECR</b> to upload all presentations, room documents and the RAC-13 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG without delay after the meeting.

**Part III. List of Attendees of the RAC-13 meeting (26-28 October 2010)**

<u>Members</u>	<u>ECHA staff</u>
ANDERSSON Alicja	ANFÄLT Lisa
BARANSKI Boguslaw	BARRUEL Philippe
BARRON Thomasina	DE BRUIJN Jack
BJØRGE Christine	ERICSSON Gunilla
BORGES Teresa	FUHRMANN Anna
DI PROSPERO FANGHELLA Paola	HONKANEN Jani
DUNAUŠKIENE Lina	KARHU Elina
GREIM Helmut	KIVELÄ Kalle
GRUIZ Katalin	KOKKOLA Leila
HALKOVA Zhivka	KULJUKKA-RABB Terhi
KADIKIS Normunds	LANKOSKI Jussi
LARSEN Poul Bo	LUOTAMO Marita
LE CURIEUX-BELFOND Olivier	LUSCHÜTZKY Evita
LEINONEN Riitta	MATTHES Jochen
LUND Bert-Ove	MERKOURAKIS Spyridon
MULLOOLY Yvonne	MULLER Birgit
NUNES Céu	NOUWEN Johan
OLTEANU Maria	NYLUND Lars
PICHARD Annick	PELTOLA Jukka
POLAKOVICOVA Helena	ROGEMAN Maarten
POSPISCHIL Erich	RÖCKE Timo
PRONK Marja	SIHVONEN Kirsi
RUPPRICH Norbert	SPJUTH Linda
SCHULTE Agnes	VAINIO Matti
SMITH Andrew	SCHÖNING Gabriele
STOLZENBERG Hans-Christian	STOYANOVA Evgenia
TADEO José L.	TARAZONA Jose
Van der HAGEN Marianne	VASILEVA Katya
Van MALDEREN Karen	
VILANOVA Eugenio	<u>Stakeholder observers</u>

	CASALEGNO Carlotta (ECEAE)
<b><u>Advisers to the RAC members</u></b>	MEISTERS Marie-Louise (ECETOC)
CONWAY Louise (adviser to Yvonne Mullooly)	ROWE Rocky (ECPA)
GRACZYK Anna (adviser to Boguslaw Baranski)	SOBALLA Volker (BusinessEurope)
DUSSART Aurelie (adviser to Karen van Malderen)	RENARD Alain (Cefic)
IHLEMANN Christina (adviser to Poul Bo Larsen)	
CEDERBERG Håkan (adviser to Alicja Andersson)	<b><u>Other observers</u></b>
VEGA Milagros (adviser to Céu Nunes)	BOREIKO Craig (an observer acting as an expert to an observer representing Eurometaux for lead and its compounds)
	COHEN Sam (an observer acting as an expert to an observer representing CEFIC for PHMB)
<b><u>Representatives of the Commission</u></b>	GAOU Isabelle (an observer acting as an expert to an observer representing CEFIC for chloroform)
BINTEIN Sylvain (DG ENV)	HENNINGER Kerstin (an observer accompanying the nominated ECPA observer for fuberidazole)
GIRAL Anne (DG ENTR)	JACOBI Sylvia (an observer acting as an expert to an observer representing CEFIC for TNPP)
GRODZKI Karola (DG ENTR)	THOMSON Mark (an observer acting as an expert to an observer representing CEFIC for HBCDD)
<b><u>SEAC Restriction (co-)rapporteurs</u></b>	WARREN Simon (an observer accompanying the nominated ECPA observer for flufenoxuron)
FURLAN Janez (invited as SEAC rapporteur following AP 9.1a DMFu)	WIEMANN Christine (an observer accompanying the nominated ECPA observer for metazachlor)
GEORGIOU Stavros (invited as SEAC rapporteur following AP 9.1b Lead)	<b><u>Observer invited to give a presentation</u></b>
	PIERSMA Aldert (invited to give a presentation under AP 12a)

	<b><u>Remote participants</u></b>
	BRISORGUEIL Emilie (a representative of the French CA following AP 9.1a,b)
	CHARLES Sandrine (a representative of the French CA following AP 8.1g)
	FOCK Lars (a SEAC rapporteur for lead dossier following AP 9.1.b.)
	FIORE Karine (a representative of the French CA following AP 9.1b)
	FORKMAN Mats (a SEAC rapporteur for DMFu dossier following AP 9.1.a)
	KOPANGEN Marit (a representative of the French CA following AP 9.1.c)
	LECOQ Pierre (a representative of the French CA following AP 9.1.a)
	LUTTIKHUIZEN Cees (a SEAC rapporteur for mercury dossier following AP 9.1.d)
	MICHEL Cecile (a representative of the French CA following AP 8.1.i)
	MORKA Heidi (a representative of the French CA following AP 9.1.c)
	PASQUIER Elodie (a representative of the French CA following AP 8.1d,g,h)
	SAMSERA Rija (a representative of the French CA following AP 8.1h)
	VERINES Lauranne (a representative of the French CA following AP 8.1g)

**Part IV. LIST OF ANNEXES**

**ANNEX I** Final Agenda of the RAC-13 meeting

**ANNEX II** List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-13 meeting



## **Final Agenda**

### **13<sup>th</sup> meeting of the Committee for Risk Assessment**

**26 – 28 October 2010**

**Helsinki, Finland**

**26 October: starts at 9:00**

**28 October: ends at 16:00**

**Item 1 – Welcome & Apologies**

**Item 2 – Adoption of the Agenda**

*RAC/A/13/2010*  
*For adoption*

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

**Item 4 – Adoption of the draft minutes of RAC-12**

- Adoption of the draft minutes

**RAC/M/12/2010 draft final**  
*For adoption*

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

- a. Status report on the RAC - 12 action points
- b. Outcome of written procedures
- c. Report from other ECHA bodies and activities

**RAC/13/2010/55**  
**ROOM DOCUMENT**  
*For information*

**Item 6 – Renewal of RAC Membership**

- State of play on the renewal of RAC Memberships

*For information*

**Item 7 – Stakeholder participation in the work of RAC (Closed Session)**

**RAC/13/2010/52\_rev.1**

*For agreement*

**Item 8 – CLH**

**8.1 CLH Dossiers**

- a. HBCDD

*For discussion and possible adoption*

- b. Fuberidazole

*For discussion and possible adoption*

- c. Acequinocyl

*For adoption*

- d. TNPP

*For adoption*

- e. Lucirin

*For first discussion*

- f. Metazachlor

*For first discussion*

- g. Flufenoxuron

*For first discussion*

- h. PHMB

*For first discussion*

- i. Chloroform

*For first discussion*

- j. Leucomalachite green

*For first discussion*

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

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

**RAC/13/2010/53\_rev1**

**ROOM DOCUMENT**

*For agreement*

**8.3 General CLH issues**

- State of play of the submitted CLH dossiers

**RAC/13/2010/56**  
**ROOM DOCUMENT**  
*For information*

## **Item 9 – Restrictions**

### **9.1 Restriction Annex XV dossiers**

- a. DMFu – state of play  
*For discussion*
- b. Lead and its compounds in jewellery – state of play  
*For discussion*
- c. Phenylmercury compounds – state of play  
*For initial discussion*
- d. Mercury in measuring devices – state of play  
*For initial discussion*

### **9.2 Appointment of RAC (co-) rapporteurs for restriction dossiers (if relevant)** *For agreement*

### **9.3 General restriction issues**

- Update on intended restriction dossiers  
*For information*

## **Item 10 – Authorisation**

### **10.1 RAC Conformity check of authorisation applications**

- Working procedure for conformity check of authorisation applications  
**RAC/12/2010/40**  
*For agreement*
- Conformity check template  
**RAC/13/2010/54**  
*For discussion*

### **10.2 Formulation of RAC opinion on authorisation applications**

- Format of an opinion
- Examples of conditions  
*For discussion*

**Item 11 – Guidance issues**

- a. Feedback from guidance consultations
- b. Report on other guidance activities
- c. Update on the ECHA Workshop for presenting the Guidance Document on the preparation of CLH dossiers

**RAC/13/2010/57**  
**ROOM DOCUMENT**  
*For information*

**Item 12 – Any other business**

- a. Presentation on the Extended One Generation Reproductive Toxicity Studies (EOGRTS) by the OECD working group
- b. Update on the ECHA-EFSA cooperation on active substances in PPP and on the workshop scheduled for 2011

*For information*

*For information*

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

- Table with main conclusions and action points from RAC- 13

*For adoption*

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## ANNEX II

### **Documents submitted to the members of the Committee for Risk Assessment for the RAC-13 meeting.**

RAC/A/13/2010_rev1	Final Draft Agenda – 13 <sup>th</sup> meeting of the Committee for Risk Assessment
RAC/M/12/2010	Minutes of the 12 <sup>th</sup> meeting of the Committee for Risk Assessment – final draft
RAC/13/2010/55 (room document)	Administrative issues and information items
RAC/13/2010/52_rev1 (confidential)	Stakeholder participation in the work of RAC
RAC/13/2010/53_rev1 (room document)	Appointment of CLH Rapporteurs intentions
RAC/13/2010/54	Format of a conformity check authorisation
RAC/12/2010/40	Working procedure for conformity check of authorisation applications
RAC/13/2010/56 (room document)	State of play of the submitted CLH dossiers
RAC/13/2010/57 (room document)	ECHA Workshop for presenting the Guidance Document on the preparation of CLH dossiers

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