RAC/M/15/2011

FINAL

4 June 2011

Minutes of the 15th meeting of the Committee for Risk Assessment (RAC-15) (8-11 March 2011)

Part I Summary Record of the Proceedings

1 Welcome and apologies

Dr Jose Tarazona, Chair of the Committee for Risk Assessment (RAC), ECHA, welcomed participants to the meeting. Nine advisers, two invited experts, six stakeholder representatives (from BusinessEurope, CEFIC, ECETOC, ECPA, ETUC and Eurometaux), nine observers accompanying stakeholder observers (STO), one representative of dossier submitters and four representatives from the Commission were welcomed.

For this meeting some participants took part in substance related discussions as remote participants via the WEBEX connection. This included: one RAC member, a SEAC rapporteur and representatives of Member State Competent Authorities (MSCA) from France and Norway. Apologies were received from three RAC members and six regular observers (CONCAWE, ECEAE, HEAL, EuCheMS, EMCEF and OECD). The list of attendees is given in Part III of these minutes.

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

2 Adoption of the Agenda

The draft 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. Nine members and two stakeholder observers declared potential conflicts of interest to the substance-related discussions in the agenda items 6.a (two members, two stakeholders), 6.b (one member), 7.1a (two members), 7.1b (two members), 7.1c (two members, one observer), 7.1d (one member), 7.1e (two members), 7.1i (one member), 8.1a (two members), 8.1b (two members), 8.1c (two members).

4 RAC Manual of Conclusions and Recommendations (MoCR)

The Secretariat presented to RAC some key suggestions for modifications and inclusions in the updated MoCR on the basis of adopted RAC minutes up to RAC-15. The members were also requested to consider and to agree on the following proposals from the Secretariat: Member State Competent Authorities (MSCA) to be granted with access to the RAC MoCR on the basis of a member's request and the previous versions of the RAC MoCR to be archived when newly updated version is produced.

One member suggested considering the inclusion of the principle for maintaining cases where rapporteurs request additional information following the accordance/conformity check on a dossier.

RAC took note of the suggested key issues for inclusion in the updated MoCR and agreed with the Secretariat's proposals for providing MSCA with access to the RAC MoCR via the Annex XV CIRCA IG and for archiving the previous versions of the manual when new updates are released.

5 Administrative issues and information items

The Secretariat provided a feedback from the second Annual Satisfaction Survey in the room document RAC/15/2011/3 and informed RAC about the outcome of the survey. 31 RAC members out of 38 and 8 stakeholder observers participated in the survey. The satisfaction of RAC members concerning the way meetings are organised has remained at the same high level as last year. Members expressed concerns about the increased amount of CLH[1] dossiers and the related difficulties to process the dossiers in time. Stakeholder observers were also continuously positive on the way meetings are organised, but concerns were expressed on the level of involvement of stakeholders in the proceedings of the meeting and on the lack of clarity in the proceedings of closed sessions.

The Chair informed that the recommendations will be taken into consideration. Two action points are addressed in the room documents RAC/15/2011/06 and RAC/15/2011/07 and were to be discussed under agenda point 7.3

The Chair asked RAC for further suggestions and thanked the participants for completing the annual survey.

6 Request under Article 77 (3)(c)

6.a Epoxiconazole

The Chair introduced the sector-specific STO observer, ECPA that was accompanied by a BASF observer for this agenda item. The Chair informed RAC that the comments from BASF/ECPA had been distributed to the Members after confirmation from the rapporteur and reminded RAC stakeholders to submit any documents for the consideration of RAC members to the RAC Secretariat in accordance with the rules laid down in the ECHA Code of Conduct for Observers from Stakeholder Organisations.

The RAC rapporteur presented a revised version of the RAC opinion and an ORCOM document following a commenting round with the RAC members before the meeting. A significant discussion took place on the revised draft opinion which included an ad hoc meeting between plenary sessions involving members, RAC stakeholders and Commission.

The key points for discussion were twofold: firstly, whether RAC should await the results of the six studies referred to in the RAC mandate and the results from further BASF studies of which RAC had also been made aware, rather than forming its opinion on the basis of the study protocols referred to in the RAC mandate; and secondly the extent to which the studies referred to in the RAC mandate were likely to

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

lead to a change in the classification proposed by RAC in its opinion of 17 March 2010 of reprotoxicity category 1B (CLP Regulation).

On the first aspect a discussion took place in which several members confirmed their scientific interest to view the results of the studies when they arrive in due course. However, the Chair clarified that the RAC mandate and hence this RAC opinion is based upon the study protocols of the six studies that were mentioned in the RAC opinion of 17 March 2010 – the so called 'reference documents'. Nevertheless, it was agreed to acknowledge in the RAC opinion that RAC had been informed of further ongoing and foreseen studies specifically relating to the cleft palate effect. The Commission also confirmed that should new information which may lead to a change of the harmonised classification become available at a later time, manufacturers shall submit a proposal to a competent authority according to Article 37(6) of the CLP Regulation.

Concerning the second aspect, the RAC opinion of 17 March 2010 was based upon a weight of evidence approach of the data for two main adverse effects of epoxiconazole on development: post implantation loss and resorptions and malformations as cleft palates. After examination of the reference documents, RAC agreed that the six studies are relevant with respect to late resorptions whilst the potential for a teratogenic effect (cleft palates) of epoxiconazole at high dose levels may remain unexplained whatever the results of these six studies. Therefore the proposal for a harmonised classification and labelling of epoxiconazole as reprotoxic category 1B (CLP) and reprotoxic category 2 (DSD) seems unlikely to be modified by the result of the studies referred to therein.

One member expressed the opinion that the proposed studies might improve the information on the mechanism and the relevance of the post implantation losses and the cleft palates for classification. However, merely on the basis of the six proposed studies the member was not able to conclude whether their outcome will affect the classification of epoxiconazole as reprotoxicity category 1B as described in the RAC opinion of 17 March 2010.

After this discussion the draft opinion was adopted by consensus with some modifications.

The Chair thanked the rapporteur and members for the work.

6.b Gallium arsenide

The Secretariat briefly presented the RAC mandate from the Executive Director of ECHA according to Article 77(3)(c) following a request to ECHA from the Commission.

The mandate specified there would be a public consultation targeted on the carcinogenicity of gallium arsenide. Following this public consultation, RAC would evaluate any new information arising to decide whether it is new and relevant and to assist the Commission to decide on the appropriate harmonised classification and labelling of gallium arsenide.

The public consultation had started on the 11 March 2011 and the deadline for comments was 25 April 2011. The Chair highlighted the scope of the public consultation was exclusively limited to new and relevant information in relation to the proposed classification of gallium arsenide as a carcinogen category 1A (CLP).

7 CLH Dossiers

7.1a Bifenthrin

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

Based on the revised draft opinion, RAC continued the discussion initiated at RAC-12 for endpoints to be further elaborated or discussed for the first time: repeated toxicity endpoints and carcinogenicity. RAC was also informed of the late industry comments on this draft opinion submitted days before the meeting via the regular RAC observer from ECPA. Following the established working approach, comments were forwarded to the rapporteurs and after their agreement they were made available to all RAC members. In this regard, the Chair reminded the RAC stakeholder observers that the submission of such late industry comments so close to the adoption of a RAC opinion on a proposal should be avoided, as it is difficult for the rapporteurs and RAC members to consider them in the opinion.

Concerning the French proposal for STOT RE 1 - H372, RAC discussed the appropriate classification for this endpoint under DSD. RAC agreed that R48/22 was more appropriate than R48/25.

With regard to carcinogenicity, the rapporteur presented his analysis based on substantial amount of information made available by the dossier submitter and by industry in order to support the industry comments submitted during the public consultation. RAC discussed tumour types observed in mice and their relevance for humans. Even if the increased incidence is limited, RAC believed that it is sufficient and should be accounted for. Liver tumours are normally rare in the strain of mice studied and no identified mode of action allows dismissing relevance for humans.

Industry representatives disagreed with the conclusion based on a different assessment of historical data, literature and histopathological findings. Evaluations of bifenthrin or benalaxyl by other bodies were also mentioned. These comments were addressed during the meeting and in the draft opinion by RAC.

Furthermore, the subcategory 1B for Sensitisation according to the 2nd ATP[2] was agreed.

RAC provisionally agreed on the classification as presented in Table 2 of Part II, conclusion and action points. The Chair invited the (co-)rapporteurs to provide a revised version of the draft opinion documents in due course for possible adoption by written procedure before or at RAC-16.

[2] Adaptation to Technical Progress to the CLP Regulation

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

In a closed session, RAC was updated and discussed new information from CLP notification and registration dossiers received by ECHA and identified issues to be further elaborated with regard to substance identification.

Thereafter, the Chair re-opened the session and introduced one observer accompanying the CEFIC stakeholder observer.

In the public session, the Chair informed that the Secretariat would organise a preliminary discussion between the dossier submitter and rapporteurs assessing the impact of this new information on the CLH proposal. Then the Secretariat will organise a discussion between the dossier submitter, rapporteurs, industry representatives and the Commission to clarify issues raised. Then the Chair and the rapporteurs would identify a way forward before RAC-16.

7.1c Metazachlor

The Chair introduced an observer accompanying the sector-specific ECPA observer and invited the rapporteur to present the revised opinion.

At the RAC-14 meeting members agreed on not to classify metazachlor for fertility and provisionally agreed on the environmental classification.

The rapporteur continued the discussion initiated in the previous meeting for the endpoints: skin sensitisation and carcinogenicity.

Metazachlor was positive in a well-conducted Guinea-pig maximisation study, but negative in two Buehler and an open epicutaneous study. During the discussions it was agreed that the maximisation test is generally considered to be more rigorous and sensitive compared to the other tests, and therefore the findings from this test take precedence. Classification as skin sensitising category 1B (according to 2nd ATP, CLP) and R43 (DSD) was proposed by the rapporteurs and agreed by RAC.

Carcinogenicity was then discussed. The classification proposal was mainly based on liver tumours in rats with supporting evidence from kidney tumours in mice. The relevance to humans was discussed by RAC and it was finally concluded that since it can not be ruled out that the mode of action is relevant to humans, carcinogenicity classification is justified.

RAC adopted by consensus the revised draft opinion and its annexes for metazachlor. The proposed classification is presented in Table 1 of Part II of this document.

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

7.1d Flufenoxuron

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

Mutagenicity and repeated dose toxicity comments had been addressed in the revised draft opinion and RAC agreed that no classification was warranted. Therefore the

discussion focused on whether effects seen on lactation represented developmental toxicity. Cross fostering study on rats with long exposure before mating and during pregnancy did not reveal signs of developmental toxicity. Teratogenicity studies were also negative: exposure during pregnancy alone did not induce toxic effects. Thus, a necessary prerequisite for flufenoxuron to induce effect on offspring observed only during lactation period is a long term exposure before mating, during pregnancy and during lactation. In order to observe any effects in offspring the exposure must continue during all these three periods.

In order to induce these effects, flufenoxuron has to accumulate in the body of dams leading to alteration of the quantity and/or quality of milk and excretion of flufenoxuron with milk. It is not possible to indicate whether the effects observed on the pups result from:

- Alteration of milk quality
- Alteration of milk quantity
- Toxicity of flufenoxuron in milk

However, RAC considered that these mechanisms are fully covered in the category "Effects on or via lactation".

RAC considered relevant to indicate the potential bioaccumulation (R33) under the DSD. This hazard statement does not have an equivalent under the CLP.

The ETUC observer noted that this information will be lost when the DSD will be repelled, and highlighted that CLP's aim is to maintain the level of information of former Directive on classification. Since it is a very important tool for trade union's work on protection of workers, especially to pregnant and breast feeding workers, ETUC strongly demanded bioaccumulative hazardous statement to be included under CLP regulation.

RAC preliminary agreed to propose flufenoxuron to be classified as indicated in Table 2 of Part II of this document. The Chair thanked the rapporteurs for preparing the draft documents. The rapporteurs will consider the comments received and revise the draft opinion documents if needed, and subsequently submit them to RAC as indicated in section 7.1d of Part II of this document for possible adoption by written procedure before RAC-16.

7.1e **Chloroform**

The Chair welcomed an adviser to the rapporteurs and introduced an observer accompanying the CEFIC observer. The adviser presented available studies on the mutagenicity endpoint in a weight of evidence approach. RAC discussed the weight to be given to respective studies.

Some members cast doubts on the reliability of some data used to propose classification. Either the protocol was unusual (Robbiano) or effects were seen as not consistent across studies (Fujie, dose) or with the mode of action (Hoechst, the only study with damaged cells). For example, in the Fujie study effects were seen at a dose range much lower than other studies. Cytotoxicity (at 400-800 mg/kg bw) may also explain effects seen in the Shelby & Witt (1995) micronucleus study. Finally not enough weight may have been given to the negative Whitwell study. This view was supported by the CEFIC observer.

Other members focussed on the facts that the top dose may not have been reached in Whitwell and that chloroform did appear to trigger some effects on somatic cells in studies. Therefore chloroform may be a potential germ cell mutagen. These members argued that this merits classification based on the guidance document. Due to the different views regarding the weight of evidence of negative and positive *in vivo* somatic cell results, the Chair asked the rapporteurs to revise the draft opinion and include a proposal for no classification with justifications so that both weight of evidence approaches are available to RAC for discussion. The rapporteurs will consider the comments received and revise the draft opinion documents, and subsequently submit them to RAC as indicated in section 7.1e of Part II of this document. The substance will be further discussed and possibly adopted at RAC-16.

7.1f Indoxacarb and indoxacarb (enantiomeric reaction mass S:R 75:25)

The Chair noted that an observer accompanying the sector-specific ECPA observer was registered for participation in this agenda item; however, the person was not able to attend the meeting.

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

With regard to acute toxicity, the oral, inhalation and dermal exposure routes were discussed. When comparing the effects and the exposure levels with the classification criteria, classification for acute toxicity by the oral and inhalation routes was proposed. No classification was proposed for acute dermal toxicity.

The proposed non-classification for specific target organ toxicity single exposure (STOT SE), oral route, was discussed. Arguments for and against classification were presented.

For skin sensitisation the proposed classification was Skin Sens 1B; H317 (according to the new criteria in 2nd ATP, CLP). Due to inconsistencies between the CLH report and the attached pesticide report, clarifications from the dossier submitter had been required.

For repeated dose toxicity, during the preliminary discussion the proposed classification as STOT RE 1 was supported by several RAC members. The observer from ECPA, however, commented on the proposed classification and said the effects seen after repeated exposure could only be considered marginal. For repeated dose toxicity by the dermal route, no classification was proposed, but classification as STOT RE; H373 (CLP) could potentially be considered if data are available. Clarifications from the dossier submitter on this issue had been required and it will be discussed further.

Concerning the environmental classification, none of the substances are considered to be rapidly degradable; indoxacarb (S enantiomer) is not bioaccumulative in contrast to indoxacarb 75:25 S:R which is considered bioaccumulative. The proposed classification was identical to the dossier submitter proposal.

The Commission observer questioned the proposed environmental classification according to the new criteria of the CLP Regulation (2nd ATP) and asked the rapporteurs to check whether it was correct. The rapporteur agreed to do this, and to revise the proposal if considered appropriate.

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

The Chair invited the rapporteurs to provide a revised version of the opinion documents in due course for possible adoption by written procedure before or at RAC-16.

7.1g 2-ethoxyethanol

The Chair invited the RAC rapporteur to present the second draft opinion on the CLH proposal submitted by Germany. A harmonised classification and labelling for this substance had been agreed at the Technical Committee for Classification and Labelling (TC C&L) under the previous legislation. The current classification proposal was identical to that agreed at TC C&L. RAC agreed with dossier submitter to remove the classification as harmful in contact with skin (CLP/DSD), to keep the existing classification as harmful if swallowed (CLP/DSD) and harmful by inhalation (DSD), but to modify the current CLP classification of 2-ethoxyethanol as harmful if inhaled to toxic if inhaled.

Based on comparison of the available reproductive toxicity data with the CLP Regulation and DSD classification criteria, RAC agreed that these data correspond with the existing classification. Although the human data seem to indicate a possible effect on reproduction for (ethylene) glycol ethers, a higher classification was not considered appropriate by RAC because the data do not present sufficient evidence for a direct association with 2-ethoxyethanol.

In conclusion, RAC adopted by consensus the revised draft opinion on the CLH proposal for 2-ethoxyethanol. The proposed classification is presented in Table 1 of Part II of this document.

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

7.1h Vinyl acetate

The Chair invited the RAC rapporteur to present the first draft opinion on the CLH proposal submitted by Germany. A harmonised classification and labelling for this substance had been agreed at the Technical Committee for Classification and Labelling (TC C&L) under the previous legislation. It was discussed whether two separate entries should be included in Annex VI for vinyl acetate (non-stabilised form and stabilised form). It was further discussed whether note D or EUH019 (May form explosive peroxides; CLP) / R19 (DSD) for the non-stabilised form is most appropriate. The ECHA Secretariat promised to consult the ECHA experts on substance identification on this issue. The Commission confirmed that it is possible to apply a note D if needed. The industry representative indicated its intention to submit information on this issue.

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

7.1i Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene

The Chair invited the RAC rapporteur to present the first draft opinion on the CLH proposal submitted by Germany. A harmonised classification and labelling for this substance had been agreed at the Technical Committee for Classification and Labelling (TC C&L) under the previous legislation. It was further discussed whether EUH019 (May form explosive peroxides; CLP) / R19 (DSD) is appropriate. The ECHA Secretariat promised to consult the ECHA experts on substance identification on this issue. The industry representative indicated its intention to submit information on this issue.

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

7.1j Aluminium-magnesium-zinc-carbonate-hydroxide-(hydrate)

The Chair invited the RAC rapporteur to present the first draft opinion on the CLH proposal submitted by the Netherlands. The current declassification proposal covers environmental hazard classes As the substance is an inorganic substance containing metals, the substance is handled here as a complex substance and toxicity to aquatic organisms is determined by considering results of the tests performed with a loading that results to maximum water solubility. Therefore more information on experimental conditions in water solubility tests seems to be warranted.
The Chair thanked the rapporteur for the presentation and invited RAC members to provide comments on the first draft opinion and its annexes by the date indicated in section 7.1j of Part II of this document.

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

Room document RAC/15/2011/04 was introduced by the Chair who explained that (co-)rapporteurs are required for 23 submitted dossiers and 13 intentions for submissions of CLH dossiers that had been received since the last meeting. A total of 48 positions were to be filled. RAC agreed to appoint as (co-)rapporteurs 11 members that had volunteered during RAC-15 for (co-)rapporteurship on 10 substances. RAC members were invited to come forward for the remaining dossiers.

7.3 General CLH issues

7.3a State of play of the submitted CLH dossiers

RAC was informed by the Secretariat on the state of play of the submitted CLH dossiers as provided in a room document (RAC/15/2011/05). Members were invited to contact the Secretariat if they needed further clarification.

A Commission representative informed RAC about the progress and timelines for the adoption process of the 2nd and 3rd ATPs. The 2nd ATP was adopted on 10 March 2011 and will be published shortly. Into the 3rd ATP the Commission intends to include thirteen substances. For three further substances, namely THF, epoxiconazole

and gallium arsenide the discussion for inclusion into the 3rd ATP is ongoing. The adoption of the 3rd ATP is foreseen for the end of the year 2011.

In this context, the Chair informed the RAC members about a new template for the table to be used in newly adopted opinions, following the experienced gained from the first transmission of opinion tables to the Commission. The new template will incorporate the format used in the classification and labelling tables in Annex VI of the CLP Regulation. The Secretariat will update the opinions adopted during this RAC-15 meeting accordingly.

The Chair also informed RAC that two letters concerning the opinions adopted by RAC on gallium arsenide and THF had been sent by RAC stakeholder observers to the Commission and the Executive Director of ECHA. The letters had been uploaded to the RAC CIRCA IG for information.

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

The Chair informed RAC members about the progress of the plant protection products (PPP) workshop preparations. The workshop is organised in view of the PPP Regulation[3] that specifies strict criteria for the approval of active substances. RAC members were already invited to the workshop in February.

The workshop is organised and hosted by the German Federal Institute for Risk Assessment (BfR) and will take place in Berlin on 12 – 13 April 2011. The draft workshop programme and the draft outline paper were uploaded to the RAC CIRCA IG together with the invitation.

The Chair explained that the workshop will cover two main topics. The first topic is dedicated to streamlining of procedural steps in the RAC opinion development and EFSA process. It includes practicalities and preparation of reporting formats and of IUCLID dossiers.

The second topic is dedicated to the improved harmonised interpretation and reporting of CMRs effects and in avoiding divergences in the interpretation. Several proposals are made in the draft outline document for RAC members' consideration. RAC members are invited to provide comments on the documents via the dedicated Newsgroup in the RAC CIRCA IG as soon as possible.

The Chair announced that the workshop is a restricted event and that Stakeholders presence is not considered, as decided by the organisation Committee. The stakeholder organisation ECPA expressed their disappointment about that.

7.3c Outcome of the RAC workshop "On the way to CLH"

The Chair presented the outcome of the workshop that took place in the ECHA conference centre on 16 February 2011. In order to cope with the increased workload

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

expected for RAC in the next three years, the needs were identified to streamline procedural steps in the opinion development, to increase the transparency during and after the public consultation, and to increase the cooperation between the dossier submitter, the (co-)rapporteurs and the Secretariat in an efficient and cost effective way. In this context the following points have been proposed and were discussed:

a. Modification of the current procedure for the accordance check

RAC agreed to the Secretariat's proposal (room document RAC/15/2011/06) to substitute the current procedure on the accordance check with formal participation of RAC rapporteurs by a framework in which the RAC members will have full commenting possibilities without playing a formal role in the process.

b. Review of the process for developing CLH opinions

RAC agreed that the Secretariat should prepare a working document with an example of a CLH opinion using a revised opinion template (including the BD) and taking the proposals made by RAC members into account.

8 Restrictions

8.1 Restriction Annex XV dossiers

8.1a Dimethylfumarate (DMFu) – fourth draft opinion

The rapporteurs presented their final remarks on the revised 4th version of the RAC opinion on DMFu, clarifying that all members' comments received during the RAC Preparatory meeting held on 15 February are taken into account in this version.

Further, RAC adopted the draft opinion on this restriction proposal and took note on its supportive documentation. It was further agreed that the rapporteurs will ensure that the common supportive documentation (BD and RCOM) to the adopted RAC opinion and to the agreed SEAC draft opinion is in line with the adopted RAC opinion for this substance before the publication on the ECHA website.

The Chair thanked the rapporteurs and the other RAC members for the fruitful work done and congratulated RAC for the first adopted RAC opinion under the restriction process.

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

The Chair introduced an observer accompanying the regular EUROMETAUX observer for the discussions on this restriction proposal.

The rapporteurs presented the revised 4th version of the RAC opinion on lead and its compounds and their responses to the RAC members' comments on it. It was noted that the revision was done on the basis of the recommendations and comments received during the aforementioned RAC Preparatory meeting held in mid-February. The rapporteurs also explained how the members' comments received during the additional consultation organised afterwards have been considered in the presented draft opinion.

In the following discussions, several issues were considered. It was concluded that RAC supports a restriction which protects consumers and especially children from

lead exposure from jewellery when mouthed without any specific derogations related to the type of the jewellery material (metallic or non-metallic parts, crystals, gems, etc.) or surface. Furthermore, the RAC opinion should reflect the current scientific knowledge on the basis of the available information provided in the original dossier and submitted during the public consultation. It can also include well-justified assumptions. Although there are uncertainties, members agreed that the risks are identified, and any additional exposure to children should be reduced.

Therefore, the RAC consensus reached on values for migration would be a basis for RAC conclusions. However, RAC acknowledged also uncertainties related to the migration measurement and problems related to the implementability and enforceability, when using only a migration based restriction and concluded that a content of 0.05 % lead can be regarded as a limit value which ensures the same protection level than the migration value. The RAC scientific assessment, as well as the uncertainties and information gaps, should be explained in the opinion, which should also provide a clear recommendation to Commission. Finally, members agreed that there is no need for exemption for crystals, as industry should just demonstrate that the lead migration is below the migration limit value to permit jewellery on the market even though the content of lead is >0.05%. Some members highlighted the uncertainties regarding the consequences of this "escape clause" for enforcement authorities, and asked whether the requirement for migration data also will apply to enforcement authorities.

An Ad Hoc working group meeting was held after the plenary day. Some sections of the draft opinion were discussed in order to build up clear conclusions on this restriction proposal and provide better justification including uncertainties for the proposed opinion covering identified risks from lead releases from both metallic and non-metallic jewellery parts.

During the following plenary discussions, RAC adopted by consensus its opinion on the proposed restriction for lead in jewellery and took note on its supportive documentation. It was further agreed that the rapporteurs will ensure that the common supportive documentation (BD and RCOM) to the adopted RAC opinion is in line with the adopted RAC opinion before its publication on ECHA website.

The Chair thanked the rapporteurs for incredible amount of work done on this restriction proposal, the other members for the constructive discussions and fruitful outcome and RAC observers for their valuable contributions and congratulated RAC for the second adopted RAC opinion under the restriction process.

8.1c Phenylmercury compounds – second draft opinion

The Chair welcomed the SEAC rapporteur to the meeting.

The RAC rapporteurs presented the main modifications in the 2nd version of the RAC opinion on phenylmercury compounds and the responses to the RAC members' comments on it. It was noted that the draft opinion had been modified according to the written comments from members as well as following the discussions at the last RAC meeting and at the second rapporteurs' dialogue.

RAC discussed several topics of the restriction. One topic concerns the scope of the restriction. If the proposed substances are replaced by alternative substances which also contain mercury the efficacy of the restriction could be challenged.

Environmental degradation is pivotal to the choice of substances for the grouping approach for the current restriction. The degradation pathway for phenylmercury carboxylates is well described. If the phenyl group is replaced by an alkyl group or a halogen, however, the degradation may be quite different. RAC also proposed to add in the opinion that organotin compounds are not suitable to be used as substitutes and are already partly restricted.

The amounts exported from the EU are already included in the scope of the restriction by its current wording.

Another topic concerns the transitional period before the restriction start applying. The rapporteur illustrated that with a sooner restriction the amount of mercury released into the environment will be considerably lower. Therefore a three year delay after entry into force of the amendment of Annex XVII is proposed, instead of the five years proposed by the dossier submitter.

Concerning the justification in the opinion, RAC members asked to focus on the non-threshold properties (PBT-like, LRT and neurodevelopmental) of the substances. All attempts in estimating PEC/PNEC ratios are non-conclusive because of difficulties of quantifying emissions and exposure and can therefore be removed from the justification in the opinion.

During the meeting the third version of the draft opinion was produced and agreed by RAC (see also section 8.1c. of part II of this document). The 3rd draft will be forwarded to the Forum. The fourth version of the RAC draft opinion will be produced by May 2011.

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

8.1d Mercury in measuring devices

The RAC rapporteurs presented the modifications in the 2nd version of the RAC opinion on mercury in measuring devices and the responses to the RAC members' comments on it. It was noted that the draft opinion had been modified according to the written comments from members on the opinion as well as on the part C, and following the discussions at the last RAC meeting and at the second rapporteurs' dialogue. The rapporteur added that only few comments on the opinion had been received until now during the ongoing public consultation, which were addressed in the RCOM. Furthermore, the rapporteur thanked the dossier submitter for the good cooperation.

One member pointed out that some conclusions in relation to the properties of methyl mercury could be added to align the opinion with the opinion for phenyl mercury compounds. RAC rapporteurs agreed to this proposal.

Since there was little discussion on the 2nd opinion, RAC agreed to consider this draft opinion on the restriction proposal for mercury in measuring devices as the 3rd version and to forward it to the Forum. The rapporteurs are requested to insert the recommendations from the plenary meeting when preparing the 4th version of the RAC draft opinion. The fourth version of the RAC draft opinion will be produced by May 2011 (see section 8.1d of Part II of this document).

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

8.2 General restriction issues

Concerning the Background Document (BD), the Chair made a clarification on its status as a supportive document to both RAC and SEAC restriction opinions. Based on legal advice, the Secretariat proposed that RAC adopts only the opinion on a restriction proposal and consider the BD as supportive document instead that as an annex to the opinion. It was also indicated that RCOM would be published on the ECHA website. Further, the rapporteurs would be requested to ensure that the supportive documentation (BD and RCOM) common for RAC and SEAC opinions on a restriction proposal is in line with the adopted RAC opinions. A disclaimer to be included in the BD was also presented for members' approval.

RAC agreed on the proposed approach that will be reflected in the revised RAC Working Procedures (incl. the opinion format) later this year and on the disclaimer that will be incorporated in the BDs to the current RAC opinions on the ongoing restriction proposals.

9 Authorisation

9.1a Format of an opinion

The Secretariat presented the updated version of the format of an opinion for application for authorisation (room document RAC/15/2011/08) and the responses to the RAC members' comments, as listed in room document RAC/15/2011/08_Add.1.

RAC members and Commission observers welcomed the response to comments. Additional comments were received from the ETUC observer shortly before the discussion, were summarised. The main ETUC comment was that authorisation also aims to remove dangerous substances from the market and, therefore, all available alternatives should be taken into account by the applicant.

The discussion focussed on how to address the level of uncertainties related to the hazard and risk assessment of the substance under authorisation and proposed alternative substances. In addition, the information required from the applicant was considered to be crucial for RAC. RAC was informed on the preparatory seminar for industry scheduled for 12 April 2011. It was emphasised by RAC members that the assessment of applications for authorisation should be anticipated as far as possible, and proposals facilitating the opinion development should be considered. RAC members pointed out the importance to balance practicalities versus intensive scientific discussions. It was suggested to organise substance-specific discussion sessions for presenting the information submitted under the registration process, in particular the CSR, and addressing its potential relevance for the future discussion on authorisation. It was agreed that the Secretariat would consider the possibility for organising such sessions during RAC-16 or RAC-17.

The Chair concluded that at this stage the format of an opinion aims to give an outline and structure for the opinions. The Secretariat informed that the document presents a compiled version of the template for the RAC and SEAC opinions in order to facilitate the understanding. The templates for the RAC and SEAC opinions would consider the need for streamlining the work of the Committees but keeping in mind

that both opinions should complement each other for facilitating the Commission decision process. The format might need to be adapted later on when the first applications for authorisation are developed.

The Chair thanked the contributions and indicated that a newsgroup in the RAC CIRCA IG will be organised to collect further comments by 26 March 2011.

9.1b Risk assessment of non-threshold substances

The Chair asked the members on exchange of views on the risk assessment of non-threshold substances.

The RAC members considered that this subject requires further special attention, with two parallel discussions, one on non-threshold CMR and the other on PBT substances.

The ETUC observer highlighted that DMELs (which have no legal basis in REACH) are risk based limit values and they should therefore be seen as an "acceptable" level of effect and certainly not a level where no potential effect can be foreseen. Moreover, she added that the definition of what is an "acceptable risk" is a political decision to be taken at EU-level and that cannot be made by the applicants, RAC or ECHA.

The Chair thanked the received contributions and concluded with the invitation of RAC members to provide their further views on risk assessment of non-threshold substances via the RAC CIRCA IG. RAC members were also invited to express their interest in supporting the ECHA Secretariat in preparing the RAC discussions. The ECHA Secretariat is to consider the comments and to organise ad-hoc working groups on CMRs and PBTs if expression of interests are received from Members.

The discussion will continue at RAC 16 and the Chair invited the RAC members to present their views by then.

9.2 Appointment of RAC rapporteurs for substances listed in Annex XIV

ECHA presented the room document (RAC/15/2011/09_rev 1) listing volunteers for rapporteurship in different pools for substances included in Annex XIV.

Additional volunteers were identified during the discussion.

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

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

10 Guidance issues

10.a Feedback from guidance consultations

No guidance consultations took place between RAC-14 and RAC-15.

10.b Report on other guidance activities

RAC was informed by the Secretariat on other guidance activities via the room document (RAC/15/2011/01). Members were invited to contact the Secretariat if they needed further clarification.

The Chair explained that a room document instead of a presentation was provided following the proposal by RAC members in the Annual Satisfaction Survey 2010. Fewer presentations during the meeting and condensed information in documents was suggested by RAC members. This practice would be applied in the future for this agenda point, unless specific guidance developments require a presentation.

11 Any other business

The Chair asked RAC to take note on the provisional RAC meeting calendar for 2012 reminding the members that the proposed dates and the duration of the meetings are tentative and will be further confirmed closer to the meetings.

12 Main conclusions and Action Points of RAC-15

The Secretariat presented the main conclusions and action points of the RAC-15 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 15th meeting of RAC)
(8-11 March 2011)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The revised Agenda (RAC/A/15/2011_rev.2) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCA IG and to the ECHA website as part of the RAC-15 minutes.
3. Declarations of conflicts of interest to the Agenda	
Nine members and two STO observers have declared a potential conflict of interest to different substance-related discussions on the Agenda.	-
4. RAC Manual of conclusions and recommendations (MoCR)	
RAC took note of the suggested key issues (from 2010 RAC minutes) for inclusion in the updated MoCR. RAC agreed MSCA to be provided with access to the RAC MoCR via the Annex XV CIRCA IG. RAC agreed to archive the previous versions of MoCR when new updates of MoCR are produced.	**SECR** to update the RAC MoCR and upload it to the RAC CIRCA IG by mid-April 2011. **Members** to suggest the inclusion of additional issues in the MoCR if needed **SECR** to ensure MSCA access to the updated RAC MoCR via Annex XV CIRCA IG after the meeting. **SECR** to maintain the archiving of MoCR when an updated version is produced.
6. Requests under Article 77 (3)(c)	
6.a. epoxiconazole	
RAC adopted by consensus the opinion	**SECR** to upload the adopted

according to Article 77(3)(c).	opinion and its annexes to the RAC CIRCA IG, to forward them to ED and publish them on the ECHA web site after the meeting.
6.b. gallium arsenide	
RAC was informed about the RAC mandate for gallium arsenide and the supplementary public consultation.	**SECR** to inform members about the start of the supplementary public consultation and to provide the **Rapporteurs** with any comments arising compiled into a table. **SECR** to invite the **Rapporteurs** to prepare an RCOM and the draft opinion**.**
7. CLH	
7.1 CLH Dossiers	
7.1a. bifenthrin	
RAC discussed the CLH proposal for carcinogenicity and repeated toxicity endpoints, based on the revised draft opinion. Carcinogenicity was tentatively agreed. Classification for repeated toxicity was agreed. Furthermore, the subcategory 1B for Sensitisation according to the 2nd ATP was agreed. RAC preliminary agreed on the classification as presented in the table 2. below.	**Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) according to the RAC-15 discussion. **SECR** to distribute the revised draft opinion documents to RAC when available for editorial comments and possible adoption by written procedure before or at RAC-16. **Members** to post their comments on the revised draft opinion via the RAC CIRCA IG Newsgroup.
7.1b. white spirit dossiers	
RAC discussed in a closed session new information from CLP notification and registration dossiers received by ECHA and identified issues to be further elaborated with regard to substance identification.	**SECR** to upload documents presented during the closed session via the confidential section of the RAC CIRCA IG. **SECR** to organise a preliminary discussion between the dossier submitter and rapporteurs assessing the impact of this new

	information on the CLH proposal. **SECR** to organise a discussion between the dossier submitter, rapporteurs industry representatives and the Commission to clarify issues raised and identify a way forward before RAC-16. **SECR** to inform RAC about the meeting conclusions and upload relevant documents before RAC-16.
7.1c. metazachlor	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for metazachlor. RAC agreed to propose metazachlor to be classified as indicated in the table 1. below.	**Rapporteurs** to confirm the latest version of opinion and its Annexes to **SECR**. **SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on metazachlor and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting.
7.1d. flufenoxuron	
RAC preliminary agreed to propose flufenoxuron to be classified as indicated in the table 2. below.	**Rapporteur** to provide the final draft of the opinion to the **SECR**. **SECR** to launch after a short editorial commenting round the adoption by written procedure after the meeting.
7.1e. chloroform	
RAC discussed the revised draft opinion. RAC agreed to continue the discussion on the classification for **- Muta. 2, H341**	**Rapporteur** to revise the draft opinion and include a proposal for no classification with justifications so that both options (classification and no classification) are available to RAC by 09 April 2011. **SECR** to distribute the revised draft opinion document to RAC when available.

7.1f. indoxacarb	
RAC discussed the first draft opinion.	**Rapporteur** to add in the BD the environmental classification according to the new criteria of CLP Regulation (2nd ATP). **Members** to post their comments on the 1st draft opinion via the RAC CIRCA IG Newsgroup by 21 March 2011. **Rapporteurs** to revise the draft opinion(s) documents (revised draft opinion and its annexes (BD and RCOM)) before RAC-16. **SECR** to distribute the revised draft opinion(s) documents to RAC when available for further discussion and possible adoption before or at RAC-16.
7.1g. 2-ethoxyethanol	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for 2-ethoxyethanol. RAC agreed to propose 2-ethoxyethanol to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion and its annexes to the RAC CIRCA IG, to forward them to COM and publish them on the ECHA web site after the meeting.
7.1h. vinyl acetate	
RAC discussed the first draft opinion.	**Members** to post their comments on the 1st draft opinion via the RAC CIRCA IG Newsgroup by 28 March 2011. **SECR** to check and to provide further information on the application of EUH019/R19 and the use of note D after the meeting. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) before RAC-16.

	SECR to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption before or at RAC-16.
7.1i. reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene	
RAC discussed the first draft opinion.	**Members** to post their comments on the 1st draft opinion via the RAC CIRCA IG Newsgroup by 18 March 2011. **SECR** to check and to provide further information on the application of EUH019/R19 and the use of note D after the meeting. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) before RAC-16. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption before or at RAC-16.
7.1j. aluminium-magnesium-zinc-carbonate-hydroxide-(hydrate)	
RAC discussed the first draft opinion.	**Members** to post their comments on the 1st draft opinion via the RAC CIRCA IG Newsgroup by 31 March 2011. **Rapporteurs** to request from the dossier submitter more information on experimental conditions in water solubility tests. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) by also considering the opportunity of classifying as Chronic 4, following the metals' approach before RAC-16.

	SECR to distribute the revised draft opinion(s) documents to RAC when available for further discussion and possible adoption before or/at RAC-16.
7.2 Appointment of (co-) rapporteurs for CLH dossiers	
RAC agreed to appoint the volunteers as (co-) rapporteurs for the intended or submitted CLH proposals (listed in room document RAC/15/2011/04_rev1).	**SECR** to upload in RAC CIRCA IG the updated document to reflect RAC appointments for CLH proposals after the meeting. **Members** are requested to come forward for the vacant positions. **SECR** to identify potential (co-) rapporteurs and encourage them to fill the vacant positions.
7.3 General CLH issues	
7.3.c Outcome of the RAC workshop "On the way to CLH	
e. Modification of the current procedure for the accordance check RAC requested the SECR to prepare a framework as replacement of the current procedure on accordance check when agreed by RAC.	**SECR** to prepare the framework and to present the proposal to RAC.
f. Review of the process for developing CLH opinions RAC requested the SECR to prepare an example for facilitating the discussions.	**SECR** to propose an example using the revised opinion template (including the BD) taking the proposals made by RAC members into account.
8. Restrictions	
8.1 Restriction Annex XV dossiers	
8.1. a Dimethylfumarate (DMFu)	
RAC adopted by consensus the opinion on the restriction proposal on DMFu and took note on its supportive documentation (BD and RCOM).	**Rapporteurs** to ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion by 14 March 2011.

	SECR to upload the adopted opinion and its supportive documentation to the RAC CIRCA IG, to forward them to COM and publish them on the ECHA web site after the meeting.
8.1.b Lead and its compounds in jewellery	
RAC adopted <u>by consensus</u> the opinion on the restriction proposal on lead and its compounds in jewellery and took note on its supportive documentation (BD and RCOM). RAC noted that its opinion on the proposed restriction on lead significantly diverges from the original dossier submitter's proposal for restriction on lead and its compounds in jewellery.	**Rapporteurs** to ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion by 21 March 2011. **SECR** to upload the adopted opinion and its supportive documentation to the RAC CIRCA IG, to forward them to COM and publish them on the ECHA web site after the meeting. **RAC Chair** to inform the ECHA ED of this RAC conclusion after the meeting.
8.1. c Phenylmercury compounds	
RAC agreed to the 3rd version of the RAC draft opinion on the restriction proposal for phenylmercury compounds. The rapporteurs are requested to insert the recommendations from the plenary meeting when preparing the 4th version of the RAC draft opinion.	**SECR** to submit the 3rd version of the RAC draft opinion on phenylmercury compounds to Forum by 16 March 2011. **SECR** to upload the 3rd version of the RAC draft opinion documents to the RAC CIRCA IG by 16 March 2011. **SECR** to send the timetable of the next steps to the rapporteurs after the meeting. **Rapporteurs** to prepare the 4th version of the RAC draft opinion document on phenylmercury compounds by May 2011. **SECR** to upload the 4th version of the RAC draft opinion documents to the RAC CIRCA IG as soon as provided and to launch the written commenting round.

8.1.d Mercury in measuring devices	
RAC agreed to the 2nd version of the RAC draft opinion on the restriction proposal for mercury in measuring devices and to consider it as the 3rd version to be sent to the Forum. The rapporteurs are requested to insert the recommendations from the plenary meeting when preparing the 4th version of the RAC draft opinion.	**SECR** to submit the questions and the 3rd version of the RAC draft opinion on mercury in measuring devices to Forum by 16 March 2011. **Rapporteurs** to prepare the 4th version of the RAC draft opinion document on mercury in measuring devices by May 2011. **SECR** to upload the 4th version of the RAC draft opinion documents to the RAC CIRCA IG as soon as provided and to launch the written commenting round.
8.2 General restriction issues	
RAC agreed with the Secretariat's suggestion to consider only a RAC opinion as a document for adoption and to take note on its supportive documentation (BD and RCOM) that is to be further modified by the RAC rapporteurs to be in line with the adopted RAC opinion. RAC also agreed, with a minor modification, with the proposed disclaimer to be later included in the BD.	**SECR** to consider this decision of RAC and modify the RAC WPs (incl. opinion format) accordingly when the WP is revised in the second half of 2011 **SECR** to incorporate the agreed BD disclaimer in the adopted restriction opinions and the ones under development after the meeting.
9 Authorisation	
9.1 RAC Formulation of RAC opinions on authorisation applications	
a. Format of an opinion RAC discussed the documents and provided several suggestions.	**SECR** to organise a Newsgroup in the RAC CIRCA IG for collecting further comments. **Member** to post comments by 25 March 2011. **SECR** to consider the comments received. **SECR** to consider specific sessions for discussion on the 6

	substances included into Annex XIV for RAC-16 or RAC-17.
b. Risk assessment of non-threshold substances RAC considered that this subject requires specific attention, with two parallel discussions, one on non-threshold CMR and the other on PBT substances.	**Members** are invited to provide their views on risk assessment of non-threshold substances via the RAC CIRCA IG and to express their interest in supporting the SECR in preparing the RAC discussions. **SECR** to consider the comments and to organise ad-hoc working groups on CMRs and PBTs if expressions of interests are received from Members. **Members** are invited to present their views at RAC-16.
9.2 Appointment of RAC rapporteurs for substances listed in Annex XIV	
RAC agreed to appoint the volunteers to the pool as (co-) rapporteurs for the substances listed in Annex XIV (room document RAC/15/20211/09_rev.1).	**SECR** to upload in RAC CIRCA IG the updated document to reflect RAC appointments for substances listed in Annex XIV. **SECR** to inform RAC as soon as an application for authorisation is submitted to ECHA. **Members** may volunteer to be added to the pool of (co-)rapporteurs any time.
GENERAL	
-	**SECR** to upload all presentations, room documents and the RAC-15 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG without delay after the meeting.

Table 1. List of adopted classifications by RAC

CLP

				Classification		Labelling				
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Hazard Class and Category Code(s)**	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**	**Specific Conc. Limits, M-factors**	**Notes**
	4-tert-Butylbenzoic acid	**202-696-3**	**98-73-7**	**Repr. 1B** **STOT RE 1** **Acute Tox. 4**	**H360F** **H372** **H302**	**GHS07** **GHS08**	**H360F** **H372** **H302**			

DSD:

				Classification	Labelling			
Index No	**International Chemical Identification**	**EC No**	**CAS No**				**Concentration Limits**	**Notes**
	4-tert-Butylbenzoic acid	**202-696-3**	**98-73-7**	**Repr. Cat. 2; R60** **T; R48/23/24/25** **Xn; R22**	**T; Xn** **R: 22-48/23/24/25-60** **S: (1/2-)-45-53**			

CLP

				Classification		Labelling				
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Hazard Class and Category Code(s)**	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**	**Specific Conc. Limits, M-factors**	**Notes**
	Metazachlor	**266-583-0**	**67129-08-2**	**Skin Sens. 1(B)**	**H317**	**GHS07**	**H317**		**M=100**	
				Carc. 2	**H351**	**GHS08**	**H351**		**(Acute = 100**	
				Aquatic Acute 1	**H400**	**GHS09**	**H410**		**Chronic = 100)**	
				Aquatic Chronic 1	**H410**	**Wng**				

(according to ATP2 criteria)

DSD

Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**	**Labelling**	**Concentration Limits**	**Notes**
	Metazachlor	**266-583-0**	**67129-08-2**	**R43** **Carc. Cat. 3; R40** **N; R50/53**	**Xn; N** **R: 40-43-50/53** **S: (2-)36-37-60-61**	**N; R50-53: C ≥ 0,25 %** **N; R51-53: 0,025 % ≤ C < 0,25 %** **R52-53: 0,0025 % ≤ C< 0,025 %**	

				Classification		Labelling				
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Hazard Class and Category Code(s)**	**Hazard state-ment Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**	**Specific Conc. Limits, M-factors**	**Notes**
603-012-00-X	**2-ethoxyethanol (stabilised); Ethylene glycol monoethyl ether(stabilised)**	**203-804-1**	**110-80-5**	**Flam. Liq. 3** **Repr. 1B** **Acute Tox. 3** **Acute Tox. 4**	**H226** **H360FD** **H331** **H302**	**GSH02** **GSH08** **GSH06** **Dgr**	H226 H360FD H331 H302			

				Classification		Labelling			Concentration Limits	Notes
Index No	**International Chemical Identification**	**EC No**	**CAS No**							
603-012-00-X	**2-ethoxyethanol (stabilised); ethylene glycol monoethyl ether(stabilised)**	**203-804-1**	**110-80-5**	**R10** **Repr. Cat. 2; R60-61** **Xn; R20/22**		**T** **R: 60- 61- 10- 20/22** **S: 53-45**				**E**

Table 2. List of preliminary RAC agreement on proposals for classification
(Agreement reached for the following endpoints)

CLP

				Classification		Labelling				
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Hazard Class and Category Code(s)**	**Hazard state-ment Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard state ment Code(s)**	**Suppl. Hazard state ment Code (s)**	**Specific Conc. Limits, M-factors**	**Notes**
				Carc.2	**H351**	**GHS06**	**H351**			
				Acute Tox. 3	**H331**	**GHS08**	**H331**			
				Acute Tox. 2	**H300**	**GHS09**	**H317**			
				STOT RE 1	**H372** (nervous system)	**Dgr**	**H372**			
	Bifenthrin	**NA**	**82657-04-3**	**Skin Sens. 1** ***(Subcat 1b)***	**H317**					
				Aquatic. Acute 1	**H400**				**M-factor = 10 000** **(M-factor = 10 000**	
				Aquatic Chronic 1	**H410**		**H410**		**M-factor= 100 000)**	
				(according to ATP2 criteria)						

DSD

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
				Carc. Cat 3; R40 T; R23/25 Xn; R48/22 R43	T, N R: 23/25-40-43-48/22-50/53	N; R50-53: C ≥ 0.0025%	
	Bifenthrin	NA	82657-04-3	N; R50/53	S: 23-24-36/37-38-45-60-61	N; R51-53: 0.00025% ≤C<0.0025% R52-53: 0.000025%≤C<0.00025 %	

CLP

				Classification		Labelling				
Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Hazard Class and Category Code(s)**	**Hazard state-ment Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard state ment Code(s)**	**Suppl. Hazard stateme nt Code(s)**	**Specific Conc. Limits, M-factors**	**Notes**
				Lact.	**H362**		**H362**			
.	**Flufenoxuron**	**417-680-3**	**101463-69-8**	**Aquatic Acute 1**	**H400**	**GHS09**	**H410**		**M-factor = 10 000**	
				Aquatic Chronic 1	**H410**				**M-factor = 10 000**	

DSD

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

Part III. List of Attendees of the RAC-15 meeting (8-11 March 2011)

Members		**ECHA staff**
ANDERSSON Alicja		ANFÄLT Lisa
BARANSKI Boguslaw		BARRUEL Philippe
BARRON Thomasina		BUCHALAN Steven
BJØRGE Christine		ERICSSON Gunilla
BORGES Teresa		FUHRMANN Anna
DUNAUSKIENE Lina		HONKANEN Jani
DUNGEY Stephen		KARHU Elina
GREIM Helmut		KIVELÄ Kalle
HALKOVA Zhivka		KOKKOLA Leila
JENSEN Frank		KULJUKKA-RABB Terhi
KADIKIS Normunds		LEBSANFT Jörg
LARSEN Poul Bo		LEFEVRE Remi
LEINONEN Riitta		LUOTAMO Marita
LOSERT Annemarie		LUSCHÜTZKY Evita
LUND Bert-Ove		MAGGIORE Angelo
NUNES Maria do Céu		MATTHES Jochen
OLTEANU Maria		MERKOURAKIS Spyridon
PIETRO Paris		MULLER Birgit
PASQUIER Elodie		NYGREN Jonas
PICHARD Annick		PELTOLA Jukka
POLAKOVICOVA Helena		RODRIGUEZ IGLESIAS Pilar
PRONK Marja		ROGGEMAN Maarten
RUCKI Marian		RÖCKE Timo
RUPPRICH Norbert		SIHVONEN Kirsi
SCHULTE Agnes		SPJUTH Linda
SMITH Andrew		VAINIO Matti
STOLZENBERG Hans-Christian		Van HAELST Anniek
TADEO José L.		SCHÖNING Gabriele
Van der HAGEN Marianne		TARAZONA Jose
Van MALDEREN Karen		VASILEVA Katya
		Stakeholder observers
Advisers to the RAC members		ANNYS Erwin (Cefic)
BECKMAN Martijn (adviser to Marja Pronk)		MEISTERS Marie-Louise (ECETOC)

CEDERBERG HÅKAN (adviser to Alicja Andersson)		ROWE Rocky (ECPA)
DUSSART Aurélie (adviser to Karen van Malderen)		SANTOS Tatiana (ETUC)
DUTTON Sarah (adviser to Andrew Smith and Steve Dungey)		MÛLLER Karsten (BusinessEurope)
EKOKOSKI Elina (adviser to Riitta Leinonen)		VEROUGSTRAETE Violaine (Eurometaux)
ESPOSITO Dania (adviser to Pietro Paris)		
Olsen Ann Karin (adviser to Marianne van der Hagen)		**Other observers**
OLSSON Ing-Marie (adviser to Bert-Ove Lund)		GAOU Isabelle (an observer acting as an expert to an observer representing CEFIC for chloroform)
SØRENSEN Peter (adviser to Poul Bo Larsen)		McKEE Richard (an observer acting as an expert to an observer representing CEFIC for white spirit)
		FEGERT Ivana (an observer acting as an expert to an observer representing ECPA for epoxiconazole_1 discussion and for flufenoxuron_2 discussion)
Invited Experts		SCHNEIDER Steffen (an observer acting as an expert to an observer representing ECPA for epoxiconazole_2 discussion)
Le Curieux-Belfond Olivier (RAC rapporteur for phenylmercury)		WIEMANN Christine (an observer accompanying the nominated ECPA observer for metazachlor)
Pospischil Erich (RAC rapporteur for white spirits)		ORTH Ann (an observer accompanying the nominated ECPA observer for bifenthrin)
		WARREN Simon (an observer accompanying the nominated ECPA observer for flufenoxuron_1 discussion)
Representatives of the Commission		BOREIKO Craig (an observer accompanying the nominated Eurometaux observer for lead)
BINTEIN Sylvain (DG ENV)		HARTNIK Thomas (Norwegian dossier submitter representative for Phenylmercury)
GRODZKI Karola (DG ENTR)		
ROZWADOWSKI Jacek (DG ENTR)		
WISTUBA Christine (DG ENV)		**Joint RAC-SEAC workshop – Thursday 10.3.2011 PM**
		Crane Mark (Expert from WCA giving a presentation)
SEAC Restriction (co-)rapporteurs		Leverett Dean (Expert from WCA giving a presentation
		Surl Luke (Expert from WCA giving a
FURLAN Janez (invited as SEAC rapporteur		

following AP 8.1a DMFu)		presentation)
GEORGIOU Stavros (invited as SEAC rapporteur following AP 8.1b Lead)		SEAC members SEAC stakeholders SEAC Secretariat
FOCK Lars (invited as SEAC rapporteur following AP 8.1.b Lead)		
Remote participants		
BAUMBUSH Angelika (a representative of the Norwegian CA following AP 7.1c phenylmercury)		
CHARLES Sandrine (a representative of the French CA following AP 7.1d flufenoxuron)		
FANKHAUSER Simone (a SEAC rapporteur for Phenylmercury (AP 8.1c)		
KOPANGEN Marit (a representative of the Norwegian CA following AP 8.1.c phenylmercury)		
LAUMONIER Elisabeth (a representative of the French CA following AP 7.1a bifenthrin)		
MORKA Heidi (a representative of the Norwegian CA following AP 7.1c phenylmercury)		
MULLOOLY Yvonne (RAC member following the whole RAC-15 meeting)		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-15 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-15 meeting

08 March 2011
RAC/A/15/2011_rev.2

Final Agenda

15th meeting of the Committee for Risk Assessment

08 – 11 March 2011

Helsinki, Finland

08 March: starts at 9:00
11 March: ends at 13:00

Joint Workshop RAC-SEAC on impact assessment

10 March: 14.00 – 17.00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/15/2011
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – RAC Manual of Conclusion and Recommendations

For information

Item 5 – Administrative issues and information items

a. Status report on the RAC - 14 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/15/2011/02
ROOM DOCUMENT

d. Outcome of the Annual Satisfaction Survey 2010

RAC/15/2011/03
ROOM DOCUMENT
For information

Item 6 – Requests under Article 77 (3)(c)

a. epoxiconazole

For discussion & possible adoption

b. gallium arsenide

For information

Item 7 – CLH

7.1 CLH Dossiers

a. bifenthrin

For discussion and possible adoption

b. white spirit dossiers

For discussion and possible adoption

c. metazachlor

For discussion and possible adoption

d. flufenoxuron

For discussion and possible adoption

e. chloroform

For discussion and possible adoption

f. indoxacarb

For first discussion

g. 2-ethoxyethanol

For discussion and possible adoption

h. vinyl acetate

For first discussion

i. reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene

For first discussion

j. aluminium-magnesium-zinc-carbonate-hydroxide-(hydrate)

For first discussion

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

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

RAC/15/2011/04
ROOM DOCUMENT
For agreement

7.3 General CLH issues

a. State of play of the submitted CLH dossiers

RAC/15/2011/05
ROOM DOCUMENT
For information

b. Preparation of the workshop on the classification and labelling of active

substances in PPP scheduled for April 2011

For information

c. Outcome of the RAC workshop "On the way to CLH"

aa. Modification of the current procedure for the accordance check

RAC/15/2011/06
ROOM DOCUMENT
For discussion and possible agreement

bb. Review of the process for developing CLH opinions

RAC/15/2011/07
ROOM DOCUMENT
For discussion

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a. DMFu – fourth draft opinion

For adoption

b. lead and its compounds in jewellery – fourth draft opinion

For adoption

c. phenylmercury compounds – second draft opinion

For discussion

d. mercury in measuring devices – second draft opinion

For discussion

8.2 General restriction issues (if relevant)

- Update on intended restriction dossiers

For information

Item 9 – Authorisation

9.1 Formulation of RAC opinions on authorisation applications

a. Format of an opinion

RAC/15/2011/08
ROOM DOCUMENT
For discussion

b. Risk assessment of non-threshold substances

For discussion

9.2 Appointment of RAC rapporteurs for substances listed in Annex XIV

RAC/15/2011/09
ROOM DOCUMENT
For discussion and possible agreement

Item 10 – Guidance issues

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

RAC/15/2011/01
For information

Item 11 – Any other business

- RAC meeting calendar for 2012

RAC/15/2011/10
ROOM DOCUMENT
For information

Item 12 – Main conclusions and Action Points of RAC-15

- Table with main conclusions and action points from RAC- 15

For adoption

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ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-15 meeting.

RAC/A/15/2011	Final Draft Agenda
RAC/15/2011/01 room doc	Guidance issues
RAC/15/2011/02 room doc	Administrative issues and information items
RAC/15/2011/03 room doc	Outcome of the Annual Satisfaction Survey 2010
RAC/15/2011/04 room doc	Appointment of CLH rapporteurs intentions
RAC/15/2011/05 room doc	State of play of the submitted CLH dossiers
RAC/15/2011/06 room doc	Modification of the current procedure for the accordance check
RAC/15/2011/07 room doc	Review of the process for developing CLH opinions
RAC/15/2011/08 room doc	Format of an opinion on authorisation application
RAC/15/2011/08_a-addendum room doc	Format of an opinion on authorisation application_addendum
RAC/15/2011/09 room doc	Appointment of RAC rapporteurs for substances listed in Annex XIV
RAC/15/2011/010 room doc	RAC meeting calendar for 2012

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