RAC/M/22/2012
23 November 2012

Minutes of the 22nd Meeting of the Committee for Risk Assessment (RAC-22)

(11-14 September 2012)

Part I Summary Record of the Proceedings

1 Welcome and apologies

Tim Bowmer, the new Chairman of the Committee for Risk Assessment (RAC) introduced himself and welcomed all the participants to the 22nd meeting. He informed the members that new RAC member Sonja Kapelari had been appointed by the Management Board on 21 May 2012 and asked her to introduce herself. The Chair informed the meeting that two RAC members were unable to attend (Apologies were received from one RAC member. One member was absent). For this meeting several participants took part in substance-related discussions by remote access.

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. He noted that the minutes would be published on the ECHA website and would include the list of participants as given in Part III of these minutes.

2 Adoption of the Agenda

The final draft agenda (RAC/A/22/2012) was adopted without modifications. The agenda and the list of all meeting documents are attached to these minutes as Annexes I and II, respectively.

3 Declarations of conflicts of interests to the Agenda

The Chair requested all participants to declare any conflicts of interest to any of the specific agenda items. Ten members, two stakeholder observers, one Commission observer and the RAC Chair declared conflicts of interest, each to specific agenda items. The members did not participate in voting under the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4 Report from other ECHA bodies and activities

a) Report on RAC 21 action points, written procedures and other ECHA bodies

The Secretariat informed the Committee on administrative issues as set out in room document RAC/22/2012/01, which included an overview of the adoptions, consultations, and agreements undertaken by written procedure since the last RAC meeting as well as reports from the last meetings of the ECHA bodies namely the Management Board, the Member State Committee, the Committee for Socio-economic Analysis and the Forum for Exchange of Information on Enforcement (Forum).

b) Implementation of the Conflict of Interest Policy

i) General principles and guidance for Committee members

The Chair informed the Committee that following a recommendation of the Court of Auditors, the Secretariat had drafted a proposal concerning general principles and guidance for Committee members of the Agency. The Secretariat then introduced meeting document RAC/22/2012/01 containing the draft general principles and guidance for Committee members of ECHA. The Secretariat noted that the document is to be introduced both to SEAC at its 16th meeting and MSC at its 25th meeting.

RAC members raised the issue of direct communication between them and stakeholders, as those RAC members who are the employees of the Member State Competent Authorities (MSCAs) have the obligation to participate in regular meetings with the stakeholders.

They also asked for clarification of the meaning of the phrase "ongoing substance", and if this applies only to the dossiers currently discussed by RAC or also to the dossiers in the preparation stage by the MSCA or to the dossiers for which decision of the Committee was adopted but the opinion was not send yet to the Commission.

One member asked for clarification on the paragraph regarding independence and in particular the interests of persons belonging to the same household or family of a Committee member. Another member had a question relating to the paragraph on not holding positions or interests that are considered incompatible with the role as a Committee member and the role of the Committee in the two years following the mandate.

The Chair concluded that the Secretariat would take note of the discussion and would consider the appropriate way to document the proposal.

ii) Eligibility criteria

The Secretariat provided an update on the eligibility criteria for ECHA bodies. The draft eligibility criteria had been briefly presented to RAC and SEAC in their June 2012 meetings. The document was then discussed by the ECHA Management Board (MB) in its June meeting, but the final decision was postponed to its September meeting (28-29 September 2012). The Secretariat explained the revised eligibility criteria and emphasised that they would be applicable to new appointments and renewals only and not to current members of the Committees.

The RAC members asked for clarification of the exact meaning of the phrase "employed by, or holding a position in a governing body of a commercial enterprise". Moreover, those RAC members who are working for the MSCA which is or was preparing dossiers were of the opinion that they may need to declare a potential conflict of interest with regard to that particular dossier.

The ECHA Secretariat responded that this would be considered on a case-by-case basis and the Secretariat offered help to the RAC members in case they have any doubts concerning potential conflict of interest.

It was agreed that the Secretariat would take note of the discussion and submit the proposal for revised eligibility criteria to the ECHA MB.

5 Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Fenoxycarb

The Chair welcomed an expert accompanying the ECPA stakeholder observer and also a representative from the dossier submitter from the German MSCA, the latter who followed the discussions as a remote participant.

The Chair reported that this was the second discussion at a RAC plenary of this dossier, and that the focus of the discussions would be on reproductive toxicity, carcinogenicity and hazard to the aquatic environment. The legal deadline for adoption of the opinion would be 14 February 2013. The substance is used as an active substance in plant protection and biocidal products.

The Chair invited the adviser to the Rapporteur to present the key findings/issues and the proposed conclusions to RAC for human health hazards.

The adviser presented firstly the key findings for reproductive toxicity. The slight increase in spina bifida and tail reduction were the only effects observed and were not statistically significant falling within the range of historical control data. In addition, both effects were not reproduced in an additional study using a larger number of animals. This view was shared by the other RAC members, and 'no classification' for reproductive toxicity was agreed.

The adviser continued her presentation, focussing on carcinogenicity. She reported that the observed liver tumours in mice might be related to peroxisome proliferation. However, the lung tumours have a different etiology. The discussion focused on whether the data supports Carc. 1B or 2. It was concluded that the data was not strong enough to warrant a classification of Carc. 1B and that Carc. 2 was considered more appropriate. The rationale and the proposed classification were agreed by RAC.

Finally the Chair asked the invited expert (acted as the co-rapporteur) to present the key findings for the aquatic environment and the proposed outcome. She supported the proposal by the dossier submitter to assign an M-factor of 1 to the acute 1 classification and of 10,000 to the chronic 1 classification. This view was shared by the other RAC members, and therefore the aforementioned M-factors for the aquatic 1 and chronic 1 classification were agreed by RAC.

The opinion was adopted by consensus. The Chair invited the Rapporteur to revise the draft opinion in line with the discussions at RAC-22. Afterwards an editorial commenting round is foreseen, before the opinion will be published on ECHA's website.

b) Tralkoxydim

The Chair welcomed the expert accompanying the ECPA stakeholder observer and a representative for the dossier submitter from UK MSCA, the latter who followed the discussions as a remote participant.

The Chair reported that tralkoxydim was being tabled for the first discussion at a RAC plenary meeting, that the substance was a plant protection product that had been included in 2008 in Annex I to the former Directive 91/414/EEC. In connection with the tabled CLH dossier, the dossier submitter proposed to classify

tralkoxydim as Carc.2 (H351), Acute Tox. 4 (H302), STOT RE 2 (H373; liver, oral route) and Aquatic Chronic 2 (H411) according to the CLP Regulation. The legal deadline for adoption of the opinion on this substance is 28 February 2013.

He invited the RAC member standing in for this item for the Rapporteur in her absence to introduce the first draft opinion on the CLH proposal. In discussing STOT RE (repeated dose toxicity) it was noted that the observations in rat, hamster and mouse occurred only at doses above the guidance values for classification, while in a 90-day and 1-year dog study, effects on liver were seen at doses below the relevant guidance values according to both CLP and DSD Regulations. Several RAC members argued that the liver effects were not severe enough to justify classification. Three RAC members mentioned vacuolation of adrenal glands, but RAC agreed that the effects seen were of a nature and severity not justifying classification. Following discussion it was concluded that no classification for STOT RE was appropriate.

Effects on fertility were discussed, based on the results from reproduction and short term repeated dose toxicity studies in rat, hamster and dog. Effects on male reproductive organs in rat, hamster and dog were noted in repeated dose studies, although the rapporteur questioned their significance in the latter two species. This combined with the absence of effects on functional fertility in a multi-generation study in rat, led the Rapporteur to propose no classification for fertility. This interpretation of the data was supported by a majority of the RAC members and the RAC agreed that no classification for fertility was warranted.

It was further agreed that classification of tralkoxydim with Carc. 2 and Acute Tox. 4 was justified based on the data and argumentation included in the draft opinion.

The environmental classification, as proposed by RAP (following the DS), was agreed without further discussion.

RAC supported the classification proposed by the rapporteur in the draft opinion and adopted the opinion by consensus.

c) 4-Vinylcyclohexene (4-VCH)

The Chair welcomed an expert accompanying the stakeholder observer for CEFIC and invited the Rapporteur to present the fourth draft opinion on the CLH proposal.

The deadline for adoption of the opinion on this substance is 29 November, 2012.

The Chair reported that this was the fourth discussion of this dossier at a RAC plenary session and that the only hazard class to be considered would be carcinogenicity.

RAC discussed the evidence for classification as Carc. 2 versus Carc. 1 B, noting that the quality of the available studies was generally poor, including a very high death rate in the two year studies. The main issues discussed related to the type of tumours seen in the various species, the quantitative differences in metabolism of VCH between mice and humans and the extent to which the tumour types seen in mice did or did not indicate carcinogenic potential in humans. Following extensive discussion in which a number of RAC members were in favour of Carc 1B and several other RAC members, including the rapporteur, were in favour of Carc 2, agreement was reached on a classification as Carc. 2, provided that the final text of the opinion adequately reflected this classification.

The opinion was adopted by consensus, pending editorial changes to the text.

The Chair invited the Rapporteur to revise the draft opinion in line with the discussions at RAC-22 so that an editorial commenting round can be completed, before the opinion is published on ECHA's website.

d) Cymoxanil

The Chair welcomed the experts accompanying the ECPA and CEFIC stakeholder observers.

The Chair reported that the Rapporteurs had updated the 3rd draft opinion document following discussions at the further targeted consultation of the of parties concerned, including industry representatives that took place in June and also following RAC consultation. Cymoxanil is currently listed in Annex VI to the CLP Regulation with the classification: Acute Tox. 4*, H302 (Xn, R22), Skin Sens. 1, H317 (Xi, R43), Aquatic Acute 1, H400 M-factor 1, Aquatic Chronic 1 H410 (N R50/53).

The dossier submitter (Austria) proposes to add additional classification as STOT RE 2 H373 (Xn, R48/22) and developmental Repr. 2, H361 (Repr. Cat. 3; R63).

The deadline for adoption of the opinion is 11 December 2012.

The Chair invited the Rapporteurs to present the 3rd draft opinion with special focus on the main issues discussed during the further targeted consultation of parties concerned, i.e. the proposals for classification for reproductive toxicity and repeated dose toxicity.

RAC agreed with the proposal to classify cymoxanil as Acute Tox. 4 and as Skin Sens. 1, without assigning a sub-category to the latter.

During discussion on repeated dose toxicity the expert accompanying the CEFIC stakeholder observer repeated his opinion expressed already during the aforementioned consultation that dogs did not tolerate cymoxanil very well and the animals were in poor condition mostly due to the lack of food intake, further pointing out that the assessment and interpretation of the thymus weight is difficult and effects seen are a result of the generally poor conditions of the animals. According to the expert, the haemoglobin findings are not relevant for classification for repeated dose toxicity for cymoxanil, as they are secondary to local irritation in the GI tract. The RAC members were of the opinion that the effects seen on thymus justify classification as STOT RE 2. Additionally there was no gastric bleeding reported in the dog studies where reduction of the haemoglobin was observed. Cymoxanil is considered to be a complex substance and reactive groups may have an effect on the haemoglobin level. RAC agreed with the proposal to classify cymoxanil as STOT RE 2.

Following initial discussion concerning the reproductive toxicity of cymoxanil, RAC concluded that the classification for reproductive toxicity needed an in-depth comparison with the criteria between Repr. 2 and 'no classification', considering Repr. 1B not to be appropriate for cymoxanil. The expert accompanying the ECPA stakeholder expressed the view that due to the very reliable negative repeated-dose toxicity studies regarding male reproductive organs in combination with the absence of effects on functional fertility in a multi-generation study in rat, cymoxanil should not be classified for reproductive toxicity. After additional discussion in an ad-hoc working group RAC concluded that both positive and negative studies need to be taken into account. Most rat studies were of sufficient

quality, thus providing no reason to dismiss any of them. Therefore, RAC agreed to classify cymoxanil for reproductive toxicity based on effects on testes and epididymis reported in the rat repeated dose toxicity study. Taking the negative studies into account, Repr. 2 – H361f is considered the most appropriate classification.

RAC agreed with the proposal to classify cymoxanil as a developmental toxicant in category Repr. 2 – H361d.

When discussing the environmental studies, a RAC member pointed out that the justification of the Dossier Submitter (DS) proposal needed further explanation in the opinion. In particular, the rapporteur should clarify that the substance is not rapidly degradable because of the slow mineralisation; there was also no toxicity data on the degradation products observed in the water sediment study. RAC agreed to classification of cymoxanil as Aquatic Acute 1 and Aquatic Chronic 1, noting that it was not readily biodegradable and neither was it rapidly degradable.

The opinion was adopted by consensus and the Chair invited the Rapporteur to revise the draft opinion in line with the discussions at RAC-22 so that an editorial commenting round can be completed before the opinion is published on ECHA's website.

e) 3-Iodo-2-propynylbutylcarbamate (IPBC)

The Chair welcomed the expert accompanying the ECPA stakeholder observer as well as the representative for the Dossier Submitter from the Danish MSCA, the latter who followed the discussions as a remote participant.

The substance is used as a biocide and is not listed in Annex VI of the CLP Regulation. The hazard classes proposed by the DS are: Acute Tox. 4 - H302 (Xn: R22); Acute Tox. 3 - H331 (T: R23), Eye Dam. 1 - H318 (Xi: R41); Skin Sens. 1 - H317 (Xi: R43); STOT SE3 - H335 (Xi: R37), Aquatic acute 1 - H400, M=10 (N: R50) and Aquatic chronic 1 - H410, M=1. Additionally the following hazard classes were highlighted during the Public Consultation (PC): Skin irritation, STOT-RE, Carcinogenicity, Reproductive toxicity and Mutagenicity.

The deadline for adoption of the opinion is 25 January 2013.

The Chair informed the RAC that all of the above hazard classes were open for discussion. RAC considered acute toxicity, skin irritation, skin sensitisation, serious eye damage/eye irritation and carcinogenicity, leaving the remaining endpoints for consideration at future meetings or by written procedure as appropriate.

RAC preliminarily agreed on the classification and labelling of IPBC for Acute Tox. 4 - H302, Acute Tox 3 - H331 and Eye Dam. 1 - H318. RAC agreed not to classify for acute dermal toxicity or skin irritation and concluded that the supplementary labelling "Repeated exposure may cause skin dryness or cracking" EUH066 (R66) was not appropriate. RAC agreed that the substance should be classified for skin sensitisation and that the classification provisions of the 2nd ATP containing new subcategories for skin sensitisation should be taken into consideration. The rapporteurs were requested by RAC to amend the justification for not classifying the substance as carcinogenic, in particular to clarify why the higher incidence in hepatocellular adenoma in CD-1 mice was not considered to be of biological relevance to humans. RAC requested to complete the argumentation and comparison with the CLP and DSD criteria for all the hazard classes in the revised draft opinion.

It was agreed that the Rapporteurs will revise the draft opinion based on the conclusion of RAC 22 and that this will be submitted for RAC consultation. The Rapporteurs will revise the draft opinion according to the written comments received from the RAC members. The draft opinion will then be submitted to RAC for possible adoption at RAC 23 or via written procedure.

f) Formaldehyde

The Acting Chair for this agenda item, Pilar Rodríguez Iglesias, welcomed two experts accompanying the CEFIC and ECPA stakeholder observers.

The Acting Chair reported that the substance was being discussed in a RAC plenary meeting for the first time, and that a first draft opinion had been circulated prior to the meeting. The substance is already listed in Annex VI to the CLP Regulation and the present proposal by the dossier submitter (France) aims at a revision. The hazard classes proposed by the DS are Muta. 2 and Carc. 1A according to the CLP criteria. The substance is a widely used industrial chemical.

The legal deadline for adoption of the opinion is 29 April 2013. The Acting Chair invited the Rapporteur and her adviser to present the key issues.

When considering mutagenicity, the discussion focused on that a systemic genotoxic effect in germ cells was unlikely, reporting that no data on human germ cells are available and furthermore, that data on germ cells in animals are not convincing. At the site of contact formaldehyde would induce genotoxic effects (such as the induction of DNA-protein crosslinks - DPX) which would be relevant for the justification of classification. Moreover, in terms of exposure, the compound is unlikely to reach the germ cells. It was pointed out that a discrepancy exists on this point between the DSD and the CLP Regulation based on the title of the class of hazard.

It was finally agreed to preliminarily classify formaldehyde as Muta. 2 (suspected germ cell mutagen) and bearing the above in mind, this discussion will be continued at RAC's 23rd meeting in November 2012.

With regard to carcinogenicity, the discussion centered on the epidemiological data and in particular that a positive association had been observed between exposure to formaldehyde and the frequency of nasopharyngeal cancer in one of three industrial cohorts and that a causal interpretation was considered to be plausible. On the other hand, chance, bias or confounding factors could not be ruled out with reasonable confidence. The Rapporteur stated that there was limited evidence of carcinogenicity in some epidemiological studies on humans, while other studies did not provide any such evidence.

The Rapporteur suggested that according to the CLP criteria, animal data alone would be sufficient for classification into Carc. 1B, while Carc. 2 would not appear to be applicable.

During the subsequent discussions it was recognised that there was further need to look into the available set of epidemiological data, seeking advice as required from epidemiologists. The Acting Chair in concluding noted preliminary agreement on Carc. 1B, but pointed out that further in-depth analysis of the data as well as a further plenary discussion were warranted.

The Acting Chair indicated that the draft opinion would be circulated to RAC for written consultation, and that the Rapporteur would revise the document afterwards and in preparation of further discussion at RAC-23.

g) Methyl-2,5-dichlorobenzoate

The Chair welcomed an expert accompanying the ECPA stakeholder observer as well as a representative for the dossier submitter from the German MSCA, the latter who followed the discussions as a remote participant.

The Chair reported that this was the first discussion of the dossier at a RAC plenary meeting. There is currently no entry for this substance in Annex VI to the CLP Regulation. The substance is used as a plant protection product. The current proposal specifically relates to the hazard classes acute toxicity, as well as aquatic acute and aquatic chronic toxicity. The first draft opinion considers also the narcotic effects of the substance by proposing a classification of STOT RE 2.

The legal deadline for adoption of the opinion is 13 February 2013.

The Chair invited the Rapporteur to present the draft opinion on the CLH proposal and to highlight comments received during the first commenting round from RAC members. The data underlying the proposed classification for Acute Tox. 4 (H302) according to CLP were clearly in the range of the classification criteria and therefore RAC agreed upon this hazard class.

Based on findings of ataxia, sedation and coma in the acute oral toxicity study some RAC members were in favour of a STOT SE 3 classification. Others, however, considered that as the effects occur at dose levels also inducing mortality, the classification for Acute Tox. 4 already covered the effects seen. As similar effects also occurred in an oral 28-d toxicity study, but it took 4 days of exposure for the effects to become evident and since they occur at lower doses than in the acute toxicity study, it was argued that it is rather a repeated dose effect. Hence in the draft opinion a classification with STOT RE 2 is proposed. Some RAC members argued that the effects are seen almost directly after dosing, last for around 6 hours and then cease until the next dosing. ECPA argued that the mechanism behind the effect is depletion of glycine, following decreased body weight gain, and that it is hence an acute effect rather than a repeated dose effect.

RAC agreed to classify the substance as Acute Tox. 4 (H302). It was also agreed that RAC members could submit further comments during the second RAC consultation on the draft opinion, which the Rapporteurs will take into account in their revised opinion. The remaining hazards will be agreed by written procedure or at RAC 23 as appropriate.

h) Tetrahydrofurfuryl alcohol (TFHA)

The Chair noted that THFA is harmonised in Annex VI to the CLP Regulation (Eye Irrit. 2, H319) and that the proposal submitted by France recommends a classification for Repr. 2, H361fd according to the CLP Regulation. The Chair noted that this was a first discussion of the dossier at a RAC plenary meeting.

Due to a rearrangement of the agenda to take care of joint RAC-SEAC agenda items, the expert of the CEFIC stakeholder observer had already left.

The legal deadline for adoption of the opinion is 24 May, 2013

The Chair invited the Rapporteur to present the first draft opinion. Where reproductive toxicity is concerned, the Rapporteur noted that the available studies indicated that THFA may have adverse effects on reproductive toxicity for both fertility and development. The conclusion for fertility was based on testicular

toxicity and delayed parturition / effects on pregnancy outcome, bearing in mind that the latter could be a direct or an indirect effect. For development, the draft opinion indicates that the decreased foetal weight was uncertain as was the toxicological relevance of filamentous tail findings. The Rapporteur noted that the resorptions, decreased number of live pups born, number of live pups on postnatal day (PND) 0 & 4 and delivery & live-birth index at some doses were not due to maternal toxicity, and thus proposed that Repr. 1B (H360Df) would be more appropriate than Repr. 2 (H361fd). In the discussion that followed, support for both Repr. 1B H360DF (CLP Regulation) and Repr. 1B (H360Df) was expressed. RAC preliminarily agreed to classify tetrahydrofurfuryl alcohol as Repr. 1B (H360Df) according to the CLP criteria.

The Rapporteur will revise the draft opinion based on the discussion at RAC-22 after which, the Secretariat will distribute the revised draft to RAC for further discussion and possible adoption at RAC-23.

i) Cycloxydim

Cycloxidim is a plant protection product and there is no current entry in Annex VI to the CLP Regulation. The Chair reported that this was the first discussion of the dossier at a RAC plenary meeting.

The legal deadline for adoption of the opinion is 13 February, 2012

Only one hazard class was proposed by the DS (Austria) (flammability): according to criteria of Directive 67/548/EEC (Dangerous Substances Directive; DSD) R 11 Highly flammable; according to CLP criteria: no classification (depending on differences in the testing methods).

The Chair invited the Rapporteurs to briefly present their proposal as to whether classification as Repr. 2; H361d (for developmental toxicity) or no classification would be justified; the aim being to inform RAC and the Stakeholders about the new considerations of reproduction toxicity before launching a RAC consultation on the draft opinion. The presentation was followed by comments from RAC members.

Should RAC members believe there is a reasonable justification to propose a classification of Repr.2; H361d, then ECHA will run a targeted expert consultation to allow interested parties the opportunity to comment on the new classification proposal.

It was concluded that the ECHA Secretariat will launch a RAC consultation immediately after RAC-22.

5.2 Requests under Art. 77(3)(c) – CLH dossiers

a) Gallium arsenide

The Chair welcomed the experts accompanying the Eurometaux and CEFIC stakeholder observers.

He noted that this was the third discussion at a RAC plenary meeting of the draft opinion on reproductive toxicity initiated by an Article 77(3)(c) request from the Executive Director of ECHA. He reminded RAC that the mandate (from 21 December 2011, revised 17 April 2012) under this article requests RAC to evaluate the information on toxicity to reproduction submitted during the public

consultation on carcinogenicity taking into account also information subsequently submitted by Eurometaux in December 2011[1]. In its opinion[2] of 25 May 2010, RAC supported the dossier submitter's proposal for classification of GaAs as Repr. 1B (CLP) based on clear evidence in repeated dose toxicity studies of testicular toxicity in two species, supported by a potential of gallium to accumulate in rat testis following inhalation exposure.

During the public consultation on carcinogenicity and in the information subsequently submitted by Eurometaux in December 2011, one newly available report (Tanaka et al, 2000) was added showing some effects on other organs than the testes (such as the lung) in the intratracheal study using hamsters by Omura et al (1996a). Industry drew RAC's attention to a peer-reviewed scientific publication on this issue.

Following the discussions and comments provided at the last RAC-21 meeting, the Rapporteur had revised the draft opinion, which had been subject to a RAC consultation and presented it at the meeting. The proposal to classify gallium arsenide as Repr. Cat. 2 was discussed based on the hypothesis that the observed adverse effects on testes are most likely the result of hypoxia as a consequence of lung toxicity.

An extensive interpretation of the collected data was provided in support of a hypothesis that the lung toxicity may cause hypoxia which in turn may cause the observed effects in the testes (testicular atrophy, reduced sperm counts and abnormal spermatids. The mechanism described mentions alveolar proteinosis, lung inflammation and hyperplasia, hypoxemia and subsequent testicular effects. Studies in humans and rats are mentioned to support this mechanism.

The Rapporteur mentioned InAs, as another example of a substance causing lung and testis toxicity and that there were haematological changes in the 14 week inhalation GaAs study in rats showing testis toxicity, indicating increased haematopoiesis with insufficient haemoglobin synthesis, supporting the hypothesis of a causative link between lung toxicity and testis toxicity.

In an extensive discussion, several RAC members questioned whether this hypothesis was sufficiently convincing to explain all the facts, and expressed the concern that the causal link between lung toxicity of GaAs and testis toxicity could not be proven. One member pointed out that even if industry managed, in the future, to prove such mechanism, a direct effect of gallium and/ or arsenide on testis would not be overruled. In that regard, one RAC member warned IND that it would be useless to perform further animal studies. For example, the severe testis toxicity (including almost complete loss of spermatogonia in some animals) observed in the inhalation studies with GaAs, has not been reported under hypobaric conditions referred to by industry in order to support the suggested hypothesis. Also, the hypothesis is not supported by the occurrence and degree of the severity of the testis toxicity at different dose levels of GaAs in e.g. the 14 week NTP inhalation study in rats, which did not match the occurrence and severity of lung toxicity at the same dose levels. Additionally, after analysing the haematological data (such as no decrease in absolute haemoglobin, increased number of erythrocytes), one RAC member concluded that there was no evidence for a real hypoxic condition in this study in rats. The data rather indicated that

[1] RAC is requested, pursuant to Art. 77(3)(c) of REACH, to: *Further to the evaluation of the information on toxicity to reproduction submitted during public consultation on carcinogenicity to take into account also information submitted by Eurometaux in December 2011 and draw up an opinion on the appropriate classification and labelling for reproductive toxicity accordingly*.

[2] ECHA/RAC/CLH-0000000792-73-03/F

the microcytic anemia reported seemed to be compensated, e.g. via an increased number of erythrocytes.

Thus, the RAC members expressed the concern that sufficient reliable data did not appear to be available to confidently support the lung toxicity mechanism as the only explanation for the observed testis effects.

The Chair thanked the Rapporteur and RAC for the discussion and urged the Rapporteur to revise and further develop the draft opinion based on the comments expressed by their RAC colleagues.

b) Epoxiconazole

The Chair welcomed an expert accompanying the ECPA stakeholder observer. The Chair shortly reminded RAC that the mandate under Art. 77(3)(c) of REACH from the Executive Director of ECHA requests RAC to develop and adopt an opinion on the classification and labelling of epoxiconazole, taking into account the previous RAC opinions, the additional information that has recently become available and the comments received during public consultation.

The Chair invited the Rapporteurs to present the 1st draft opinion, which included a summary of previous RAC opinions[3], a presentation of the new studies performed and summarised by industry in an additional information report (AIR), as well as comments received during the PC of the AIR. The scientific grounds for the proposed opinion, including mode of action and relevance to humans, using the guinea pig as a model were presented. It was proposed that based on effects related to an endocrine disrupting mechanism and the prenatal effects, observed in the rat and guinea pig, epoxiconazole should be classified as Repr. 1B (CLH).

In considering the examination of the data under the three headings: a) the mode of action and relevance to humans, b) the choice of guinea pig as a model for reproduction toxicity and c) the definition of maternal toxicity and its role in this case, RAC recommended additionally to concentrate on the prenatal effects, in particular the malformations, in support of a classification with possibly less emphasis on endocrine disruption as a mode of action. According to some members, Category 1B is relevant solely on the basis of the cleft palates observed at a high incidence in the rat. One RAC member mentioned that post-implantation losses had not only been observed in the rat but also in the baboon and did therefore not agree that the post-implantation losses in the rat, which most probably was related to the aromatase inhibition effect by epoxiconazole, should be regarded as irrelevant to the human. Another RAC member noted that malformations had also been reported in the rabbit. The expert accompanying the ECPA observer, described the cleft palates observed in the rat as a threshold effect that occurs in the presence of marked maternal toxicity, which supported classification for developmental toxicity in Repr. Cat. 2 in his view.

The Rapporteurs were asked to re-structure the text of the opinion to firstly present a comparison of the data and thereafter to discuss the mechanism/mode of action.

RAC preliminarily agreed to classify epoxiconazole as Repr. Cat. 1B on the basis of the evaluation of the complete data set, including the new studies presented by industry in the AIR. The ECHA Secretariat will launch a RAC commenting round on the first draft opinion after RAC-22. The Rapporteurs will revise the draft opinion

[3] RAC opinion No. CLH-O-0000000630-85-05/F of 17 March 2010
RAC opinion No. ECHA/RAC/A77-O-0000001412-86-02/F of 11 March 2011

in accordance with the discussion at RAC 22 and the RAC consultation. The revised draft opinion documents will be distributed to RAC for further discussion and possible adoption at RAC-23.

5.3 Appointment of RAC (co-) Rapporteurs for CLH dossiers

The ECHA secretariat collected names of volunteers for CLH dossiers listed in the room document. The Chair pointed out that while some vacancies had been filled, many were still open and therefore requested again for RAC members to volunteer. It became apparent during the meeting that some of the regular volunteer rapporteurs already had a full workload and therefore the Chair appealed to the RAC membership for new volunteers to take on this important task for the Committee.

5.4 General and procedural CLH issues

a) State of play of CLH dossiers

This agenda point was skipped in order to grant more time for the discussion of CLH dossiers.

b) Opinion development process

The Chair invited the ECHA Secretariat to give a presentation on the implementation of the framework for the development of opinions on CLH dossiers by RAC. The framework was discussed by RAC during RAC 21 and agreed in July 2012. The framework replaces the working procedure on processing CLH dossiers agreed in 2010.

The ECHA Secretariat underlined that all stakeholders and interested parties should ensure that they provide all relevant comments and supporting data on a specific CLH proposal during the opportunity provided by public consultation and hence, in the early stages of the CLH opinion development process.

The Secretariat then explained the approach of issue identification and the subsequent tailoring of the CLH opinion development process in order to identify as far as possible the need for further interaction with experts, including those of the Stakeholder Organisations. In exceptional cases the Secretariat could decide on further targeted consultation with parties concerned on the issues so identified. The Secretariat referred to the consultation of parties held on one particular substance and which had been positively received. Such measures could be agreed as appropriate and were intended to provide additional opportunity for dialogue and contributions. RAC then discussed these experiences briefly.

The Secretariat pointed out that under the CLH Framework, as already agreed and starting from RAC-23 onwards, the RAC observers from accredited stakeholder organisations would not be allowed to invite accompanying experts to the plenary meetings. The only exceptions to this rule would be: a) in the case of currently ongoing dossiers which have already been considered at a RAC plenary discussion and b) when ECHA sees a need for specific expertise and issues a targeted consultation with parties concerned on identified issues accordingly.

CEFIC noted that the public consultation had not always been properly used by industry in the past and that there had been a tendency to submit late information but reported that this would be improved in the future. Industry could not accept the change in procedure where the regular stakeholder observers are no longer allowed to invite their experts to plenary discussions of the RAC. This they considered to be especially important for substances used in biocidal and plant protection products, where the classification may have a substantial impact on the continuation of the use of the substance. Industry was of the opinion that the participation of experts was very useful for the Committee and that this decision will not increase trust in and transparency of the Committee's decisions. This position was fully supported by other stakeholder observers.

With regard to the issue of the presence of the experts accompanying stakeholder observers at plenary sessions, the RAC members showed sympathy for the industry position and in particular, expressed appreciation for the expertise and the contribution of the industry experts on the CLH proposals during the plenary meetings.

The Secretariat reiterated that the focus should be on the more substantial opportunities for dialogue earlier on in the process and explained the reasons behind preparing and agreeing on the framework, noting that the involvement of stakeholders' experts is only one aspect of its implementation. The Secretariat emphasised that it is not the intention of the framework to exclude the involvement of industry experts and their valuable contributions during the process. Nevertheless, in order to increase the output of the Committee in terms of completed opinions, in ECHA's view the stakeholder involvement needs to be moved further back towards the beginning of the process of considering dossiers.

The Chair noted that the framework would be a continuing discussion and repeated the ECHA Secretariat's undertaking to come back with further information for the members at forthcoming plenary meetings as required.

6 Restriction

6.1 General restriction issues

a) Update on intended restriction dossiers

The Secretariat provided an update on up-coming restriction dossiers. As already informed in June 2012, there are currently two new substances in the Registry of Intentions:

- lead and lead compounds in articles intended for consumer use prepared by Sweden and
- 1-methyl-2-pyrrolidone (NMP) prepared by the Netherlands.

Submission of both dossiers is currently foreseen in April 2013.

The Secretariat noted also that the Commission has asked ECHA to investigate certain applications of cadmium in relation to the current restriction entry. The request from the Commission to prepare an Annex XV dossier for cadmium in plastics (and possible other applications) is expected to come in November 2012.

b) Update on the review of restriction process

The Secretariat reminded the Committees that in the March plenary meetings of RAC and SEAC, the plans to revise the Forum procedure for elaboration of the Forum advice on enforceability of restriction proposals had been introduced while in June, some further explanation on this topic had been provided. The revised Forum procedure was then adopted by the Forum at its 12th meeting in June 2012. The Secretariat introduced changes reflecting the revised Forum procedure to the RAC and SEAC working procedures on opinion development (room document RAC/22/2012/04 for RAC and room document SEAC/16/2012/03 for SEAC). The Secretariat then provided an overview of modifications and explained that as the Forum had agreed to start applying the new system to all future and current restriction dossiers starting from the dichlorobenzene (DCB) dossier, the same is proposed to RAC and SEAC.

The Committees agreed to start applying the revised working procedures on opinion development to all restriction dossiers starting from the DCB dossier.

6.2 Restriction Annex XV dossiers

a) Dichlorobenzene – first version of the draft opinion

The Chair welcomed the SEAC Rapporteurs and the dossier submitter to the plenary session. The RAC Rapporteurs provided a presentation on the first version of the RAC opinion, focussing on the key issues brought of the risk assessment and health impact assessment.

The purpose of the proposed restriction is to ban of the use of 1,4-dichlorobenzene (DCB) in toilet bocks and air fresheners used in toilets or other domestic or public indoor areas, or offices. The Chair reminded the RAC that the dossier submitter in this case was ECHA and that the dossier was under RAC consultation until 10 August 2012; one comment being received from a RAC member. The RAC consultation on the first version of the RAC opinion was then launched on 20 August with one comment received from a RAC member by the deadline of 9 September 2012.

The RAC opinion is due by March 2013.

The Rapporteurs asked for RAC's advice on whether the observed liver and kidney effects were relevant for risk assessment considering that these effects might be merely adaptive responses. RAC members pointed out that a number of the documented findings are not adaptive responses and as such they should be considered in the risk assessment. The rapporteurs asked if it is sufficient to consider the most severe effects only or whether also other less critical effects should be considered in the report. In the RAC point of view, all effects should be considered.

Additionally, it was pointed out that as the substance was assessed already (EU Risk Assessment Report (RAR, 2004) under the Existing Substances Regulation (EEC 793/93), Harmonised classification under Regulation EC 1272/2008), RAC should avoid re-discussing the same issues, unless new data becomes available which would bring it into question.

RAC members stated that from a methodological point of view one should identify the most critical toxicological effects for the risk assessment. As background information, it was mentioned that the national Occupational Exposure Levels

(OELs) in Germany are based on the liver tumours. They considered it important to identify the route of exposure in order to identify the most critical effect. The rapporteurs confirmed that the route of exposure is inhalation. RAC then proposed that the comparison of DNELs derived for all different effects would be the best methodology with which to select the most critical effect. The toxicological data on its own is not sufficient for such decision.

In addition, RAC discussed the relevance of the observed nasal toxicity and reduced lung function and was provided by the rapporteurs with clarification on the measurement of lung function. Some debate took place on whether epidemiological studies can or cannot be used for the risk assessment. The ECHA Secretariat in their role of the dossier submitter explained that the epidemiology studies were not described in much detail in the report, but promised to provide the rapporteurs with an analysis of some additional studies, providing supporting evidence of the effect of DCB on the lungs. RAC considered one the study used in the report in particular (Elliot, 2006[4]) to be crucial and requested it and related studies to be distributed to the RAC to prepare for this discussion at the next meeting.

Finally, the DNELs used in the report were presented to the Committee. The Rapporteurs explained that the risk assessment is based on carcinogenicity, whereas the available OEL values were based on irritancy. The rapporteurs asked if RAC considers the information on carcinogenicity sufficient to warrant a human health risk assessment. RAC concluded that the available information is sufficient and that the Rapporteurs should follow this line. RAC discussed also a question on the values of Assessment Factors, especially the one for carcinogenic effect, but the discussion did not end with a clear conclusion.

The rapporteurs were invited to take the RAC comments into account while preparing the second version of the RAC opinion. In addition, the rapporteurs were requested to provide a response to comments for distribution to RAC members.

b) Nonylphenol, 4-nonylphenol, branched and nonylphenol ethoxylates – outcome of the conformity check

The Chair welcomed the SEAC rapporteurs and a representatives of the dossier submitter from the Swedish MSCA (the latter followed the discussions remotely as observers) and one representative of the Danish MSCA.

According to this restriction proposal, textile articles or articles containing textiles shall not be placed on the market 36 months after entry into force of the proposed restriction if they contain nonylphenol, 4-nonylphenol or nonylphenol ethoxylates (further referred to as NP) in concentrations equal to or higher than 20 mg/kg textile. The Chair reminded RAC that the restriction dossier on NP was submitted to ECHA on 3 August 2012. The conformity check in RAC and SEAC was launched on 16 August 2012, during which comments from two SEAC members were received. The Committees are expected to reach a conclusion on conformity by 14 September 2012 at the latest.

The RAC rapporteurs presented the outcome of the RAC conformity check and recommended that the dossier would be declared not to be in conformity. The justification for the restriction proposal relies heavily on the endocrine disrupting (ED) properties of nonylphenol. However, only a few (around 8) studies are

[4] Elliot L., Longnecker M.P., Kissling G.E., London S.J. (2006) Volatile organic compounds and Pulmonary function in the third National Health and Nutrition Examination Survey 1988-1994, Environmental Health Perspectives, 114 (8)

described in the report, and there is no discussion of the overall weight of scientific evidence available. The RAC rapporteurs considered this omission, and the resulting basic difficulties in evaluating the proposal's risk reduction capacity, as a major issue for non-conformity. A range of other reasons, some substantial for non-conformity were also described. Several members expressed support for the views of the RAC (co-)rapporteurs. It was agreed that it is essential that the dossier submitters properly refer to the old data (e.g. as already summarised in the EU RAR's) and describe the new data available.

RAC agreed by consensus that the dossier does not conform to the requirements of Annex XV of REACH.

The Chair pointed out that the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter and would inform the Committee about the dossier submitter's plans regarding resubmission of their dossier.

c) Chromium VI – second version of the draft opinion

The purpose of this proposed restriction is to limit the content of Chromium VI (CrVI) in leather articles in order to reduce the incidence of allergic contact dermatitis in the EU. The Chair reported on the background and urgency of this dossier submitted by the Danish MSCA, noting that the public consultation ends on 16 September 2012 and that the Committee is expected to adopt the opinion by 16 December 2012 at the latest. The 2nd rapporteurs` dialogue took place in August 2012 and included discussions with an expert on contact dermatitis.

The Chair invited the rapporteurs to present the 2nd version of the RAC opinion. The rapporteurs reported on the current comments received via public consultation, as well as on the outcome of the rapporteurs' dialogue. They informed RAC on their findings with regard to the exposure assessment.

The rapporteurs presented their opinion on 'post-formation' of CrVI from Chromium III (CrIII) after the production of the leather article. Furthermore, there is no evidence that CrIII causes an allergic reaction comparable to CrVI, the latter being a very potent sensitizer. Finally, the available technical information indicates that methods are available to ensure that the potential for post-formation is minimised. It appears that extreme artificial conditions (by use of heat and/or UV) are then needed for the concentration of CrVI to increase in leather articles. RAC agreed that on the basis of current knowledge, the issue of the potential oxidation of CrIII to CrVI in leather articles would not be a significant contributing factor in the risk and impact assessments of CrVI.

RAC agreed that clinical data on new cases of allergic contact dermatitis show that there is a current and tangible risk (new cases appear every year) posed to consumers by CrVI in leather articles. Further, there is no need for additional justification via standard risk assessment methods, i.e. through defining DNELs (NOEL/LOEL), although the rapporteurs carried out such a risk assessment for illustrative purposes. In this assessment, the exposure was assessed based on German market surveys, the results of which showed that in at least 30% of leather articles detectable levels (> 3 mg/kg) of CrVI were found.

In the worst case assumption, the total amount of extractable CrVI is capable of migrating from a typical article to the exposed skin, but the rapporteurs supported a more realistic migration rate than this 100% proposed by the DS. A conservative approach was presented in the German study on the influence of pH

on the transfer of CrVI, reporting a maximum migration of the CrVI content of up to 30%.

RAC agreed with the rapporteurs' proposal for calculating the scale of the risk. The prevalence of CrVI allergy in the general population was calculated at 0.04% to 0.11% using the Clinical Epidemiological Drug Utilisation Research (CE-DUR) method[5] while applying Cr-specific factors. In terms of new cases associated with leather exposure, the median value is calculated at 16,875 cases per year in the EU.

With regard to the Risk Management Options (RMOs), following the 1st Forum advice and based on arguments presented, the rapporteurs proposed to modify the wording of RMO 1 and delete the phrase "direct and prolonged". RAC discussed the usefulness (or not) of defining and using this term in the proposed RMO, favouring its deletion, because the phrase is difficult to define and could cause problems in the enforcement of the proposed restriction. RAC further recommended specifying that the restriction should apply to articles which come into "direct and indirect" contact with the skin. The example given was that of shoe leather, where CrVI is known to migrate through the sock in the moist environment next to the foot, i.e. an indirect but significant exposure.

To complete information about progress in the opinion development the rapporteurs informed RAC that they had considered also the other RMOs (presented in the Annex XV report) but they are of the opinion that in case of CrVI the other options are not appropriate.

RAC agreed that the ECHA Secretariat should ask the Forum for the second advice, based on the new wording of the restriction proposal as concluded by RAC.

The rapporteurs were requested to prepare the draft final opinion in accordance with the outcome of the discussion in RAC and any further comments from the Forum. The ECHA Secretariat will distribute the revised draft opinion for discussion and possible adoption at RAC 23.

6.3 Restriction Annex XV dossiers- Restriction dossiers

c) Non-classified phthalates (DINP and DIDP) – Article 77(3)(c)

For this agenda point, the Chair welcomed an expert accompanying CEFIC and a Commission observer who participated in the meeting via remote access. The Chair reminded RAC that this is an Article 77(3)(c) request for an opinion on a draft review report prepared by ECHA, entitled: *Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to Regulation (EC) No 1907/2006 (REACH)*. The ECHA's draft review report was under public consultation for 12 weeks (until 31 July). The Chair invited the Rapporteur to present the first draft opinion and the comments received by RAC members.

The deadline for the RAC opinion is December 2012.

[5] Thyssen JP, Uter W, Schnuch A, Linneberg A, Johansen JD. (2007a). 10-year prevalence of contact allergy in the general population in Denmark estimated through the CE-DUR method. Contact Dermatitis; 57:265-272.
Schnuch A, Uter W, Geier J and Gefeller O (2002), Epidemiology of contact allergy: an estimation of morbidity employing the cliical epidemiology and drug-utilizatiion reseach (CE-DUR) approach. Contact Dermatitis, 47, 32-39

In his presentation, the rapporteur indicated that he could support the DNEL calculations presented in the ECHA's draft review report for DINP, based on a NOAEL of 15 mg/kg/d. This conclusion was not questioned by RAC. Concerning DIDP, the rapporteur suggested however to use as a starting point the 90-day dog study instead of the 2 years dietary study in rats from Cho et al for DNEL derivation, leading to the same points of departure for DINP and DIDP (15 mg/kg/d). The rapporteur concluded that following the uncertainties with migration data, exposure might be overestimated. He therefore questioned the conclusion that RCRs of around 2 would justify a restriction on these phthalates in toys and childcare articles.

Some of the members voiced disagreement to dismiss the Cho et al study and the conclusion of the rapporteur that spongiosis hepatis would not be relevant for setting a NOAEL/LOAEL. It was briefly discussed whether liver effects from chronic studies are to be considered relevant for exposure of children, several members expressing their support. RAC members supported the migration rates presented in the ECHA report and pointed out that the migration rates may equally well be underestimated.

EEB made a similar comment as above regarding the migration rates. The expert accompanying CEFIC underlined that industry provided many comments and scientific information via the public consultation, which are critical to the conclusion of the ECHA report. Industry hopes that information so provided will be considered in the drafting process and that there will be response to the comments submitted during the public consultations. In this respect, it is noted that a response to comments is currently done in an RCOM table as a supporting documentation accompanying the opinion. The CEFIC expert expressed the view that these non classified phthalates can be safely used in toys.

The need to explicitly respond to the specific questions of the mandate in the opinion of RAC was raised. The Chair took RAC through the questions of the mandate. The overall quality and completeness of the report was not questioned by RAC (question A of the mandate).

The rapporteur summarised that the question concerning NOAEL and DNEL derivation has been addressed in the draft opinion and invited RAC members and stakeholder observers to provide comments concerning the mouthing time and migration rates.

The rapporteur pointed out that there is a need for further discussion in RAC, as the Risk Characterisation Ratio (RCR) for children of around 2 may change when the exposure data is refined as mentioned above. He questioned whether at this level of risk and given the uncertainties involved in the calculation whether the restriction would be justified.

The rapporteur was of the opinion that there is no consumer risk (for adults) considering that the RCR's presented in the draft report are below 1.

The issue of 'combined assessment' was discussed, e.g., where 2 scenarios are calculated, one for 100% DINP and one for 100% DIDP exposure via toys and childcare articles. The real-life exposure will may be somewhere in between the putative RCRs from both scenarios because a child mouths several articles indiscriminately and because it cannot be ruled out that DINP and DIDP are both found in the same article.

One RAC member expressed the view that the exposure assessment is not problematic and that the correct parameters had been chosen in the draft report. The RWC scenario around 2h/day mouthing time seems reasonable. In his opinion

the ECHA report defends current restriction as scientifically justified. He said that further explanation of the combined exposure is needed.

RAC members proposed to proceed on a step-by-step basis. The rapporteur was asked to prepare a second draft opinion in accordance with the discussion in RAC; this including answers to all of the questions listed in the mandate, in order to come to the overall conclusion that will be distributed to RAC for written comments. The third draft opinion should be ready for discussion and possible adoption at RAC 23.

6.4 Appointment of (co-)rapporteurs for restriction dossiers

The ECHA Secretariat informed RAC about the pool of Rapporteurs for the appointment of (co-)rapporteurs for the restriction dossiers on 1-methylpyrrolidin-2-one (NMP) and lead and lead compounds, noting that the formal appointment will be made 14 weeks before expected submission date.

7 Authorisation

a) Capacity building

- **Substance information packages**

The Secretariat presented and explained the content of the information packages that will be provided to RAC members for substances listed on Annex XIV. This package summarises the information, looks briefly at the relevance of the data found in the documents and includes a reading order recommendation. RAC welcomed the steps taken by the Secretariat in preparing for the arrival of Applications for Authorisation (AfA) and thought that the substance information packages would be very useful.

- **Establishing DNELs and dose-response functions**

The Secretariat presented a proposal, as part of setting up an efficient authorisation process, to set DNELs and dose-response curves for substances prior to receiving multiple AfA. These could serve as a 'reference' for industry when preparing applications and for RAC when evaluating them. The proposal is thought to improve efficiency of the AfA process as a result of higher consistency amongst applications, better use of the legally defined period of opinion forming in RAC. The 'reference' values could make the work of applicants more targeted. The Secretariat underlined that establishing dose-response functions for non-threshold substances is essential in order to evaluate the impact of risk, in other words the step from risk assessment to impact assessment. It was suggested to start with a trial exercise consisting of two substances.

RAC generally welcomed the proposal to set DNELs and dose-response curves prior to receiving multiple applications. However, practical questions were raised regarding the scope (for which substances to do the work) and the timing (how far in advance) for the first wave of applications that is expected next year. With respect to the derivation of dose-response curves, members pointed out the need of the rather specialist knowledge required, including also access to the appropriate software. One member pointed out a group in Germany actively involved in developing dose-response curves and offered to make contact.

Industry stakeholder observers also welcomed the proposal and underlined that registrants/applicants remain responsible for the DNEL derivation, and that it is not certain that applicants will in fact use the 'reference' DNELs and dose-response curves. The Secretariat confirmed that RAC would not take over responsibility from registrants/applicants.

RAC agreed to start a trial project to establish 'reference' DNELs and dose-response functions for DEHP and TCEP. The Secretariat will inform RAC members as soon as possible about the practical follow up. Members will be asked to advise on appropriate methodologies and were asked to volunteer for the proposed tasks.

- **Valuation of environmental impacts of PBT**

A RAC member reported on a recently commissioned project sponsored by Luxembourg on the valuation of environmental impacts of Persistent, Bioaccumulative and Toxic (PBT) substances. The project will run until the end of 2012 and is aimed at supporting and structuring the decision-process within the socio-economic authorisation route for non–threshold substances for which no adequate control can be established.

RAC and SEAC members welcomed the initiative, noted the relevance for their work in issuing opinions on authorisation applications in the future and asked to be informed of the results once available.

- **Proportionality in evaluating Applications for Authorisation (AfAs)**

A SEAC member provided some background information on the basis of the proportionality principle in evaluating applications for authorisation, focusing on the REACH Regulation, the available guidance documents, as well as other relevant EU legislation.

The Secretariat noted that proportionality can be understood in different ways depending on the point of view i.e. whether the analysis is proportionate (meaning targeted analysis - how much we need to know to be able to make an opinion) or whether something is proportional in terms of risks vs benefits for authorisations. The Chair concluded that more practical experience from applications is needed in order to see how this will work in practice.

- **Applications for Authorisations with 'multiple dimensions'**

Applications for Authorisation may have multiple dimensions in the sense that they may include a variety of cases, from several distinct applications to joint applications, from one use to several uses, from new applications to subsequent or to review applications, etc. A SEAC member had prepared a discussion document (distributed as a room document RAC/22/2012/07 and SEAC/16/2012/05) outlining some of the cases that RAC and SEAC may need to evaluate.

As a response to questions concerning applications with these "multiple dimensions" brought up by the SEAC member, the Secretariat presented RAC and SEAC with the procedural timelines for processing such applications. The overview explained how the submission windows are synchronised with the frequency of the plenary meetings within the ten month opinion-development period. There is also a mechanism for fitting in applications which are received outside the submission windows.

In addition, the topic of subsequent applications was summarised. ECHA recommends in its data submission manual that the applicants would submit

subsequent applications only for the same use with the same substance that was previously submitted. From the procedural point of view, the subsequent applications are to be submitted similarly within the submission windows.

The Secretariat reported that the ECHA policy on the linguistic regime for applications for authorisation has recently been finalised with a view of having applications only in one language. Further considerations or potential need for translations can be discussed.

It was also concluded that when large numbers of applications for the same substance potentially arrive, the current rapporteur pool might not be sufficient to evaluate them. Therefore, the background information packages for Annex XIV substances could be useful for all members to gain familiarity with a given substance in advance of applications arriving.

For the evaluation of the joint applications containing different assessment reports per use and per applicant, the Secretariat reported that it has set the procedure so that the application is submitted by one applicant submitting only one dossier for the whole group. ECHA recommends that joint applications are submitted when all applicants apply for all uses and where there are no CBI or competition law issues between the applicants. Alternatively, it might be preferable for all applicants to develop certain parts in common but to submit them separately.

Some clarifications were asked on the written procedure option. A stakeholder also called for maximization of the use of the submission windows. He said there is a need to streamline the process, otherwise, there could be a potential bottle neck depending on a large number of complex applications.

b) Participation of case-owners and stakeholder observers in Authorisation opinion development process

The Secretariat informed RAC and SEAC that a document prepared for the MB on the participation of case-owners and stakeholder observers in the opinion development process had been provided as a room document (RAC/22/2012/08 and SEAC/16/2012/07). The issue was discussed by RAC, SEAC and the MB in June and the previous proposal was revised on the basis of that discussion. The Secretariat then presented the new proposal for the participation of case-owners, stakeholder observers and third parties in authorisation.

Several members noted that it would be necessary for ECHA to clarify the definition of confidential business information (CBI), especially because the Committee members come from different MSs and their views on what is considered CBI and what not might be different. However, one member also remarked that there may not be much time in the opinion-making process for going into details and CBI. The ECHA Secretariat confirmed that the guidance on the definition of CBI would be developed and that training might also be considered. In response to a member, the Secretariat indicated that the policy regarding participation of case-owners and stakeholder observers was within ECHA's mandate and did not need discussion at or agreement from CARACAL.

One NGO stakeholder observer strongly disagreed with the proposal – she felt that as these are hazardous substances, it is important also for observers to know the producers, production volumes, etc. Furthermore, all stakeholder observers of RAC and SEAC have signed the confidentiality declarations. This statement was supported by another NGO stakeholder observer, while an industry stakeholder observer found the new proposal a good solution now providing for as much stakeholder participation as possible.

A Commission representative expressed the appreciation of the Secretariat's efforts in trying to find solutions to the outstanding issues after the June discussion, but also expressed some reservations to the proposed system with regard to the efficiency in protecting CBI and the complexity of the process.

It was agreed that the Secretariat would update both Committees after the MB discussion.

8. AOB

a) C&L Inventory

This agenda point was cancelled due to the lack of time.

b) Feedback on the first four restrictions from the Commission's Impact Assessment point of view

The Secretariat reported back from the meeting of 12 July 2012 between the ECHA Secretariat and the Commission services on feedback from the Commission on the first four restrictions. The Secretariat pointed out that based on the feedback received from the Commission ECHA can conclude that it is on the right path. It is important, however, to aim for condensed and clear opinions' justifications and Background Documents, as well as to reduce repetition in the justification of RAC and SEAC opinions.

One member questioned why the Commission had expressed the view that the six month long public consultation should not be used to "improve the dossier". The Secretariat replied that the idea behind this remark is that the MS submitting the dossier should organize a public consultation before submitting the dossier to ECHA, to avoid receiving a lot of new information during the public consultation organized by ECHA. Another member supported the idea of the Commission to limit the size of the Background Documents, however, he stressed the importance of being flexible in this respect.

<u>Application for authorisation – opinion format and what to make public</u>
The Secretariat introduced the technical modifications that are proposed to be included in the template for the public version of RAC and SEAC opinions that had been agreed by both Committees earlier. RAC and SEAC agreed with the proposed technical modifications.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
From the 22nd Meeting of RAC
11 September – 14 September 2012

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/22/2012**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC 22 minutes.
5. Harmonised classification and labelling (CLH)	
5.1 CLH dossiers	
5.1 a Fenoxycarb	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC on carcinogenicity and aquatic chronic classification and to provide it to the SECR. **SECR** to launch an editorial commenting round once the revised opinion is received. **SECR** to forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1 b Tralkoxydim	
RAC adopted by consensus the opinion with a proposal for the harmonised classifications as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to the SECR. **SECR** to launch an editorial commenting round once the revised opinion is received. **SECR** to forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1 c 4-Vinylcyclohexene (VCH)	
RAC adopted by consensus, the opinion and its annexes with a proposal for the harmonised classifications as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC on carcinogenicity classification and to provide it to the SECR by 30 September. **SECR** to organise an editorial commenting round. **SECR** to forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1 d Cymoxanil	
RAC adopted by consensus, the opinion and its annexes with a proposal for the harmonised classifications as indicated in Table 1 below.	**Rapporteurs** to editorially revise the opinion in accordance with the discussion in RAC on endpoints regarding Skin Sensitisation, STOT RE and Reproductive toxicity (fertility) and to provide them to

	SECR by 30 September. **SECR** to organise an editorial commenting round. **SECR** to forward the adopted opinion and its annexes to COM and to publish it on the ECHA website.
5.1 e 3-Iodo-2-propynylbutylcarbamate (IPBC)	
RAC preliminarily agreed on the classification and labelling of IPBC for acute toxicity and serious eye damage as indicated in Table 2 below.	**Rapporteurs** to revise the draft opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to distribute the revised draft opinion documents to RAC for written comments. **Rapporteurs** to revise the draft opinion according to the written comments received. **RAC** to adopt the opinion at RAC 23 or via written procedure.
5.1 f Formaldehyde	
RAC discussed the first draft opinion. As to mutagenicity, RAC preliminary agreed as indicated in table 2 and recognised that further discussion is needed on this hazard class and cancerogenicity.	**SECR** to distribute the draft opinion to RAC for consultation until 17 October. **Rapporteurs** to revise the draft opinion and to provide it to SECR. **SECR** to distribute the documents to RAC for further discussion.
5.1 g Methyl-2,5-dichlorobenzoate	
RAC preliminarily agreed to classify Methyl-2,5-dichlorobenzoate as indicated in Table 2 below.	**SECR** to launch a second commenting round on the first draft opinion until 30 September. **Rapporteur** to revise the draft opinion following the comments received and to provide it to the SECR. **SECR** to distribute the revised draft opinion to RAC for possible adoption before or at RAC 23.
5.1 h Tetrahydrofurfuryl alcohol (THFA)	
RAC preliminarily agreed to classify tetrahydrofurfuryl alcohol as indicated in Table 2 below.	**SECR** to launch a second commenting round on the first draft opinion until 30 September. **Rapporteur** to revise the draft opinion following the comments received and to provide it to the SECR. **SECR** to distribute the revised draft opinion to RAC for possible adoption at RAC 23.
5.1 i Cycloxydim	
RAC discussed the first draft opinion.	**SECR** to launch the commenting round on the first draft opinion.
5.2 Requests under Article 77(3) (c) - CLH dossiers	
5.a Gallium arsenide	
RAC discussed the revised draft opinion on reproductive toxicity.	**Rapporteurs** to revise the draft opinion reflecting the view of RAC discussions by mid October. **SECR** to launch the RAC consultation with a

	view of reaching agreement on the revised draft opinion. **SECR** to distribute the revised draft opinion documents to RAC for discussion and possible agreement at RAC 23.
5.b Epoxiconazole	
RAC preliminarily agreed to classify epoxiconazole as indicated in the table 2 below.	**SECR** to launch a commenting round on the first draft opinion after RAC 22 until 12 October. **Rapporteurs** to revise the draft opinion in accordance with the discussion in RAC and in the RAC consultation. **SECR** to distribute the revised draft opinion documents to RAC for discussion and possible adoption at RAC 23.
5.3 Appointment of RAC (co-)rapporteurs for CLH dossiers	
Agreement (co-) rapporteurs for the substances listed in the room document **RAC/22/2012/03**.	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for CLH substances. **Members** to volunteer for CLH substances.

6. Restrictions	
6.2 Restriction Annex XV dossiers	
a) Chromium VI – 2nd version of the draft opinion	
RAC rapporteurs presented the second version of the draft opinion.	**SECR** to ask Forum for the second advice. **Rapporteurs** to prepare the 3rd version of the draft opinion in accordance with the discussion in RAC and to provide them to SECR. **SECR** to distribute the revised draft opinion to RAC for discussion and adoption at RAC 23.
b)Dichlorobenzene – first version of the draft opinion	
RAC rapporteurs presented the first version of the RAC opinion.	**Rapporteurs** in cooperation with the Secretariat to submit a response to comments of RAC members on the dossier to the Secretariat for distribution to RAC members. **Rapporteurs** to take the comments received as well as RAC discussions in the plenary into account while preparing the 2nd version of the RAC opinion.
c) Nonylphenol – outcome of the conformity check	
RAC agreed that the dossier does not conform to the Annex XV requirements and agreed on the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
6.3 Requests under Article 77(3)(c) - restriction dossiers	
a) Non-classified phthalates (DINP and DIDP)	

RAC rapporteur presented the first version of the draft opinion and responds to RAC member's comments.	**Rapporteur** to prepare the 2nd draft opinion in accordance with the discussion in RAC and to provide them to SECR by 15 October. **Rapporteur** to prepare the 3rd version of the draft opinion following RAC comments by 12 November. **SECR** to distribute the 3rd draft opinion to RAC for discussion and adoption at RAC 23.
6.4 Appointment of (co-)rapporteurs for restriction dossiers	
RAC was informed about the pool of (co-) rapporteurs for the substances NMP (1-mehthyl-2-pyrrolidone), lead and lead compounds in articles (room document **RAC/22/2012/05**).	**SECR** to re-initiate the appointment procedure 16 weeks before the expected submissions date (expected submission date is 19/04/2013) based on the procedure for appointment of rapporteurs.

7. Authorisation	
a) Capacity building	
- Establishing DNELs and dose-response functions **RAC/22/2012/06 (*room document*)** Participants welcomed the initiative and discussed some issues. To start a trial initiative was agreed.	**SECR** to inform RAC about the practical follow up. **Members** to volunteer for the proposed tasks.

8. AOB

Item 9 – Action points and main conclusions of RAC 22	
	SECR to upload the adopt action points to CIRCABC.

Table 1. Proposed new or revised classification in Annex VI, CLP and DSD, adopted by RAC

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	Fenoxycarb (ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate)	276-696-7	72490-01-8	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		Acute M= 1 Chronic M=10 000	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Fenoxycarb (ethyl [2-(4-phenoxyphenoxy)ethyl]carbamate)	276-696-7	72490-01-8	Carc. Cat. 3; R40 N; R50/53	Xn; N R: 40-50/53 S: (2)-22-36/37-6-61	N; R50/53 C ≥ 25% N; R51/53 2,5% ≤ C < 25% R52/53 0,25% ≤ C < 2,5%	

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	Tralkoxydim	–	87820-88-0	Acute Tox. 4 Carc. 2 Aquatic Chronic 2	H302 H351 H411	GHS07 GHS08 GHS09 Wng	H302 H351 H411			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Tralkoxydim	–	87820-88-0	Carc. Cat. 3; R40 Xn; R22 N; R51/53	Xn, N R: 22-40-51/53 S: (2-)36/37-46-61		

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
616-035-00-5	Cymoxanil (ISO): 2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide	261-043-0	57966-95-7	**Repr. 2 Acute Tox. 4 Skin Sens. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1**	**H361fd H302 H317 H373 (Blood, thymus) H400 H410**	GHS07 GHS08 GHS09 Wng	H361fd H302 H317 H373(Blood, thymus) H410		M(acute) = 1 M(chronic) = 1	

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
616-035-00-5	Cymoxanil (ISO): 2-cyano-*N*-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide	261-043-0	57966-95-7	**Xn; R22-48/22-62-63 R43 N; R50/53**	Xn, N R: 22-48/22-43-62-63-50/53 S : (2-)36/37-46-60-61	N; R50/53: C ≥ 25 % N: R51/53 : 2.5% ≤ C < 25% R52/53 : 0.25% ≤ C < 2.5%	

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	4-vinylcyclohexene (VCH)	202-848-9	100-40-3	**Carc. 2**	**H351**	Wng	**H351**			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	4-vinylcyclohexene (VCH)	202-848-9	100-40-3	**Carc. Cat. 3; R40**	**Xn** **R40** S36/37		

Table 2. Proposed new or revised classification in Annex VI, CLP, preliminary agreed by RAC [6]

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
	Formaldehyde		50-00-0	**Muta. 2** **Carc. 1B** Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Skin Sens. 1	**H341** **H350** H331* H311* H301* H314 H317	GHS07 **GHS08** **Dgr**	**H341** **H350** H331* H311* H301* H314 H317		SCL: Skin Corr 1B ≥25%, 5%≤ Skin Irrit 2/Eye Irrit 2<25%, STOT SE 3 – H335 ≥5% Skin sens 0.2%	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC

Index No	International Chemical	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes

[6] Hazard classes, category and hazard statement codes are written in **bold** if preliminary agreed by RAC during the present meeting. Discussions on other hazard classes are possibly ongoing.

	Identification						
	Formaldehyde		50-00-0	**Xn, T** **Muta. Cat. 3; R68** Carc. Cat. 2; R45 T; R: 23/24/25 C; R34 R43	**Xn** **R: 45 – 68** R: 23/24/25 R34 R43	SCL: T ≥25%, 5%≤Xn<25% SCL: C ≥25%, 5%≤Xi; R36/37/38<25% R: 43 SCL of 0.2%	

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	Methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	**Acute Tox. 4**	**H302**	To be filled in after adoption	**H302**			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Methyl 2,5-dichlorobenzoate	220-815-7	2905-69-3	**Xn; R22**	**Xn**; To be filled in after adoption		

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	**Acute Tox 4 Acute Tox 3 Eye Dam. 1**	**H302 H331 H318**	**GHS06 GHS05 GHS07**	**H302 H331 H318**			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	3-iodoprop-2-yn-1-yl butylcarbamate	259-627-5	55406-53-6	**Xn; R22 T; R23 Xi; R41**	**R: 22-23-41**		

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

				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 statement Code(s)**	**Specific Conc. Limits, M-factors**	**Notes**
603-061-00-7	tetrahydro-2-furylmethanol; tetrahydrofurfuryl alcohol	202-625-6	97-99-4	**Repr. 1B** Eye Irrit. 2	**H360Df** H319	GHS07 **GHS08** Wng	H360Df			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

				Classification	**Labelling**	**Concentration Limits**	**Notes**
Index No	**International Chemical Identification**	**EC No**	**CAS No**				
603-061-00-7	tetrahydro-2-furylmethanol; tetrahydrofurfuryl alcohol	202-625-6	97-99-4	**Repr Cat 2; R61** **Repr. Cat 3; R62** Xi; R36	Xn R: 36-61-62 S: 2-36/37/39-46	Xi; R36: C ≥ 10%	

Proposed new or revised entries in Table 3.1, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
613-175-00-9	epoxiconazole (ISO)	406-850-2	133855-98-8	**Repr. Cat. 1B** Carc. 2 Aquatic Chronic 2	**H360D**f H351 H411	GHS08 GHS09 **Dgr**	**H360D**f H351 H411			

Proposed new or revised classification in Table 3.2, Annex VI, CLP (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
613-175-00-9	epoxiconazole (ISO)	406-850-2	133855-98-8	**Repr. Cat. 2; R61** Carc. Cat.3; R40 Repr. Cat. 3; R62 N; R51/53	**T**;N R: **61**-40-62-51/53 S: 45-53-61		

Part III. List of Attendees of the RAC-22 meeting (11-14 September 2012)

RAC members
ANDERSSON Alicja
BARANSKI Boguslaw
BARRON Thomasina
BJORGE Christine
BORGES Teresa
BRANISTEANU Radu
DI PROSPERO FANGHELLA Paola
DUNAUSKIENE Lina
DUNGEY Stephen
GREIM Helmut
GRUIZ Katalin
HAKKERT Betty
HALKOVA Zhivka
JENSEN Frank
KADIKIS Normunds
KAPELARI Sonja
LEINONEN Riitta
LOSERT Annemarie
LUND Bert-Ove
MULLOOLY Yvonne
PARIS Pietro
PICHARD Annick
PINA Benjamin
POLAKOVICOVA Helena
RUCKI Marian
RUPPRICH Norbert
SCHLUETER Urs
SCHULTE Agnes
SMITH Andrew
SOERENSEN Peter
SPETSERIS Nikolaos
STASKO Jolanta

ECHA staff
ANFÄLT Lisa
ATLASON Palmi
BALDUYCK Bo
BARMAZ Stefania
BOWMER Tim
BROECKAERT Fabrice
DE BRUIJN Jack
DUBOURG Richard
ERICSSON Gunilla
FUHRMANN Anna
HELLSTEN Kati
HONKANEN Jani
HUUSKONEN Hannele
KARJALAINEN Ari
KIOKIAS Sotirios
KIVELÄ Kalle
KLAUK Anja
KOKKOLA Leila
LUSCHÜTZKY Evita
MAGGIORE Angelo
MALM Jukka
MATTHES Jochen
MERKOURAKIS Spyridon
KOSK-BIENKO Joanna
NICOT Thierry
NYGREN Jonas
ORISPÄÄ Katja
PELTOLA Jukka
RIVERO Debora
RODRIGUEZ IGLESIAS Pilar
ROECKE Timo
ROGGEMAN Maarten

STOLZENBERG Hans-Christian		SADAM Diana
TADEO José Luis		SIHVONEN Kirsi
van der HAGEN Marianne		SOSNOWSKI Piotr
Advisers to the RAC members		SPJUTH Linda
BROSCHINSKI Lutz (Schulte)		VAINIO Matti
GUSTAFSSON Anne-Lee (Andersson)		Van HAELST Anniek
McGARRY Helen (Smith)		
McMICKAN Sinead (Mullooly)		**SEAC members**
FLORIDI Elena (Paris)		DALTON Marie
HOFER Tim (van der Hagen)		FANKHAUSER Simone
JANONYTE Agne (Dunauskiene)		FEYAERT Jean-Pierre
MAHIOUT Selma (Leinonen)		FIORE-TARDIEU Karine
NUNES Laura (Tadeo)		FURLAN Janez
PAPPONEN Hinni (Leinonen)		GEORGIOU Stavros
PECZKOWSKA Beata (Baranski)		SCHUCHTÁR-GREGORIK Endre
STARKE Sue-Martina (Stolzenberg)		
VIVIER Stéphanie (Pichard)		
		Remote participants
Representatives of the Commission		SOERENSEN Peter Hammer (RAC member, 14.9.2012)
ROZWADOWSKI Jacek (DG ENTR)		GUNNARSDOTTIR Sjöfn (RAC advisor for Gitte Tiesjema who is representing Marja Pronk)
SCAZZOLA Roberto (DG ENTR)		HELLMER Lena (RAC advisor for Alicja Andersson)
BINTEIN Sylvain (DG ENV)		LUNDBERG Katarina (RAC advisor for Alicja Andersson)
LEFEVRE Remi (DG ENV)		GARCIA JOHN Enrique (COM observer)
		GIRAL Anne (COM observer)
Invited experts		KUBICKI Michal (COM observer)
NUNES Céu (Fenoxycarb co-rapporteur)		CAITENS Andrea (a representative of the UK CA following tralkoxydim)
KORATI Safia		CEDERBERG Inger (a representative of the Swedish CA following nonylphenol)
MICHEL Cécile (Invited expert supporting Elodie Pasquier who was absent)		HENRIKSSON Jörgen (a representative of the Swedish CA following nonylphenol)
TIESJEMA Gitte (Invited expert supporting Marja Pronk who was absent)		IVARSSON Jenny (a representative of the Swedish CA following nonylphenol)
		MUNCH CHRISTENSEN Anne (a

		representative of the Danish CA following nonylphenol)
Stakeholder observers		NYLANDER Anna (a representative of the Swedish CA following nonylphenol)
ROWE Rocky (ECPA)		STARK Christiane (a representative of the German CA following Fenoxycarb and methyl-2,5-dichlorobenzoate)
MUNARI Tomaso (EuCheMS)		
MEISTERS Marie-Louise (ECETOC)		**Excuses**
ANNYS Erwin (CEFIC)		TROISI Gera (RAC member)
DMYTRASZ Bohdan (CONCAWE)		GOURMELON Anne (OECD)
SANTOS Tatiana (EEB)		**Absent**
REGO Laura (ECEAE)		TSITSIMPIKOU Christina (RAC member)
WAETERSCHOOT Hugo (Eurometaux)		
MüLLER Karsten (Business Europe) (replacing Volker Soballa)		
Other observers		**Other observers**
VARNAI Veda (Croatian observer)		MORFELD Peter (an observer acting as an expert (Evonik Services) to an observer representing ECPA for formaldehyde
ANDREW David (an observer acting as an expert (DuPont) to an observer representing CEFIC for cymoxanil)		PICCIRILLO Vincent J (an observer acting as an expert (VJP Consulting) to an observer representing Cefic for THFA
BOMHARD Ernst (an observer acting as an expert (consultant) to an observer representing Eurometaux for GaAs)		SARGINSON Nigel (an observer acting as an invited expert (ExxonMobil) to an observer representing CEFIC for non-classified phthalates)
FRANKE Kristian (an observer acting as an expert (Stalher Int GmbH) to an observer representing ECPA for MDCB		STINCHCOMBE Stefan (an observer acting as an expert (BASF) to an observer representing ECPA for epoxiconazole
GELBKE Heinz-Peter (an observer acting as an expert (GMX) to an observer representing Cefic for GaAs, formaldehyde and VCH)		WARREN Simon (an observer acting as an expert (DuPont) to an observer representing ECPA for cymoxanil)
LLOYD Sara (an observer acting as an expert (Syngenta) to an observer representing ECPA for Fenoxycarb and tralkoxydim		WERNER Michael (an observer acting as an expert (SCC) to an observer representing ECPA for IPBC

RAC-22/SEAC-16 Joint Session

In addition to the list of Attendees of the RAC-22 meeting the following SEAC meeting participants took part in the Joint Session

SEAC Members
ALEXANDRE João
BENDL Jiri
BRIGNON Jean-Marc
CECCARELLI Federica (via WEBEX)
CSERGO Robert
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GULBRANDSEN Magnus Utne
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SKARŽINSKAS Vitalius
SLEZAK Zbigniew
THIELE Karen
THORS Åsa
TIRCHILA Luminita

Advisors, Dossier Submitters (DS) & Observers
CEDERBERG Inger, IVARSSON Jenny, NYLANDER Anna and VASS Anne Marie (DS representatives)
COGEN Simon (Advisot to J-P. FAYAERTS)
KORHONEN Hanna (Advisor to J. Kiiski)
JENSEN Frank (Phthalates DS representative and RAC Member)
LANGTVET Espen (Advisor to M. Gulbrandsen)
LESTANDER Dag (Advisor to A. Thors)
MCMICKAN Sinead (Advisor to RAC Member Y. Mullooly)
PUES Jonathan (Advisor to C. Dantinne)
VERHOEVEN Julia (Advisor to C. Luttikhuizen)

Stakeholder Observers

BUONSANTE Vito (EEB)

JÀNOSI Amaya (CEFIC)

KÜHN Ingolf (Business Europe)

Representative of the European Commission
KUBICKI Michal (via Webex)
ZIELINSKI Janusz

ECHA staff

MOTTET Denis

BROERE William

CALVO TOLEDO Juan Pable

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-22 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-22 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-22 meeting

ANNEX I

11 September 2012
RAC/A/22/2012
Annex I

Final Agenda

22nd meeting of the Committee for Risk Assessment

11-14 September 2012
ECHA Conference Centre (Annankatu 18, Helsinki)
11 September: starts at 9:00
14 September: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/22/2012
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 21 action points, written procedures and other ECHA bodies

RAC/22/2012/01
For information

b) Implementation of Conflict of Interest Policy

a. General principles and guidance for Committee members

RAC/22/2012/02
For discussion

b. Eligibility criteria

For information

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

a) Fenoxycarb
b) Tralkoxydim
c) 4-Vinylcyclohexene (VCH)
d) Cymoxanil
e) 3-Iodo-2-propynylbutylcarbamate (IPBC)
f) Formaldehyde
g) Methyl-2,5-dichlorobenzoate
h) Tetrahydrofurfuryl alcohol (THFA)
i) Cycloxydim

For discussion/adoption

5.2 Requests under Article 77(3) (c) - CLH dossiers

a) Gallium arsenide
b) Epoxiconazole

For discussion/adoption

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

RAC/22/2012/03
For agreement

5.4 General and procedural CLH issues

a) State of play of CLH dossiers

b) Opinion development process

For information

Item 6 – Restrictions

6.1 General restriction issues

a) Update on intended restriction dossiers

b) Update on the review of restriction process

RAC/22/2012/04 ***(room document)***
For information

6.2 Restriction Annex XV dossiers

a) Chromium VI – 2nd version of the draft opinion

For discussion

b) Dichlorobenzene – 1st version of the draft opinion

For discussion

c) Nonylphenol – outcome of the conformity check

For agreement

6.3 Requests under Article 77(3)(c) - restriction dossiers

a) Non-classified phthalates (DINP and DIDP)

For discussion/adoption

6.4 Appointment of (co-)rapporteurs for restriction dossiers

RAC/22/2012/05 ***(room document)***

For information

Item 7 – Authorisation

a) Capacity building
   - Establishing DNELs and dose-response functions

     RAC/22/2012/06 (*room document*)

     For discussion
   - Valuation of environmental impacts of PBTs

     For discussion
   - Proportionality in evaluating Applications for Authorisation (AfAs)

     For discussion
   - AfAs with 'multiple dimensions'

     RAC/22/2012/07 ***(room document)***

     For discussion

b) Participation of case-owners and stakeholder observers in opinion development process

For discussion

Item 8 – AOB

b) C&L Inventory

c) Feedback on the first four restrictions from the Commission´s Impact Assessment point of view

For information

Item 9 – Action points and main conclusions of RAC-22

Table with Conclusions and Action points from RAC-22

For adoption

ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-22 meeting.

Number	**Title**
RAC/A/22/2012	Final Draft Agenda
RAC/22/2012/01	Feedback from other bodies and activities (AP 4a)
RAC/22/2012/02	Implementation of Conflict of Interest Policy (AP 4b)
RAC/22/2012/03	Appointment of RAC (co-) rapporteurs for CLH dossiers (AP 5.3)
RAC/22/2012/04 Room doc	RAC WP on processing Annex XV restriction dossiers revision (AP)
RAC/22/2012/05 Room doc	Appointment of RAC (co-) rapporteurs for restriction dossiers (AP 5.3)
RAC/22/2012/06	Establishing DNELs and dose-response functions
RAC/22/2012/07 Room doc	AfAs with 'multiple dimensions'
RAC/22/2012/08 Room doc	Participation of case-owners and stakeholder observers in opinion development process
Room document	Restriction proposal on Chromium VI in leather

o0o

ANNEX III

The following participants declared conflicts of interest with the agenda items (according to Art 9 (2) of RAC RoPs)

Name of participant	Potential conflict of interest in relation to	Reason
RAC members		
Stephen DUNGEY	Tralkoxydim	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Helmut GREIM	Epoxiconazole	He was involved in the scientific discussion on the mechanism of epoxiconazole organised by US consultant
Frank JENSEN	Chromium VI Styrene	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Annemarie LOSERT	Cymoxanil Cycloxydim	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Bert-Ove LUND	Nonylphenol	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Annick PICHARD	Formaldehyde Gallium Arsenide	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Peter Hammer SØRENSEN	Chromium VI Styrene	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Andrew SMITH	Tralkoxydim	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Invited expert		
Cécile MICHEL	Gallium Arsenide Formaldehyde 4-Vinylcyclohexene	(His or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Stakeholders	Potential conflict of interest in relation to	Reason
ECETOC Marie-Louise Meisters	Cymoxanil Formaldehyde	She is an employee at DuPont
BusinessEurope Karsten Müller	Formaldehyde Epoxiconazole 4-Vinylcyclohexene	He is an employee at BASF

COM	Potential conflict of interest in relation to	Reason
Roberto SCAZZOLA	Formaldehyde	He worked in the team who prepared the registration dossier
RAC CHAIR	Potential conflict of interest in relation to	Reason
Tim BOWMER	Formaldehyde	Recent experience with formaldehyde projects for industry

o0o