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Final

Minutes of the 21st meeting of the Committee for Risk Assessment (RAC-21)

(12-15 June 2012)

Part I Summary Record of the Proceedings

1 Welcome and apologies

Pilar Rodríguez Iglesias, Acting Chair of the Committee for Risk Assessment (RAC) welcomed all the participants to the meeting. The Acting Chair informed RAC members that the new RAC member, Sonja Kapelari was appointed by the Management Board on 21 May 2012 and informed about two replacements for RAC members at this meeting. Furthermore, RAC was informed about changes in the Secretariat and in particular that a new colleague Dana Dvorakova joined the RAC Secretariat on 1 June. All the meeting participants are listed in Part III.

For this meeting several participants took part in substance-related discussions as remote participants, see Part III.

Apologies were received from four RAC members and one member was absent. The list of attendees is given in Part III of these minutes.

Participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes and that the minutes, to be published on the ECHA website, would include the list of participants.

2 Adoption of the Agenda

The final draft agenda (RAC/A/21/2012_rev.1) 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 Acting Chair asked the members and their advisers, as well as the observers, whether there were any conflicts of interests to be declared specific to the agenda items. Nine members declared potential conflicts of interests to the substance-related discussions due to their participation and/or the participation of their institutions in the preparation of the dossiers submitted by the MSCA. These members did not participate in voting of the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. One stakeholder observer also declared potential conflicts of interest to the substance-related discussions. The list with declared potential conflicts of interests of members and observers are recorded in these minutes in the attached table in Annex III.

4 Report from other ECHA bodies and activities

a) Report on RAC-20 action points, written procedure and other ECHA bodies

The Secretariat informed the Committee on administrative issues as set out in room document RAC/21/2012/01.

b) Implementation of the Conflict of Interest Policy - Modification of the RAC Rules of Procedure

The Acting Chair introduced the room document RAC/21/2012/02 by outlining that a review of the Committees' Rules of Procedure (RoPs) is necessary to include provisions that members are not allowed to participate in meetings unless they have a valid declaration of interest. The Acting Chair further explained that

the respective addition to the RAC RoPs is suggested to Article 9(1): *"Members who have not submitted the declaration of interests shall not take part in meetings of the Committee and its working groups or decisions by written procedure".*

The Acting Chair informed the Committee that the room document will be circulated to RAC afterwards for agreement via written procedure.

If agreed by RAC via written procedure, the Secretariat will submit the revised RoPs to the ECHA Management Board for approval.

c) Co-opted members

In accordance with Article 85(4) of the REACH Regulation, the Committees shall aim to have a broad range of relevant expertise among their members. To this end each Committee may co-opt a maximum of five additional members chosen on the basis of their specific competence.

The Acting Chair introduced this topic and referred to the first discussions that had taken place at RAC-1 and SEAC-1. The Acting Chair added that according to Article 4(2) of the Rules of Procedure for RAC and SEAC, the Committees may decide whether additional members should be co-opted and, furthermore, the Committees shall agree on the required competences and on the selection procedure.

The Secretariat would like to invite RAC to discuss the general and specific needs for co-opting additional members to the Committee.

Several members expressed the view that a further discussion on the topic would be needed and that especially the area of expertise needed in RAC would require some further analysis. Some members asked further clarification on the financial aspects of co-opting additional members.

The Acting Chair thanked the members for their comments and concluded that the matter will be tabled at a forthcoming RAC plenary meeting(s), addressing the comments made.

d) Rules of procedure pursuant to Article 110 of REACH on food safety and worker protection

The Acting Chair introduced the room document RAC/21/2012/03 on the specific requirements for ECHA according to Article 110 of the REACH Regulation to establish Rules of Procedure concerning food safety and worker protection.

The Acting Chair reminded that the initial involvement of RAC and SEAC in drafting the Rules of Procedure had taken place in summer 2009 when a roadmap towards possible elements for co-operation had been introduced. Consequently, draft texts establishing the Rules of Procedure concerning worker protection and food safety, respectively, was prepared by the ECHA Secretariat, which are now open for consultation by the Committees. The draft Rules of Procedure define the framework for cooperation of ECHA on matters related to food safety and worker protection, respectively, with a view to ensuring coherence in the work of ECHA and sharing relevant information with other relevant EU bodies working in the same area.

The Acting Chair pointed out that the document is being put forward for consultation in view of its submission to the ECHA Management Board for discussion and possible adoption.

5 Requests under Article 77(3)(c)

a) Gallium arsenide (toxicity to reproduction)

The Acting Chair welcomed an expert accompanying the Eurometaux stakeholder observer and an accompanying expert from Cefic.

The Acting Chair informed RAC about the revised and extended mandate, i.e. asking RAC to evaluate the information on toxicity to reproduction submitted during Public Consultation (PC) on carcinogenicity and take into account also information submitted by Eurometaux in December 2011 in order to decide whether the current opinion on the proposed classification for reproductive toxicity should be revised.

The (co-)rapporteurs presented the revised draft opinion based also on the information from industry submitted in the special format of an additional information report (AIR). The draft opinion proposes to classify gallium arsenide as Repr. Cat 2 based on that the adverse effects on testes are probably secondary to lung toxicity. Newly available information showed some effects in other organs than the testes (Tanaka et al, 2000) in the intratracheal study in hamsters (Omura et al, 1996a).

Supportive arguments provided were that lung toxicity may be related to hypoxia which may cause testes toxicity. It was emphasised that effects on the lung started to occur at lower doses than the testes effect. However, it had not been shown that the specific lung effects observed in the key studies on GaAs (where testicular toxicity is demonstrated) cause hypoxia. It has also not been demonstrated in these studies that hypoxia causes the specific testicular toxicity observed (including testis atrophy). Data showing hypoxia in other organs is also lacking.

In the discussion RAC members pointed out that the conclusions in the draft opinion are mainly based on assumptions on qualitative relationships. They asked if any quantitative data were available showing a dose-response relationship between hypoxia and testes effects that may support the assumption that the toxic effects on the testes by GaAs may be caused by hypoxia.

It was noted that there are no new data available (except for the additional information on organ toxicity in the hamster study (Omura et al, 1996a)) and that all data had already been assessed when RAC draw its first opinion in 2010. The issue of hypoxia and lung toxicity had already been discussed previously by RAC.

Some members were of the opinion that a direct effect on testes cannot be excluded (also considering the shown increase in concentrations of Ga and As in the testes after long-term exposure in the rat) and it was noted that there is not sufficient data in order to conclude that the observed testes effects by GaAs are caused by hypoxia (no data is available showing a clinically relevant hypoxia in the animals). A causal link between the lung damage caused by GaAs, and the observed testes effects had not been demonstrated. It was also not clear if the assumed mode of action would be "non-specific" as mentioned in the criteria. A question was raised whether there were examples on other chemicals where a causal relationship between lung toxicity causing hypoxia leading to testicular damage had been shown.

Some members highlighted that if hypoxia occurred in the studies on GaAs, also other organs more sensitive to lack of oxygen than the testes would be expected to show signs of adverse effects, which was not clearly the case.

The Acting Chair thanked the (co-)rapporteurs and RAC for the discussion and invited (co-)rapporteurs to revise and further develop the draft opinion based on the discussion including a more detailed description of the effects, especially on the lungs, observed in the Tanaka et al. (2000) study. No conclusion on

classification was made. The Secretariat is to distribute the revised draft opinion to RAC for comments before the next plenary meeting.

b) Epoxiconazole

The Acting Chair welcomed an accompanying expert of ECPA.

The Acting Chair informed RAC about the new mandate (asking RAC to develop and adopt an opinion on epoxiconazole taking into account additional studies that have been recently made available) and the preliminary timeframe for the development of the opinion.

RAC agreed to appoint the rapporteur and co-rapporteur for the new mandate.

c) Non-classified phthalates (DINP and DIDP)

The Acting Chair invited the Secretariat to present the new mandate regarding ECHA's draft review report evaluating new scientific evidence concerning DINP and DIDP.

ECHA prepared the review report on request by the European Commission. The request was based on a review clause in the restriction entry 52 of Annex XVII to REACH. According to this entry, DINP, DIDP and DNOP are restricted in toys and childcare articles which can be placed in the mouth by children. The assessment in the review report was however not limited to exposure from toys and childcare articles.

In its draft report, ECHA concluded that the existing restriction is justified and that no further risk reduction measures are needed to reduce the exposure of children to DINP and DIDP. There is a potential risk to adults from the use of sex toys, but this conclusion is associated with substantial uncertainties.

The 12-week public consultation (PC) on the draft scientific review report will end on 31 July 2012. RAC has been requested to provide a scientific opinion by the end of the year on the draft report, taking into account comments from this public consultation. RAC is requested to make an assessment of the scientific quality and completeness of the report and to answer to the questions listed in the mandate.

ECHA will amend the report based on the PC comments and the RAC opinion, and send the update to the Commission.

RAC agreed to appoint the rapporteur for non-classified phthalates (DINP and DIDP) as recommended by the Acting Chair. The first draft opinion is expected to be discussed at RAC-22.

6 Harmonised classification and labelling (CLH)

6.1 CLH dossiers

a) Para-tert-butylphenol (ptBP)

The Acting Chair welcomed the representative of the dossier submitter from the Norwegian MSCA[1] who followed the discussions as a remote participant. The Acting Chair invited the (co-)rapporteurs to present the revised draft opinion on the CLH proposal.

Currently there is for this substance no entry in Annex VI to the CLP Regulation. A harmonised classification and labelling was previously agreed under TC C&L[2]. The

[1] Member State Competent Authority

[2] Technical Committee for Classification and Labelling

current proposal relates to the hazard classes skin irritation, eye damage, respiratory tract irritation and reproductive toxicity.

The discussions continued from the last RAC-19 and RAC-20 meetings on Skin Irrit. 2 - H315 (CLP) and R38 (DSD) versus Skin Corr. (CLP) and classification versus no classification of respiratory tract irritation with STOT SE 3 - H335 (CLP) and R37 (DSD).

During the discussion on Skin Irritation, RAC members pointed out that the term "irreversible necrosis" used in some of the studies and in the draft opinion is not correct since necrosis means irreversible damage. Furthermore, members mentioned that the observed necrosis in several studies may justify classification for Skin Corrosion. RAC agreed that as classification for Skin corrosion should be applied to substances where irreversible skin damage is seen after up to 4 hour exposure, and given that with ptBP only reversible skin alterations were reported following the application of a test substance for up to 4 hours, the substance should be classified as Skin Irrit. and not as Skin Corr.

Regarding the respiratory tract irritation it was reiterated that the lack of human data was not considered crucial in the justification for not classifying. The observed effects in the different animal studies are not considered to justify classification, namely due to the high dose used in an acute inhalation study (5600 mg/m^3) and due to the administration procedure (gavage) used in a repeated dose study. It was also argued that the effects seen in the acute inhalation study could possibly be a physico-mechanical effect of the dust particles rather than an effect of the substance itself, but it was concluded that an exclusive cause by either of the effects is unlikely. The high dose used was seen as the main argument not to classify. In the other studies used in the evaluation for this hazard class, no respiratory tract irritation was seen.

The opinion was adopted by consensus as indicated in table 1 of this document. It was also concluded that the (co-)rapporteurs should revise the adopted opinion based on the discussion at RAC-21, and circulate the revisions to RAC members before sending the opinion to the Commission and uploading it to the ECHA website.

b) Penconazole

The Acting Chair welcomed the representative of the dossier submitter from the German MSCA and an expert accompanying the ECPA stakeholder observer.

Further, the Acting Chair invited the ECHA Secretariat to present the revised draft opinion on penconazole.

The acute toxicity and environmental hazards had already been provisionally agreed at RAC-17 and RAC-18 and were not discussed in this meeting. At RAC-20 a preliminary agreement was reached to classify penconazole as Repr. 2 (CLP). RAC continued discussion on reproductive toxicity and whether or not the provided information justifies Repr. 2 classification for both fertility and development.

The Acting Chair thanked RAC for the discussion and asked the Secretariat to add more details on data that supports classification for Repr. 2 (fertility and development) in the opinion document. The Acting Chair also concluded that, before the 18-month deadline on 16 July 2012, a short editorial commenting round on the reproductive toxicity part of RAC evaluation in the penconazole's opinion document will take place preceding the adoption by written procedure.

c) Benzoic acid

The Acting Chair welcomed the representative of the dossier submitter from the German MSCA who followed the discussion as remote participant.

The Acting Chair reported that in the follow-up to the discussions that had taken place at RAC-20, the rapporteur had revised the draft opinion. She invited the rapporteur to present the main issues involved in the revision of the draft.

One main issue was the classification for Skin Corr. 1 (CLP) vs. Skin Irrit. 2 (CLP). RAC preliminarily agreed to classify the substance as Skin Irrit. 2 (CLP), based on a 28-day study. It was concluded that a classification as skin corrosive is not warranted as no data to support this was available in the dossier or through public consultation.

A second issue discussed was whether a classification as respiratory sensitiser would be justified. The rapporteur presented data that could indicate respiratory sensitising effects. Several RAC members questioned this as the existing human data indicating that benzoic acid could induce asthmatic symptoms comes from extra sensitive individuals already suffering from asthma. There is however no data available showing that Benzoic acid can induce asthma in healthy individuals, and hence a classification for respiratory sensitisation was not considered justified.

Concerning STOT RE, there was a discussion whether category 1 or 2 would be most appropriate. The existing data (effects on lungs) comes from a 28-day study, while the cut-off values used to distinguish between the different categories are based on 90-day studies. When using the conversion method stated in the CLP Regulation, the value ends up just on the border between Category 1 and 2 if the lowest dose where effects are seen in the 28-day study is used. Some RAC members argued that the effects seen at the lowest dose (interstitial inflammation and lung fibrosis) are not relevant for classification due to lack of data on the severity of the effects, while others argued that they are relevant. After the discussion it was concluded that the effects seen at the lowest dose would justify classification and there was a preliminary agreement to classify Benzoic acid for STOT RE 1 - H372.

It was finally agreed that the rapporteur revises the draft opinion/ background document based on the conclusions at RAC-21. The Secretariat would afterwards launch a written procedure for adoption of the opinion.

d) 4-Vinylcyclohexene

The Acting Chair welcomed the expert accompanying the Cefic stakeholder observer as well as the dossier submitter, the latter as remote participant. The Acting Chair also welcomed the co-rapporteur as remote participant.

The (co-)rapporteurs introduced the third draft opinion on the CLH proposal submitted by France.

RAC discussed the proposal to classify 4-vinylcyclohexene (VCH) for carcinogenicity. There was consensus that the data showing VCH treatment-related ovary tumours in female mice constituted evidence for carcinogenicity of 4-VCH.

Some RAC members supported the proposal to classify VCH as Carc. 1B (CLP). Other members supported classification as Carc. 2 (CLP) but asked for additional clarification on the mode of action and the relevance for humans of other tumours seen in rats.

The Acting Chair thanked the (co-)rapporteurs and invited them to revise the draft opinion in accordance with the discussion in RAC with a view for possible adoption during the next RAC meeting. It was noted that the 18-month deadline for adoption was in November 2012.

e) Acrolein

The Acting Chair reported that the dossier was for first discussion at a RAC plenary, and that the substance already had an Annex VI entry as flammable liquid, as acutely toxic (by dermal, oral and inhalation routes) , Skin Corr. 1B (CLP) and as acutely toxic to the aquatic environment.

The Acting Chair reported that the dossier had gone through RAC consultation and that the draft opinion / background document had been revised thereafter. She invited the (co-)rapporteurs to present key findings and proposed conclusions to RAC. Afterwards the Acting Chair opened the floor for discussion.

Regarding skin corrosion, RAC concluded to classify acrolein as corrosive to skin without specifying the sub-category (in absence of detailed study results) and with a specific concentration limit of 0.1% in view of human data showing skin irritation at 1.0%.

For acute toxicity by three routes of exposure, RAC agreed to the proposal by the dossier submitter to classify acrolein as Acute Tox. 1 - H330 (fatal if inhaled, CLP), Acute Tox. 2 - H300 (CLP, fatal if swallowed) and Acute Tox. 3 - H311 (CLP, toxic in contact with skin).

In relation to the proposal from a RAC member to classify acrolein for skin sensitisation due to its high reactivity and other considerations, RAC concluded that the available data does not warrant classification.

In relation to the aquatic environment, RAC agreed to classify acrolein as Aquatic Acute 1 (M = 100) and Aquatic Chronic 1 (M = 1). A classification according to Directive 67/548/EEC as R50 with a SCL of 0.25% was seen as warranted.

The opinion was adopted by consensus. It was agreed that the Secretariat make an editorial check and consult with the (co-)apporteurs before uploading the adopted opinion to RAC CIRCABC, forwarding the document to COM and publishing it on the ECHA website.

f) Ethephon

Due to time constraints, the substance was not discussed at RAC-21.

g) Styrene

The Acting Chair welcomed the expert accompanying the Cefic stakeholder observer. She reported that the dossier was for first discussion at a RAC plenary. She invited the rapporteur to introduce the first draft opinion on the CLH proposal submitted by Denmark.

The dossier submitter proposed STOT RE1 (nervous system) and Repr 1B -H360D (CLP). The draft opinion agreed with the STOT RE1 proposal, and it was suggested that the description could be confined to hearing organs. Comments during the discussion were supportive of this classification proposal for STOT RE1 (hearing organs), and classification for this endpoint was preliminarily agreed.

The rapporteur indicated that based on a balanced consideration of the data a classification as Repr. 2 - H360d could be considered. While most comments from RAC members were in agreement with this assessment, views were also expressed in favour of the originally proposed Repr. 1B classification.

The expert accompanying the Cefic stakeholder observer expressed the view that the information that they had submitted during public consultation was not adequately reflected in the draft opinion. The Acting Chair clarified that the information provided by industry had actually been taken into account by the rapporteur.

It was finally agreed that the rapporteur revises the draft background document based on the conclusions at RAC-21. The Secretariat would afterwards launch a written procedure for adoption of the opinion.

h) Fenoxycarb

The Acting Chair welcomed an expert accompanying the ECPA stakeholder observer. The Acting Chair reported that the dossier was for first discussion at a RAC plenary, and that the dossier had gone through RAC consultation. She invited the rapporteur to present the main issues involved in the dossier and proposed conclusions to RAC.

The rapporteur reported that based on the evidence available, a classification as Carc. 1B vs. Carc. 2 could be warranted. RAC discussed the relevance of peroxisome proliferation for the development of tumours. One RAC member pointed out that in 2010, it was concluded by EFSA to classify for cat. 2 due to the relevance of peroxisome proliferation for liver tumours. Another RAC member stated that the genotoxicity of the substance and its metabolite urethane should be scrutinised in order to conclude on the carcinogenicity classification.

In relation to STOT-RE 2, the draft opinion proposed not to classify in this category as the effects observed would not appear severe enough to warrant classification. RAC preliminarily agreed to this proposal.

It was finally agreed that the rapporteur revises the draft background document based on the discussion at RAC-21. The Secretariat would afterwards distribute the revised draft to RAC for further discussion at RAC-22 or RAC-23.

i) Cymoxanil

The Acting Chair invited the ECHA Secretariat to report on the proceedings of the expert meeting on cymoxanil.

During the expert meeting the following two key questions were discussed:

- Do the effects seen on male reproductive organs in repeated dose studies summarised in the CLH report provide evidence for adverse effects of Cymoxanil on sexual function and fertility?
- Do the haematology and thymus atrophy effects observed in 90-day dog studies, along with the effects on the eye (retina and lenticular degeneration seen in a two-year rat and one-year dog study), constitute significant toxic effects of Cymoxanil after repeated exposure?

The meeting was attended by two industry experts, eight RAC members and one observer from the Commission. Each of the experts gave a presentation on one key question and ample time was set aside for a discussion after each presentation.

The discussion was very lively and ECHA has received positive feedback from participants. The draft meeting notes will be circulated for comments to participants before they are finalised.

RAC members were of the opinion that, although the meeting was very useful and helped them to understand better the industry point of view, in the future this type of meetings should be organised only in exceptional cases. Input from industry should in principle be done exclusively via the public consultation.

Industry underlined the usefulness of the meeting and underlined the high quality of scientific discussion during the meeting.

The Acting Chair underlined that the expert meeting is not a standard step of the procedure and decision to organise such meetings will only be done in exceptional circumstances.

j) Tralkoxydim

Due to time constraints, the substance was not discussed at RAC-21.

k) Fluazinam

The Acting Chair welcomed an expert accompanying the ECPA stakeholder observer. The Acting Chair reported that the dossier was for discussion and that at RAC-20, the classification as Acute Tox. 4 (inhalation; H332) and as Eye Dam. 1 (H318) had been preliminarily agreed. She asked the adviser to the rapporteur to present key findings and conclusions on the draft opinion.

As to skin irritation, the revised draft opinion proposed no classification. Based on further evaluation, it was also concluded that classification as Skin Sens. 1A was warranted. Both views were supported by RAC.

In relation to STOT-RE, the draft opinion proposed that the data were not conclusive enough to warrant classification.

In relation to reproductive toxicity, it was reported that adverse effects on development were seen in both species (rat and rabbit), but only at dose levels with maternal toxicity. In the 2-generation study, no clear effects on fertility and on postnatal development were observed. This supported the conclusion on Repr. 2 (H361), which was shared by RAC.

RAC also agreed to the proposal to classify fluazinam as Aquatic Acute 1 and Chronic 1 (M-factor = 10 in both cases).

The opinion was adopted by consensus. It was agreed that the Secretariat make an editorial check and consult with the rapporteurs as appropriate before uploading the adopted opinion to RAC CIRCABC, forwarding the document to COM and publishing it on the ECHA website.

l) Tetrahydrofurfuryl alcohol

Due to time constraints, the substance was not discussed at RAC-21.

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

RAC members volunteered to be (co-)rapporteurs for the intended or submitted CLH proposals as listed in room document RAC/20/2012/04. The appointment will be done via written procedure (by 1 July 2012).

6.3 General and procedural CLH issues

a) State of play of CLH dossiers

The Acting Chair pointed to room document RAC/21/2012/05, presenting the usual update about CLH dossiers and their state in the opinion development.

b) New approach for opinion development (Partly closed session)

The Acting Chair summarised the development since the last RAC meeting in March: The Secretariat had called for comments on document RAC/20/2012/09 about improving the CLH opinion development process. The deadline for

comments was 4 May 2012. Further to this, the Secretariat has drafted a framework procedure that outlines the general principles and main elements of the process on the opinion development by RAC on proposals for harmonised classification and labelling (CLH dossiers). The framework also clarifies the roles and responsibilities of the different parties as well as their input throughout the process with the aim to further increase the overall efficiency and transparency and that was proposed to replace the current RAC working procedure on opinion development.

The Acting Chair gave the floor to the Secretariat to summarise the comments received and the replies ((RAC/21/2012/08)) and to present the new framework procedure (RAC/21/2012/06). Following the presentation the Acting Chair invited for discussion.

The representatives of the ECPA and the Cefic stakeholder observers noted that at the recent expert meeting about cymoxanil, high level discussions and good dialogue had taken place which would be suited to support RAC in drawing their conclusions.

In relation to opinion development, one RAC member expressed his preference to work with a background document plus a draft opinion, mainly because working with the background document under the new approach was considered to be more cumbersome from a technical point of view. In this connection, another RAC member proposed to first elaborate the RAC boxes in a draft opinion document and then to transfer them into the background document. A third RAC member noted that in some cases there was duplication of information in different parts of the RAC boxes.

In relation to the framework document, one RAC member requested to clarify the term "further information".

Other RAC members pointed out that the quality of the dossiers should be improved. The Secretariat clarified that indeed the quality of incoming dossiers was crucial while public consultation should finally provide the opportunity to source possible missing information from parties concerned. Targeted consultations afterwards would be organised only in exceptional and well justified specific cases.

The Acting Chair proposed to accommodate in the Framework document the comments provided by RAC, and to circulate the document to RAC afterwards for agreement via written procedure.

7 Restrictions

7.1 General restriction issues (Joint RAC/SEAC session)

a) Update on intended restriction dossiers

The Secretariat informed the Committees about two new intentions included in the Registry of Intentions: lead and lead compounds in articles intended for consumer use prepared by Sweden and 1-methyl-2-pyrrolidone (NMP) in coatings and cleaners for consumers and professionals prepared by the Netherlands (submission foreseen for both dossiers in April 2013).

The Chair mentioned that soon after the RAC-21/SEAC-15 meeting, the call for expressions of interest in (co-)rapporteurship will be launched for the above mentioned expected restriction dossiers and encouraged RAC and SEAC members to volunteer.

b) Update on the review of the restriction process

The Chair first pointed out that with regard to the discussion note "How to document an opinion not supporting a restriction proposal?" that had been presented and discussed by both Committees in March, the Secretariat proposes that after gaining experience with the opinions on the Phthalates restriction dossier, possible further guidance to the (co-)rapporteurs or the updating of the opinion template could be considered.

The Secretariat then reminded that in the last RAC and SEAC plenary meetings, the Committees had been informed about the plans to revise the working procedure for elaboration of the Forum advice on enforceability of restriction proposals and provided an update on the ongoing revision of the restriction process in the Forum. The Forum Working Group on Enforceability of Restrictions met on 21 March 2012 and agreed on the main lines for the revised working procedure. According to the revised procedure, the Forum will be consulted twice during the restriction process. The Forum will elaborate the draft advice by the end of week 12-16 and the final advice by the end of week 33 of the restriction process (before RAC adopts its opinion and SEAC agrees on its draft opinion). The draft Forum advice will be based on the original Annex XV proposal while the final Forum advice will take into account the third versions of the RAC opinion and the SEAC draft opinion as well as comments from the public consultation. The final advice will be adopted by the Forum in written procedure. The support on enforcement related issues to the RAC and SEAC (co-)rapporteurs will be provided by the Forum's lead member, in co-operation with the Forum's Working Group, throughout the whole opinion development process of RAC and SEAC. The Secretariat explained that the revised working procedure will be submitted to the Forum for adoption at Forum-12 (18-20 June 2012) and will be applied for next dossiers in conformity with REACH Annex XV requirements starting already from the DCB restriction dossier. The Chair mentioned that the RAC and SEAC working procedures for opinion development will be revised to reflect the Forum changes in autumn/winter 2012.

One member gave a recommendation to the Forum to elaborate further administrative tools to check whether companies comply with the provisions of Annex XVII of REACH (e.g. looking into handbooks, production data sheets, etc). The Secretariat agreed to submit this suggestion to the Forum.

Another member referred to the report on enforcement activities performed by MS authorities as well as companies, combined by the Commission within the REACH review, and suggested that RAC and SEAC should also study and learn from this report. The Secretariat as well as other members of RAC and SEAC, supported this proposal.

7.2 Restriction Annex XV dossiers

a) Phthalates – fourth version of the draft opinion

The RAC (co-)rapporteurs gave an overview of the events since the RAC meeting in March 2012 and reported on the third party comments received in the second half of the public consultation. Furthermore, they presented the key developments in the fourth version of the opinion and reflected on the comments received on it from RAC members prior to the meeting. They presented calculations which resulted in risk characterisation ratios (RCR) just above 1 for 2007 using biomonitoring data and concluded that the level of current risk (2012) was even closer to 1 taking into account uncertainties in the assessment, the observed and future trends in the volumes of the four phthalates placed on the

market, as well as the effect of existing legal measures on the exposure to phthalates.

As a result of this assessment, the fourth version of the opinion suggested that the proposed restriction was not justified. SEAC (co-)rapporteurs complemented this by a presentation of the past trends in market of the four phthalates and the future projections with and without the effect of the authorisation requirements.

During the discussion, some members expressed their support for the assessment and conclusion proposed in the draft opinion. Other members raised their concern over the conclusion that there would not be a risk. These members pointed to the identified risk for 2007 in a limited set of biomonitoring data and on the uncertainty in future forecasts of the phthalate market. In particular, uncertainties in forecasting the amount of phthalates in imported articles were put forward as an argument.

Moreover, some members considered the conclusions being not in line with the ECHA guidance with regard to the question whether there is a risk while uncertainty remains leading to RCRs above 1. The (co-)rapporteurs referred to the ECHA guidance indicating that the interpretation of the risk characterisation is to be accompanied with a qualitative description of the risk. This should include uncertainties related to the exposure and hazard assessment, in order to decide on the robustness of the risk estimate, as done in the draft opinion.

Furthermore, it was stressed that RAC is to give its view on the risk reduction capacity of restriction proposals. In doing so, the point of departure is always "the baseline" or "business as usual" scenario, which is the projected risk in the foreseeable future.

Some members, in support of the fourth version of the RAC opinion, pointed to the choice of conservative assessment factors for the purposes of DNELs derivation for the four phthalates (e.g. factor for interspecies difference), and questions with regards to comparability of the exposure regime of test animals (pregnant animals) with exposure of children. Should the approach in the hazard assessment have been less conservative, RCRs would have been even lower?

After further consideration of uncertainties in the risk assessment, RAC came to the conclusion that for the 2007 situation the cumulative RCRs could well be lower than the ones calculated, so closer to or below 1.

To gain more certainty in the conclusions on the current risk, some members proposed that more attention would be paid to the observed steady decline of the volumes of the four phthalates in articles marketed in the EU in the past (of 35% over the period 2007-2010) and the considerable downward effect on the body burden (as demonstrated by some studies over the period 1988-2008).

Following this, RAC concluded that the data available do not indicate that currently there is a risk from combined exposure to the four phthalates, and therefore considered action on a Community-wide basis in the form of the proposed restriction (or any of the other proposed RMOs) not justified. Furthermore, RAC agreed that the regulatory requirements and consequent reduction in use will further reduce the risk, as will the authorisation requirements imposed on these phthalates in the next few years.

Given the uncertainties identified, RAC recommended that the developments on the four phthalates (e.g. market trends, biomonitoring, content and migration from articles, etc.) should be monitored within an appropriate time period. RAC stressed that REACH requires ECHA to consider whether the use of the four phthalates in articles (including the ones imported into the EU) poses a risk that

is not adequately controlled, given that all four phthalates are listed in REACH Annex XIV. If the risk is not adequately controlled, according to Article 69(2), ECHA is required to prepare a restriction proposal.

RAC adopted by consensus the opinion on this restriction proposal concluding that it is not justified and took note of the Background Document (BD). It was further agreed that the (co-)rapporteurs will ensure that the supportive documentation (BD and RCOM) to the RAC opinion is in line with the adopted RAC opinion for this substance before the publication on the ECHA website. The Secretariat will upload the adopted opinion and its supportive documentation to the RAC CIRCA IG and publish them on the ECHA website after the meeting. The Secretariat will forward the RAC opinion to the Commission.

The Acting Chair thanked the (co-)rapporteurs for the enormous work carried out on this restriction proposal and RAC for the valuable contributions and fruitful discussion as well as RAC observers and dossier submitter for their input into the restriction process.

b) Chromium VI – first version of the draft opinion

The Acting Chair welcomed the SEAC (co-)rapporteurs and the dossier submitter. The Acting Chair invited the RAC (co-)rapporteurs to present the first version of the RAC opinion on the Cr VI dossier.

The (co-)rapporteurs briefly summarised the proposal. The dossier submitter had proposed that articles of leather, coming into direct and prolonged or repetitive contact with the skin, shall not be placed on the market if the leather contains chromium (VI) in concentrations equal to or higher than 3 mg/kg.

The main reason to propose this restriction was that Cr VI easily penetrates epidermis and has high potency for skin sensitisation. Prevalence for Cr VI allergy is of 0.2-0.7% in the general public and Danish data suggest that approximately 45% of the new Cr VI allergies were caused by leather articles (mainly shoes and gloves). The current RMM are not sufficient as inspection of the product on the market shows that about 30% of articles contains Cr VI in the concentration higher than 3 mg/kg.

The dossier submitter had proposed 3 types of RMOs:

RMO1 - restriction of the chromium (VI) content of articles of leather which may come into direct and prolonged contact with the human skin;

RMO2 - restriction of chromium (VI) content in all articles of leather;

RMO3 - restriction of total chromium content of leather.

Concerning the risk assessment, the (co-)rapporteurs underlined that every year there are documented cases of the Cr VI allergies in the EU, so indicating that there is a risk. Moreover, the DS tried to asses risk using toxicological data. Potential dermal exposure exceeds the LOAEL/DMEL by 22.5.

The (co-)rapporteurs informed RAC about the first Forum advice, where Forum expressed preferences for RMO2 due to the lack of the definition of prolonged contact with skin in RMO1. The Forum also proposed a higher concentration limit (4.5 mg/kg) and derogation for articles on the second hand market.

The comments from RAC members on the dossier proposed lower Cr VI concentration limits than 3 mg/kg. The comments from SEAC members were mainly focused on the effectiveness of the restriction.

The comments received via the public consultation are generally in favour of the restriction. Some of them provided also additional data on number of cases in some of the EU MS.

During the discussion RAC agreed that there is a risk but the scale of the risk should be better defined. Some members argued that the risk assessment should be further developed to include a time factor. However, the need for further work was questioned by the (co-)rapporteurs as there is clinical data available to demonstrate the risk. Also the scope of the restriction could be further analysed and a reduction of the scope to certain articles should be considered. The post formation of Cr VI from Cr III in the produced articles during storage or use period could be further assessed.

The Secretariat informed that ECHA is currently working on the definition of the prolonged contact with the skin in the context of the restriction of nickel. Overall, it is very difficult to define "prolonged" because it seems to be case specific and a more practical approach might be to define the limit concentration in the article (or released concentration) that may come into contact with the skin. However, consideration of some data given in the Annex XVII report (migration rates, minimal elicitation threshold) would support similar "prolonged" contact times between nickel and chromium despite of several differences in mechanistical aspects. The Secretariat will keep RAC updated of the further developments on this topic and a document to support enforcement would be prepared, if RMO1 would be eventually favoured by the Committees.

The (co-)rapporteurs, in cooperation with the Secretariat, are requested to submit a response to comments of RAC members on the dossier and on the first version of the RAC opinion to the Secretariat for distribution to RAC members. The (co-) rapporteurs should take these comments into account while preparing the second version of the draft opinion.

c) Dichlorobenzene – outcome of the conformity check

The Chair welcomed the SEAC (co-)rapporteurs, who were following the discussion as meeting participants. The Chair also informed that the ECHA scientific dossier managers were following the discussions as observers, in order to provide technical support, if needed. They were not representing the dossier submitter.

The Chair invited the RAC (co-)rapporteurs to give a presentation on the outcome of the conformity check. The (co-)rapporteurs first presented the basis for initial conclusion and secondly the justification to recommend the Committee to agree that the dossier conforms to the requirements of Annex XV of the REACH Regulation.

Finally, the (co-)rapporteurs presented to RAC the recommendations to the dossier submitter.

After a discussion, RAC agreed that the dossier is in conformity.

It was agreed that the (co-)rapporteurs would make amendments to the recommendations based on comments received at RAC-21. The Secretariat would compile the RAC and SEAC outcomes of the conformity check, and upload this to CIRCABC. The Secretariat would also inform the dossier submitter on the Committees' recommendations and inform the Forum on the decision and request its advice. The (co-)rapporteurs were invited to start developing the draft opinion in accordance with the procedure on opinion development. The Secretariat would launch a public consultation on this restriction proposal on 19 June 2012.

In the joint RAC/SEAC session:

After the dossier was agreed to be in conformity by both Committees, the dossier submitter presented the proposed restriction dossier to RAC and SEAC. Some questions were raised about the alternatives and the reason why the proposal was justified as priority by the Commission. Both ECHA and Commission provided additional clarification on this.

Appointment of (co-)rapporteurs for restriction dossiers

The Acting Chair has recommended two RAC members (from the pool of 6 eligible candidates agreed at RAC-18) to be (co-)rapporteurs for the nonylphenol restriction dossier covering 3 substances – nonylphenol; 4-nonylphenol, branched and nonylphenol ethoxylates. They are listed in room document RAC/21/2012/10. The appointment will be done via written procedure (by 1 July 2012).

8 Authorisation (Joint RAC/SEAC session)

a) Report from the Den Haag workshop on Environmental Impact Assessment and future steps with regards to capacity building

The Secretariat introduced the topic of the authorisation capacity building and gave an update of its current status and future plans. It was emphasised that specifically the RAC-SEAC interface needs to be further developed, other key issues identified and the programme updated accordingly.

In further closing the RAC-SEAC interface, one of the organisers of the Den Haag workshop gave a presentation on the methodology developed and case studies of environmental impact assessment and results of the workshop.

RAC and SEAC members welcomed the presentation on steps taken in closing the gap between risk assessment and impact assessment. Nevertheless, members pointed out that further development may be needed. For example the proposed PBT-scoring approach may need to be further developed to include also vPvB-scoring and in the future probabilistic approaches. Also human health hazard classes could be included.

Members pointed out that the dataset of a substance and its alternative(s) might be very unequal in "real cases" and this may make the comparison difficult, e.g. when comparing possibly "information rich" SVHCs to possibly "information poor" alternatives. Furthermore, it was mentioned that the actual link needs to be established between the weighing of impact indicators to welfare relevant endpoints that are needed for SEA. The advantage of this presented approach to other earlier developed methods, such as eco system services, could be better explained.

The stakeholder observer from Eurometaux welcomed as well the presentation and stressed industries' effort to support further work made in closing the gap as it is needed for their authorisation dossiers. The stakeholder observer from Cefic noted many improvements in risk assessment at different occasions serving different processes (e.g. the ECHA workshop on dossier and substance evaluation in February 2012). He proposed to combine and coordinate all the initiatives taken in the different processes like authorisation and restriction but also evaluation in order to improve risk assessment in general.

b) Public information in the process of application for authorisation

The Secretariat presented the outcome of the consultation process with stakeholders from industry, NGO, and trade unions on what information needs to be published in the authorisation process and how the outcome was aligned to the ECHA values of transparency, independence, trustworthiness and efficiency.

Further information on these subjects was provided in the meeting documents a) (RAC/21/2012/12; SEAC/15/2012/06) on broad information on uses (BIU) and b) (RAC/21/2012/11; SEAC/15/2012/05) on elements of the opinion that will be published once an opinion is adopted.

RAC and SEAC members were supportive of the conclusions in the documents.

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

The Secretariat presented the content of the meeting document (RAC/21/2012/13; SEAC/15/2012/07) on the participation of case-owners and stakeholder observers (STOs) in the opinion development process on applications for authorisation (AfA).

The suggested approach takes into account the experience so far in the MSC. Furthermore, the complexity of the authorisation process (where each case is discussed eight or ten times in RAC and SEAC meetings) was highlighted as a consideration. For efficiency reasons and to ensure a smoothly running procedure, it is proposed that case-owners would participate in separate "hearings" in the AfA process, rather than in plenary meetings. These would be held about 6-7 weeks after the close of the consultation. Members and STOs concurred with this approach.

There is a desire to include STOs in Committees' work to ensure transparency and accountability. However, it was recognised that Confidential Business Information (CBI) is likely to be discussed in the plenary sessions. ECHA needs to ensure that such information is treated in a trustworthy manner so that the applicants will provide accurate information that is necessary for the Committees to form their opinions. For this reason, it was proposed that STOs should not participate in Committees' plenary sessions where specific cases are to be discussed. This policy would operate for a period of 18 months while the significance of CBI in cases and the necessary arrangements to manage it are assessed. In the interim, STOs would receive a non-confidential briefing in open session of the Committees' deliberations and any issues which had been raised.

RAC members pointed out that the AfA process is new to all and they thought that comments from observers have been valuable during the opinion making process in the past and this could also be the case in AfA.

Some RAC and SEAC members thought that the proposed approach was appropriate and well justified. It was also noted that STOs will primarily provide information on alternatives during public consultation.

Some STO pointed out that they are bound to signed declarations of confidentiality. Furthermore, they expressed a concern of opinions being adopted in a "black box" without providing an opportunity to contribute to the process.

The Secretariat replied that while understanding the arguments provided it will be essential for the good functioning of the process that CBI is not disclosed. The Secretariat also emphasised the need for equal treatment as well as the good independent functioning of the Committees to be ensured at all times. The Secretariat recognised the concerns expressed by STOs and some members.

Following the presentation at this plenary meeting, the document will be discussed at the Management Board in June 2012. ECHA will give a summary of the views expressed by the Committees at the meeting.

d) Pool appointment of (co-)rapporteurs for substances listed in Annex XIV

Members volunteered for (co-)rapporteurship during the meeting. The pool appointment of (co-)rapporteurs was agreed to be proceeded via written adoption due to time constraints.

9 AOB

a) News from the Nordic Exposure Group (human health, NEGh)

A RAC member informed about activities of the Nordic Exposure group (human health) and invited participants to the workshop taking place in Copenhagen, 25-26 September 2012.

10 Action points and main conclusions of RAC-21

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
From the 21st meeting of RAC
12 June – 15 June 2012

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The revised Agenda (**RAC/A/21/2012 rev. 1**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-21 minutes.
4. Report from other ECHA bodies and activities	
4.b Implementation of the Conflict of Interest Policy – Modification of the RAC Rules of Procedure	
RAC took note of the room document **(RAC/21/2012/02)**.	**SECR** to launch written procedure for agreement of room document (RAC/21/2012/02). If agreed by RAC via written procedure, **SECR** to submit the revised RoPs to the ECHA Management Board for approval.
4.c Co-opted members	
RAC discussed the need for co-opting additional members to the Committee based on Article 85(4) of REACH.	**SECR** to further develop the analysis of expertise needed for RAC tasks and to schedule a further discussion at a forthcoming RAC plenary meeting(s).
4.d Rules of procedure pursuant to Articles 110.1 & 110.4 of REACH on food safety and worker protection	
RAC was informed of the consultation on the room document **(RAC/21/2012/03)**.	**SECR** to collect comments from RAC in view of submission of the draft RoPs to the ECHA Management Board for discussion and possible adoption.
5. Requests under Article 77 (3)(c) - gallium arsenide	
5.a Gallium arsenide	
RAC discussed the revised draft opinion.	**Rapporteurs** to revise the draft opinion reflecting questions raised during the discussion and produce the revised draft opinion for consultation of RAC and discussion at RAC-22 (in accordance with the revised timetable). **SECR** to launch a commenting round on the revised draft opinion as soon as it is ready.
5.b Epoxiconazole	
RAC agreed to appoint (co-) rapporteurs for this mandate.	**SECR** to finalise the appointment procedure to reflect RAC appointments for

RAC discussed the procedure for the preparation of the opinion.	epoxiconazole. **SECR** to make the additional information report (AIR) available to rapporteurs and at RAC CIRCABC a soon as submitted by **IND** and to launch a public consultation on the AIR in accordance with agreed time table. **Rapporteurs** to prepare the first draft opinion in accordance with the mandate and comments received in PC for discussion at RAC-22.
5.c Non-classified phthalates (DINP and DIDP)	
The request to RAC for an opinion on this report was explained. The draft review report of ECHA evaluating new scientific evidence concerning DINP and DIDP was presented to RAC. RAC agreed to appoint a rapporteur for this mandate.	**SECR** to finalise the appointment procedure reflecting RAC appointments for a rapporteur for non-classified phthalates (DINP and DIDP). **Rapporteur** to prepare the first draft opinion for discussion at RAC-22.

6. CLH	
6.1 CLH dossiers	
a) Para-tert-butylphenol	
RAC adopted by consensus the opinion and its annexes on the CLH proposal on para-tert-butylphenol. RAC agreed to propose para-tert-butylphenol to be classified as indicated in table 1. below.	**Rapporteurs** to make editorial changes to the opinion according to members' comments during RAC-21 and to send the revised opinion to the SECR by 30 June at the latest. **SECR** to launch a short editorial commenting round as soon as revised opinion is received. **SECR** to forward the adopted opinion on para-tert-butylphenol and its annexes to COM and publish them on the ECHA website.
b) Penconazole	
RAC discussed effects on reprotoxicity. Other hazard classes, acute toxicity and environmental hazards, were already provisionally agreed at RAC-17 and RAC-18.	**SECR** to modify the opinion document in accordance with the discussion in RAC and to launch an editorial commenting round in RAC on the opinion document and to circulate it afterwards to RAC for adoption by written procedure before the deadline of 17 July 2012.
c) Benzoic acid	
RAC preliminarily agreed to classify benzoic acid as indicated in Table 2 below.	**Rapporteurs** to revise the draft OPBD in accordance with the discussion in RAC and to provide them to SECR.

	SECR to launch adoption of the opinion via written procedure.
d) 4-Vinylcyclohexene	
RAC discussed the evidence on carcinogenicity for the proposal to classify 4-vinylcyclohexene (VCH).	**Rapporteurs** to revise the draft opinion and its annexes in accordance with the discussion in RAC and to provide them to SECR. **SECR** to distribute the revised draft opinion documents to RAC for discussion at RAC-22.
e) Acrolein	
RAC adopted by consensus the opinion and its annexes with a proposal for the harmonised classifications as indicated in Table 1 below.	**SECR** to make an editorial check and consult with the rapporteurs as appropriate before forwarding the adopted opinion and its annexes to COM and publishing it on the ECHA website.
f) Ethephon	
This item was postponed.	
g) Styrene	
RAC discussed the draft opinion. RAC preliminarily agreed to classify styrene as indicated in Table 2 below.	**Rapporteurs** to revise the draft OPBD in accordance with the discussion in RAC and to provide them to SECR. **SECR** to launch adoption of the opinion via written procedure.
h) Fenoxycarb	
RAC discussed the draft OPBD. RAC preliminarily agreed to classify fenoxycarb as indicated in Table 2 below. No agreements were reached on the carcinogenicity classification, reprotoxicity or on the M-Factors for the aquatic hazard classification.	**Rapporteurs** to revise the draft OPBD in accordance with the discussion in RAC and to provide them to SECR. **SECR** to distribute the revised draft OPBD to RAC for discussion at RAC-22.
i) Cymoxanil	
Report back (debriefing) from the expert meeting.	**Rapporteurs** to revise the draft opinion and its annexes after the expert meeting if appropriate. **SECR** to distribute the revised draft opinion documents to RAC for discussion at RAC-22.
j) Tralkoxydim	
This item was postponed.	
k) Fluazinam	
RAC adopted by consensus the opinion and its annexes with a proposal for the harmonised classifications as indicated in Table 1 below.	**SECR** to make an editorial check and consult with the rapporteurs as appropriate before forwarding the adopted opinion and its annexes to COM and publishing it on the ECHA website.
l) Tetrahydrofurfuryl alcohol	

This item was postponed.	

6.2 Appointment of RAC (co-) rapporteurs for CLH dossiers	
Appointment of (co-) rapporteurs for the intended or submitted CLH proposals (listed in room document **RAC/21/2012/04**).	**SECR** to launch a written procedure to appoint (co-)rapporteurs. **SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for CLH proposals. **RAC members** are requested to come forward for the remaining proposals.
6.3 General and procedural CLH issues	
b) New approach for opinion development (Partly closed session)	
The framework for RAC opinion development (**RAC 21/2012/06**) was presented to RAC and discussed	**SECR** to accommodate in the Framework document the comments given by RAC. **SECR** to circulate via written procedure the Framework document to RAC for agreement.

7. Restrictions	
7.2 Restriction Annex XV dossier	
a) Phthalates – fourth version of the draft opinion	
RAC rapporteurs presented the draft opinion. RAC discussed the main changes made to the draft opinion of RAC. RAC adopted the opinion by consensus. RAC took note of the Background Document.	**Rapporteurs** to ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supportive documentation to COM and to publish them on the ECHA website.
b) Chromium VI – first version of the draft opinion	
RAC rapporteurs presented the first version of the draft opinion, the first Forum advice and comments received from the Committee members, through the public consultation and from the dossier submitter.	**Rapporteurs** to prepare written response to RAC members comments on the dossier. **SECR** to organise rapporteurs dialogue with DS's expert. **Rapporteurs** to prepare the 2nd 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 at RAC-22.
b) Dichlorobenzene – outcome of the conformity check	
RAC agreed that the dossier is in conformity with the Annex XV requirements and discussed the	**SECR** to compile the RAC and SEAC outcomes of the conformity check and to upload this to CIRCABC.

recommendation to the dossier submitter.	**Rapporteurs** to make the amendments to the recommendations based on comments received at RAC-21. **SECR** to inform DS on the decision. **SECR** to inform DS and the Commission on the Committees' recommendations. **SECR** to launch a public consultation on 19 June 2012. **SECR** to inform Forum on the decision and request its advice. **Rapporteurs** to prepare the 1st draft opinion in accordance with the procedure on opinion development.
7.3 Appointment of (co-)rapporteurs for restriction dossiers	
Appointment of (co-)rapporteurs for the Annex XV restriction dossier for 3 substances – nonylphenol; 4-nonylphenol, branched and nonylphenol ethoxylates (room document **RAC/21/2012/10***).*	**SECR** to launch a written procedure to appoint (co-)rapporteurs **SECR** to inform RAC as soon as the dossier is submitted to ECHA.

9.2 Appointment of RAC rapporteurs for substances listed in Annex XIV	
Agreement on the pool of (co-) rapporteurs for the substances listed in Annex XIV (room document **RAC/21/2012/14**).	**SECR** to launch a written procedure to appoint (co-)rapporteurs to the pool. **SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for substances listed in Annex XIV. **SECR** to inform RAC as soon as an application for authorisation is submitted to ECHA. **Members** may volunteer to be added to the pool of (co-) rapporteurs any time.

Item 10 – Action points and main conclusions of RAC-21	
	SECR to launch a written procedure to adopt action points.

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

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)		
	p-tert-butylphenol	202-679-0	98-54-4	**Skin Irrit. 2** Eye Dam. 1 Repr. 2	**H315** H318 H361f	GHS05 GHS08 Dgr	H315 H318 H361f			

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
	p-tert-butylphenol	202-679-0	98-54-4	Xi; **R38**-41 Repr. Cat. 3; R62	Xn, R: 38-41-62 S: (2-)26-36/37-39-46		

[1] Hazard classes, category and hazard statement codes are written in **bold** if agreed by RAC during the present meeting.

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)		
605-008-00-3	Acrolein; prop-2-enal; acrylaldehyde	203-453-4	107-02-8	Flam. Liq. 2 **Acute Tox. 1** **Acute Tox. 2** **Acute Tox. 3** **Skin Corr. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	H225 **H330** **H300** **H311** **H314** **H400** **H410**	GHS02 **GHS06** **GHS05** **GHS09** **Dgr**	H225 **H330** **H300** **H311** **H314** **H410**	EUH071	**Skin Corr. 1B; H314: C ≥ 0.1 %** **M = 100 (Acute)** **M = 1 (Chronic)**	**D**

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
605-008-00-3	Acrolein; prop-2-enal; acrylaldehyde	203-453-4	107-02-8	F; R11 **T+; R26/28** **T; R24** **C; R34** **N; R50**	F; **T+; N** **R: 11-24-26/28-34-50** **S: 23-26-28-36/37/39-45-61**	**N; R50: C ≥ 0.25%** **C; R34: C ≥ 0.1%**	**D**

Note D is defined in Annex VI, 1.1.3.1 of Regulation (EC) No 1272/2008

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)		
	Fluazinam		79622-59-6	**Acute Tox. 4** **Eye Dam. 1** **Skin Sens. 1A** **Repr. 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H332** **H318** **H317** **H361** **H400** **H410**	**GHS05** **GHS07** **GHS08** **GHS09** **Dgr**	**H332** **H318** **H317** **H361** **H410**		**Acute: M=10** **Chronic: M=10**	

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
	Fluazinam		79622-59-6	**Xn; R20** **Xi; R41** **R43** **Repr. Cat. 3; R63** **N; R50/53**	**Xn** **R: 20-41-43-50/53-63** **S: (2-)26-36/37-39-46-60-61**	**N; R50/53: C ≥ 2,5 %** **N; R51/53: 0,25 % ≤ C < 2,5 %** **R52/53: 0,025 % ≤ C < 0,25 %**	

Table 2. Proposed new or revised classification in Annex VI, CLP, preliminary agreed by RAC [4]

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)		
	Benzoic acid	200-618-2	65-85-0	Eye Dam. 1 **Skin Irrit. 2** **STOT RE 1 (lungs, inhalation)**	H318 **H315** **H372**	GHS05 GHS08 Dgr	H318 **H315** **H372**			

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
	Benzoic acid	200-618-2	65-85-0	**Xi; R38** R41 **Xn; R48/20**	**Xn** R: **38**-41-**48/20** S: to be completed when opinion is fully adopted		

[4] Hazard classes, category and hazard statement codes are written in **bold** if preliminary agreed by RAC during the present meeting.

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)		
601-026-00-0	Styrene	202-851-5	100-42-5	Flam. Liq. 3 **Repr. 2** Acute Tox. 4* Eye Irrit. 2 Skin Irrit. 2 **STOT RE 1 (nervous system, inhalation)**	H226 **H361d** H332 H319 H315 **H372**	GHS02 GHS07 **GHS08** **Dgr**	H226 **H361d** H332 H319 H315 **H372**		*	D

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
601-026-00-0	Styrene	202-851-5	100-42-5	R10 **Repr. Cat. 3; R63** Xn; R20 Xi; R36/38 **Xn; R48/20**	Xn R: 10-20-36/38-48/20-**63** S: (2-)23-**45-53**	Xn; R20: C ≥12.5% Xi; R36/38: C ≥12.5%	D

Note D is defined in Annex VI, 1.1.3.1 of Regulation (EC) No 1272/2008

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. 1B Repr. 2 ~~**STOT RE 2**~~ Aquatic Acute 1 Aquatic Chronic 1	H350 H361 ~~**H373**~~ H400 H410	GHS08 GHS09 Dgr	H350 H361 ~~**H373**~~ 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. 2; R49 Repr. Cat. 3; R63 N; R50/53 ~~**Xn ; R48/20**~~	T; N R: 49-50/53-63 S: to be completed	N; R50/53 C ≥ 25% N; R51/53 2,5% ≤ C < 25% R52/53 0,25% ≤ C < 2,5%	

Part III. List of Attendees of the RAC-21 meeting (12-15 June 2012)

Eight advisers, six stakeholder representatives (from Business Europe, Cefic, ECETOC, ECPA, Eurometaux and EuPC, nine observers accompanying stakeholder observers (STO), two representatives from the Commission, and the Croatian observer were welcomed by the Acting Chair.

For this meeting several participants took part in substance-related discussions as remote participants. This included two members, four RAC advisers, representatives of Member State Competent Authorities (MSCA) from Germany and Norway, and three Commission observers.

Members
ANDERSSON Alicja
BARANSKI Boguslaw
BARRON Thomasina
BJØRGE Christine
BORGES Teresa
Di PROSPERO FANGHELLA Paola
DUNAUSKIENE Lina
DUNGEY Stephen
GREIM Helmut
GRUIZ Katalin
HAKKERT Betty
JENSEN Frank
KADIKIS Normunds
LEINONEN Riitta
LOSERT Annemarie
LUND Bert-Ove
MULLOOLY Yvonne
OLTEANU Maria
PARIS Pietro
PICHARD Annick
PINA Benjamin
POLAKOVICOVA Helena
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SCHLUETER Urs
SCHULTE Agnes

ECHA staff
ANFÄLT Lisa
ATLASON Palmi
BARMAZ Stefania
BROECKAERT Fabrice
CALVO TOLEDO Juan Pablo
DE BRUIJN Jack
DUBOURG Richard
DVORAKOVA Dana
ERICSSON Gunilla
FUHRMANN Anna
HELLSTEN Kati
HONKANEN Jani
HUUSKONEN Hannele
KARJALAINEN Ari
KIOKIAS Sotirios
KIVELÄ Kalle
KLAUK Anja
KOKKOLA Leila
MERKOURAKIS Spyridon
LEFEVRE Remi
LIPKOVA Adriana
LUSCHÜTZKY Evita
MAGGIORE Angelo
MATTHES Jochen
KOSK-BIENKO Joanna
NICOT Thierry
NYGREN Jonas

SMITH Andrew	PELTOLA Jukka
SØRENSEN Peter	RIVERO Debora
SPETSERIS Nikolaos	RODRIGUEZ IGLESIAS Pilar
STASKO Jolanta	ROECKE Timo
STOLZENBERG Hans-Christian	ROGGEMAN Maarten
TADEO José Luis	SADAM Diana
TSITSIMPIKOU Christina	SIHVONEN Kirsi
Van der HAGEN Marianne	SOSNOWSKI Piotr
CURABA Mara (replacing Van Malderen Karen)	SPJUTH Linda
	VAINIO Matti
	Van HAELST Anniek
Advisers to the RAC members	
CITRO Lucia (adviser to Pietro Paris)	**SEAC**
DOBEL Shima (adviser to Frank Jensen)	BRIGNON Jean-Marc (SEAC member)
JANONYTE Agne (adviser to Lina Dunauskiene)	DALTON Marie (SEAC member)
Mc Garry Helen (adviser to Andrew Smith) and adviser supporting rapporteurs on the tetrahydrofurfuryl	FURLAN Janez (SEAC member)
MAHIOUT Selma (adviser to Riitta Leinonen)	GEORGIOU Stavros (SEAC member)
PAPPONEN Hinni (adviser to Riitta Leinonen)	SCHUCHTÁR-GREGORIK Endre (SEAC member)
SCHUUR Gerlienke (adviser to Marja Pronk)	VERHOEVEN Julia (SEAC adviser)
VIVIER Stéphanie (adviser to Annick Pichard) and adviser supporting rapporteurs on the fluazinam	
	Remote participants
Representatives of the Commission	MICHEL Cécile (replacing RAC member Elodie Pasquier)
GIRAL Anne (DG ENTR)	Van der HAGEN Marianne (RAC member)
SCAZZOLA Roberto (DG ENTR)	Van Malderen Karen (RAC member)
	GABBERT Silke, STARKE Sue-Martina (RAC advisers for Hans-Christian Stolzenberg)
Invited experts	McMICKAN Sinead (RAC advisor for Yvonne Mullooly)

NUNES Céu (Fenoxycarb co-rapporteur)	MURPHY Roseleen (RAC adviser for Yvonne Mullooly)
VILANOVA Eugenio (ptBP rapporteur)	LARSEN Ann-Kristin (a representative of the Norwegian CA following ptPB)
Stakeholder observers	STARK Christiane (a representative of the German CA following benzoic acid and penconazole)
ANNYS Erwin (Cefic)	
FRUITIER-POLLOTH Claudia (EuPC following phthalates)	**Excuses**
MEISTERS Marie-Louise (ECETOC)	BRANISTEANU Radu (RAC member)
ROWE Rocky (ECPA)	HALKOVA Zhivka (RAC member)
VEROUGSTRAETE Violaine (Eurometaux)	KAPELARI Sonja (RAC member)
VOLKER Soballa (Business Europe)	MICHEL Cécile (replacement for Elodie Pasquier)
	McKINLAY Rebecca (European Environmental Bureau)
Other observers	MUNARI Tomaso (EuCheMS)
VARNAI Veda (Croatian observer)	SEIDLE Troy (HIS, Eurogroup for animals)
BARNES Emma (an observer acting as an expert (Syngenta) to an observer representing ECPA for fenoxycarb, penconazole and tralkoxydim)	TAYLOR Katy (ECEAE)
BOMHARD Ernst (an observer acting as an expert (consultant) to an observer representing Eurometaux for GaAs)	**Absent**
GELBKE Heinz-Peter (an observer acting as an expert (GMX) to an observer representing Cefic for GaAs, styrene and VCH)	TROISI Gera
NOMURA Masanao (an observer acting as an expert (ISK Biosciences Japan) to an observer representing ECPA for fluazinam)	
PICCIRILLO Vincent J (an observer acting as an expert (VJP Consulting) to an observer representing Cefic for THFA)	
SARGINSON Nigel (an observer acting as an expert (ExxonMobil) to an observer representing Cefic for non-classified phthalates)	
SCHNEIDER Klaus (an observer acting as an expert (Fobig) to an observer	

representing Cefic for phthalates)		
WARREN Simon (an observer acting as an expert (DuPont) to an observer representing ECPA for cymoxanil)		
WESTPHALEN Karl-Otto (an observer acting as an expert (BASF) to an observer representing ECPA for epoxiconazole)		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-21 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-21 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-21 meeting

12 June 2012
RAC/A/21/2012_rev 1

Final Agenda

21st meeting of the Committee for Risk Assessment

12-15 June 2012
ECHA Conference Centre (Annankatu 18, Helsinki)
12 June: starts at 9:00
15 June: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/21/2012_rev 1
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

b) Report on RAC-20 action points, written procedure and other ECHA bodies

RAC/21/2012/01
For information

c) Implementation of the Conflict of Interest Policy - Modification of the RAC Rules of Procedure

RAC/21/2012/02
For agreement

d) Co-opted members

For discussion

e) Rules of procedure pursuant to Article 110 of REACH on food safety and worker protection

RAC/21/2012/03
Room document
For consultation

Item 5 – Requests under Article 77(3)(c)

a) Gallium arsenide

For discussion

b) Epoxiconazole

For information

c) Non-classified phthalates (DINP and DIDP)

RAC/21/2012/15
Room document
For information

Item 6 – Harmonised classification and labelling (CLH)

6.1 CLH dossiers

a) Para-tert-butylphenol
b) Penconazole
c) Benzoic acid
d) 4-Vinylcyclohexene
e) Acrolein
f) Ethephon
g) Styrene

For discussion and possible adoption

h) Fenoxycarb
i) Cymoxanil
j) Tralkoxydim
k) Fluazinam
l) Tetrahydrofurfuryl alcohol

For discussion

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

RAC/21/2012/04
For agreement

6.3 General and procedural CLH issues

a) State of play of CLH dossiers

RAC/21/2012/05
RAC/21/2012/07
Room documents
For information

b) New approach for opinion development (Partly closed session)

RAC/21/2012/08
Room document
For discussion

RAC/21/2012/06
For discussion and agreement

Item 7 – Restrictions

7.1 General restriction issues

a) Update on intended restriction dossiers

For information

b) Update on the review of the restriction process

For information

7.2 Restriction Annex XV dossiers

a) Phthalates – fourth version of the draft opinion

For discussion and possible adoption

b) Chromium VI – first version of the draft opinion

For discussion

d) Dichlorobenzene – outcome of the conformity check

For agreement

7.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/21/2012/10
Room document
For agreement

Item 8 – Authorisation

e) Report from the Den Haag workshop on Environmental Impact Assessment and future steps with regards to capacity building

For discussion

f) Public information in the process of application for authorisation

RAC/21/2012/11
RAC/21/2012/12
For discussion

g) Participation of case-owners and stakeholder observers in opinion development process (Closed session)

RAC/21/2012/13
Room document
For discussion

h) Pool appointment of (co-)rapporteurs for substances listed in Annex XIV

RAC/21/2012/14
For agreement

Item 9 – AOB

Item 10 – Action points and main conclusions of RAC-21

Table with conclusions and action points

For adoption

ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-21 meeting.

RAC/A/21/2012_rev 1	Final Draft Agenda
RAC/21/2012/01	Feedback from other bodies and activities (AP 4a)
RAC/21/2012/02	Revised RAC RoPs (AP 4b)
RAC/21/2012/03 Room doc	RoPs pursuant to Art 110 of REACH on worker protection (AP 4d)
RAC/21/2012/04	Appointment of RAC (co-) rapporteurs for CLH dossiers (AP 6.2)
RAC/21/2012/05 Room doc	State of play of CLH dossiers (AP 6.3a)
RAC/21/2012/06 Room doc	New approach for opinion development framework document (AP 6.3b)
RAC/21/2012/07 Room doc	Outlook table (AP 6.3a)
RAC/21/2012/08 Room doc	CLH opinion development - RCOM received from RAC/CARACAL (AP 6.3b)
RAC/21/2012/10 Room doc	Recommendation on the appointment of (co-) rapporteurs for Nonylphenol restriction dossier (AP 7.3)
RAC/21/2012/11 RAC/21/2012/12	Public information in the process of application for authorisation (AP 8b): - parts of the opinions that would be made public - broad information on uses
RAC/21/2012/13 Room doc	Participation of case-owners and stakeholder observers in opinion development process (AP 8c)
RAC/21/2012/14	Appointment of (co-)rapporteurs for substances listed in Annex XIV
RAC/21/2012/15 Room doc	AP 05.c_Recommendation for rap for restriction dossier RAC DINPDIDP Art 77

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ANNEX III

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

Name of participant	**Agenda item**	**Interest declared**[5]
RAC members		
Christine BJOERGE	P-tert-butylphenol (ptBP)	Dossier submitter
Stephen DUNGEY	Acrolein Tralkoxydim	Dossier submitter
Helmut GREIM	Epoxiconazole	He attended a workshop sponsored by BASF where epoxiconazole was discussed.
Frank JENSEN	Phthalates Chromium	Dossier submitter
Annemarie LOSERT	Fluazinam Cymoxanil	Dossier submitter
Peter Hammer SØRENSEN	Phthalates Chromium Styrene	Dossier submitter
Marja PRONK	Ethephon	Dossier submitter
Andrew SMITH	Acrolein Tralkoxydim	Dossier submitter
Hans-Christian STOLZENBERG	Penconazole Benzoic acid Fenoxycarb	Dossier submitter
Stakeholders		
ECETOC Marie-Louise Meisters	Cymoxanil	She is an employee at DuPont

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[5] Dossier submitter means (his or her institution's) participation in the preparation of the dossiers submitted by the MSCA.