RAC/M/20/2012

FINAL

07 May 2012

Minutes of the 20th meeting of the Committee for Risk Assessment (RAC-20) (06 March – 09 March 2012)

Part I Summary Record of the Proceedings

0. Welcome address

Pilar Rodriguez Iglesias, Acting Chair of the Committee for Risk Assessment, ECHA, welcomed participants to the meeting and gave the floor to the Executive Director of ECHA for his welcome address to RAC.

The Executive Director considered the Twentieth meeting of the Committee for Risk assessment as a landmark and highlighted the challenges for RAC due to the increasing workload. In his speech he acknowledged the great merits of RAC's work so far and highlighted in particular the increasing number of RAC opinions adopted on different REACH and CLP processes such as harmonised classification and labelling (CLH) and restrictions. The Executive Director stressed that the cooperation between RAC and SEAC is essential for restriction and authorisation applications.

The Executive Director informed about personnel changes in the Secretariat staff, including that of the Chair. In addition, he mentioned the efforts to improve the transparency and stakeholder involvement in the work of RAC and SEAC. He also highlighted ECHA's four strategic objectives and explained the related challenges for the coming years.

In his speech, the Executive Director also thanked the observers from the European Commission and the regular stakeholder observers for their participation in RAC meetings and urged them as before to fully comply with the ECHA Code of Conduct and the other RAC procedures

1 Welcome and apologies (cont.)

The Acting Chair welcomed a RAC member who was appointed in the December 2011 MB meeting and invited her to briefly introduce herself. The representatives from stakeholder observers as well as the experts accompanying them, the Commission and from Croatia, see Part III, were welcomed as well.

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 agenda (RAC/A/20/2012_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 interest to the Agenda

The Acting Chair asked the members and their advisers, as well as the observers, whether there were any conflicts of interest to be declared specific to the agenda items. Ten members declared potential conflicts of interest 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. Two stakeholder observers also declared potential conflicts of interest to the substance-related discussions. The documentation of the oral declarations of possible conflicts of interest of members and observers are recorded in these minutes in the attached table in Annex III.

4 Adoption of the minutes of RAC-19

RAC adopted the draft minutes of the RAC-19 meeting by written procedure before RAC-20. The minutes are available on the ECHA web site.

5 Administrative issues and information items

5.1 Report on RAC-19 action points, written procedures and other ECHA activities

The Secretariat informed the Committee on administrative issues as set out in room document RAC/20/2012/01.

The Acting Chair asked RAC to use the new declaration of interest template as agreed previously by RAC and the MB when filling in the annual declarations. The new template was presented and clarified further in detail by the Secretariat.

5.2 Report on the satisfaction survey

The Secretariat reported on the results of the satisfaction survey 2011. From RAC 15 out of 40 members, 3 stakeholder observers and 1 COM observer responded to the questionnaire.

Overall RAC members were satisfied with the support provided by the Secretariat and they provided suggestions concerning further improvement.

Stakeholder observers' answers varied from very satisfied to very dissatisfied. Ideas of issues for improvement were also provided.

6 Requests under Article 77(3)(c)

6.1 Gallium arsenide (reproductive toxicity)

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

The Commission observer informed RAC of a new request to ECHA pursuant to Art. 77(3)(c) related to gallium arsenide. In particular, the Commission informed that a note is being drafted asking for RAC assessment of the data provided by Eurometaux in December 2011 in relation to toxicity to reproduction of gallium arsenide. The Acting Chair specified that based on the note a new RAC mandate extending the current mandate on toxicity to reproduction would be prepared. It was also confirmed that the existing (co-)rapporteurs will take on board the new mandate.

The (co-)rapporteurs presented the first conclusions on the toxicity to reproduction of gallium arsenide based on data provided in the public consultation

on carcinogenicity of gallium arsenide. Also a re-assessment of some relevant studies already included in the original Background Document was provided.

The preliminary assessment suggests that there is evidence that in male rats the effects on testes, epididymal weights and spermatid counts, morphology and motility occurred in presence of other effects, especially in the lungs. Severe lung effects had been observed at lower concentrations than effects observed in the testes. This may suggest that hypoxia affects the male reproductive organs as a result of lung toxicity and that the testicular impairment due to GaAs exposure consequently should be considered to be secondary to the lung effects.

In the following discussion both scientific and procedural questions were raised.

Lung toxicity had already been recognised by RAC and had led to the proposed classification on STOT-RE (respiratory system) (RAC opinion, 25 May 2010). One member expressed the view that the presented preliminary re-assessment focused on the rat studies and 2 year studies whereas mice data were not addressed in sufficient detail, where it is less clear that hypoxia was involved. The (co-)rapporteurs confirmed that the results of the mice studies would also be considered in the draft opinion although the mice were less sensitive than the rat for effects on lungs and testis. Some members expressed the view that a potential link between gallium arsenide, lung effects, hypoxia, and testicular effects requires further analysis and justification.

The discussion also focused on how to best handle Art. 77(3)(c) requests. In some cases RAC is asked to assess certain studies or other information without having detailed summaries of the data available and an explanation of the relevance of the information for the classification. This imposes a significant burden on RAC, on (co-)rapporteurs and on the Secretariat. COM confirmed that the aim is to formulate requests under Art. 77(3)(c) in such a way that potential unnecessary burden is avoided. Secretariat stressed that it is the task of the submitter of the information to present detailed study summaries and to explain why the information is considered relevant for the classification[1].

In reply to a question from COM, a stakeholder observer confirmed that IND plan to update the registration dossier on gallium arsenide in coming months.

As a conclusion, the Acting Chair confirmed that the new mandate would be prepared following the request from COM and made available to RAC. The (co-)rapporteurs were invited to prepare a revised draft opinion based on the discussion and the new mandate for further discussion either via webex or at the next plenary meeting.

7 CLH

7.1 CLH dossiers

RAC was informed that the opinion on the CLH dossier for nitrobenzene was adopted by consensus before the meeting following a written procedure.

7.1.a P-tert-butylphenol (ptBP)

The Acting Chair welcomed an observer accompanying the CEFIC stakeholder observer.

The Acting Chair invited the (co-)rapporteurs to present the revised draft opinion on the CLH proposal.

[1] This is also envisaged in the *Framework for dealing with requests according to Art 77(3)(c)* agreed at RAC-10 which envisages **'Adequacy evaluation'** of the relevant documentation by the rapporteur and tasks the Secretariat to come back to the submitter to complete the documentation if needed.

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. The 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 meeting on respiratory tract irritation with STOT SE 3 H335 (CLP) and R37 (DSD) and on skin irritation with Skin Irritation 2 H315 (CLP) and R38 (DSD).

The data justifying the proposal on the other hazard classes was conclusive and did not require further discussion.

Concerning skin irritation, questions were raised about whether the substance should be classified for skin irritation or skin corrosion. Clear arguments and justification concerning the hazard class/category should be stated in the draft opinion. It was concluded to ask the dossier submitter for more details on the studies provided to be able to conclude on this hazard class.

Regarding respiratory tract irritation, the proposal justifies the classification mainly by two studies, a repeated dose toxicity study and an acute inhalation toxicity study with dust aerosol. The repeated dose toxicity study conducted by gavage reports on respiratory effects (e.g. noisy respiratory sound) following daily oral exposures to 200 mg/kg bw. The respiratory effects were not confirmed by histopathological examinations. The acute inhalation study reported signs of mucosal irritation and respiratory distress (audible respiration, gasping, and a decreased respiration rate) in rats exposed to dust aerosol with a concentration of 5600 mg/m3 (the median diameter of the dust is 3.6 μm).

Due to some uncertainty in the interpretation of effects seen in these two studies, and the fact that there were two other inhalation studies in the RAR that did not describe any irritating effects at all, RAC concluded that the classification of this hazard class is borderline..Some RAC members expressed doubts on the value for classification of the two other inhalation studies due to limitations in the study design, e.g. regarding the dose levels used.

Further scientific arguments supporting a classification named by RAC were a) that signs of irritation are clear and that in the high dose inhalation study two dead animals showed dark red or purple discoloration, and b) that an irritation of the respiratory tract seems suggestive considering the severe eye damage and skin irritation effects. Furthermore, the inventory for classification and labelling states that over 1000 notifications were received that classify for STOT SE 3, and the TC C&L agreed in its meeting in March 2006 to classify for R37 (DSD).

The arguments for not classifying were that only in two studies signs of irritation were reported. The dose was very high in one study and the other study was conducted by gavage that might have caused dust to enter the respiratory tract. Some members said that the effects seen in the inhalation study are likely to be due to the dust particles (physical/mechanical effect) rather than due to the substance itself. Some other members disagreed and said it could not be excluded that the effects seen were due to the substance. There was also a discussion on whether the CLP criteria for this hazard category require human data to classify. RAC considered the lack of human data secondary for the justification not to classify. Two RAC members stressed that the argumentation for why not to classify with STOT SE 3 – H335 should be focused on the high dose used in the inhalation study, and not on the lack of effects or the lack of human human data.

The Acting Chair thanked the (co-)rapporteurs and RAC for the discussion and concluded that RAC preliminarily agreed on the classification as indicated in table 2 of this document. It was also concluded that the (co-)rapporteurs would revise

the draft opinion based on the discussion for possible adoption either through written procedure or at RAC-21.

7.1.b 4-vinylcyclohexene (VCH)

The Acting Chair welcomed the adviser to the rapporteur and invited the (co-)rapporteurs to introduce the revised draft opinion on the CLH proposal submitted by France.

Currently there is for this substance no entry in Annex VI to the CLP Regulation.

RAC discussed the proposal to classify 4-vinylcyclohexene (VCH) for carcinogenicity. Concerning carcinogenicity, there was evidence for VCH treatment-related ovary tumours in female mice. Interpretation of findings of tumours in other tissues in rats and mice were hampered by the very high mortality seen in these studies.

Some RAC members supported the proposal to classify VCH as Carc. 1B and others proposed Carc. 2, recognizing that this is a borderline case. In a subsequent discussion following an *ad hoc* meeting the latter classification proposal was particularly emphasised based on the impression that the NTP studies gave little additional weight of evidence for other types of tumours due to the high mortality.

The available data for VCH were insufficient to enable classification for mutagenicity.

Concerning the mode of action, the human CYPs have been shown to capable of metabolising VCH to VCD *in vitro* (vinylcyclohexane diepoxide; classified in Annex VI to the CLP Regulation as Carc. 2) but whether there were relevant detoxification pathways in humans was not known.

The Acting Chair thanked the (co-)rapporteurs and invited members to comment on the draft opinion by 26 March. The (co-)rapporteurs were invited to revise the draft opinion and its annexes in accordance with the discussion in RAC and comments received from members, for further discussion via webex in view of possible adoption at the next plenary meeting.

7.1.c Penconazole (Closed session)

The Acting Chair informed RAC about the change in rapporteurship for penconazole. The rapporteur had resigned and the co-rapporteur took over the rapporteurship for the opinion. The Acting Chair invited the ECHA Secretariat to present the case.

The proposal being considered by RAC was to classify penconazole as Acute Tox.4, as Aquatic Acute 1, and as Aquatic Chronic 1 as proposed by the dossier submitter. RAC additionally added two M factors according to the 2nd ATP criteria. Concerning repeated dose toxicity, previous RAC discussions concluded not to classify for this hazard class. It was also indicated that during the discussion in RAC-17 the toxicity due to an impurity was raised but no relevant data were available.

During the discussion, one RAC member referred to the EFSA review on penconazole[2] in which the assessment suggested reprotoxicity (R62 and R63). Based on the discussion and available data RAC preliminarily agreed to classify penconazole for reproductive toxicity as Repr. Cat. 2.

[2] EFSA Scientific Report (2008) 175, 1-104. Conclusion on the peer review of penconazole. Link: http://www.efsa.europa.eu/en/scdocs/doc/s175r.pdf

The Acting Chair thanked RAC for the discussion and concluded to revise the draft opinion for RAC commenting round and further possible adoption by written procedure or at RAC-21.

7.1.d Proquinazid

The Acting Chair welcomed an observer accompanying the ECPA stakeholder observer.

The Acting Chair invited the (co-)rapporteurs to introduce the draft opinion revised on the basis of previous RAC discussions.

The dossier submitter proposed to classify proquinazid as Carc. 2 and Aquatic Acute 1 with an M-factor 1 and Aquatic Chronic 1 with an M-factor 10.

The draft opinion was adopted by consensus. The Acting Chair thanked the (co-)rapporteurs and the members for their work.

7.1.e Dioctyltin bis(2-Ethyhexyl mercaptoacetate)

The Acting Chair welcomed the representatives from the industry dossier submitter. The Acting Chair also welcomed an observer accompanying the CEFIC stakeholder observer.

The Acting Chair gave the floor to the dossier submitter, who presented their position for the hazard class reproductive toxicity of the substance, including the results of a recent in vivo study in rats. The dossier submitter presented a graphic displaying the various studies/endpoints compared to the dose levels administered in the various studies. An attempt was made to distinguish between dose descriptors (e.g. NOEL) and some effects (e.g. maternal toxicity). The dossier submitter also used the results of a recent in vivo study in rats and claimed that based on the outcome of the study, it would not be possible to identify maternal toxicity for lower administration doses. The dossier submitter indicated that the study should not be disregarded simply because it was not a full study report.

Then the Acting Chair gave the floor to the rapporteur who presented the findings in relation to the evidence provided during the opinion development process. Thymotoxicity indicates maternal (immuno-)toxicity, no other toxic effect or clinical sign of toxicity were reported. Strongest maternal thymotoxicity was found in rats, less in mice, but not reported for rabbits. However, mice and rabbits were sensitive to developmental toxicity. Thymus weight reduction of about 20% seen in rats was not considered severe enough to explain post-implantation losses and reduced pub viability.

The default assumption was that developmental effects are relevant for humans as no mode of action was identified indicating otherwise . Developmental effects were seen in three species at doses below or without maternal thymotoxicity. The developmental effects were therefore considered as direct effect rather than secondary.

Consequently, there would be evidence of developmental effects in three species, supporting the classification in Cat. 1B (H360D) and T; R61.

The classification in category 1B was supported by RAC members. The following discussion focussed on the hazard statement, namely whether the letter "D" was warranted because effects on fertility could be excluded. After some exchange of views it was finally concluded to assign the letter "D" and include a footnote to indicate that only developmental toxicity had been examined in detail, to be consistent with other RAC opinions.

In relation to the text of the draft opinion, it was agreed to expand on the justification for read-across, similar to the presentation of the issue in the

background document.

The Acting Chair thanked RAC for the discussion and concluded that the Secretariat is to perform an editorial check of the documents after the agreed amendments to the draft opinion text had been done, and to circulate the draft opinion afterwards to RAC for adoption via written procedure.

7.1.f Amidosulfuron

The Acting Chair welcomed the (co-)rapporteurs and invited them to give a presentation of the draft.

The substance is currently not in Annex VI CLP. The dossier submitter proposed a classification as Aquatic Acute 1, H400 with M=100, Aquatic Chronic 1, H410 with M=10. The (co-)rapporteurs recommended however a chronic M-factor of 100, in response to comments provided in the public consultation and after thorough evaluation of the available data.

RAC agreed with the aforementioned proposal and adopted the draft opinion by consensus.

The Acting Chair thanked the (co-)rapporteurs and the members for their work. She concluded that the Secretariat would edit the opinion documents in consultation with the (co-)rapporteurs, forward the opinion to COM and publish it on the ECHA website.

7.1.g Tebufenpyrad

The Acting Chair welcomed the representatives of the dossier submitter from the German Competent Authority (MS CA), who followed the discussions as remote meeting participants.

The Acting Chair also welcomed an observer accompanying the regular ECPA observer.

The Acting Chair invited the (co-)rapporteurs to present the draft opinion, including any changes following the comments received during RAC consultation.

In relation to repeated dose toxicity, it was proposed to classify the substance according to the CLP criteria, as STOT-RE 2, but not according to the DSD criteria, i.e. not as Xn; R48/22, because the effects seen in dogs would be above the cut-of of 150 mg/kg bw. This view was supported by RAC.

In relation to skin sensitisation, the discussion focused on the positive findings in the more rigorous maximisation test versus the negative outcome of the Buehler test. ECPA observer clarified that the induction dose in the negative Buehler test was 50% in olive oil. Although the results from the GPMT could justify Skin Sens. 1A, RAC was in favour of Skin Sens 1B based on a weight of evidence approach taking into account the negative Buehler test..

In relation to the aquatic classification, the proposal for Aquatic Acute 1 and Aquatic Chronic 1 (M-factor in both cases = 10) and for N; R50/53 (SCL ≥ 2,5%), was supported by RAC.

The Acting Chair asked RAC to adopt the opinion. RAC adopted the opinion by consensus.

The Acting Chair thanked the (co-)rapporteurs and the members for their work. She concluded that the Secretariat would edit the opinion documents in consultation with the (co-)rapporteurs, forward the opinion to COM and publish it on the ECHA website.

7.1.h 1,1',1''-nitrilotripropan-2-ol (TIPA)

The Acting Chair welcomed the German dossier submitter, who were following the discussion as remote meeting participants.

The Acting Chair invited the (co-)rapporteurs to give a presentation of the draft. TIPA is currently classified in Annex VI CLP as Eye Irrit. 2 (H 319) Aquatic Chronic 3 (H412). The proposal is to delete environmental classification: Aquatic Chronic 3 (H412). The (co-)rapporteurs supported the proposal of the dossier submitter.

The draft opinion was adopted by consensus: RAC agreed on keeping the classification as Eye Irrit. 2 (H 319) and on the proposal to remove the environmental classification Aquatic Chronic 3 (H 412).

The Acting Chair thanked the (co-)rapporteurs and the members for their work. She concluded that the Secretariat would edit the opinion documents in consultation with the (co-)rapporteurs, forward the opinion to COM and publish it on the ECHA website.

7.1.i Fluazinam

The Acting Chair welcomed an observer accompanying the regular ECPA observer. The Acting Chair also welcomed the adviser to the (co-)rapporteurs.

The Acting Chair invited the adviser to present, on behalf of the (co-)rapporteurs, the draft opinion including any changes following the comments received during RAC consultation.

In relation to acute toxicity, the proposal was for category 4 (inhalation; H332). It was clarified by some RAC members that EFSA had confirmed this classification earlier. RAC members expressed their support for this classification.

In relation to STOT-SE 3 (H335), RAC agreed not to classify for this hazard class.

In relation to EUH071 (additional labelling element), the proposal was that this would not be warranted because there were no signs of corrosivity in the acute toxicity inhalation study. This was supported by RAC.

In relation to skin irritation, some RAC members requested that skin irritation studies should be referred to in order to conclude on skin irritation, but not sub-chronic studies. The ECPA representative indicated that certain ECPA member companies could provide acute studies; one RAC member commented that a comment made during public consultation suggested the availability of a new study indicating Skin Irritation (cat. 2) but a study summary was not submitted. One RAC member stated that the data should normally suffice already as the proposal referred to a pesticide active substance. The Acting Chair clarified that since the dossier had passed the accordance check, RAC should develop an opinion, considering the data provided by the dossier submitter and during public consultation, but no new data that had come in afterwards. There was no conclusion drawn on whether classification of fluazinam as skin irritant is justified but it was argued that it may not be warranted because data of sufficient adequacy are lacking.

It was also discussed whether classification for repeated dose toxicity (STOT RE 1) is justified due to effects seen on liver and skin. Several RAC members supported this, but no conclusion was reached.

Regarding reproductive toxicity, some RAC members supported classification but no conclusion was reached at this meeting. Further details on incidences, percentages of the effects seen were requested, as well as a more detailed discussion on maternal toxicity. Also the fact that there are effects on the heads seen in two species was mentioned.

In relation to skin sensitisation, the discussion focused on category 1A. One RAC member requested the rapporteur to check the concentration for intradermal induction.

There was agreement on the preliminary classification for serious eye damage (Eye Dam. 1- H318).

There was a comment by a stakeholder observer that two forms of fluazinam are on the market, and the impurity profiles of these are different. Since the dossier submitter had argued that part of the effects seen is due to a specific impurity. RAC members replied to this comment, that the impurities are part of the substance and are evaluated within the substance; in case the substance has a harmonised classification, the manufacturers need to take into account the specific impurities of their own substance for their classification.

It was agreed that the (co-)rapporteurs should review and further develop the draft opinion document based on the discussions in RAC-20. The SECR is to distribute the revised draft opinion document to RAC when available.

7.1.j Benzoic Acid

The Acting Chair welcomed the dossier submitter representatives as remote participants and invited the (co-)rapporteurs to introduce the first draft opinion on the CLH proposal submitted by Germany.

Currently there is for this substance no entry in Annex VI to the CLP Regulation. The proposal from the dossier submitter relates to the hazard classes skin irritation and eye damage. The discussion also focused on classification for repeated dose toxicity (STOT RE 2 – H373, lungs, by inhalation).

RAC agreed that the data provided supports the classification of the hazard classes eye damage and STOT RE 2.

The human data provided as basis for the proposal to classify for skin irritation states that there is a solid record of erythema and oedema in human voluntaries. In the animal studies no effects of skin irritation were observed. No further criteria or guidance is provided in the context of CLP on how human data in general and effects specifically should be taken into account for classification.

The CLP criteria for skin corrosion/irritation (cat 1 corrosive, cat 2 irritant) were discussed.

Another RAC member mentioned concerning the human data that great care must be taken when evaluating it. It might contain uncertainties due to the purpose of the study and the history of the test persons in regard to contact with chemicals and other variable influences. Also, the selection of the test persons may be biased. More details (e.g. individual data, potential confounding factors) are required in order to take the studies into consideration.

An observer representing Business Europe noted that from his experience human data acquired in the context of testing cosmetic products is usually performed on groups of specifically susceptible persons in order to ensure the greatest safety. Some studies used as carrier solvents isopropanol that may cause more irritation than what could be expected from the test substance.

RAC agreed that further information on the human tests should be requested from the dossier submitter in order to conclude on this endpoint.

The Acting Chair thanked the (co-)rapporteurs for their presentation and invited members to provide their comments as soon as possible and (co-)rapporteurs to

update the draft opinion. RAC preliminarily agreed on the classification as in table 2 of this document.

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

RAC agreed to appoint the volunteers as (co-)rapporteurs for the intended or submitted CLH proposals as listed in room document RAC/20/2012/02.

7.3 General and procedural CLH issues

7.3.a State of play of the submitted CLH dossiers

The Acting Chair pointed to room document RAC/20/2012/08. No further questions were posed.

7.3.b Practicalities and ECHA's support in the new approach for opinion development

The Acting Chair invited the Secretariat to give a presentation about the opinion forming process.

In relation to the new approach, several RAC members noted that they would prefer to work with the opinion document only, and then afterwards copy and paste this to the background document. Others noted that based on their recent experience, they would be happy to work with the new approach.

Regarding the proposal to hold expert meetings on problematic issues identified following the PC, several comments were made. One RAC member noted that expert meetings might have to be conducted case by case, otherwise they would be too resource consuming. Another RAC member stated that expert meetings might include discussions about comments/data received during public consultation. However, where the issue was a wrong application of the CLP criteria, then no expert meeting was needed, but it should be rather up to SECR to clarify this. Further RAC members stated that more elaboration about the details was needed.

The Acting Chair indicated that a document on the aforementioned proposals for improving the process was being prepared for the forthcoming CARACAL meeting. The Secretariat clarified that the CARACAL document would also be provided to RAC. The Secretariat also pointed out that improvements in various elements in the opinion development process may be considered, in order to ensure robust opinions which do not need to be revisited after their adoption. An ECHA representative explained that it would be important to have some flexibility to adapt the process case by case.

It was finally concluded that further details would be provided to RAC after the meeting, in view of continuing discussion at the next meeting.

7.3.c Public C&L Inventory

The presentation was suspended, due to time constraints. The Acting Chair pointed to the presentation that had been uploaded on CIRCABC and to the ECHA website where various explanatory documents are available.

8 Restrictions

8.1 Restriction Annex XV dossiers

8.1.a Phthalates– second version of the draft opinion

The Acting Chair welcomed the SEAC (co-)rapporteurs, who followed this discussion as remote meeting participants. The Acting Chair also welcomed the Danish dossier submitter and an observer accompanying the regular CEFIC observer.

The RAC (co-)rapporteurs presented the second version of the draft opinion and the proposals made by a RAC informal group on "Hazard".

Regarding hazard assessment, the proposals presented concerned the selection of the relevant endpoint for this case, selection of the key studies and the N(L)OAEL (per phthalate) for DNEL derivation, the selection of the method to be used for dose addition and the selection of assessment factors to be applied in DNEL derivation.

RAC agreed that the method for dose addition used (HI, hazard index) is the most appropriate one. It was agreed that the starting point for dose addition is the lowest N(L)OAEL taking into account all reproductive effects (not only effects on the testis). Furthermore, RAC agreed on the key studies and N(L)OAELs for DNEL derivation.

Having reviewed the evidence submitted so far via public consultation, RAC agreed to change the absorption rates for DEHP from 50% to 70% in adults for the oral route. RAC discussed the assessment factor for the LOAEL to NOAEL extrapolation for DIBP and DBP and agreed that a factor of 3 is appropriate.

Considerable discussion took place on the subject of the assessment factors to account for interspecies differences since some comments from public consultation suggested that humans are not more sensitive than rats. RAC members discussed the evidence and agreed to keep the default assessment factor of 10 for interspecies differences, due to uncertainty in the information from marmosets and on metabolism. It was pointed out that the discussion on the sensitivity of humans versus rats needs to be clearly documented in the background document.

RAC agreed that no additional assessment factors for the derivation of DNELs relevant for the restriction proposal are needed.

Regarding exposure assessment, RAC proposed to use 50 mg dust intake for 6/7 years old instead of 100mg. It was agreed to use the total diet study as the most recent data for estimating the exposure via food (COT 2011). Agreement was expressed to use all 3 biomonitoring studies (Frederiksen, Koch & Wittasek) for estimating the exposure. Furthermore, RAC expressed support for the other suggestions from the (co-)rapporteurs regarding exposure assessment calculations.

Having considered the calculations of the risk characterisation ratios, RAC concluded that based on the available information there is a risk which should be reduced. In particular, biomonitoring data were considered by the members as very useful and in support of the conclusion. The samples were, however, taken before 2008, when the migration limit for food contact materials became applicable, and relate to *all* phthalate exposure sources (so also including sources not falling under the restriction proposal), both leading to possible overestimations. The end result may also be overestimated due to summation of the 95th percentiles of the individual phthalates. On the other hand the sample population might not be representative for all populations in Europe, which could potentially lead to underestimations. RAC members suggested that these uncertainties would be clearly communicated to SEAC and the policy makers. Some of the RAC members proposed to consider a more targeted restriction i.e. on two of the four phthalates or a ban on use of certain articles. Another member argued that to include all four would be in line with the similar MoA reasoning in

the proposal and in line with the opinion from other scientific committees on Toxicity and Assessment of Chemical Mixtures[3].

The (co-)rapporteurs briefly presented the discussion on the wording of the proposed restriction. It was suggested to consider a new wording of the proposed restriction based on a general ban on the placing on the market of all articles containing the four phthalates combined with general exemptions for articles a) solely used outdoors b) without prolonged contact to skin c) without any contact with mucous membranes. Adding an exhaustive list of exempted articles was considered not wise due to difficulties with deriving such list and keeping it up-to-date. It was indicated that while the wording had improved there is still room for interpretation and some terms introduced may need to be defined.

After some discussion, RAC was invited to provide any further comments on the revised wording by 30 March 2012 via CIRCABC Newsgroup. The Secretariat agreed to request the 2nd Forum advice on the basis of the wording discussed at RAC-20 (no later than 16 March 2012).

The (co-)rapporteurs were requested to prepare the third version of the draft opinion by 23 March 2012 in line with the RAC-20 recommendations and considering the comments of members submitted via CIRCABC Newsgroup on the 2nd version of the draft opinion. The dossier submitter was requested to revise the Background Document following the instructions of the RAC (co-)rapporteurs and taking into account the comments from the public consultation by 10 April 2012. The (co-)rapporteurs are expected to prepare the fourth version of the draft opinion by early May 2012.

8.1.b Chromium VI – outcome of the conformity check

The Acting Chair welcomed the SEAC (co-)rapporteurs and the Danish dossier submitter, who were following the discussion as remote meeting participants.

The Acting Chair invited the RAC (co-)rapporteurs to give a presentation on the outcome of the conformity check. The (co-)rapporteurs recommended to RAC to agree that the dossier conforms to the requirements of Annex XV of the REACH Regulation. They informed RAC that there was a consensus view of the RAC & SEAC (co-)rapporteurs and the ECHA Secretariat and no views to the contrary had been received by RAC members during the consultation period prior to RAC-20.

The (co-)rapporteurs also informed that they have a few recommendations to the dossier submitter, however, these should not affect the agreement of the Committee on conformity.

RAC agreed that the dossier is in conformity.

The Secretariat will inform SEAC on the RAC decision. After the SEAC decision on conformity, the Secretariat will compile the RAC and SEAC outcomes of the conformity check, upload this to CIRCABC and inform the dossier submitter on the decisions. The Secretariat will also inform the dossier submitter on the Committees' recommendations.

Provided that SEAC supports conformity in its meeting, the Secretariat will launch a public consultation on the restriction proposal on 16 March 2012.

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3 http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_consultation_06_en.htm

After the conformity check was completed, the dossier submitter presented the dossier in detail.

8.2 General restriction issues

8.2.a Update on intended restriction dossiers

The Secretariat briefly informed the RAC members on restriction dossiers foreseen for the near future. For year 2012 the following dossiers are foreseen:

- 1,4-Dichlorobenzene (DCB) prepared by ECHA; submission date April.
- Nonylphenol (3 substances in one dossier); prepared by Sweden; submission date foreseen in August but with information on possible delay.

8.2.b New mandate for RAC under Article 77.3 (c) concerning non-classified phthalates

The Acting Chair welcomed an accompanying the regular CEFIC observer for this point. RAC was informed about the preparation of a new mandate for RAC under Article 77.3 (c) concerning non-classified phthalates in entry 52 of Annex XVII.

The Secretariat explained that the two existing restriction entries 51 and 52 of Annex XVII concerning phthalates in toys and childcare articles contain a review clause that requires the Commission to re-evaluate the restrictions in the light of new scientific information. This has led to a first request from the Commission to ECHA to review the new scientific information in September 2009. In December 2010 ECHA has received a second request from the Commission to further evaluate new scientific evidence concerning the restrictions in Entry 52 of Annex XVII. ECHA is currently finalising a draft review report for two of the phthalates that required an in-depth assessment (DINP and DIDP). It was underlined that the review report is not an Annex XV restriction dossier.

The Executive Director will request RAC to peer review the draft report by the end of the year 2012. The mandate was told to be in preparation and could thus not yet be shared with the members. The expected date of submission of the draft to RAC is end of April, where after a public consultation is planned to be launched. RAC will be requested to give an opinion based on the draft report and the public consultation comments (no correction of the report – no BD). ECHA intends to finalise the review report taking into account the RAC opinion and the public consultation comments and send it to the Commission.

The Secretariat will distribute the new mandate to RAC. RAC members will be requested to express their interest in rapporteurship.

8.2.c Update on the review of the restriction process

The Secretariat reminded that the revision of the restriction process had been quite extensively discussed in the margins of the SEAC-13 meeting in December 2011. Three break-out groups had been organised with the involvement of two RAC members (on conformity check, on issues related to opinion development and on Background Document). A report summarising the discussions had been compiled and distributed to both RAC and SEAC at the end of January 2012. The Secretariat introduced a solution for the RAC involvement in the restriction process in months 10-12, as discussed and proposed within the SEAC-13 meeting. It was proposed that in months 10 and 11, the RAC (co-)rapporteurs would continue working with the SEAC (co-)rapporteurs and would also follow the public consultation on the SEAC draft opinion. In month 12, when SEAC finalises

its opinion, the RAC (co-)rapporteurs would inform RAC about this in the plenary meeting. If SEAC final opinion is unchanged, it would be stated in the meeting minutes that RAC takes note of that. If SEAC final opinion is changed, it would be stated in the meeting minutes that RAC takes note of that as well as any observations/comments as a result of that change would be provided. The Committee agreed with the proposal presented by the Secretariat.

RAC was informed about the proposals from an informal joint RAC-SEAC working group. The proposals were included in the RAC document distributed before the meeting. Two following points were discussed:

- How to document an opinion not supporting the restriction proposal?
- Prioritisation of recommendations during conformity check

Concerning how to document an opinion of RAC not supporting a restriction proposal. The working group proposed to draft statements (in a "comment box") above the section in the BD where the Committees are not supporting the conclusions in the sections.

Proposed approach can be difficult in case when the (co-)rapporteurs decide to add some information or correct calculation.

Similar situation is when the relevant information is splitted in different parts of BD. Some of the RAC members suggested not to change BD but supported additional boxes.

Concerning prioritisation of recommendations during conformity check, this included tentative priority setting for the RAC and SEAC meeting, when the outcome of the conformity check is discussed, but the final priority setting would be left for the (co-)rapporteurs.

- Revision of the restriction process in the Forum

RAC was informed on the revision of the restriction process in the Forum. To facilitate the cooperation and to improve the efficiency, the Forum proposes a more flexible approach by reducing the number of official Forum advices to one. Forum will be involved in the process from the beginning (start of PC) and Forum members would provide informal advice as often as necessary. The formal advice can be provided in the middle of discussion in the Committees (14-16 week) or close to the end before the adoption of RAC or SEAC opinion.

RAC was in favour of the second option that the Forum advice is provided in the end of the restriction procedure keeping in mind that the informal cooperation continues during the process.

Forum will consider RAC comments in further discussion and inform RAC about the final results.

Additionally RAC was informed that the Working Group (WG) on Enforceability of Restrictions is revising the guide for drafting Forum advice. RAC members provided comments to this revised version during the consultation period. The WG will meet on 21/03/2012 when the guide is expected to be finalised. The final results will be communicated to both Committees.

- Update on the project on improving the quality of future restriction dossiers

RAC was informed about the progress in the project on improving the quality of future restriction dossiers.

The Secretariat will screen possibilities for methodology development based on recent studies and past and current restriction cases. ECHA proposed also small changes to clarify the structure of the reporting format. In the near future ECHA will organise workshops for the MS CA - potential submitters.

The Secretariat will take note of the discussion under above mentioned bullet points and consider the appropriate way to document the conclusions. The update on any further work regarding the review of the restriction process will be given at the next RAC meeting in June 2012. RAC Members can apply the proposed approach for coming restriction dossiers.

9 Authorisation

9.1 Capacity building

9.1.a Common approach of RAC and SEAC in opinion development on Applications for Authorisation

The Secretariat presented the revised document on the common approach in opinion development on AfA (RAC/20/2012/06). The revision followed the comments from RAC and SEAC received on the draft document (RAC/20/2011/37) presented at RAC-19 and SEAC-13. The document developed by the Secretariat and consulted with the Commission describes how to deal during the opinion development on authorisation applications efficiently with issues identified in earlier discussions.

RAC preliminarily agreed to the document, subject to agreement in SEAC following the inclusion of a comment from a RAC member for an editorial improvement in chapter 3 on the approach to missing or inadequate information.

9.1.b Preparation for first authorisation applications (substances and uses) (closed session)

In the context of the capacity building program, the Secretariat provided RAC with an information package on the SVHC substance DBP with the aim to get members familiar with the available information on Annex XIV substances before the first applications are received, to discuss the usefulness of that information and to establish work practices for future substances.

The information package contained an IUCLID dossier and the chemical safety report (CSR) of a registration of DBP as well as documents from the SVHC prioritisation/Annex XIV recommendation process and the EU risk assessment report.

Following the Secretariat's introductory presentation three break out groups were formed in order to better facilitate the discussions based on three questions:

#1: How useful is this type of data to get more familiar with Annex XIV substances?

#2: to what extend could ECHA compile additional information from other sources?

#3: Any idea for the establishment of work practice for future substances?

Conclusion

The information was considered useful and a good starting point to get familiar with the substance and to get a common understanding among members.

However, as it contains already several hundred pages of information, no further generic information is required. In fact too much information was considered useless. Additional background information should only be provided on a case by case basis.

RAC members expressed that it would be helpful to get the information in a condensed and extracted form that focuses on key information on uses, exposures and hazards of alternatives. Also presentations about data assessed in the previous steps of the authorisation procedure by the MSC (member state committee) were considered as another possible valuable contribution to the capacity building, in the future.

As information on alternatives is only very scarcely described in the information package and the information from public consultation on possible alternatives will be received only once an application arrived, it was considered useful by some RAC members to get a package on possible alternatives before an application is received. The ECHA Secretariat pointed out that it would not normally be possible to prepare such a package.

RAC members pronounced also the synergy effect attributed to information from one substance or from one use to another. A communication pool ensuring the information flow and collaboration between the groups on substances, hazards and exposure installed on CIRCA were considered important.

The Secretariat replied to consider the various suggestions and to develop a proposal on how to follow-up and to update the capacity program accordingly, if necessary.

This session was closed, because the basis for discussion contained parts of a registration dossier, which is confidential. The Acting Chair provided in the following open session a summary of the closed one.

The ETUC representative mentioned that the Secretariat should ensure as much as possible the ECHA value of transparency and suggested that, in the future, the justification for a closed session should systematically be provided in advance to the meeting, e.g. with the draft Agenda.

The Acting Chair thanked the presenters and the RAC members for the discussions.

9.2 Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications

The Secretariat presented the document (RAC/20/2012/07) for agreement.

RAC members mentioned that this document states clearly in which tasks the Secretariat will support the (co-)rapporteurs. This clear description should be taken as an example and applied in the currently changing new approach of CLH opinion development and in the revision of the restriction process.

RAC members preliminarily agreed on the document, subject to agreement in SEAC.

Other general authorisation topics: registration dossiers for new substances on Annex XIV

RAC was informed about the amount of registration dossiers for non intermediate uses received so far by ECHA for the eight new substances which were added to Annex XIV of REACH in February 2012. The numbers can be read as a first indicator to the potential for receiving applications for authorisations for these substances, but must be read with great care when trying to estimate the actual amount of applications to be received, due to various factors that are not reflected in the figures which were presented (e.g. possible applications for uses below the registration threshold of 1t/y, reasons for prioritising certain

substances of a group for authorisation, potential variations in the assessment of the intermediate status of certain uses).

10 Guidance issues

10.1 Update on guidance activities and report from the workshop on the concept of "rapid" removal"

The Acting Chair explained that new guidance developments are under way. She informed RAC that on 8 February 2012, ECHA had organised a workshop to clarify the validity of the use of the concept of "rapid removal" of metals from the water column.

The Acting Chair invited the Guidance and Forum Secretariat to give a presentation about the outcome of the workshop and ongoing and planned guidance developments. During the presentation it became clear that various guidance projects would require the involvement of RAC.

11. Any other business

The Acting Chair gave the floor to COM to explain the possible new Article 77.3.c request concerning the evaluation of technical aspects of the OECD test guidelines on extended one generation reproductive toxicity studies. Several RAC members questioned the background of the announced Article 77.3.c request and expressed their concern about possible overlap between work already done at several (inter)national expert groups dealing already with the extended one generation reproductive toxicity studies and/or the work done within the MSC. One RAC member wanted to have clarification whether background documentation would be delivered together with the Article 77.3.c request. Another RAC member indicated that this is an important overarching topic that requires specialists to provide meaningful input. Such specialized input on important questions of general scientific nature can be requested via Article 76.3. In view of the fact that there is already an EU expert group on this topic it was recommended to ask this group, in accordance with Art 76.3.

COM explained that at this stage no further details could be given, but that the request will be tailored upon the RAC's mandate and should not cover work already done in other fora. The Acting Chair summarised the discussion and mentioned that the Article 77.3.c request was announced at the meeting with the intention for RAC to already take note of the new request. More clarification will be given to RAC once the Article 77.3.c request is received by ECHA.

RAC was informed of a scheduled joint BAUuA/BfR Workshop, 29 March 2012 in Berlin, on how to address article 57(f) on non-endocrine disrupting human health hazards leading to SVHC identification.

12. Main conclusions and Action Points of RAC-19

The Secretariat presented the main conclusions and action points of the plenary meeting for final comments and agreement by the Committee. As by the end of the session the necessary quorum for adoption of the action points could not be reached, the Acting Chair clarified that under these circumstances, adoption of the action points document would have to be done through written procedure which would be launched immediately after the meeting.

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23 March 2012

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted by written procedure on 23 March 2012)
06 March - 09 March 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/20/2012_rev. 1) was adopted.	**SECR** to upload the adopted agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-20 minutes.
3. Declarations of conflicts of interest to the Agenda	
10 members and 2 STO observers have declared interests in different substance-related items of the agenda.	
5. Administrative issues and information items	
5.1 A report on RAC-19 action points, written procedures and other ECHA bodies was presented.	
6. Requests under Article 77 (3)(c) - gallium arsenide	
6.1 Gallium arsenide (reproductive toxicity)	
RAC was informed on a forthcoming mandate extending the current mandate pursuant to Art. 77(3)(c). Accordingly, RAC will be asked to consider data related to toxicity to reproduction sent by industry to ECHA in December 2011. RAC Rapporteurs presented the first conclusions based on data related to reproductive toxicity provided in the public consultation on carcinogenicity of gallium arsenide.	**SECR** to circulate the extended mandate within RAC. **Rapporteurs** to evaluate the new information and to prepare draft opinion to be discussed by RAC.
7. CLH	
7.1 CLH dossiers	
7.1.a p-tert-butylphenol (ptBP)	

RAC preliminarily agreed on individual classifications as displayed in table 2 below.	**RAPs** to revise the draft opinion document according to the RAC discussions. **SECR** to distribute the revised draft opinion document to RAC when available for adoption either by written procedure or at the RAC-21 plenary meeting.
7.1.b 4-vinylcyclohexene (VCH)	
RAC discussed the proposal to classify 4-vinylcyclohexene (VCH) for carcinogenicity.	**RAC members** to express further views on the carcinogenicity classification by Monday, 26 March. **Rapporteurs** to revise the draft opinion and its annexes in accordance with the discussion in RAC and comments received and to provide them to SECR. **SECR** to distribute the revised draft opinion documents to RAC when available for discussion during the next webex meeting.
7.1.c Penconazole (Closed session)	
RAC preliminarily agreed on the classification of Penconazole as Repr. 2. It was agreed that effects on fertility and a corresponding change of the hazard statement will be tabled for discussion at RAC-21. Other hazard classes, i.e. acute toxicity and environmental hazards, were already provisionally agreed at RAC-17. The preliminarily agreed classifications are indicated in table 2 below.	**SECR** to edit the opinion document in consultation with the Rapporteur, to launch an editorial commenting round in RAC on the opinion document and to circulate it afterwards to RAC for adoption at RAC-21.
7.1.d Proquinazid	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for Proquinazid. RAC agreed on the classification as indicated in table 1 below.	**SECR** to edit the opinion document in consultation with the Rapporteur. **SECR** to upload the opinion document including its annexes to RAC CIRCABC, to forward it to COM and publish it on the ECHA website.
7.1.e Dioctyltin bis(2-Ethyhexyl mercaptoacetate)	
RAC agreed on the classification of Dioctyltin bis as Repr. 1B (H360D), see also table 2 below.	**RAP** to expand on the justification for the read-across in the opinion document. **SECR** to perform an editorial check of the opinion document and to circulate it afterwards to RAC for adoption by Written Procedure.
7.1.f Amidosulfuron	
RAC adopted by consensus the	**SECR** to edit the opinion document in

opinion including its annexes on the CLH proposal for Amidosulfuron. RAC agreed on the classification as indicated in table 1 below.	consultation with the Rapporteur. **SECR** to upload the opinion document including its annexes to RAC CIRCABC, to forward it to COM and publish it on the ECHA website.
7.1.g Tebufenpyrad	
RAC adopted <u>by consensus</u> the opinion including its annexes on the CLH proposal for Tebufenpyrad. RAC agreed on the classification as indicated in table 1 below.	**SECR** to edit the opinion document in consultation with the Rapporteur. **SECR** to upload the opinion document including its annexes to RAC CIRCABC, to forward it to COM and publish it on the ECHA website.
7.1.h 1,1',1''-nitrilotripropan-2-ol (TIPA)	
RAC adopted <u>by consensus</u> the opinion including its annexes on the CLH proposal for TIPA. RAC agreed on the classification as indicated in table 1 below.	**SECR** to edit the opinion document in consultation with the Rapporteur. **SECR** to upload the opinion document including its annexes to RAC CIRCABC, to forward it to COM and publish it on the ECHA website.
7.1.i Fluazinam	
RAC preliminarily agreed on individual classifications as displayed in table 2 below. It was also agreed not to classify as STOT SE 3 – H335, and not to add the additional labelling with EUH071. RAC agreed to continue the discussion at upcoming webex/RAC meetings.	**RAPs** to review the opinion document based on the discussions at RAC-20. **SECR** to distribute the revised draft opinion documents to RAC when available for the second commenting round.
7.1.j Benzoic Acid	
RAC preliminarily agreed on the classification as STOT-RE 2 (H373) and Eye Dam. 1 (H318), see also table 2 below.	**RAPs** to review the opinion document based on the discussion at RAC-20. **SECR** to distribute the revised draft opinion document to RAC when available for the second commenting round.
7.2 Appointment of RAC (co-) rapporteurs for CLH dossiers	
RAC agreed to appoint the volunteers as (co-) rapporteurs for the intended or submitted CLH proposals (listed in room document RAC/20/2012/08).	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for CLH proposals after the meeting.
7.3 General and procedural CLH issues	
7.3.a State of play of the submitted CLH dossiers	
For information only.	
7.3.b Practicalities and ECHA's support in the new approach for opinion	

development	
RAC welcomed the proposal for streamlining the CLH process in general and the RAC opinion development in particular. Further discussion will take place at the next meeting.	**SECR** to provide further details in a document on the proposals for improving the opinion development process to RAC.
8. Restrictions	
8.1 Restriction Annex XV dossiers	
8.1.a Phthalates– second version of the draft opinion	
RAC rapporteurs presented the second version of the draft opinion and the proposals made by the RAC Informal Group on Hazard regarding relevant hazard issues. Regarding hazard assessment, RAC agreed on the method for the dose addition and the endpoint relevant in this case, key studies and N(L)OAELs relevant for DNEL derivation and related assessment factors as well as the absorption rates via oral route. Regarding exposure assessment, RAC suggested the dust intake assumptions and biomonitoring studies to base the assessment on and agreed to all the other proposals suggested by the RAC rapporteurs regarding exposure assessment. RAC concluded that based on the available information, there is a risk which should be reduced.	**Rapporteurs** to prepare the third version of draft opinion by 23 March 2012 in line with the RAC-20 recommendations and considering the comments of members submitted via CIRCABC Newsgroup on 2nd version of draft opinion. **RAC members** to comment on the new restriction proposal wording by 30 March 2012 via CIRCABC Newsgroup. **SECR** to request the 2nd Forum advice (to be requested no later than 16 March 2012). **Dossier submitter** to revise the BD following the instructions of RAC rapporteurs and taking into account the comments from public consultation by 10 April 2012. **Rapporteurs** to prepare the fourth version of draft opinion by early May 2012.
8.1.b Chromium VI – outcome of the conformity check	
RAC agreed that the dossier is in conformity.	**SECR** to inform SEAC on the RAC decision. **SECR** to compile the RAC and SEAC outcomes of the conformity check and to upload this to CIRCABC. **SECR** to inform DS and the Commission on the decision. **SECR** to inform DS and the Commission on the Committees' recommendations. **SECR** to launch a public consultation on 16

	March 2012.
8.2 General restriction issues	
8.2 a Update on intended restriction dossiers	
For information only.	
8.2.b New mandate for RAC under Article 77.3 (c) concerning non-classified phthalates	
RAC was informed about the preparation of a new mandate under Article 77.3 (c) concerning non-classified phthalates.	**SECR** to distribute the new mandate to RAC. **Members** to express their interest in rapporteurship.
8.2.c Update on the review of the restriction process	
RAC was informed about the proposal of the Working Group how to document an opinion of RAC not supporting a restriction proposal and how to prioritise recommendations during conformity check. The proposals are also included in the RAC document distributed before the meeting. RAC was informed about the progress in the project on improving the quality of future restriction dossiers.	**SECR** to take note of the discussion and consider the appropriate way to document the conclusions. The update on any further work regarding the review of the restriction process will be given at the next RAC meeting in June 2012. **Members** can apply the proposed approach for coming restriction dossiers.
9 Authorisation	
9.1 Capacity building	
9.1.a Common approach of RAC and SEAC in opinion development on applications for authorisation	
RAC preliminarily agreed to the concepts provided in the document (**RAC/20/2012/06**) which was presented at RAC-20. Proposals following RAC-19 and SEAC-14 discussions were implemented in document **RAC/19/2011/37**.	**SECR** to upload to the RAC CIRCABC, the document once agreed in SEAC next week.
9.1.b Preparation for first authorisation applications (substances and uses) (Closed session)	
In three breakout groups RAC discussed the usefulness of the information package provided by the SECR on one of the Annex XIV substances, possible additional	**SECR** to establish substance folders on CIRCABC, to which relevant substance specific information will be uploaded. **SECR** to consider the suggestion made by

information and ideas on work practice for future substances.	RAC (e.g. condensed, extracted key information, uploading to the RAC CIRCABC the information package for other relevant Annex XIV substances, substance specific presentations, WS ECHA industry including RAC, establish RAC expert groups, information on alternatives) and to update the capacity program if relevant in order to better organise the next months.
9.2 Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications	
RAC preliminarily agreed to the document prepared by SECR including to the proposed modifications.	**SECR** to submit the revised document to SEAC for agreement.
10. Guidance issues	
10.1 Update on current and forthcoming guidance projects	
SECR informed RAC about ongoing and forthcoming guidance projects and about the outcome of the workshop on rapid removal of metals from the water column (held 8 Feb 2012 in ECHA).	
11. AOB	
COM informs RAC about a forthcoming note requesting RAC to deliver an opinion, in accordance with REACH Article 77(3)(c), on the usability and applicability of information generated by the extended one generation reproductive toxicity study (EOGRTS). SECR informs that a rapporteur needs to be appointed after the new mandate has been received.	**SECR** to provide RAC with the text of the mandate when this is available.
RAC was informed about a workshop to address REACH Article 57(f) on non-endocrine disrupting human health hazards leading to SVHC identification, to take place in Berlin on 29 March 2012.	
GENERAL	
	SECR to upload all presentations, room documents and the Main conclusions and action points document for RAC-20 to RAC CIRCABC without delay after adoption of the action points document by Written Procedure after the meeting.

Table 1. List of adopted classifications by RAC[1]

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 state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statemen t Code(s)		
n/a	Tebufenpyrad (ISO); N-(4-tert-butylbenzyl)-4-chloro-3-ethyl-1-methyl-1H-pyrazole-5-carboxamide	-	119168-77-3	**Acute Tox. 3 Acute Tox. 4 Skin Sens. 1B STOT RE 2 (Gastro-intestinal tract, Oral) Aquatic Acute 1 Aquatic Chronic 1**	**H301 H332 H317 H372 H400 H410**	**GHS06 GHS09 Dgr**	**H301 H332 H317 H372 H410**		**M (acute) = 10 M (chronic) = 10**	

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

				Classification	Labelling	Concentration Limits	Notes

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

Index No	**International Chemical Identification**	**EC No**	**CAS No**				
n/a	Tebufenpyrad (ISO); N-(4-tert-butylbenzyl)-4-chloro-3-ethyl-1-methyl-1H-pyrazole-5-carboxamide	-	119168-77-3	**Xn, R20/22 R43 N, R50/53**	**Xn; N R: 20/22-43-50/53 S: (2)-24-37-46-60-61**	**N; R50/53: C ≥ 2.5 % N; R51/53: 0.25 % ≤ C < 2.5 % R52/53: 0.025 % ≤ C < 0.25 %**	

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 state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	1,1',1''-nitrilotripropan-2-ol; triisopropanolamine	204-528-4	122-20-3	**Eye Irrit. 2 ; ~~Aquatic Chronic 3~~**	**H319 ~~H 412~~**	**GHS07 Wng**	**H319 ~~H 412~~**			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	1,1',1''-nitrilotripropan-2-ol; triisopropanolamine	204-528-4	122-20-3	**Xi; R36 ~~R52-53~~**	**Xi R36-~~52/53~~ S: (2-)26-~~61~~**		

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 state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	Amidosulfuron	407-380-0	120923-37-7	**Aquatic Acute 1** **Aquatic Chronic 1**	**H400** **H410**	**GHS09** **Wng**	**H410**		**M (acute) = 100** **M (chronic) = 100**	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Amidosulfuron	407-380-0	120923-37-7	**N; R50/53**	**N** **R50/53**	**N, R50/53: C ≥ 0.25%** **N, R51/53: 0.025% ≤ C < 0.25%** **R52/53: 0.0025% ≤ C <0.025%**	

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 statement Code(s)	Suppl. Hazard statement Code(s)		
	Proquinazid	-	189278-12-4	**Carc. 2 Aquatic Acute 1 Aquatic Chronic 1**	**H351 H400 H410**	**GHS08 GHS09 Wng**	**H351 H410**		M (acute) = 1 M (chronic) = 10	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Proquinazid	-	189278-12-4	**Carc Cat 3; R 40; N; R50-53**	**Xn; N R: 40-50/53 S: (2-)36/37-46-60-61**		

Table 2. List of preliminary RAC agreements on proposals for harmonised classification and labelling[5]

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 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**			

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

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, **Xi** **R:** 38-**41-62** **S: (2-)26-36/37-39-46**		

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

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 state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard stateme nt Code(s)		
	Penconazole (1-[2-(2,4-dichloro-phenyl)pentyl]-1H-1,2,4-triazole)	266-275-6	66246-88-6	Acute Tox. 4 **Repr. 2** Aquatic Acute 1 Aquatic Chronic 1	H302 **H361** H400 H410	GHS07 **GHS08** GHS09 Wng	H302 **H361** H410		M (acute) = 1 M (chronic) = 1	

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Penconazole (1-[2-(2,4-dichloro-phenyl)pentyl]-1H-1,2,4-triazole)	266-275-6	66246-88-6	Xn; R22 N; R50/53 **T; R63**	R: 22-50/53-63 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%	

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 state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	Dioctyltin bis(2-ethyhexyl mercaptoacetate)	239-622-4	15571-58-1	**Repr. 1B**	**H360D**	**GHS08 Dgr**	**H360D**			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Dioctyltin bis(2-ethyhexyl mercaptoacetate)	239-622-4	15571-58-1	**Repr. Cat 2; R61**	**T R: 61 S: 45-53**		

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 statement Code(s)	Suppl. Hazard statement Code(s)		
	Fluazinam		79622-59-6	**Acute Tox. 4** **Eye Dam. 1**	**H332** **H318**	**GHS07** **Wng**	**H332** **H318**			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Fluazinam		79622-59-6	**Xn; R20** **Xi; R41**	**Xn** **R: 20-41** S: to be completed when the opinion is adopted in full		

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 statement Code(s)	Suppl. Hazard statement Code(s)		
	Benzoic acid	200-618-2	65-85-0	**Eye Dam. 1** **STOT RE 2**	**H318** **H373**	**GHS05** **GHS08** **Dgr**	**H318** **H373**			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Benzoic acid	200-618-2	65-85-0	**Xi; R41** **Xn; R48/22**	**Xn, Xi** **R: 41-48/22** S: to be completed when the opinion is adopted in full		

Part III. List of Attendees of the RAC-20 meeting (6-9 March 2012)

Twelve advisers, eight stakeholder representatives (from Business Europe, CEFIC, ECETOC, ECPA, EuCheMS, ETUC, Eurometaux and European Environmental Bureau), nine observers accompanying stakeholder observers (STO), one industry dossier submitter, four 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 SEAC members, four RAC advisers, representatives of Member State Competent Authorities (MSCA) from Denmark, Germany, the Netherlands, Norway and UK, and five Commission observers.

Members		**ECHA staff**
ANDERSSON Alicja		ANFÄLT Lisa
BARANSKI Boguslaw		ATLASON Palmi
BARRON Thomasina		BROECKAERT Fabrice
BJØRGE Christine		CALVO TOLEDO Juan Pablo
BORGES Teresa		CSÁK Viktória
Di PROSPERO FANGHELLA Paola		DE BRUIJN Jack
DUNAUSKIENE Lina		DVORAKOVA Dana
DUNGEY Stephen		ERICSSON Gunilla
GREIM Helmut		FUHRMANN Anna
GRUIZ Katalin		HELLSTEN Kati
HAKKERT Betty		HLADE Anja
HALKOVA Zhivka		HONKANEN Jani
JENSEN Frank		KARJALAINEN Ari
KADIKIS Normunds		KIOKIAS Sotirios
LEINONEN Riitta		KIVELÄ Kalle
LOSERT Annemarie		KLAUK Anja
LUND Bert-Ove		KOKKOLA Leila
MULLOOLY Yvonne		LEBSANFT Joerg
NUNES Céu		LEFEVRE Remi
OLTEANU Maria		LIPKOVA Adriana
PARIS Pietro		LUSCHÜTZKY Evita
PASQUIER Elodie		MAGGIORE Angelo
PICHARD Annick		MATTHES Jochen
PINA Benjamin		MOSSINK Jos
POLAKOVICOVA Helena		NICOT Thierry

PRONK Marja		NYGREN Jonas
RUCKI Marian		PELTOLA Jukka
SCHLUETER Urs		RODRIGUEZ IGLESIAS Pilar
SCHULTE Agnes		ROECKE Timo
SMITH Andrew		ROGGEMAN Maarten
SOERENSEN Peter		SADAM Diana
STASKO Jolanta		SCHÖNING Gabi
STOLZENBERG Hans-Christian		SIHVONEN Kirsi
TADEO José Luis		SOSNOWSKI Piotr
TROISI Gera		SPJUTH Linda
Van der HAGEN Marianne		VAINIO Matti
Van MALDEREN Karen		Van HAELST Anniek
Advisers to the RAC members		**Stakeholder observers**
BOGERG Julie (adviser to Frank Jensen)		ANNYS Erwin (Cefic)
CARVALHO João (adviser to Céu Nunes) and adviser supporting rapporteurs on TIPA		McKINLAY Rebecca (EEB)
DOBEL Shima (adviser to Frank Jensen)		MEISTERS Marie-Louise (ECETOC)
HOFER Tim (adviser to Marianne van der Hagen) and and adviser supporting rapporteurs on VCH		MUNARI Tomaso (EuCheMS)
KORATI Safia (adviser to van Karen van Malderen)		MÜLLER Karsten (Business Europe)
MYÖHÄNEN Kirsi (adviser to Riitta Leinonen)		ROWE Rocky (ECPA)
ROMOLI Debora (adviser to Pietro Paris)		SANTOS Tatiana (ETUC)
ROSENTHAL Ester (adviser to Agnes Schulte)		VEROUGSTRAETE Violaine (Eurometaux)
RUSSO Maria Teresa (adviser to Paola di Prospero)		**Remote participants**
SCHUUR Gerlienke (adviser to Marja Pronk)		SOERENSEN Hammer Peter (RAC member, Friday 9.3.)
Smith Helen (adviser to Andrew Smith) and adviser supporting rapporteurs on the tebufenpyrad		
VIVIER Stéphanie (adviser to Annieck Pichard) and adviser supporting rapporteurs on the fluazinam		BRIGNON Jean-Marc (SEAC rapporteur for phthalates)

		HENNIG Philipp (SEAC rapporteur for phthalates)
Representatives of the Commission		
BINTEIN Sylvain (DG ENV)		SCHLUCHTAR Endre (SEAC rapporteur for chromates)
GIRAL Anne (DG ENTR)		CONWAY Louise (RAC advisor for Yvonne Mullooly)
SCAZZOLA Roberto (DG ENTR)		DOWLING Vera (RAC advisor for Yvonne Mullooly)
ZIELINSKI Janusz (DG ENV)		McMICKAN Sinead (RAC advisor for Yvonne Mullooly)
Other observers		MURPHY Vera (RAC advisor for Yvonne Mullooly)
VARNAI Veda (Croatian observer)		CAITENS Andrea (a representative of the UK CA following proquinazid)
BOMHARD Ernst (an observer acting as an expert (consultant) to an observer representing Eurometaux for GaAs)		FOCK Lars (a representative of the Danish CA following chromium)
GELBKE Heinz-Peter (an observer acting as an expert (consultant) to an observer representing Business Europe GaAs)		
MEURER Krista (an observer acting as an expert (BASF) to an observer representing ECPA for tebufenpyrad)		
MÜLLER Severin (an observer acting as an expert (SI Group) to an observer representing CEFIC for p-tert-butylphenol)		KORENROMP René (a representative of the Dutch CA)
NOMURA Masanao (an observer acting as an expert (ISK Biosciences Japan) to an observer representing ECPA for fluazinam)		LARSEN Poul Bo (a representative of the Danish CA following chromium)
SARGINSON Nigel (an observer acting as an expert (ExxonMobil) to an observer representing CEFIC for general restriction)		NIEDERSTRASSER Bernd (a representative of the German CA following benzoic acid, tefufenpyrad
SCHNEIDER Klaus (an observer acting as an expert (Fobig) to an observer representing CEFIC for phthalates)		STAUDE Claudia (a representative of the German CA following TIPA)
SCHRIEVER-SCHWEMMER Gerlinde (an observer acting as an expert (Eurotoxist GmbH) to an observer representing CEFIC for diocyltin)		BARRETT Patrick (COM)
SOUFI Maria (an observer acting as an expert (DuPont) to an observer		GIRAL-ROEBLING Anne (COM)

representing ECPA for proquinazid)		
Dossier submitters		SCAZZOLA Roberto (COM)
COSTLOW Richard D.(ARKEMA dossier submitter for Dioctyltin)		VLANDAS Penelope (COM)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-20 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-20 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-20 meeting

6 March 2012
RAC/A/20/2012

Final Agenda

20th meeting of the Committee for Risk Assessment

06 – 09 March 2012

Helsinki, Finland

06 March: starts at 9:00
09 March: ends at 13:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/20/2012
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the minutes of RAC-19[6]

RAC/M/19/2011
For adoption

Item 5 – Administrative issues and information items

5.1 Report on RAC-19 action points, written procedures and other ECHA bodies

RAC/20/2012/01
Room document
For information

5.2 Report on the satisfaction survey

For information

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

6.1 Gallium arsenide (reproductive toxicity)

For discussion

Item 7 – CLH

7.1 CLH Dossiers

a. p-tert-butylphenol (ptBP)
b. 4-vinylcyclohexene (VCH)
d. Proquinazid
e. Dioctyltin bis(2-Ethyhexyl mercaptoacetate)

[6] If adopted via written procedure, the item will be deleted from the agenda.

f. Amidosulfuron

g. Tebufenpyrad

h. 1,1',1''-nitrilotripropan-2-ol (TIPA)

For discussion and possible adoption

c. Penconazole - **CLOSED SESSION**

i. Fluazinam

j. Benzoic Acid

For discussion

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

RAC/20/2012/02
Room document
For agreement

7.3 General and procedural CLH issues

a. State of play of the submitted CLH dossiers

RAC/20/2012/08
Room document
For information

b. Practicalities and ECHA's support in the new approach for opinion development

c. Public C&L Inventory

For information

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a. Phthalates – second version of the draft opinion

For discussion

b. Chromium VI – outcome of the conformity check

For agreement

8.2 General restriction issues

a. Update on intended restriction dossiers

For information

b. New mandate for RAC under Article 77.3 (c) concerning non-classified phthalates

For information

c. Update on the review of the restriction process

- How to document an opinion not supporting the restriction proposal?

RAC/20/2012/04
For discussion

- Prioritisation of recommendations during conformity check

RAC/20/2012/03

For discussion

- Revision of the restriction process in the Forum

For information

- Update on the project on improving the quality of future restriction dossiers

RAC/20/2012/05

For information

Item 9 – Authorisation

9.1 Capacity building

a. Common approach of RAC and SEAC in opinion development on applications for authorisation

RAC/20/2012/06

For agreement

b. Preparation for first authorisation applications (substances and uses)

(Closed session)

For discussion

9.2 Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications

RAC/20/2012/07

For agreement

Item 10 – Guidance issues

10.1 Update on guidance activities

10.2 Report from the workshop on the concept of "rapid" removal" for long-term aquatic classification of metals

For information

Item 11 – Any other business

Item 12 – Main conclusions and Action Points of RAC-20

Table with main conclusions and action points from RAC- 20

For adoption

ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-20 meeting.

RAC/A/20/2012 rev.1	Final Draft Agenda
RAC/M/19/2011	Adopted minutes of RAC-19
RAC/20/2012/01	Administrative issues and information items
RAC/20/2012/02	Appointment of CLH rapporteurs intentions
RAC/20/2012/03	Update on the review of the restriction process "Prioritisation of recommendations during conformity check"
RAC/20/2012/04	Update on the review of the restriction process "How to document an opinion not supporting the restriction proposal?"
RAC/20/2012/05	Update on the review of the restriction process "Update on the project on improving the quality of future restriction dossiers"
RAC/20/2012/06	Capacity building "Common approach of RAC and SEAC in opinion development on applications for authorisation"
RAC/20/2012/07	Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications
RAC/20/2012/08	General and procedural CLH issues "State of play of the submitted CLH dossiers"

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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	Potentail conflict of interest in relation to	Reason
RAC members		
Christine BJOERGE	P-tert-butylphenol (ptBP)	(Her or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Stephen DUNGEY	Proquinazid	(His or his institution's) participation in the preparation of the dossiers submitted by the MSCA
Marianne van der HAGEN	P-tert-butylphenol (ptBP)	(His or his institution's) participation in the preparation of the dossiers submitted by the MSCA
Frank JENSEN	Phthalates Chromium	(His or his institution's) participation in the preparation of the dossiers submitted by the MSCA
Annemarie LOSERT	Fluazinam	(Her or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Peter Hammer SØRENSEN	Phthalates Chromium	(His or his institution's) participation in the preparation of the dossiers submitted by the MSCA
Elodie PASQUIER	Gallium Arsenide 4-vinylcyclohexene (VCH)	(Her or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Annick PICHARD	Gallium Arsenide VCH	(Her or her institution's) participation in the preparation of the dossiers submitted by the MSCA
Andrew SMITH	Proquinazid	(His or his institution's) participation in the preparation of the dossiers submitted by the MSCA
Hans-Christian STOLZENBERG	Penconazole TIPA Benzoic acid Tebufenpyrad	(His or his institution's) participation in the preparation of the dossiers submitted by the MSCA
Stakeholders	Potentail conflict of interest in relation to	Reason
BUSINESS EUROPE, Karsten MÜLLER (replacement to	VCH Tebufenpyrad TIPA	The company (BASF) the observer is employed by has these three substances

Volker Soballa)		in their portfolio.
ECETOC, Marie-Louise MEISTERS	Proquinazid	The company (DuPont) the observer is employed by has this substance in their portfolio.

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