RAC/M/32/2015
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21 May 2015

Minutes of the 32nd Meeting of the Committee for Risk Assessment (RAC-32)

2-6 March 2015
10-12 March 2015

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed the participants to the 32nd meeting of the Committee for Risk Assessment (RAC-32). Apologies were received from four Members at the RAC-32 A part and from seven Members at the RAC-32 B part of the meeting. The Chairman welcomed two new RAC Members and informed the Committee that one RAC Member had resigned. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the Agenda for the meeting and reminded the meeting participants that RAC-32 is one meeting spread over two weeks informing them that the meeting would be suspended on Friday 6th March in the afternoon and reopened on Tuesday 10th March at 09:00. Agenda item 5.3: the follow-up discussion on the ECHA-workshop on 'Mode of Action (MoA) and Human Relevance Framework in the context of Classification and Labelling' would be rescheduled to Thursday 5th March in the evening.

The Agenda (RAC/A/32/2015) was adopted. The Agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the Agenda items. Potential conflicts declared at previous meetings were carried forward to this meeting where relevant and are reflected in Annex III. Fifteen Members then declared potential conflicts of interest, each to specific items on this Agenda. In the event of a vote, these Members were requested to refrain from voting on the respective Agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. For any newly arrived Members, the request for declarations was repeated at the start of the second week. The list of all persons declaring potential conflicts is attached to these minutes as Annex III.

4. Report from other ECHA bodies and activities

a) Report on RAC-31 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points of RAC-31 had been completed, or were on-going. The summary of all consultations, calls for expression of interest in rapporteurships and written procedures is available in the usual meeting document on CIRCABC (see Annex IV). He also informed the Committee that the final minutes of RAC-31 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 19 February 2015, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman presented the updated RAC work-plan for Q1&Q2/2015, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances. He informed Members that they could find the expected schedules for Restriction and Authorisation dossiers in the work plan. In addition, the scheduling and the endpoints to be considered for each Harmonised Classification and Labelling (CLH) dossier for the next two meetings ahead are given in the relevant section, including those for human health and the environment.

The Chairman informed RAC that in the light of the steadily increasing workload of the Committee and an expected peak in authorisation dossiers in late 2015 through 2016, a paper will be presented to the ECHA Management Board on 19-20 March on the co-option of additional Members to RAC and SEAC and their remuneration. Should the Management Board decide to amend its previous decision on remuneration of experts to also enable the remuneration of co-opted Members for their work as Rapporteurs in the Committee's, a paper on co-opting Members will be scheduled for possible agreement in the RAC and SEAC plenary meetings in June.

c) General RAC procedures

The Agenda item on the revised general approach for the admission of accredited stakeholder organisations to RAC and SEAC was postponed until later this year.

5. Harmonised classification and labelling (CLH)

5.1 CLH dossiers

A. Hazard classes for agreement without plenary debate

a) Carbetamide (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Skin / Eye irritation, Skin / Eye corrosion, Respiratory sensitisation, Skin sensitisation, Germ cell mutagenicity, Aspiration hazard, Aquatic acute toxicity, Aquatic chronic toxicity

b) Bendiocarb (ISO): Acute toxicity (oral, dermal), Aquatic acute toxicity, Aquatic chronic toxicity

c) Spiroxamine (ISO): Acute toxicity (oral, dermal)

d) Tefluthrin (ISO): Aquatic acute toxicity, Aquatic chronic toxicity

e) Chlorophene (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Germ cell mutagenicity

B. Substances with hazard classes for agreement in plenary session

a) Thiacloprid (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that thiacloprid (ISO) is mainly used in the EU as an insecticidal plant protection product in the form of foliar spray applications for professional use. The substance has no current entry in Annex VI of the CLP Regulation and the legal deadline for the adoption of an opinion is 3 August 2015.

The Dossier Submitter (United Kingdom) proposed to classify the substance for acute toxicity (Acute Tox. 3; H301, Acute Tox. 4; H332), carcinogenicity (Carc. 2; H351) and toxicity to reproduction (Repr. 2; H361f) and for environmental hazards as Aquatic Acute 1; H400 with M factor =100 and Aquatic Chronic 1; H410 with M factor =100.

As thiacloprid (ISO) is an active substance with no existing harmonised classification, all hazard classes were assessed. The Chairman noted that all proposed hazard classes with the exception of toxicity to reproduction had been agreed at RAC-31 and invited the Committee to agree on this endpoint in order to conclude the dossier.

At RAC-31 it was questioned whether dystocia should be considered as an adverse effect on sexual function and fertility or on development or whether it should not be considered under either of these subdivisions but rather under reproductive toxicity in general without further specification. Based on this discussion, the Rapporteur prepared the revised presentation describing in detail the exposure periods in all studies showing dystocia and presenting the reproductive and maternal toxicity data for all individual studies relevant for the hazard class.

Two Members were of the opinion that as maternal death (but no dystocia) occurred in the short-term study with a relatively low exposure shortly before parturition (GD18-21) but not in the acute toxicity studies, thiacloprid causes severe specific maternal toxicity that affects foetuses as well as pregnant mothers and therefore classification for developmental toxicity was warranted rather than classification for fertility effects.

Industry was of the view that mortality was due to stress of the test animals, and that parturition problems in stressed animals were caused by enzyme induction that they considered not to be relevant to humans. RAC pointed out that even if animals would have been stressed, deaths did not occur at lower doses and hormonal disturbances were unlikely on their own to cause death.

The majority of the Members were of the opinion that dystocia should not be dismissed because of severe specific maternal toxicity in some studies and that dystocia per se should rather be considered an adverse effect on fertility because it appeared only in studies having exposure already during the pre-mating period. It was also discussed whether in this case dystocia would warrant classification as a reproductive toxicant without further specification because although parturition problems are generally specified as adverse effects on sexual function and fertility, the communication of the specific hazard to pregnant mothers was also warranted.

The European Commission representative referred to recent revisions in the CLP Guidance which encourage the specification of developmental or fertility effects and which, with downstream consequences in mind, were introduced with the aim of addressing this issue.

RAC agreed that Category 1B for adverse effects on sexual function and fertility was warranted because there was clear evidence of dystocia (one Member was of the view that there was only some evidence of dystocia), and it was not considered to be a secondary nonspecific consequence of maternal toxicity as it did not always co-occur with severe maternal toxicity and the decreased food consumption and body weight/body weight gain were not considered as the cause of dystocia. In addition, RAC did not consider the mechanistic information as sufficient to dismiss dystocia or to raise any doubt as to the relevance of the effect in humans.

With regards to developmental toxicity, the Members agreed that the decrease in body weight and body weight gain observed in pups after birth in both one-generation and 2-generation studies (observed on day 4 and day 7 respectively) could not be accounted for only by maternal toxicity, as maternal body weight gain was higher in treated when compared to untreated animals in the one-generation range finding and two-generation studies. RAC also concluded that post-implantation losses could not be caused by weight loss of dams as feed restriction and a consequent body weight decrease of up to 50% had not been associated with post-implantation losses in literature studies. In addition, the cannibalization of pups in the two-generation study could have been a sign of weak pups. Also the severe specific maternal toxicity that affected also foetuses by increasing the number of stillborns warranted a classification for developmental effects. Taken everything together, RAC concluded that there

was clear evidence of adverse effects on development in two species that were not considered solely as secondary non-specific consequences of maternal toxicity and that the mechanistic information was not sufficient to dismiss the developmental effects or to raise doubt as to their relevance to humans. Therefore RAC agreed that the developmental effects also warranted a classification in Category 1B.

In conclusion, the Committee classified thiacloprid (ISO) as Repr. 1B; H360FD. RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their participation in the discussion.

b) Linalool

The Chairman welcomed an expert accompanying the Cefic stakeholder observer and the Dossier Submitter (DS) representatives from Sweden who followed the discussion remotely.

The Chairman reported that linalool is a ubiquitous fragrance found in various types of consumer products. The substance has currently no entry in Annex VI to the CLP Regulation, and the Dossier Submitter is proposing to classify the substance as skin sensitiser 1A. The deadline for the adoption of the opinion is 27 November 2015. The Chairman also reminded the Members that a Scientific Committee on Consumer Safety (SCCS) opinion on fragrance allergens in cosmetic products which also includes linalool is available on the website of the European Commission.

The Chairman informed the meeting that 20 comments were received during public consultation and that a recurring issue was whether oxidised linalool, stabilised or non-stabilised linalool should be classified, and which data to use. Similar comments had been provided by RAC Members during RAC consultation.

During their presentation, the Rapporteurs clarified which data, including human data and animal studies, had been provided in the dossier or during Public Consultation (PC) for 'oxidised', 'stabilised' and 'non-stabilised' linalool. The European Commission representative pointed out that when classifying linalool the forms or physical states in which linalool is placed on the market ('commercial linalool') and in which it can reasonably expected to be used, should be considered. The Rapporteurs considered that this could best be reflected by the form described in the lead registrants REACH dossier. The Chairman asked Industry to confirm which forms were present on the market, who then responded that the trend was towards the 'stabilised' form but that unstabilised forms could still indeed be present. The Committee concluded that linalool and its d- and l-isomers as defined by their CAS numbers mentioned in the CLH report is the substance to be classified regardless of the presence of stabilisers or not.

The Rapporteurs presented the sum of positive cases of sensitisation in human patch test studies carried out with either stabilised or non-stabilised linalool and in agreement with the DS, RAC considered the sensitisation frequency to be low. In addition, RAC agreed with the DS that exposure to linalool is estimated to be low. The discussion then focussed on the relevance of the human *vs.* animal data, on the relevance of the Basketter (2002) LLNA test, including the extent to which irritation could have interfered with detecting sensitisation, on the findings of the different studies presented in the CLH report and on evidence which either proved the absence or the presence of a classifiable sensitisation hazard.

The Dossier Submitter, contributing remotely to the discussions, clarified a number of study details and pointed out the low validity of the semi-quantitative (colorimetric) test used in the paper provided by the lead registrant (during the PC), a view also shared by the Rapporteurs. The DS also noted the results from a recent publication from the fragrance industry, Kern et al

(2014), showing that the presence of a stabiliser did not prevent linalool transformation into its hydroperoxides.

The Cefic expert argued that linalool should not be classified for skin sensitisation because the study of Kern et al (2014) showed no significant oxidation of commercial products, and while acknowledging that clinical patch testing does play an important role, noted that some of the results could be questioned, for example due to cross-reactions with other agents.

The Committee concluded that the low frequency/low exposure criteria (leading to Skin Sens. 1) are met for non-stabilised linalool. Due to a lack of animal data (in particular for the commercial, 'stabilised' form) it was not sufficiently clear to what extent the stabiliser reduced the skin sensitisation potential of linalool. RAC justified a classification as Skin Sens. 1B based mainly on the Basketter (2002) LLNA study with commercial, unstabilised linalool (non-redistilled), backed up by human evidence. The Committee agreed not to assign Note F to the proposed Annex VI entry.

The Committee adopted the opinion by consensus.

The Chairman thanked the Rapporteurs for the comprehensive analysis of the case, the Dossier Submitter for the targeted clarifications and the Committee for the thorough discussion.

c) Fenpyrazamine (ISO)

The Chairman reported that fenpyrazamine is a fungicide used in the control of grey mould (*Botrytis*). In November 2012 RAC adopted an opinion where fenpyrazamine was classified as Aquatic Chronic 2; H411. In 2013, additional ecotoxicity data was made available to the Dossier Submitter (Austria) and a new CLH report proposing revision of the environmental classification was submitted to ECHA in June 2014 (other hazard classes were not included in the proposal). The new proposal by Austria proposes classification as Aquatic Acute 1 (H400) with an M-factor of 10 and Aquatic Chronic 1 (H410) with an M-factor of 10, based on the lowest acute L(E)C_{50} of 0.034 mg/L for growth rate of the alga *Skeletonema costatum* and the lowest chronic NOEC of 0.0049 mg/L based on yield for the alga *Navicula pelliculosa*. Legal deadline for adoption of the CLH opinion is 3 December 2015.

The Rapporteurs noted that during the public consultation, comments were received from four Member States, who all supported the Dossier Submitter's proposal for Aquatic Acute 1 and Aquatic Chronic 1. One Member State disagreed with the proposed chronic M-factor of 10 and suggested to use the 96-h NOErC of 0.011 mg/L for *Skeletonema costatum* as the most sensitive algal result instead of the 96-h NOEC of 0.0049 mg/L for *Naviculla pelliculosa* based on cell density, as growth rate is the preferred endpoint for classification because it is independent of test design. Another Member State asked for an explanation of why the yield endpoint was used when a NOErC was available from the same study. In reply, the Dossier Submitter stated that the most sensitive endpoint should be used for chronic classification. No information is given in the CLP guidance about which of these endpoints should be used for chronic classification. However, RAC considers that the yield endpoint in the new OECD TG 201 from 2006 (E_yC_{50}, based on biomass measurement at the beginning and end of the experiment) suffers from similar statistical drawbacks as the biomass endpoint (E_bC_{50}) in the obsolete OECD TG 201 from 1984. The growth rate endpoint is therefore preferred when available. This is consistent with the CLP guidance for acute endpoints and also EFSA Guidance for plant protection products.

Members agreed with the proposal of the Rapporteurs to classify fenpyrazamine Aquatic Acute 1 (H400) with an M-factor of 10, and Aquatic Chronic 1 (H410) with an M-factor of 1.

d) Carbetamide (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer.

The Chairman reported that carbetamide is a systemic herbicide used for the control of annual grasses and broad weeds. It has no entry in Annex VI to the CLP Regulation. The Dossier Submitter (France) proposed a harmonised classification of the substance as Carc. 2 (H351), Repr. 2 (H361d), Acute Tox. 4 (H302) and Aquatic Chronic 2 (H411). RAC agreed on the classification for oral acute toxicity and chronic aquatic toxicity, as well as on the following endpoints with no classification: acute dermal and inhalation toxicity, STOT SE, skin and eye corrosion/irritation, respiratory and skin sensitisation, germ cell mutagenicity, aspiration hazard and aquatic acute toxicity. The legal deadline for adoption of the CLH opinion is 31 December 2015.

The potential specific target organ toxicity after repeated exposure (STOT RE) of carbetamide by oral route has been investigated in rats, mice and dogs. No study was performed by inhalation or dermal application. No classification for STOT RE was proposed by the DS although some comments regarding neurotoxicity, liver and thyroid toxicity were raised during the public consultation and by RAC. Based on the evidence provided, the Committee supported the Dossier Submitter's opinion that carbetamide did not warrant classification for STOT RE.

The Rapporteur presented the DS's proposal to classify carbetamide as Carc. 2; H351 (suspected of causing cancer). RAC agreed on the classification using a weight of evidence approach, mainly on the basis of effects observed in a GLP study in rats (combined oncogenicity and toxicity study) where astrocytomas (rare brain tumours) were observed above the historical control data at a dose of 9000ppm.

Reproductive toxicity was assessed by the DS on the basis of a two-generation reproductive study in rats and two teratogenicity studies (one in rat and one in rabbit).

RAC supported the DS proposal for no classification for effects on fertility.

In the discussion on developmental effects, RAC supported the Rapporteur's conclusion that carbetamide warrants a classification for developmental toxicity in category 1B (H360D), based on the clear evidence of severe effects in rats (including delayed development, skeletal and rare/complex visceral abnormalities) and in rabbits (including post-implantation loss and skeletal abnormalities). In addition, the increased incidence of cardiovascular defects and the vestigial/absence tail reported in rats could not be explained on the basis of developmental delays, immaturity or a mechanism of action. RAC noted that these effects occurred at the highest dose tested (1000 mg/kg bw/day) with no evident signs of maternal toxicity.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee members for their comments.

e) Bendiocarb (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that bendiocarb was a biocidal active substance with an existing entry in Annex VI to the CLP Regulation for acute toxicity (minimum classification as Acute Tox. 3*; H331, Acute Tox. 3*; H301 and Acute Tox. 4*; H312) and for environmental hazards as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with no M factors. The legal deadline for the adoption of an opinion is 1 January 2016.

Based on the evaluation of acute toxicity, the Dossier Submitter (UK) proposed to classify bendiocarb (ISO) for acute toxicity via all routes of exposure as follows: Acute Tox. 2; H330,

Acute Tox. 2; H300 and Acute Tox. 3; H311 and to add M-factors for environmental hazards (M=10 for aquatic acute toxicity and M=100 for aquatic chronic toxicity).

The Committee supported the DS and agreed on the proposed acute toxicity classification via oral and dermal routes of exposure and on the addition of the proposed M-factors for environmental hazards.

Acute toxicity via inhalation was considered a border-line case between category 2 and 3. In the available acute inhalation study, females appeared slightly more sensitive than males and the LC_{50} of 0.47 mg/l calculated for females was within the range for Acute Tox 2; H330 (0.05 mg/l < LC_{50} ≤ 0.5 mg/l for dusts and mists). Small variations in the numerical result for the LC_{50} were expected depending on how the statistical analysis of the dose-response data was performed. Following a proposal by a RAC Member during the RAC consultation, a re-evaluation of the data for female rats using PROAST software had been performed to recalculate the LC50 according to a dose-response model that better fitted the data. Using the Weibull model that fitted the data with the highest likelihood, a LC_{50} of 0.511 mg/l had been determined with a 95% confidence interval of 0.438-0.592 mg/l. Consequently RAC concluded that the reported LC_{50} of 0.47 mg/l for female rats was not robust enough to conclude that the LC_{50} in females was below the threshold for category 2. Instead, RAC concluded that a classification Acute Tox 3; H331 was justified for bendiocarb on the basis of the recalculated female LC_{50} of 0.51 mg/l. This conclusion was supported by the LC_{50} of 0.55 mg/l for combined male and female rats.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

f) Spiroxamine (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that spiroxamine was used as fungicide in plant protection products.

The substance currently has a harmonised classification and labelling for acute toxicity (Acute Tox. 4, minimum classification for all routes of exposure), skin irritation (Skin Irrit. 2; H315), skin sensitisation (Skin Sens. 1; H317) and for environmental hazards as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with no M factors.

The legal deadline for the adoption of an opinion is 1 January 2016.

The Dossier Submitter (Germany) proposed to confirm the classification for acute toxicity (Acute Tox. 4 for all routes of exposure), to add classification for toxicity to reproduction (Repr. 2; H361d), to change classification for skin sensitisation to Skin Sens. 1B and to add M factors for environmental hazards (M=100 for both Acute and Chronic Aquatic toxicity).

The Committee agreed with the DS's proposal for classification for acute toxicity via the oral and dermal exposure.

RAC also supported the proposal for acute toxicity category 4, via inhalation, but concluded that the current category 1 for skin sensitisation without sub-categorization should be retained.

The Rapporteur presented the DS' proposal for classification of developmental toxicity. The DS' proposal was mainly based on the results of an oral developmental toxicity study in Wistar rats (OECD TG 414). In this study *palatoschisis* (cleft palate; in 3 foetuses out of 265, from 3 out of 24 litters) as well as delayed ossification and reduced foetal body weight were observed in the foetuses at a dose level of 100 mg/kg bw/day which also caused slight maternal toxicity (reduced feed intake and decreased corrected body weight gain). No maternal clinical signs, symptoms or mortality were reported. There were no cases of cleft palate in any other group

and the incidence was outside the range of historical control data. Cleft palates were also observed in two range-finding studies: at 100 mg/kg/day 3 foetuses (out of 46, i.e. 6%) from 2/4 litters had cleft palates, when also a slight reduction in maternal body weight gain was reported as well as clinical signs (ruffled fur, dyspnea, sedation and hunched posture) in the maternal animals. At 150 mg/kg/day, cleft palate was observed in 3 foetuses (out of 18) in 2 out of 4 litters of the surviving maternal animals (21/24 maternal animals died). Based on the high mortality in the latter range finding study, several RAC Members considered that the criteria for STOT RE 2 might be fulfilled. However, data from repeat dose studies had not been assessed by the DS and therefore the CLH dossier did not contain a proposal for STOT RE 2. The suggestion was supported that a sentence could be included in the opinion clarifying that according to RAC, the data provided on maternal toxicity in the range finding studies, might be sufficient to fulfil the criteria for STOT RE 2.

Two more studies were included in the CLH report – a developmental oral toxicity study in rabbits (performed in accordance with OECD TG 414) and a developmental dermal toxicity study in rats. No foetal effects were observed in these two studies.

The ECPA expert mentioned that induction of cleft palate in rats may be the result by stress via irritation. Also, various spontaneous malformations had been reported in rats after inhalation of an irritating substance, causing reflectory induced bradypnea in the maternal animals and hypoxia, according to the expert. The incidence of malformations decreased after co-administration of oxygen. This suggested, according to the ECPA expert that the malformations in the rat studies with spiroxamine (i.e. the cleft palates), might have been induced by unspecific stress in the rats.

One RAC Member, considered cleft palate as an acute effect generated in a specific time window, and would therefore not support to extrapolate from toxicity observed in other repeat dose studies, when assessing the cleft palates observed in the developmental toxicity study in relation to the criteria for classification. In general, when comparing with historical control data, the range values may not be the most appropriate values to be considered, but rather the historical control data within a relevant time period. The RAC Member also reminded of earlier similar cases where RAC had made clear statements in the opinions in relation to cleft palate and maternal toxicity in the rat. The incidence of the cleft palate, a severe developmental effect, should be determinative factor in this case, according to his view. Another RAC Member supported this view and underlined that the important entity or unit is the mother animal and her foetuses, between which individual correlations should be made in case maternal toxicity should be further looked at.

The RAC Members agreed with the Rapporteur that as the mechanism of induction of cleft palates by spiroxamine in rats was not known, the relevance for humans could not be excluded.

RAC concurred with the Rapporteur's conclusion that the occurrence of cleft palates /*palatoschisis* was a specific treatment-related effect. However, even if some RAC Members had doubts about the role of maternal toxicity observed in the developmental toxicity study in the assessment of the cleft palates, RAC considered that in this case, data on repeated dose toxicity could be valuable in completing the toxicity profile of the substance. Thus, RAC recommended that before concluding on toxicity to reproduction, such data should be requested from the DS in this specific case. Thus, the Committee asked the Secretariat to contact the Dossier Submitter with a request to provide data related to STOT RE. The Secretariat informed that in the event of additional data being provided, a targeted public consultation would be launched and the discussion on this hazard class would be resumed at RAC-33 in June 2015.

The Committee supported the DS proposal for adding the M factors of 100 for both Aquatic Acute and Aquatic Chronic classification based on toxicity to the alga *Skeletonema costatum* and the lack of rapid degradation in water and water-sediment simulation tests.

g) Chlorophene

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. He reported that chlorophene was a biocidal active substance used as a disinfectant for professional and private uses. Chlorophene has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 25 February 2016.

The DS (Norway) proposed to classify the substance for acute toxicity (Acute Tox 4; H332), for skin irritation and skin sensitisation (Skin Irrit 2; H315, Skin Sens 1A; H317, but agreeing with Cat 1 without a subcategory following the comments during public consultation), for serious eye damage (Eye Dam 1; H318), for specific target organ (kidney) toxicity after repeated exposure (STOT RE 1; H372), as suspected carcinogen (Carc 2; H351), as suspected of damaging fertility (Repr. 2; H361f) and as very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) with an M-factor of 1 for the aquatic acute and an M-factor of 100 for the aquatic chronic classification. As chlorophene (ISO) is an active substance with no existing harmonised classification, all hazard classes were assessed.

The Committee agreed on no classification for acute toxicity via oral and dermal routes of exposure, for targeted organ toxicity after single exposure and for germ cell mutagenicity. The Committee supported the DS's proposal for harmonised classification and labelling for acute toxicity via inhalation.

The Rapporteur supported the DS's proposal for skin irritation in category 2. In the key study (2000; in accordance with OECD TG 404), both mean erythema and oedema scores were above 2.3 and below 4.0, i.e. in accordance with the criteria for category 2. However, although the effects were reported to be reversible by 21 days, "necrotic appearing area" was reported at 72 and 96h and "scar-like tissue" was reported at 14 and 21 days in all three rabbits tested. Two Members were of the opinion that necrosis proceeded scar formation and therefore there were indications of skin corrosion. The Rapporteur did not find the evidence for skin corrosion sufficient as the nature of skin destruction was not described in sufficient detail, because the effects were reversible in two supporting studies and because no clear corrosivity was reported in skin sensitisation and repeated dose studies. Following the proposal by the DS and Rapporteur, RAC agreed to the classification in category 2 for skin irritation.

RAC supported the DS's proposal on classification for skin sensitisation in category 1 without a subcategory (revised from 1A following PC) based on three positive Buehler tests each having shortcomings. In the Buehler study with the results per se meeting the criteria for sub-category 1A, the induction and challenge doses were too high and accordingly RAC concluded that the study could not be used to provide a reliable estimate of skin sensitisation potency of chlorophene. On the other hand, the results of the two other positive Buehler tests did not provide sufficient information to exclude the possibility of chlorophene being a strong sensitiser. The expert accompanying the Cefic stakeholder observer questioned the validity of the data from the 2001 Buehler test due to high doses used and pointed out that the human data seemed to be insignificant and did not either support the classification in subcategory 1A.

For repeated dose toxicity, the kidney was the main target organ in four species. The DS had proposed to classify chlorophene in category 1 based on tubular calcinosis at a dose of 40 mg/kg bw/day observed in the 21-day dermal study in rabbits. However, RAC did not consider this effect severe enough to justify the classification for STOT RE. Increased incidence and severity of nephropathy and increased kidney weight were observed in rodents after oral administration and in rabbits after dermal administration at doses meeting the criteria for

STOT RE 2 and consequently RAC concluded that chlorophene should be classified with STOT-RE 2 (H372 – may cause damage to kidneys through prolonged exposure).

The DS proposed to classify chlorophene in Category 2 for carcinogenicity. A dose-related increase in renal tubule adenoma was observed in mice in the extended evaluation of the tissue and an increased incidence of renal tubule carcinoma was observed at mid and high doses without a dose-response in the standard and extended evaluations. These findings occurred in the presence of nephropathy and mortality that may have been related to tumour incidences according to RAC. As these tumour findings were reported in one study only, there were unresolved questions about the interpretation of the results of the study, the exposure-associated tumours were benign and as there were no mechanistic information to disregard the human relevance of these tumours, RAC considered the renal tumour findings in male mice provided limited evidence of carcinogenicity. Weak supporting evidence for this classification was observed in female F344 rats, in which single incidences of a rare renal tumour type, transitional cell carcinoma, occurred at the mid and top doses. RAC concluded that although transitional cell carcinoma was a very rare tumour type to occur spontaneously in F344 rats, single incidences of this tumour type were plausible. RAC also noted that no clear relationship was established between renal transitional cell hyperplasia and susceptibility of animals to this tumour type carcinogenesis as there was an inverse relationship between males and females for renal transitional cell hyperplasia and tumour incidence. However, as the overall incidence was two for this tumour type, RAC concluded that the evidence for a carcinogenic effect of chlorophene in female rats could not be disregarded completely. Based on the weight of evidence, mainly taking into account the mice data (renal tumours), RAC agreed with the DS to classify Chloroprene in Category 2 for carcinogenicity.

The Rapporteur supported the DS in classifying chlorophene for effects on fertility in category 2 based on data from 2-generation study in rats. A dose-related slightly reduced fertility index was observed in P and F1 generation female rats indicative of a weak adverse effect on fertility in the absence of marked systemic toxicity. The historical control range for female rat fertility index was 80-100% (incorrect value of 88-100% was provided in the CLH report) and the value derived only for P females in the current study was outside of this. However, RAC considered the concurrent control values to provide the most relevant comparison and there was a clear reduction in both generations when compared to these. The expert accompanying the Cefic stakeholder observer confirmed that the re-calculated historical control data were correct and proposed no classification as there were no effects on reproductive organs, the substance was not genotoxic and as it was normal according to the expert that 6/30 animals did not get pregnant. However, RAC supported the analysis by the DS and Rapporteur and agreed on classification of chlorophene for adverse effects on sexual function and fertility in category 2. Developmental studies in rats and rabbits did not provide any findings to justify classification for developmental toxicity.

RAC supported the DS proposal for environmental classification. One RAC member commented that the applicability domain should be added to the QSAR estimates that were used as supportive information in the opinion.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

5.2 Appointment of RAC Rapporteurs for CLH dossiers

The Secretariat collected the names of volunteers for the CLH dossiers listed in the room document and the Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted CLH dossiers.

5.3 General CLH issues

As a follow up of the ECHA-workshop on 'Mode of Action (MoA) and Human Relevance Framework in the context of Classification and Labelling' in November 2014 and a short discussion on the subject at RAC-31, the Secretariat provided a tabular summary of all currently adopted CLH opinions including the justification as regards liver tumours and the CAR mediated MoA.

The summary was presented to the Committee with the aim to collect the feedback from Members on the most efficient next steps. The Members responded that the maintenance of case history summaries going forward would be very useful to their work and RAC thanked the Secretariat for preparing the tables, encouraging them to continue this practice. It was agreed that when further substances with CAR-mediated MoA's are scheduled for discussion, that the updated tables could be briefly presented and reviewed to support the Committee's decision making and ensure consistency.

A need for the identification of key steps which are necessary in evaluating the mechanistic studies and the types of questions that need to be answered was clearly recognised as being useful. In the discussion, some Members pointed out that given the current and expected workload of the Committee, RAC should not commit itself to an extensive project on MoAs, nor should the Committee get involved in the scientific development in this area. The employment of tools for easier data assessment, e.g. the WHO/IPCS template was briefly discussed, as it had been considered at the MoA workshop. Without wanting to place any additional burden on MSCA's through formal requests to use such templates, it was felt that streamlining the collation of data would help evaluation in Committee.

Finally, it was noted from the discussion that training in the field of MoA might be useful for some Committee Members and ECHA agreed to look into this.

6. Restrictions

6.1 Restriction Annex XV dossiers

a) General restriction issues

The Chairman invited a representative of the Secretariat to present the '*Implementation of the recommendations from the task force*'. The main revisions in the templates concerned separating the conformity check issues and the recommendations in the respective documents and the insertion of the Annex on clear scope setting as agreed by the Restriction Efficiency Task Force (RETF). The Secretariat added that the opinion template and Annex XV report format are under revision.

RAC agreed with the revised conformity check templates and agreed to implement the templates for the restriction dossiers D4/D5 and PFAS. In addition, RAC agreed to move the presentation of key issues to follow, immediately after the conformity check agreement in plenary; the first version of the opinion would then be introduced at the next meeting instead of key issue document. The working procedures will be updated accordingly.

One of the recommendations from the RETF was to set up an expert group to discuss improved ways of dealing with societal impacts. The Secretariat invited volunteers (1-2) from RAC to participate to this 'impact' expert group.

The Secretariat then presented an '*outline for a common approach for RAC and SEAC in opinion development for restriction proposals*'. The RAC Members were invited to send their

comments on the common approach paper by 27 March, which will be tabled for agreement at a forthcoming plenary meeting in June.

b) Opinion Development

1) Isopropylidenediphenol (Bisphenol A) – revised draft opinion

The Chairman welcomed an expert accompanying the Cefic stakeholder observer, an expert accompanying the EEB stakeholder observer and the EFSA representative. The Chairman also welcomed the Dossier Submitter representatives (France) and one of the SEAC Rapporteurs. The Committee was informed about the state of play regarding the opinion development. On 29 January 2015, RAC held a consultation with 18 RAC Members, the SEAC Rapporteurs, stakeholders and an EFSA representative, to discuss the 2nd draft opinion on the restriction proposal and the EFSA (2015) scientific opinion on bisphenol A (adopted 11 December and published 21 January).

For RAC-32, the Rapporteurs had revised the draft opinion taking into account the discussions at the above RAC consultation and eight detailed comments were received from RAC Members on the subsequent 3rd draft opinion.

The EFSA representative presented their opinion on the risk to public health related to exposure to BPA. The EFSA opinion covers not only the hazard assessment of BPA but also the exposure to BPA from thermal paper to consumers (in addition to the exposure from food and cosmetics.

RAC then reconsidered in detail the hazard data reviewed in the dossier in the light of earlier discussions and the EFSA opinion. The discussion focussed on the approach and the interpretation of the EFSA t-TDI, and the uncertainty analysis for mammary gland, reproductive, metabolic, neuro-behavioural and immune effects. The Rapporteurs then described the exposure assessment in full for the first time in plenary. Members discussed input parameters and the outcome of exposure modelling and the comparison to biomonitoring data for consumers and for workers.

The Chairman summarized and noted that substantial progress had been made on the details of hazard and exposure assessment and on the risk characterization for consumer and workers but that the Rapporteurs would need to develop the opinion further. In particular, the uncertainties for both hazard and exposure sections need to be described and evaluated (EFSA's likelihood estimates with regards to the effects need to be considered) and an interpretation needs to be provided on all the Risk Characterisation Ratio's derived. A consultation round would therefore be launched on the revised draft opinion.

The opinion will then be scheduled for RAC-33. The Chairman clarified that the legal deadline for adoption in RAC is 18 March 2015 and that the process would be extended as needed to ensure a thorough analysis and mature consideration of this extensive dossier. The justification for extending the opinion process is the need for alignment with the EFSA's opinion according to Article 95 of REACH and the publication of EFSA's opinion on 21 January, hence only 2 months before the deadline for adoption of the RAC opinion.

As a consequence of the continued discussions on the restriction proposal in RAC, the agreement on the revised draft SEAC opinion will be similarly extended.

2) Ammonium salts – revised draft opinion

The Chairman welcomed the Dossier Submitter's representative (France), who followed the discussion remotely via WebEx. He reminded the participants that this restriction dossier has

been submitted under Article 129 of the REACH Regulation (safeguard clause). Substances in the scope of the restriction proposal are inorganic ammonium salts that are used as additives in cellulose insulation for their flame retardant properties. The revised draft opinion of RAC, the responses to public consultation comments and the background document were uploaded on CIRCABC in early February and comments were received from two Members in the following written consultation.

The RAC Rapporteurs presented the revised draft opinion to the Committee. They explained that within the public consultation, a proposal for a derogation had been received from industry for outdoor exterior products such as cladding where there is no release to the indoor environment. The Rapporteurs were interested to hear the views of other RAC Members whether there is a need for such a derogation and whether the information is solid enough to justify it. Several Members expressed the view that RAC has no indication that such materials even contain ammonium salts and it would therefore not be justified to include such a derogation. One Member pointed out that RAC should not go for exemption if the product is not used in reality, as there are consequences for enforcement. The Secretariat pointed out that Industry had been requested to clarify the basis for such an exemption but had not responded. It was agreed not to include a derogation for outdoor exterior articles and to clarify the situation in the opinion for the benefit of SEAC.

Furthermore, the Rapporteurs explained that during the third Rapporteurs' dialogue, the European Commission had clarified to them that a working group for testing ammonia emission will be established with CEN in spring 2015. The group will work on the different parameters, sampling and testing issues and other questions raised by the Committees and the Forum. This group will present their results in either a technical report or an amendment to CEN/TS 16 516. The Rapporteurs have therefore suggested to include a footnote to the proposed Annex XVII entry inviting the European Commission to develop, by the entry into force of the regulation, technical specifications for the testing of mixtures or articles containing cellulose treated with inorganic ammonia salts under standard room parameters (size, ventilation) at 90% relative humidity for a period of at least 14 days. RAC agreed with the Rapporteurs on this.

RAC adopted its opinion on the dossier on inorganic ammonium salts by consensus. It was agreed that the Rapporteurs, together with the Secretariat, will make the final editorial changes to the adopted opinion and will ensure that the supporting documentation (Background Document and Response-to-Comments) is in line with the adopted RAC opinion. The Secretariat will forward the adopted opinion and its supporting documents to SEAC as well as publish it on the ECHA website and CIRCABC. The Chairman thanked the Rapporteurs for their efficient handling of the case and the participants for their contributions.

3) DecaBDE – first draft opinion

The Chairman welcomed the DS representatives (ECHA and Norway), two experts accompanying stakeholder observers (Cefic and EEB) and the SEAC Rapporteurs. He reminded the participants that decaBDE was identified as an SVHC and included in the Candidate List as PBT/vPvB. DecaBDE has a widespread occurrence in the environment and in wildlife. This bromine saturated diphenyl ether debrominates in the environment to lower homologues which are PBTs/vPvBs or act as precursors to substances with PBT/vPvB properties. In addition to PBT/vPvB concerns, other potential impacts of exposure to decaBDE may result in neurotoxicity in mammals, including humans. The proposal focuses on the hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles.

The Rapporteurs then presented their first draft opinion to RAC focusing on environmental hazards and emissions as a surrogate to risk. Based on the information provided, some

Members as well as the European Commission observer asked whether a qualitative risk assessment of neurotoxicity would be sufficient, especially with regard to providing input for SEAC's purposes. RAC concluded that there is a risk to be addressed based on the PBT/vPvB hazard without an identified threshold, that the emissions are a suitable proxy for the emissions (and risks) of hazardous transformation products. RAC also agreed that action needs to be taken on EU wide basis and that the proposed restriction is the most appropriate measure to reduce the emissions and thereby the risks of decaBDE.

RAC agreed that despite concerns that some of the alternatives could pose similar hazards, at least some are likely to be less hazardous overall.

The Chairman asked the Rapporteurs to take the RAC discussion into account in the revised draft opinion (due by end of April 2015).

4) Perfluorooctanic acid (PFOA) – key issues document

The Chairman welcomed the Dossier Submitter representatives (Germany and Norway) and the SEAC Rapporteurs as well as an industry expert accompanying a stakeholder observer. The Chairman reminded the Committee that the dossier on Perfluorooctanoic acid (PFOA) was submitted by Germany jointly with Norway in October 2014 and was considered to be in conformity by both Committees in December last year. The Dossier Submitter proposes a restriction on manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances. The Chairman informed the participants that the key issues document prepared by the Rapporteurs was made available to RAC on 10 February and comments were received from five RAC Members in the following written consultation.

The Rapporteurs presented the key issues document to RAC. They asked what should be the RAC main focus and whether emission and human health risk assessment should be looked at with the same level of detail. The Rapporteurs noted that all Members who provided comments within the written commenting round were of the opinion that RAC should avoid examining human health risk assessment and should focus on emissions. Several Members expressed their view that RAC should not assess the human health risk assessment in detail, as the focus of this restriction is based on PFOA being a PBT-substance. However, some Members suggested taking human health issues into consideration, at least in a qualitative manner, without going into detail quantitatively. Other Members questioned what is meant by a qualitative assessment – as the substance is classified, human health impacts are qualitatively assessed anyway already. It was agreed to ask the Dossier Submitter to clarify their views on the relevance of the human health risk assessment to the scope of the restriction before deciding on the next steps.

RAC agreed with the Rapporteurs that inclusion of PFOA-related substances in the scope is essential to this restriction. One Member suggested using the term PFOA-releasing substances instead of PFOA-related. The Committee also agreed with defining the precursor 8:2 FTOH 8:2 (fluorotelomer alcohol) as a PFOA-related substance.

RAC agreed with the principle of using the emissions of PFOA as a surrogate for risk. Members also agreed to use the available emission factors for different uses (scenarios) as the basis for the emission estimates as well as with the approach proposed by the Rapporteurs for assessing potential degradation.

An industry expert explained that industry in Europe has over the last 10 years moved away from PFOA to shorter chain fluorinated compounds and industry is therefore in favour of this restriction, including the polymeric PFOA related substances regardless of degradation time. According to the expert there is no use of PFOA in Europe and all emissions indicated in the

dossier are historical and do not correspond to current emissions. The current emissions in Europe are going down due to efforts made by industry. An NGO observer pointed out that as there is evidence that PFOA has endocrine disrupting adverse affects, it should also be considered a non threshold substance from a human health perspective.

RAC considered the role and relative importance of the human health data presented in the dossier (in addition to the key environmental emissions), agreeing that its relevance needs to be made clearer. The DS responded that the worker and consumer/general population exposure data were included to provide supplemental information to primarily assist SEAC with calculating impacts. The European Commission, while not disagreeing that the environmental properties of a PBT are dominant in such a risk assessment, informed that the scope of the restriction needs to be justified by the risk assessment and that issues such as worker exposure contained in the dossier should therefore be clarified. The Secretariat was requested by the Committee to discuss with the Dossier Submitter their views on the relevance of the human health risk assessment to the scope of the restriction before deciding on the next steps.

In summary, RAC agreed on the main elements presented by the Rapporteurs. The Chairman informed that the Rapporteurs will need to deliver their first draft opinion on this dossier by end of April 2015 (to be discussed at RAC-33).

b) Conformity check

1) Methanol

The Chairman welcomed the Dossier Submitter representative from Poland, who followed the meeting remotely via WebEx and welcomed the SEAC Rapporteurs. He informed the participants that the restriction dossier on methanol had been resubmitted by Poland on 16 January 2015 following the decisions made by RAC and SEAC in September 2014 that the original dossier was not in conformity. The RAC commenting round finished on 23 February with comments received from one Member. The Chairman mentioned that the proposed restriction is aimed to prevent poisoning cases in consumers (deliberate abuse or accidental misuse) resulting from oral exposure to windshield washing fluids and denaturated alcohol containing methanol in concentrations equal to, or greater than 3.0% by weight.

The Rapporteurs then presented the outcome of the conformity check and the recommendations to the Dossier Submitter and informed the Committee that the dossier can be considered in conformity from the RAC point of view.

The Members agreed with the recommendations of the Rapporteurs. In addition, it was suggested to reconsider the relevance and need for toxicokinetic data after exclusively inhalatory and dermal exposure to methanol in humans, as they were considered not to be relevant for the hazard and risk evaluation.

The Committee agreed that the dossier conforms to the Annex XV requirements. The Chairman informed that SEAC will conclude on the conformity of this dossier at SEAC-26. If the dossier will be considered in conformity by both Committees, the public consultation on the Annex XV report will be launched on 18 March 2015.

2) Dimethylformamide

The Chairman welcomed the Dossier Submitter representatives (Italy) and the SEAC Rapporteurs (who followed via WebEx). The Chairman reminded the Committee that the dossier on DMF was submitted by Italy on 16 January 2015. The conformity check process was

launched in RAC and SEAC on 12 February and the Committees were expected to reach a conclusion on conformity in March.

The Rapporteurs then presented the outcome of the RAC conformity check and recommended that the dossier should be considered not in conformity due to shortcomings in information on hazard and risks as well as in justification that the restriction is the most appropriate community wide action.

Several Members voiced support to the Rapporteurs' conclusions. The Chairman concluded that the Committee supported the Rapporteurs' conclusion for non-conformity.

6.2 Appointment of Rapporteurs for restriction dossiers

Following the Chairman's proposal the appointment of Rapporteurs has been postponed.

7. Authorisation

7.1 General authorisations issues

a) General authorisation issues

The Chairman reminded the Committee that in November 2014, RAC and SEAC in a joint session adopted a revised Working Procedure for Developing Opinions on Applications for Authorisation (RAC/31/2014/07 rev 01 and SEAC/24/2014/05 rev 1). As agreed in that document, prior to implementation of one of the measures, i.e. fast-tracking of opinions through an A-list, criteria would need to be developed and agreed by the Committees for selecting suitable candidate dossiers. In between the plenary meetings, the Secretariat developed draft A-listing criteria. Short RAC and SEAC consultations were held (11-17 February 2015). The Secretariat received comments from one RAC Member and from five SEAC Members. The original draft document has been revised according to the received comments.

The Secretariat presented the draft A-listing criteria.

The Committee agreed on the document "Introduction of a differentiated approach to agreement on the Committees' draft opinions on the applications for authorisation" (RAC/31/2015/08). Furthermore, RAC was informed of changes to the opinion template.

b) Capacity building: RAC Reference Values

The Chairman reminded the Committee about the ongoing work on developing carcinogenicity dose-response relationships for three new substances on Annex XIV of the REACH Regulation:

- 1,2-dichloroethane (EDC);
- 2,2'- dichloro-4,4'-methylenedianiline (MOCA);
- formaldehyde, oligomeric products with aniline (technical MDA).

In addition, the setting of derived no-effect levels (DNEL's) for one further Annex XIV substance which is toxic to reproduction was also required:

- bis(2-methoxyethyl)ether, 'diglyme'

In November 2014 the Committee discussed the ECHA consultant's report and four draft RAC notes on these reference values. Four Members who volunteered to act as Rapporteurs

reviewed the draft notes and provided their comments on the content. The Chairman then invited a representative of the consultant to present the draft notes.

1. DNEL values setting for the reproductive toxicant bis(2-methoxyethyl)ether (diglyme)

The consultant presented a revised note on the DNEL setting for the reprotoxic properties of Diglyme. Members noted that the approach taken deviates from the REACH guidance and advised the consultant to develop the calculations according to the appropriate guidance. They noted that from the literature studies that, next to developmental toxicity, testicular toxicity is possibly also a sensitive endpoint. RAC requested the consultant to derive DNEL values for the reprotoxic properties of Diglyme, based on four identified reliable studies (two oral, two inhalation), noting that route-specific studies are preferred for DNEL derivation. Members also discussed relevant routes of exposure for the general population.

The Committee agreed to request the consultant to redraft the note, add in missing references to the background paper, after which a 3 to 4 weeks consultation would be launched. Depending on the outcome, the note could be agreed by written procedure as time was pressing or, if further work was still needed, revisited at RAC-33 for agreement.

2. Carcinogenicity dose-response relationship setting for 1,2-dichloroethane (EDC)

The Chairman welcomed the expert from industry consortium for EDC accompanying the Cefic stakeholder observer. The consultant presented the approach taken for deriving the carcinogenicity dose-response relationship for EDC. The Rapporteur noted that the substance is not only a mammary gland carcinogen in mice; it also produces tumours in other tissues. Members discussed the issues regarding the choice of the most appropriate tumour study, genotoxic *vs.* non-genotoxic mechanisms for EDC-induced carcinogenicity and human dermal absorption factor values. One Member noted the importance of the oral route of exposure for man via environment. Members requested the consultant to update the draft note on the dose-response relationship by adding additional information from the report in order to provide transparency. There was general agreement between Members that the Nagano mammary tumour study (inhalation exposure) is the only really complete one and therefore the most appropriate study.

With regard to the mode of action of the substance one Member noted that EDC is a multi-tissue carcinogen in animals. However, existing *in vivo* mutagenicity studies do not prove sufficiently a mechanism of carcinogenesis. A number of existing *in vitro* mutagenicity studies are inconclusive and might even give false positive results. The Cefic expert noted that historically the substance has been classified in EU under the Directive 67/548/EEC as a Cat. 2 carcinogen, which corresponds to CLP Carc. 1B, but was not classified as mutagenic. He noted that there are no new tests available that, would support a mutagenic/genotoxic mode of action for carcinogenicity by EDC; to the contrary, EDC was negative in a recent comet assay. In discussing this assay, it was pointed out by one Member that this test was not validated for mammary gland tissue. RAC decided that there was insufficient evidence on both mode of action for carcinogenicity and on genotoxicity to rule out the latter or to consider EDC as a carcinogen with a threshold. The Committee therefore decided to continue developing dose-response curves for EDC and agreed that a linear dose-response would be appropriate.

RAC requested the consultant and the Rapporteur to consider the weight of evidence of the available studies on the dermal absorption and to update the draft note accordingly and to align it with the report.

The Committee agreed to request the consultant to redraft the note, add in missing references to the background paper after which, a 3 to 4 weeks consultation would be launched. Depending on the outcome, the note could be agreed by written procedure as time was pressing or, if further work was still needed, revisited at RAC-33 for agreement.

3. Carcinogenicity dose-response relationship setting for 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

The ECHA consultant presented a revised note on the carcinogenicity dose-response relationship for MOCA. The Rapporteur listed selected key studies noting that the dermal route of exposure was the most significant with this substance and that the oral and dermal absorption factors should be the same (default assumption). RAC agreed on the proposed key studies and on the genotoxic mechanism of carcinogenesis by MOCA. In general RAC agreed on the approach taken by the consultant and agreed in principle on the updated draft note. The Committee requested the consultant and the Rapporteur to update the draft note according to the discussion at the plenary, and the Secretariat to make a final editing of the note for publication on the ECHA website.

4. Carcinogenicity dose-response relationship setting for formaldehyde, oligomeric reaction products with aniline (technical MDA)

The consultant presented a revised note on the carcinogenicity dose-response relationship for technical MDA. The Cefic stakeholder noted that technical MDA is not a registered substance under REACH, which means that it may be used by small to very small downstream users, making communication of the dose-response curves more difficult. The Rapporteur brought to attention of the Committee that although technical MDA might contain up to 50 % of the substance in oligomeric form, it should be assessed as for pure MDA, i.e. oligomeric MDA forms should be considered as potent as the pure substance. The Committee agreed on the genotoxic carcinogenesis induction mechanism.

Regarding absorption of the substance via different routes of exposure, the Committee agreed on the following: 100 % for inhalation, 100 % for oral and 50 % for the dermal routes of exposure. The latter value is supported by published studies. In general RAC agreed on the approach taken by the consultant and agreed in principle on the updated draft note. The Committee requested the consultant and the Rapporteur to update the draft note according to the discussion at the plenary, and the Secretariat to make a final edit of the note prior to publication on the ECHA website.

7.2 Authorisation applications

a) Authorisation application – first version of RAC draft opinion

For all TCE cases and for further applications for authorisation in future, it was agreed by RAC that the information on 'additional statistical cancer cases' should be moved to section 8, and deleted from section 6, which would discuss only the unit risks. This was to avoid confusion between the two sets of values in discussing opinions and to focus clearly on the unit risk.

An NGO observer requested clarification in relation to the REACH legal text Article 64(3) on the Committee's practise of asking applicants for additional information. The Chair answered that he would consult the issue and respond at the next meeting.

1. Trichloroethylene 1:

Use 1 Trichloroethylene used as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries

RAC agreed that for Worker Contributing Scenario 3, which dominates the exposure of workers, the operational conditions and risk management measures are **not** appropriate in limiting the risks. In case the authorisation will be granted, operational conditions and risk management measures need to be improved by appropriate technical measures to reduce exposures in the plant. RAC agreed to recommend air monitoring and biomonitoring (TCA in urine).

RAC drew SEAC's attention to the potentially high exposures and inadequate RMM. RAC also agreed on the basis of the uncertainties with regards to the exposures that SEAC should consider a short review period, so that the applicant can address these issues.

RAC agreed on the draft opinion by consensus.

2. Trichloroethylene 2a:

The Chairman welcomed the Rapporteurs and reported on the state of play of the dossier; the Members then discussed the 5 draft opinions, considering in particular exposure in the workplace and agreeing on the appropriateness or not of the operational conditions and risk management measures in each case.

Use 1 Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be opened for consultation with RAC and discussed for agreement at RAC-33.

Use 2 Industrial use as process chemical (enclosed systems) in Alcantara Material production

RAC agreed by consensus on its opinion and requested the Rapporteurs to make editorial changes after which it would be sent to the applicant.

Use 3 Use of tricholoroethylene in packaging

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be discussed for agreement at RAC-33 following a RAC consultation on the proposed draft.

Use 4 Use of tricholoroethylene in formulation

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be discussed for agreement at RAC-33 following a RAC consultation on the proposed draft.

Use 5 Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be circulated for agreement via written procedure.

3. Trichloroethylene 2b:

The Chairman welcomed the Rapporteurs and reported on the state of play of the dossier; the Members then discussed the 2 draft opinions, considering in particular exposure in the workplace and agreeing on the appropriateness or not of the operational conditions and risk management measures in both cases.

Use 1 Use of Trichloroethylene in formulation

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be discussed for agreement at RAC-33 following a RAC consultation on the proposed draft.

Use 2 Use of trichloroethylene in packaging

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be discussed for agreement at RAC-33 following a RAC consultation on the proposed draft.

4. Trichloroethylene 3:

Use 1 Use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin

The Chairman introduced the application for authorisation.

The Rapporteurs presented the first version of the RAC draft opinion. RAC agreed that risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC agreed to recommend further air monitoring arrangements for presentation at any review. RAC agreed on the draft opinion by consensus, providing no advice to SEAC on the length of the review period.

5. Trichloroethylene 4:

Use 1 Use of trichloroethylene (TCE) as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes

The Chairman introduced the application for authorisation.

The Rapporteurs presented the first version of the RAC draft opinion. RAC considered that the operational conditions and risk management measures in place appeared to be appropriate in limiting the risks. RAC also proposed that any changes to the manufacturing plant should include risk management measures sufficient to limit exposures to workers and humans via

the environment to the least the currently described levels and preferably lower. RAC agreed on the draft opinion by consensus, providing no advice to SEAC on the length of the review period.

6. Trichloroethylene 6:

   Use 1 Trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries

The Chairman introduced the application for authorisation and the Rapporteurs presented the first version of the RAC draft opinion. RAC agreed that the operational conditions and risk management measures are **not** appropriate in limiting the risks. In case the authorisation will be granted, operational conditions and risk management measures need to be improved by appropriate technical measures to reduce exposures in the plant. RAC agreed to recommend biomonitoring arrangements (TCA in urine). RAC agreed on the draft opinion by consensus and recommended that SEAC should consider a short review period on the basis of the uncertainties with regards to the exposures.

7. Trichloroethylene 7:

   Use 1 Use of tricholoroethylene-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber transportation belts in underground hard coal mining

The Chairman introduced the application for authorisation.

The Rapporteurs presented the first version of the RAC draft opinion. RAC considers that the risk management measures and operational conditions as described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC agreed that in case the authorisation will be granted to recommend monitoring arrangements, specifically personal air monitoring (passive monitoring). RAC agreed on the draft opinion by consensus. RAC also agreed on the basis of the uncertainties with regards to the exposures that SEAC should consider a short review period (as requested by the applicant in any case).

8. Trichloroethylene 8:

   Use 1 Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil

The Chairman briefly introduced the case and then invited the Rapporteurs to present the first version of the draft opinion. The Rapporteurs informed the committee regarding their concerns relating to the integrated approach used by the Applicant for calculating combined exposure and statistical cancer cases for impact assessment. The approach was based on calculating the number of "standard employees" required to undertake tasks in Worker Contributing Scenarios over the period of a year. RAC considered that this approach was difficult to evaluate and questioned its suitability. The Rapporteurs had previously expressed their concerns on this issue to the Applicants in written requests for clarification. The Rapporteurs summarised that

based on their assessment, the individual risks for process workers are in the order of 4 x 10-4 and for laboratory workers 3 x 10-5. Whilst this level of risk compared reasonably with the applicant's own assessment of individual risks back-calculated from their "standard employee" approach (process workers: 1.7 x 10-4, laboratory workers: 2.8 x 10-5) the Rapporteurs expressed strong reservations with regards to the quality (i.e. the representativeness) of the exposure assessment undertaken by the applicant because of the use of generic exposure modelling data and uncertainties with respect to the monitoring data used in the assessment (e.g. number of samples used to derive mean values and absence of data on variability). Nevertheless, concerning the RMMs and Operational conditions the Rapporteurs were of the opinion that they are effective and appropriate in limiting the risk. However, due to the risk level reported by the Applicant, and the uncertainties created by the quality issues noted with the exposure assessment, the Rapporteurs advised RAC to recommend several conditions and that SEAC should consider a short review period.

During the discussion Members expressed their concerns on the risk level calculated on the basis of models which are foreseen for indoor activities while the Applicant operates an outdoor installation. RAC supported the Rapporteurs' conclusions and recommendations, agreeing on the draft opinions by consensus. The Rapporteurs together with the Secretariat will finalise the editorial checking of the draft opinions. The Secretariat will send the combined RAC and SEAC draft opinion to the Applicant for their possible comments. The Chairman thanked the Rapporteurs for their efficient and thorough work.

9. Trichloroethylene 9:

Use 1 Industrial use as a process chemical in caprolactam purification

The Chairman briefly introduced the case and then he invited the Rapporteurs to present the first version of the draft opinion. The Rapporteurs explained the exposure assessment for workers and for humans via the environment presented by the Applicant, agreeing with the Applicant's exposure assessment, which was primarily based on biomonitoring data, and the corresponding excess cancer risk calculations. In the Rapporteurs' opinion the OCs and RMMs described in the application appear to be appropriate and effective in limiting the risk to workers and the general population. They proposed that RAC would recommend additional monitoring arrangements for the review report but no recommendation to SEAC for the review period was considered necessary.

RAC supported the Rapporteurs' conclusions and recommendations, agreeing on the draft opinions by consensus. The Rapporteurs together with the Secretariat will finalise the editorial checking of the draft opinions. The Secretariat will send the combined RAC and SEAC draft opinion to the Applicant for their possible comments. The Chairman thanked the Rapporteurs for their efficient and thorough work.

10. Trichloroethylene 10

Use 1 Use as an extraction solvent in caprolactam production

The Chairman briefly introduced the case and then he invited the Rapporteurs to present the first version of the draft opinion. The Rapporteurs presented the draft opinion expressing their concerns on the quality of the application including the reliability of the worker and environmental exposure estimates. They pointed out that the exposure assessment for

workers is highly uncertain, does not address the potential for combined exposure across different tasks and may not correspond completely with the activities actually carried out at the site. They did not support the Applicant's statement that TCE exposures are low. In their opinion the Applicant's assessment of indirect exposure of TCE to humans via the environment is also uncertain. Based on a worst case exposure assessment for workers undertaken by RAC the individual risk level, after taking into account the potential for combined exposure, is in the order of 4 x 10-4.

Having discussed that the level of ambiguity and contradictory information in the application was too high to be able to assess the risk, the Rapporteurs proposed that despite the considerable uncertainties, the worst-case exposure assessment may be suitable for impact assessment.

As a result of the level of individual worker risk associated with the use and the considerable uncertainties outlined above, the Rapporteurs proposed that the risk management measures and operational conditions described in the application appear **not** to be appropriate and effective in limiting the risks. Members agreed to recommend the additional conditions and monitoring arrangements as proposed by the Rapporteurs should an Authorisation be granted and to recommend a short review period to SEAC.

RAC agreed on the draft opinions by consensus. The Rapporteurs together with the Secretariat will finalise the editorial checking of the draft opinions. The Secretariat will send the combined RAC and SEAC draft opinion to the Applicant for their possible comments. The Chairman thanked the Rapporteurs for their efficient and thorough work.

11. Trichloroethylene 11:

Use 1 Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers

The Chairman introduced the application for authorisation. The Rapporteurs presented the first version of the RAC draft opinion. The application considers two plants which have been built but are not yet on stream; the Rapporteurs considered that the CSA provided a good description of the process. Risk management measures and operational conditions as described in the application appear to be appropriate and effective in limiting the risk to workers and the general population. As the applicant had included information on monitoring programmes in the application, RAC did not consider that further monitoring arrangements were necessary. RAC agreed on the draft opinion by consensus, providing no advice to SEAC on the length of the review period.

12. Trichloroethylene 12:

Use 1 Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

The Chairman welcomed the Rapporteurs and reported on the state of play of the dossier; the Members then discussed the draft opinion, in particular the exposure in the workplace and agreeing on the appropriateness or not of the operational conditions and risk management measures.

The Rapporteurs will revise the opinion in accordance with the discussion held at RAC-32. An updated version of the draft opinion will be discussed for agreement at RAC-33 following a RAC consultation on the proposed draft.

b) Authorisation applications – conformity check and presentation of key issues document

1. Lead chromate 1:

Use 1: Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection

The Rapporteur provided brief information on the application for authorisation and presented the draft outcome of the conformity check. The Rapporteur also presented her first impression of the application, highlighting some key issues for the attention of the Committee.

RAC agreed that the application is in conformity and on the Rapporteur's proposals with regard to the key issues in the application. The Secretariat will inform the applicant about the outcome of the conformity check.

7.3 Appointment of Rapporteurs for authorisation applications (closed session)

Following the Chairman's proposal, RAC agreed on the same pool of Rapporteurs for substances no 16 to no 22 of Annex XIV. The pool of Rapporteurs, as outlined in the amended restricted room document RAC/32/2015/13 rev 1, was agreed by RAC.

8. AOB

a) Introduction to Secure CIRCABC Project by the Secretariat

The Secretariat provided information about the Secure-CIRCABC project. The presentation explained the scope of the project, timelines and informed the Members what they can expect and what will be expected from them in next 6 months concerning the collaboration platform. During Q&A session Members provided feedback mainly concerning alternative options for 2-factor identification via mobile personal identification number and asked what will happen with group accounts.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC-32 2-6 March and 10-12 March 2015

(Adopted at the meeting)

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/32/2015**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-32 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC-31 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/32/2015/01** and document **RAC/32/2015/02.**	**SECR** to upload the documents to the CIRCABC non-confidential website.
b) RAC work plan for all processes **SECR** presented the update on the Q1 and Q2/2015 work plan for RAC covering the Classification and Labelling, Restriction and Authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-32 meeting on CIRCABC.
5. Harmonised classification and labelling (CLH)	
A. Hazard classes for agreement without plenary debate a) Carbetamide (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Skin / Eye irritation, Skin / Eye corrosion, Respiratory sensitisation, Skin sensitisation, Germ cell mutagenicity, Aspiration hazard, Aquatic acute toxicity, Aquatic chronic toxicity b) Bendiocarb (ISO): Acute toxicity (oral, dermal), Aquatic acute toxicity, Aquatic chronic toxicity c) Spiroxamine (ISO): Acute toxicity (oral, dermal) d) Tefluthrin (ISO): Aquatic acute toxicity, Aquatic chronic toxicity e) Chlorophene (ISO): Acute toxicity (oral dermal, inhalation), STOT SE, germ cell mutagenicity	
B. Substances with hazard classes for agreement in plenary session a) Thiacloprid (ISO) b) Linalool c) Fenpyrazamine (ISO) d) Carbetamide (ISO)	

e) Bendiocarb (ISO)

f) Spiroxamine (ISO)

g) Tefluthrin (ISO)

h) Chlorophene (ISO)

a) Thiacloprid (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Repr. 1B; H360FD, Acute Tox. 3; H301, Acute Tox. 4; H332, STOT SE 3; H336, Aquatic Acute 1; H400, M=100, Aquatic Chronic 1; H410, M=100]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
b) Linalool	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1B; H317]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
c) Fenpyrazamine (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
d) Carbetamide (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Repr. 1B; H360D, Acute Tox. 4; H302, Aquatic Chronic 2; H411]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
e) Bendiocarb (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**.

[Acute Tox. 2; H300, Acute Tox. 3; H311, Acute Tox. 3; H331, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410; M=100]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
f) Spiroxamine (ISO)	
RAC agreed on hazard classes for the harmonised classification and labelling as indicated in Table 2 below. RAC could not conclude on toxicity to reproduction due to the lack of relevant data on repeated dose toxicity in the original CLH report. [Acute Tox. 4; H302, Acute Tox. 4; H312, Acute Tox. 4; H332, Skin Sens. 1; H317, Aquatic Acute 1; H400, M=100, Aquatic Chronic 1; H410, M=100]	**SECR** to contact the Dossier Submitter with request for the relevant data. In the event of additional data being provided, **SECR** to launch a new (targeted) public consultation. **Rapporteur** to revise the opinion in accordance with the comments provided in the targeted PC. **SECR** to launch a RAC consultation prior to RAC 33 plenary meeting.
g) Tefluthrin (ISO)	
RAC agreed on hazard classes for the harmonised classification and labelling as indicated in Table 2 below. [Aquatic Acute 1; H400, M=10000, Aquatic Chronic 1; H410, M=10000]	**Rapporteur** to prepare the opinion on human health hazards and to provide it to **SECR**. **SECR** to launch a RAC consultation on human health hazards prior to RAC 33 plenary meeting
h) Chlorophene (ISO)	
RAC agreed <u>by consensus</u> on hazard classes for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H332, Skin Irrit. 2; H315, Eye Dam. 1; H318, Skin Sens. 1; H317, STOT RE 2; H373 (kidney), Carc. 2; H351, Repr. 2; H361f, Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=100]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to **SECR**. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.2 Appointment of RAC Rapporteurs for CLH dossiers	
RAC appointed the new Rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed Rapporteurs to CIRCABC confidential.
5.3 General CLH issues	Maintenance of case history summaries would be very useful for the work of RAC; Streamlining the collation of data would help evaluation in Committee.
6. Restrictions	
6.1 Restriction Annex XV dossiers	

a) General restriction issues	
SECR presented the '*recommendations from the task force*' and '*outline for a common approach of RAC and SEAC in opinion development for restriction proposals*' RAC agreed with revised conformity check templates and to implement the templates for the restriction dossiers D4/D5 and PFAS. RAC agreed to introduce the key issues document (KID) during the first plenary meeting, after the conformity check agreement.	**SECR** to upload the agreed templates to the non-confidential CIRCABC restriction folder.
b) Opinion Development	
1. Isopropylidenediphenol (Bisphenol A) – revised draft opinion EFSA representative presented the EFSA scientific opinion on bisphenol A. Rapporteurs presented the revised draft opinion.	**Rapporteur** to revise the opinion in accordance with the discussion. **SECR** to organise a four weeks consultation on the revised draft opinion. **Rapporteurs** to prepare the (second) revised opinion, taking into account the comments from the consultation, for discussion and adoption at RAC 33. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion.
2. Ammonium salts – revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC agreed not to include a derogation for outdoor exterior articles (but to clarify it in the opinion for the benefit of SEAC). RAC adopted the opinion on Ammonium salts by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
3. DecaBDE – first draft opinion Rapporteurs presented and RAC discussed the first draft opinion. Pending conclusion of the Public Consultation, RAC agreed on the environmental hazards, the emissions as a surrogate to risk, that action needs to be taken on EU wide basis and that the proposed restriction is the most appropriate measure to	**Rapporteurs** to take the RAC discussion into account in the revised draft opinion (by end of April 2015). **Rapporteurs** to further consider a qualitative risk assessment of decaBDE with respect to neurotoxicity.

reduce the emissions and thereby the risk.	
4. Perfluorooctanoic acid (PFOA) – key issues document Rapporteurs presented and RAC discussed the key issues document for the RAC opinion. RAC agreed to ask the Dossier Submitter to clarify their views on human health [**NOTE FROM SECR**. more specifically on the relationship between the identified risks and the scope of the restriction and whether a quantitative risk assessment of the human health exposure scenarios is necessary]. RAC agreed that inclusion of PFOA-related substances in the scope is essential to this restriction. RAC agreed to use the available emission factors for the different uses (scenarios) as the basis for the emission estimates. RAC agreed with defining 8:2 FTOH as a PFOA-related substance. RAC agreed with the approach proposed by Rapporteurs for assessing potential degradation.	**SECR** to approach the Dossier Submitter for clarifications of their views on human health. **Rapporteurs** to take the RAC discussion and the Dossier Submitter`s clarifications into account in the first version of the draft opinion (by end of April 2015).
c) Conformity check	
1. Methanol RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to CIRCABC. **SECR** to inform the Dossier Submitter on the outcome of the conformity check.
2. Dimethylformamide RAC agreed that the dossier does not conform to the Annex XV requirements and took note of the recommendations to the Dossier Submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to CIRCABC. **SECR** to inform the Dossier Submitter on the outcome of the conformity check.
7. Authorisation	
7.1 General authorisation issues	
a) General authorisation issues	
The Committee agreed on the document "Introduction of a differentiated approach to agreement on the Committees' draft opinions on the applications for authorisation" (RAC/31/2015/08).	**SECR** to do the final editing of the agreed document. **SECR** to publish the agreed document on the ECHA website.
b) Capacity building	

1. DNEL values setting for the reproductive toxicant bis(2-methoxyethyl)ether (diglyme) RAC requested the consultant to derive DNEL values for reprotoxic properties of Diglyme, based separately on four identified reliable studies.	**SECR** to launch RAC consultation on the updated draft note.
2. Carcinogenicity dose-response relationship setting for 1,2-dichloroethane (EDC) RAC requested the consultant to update the draft note on the dose-response relationship by adding additional information from the report in order to provide transparency to the causal link. RAC requested the consultant and the RAC Rapporteur to consider the weight of evidence of the available studies on the dermal absorption, and to update the draft note accordingly and to align it with the report.	**SECR** to launch RAC consultation on the updated draft note.
3. Carcinogenicity dose-response relationship setting for 2,2'-dichloro-4,4'-methylenedianiline (MOCA) RAC agreed on the proposed key studies as suggested by the consultant and the RAC Rapporteur. RAC agreed on the genotoxic mechanism of carcinogenesis by MOCA. In general RAC agreed on the approach taken by the consultant and agreed in principle on the updated draft note.	The consultant and the RAC Rapporteur to update the draft note according to the discussion at the plenary. **SECR** to do the final editing of the agreed note.
4. Carcinogenicity dose-response relationship setting for formaldehyde, oligomeric reaction products with aniline (technical MDA) RAC agreed on the genotoxic carcinogenesis induction mechanism of the substance. RAC agreed on the approach taken by the consultant and agreed in principle on the updated draft note.	The consultant and the RAC Rapporteur to update the draft note according to the discussion at the plenary. **SECR** to do the final editing of the agreed note.
7.2 Authorisation applications	
a) Authorisation application – 1st version of RAC draft opinion	
1. Trichloroethylene 1: [Confidential until the draft received by the applicant] **<u>Use 1</u>:** Trichloroethylene used as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries RAC agreed on the draft opinion by consensus. RAC agreed that for WCS 3 operational	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

conditions and risk management measures are not appropriate in limiting the risks. In case the authorisation will be granted, operational conditions and risk management measures need to be improved by appropriate technical measures to reduce exposures in the plant. RAC agreed to recommend monitoring arrangements (air monitoring, biomonitoring as TCA in urine). RAC agreed to recommend to SEAC a short review period.	
2. Trichloroethylene 2a: **<u>Use 1:</u>** Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist **<u>Use 2:</u>** Industrial use as process chemical (enclosed systems) in Alcantara Material production **<u>Use 3</u>**: Use of Trichloroethylene in packaging **<u>Use 4</u>**: Use of Trichloroethylene in formulation **<u>Use 5:</u>** Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis **Use 1:** The draft opinion is still under consideration by RAC. **<u>Use 2:</u>** RAC agreed on the draft opinion by consensus.	Actions: **TCE2a use 1** **SECR** to ask Applicant on clarification regarding the types of machines used and how these relate to the operational conditions and exposures described in the application. **Rapporteurs** to revise the opinion in accordance with the discussion held at RAC 32. **SECR** to organise a consultation on the revised draft opinion. **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, which will be tabled for discussion and adoption at RAC 33. **TCE2a use 2** **Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to

	comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
Use 3: RAC agreed in principle with the Rapporteurs' conclusions regarding exposure and the appropriateness and effectiveness of the RMMs and OCs.	**TCE2a use 3** **Rapporteurs** to revise the draft opinion in accordance with the discussion held at RAC 32 (for this use and related uses: TCE2a/use4 and TCE2b/use1&2) following advice by the Secretariat on some specific issues. **SECR** to organise a consultation on the revised draft opinion. **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, which will be tabled for discussion and adoption at RAC 33.
Use 4: RAC agreed in principle with the Rapporteurs' conclusions regarding exposure and the appropriateness and effectiveness of the RMMs and OCs.	**TCE2a use 4** **Rapporteurs** to revise the draft opinion in accordance with the discussion held at RAC 32 for this use and related uses (TCE2a/use3 and TCE2b/use1&2). **SECR** to organise a consultation on the revised draft opinion. **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, which will be tabled for discussion and adoption at RAC 33.
Use 5: RAC agreed on the appropriateness and effectiveness of the RMMs and OCs.	**TCE2a use 5** **Rapporteurs** to revise the draft opinion in accordance with the discussion held at RAC 32. **SECR** to organise a one week consultation **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, for which **SECR** will launch

	written procedure.
3. Trichloroethylene 2b: **<u>Use 1</u>**: Use of Trichloroethylene in formulation **<u>Use 2</u>**: Use of Tricholoroethylene in packaging **<u>Use 1</u>**: RAC agreed in principle with the Rapporteurs' conclusions regarding exposure and the appropriateness and effectiveness of the RMMs and OCs. **<u>Use 2</u>**: RAC agreed in principle with the Rapporteurs' conclusions regarding exposure and the appropriateness and effectiveness of the RMMs and OCs.	**TCE2b use 1** **Rapporteurs** to revise the draft opinion in accordance with the discussion held at RAC 32 (for this use and related uses: TCE2a/uses 3&4 and TCE2b/use 2) following advice by the Secretariat on some specific issues. **SECR** to organise a consultation on the revised draft opinion. **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, which will be tabled for discussion and adoption at RAC 33. **TCE2b use 2** **Rapporteurs** to revise the draft opinion in accordance with the discussion held at RAC 32 (for this use and related uses: TCE2a/uses 3&4 and TCE2b/use1) following advice by the Secretariat on some specific issues. **SECR** to organise a consultation on the revised draft opinion. **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, which will be tabled for discussion and adoption at RAC-33.
4. Trichloroethylene 3: **<u>Use 1:</u>** Use of Trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will

	inform RAC.
5. Trichloroethylene 4: **<u>Use 1:</u>** Use of Trichloroethylene (TCE) as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
6. Trichloroethylene 6: **<u>Use 1:</u>** Trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicants for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
7. Trichloroethylene 7: **<u>Use 1:</u>** Use of tricholoroethylene-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber transportation belts in underground hard coal mining RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicants for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
8. Trichloroethylene 8: **<u>Use 1</u>**: Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil RAC agreed on the draft opinion by consensus	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1:* Should the Applicant not wish to comment or fails to comment by the

	deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
9. Trichloroethylene 9: **<u>Use 1:</u>** Industrial use as a process chemical in caprolactam purification RAC agreed on the draft opinion by consensus	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1:* Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
10. Trichloroethylene 10: **<u>Use 1:</u>** Use as an extraction solvent in caprolactam production RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
11. Trichloroethylene 11: **<u>Use 1:</u>** Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicants for commenting. *Option 1:* Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2:* Should the Applicant wish to

	comment, **SECR** will make the Applicant's comments available on CIRCABC and will inform RAC.
12. Trichloroethylene 12: **Use 1:** Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems The draft opinion is still under consideration by RAC.	**TCE 12** **Rapporteurs** to revise the opinion in accordance with the discussion held at RAC 32. **SECR** to organise consultation on the revised draft opinion. **Rapporteurs** to prepare the second version of the draft opinion, taking into account the comments from the consultation, which will be tabled for discussion and adoption at RAC 33.
b) Authorisation application – outcome of conformity check and presentations of key issues	
1. Lead chromate 1: **Use 1:** Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection RAC agreed on conformity of the application for authorisation. RAC agreed on Rapporteur's proposals with regard to the key issues in the application.	**SECR** to upload to CIRCABC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
7.3 Appointment of Rapporteurs for authorisation applications RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
8. AOB	
1. Introduction to Secure CIRCABC Project by the Secretariat	
9. Action points and main conclusions of RAC-32	
SECR to upload the adopted action points to CIRCABC.	

Table 1: Dossiers where the harmonised classification and labelling was adopted by RAC, i.e. the opinion was adopted

Thiacloprid (ISO); {(2Z)-3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene}cyanamide

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitter proposal		thiacloprid (ISO); {(2Z)-3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene}cyanamide	-	111988-49-9	Carc. 2 Repr. 2 Acute Tox. 4 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H351 H361f H332 H301 H400 H410	GHS06 GHS08 GHS09 Wng	H351 H361f H332 H301 H410		 M=100 M=100	
RAC opinion		thiacloprid (ISO); {(2Z)-3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene}cyanamide	-	111988-49-9	Carc. 2 Repr. 1B Acute Tox. 4 Acute Tox. 3 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H351 H360FD H332 H301 H336 H400 H410	GHS06 GHS08 GHS09 Dgr	H351 H360FD H332 H301 H336 H410		 M=100 M=100	
Resulting Annex VI entry if agreed by COM		thiacloprid (ISO); {(2Z)-3-[(6-chloropyridin-3-yl)methyl]-1,3-thiazolidin-2-ylidene}cyanamide	-	111988-49-9	Carc. 2 Repr. 1B Acute Tox. 4 Acute Tox. 3 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H351 H360FD H332 H301 H336 H400 H410	GHS06 GHS08 GHS09 Dgr	H351 H360FD H332 H301 H336 H410		 M=100 M=100	

Linalool; 3,7-dimethyl-1,6-octadien-3-ol; *dl*-linalool [1]

Coriandrol; (*S*)-3,7-dimethyl-1,6-octadien-3-ol; *d*-linalool [2]

Licareol; (*R*)-3,7-dimethyl-1,6-octadien-3-ol; *l*-linalool [3]

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)		
Current Entry	**No current Annex VI entry**										
Dossier submitter proposal		linalool; 3,7-dimethyl-1,6-octadien-3-ol; *dl*-linalool [1] coriandrol; (*S*)-3,7-dimethyl-1,6-octadien-3-ol; *d*-linalool [2] licareol; (*R*)-3,7-dimethyl-1,6-octadien-3-ol; *l*-linalool [3]	201-134-4 [1] 204-810-7 [2] 204-811-2 [3]	78-70-6 [1] 126-90-9 [2] 126-91-0 [3]	Skin Sens. 1A	H317	GHS07 Wng	H317			
RAC opinion		linalool; 3,7-dimethyl-1,6-octadien-3-ol; *dl*-linalool [1] coriandrol; (*S*)-3,7-dimethyl-1,6-octadien-3-ol; *d*-linalool [2] licareol; (*R*)-3,7-dimethyl-1,6-octadien-3-ol; *l*-linalool [3]	201-134-4 [1] 204-810-7 [2] 204-811-2 [3]	78-70-6 [1] 126-90-9 [2] 126-91-0 [3]	Skin Sens. 1B	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM		linalool; 3,7-dimethyl-1,6-octadien-3-ol; *dl*-linalool [1] coriandrol; (*S*)-3,7-dimethyl-1,6-octadien-3-ol; *d*-linalool [2]	201-134-4 [1] 204-810-7 [2] 204-811-2 [3]	78-70-6 [1] 126-90-9 [2] 126-91-0 [3]	Skin Sens. 1B	H317	GHS07 Wng	H317			

		licareol; (*R*)-3,7-dimethyl-1,6-octadien-3-ol; *l*-linalool [3]									

Fenpyrazamine (ISO); S- allyl 5-amino-2- isopropyl-4-(2-methylphenyl)-3-oxo-2,3-dihydro-1H-pyrazole-1- carbothioate

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)		
Current Entry	613-318-00-5	fenpyrazamine (ISO); S- allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3- dihydro-1H-pyrazole-1-carbothioate	-	473798-59-3	Aquatic Chronic 2	H411	GHS09	H411			
Dossier submitter proposal	613-318-00-5	fenpyrazamine (ISO); S- allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3- dihydro-1H-pyrazole-1-carbothioate	-	473798-59-3	**Add** Aquatic Acute 1 **Modify** Aquatic Chronic 1	**Add** H400 **Modify** H410	GHS09 **Add** Wng	H410		**Add** M=10 M=10	
RAC opinion	613-318-00-5	fenpyrazamine (ISO); S- allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3- dihydro-1H-pyrazole-1-carbothioate	-	473798-59-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 M=1	
Resulting Annex VI entry if agreed by COM	613-318-00-5	fenpyrazamine (ISO); S- allyl 5-amino-2-isopropyl-4-(2-methylphenyl)-3-oxo-2,3- dihydro-1H-pyrazole-1-carbothioate	-	473798-59-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 M=1	

Carbetamide (ISO); (2*R*)-1-(ethylamino)-1-oxopropan-2-yl phenylcarbamate

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)		
Current Entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	carbetamide (ISO); (2*R*)-1-(ethylamino)-1-oxopropan-2-yl phenylcarbamate	240-286-6	16118-49-3	Carc. 2 Repr. 2 Acute Tox. 4 Aquatic Chronic 2	H351 H361d H302 H411	GHS08 GHS07 Wng	H351 H361d H302 H411			
RAC opinion	TBD	carbetamide (ISO); (2*R*)-1-(ethylamino)-1-oxopropan-2-yl phenylcarbamate	240-286-6	16118-49-3	Carc. 2 Repr. 1B Acute Tox. 4 Aquatic Chronic 2	H351 H360D H302 H411	GHS08 GHS07 GHS09 Dgr	H351 H360D H302 H411			
Resulting Annex VI entry if agreed by COM	TBD	carbetamide (ISO); (2*R*)-1-(ethylamino)-1-oxopropan-2-yl phenylcarbamate	240-286-6	16118-49-3	Carc. 2 Repr. 1B Acute Tox. 4 Aquatic Chronic 2	H351 H360D H302 H411	GHS08 GHS07 GHS09 Dgr	H351 H360D H302 H411			

Bendiocarb (ISO); 2,2-dimethyl-1,3 benzodioxol-4-yl n-methylcarbamate

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)		
Current Entry	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H312 H400 H410	GHS06 GHS09 Dgr	H331 H301 H312 H410			
Dossier submitters proposal	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	**Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	**Modify** H330 H311 H300 **Add** H400 **Retain** H410	**Retain** GHS06 GHS09 Dgr	**Modify** H330 H311 H300 **Retain** H410		**Add** M=10 M=100	
RAC opinion	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	Acute Tox. 3 Acute Tox. 3 Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H300 H400 H410	GHS06 GHS09 Dgr	H331 H311 H300 H410		 M=10 M=100	
Resulting Annex VI entry if agreed by COM	006-046-00-8	bendiocarb (ISO); 2,2-dimethyl-1,3-benzodioxol-4-yl N-methylcarbamate	245-216-8	22781-23-3	Acute Tox. 3 Acute Tox. 3 Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H300 H400 H410	GHS06 GHS09 Dgr	H331 H311 H300 H410		 M=10 M=100	

Clorofene (ISO); chlorophene (ISO); clorophene (ISO); 2-benzyl-4-chlorophenol

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)		
Current Entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	Clorofene (ISO); chlorophene (ISO); clorophene (ISO); 2-benzyl-4-chlorophenol	204-385-8	120-32-1	Carc. 2 Repr. 2 Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1A Eye Dam. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H361f H332 H315 H317 H318 H372 (kidney) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H361f H331 H315 H317 H318 H372 (kidney) H410		M=1 M=100	
RAC opinion	TBD	Clorofene (ISO); chlorophene (ISO); clorophene (ISO); 2-benzyl-4-chlorophenol	204-385-8	120-32-1	Carc. 2 Repr. 2 Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Dam. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361f H332 H315 H317 H318 H373 (kidney) H400 H410	GHS08 GHS05 GHS07 GHS09 Dgr	H351 H361f H332 H315 H317 H318 H373 (kidney) H410		M=1 M=100	
Resulting Annex VI entry if agreed by COM	TBD	Clorofene (ISO); chlorophene (ISO); clorophene (ISO); 2-benzyl-4-chlorophenol	204-385-8	120-32-1	Carc. 2 Repr. 2 Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Dam. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361f H332 H315 H317 H318 H373 (kidney) H400 H410	GHS08 GHS05 GHS07 GHS09 Dgr	H351 H361f H332 H315 H317 H318 H373 (kidney) H410		M=1 M=100	

Table 2: Dossiers where some, but not all proposed hazards classes were agreed by RAC

Spiroxamine (ISO); 8-*tert*-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine

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)		
Current Entry	612-150-00-X	spiroxamine (ISO); 8-*tert*-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H332 H312 H302 H315 H317 H400 H410	GHS07 GHS09 Wng	H332 H312 H302 H315 H317 H410			
Dossier submitters proposal	612-150-00-X	spiroxamine (ISO); 8-*tert*-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	**Add** Repr. 2 **Modify** Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Skin Sens. 1B **Retain** Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	**Add** H361d **Retain** H332 H312 H302 H317 H315 H400 H410	**Add** GHS08 **Retain** GHS07 GHS09 Wng	**Add** H361d **Retain** H332 H312 H302 H315 H317 H410		**Add** M=100 M=100	
RAC opinion	612-150-00-X	spiroxamine (ISO); 8-*tert*-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine	-	118134-30-8	Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Skin Sens. 1 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 Repr.	H332 H312 H302 H317 H315 H400 H410 …	GHS07 GHS09 Wng …	H332 H312 H302 H317 H315 H410 …		M=100 M=100	

Resulting Annex VI entry if agreed by COM	612-150-00-X	spiroxamine (ISO); 8-*tert*-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine									

Tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate

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)		
Current Entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	-	79538-32-2	Acute Tox. 1 Acute Tox. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H300 H372 (nervous system) H400 H410	GHS06 GHS08 GHS09 Dgr	H330 H310 H300 H372 (nervous system) H410		M=10000 M=10000	
RAC opinion	TBD	tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	-	79538-32-2	Aquatic Acute 1 Aquatic Chronic 1 Acute Tox. 1 Acute Tox. 2 Acute Tox. 2 STOT RE 1	H400 H410 H330 H310 H300 H372 (nervous system)	GHS09 GHS06 GHS08 Dgr	H410 H330 H310 H300 H372 (nervous system)		M=10000 M=10000	
Resulting Annex VI entry if agreed by COM	TBD	tefluthrin (ISO); 2,3,5,6-tetrafluoro-4-methylbenzyl (1RS,3RS)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	-	79538-32-2							

Part III. List of Attendees of the RAC-32 A meeting

2-6 March 2015

RAC Members
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
CARVALHO João
CZERCZAK Slawomir
Di PROSPERO FANGHELLA Paola
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HÖLZL Christine
ILIE Mihaela
JENSEN Frank
KADIĶIS Normunds
KAPELARI Sonja
KORATI Safia
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MULLOOLY Yvonne
NEUMANN Michael
PARIS Pietro
PASQUIER Elodie
PRONK Marja

RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLÚTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SOERENSEN Peter
SPETSERIS Nikolaos
STAHLMANN Ralf
STASKO Jolanta
TADEO José Luis
TSITSIMIPIKOU Christina
UZOMECKAS Zilvinas
VARNAI Veda Marija
Excuses
BRANISTEANU Radu
KALOGIROU Andreas
MURRAY Brendan
VIVIER Stephanie
Advisers to the RAC Members
BISCEGLIE Sara (adviser to Pietro Paris)
KOPONEN Milja (adviser to Tiina Santonen)
VÄÄNÄNEN Virpi (adviser to Tiina Santonen)

Stakeholders observers
ANNYS Erwin, Cefic
BARRY Frank, ETUC
MUNARI Tomaso, EuCheMS
ROHDE Arlean, CONCAWE
ROMANO Dolores, EEB
VEROUGSTRAETE Violaine, Eurometaux
Industry experts
BEYER Dieter (Cefic, bisphenol A)
BOCK Ronald (Cefic, PFOA)
MICHAUX Michel (Cefic, DecaBDE)
ÅGERSTRAND Marlene (BPA, DecaBDE, PFOA)
SEAC Rapporteur
KIISKI Johanna (PFOA)
Dossier Submitters
Norwegian Dossier Submitters:
GUTZKOW Kristine (PFOA)
MYHRE Ingunn Correll (PFOA)
MYHRE Oddvar (DecaBDE)
German Dossier Submitters :
STARKE Sue-Martina (PFOA)
French Dossier Submitters:
ROUSSELLE Christophe (bisphenol A)

EFSA expert
PIROW Ralph (BPA)
European Commission observers
FERNANDES DE BARROS Mariana (DG GROW)
HEIDORN Christian (DG ENV)
ECHA staff
BERGES Markus
BLAINEY Mark
BOWMER Tim, Chairman
DVORAKOVA Dana
HENNIG Philipp
JOVER BUSTILLO Vanessa
KANELLOPOULOU Athanasia
KIOKIAS Sotirios
KIVELÄ Kalle
KOKKOLA Leila
KOSK-BIENKO Joanna
KOSTIKA Xenia
LEGZDIPA Ilze
LOGTMEIJER Christiaan
LUDBORŽS Arnis
MARQUEZ-CAMACHO Mercedes
MAZZOLINI Anna
MERKOURAKIS Spyridon
MOTTET Denis
ORISPÄÄ Katja
PELTOLA Jukka
PENNESE Daniele
REGIL Pablo
RODRIGUEZ-IGLESIAS Pilar

ROGGEMAN Maarten		**Dossier Submitters**
SADAM Diana		
SIMPSON Peter		**DE Dossier Submitters:**
SMILOVICI Simona		BIEGEL-ENGLER Annegret
SOSNOWSKI Piotr		NIEDERSTRASSER Bernd (PFOA)
STOYANOVA Evgenia		STAUDE Claudia (PFOA)
VAN HAELST Anniek		
		FR Dossier Submitters:
REMOTE PARTICIPANTS		FIORE Karine (BPA)
RAC Members		LECOQ Pierre (ammonium salts)
BRANISTEANU Radu VIVIER Stephanie		PERNELET-JOLY Valérie (ammonium salts)
Advisers :		**IT Dossier Submitters:**
		ATTILAS Leonello (DMF)
GRAVE-LARSEN Louise (adviser to Frank Jensen)		
GRUVMARK Jesper (adviser to Frank Jensen)		**NO Dossier Submitters:**
LOSERT Annemarie (adviser to Christine Hölzl)		FOTLAND Tor Oystein (DecaBDE)
		HOFER Tim (DecaBDE)
SEAC Rapporteurs		MYHRE Ingunn Correll)DecaBDE)
BRIGNON Jean-Marc (PFOA)		KOPANGEN Marit (PFOA, DecaBDE)
CSERGO Robert		
FIORE Karine (lead chromate 1)		**PL Dossier Submitters:**
FOCK Lars (DMF)		GODALA Mariusz (methanol)
GRANDI Silvia (methanol)		MAJKA Jerzy (methanol)
SLETTEN Thea (BPA)		
THIELE Thiele (DecaBDE)		
SEAC adviser		
RONGENEEL Rob (ammonium salts)		
European Commission observers:		
BERTATO Valentina		
GARCIA JOHN Enrique		
LUVARA Giuseppina		
RIEPMA Wim		
ROZWADOWSKI Jacek		

Part III. List of Attendees of the RAC-32 B meeting

10-12 March 2015

RAC Members
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
CARVALHO João
CZERCZAK Slawomir
Di PROSPERO FANGHELLA Paola
DUNAUSKIENĖ Lina
DUNGEY Stephen
GUSTAFSON Anne-Lee
HAKKERT Betty
HÖLZL Christine
ILIE Mihaela
JENSEN Frank
KADIĶIS Normunds
KAPELARI Sonja
KORATI Safia
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MURRAY Brendan
NEUMANN Michael
PARIS Pietro
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHULTE Agnes

SMITH Andrew
SOGORB Miguel
SOERENSEN Peter
SPETSERIS Nikolaos
TSITSIMIPIKOU Christina
UZOMECKAS Zilvinas
VARNAI Veda Marija
VIVIER Stephanie
Apologies
RAC Members:
BRANISTEANU Radu
GRUIZ Katalin
KALOGIROU Andreas
MULLOOLY Yvonne
PASQUIER Elodie
SCHLUETER Urs
STAHLMANN Ralf
Invited experts
RUMSBY Paul (AfA dose-response)
European Commission observers
SCAZZOLA Roberto (DG GROW)

Advisers to the RAC Members		**WEBEX – remote participants**
ALESSANDRELLI Maria (adviser to Paola di Prospero)		**RAC Members**
CROWTHER Ally (adviser to Andrew Smith, and CLH dossier chlorophone)		BRANISTEANU Radu
GIARDINA Silvia (adviser to Pietro Paris)		GRUIZ Katalin
PECZKOWSKA Beata (adviser to Boguslaw Baranski, and CLH dossier spiroxamine)		PASQUIER Elodie
RISSANEN Eeva (adviser to Riitta Leinonen)		HAKKERT Betty (10.3)
STOCKMANN-JUVALA (adviser to Tiina Santonen)		**RAC Advisers**
WINTHER Toke (adviser to Peter Hammer Soerensen)		LOSERT Annemarie (adviser to Hölzl)
		Dossier Submitters
Stakeholders observers		HARALDSEN Terje (chlorofene) - NO
ANNYS Erwin, Cefic		KARLBERG Ann-Therese (linalool) - SE
POOLE Alan		OREDSSON HAGSTRÖM Brita (linalool) - SE
ROWE Rocky, ECPA		
VEROUGSTRAETE Violaine, Eurometaux		**European Commission observers**
		BERTATO Valentina
Industry experts		GARCIA JOHN Enrique
HENNINGER Kerstin (ECPA, thiacloprid, spiroxamine)		LUVARA Giuseppina
TEGETHOFF Kerstin (Cefic, chlorophone)		RIEPMA Wim
SHIP Elizabeth (ECPA, bendiocarb)		ROZWADOWSKI Jacek
STRUPP Christian (ECPA, carbetamide)		DE-GAETANO Federica (linalool)
VEY Matthias (Cefic, linalool)		
WILMER Jan (Cefic, AfA dose-response)		**EFSA :**
		ISTACE Fréderique

ECHA staff	
BERGES Markus	
BOWMER Tim, Chairman	
BROECKAERT Fabrice	
DVORAKOVA Dana	
ERICSSON Gunilla	
GEORGIADIS Nikolaos	
JOVER BUSTILLO Vanessa	
HELLSTEN Kati	
HONKANEN Jani	
KARJALAINEN Ari	
KIVELÄ Kalle	
KLAUK Anja	
KOKKOLA Leila	
KOSK-BIENKO Joanna	
KOSTIKA Xenia	
LAPENNA Silvia	
LUDBORŽS Arnis	
LIOPA Elina	
LOGTMEIJER Christiaan	
LUSCHÜTZKY Evita	
MAZZOLINI Anna	
NICOT Thierry	
NYGREN Jonas	
PENNESE Daniele	
PERAZZOLA Chiara	
REGIL Pablo	
RODRIGUEZ-IGLESIAS Pilar	
SMILOVICI Simona	
SOSNOWSKI Piotr	
VAN HAELST Anniek	

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-32 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-32 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-32 meeting

ANNEX IV Administrative issues and information items

ANNEX I (RAC-32)

2 March 2015
RAC/A/32/2015

Final Agenda
32nd meeting of the Committee for Risk Assessment

2-6 March 2015
10-12 March 2015

ECHA Conference Centre (Annankatu 18, Helsinki)

2 March starts at 9.00
6 March ends at 12:30
10 March starts at 9.00
12 March ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/32/2015
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 31 action points, written procedures and an update on other ECHA bodies

RAC/32/2015/01
RAC/32/2015/02 (room document)
For information

b) RAC workplan for all processes

For information

c) General RAC procedures
(Closed session)

RAC/32/2015/03
(Restricted document)
For agreement

Item 5 – Harmonised classification and labelling (CLH)

5.1 CLH dossiers

A. Hazard classes for agreement without plenary debate (fast-track)

f) Carbetamide (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Skin / Eye irritation, Skin / Eye corrosion, Respiratory sensitisation, Skin sensitisation, STOT RE, Germ cell mutagenicity, Aspiration hazard, Aquatic acute toxicity, Aquatic chronic toxicity

g) Bendiocarb (ISO): Acute toxicity (oral, dermal), Aquatic acute toxicity, Aquatic chronic toxicity

h) Spiroxamine (ISO): Acute toxicity (oral, dermal)

i) Tefluthrin (ISO): Aquatic acute toxicity, Aquatic chronic toxicity

j) Chlorophene: Acute toxicity (oral, dermal, inhalation), STOT SE, Eye damage*, Germ cell mutagenicity

** May be discussed depending on the outcome of Skin irritation*

B. Hazard classes for agreement with plenary debate

f) Thiacloprid (ISO)

g) Linalool

h) Fenpyrazamine (ISO)

i) Carbetamide (ISO)

j) Bendiocarb (ISO)

k) Spiroxamine

l) Chlorophene

For discussion/adoption

5.2 Appointment of RAC Rapporteurs for CLH dossiers

RAC/32/2015/04 (room document)
For agreement

5.3 General CLH issues

Item 6 – Restrictions

6.1 Restriction Annex XV dossiers

a) General restriction issues

RAC/32/2015/05
RAC/32/2015/06
For discussion and agreement

b) Opinion development

1) Isopropylidenediphenol (Bisphenol A) – revised draft opinion

For adoption

2) Ammonium salts – revised draft opinion

For adoption

3) DecaBDE – first draft opinion

For discussion

4) Perfluorooctanic acid (PFOA) – key issues

For discussion

c) Conformity check

i. Methanol

For agreement

ii. Dimethylformamide

For agreement

6.2 Appointment of Rapporteurs for restriction dossiers

RAC/32/2015/07
(Restricted room document)
For agreement

Item 7 – Authorisation

7.1 General authorisation issues

b) General authorisation issues

RAC/32/2015/08
For discussion and agreement

b) Capacity building:

1. DNEL values setting for the reproductive toxicant bis(2-methoxyethyl)ether (diglyme),

RAC/32/2015/09
For discussion and agreement

2. Carcinogenicity dose-response relationship setting for 1,2-dichloroethane (EDC),

RAC/32/2015/10
For discussion

3. Carcinogenicity dose-response relationship setting for 2,2'-dichloro-4,4'-methylenedianiline (MOCA),

4. Carcinogenicity dose-response relationship setting for formaldehyde, oligomeric reaction products with aniline (technical MDA)

7.2 Authorisation applications

b) Authorisation application – first version of RAC draft opinion

13. The use of trichloroethylene submitted by *Microporous GmbH* (Trichloroethylene 1):

    Use 1: Trichloroethylene used as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries

14. Five uses of trichloroethylene submitted by *DOW Deutschland Anlagengesellschaft mbH* (Trichloroethylene 2a):

    Use 1: Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist

    Use 2: Industrial use as process chemical (enclosed systems) in Alcantara Material production

    Use 3: Use of tricholoroethylene in packaging

    Use 4: Use of tricholoroethylene in formulation

    Use 5: Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis

15. Two uses of trichloroethylene submitted by *Richard Geiss GmbH* (Trichloroethylene 2b):

    Use 1: Use of Trichloroethylene in formulation

    Use 2: Use of tricholoroethylene in packaging

16. The use of trichloroethylene submitted by *ROQUETTE Frères* (Trichloroethylene 3):

    Use 1: Use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin

17. The use of trichloroethylene submitted by *Parker Hannifin Manufacturing Netherlands (Filtration and Separation) bv* (Trichloroethylene 4):

Use 1: Use of trichloroethylene (TCE) as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes

18. The use of trichloroethylene submitted by *ENTEK International Limited* (Trichloroethylene 6):

    Use 1: Trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries

19. The use of trichloroethylene submitted by *RAG Aktiengesellschaft* and *RAG Anthrazit Ibbenbüren* (Trichloroethylene 7):

    Use 1: Use of tricholoroethylene-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber transportation belts in underground hard coal mining

20. The use of trichloroethylene submitted by *DOMO Caproleuna GmbH* (Trichloroethylene 8):

    Use 1: Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil

21. The use of trichloroethylene submitted by *Grupa Azoty S.A.* (Trichloroethylene 9):

    Use 1: Industrial use as a process chemical in caprolactam purification

22. The use of trichloroethylene submitted by *Spolana, a.s.* (Trichloroethylene 10):

    Use 1: Use as an extraction solvent in caprolactam production

23. The use of trichloroethylene submitted by *A.L.P.A.-AZIENDA LAVORAZIONE PRODOTTI AUSILIARI S.P.A.* and *CAFFARO INDUSTRIE S.P.A.* (Trichloroethylene 11):

    Use 1: Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers

24. The use of trichloroethylene submitted by *Chimcomplex SA Borzesti* (Trichloroethylene 12):

    Use 1: Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

For discussion/agreement

c) Authorisation applications – conformity check and presentation of key issues
   a. Lead chromate 1:

   Use 1: Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection

For agreement

7.3 Appointment of Rapporteurs for authorisation applications (closed session)

RAC/32/2015/13
(Restricted room document)
For agreement

Item 8 – AOB

Introduction to Secure CIRCABC Project by the Secretariat

For information

Item 9 – Action points and main conclusions of RAC-32

Table with Conclusions and Action points from RAC-32

For adoption

ANNEX II (RAC-32)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-32 meeting.

Document number	Title
RAC/A/32/2015	Final Draft Agenda
RAC/32/2015/01	Report from other ECHA bodies and activities
RAC/32/2015/02 Room document	Administrative document
RAC/32/2015/03 Restricted	General RAC procedures (stakeholder document)
RAC/32/2015/04 Room document Restricted	Appointment of RAC Rapporteurs for CLH dossiers
RAC/32/2015/05 a+b RAC/32/2015/06 a+b	General restriction issues – revised conformity check report for restriction process General restriction issues – revised recommendations for restriction process
RAC/32/2015/07 Restricted	Appointment of Rapporteurs for restriction dossiers
RAC/32/2015/08	General authorisation issues
RAC/32/2015/09	Capacity building: DNEL values setting for the reproductive toxicant bis(2-mothoxyethyl)ether (diglyme)
RAC/32/2015/10	Capacity building: carcinogenicity dose-response relationship setting for 1,2-dichloroethane (EDC)
RAC/32/2015/11	Capacity building: carcinogenicity dose-response relationship setting for 2,2-dichloro-4,4-methylenedianiline (MOCA)
RAC/32/2015/12	Capacity building: carcinogenicity dose-response relationship setting for formaldehyde, oligomeric reaction products with aniline (technical MDA)
RAC/32/2015/13 Room document Restricted	Appointment of Rapporteurs for authorisation applications

ANNEX III (RAC-32)

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT RAC 29, 30 and/or 31		
RESTR: Ammonium salts (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Tiina SANTONEN	Being involved in a study on BPA performed by her employer.
RESTR: DecaBDE (ECHA)	Christine BJØRGE	Working for the CA who collaborated with ECHA on the preparation of the dossier.
CLH: Thiacloprid (ISO) (UK)	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: PFOA	Christine BJØRGE	Working for the CA who collaborated with Germany on the preparation of the dossier.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
REST: DMF (IT)	Paola DI PROSPERO FANGHELLA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Stephanie VIVIER	Being involved in the preparation of a 'RMO-like' report performed by INERIS for a MSCA
REST: Methanol (FI & PL)	Riitta LEINONEN	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
	Boguslaw BARANSKI	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
CLH: Carbetamide (ISO) (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Bendiocarb (ISO) (UK)	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Spiroxamine (ISO) (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Tefluthrin (ISO) (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Chlorophene (NO)	Christine BJØRGE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Linalool (SE)	Anne-Lee GUSTAFSON	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Fenpyrazamine (AT)	Christine HÖLZL	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

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Annex IV

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-31 Action Points

The RAC-31 action points due for RAC-32 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions / minutes of the meeting

Opinions / minutes adopted via written procedure	Deadline	Report on the Outcome
AfA: Adoption of the RAC Final Opinion on uses 1 and 2 of the application for authorisation DH003731-61 (DEHP2c)	26 January 2015	Adopted
Written procedure for adoption of the minutes of RAC-31	12 February 2015	Adopted

2.2 Written dossier consultations (status by 2 March 2015)

Subject / Document	Deadline	Status / follow-up
CLH: Thiacloprid (ISO) – 2nd RAC consl.	10 February 2015	Closed
CLH: Chlorophene	10 February 2015	Closed
CLH: Bendiocarb (ISO)	10 February 2015	Closed
CLH: Carbetamide (ISO)	6 February 2015	Closed
CLH: Fenpyrazamine (ISO)	6 February 2015	Closed
CLH: Spiroxamine	10 February 2015	Closed
CLH: Tefluthrin (ISO) – ENV only	10 February 2015	Closed
CLH: Linalool	8 February 2015	Closed
AfA: Trichloroethylene 1 (application)	5 January 2015	Closed
AfA: Trichloroethylene 2a (application)	5 January 2015	Closed
AfA: Trichloroethylene 2b (application)	5 January 2015	Closed

Subject / Document	Deadline	Status / follow-up
AfA: Trichloroethylene 3 (application)	5 January 2015	Closed
AfA: Trichloroethylene 4 (application)	5 January 2015	Closed
AfA: Trichloroethylene 6 (application)	5 January 2015	Closed
AfA: Trichloroethylene 7 (application)	5 January 2015	Closed
AfA: Trichloroethylene 8 (application)	5 January 2015	Closed
AfA: Trichloroethylene 9 (application)	5 January 2015	Closed
AfA: Trichloroethylene 10 (application)	5 January 2015	Closed
AfA: Trichloroethylene 11 (application)	5 January 2015	Closed
AfA: Trichloroethylene 12 (application)	5 January 2015	Closed
AfA: Lead chromate 1 (conformity)	11 February 2015	Closed
AfA: Lead chromate 1 (application)	25 March 2015	Ongoing
REST: Ammonium salts	20 February 2015	Closed
REST: Bisphenol A	24 February 2015	Closed
REST: DecaBDE	20 February 2015	Closed
REST: PFOA	20 February 2015	Closed
REST: Methanol (conformity)	23 February 2015	Closed
REST: DMF (conformity)	23 February 2015	Closed

2.3 Other written consultations of RAC (status by 2 March 2015)

Other written consultations	Deadline	Status / follow-up
RAC consultation on the draft minutes of RAC-31	16 January 2015	Closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
CLH: Call for expression of interest for rapporteurship	12 December 2014 – 9 January	Seven dossiers; volunteers appointed via

	2015	WP
CLH: URGENT call for expression of interest for rapporteurship	9 – 16 January 2015	Two dossiers; volunteers appointed via WP
Restriction: call for expression of interest for rapporteurship for Perfluorooctyl silanes (PFAS) restriction proposal	2 - 24 February 2015	Volunteers to be appointed via WP or at the plenary

2.5 Written procedures for appointment of Rapporteurs

Appointment (co-)RAP	For Substance	Deadline	Outcome
CLH: Written procedure for appointing of Rapporteur(s)	▪ mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one ▪ Flutianil;(Z)-2-[2-fluoro-5-(trifluoromethyl)phenylthio]-2-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile ▪ Pinoxaden; 8-(2,6-diethyl-p-tolyl)-1,2,4,5-tetrahydro-7-oxo-7H-pyrazole[1,2-d][1,4,5]oxadiazepin-9-yl2,2-dimethylpropionate	22 January 2015	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC Rapporteurs were appointed with tacit agreement.
	▪ Phosmet (ISO) ▪ 2-benzyl-2-dimethylamino-4-morpholinobutyrophenone ▪ Penthiopyrad (ISO) ▪ Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) C(M)IT/MIT ▪ S-methoprene; Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	2 February 2015	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC Rapporteurs were appointed with tacit agreement.