RAC/M/34/2015
Final
23 November 2015

Minutes of the 34rd Meeting of the Committee for Risk Assessment (RAC-34) 7-11 September 2015

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 34th meeting of the Committee for Risk Assessment (RAC-34). Apologies were received from three Members. One Member was absent. The Chairman welcomed one new RAC Member and informed the Committee that one RAC Member has resigned. The Chairman also welcomed three invited experts who are candidate RAC Members to be considered for appointment to the Committee at the ECHA Management Board meeting in September 2015.

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, adding that the recordings from RAC 33 in June had already been destroyed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants in Part III.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting.

The Agenda (RAC/A/34/2015) was adopted by the Committee; no points were raised under Agenda Point 10, Any Other Business. 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. Eleven Members declared potential conflicts of interest, each to specific agenda items. 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. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Report from other ECHA bodies and activities

a) Report on RAC 33 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points of RAC-33 had been completed, or were on-going. He explained that a report covering the developments in the ECHA Management Board, RAC, MSC, the Forum and BPC had been compiled and distributed to RAC as a meeting document (RAC/34/2015/01). 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).

The Chairman also informed the Committee that the final minutes of RAC-33 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website; he 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 Q4/2015 and Q1/2016, 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.

c) General RAC procedures

Admission new stakeholder organisations (closed session)

RAC discussed and agreed on the annual update of the Committee's list of accredited stakeholder organisations (ASOs) based on the revised procedure as agreed at RAC-33[1].

Under the new approach, seven stakeholder organisations that represent a larger general/cross-sectorial/broader interest group and who have a good record of attendance and a high level of participation are regarded as 'regular observers'. These will be invited to RAC plenary meetings by the Secretariat and be granted access to non-confidential documentation for the respective meetings.

All organisations interested in RAC who represent sectors with more specific interests, or whose participation is less frequent are regarded as 'occasional observers'. Occasional stakeholder observers are welcome to request the Secretariat to participate in a RAC meeting for a specific case, substance, agenda item or Committee discussion, following an expression of interest in advance of the respective meeting. They will be granted access to the non-confidential documents via the collaboration website for the specific meeting for which they request and are granted attendance.

The updated list of stakeholders will be published on ECHA's website and be applied with immediate effect following the end of the plenary.

Co-opted Members to RAC (closed session)

As a follow-up to the discussions at RAC-33, the SECR informed the Committee that the call for expression of interests published on 6 May, 2015 resulted in 99 candidates applying for nomination for RAC (81) and SEAC (18), including some who expressed interest in both Committees.

In line with the selection process and the required expertise as agreed at RAC-33, the SECR explained the pre-selection of suitable candidates based on their track record, expertise and personal abilities as presented in CVs and in the interviews, their availability and their declarations of interests. In August, a short-list of candidates, including the Chairman's recommendations, was presented for peer-review to a panel of six representatives of the Committee. This led to agreement on the selection of 5 nominees and 1 reserve candidate for RAC, which are now proposed to RAC for co-option to the Committee. The reserve candidate would be called upon in case one of the nominees could not take up duty as foreseen;this would avoid having to consult RAC a second time.

The SECR noted that the candidates had been screened with regard to the ECHA eligibility criteria for Committees and for potential conflict of interest, the latter on the basis of written

[1] http://echa.europa.eu/documents/10162/13580/admission_of_stakeholder_organisations_as_observers_en.pdf

declarations as well as further checks and was satisfied as to the suitability of the candidates. Finally, The SECR reminded the Committee that the co-opted Members would work on applications for authorisations and that they would not have voting rights like the regular Members of RAC.

A short profile of each of the nominees and the reserve candidate was then presented to RAC. As one of the nominees was a Swiss national (i.e. not from an EU or EEA country), the SECR clarified that endorsement in principle by ECHA's Management Board would be sought.

The nominees (and provisionally, the reserve candidate) were co-opted as Members of RAC by the Committee. The Chairman thanked the Committee and especially the peer-review panel for their engagement in this matter.

5. Requests under Article 77 (3)(c)

No agenda items on this occasion.

6. Requests under Article 95 (3)

a) 1-methyl-2-pyrrolidone (NMP)

The Chairman reported on the state of play concerning the request from the Commission (EMPL, GROW, ENV) under Article 95 of REACH to RAC to resolve, in cooperation with the Scientific Committee on Occupational Exposure Limits (SCOEL), the differences between the Derived No Effect Level (DNEL) and the Occupational Exposure Limit (OEL) for the aprotic solvent n-methylpyrrolidone (NMP) and informed the meeting that the Terms of Reference of the request to RAC were uploaded to CIRCABC and will be published on ECHA website. The target date for conclusion on the RAC-SCOEL joint opinion is February 2016.

The Chairman informed the meeting that seven RAC-Members had expressed an interest in becoming a Member of the Joint Working Group, which would be composed of RAC and SCOEL experts and which would work specifically on NMP. He noted that SCOEL was currently updating its 2007 recommendation on NMP in the light of recent literature and that this would be provided to the group when available. The Chairman invited all seven Members to discuss a draft analysis of existing documents of RAC and SCOEL concerning the exposure levels of NMP, which would be available after RAC-34. The first meeting of the joint working group RAC-SCOEL is scheduled for the end of October 2015.

7. Harmonised classification and labelling (CLH)

7.1 CLH dossiers

A. Hazard classes for agreement <u>without</u> plenary debate[2]

a) (2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H—1,2,4-triazol-1-yl)butan-2-ol; cyproconazole (ISO): acute toxicity – dermal & inhalation routes, STOT SE, Skin / Eye irritation, Skin sensitisation

[2] Following adequate scrutiny by the Rapporteur and commenting Members and taking the comments from the Public Consultation into account, selected hazard classes are proposed for agreement through a list ('fast-track') without further debate in Committee.

RAC agreed to the proposal by Ireland not to classify for the hazards acute dermal and inhalation toxicity, STOT SE, skin/eye corrosion/irritation and skin sensitisation. As to the discussion of other hazards, please see the minutes' text below.

b) 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl (Z)-(1R,3R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylat; momfluorothrin (S-1563): acute toxicity - all routes, skin/eye/respiratory tract irritation, skin/respiratory sensitisation, STOT SE, STOT RE, mutagenicity, toxicity to reproduction, aquatic hazards

RAC agreed to the proposal by the United Kingdom to classify momfluorothrin as Acute Tox. 4 (H302), STOT SE 2 with effects on the central nervous system (H371 (CNS)), as Aquatic Acute 1 and Aquatic Chronic 1, assigning an M-factor of 100 to both the acute and the chronic aquatic hazard. No classification was agreed for the hazards acute dermal and inhalation toxicity, STOT RE, skin/eye corrosion/irritation, respiratory tract irritation, respiratory/skin sensitisation, mutagenicity and reproductive toxicity. For the discussion of carcinogenicity, see further below.

c) *(RS)*-4-[1-(2,3-dimethylphenyl)ethyl]-1*H*-imidazole; medetomidine: aquatic hazards and M-factors

RAC agreed to the proposal by the United Kingdom to classify medetomidine as Aquatic Acute 1 and Aquatic Chronic 1 and to add an M-factor of 1 to the acute and an M-factor of 100 to the chronic aquatic hazard. The human health hazards are scheduled for discussion at RAC-35.

d) 5-chloro-2-(4-chlorophenoxy)phenol (DCPP): aquatic hazards and M-factors

RAC agreed to the proposal by Austria to retain the aquatic classifications Acute 1 and Chronic 1 and to add an M-factor of 10 for both hazards. RAC adopted the opinion by consensus.

B. Substances with hazard classes for agreement <u>in plenary session</u>

a) 8-tert-butyl-1,4-dioxaspiro[4.5]decan-2-ylmethyl(ethyl)(propyl)amine; 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 as Aquatic Acute 1 and Aquatic Chronic 1 while M-factors have not been set in Annex VI. The legal deadline for the adoption of the 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 a classification for toxicity to reproduction (Repr. 2; H361d), to change the classification for skin sensitisation to Skin Sens. 1B and to add M-factors of 100 for both the acute and the chronic aquatic hazard.

At RAC-32 in March, the Committee supported the DS proposal for adding M-factors of 100 for both the acute and chronic aquatic classifications, and for Acute Tox. 4 for all routes of exposure. As to skin sensitisation, RAC concluded that the current category 1 without sub-categorization should be retained.

In order to get a more complete picture of the toxicity profile before concluding on reproductive toxicity, the Committee requested the DS (DE) to provide repeated dose toxicity data which was not previously assessed in the original CLP proposal. Germany provided the requested data in the form of a second CLH proposal devoted to the hazard class STOT RE,

which was processed in a standard way. In relation to that hazard class, the DS proposed classification as STOT RE 2, based on mortality, ocular and hyperkeratosis findings.

The Rapporteur noted that at levels below or slightly above the guidance values for STOT RE 2 high mortality was observed in two dose range-finding oral developmental toxicity studies in the rat, changes of the eye (cataract, opacity of lens) in an oral long-term dog study, and marked or severe hyperkeratosis of oesophagus and the gastrointestinal tract only in an oral rat 13-week study. RAC considered that more weight should be given to the systemic effect (on the eye) than to local, possibly adaptive effects. Thus, the Committee concluded that classification for repeated dose toxicity in category 2, with effects on the eyes was justified (STOT RE 2 (eyes)).

In relation to developmental toxicity, palatoschisis was observed in one rat oral developmental toxicity study (in 3 fetuses out of 265 in 3/24 litters) at 100 mg/kg/day which also caused slight maternal toxicity (reduced feed intake and decreased corrected body weight gain) and in two oral range-finding studies: in 3 (out of 46) fetuses in 2/4 litters at 100 mg/kg with clinical signs in maternal animals (ruffled fur, dyspnea, sedation and hunched posture) and 3 fetuses (out of 18) in 2 out of 4 litters of the surviving maternal animals at 150 mg/kg (21/24 mothers died). The incidence per litter but not the fetal incidence was above the historical control values during 1990-1991 when the studies had been performed.

No embryo/fetal effects were observed in an oral developmental toxicity study in rabbits, and a dermal developmental toxicity study in rats.

Palatoschisis was observed in the range-finding studies in the presence of clinical symptoms in the dams. In the main study, the malformations were only observed at low incidences, and these were only slightly above the historical control values on a litter basis only. RAC concluded that the evidence fulfilled the criteria for category 2 but not for 1B for developmental toxicity.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for their careful preparation of the opinion, the Dossier Submitter (Germany) for their willingness to provide the additional STOT-RE data in the form of a second CLP proposal and the Committee for their active involvement in the discussions.

Formaldehyde releasing biocides:

b) 4,4'-methylenedimorpholine (MBM) (environmental hazards only)

c) Reaction products of paraformaldehyde and 2-hydroxypropylamine (RP 3:2; MBO)

d) Reaction product of paraformaldehyde and 2-hydroxypropylamine (RP 1:1; HPT)

The Chairman reported that the three 'formaldehyde releasers' (MBM, MBO and HPT) were biocidal active substances; none of these three substances has an existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion for MBM and MBO is 15 March 2016 and 11 June 2016 for HPT.

The Dossier Submitter (Austria) proposed to classify all three formaldehyde releasers for skin corrosion (Skin. Corr. 1B; H314), carcinogenicity (Carc. 1B; H350) and mutagenicity (Muta. 2; H341). MBM was proposed to be classified as a skin sensitiser in category 1 without sub-categorisation and a specific concentration limit of 1.2% was proposed. The other two

formaldehyde releasers RP 3:2 (MBO) and RP 1:1 (HPT) were proposed to be classified as Skin. Sens. 1A; H317 and as Aquatic Chronic 3; H412.

As the three formaldehyde releasers are biocidal active substances with no existing harmonised classification, all hazard classes were assessed.

In accordance with the CLP Regulation a weight of evidence evaluation of the available data was applied and where the data on a substance itself was missing, data on the hydrolysis products of formaldehyde, i.e. formaldehyde and 2-hydroxypropylamine were considered.

All endpoints were discussed for RP 3:2 and RP 1:1; the discussion on human health for MBM is scheduled for RAC 35.

Environment

The Committee concurred with the DS that no classification was warranted for aquatic hazards of MBM.

It was noted that for UVCB's RP 3:2 and RP 1:1, the hydrolysis pathway is complex. A stakeholder expert pointed out that the hydrolysis products of RP 3:2 and RP 1:1 do not meet the criteria for environmental hazard classification and suggested that the substances should be considered as rapidly degradable and classification should be Aquatic Chronic 3; H412. However, the Committee agreed that for both substances, the data provided were insufficient to demonstrate that the hydrolysis products do not fulfil the criteria for classification as hazardous to the aquatic environment and therefore that they were not rapidly degradable.

RAC agreed to classify both substances as Aquatic Chronic 2; H411.

Acute toxicity

Oral:
Contrary to the DS proposal not to classify RP 3:2 and RP 1:1 for acute toxicity (presuming that the endpoints were covered by the classification as corrosive), based on the oral LD50 values range between 750mg/kg bw and 900mg/kg bw in rats, the Committee agreed to classify both as Acute Tox. 4; H302 (oral exposure).

Dermal:
For dermal toxicity RAC agreed to classify RP 3:2 as Acute Tox. 3; H311 based on the results of an OECD 402 dermal LD50 value of 760mg/kg bw in female rats which is in the range for category 3. For RP 1:1 there were no effects observed in two OECD 402 studies and the Committee concurred with the DS that no classification was warranted for dermal toxicity.

Inhalation:
Acute inhalation toxicity was discussed; the original DS proposal was for no classification due to the classification as corrosive. RAC agreed to classify both RP 3:2 and RP 1:1 in category 4 based on read–across to formaldehyde, but to correct for the maximum amount of formaldehyde released from both substances as presented by the Rapporteur. This was also supported by the industry representative who noted that an additional study conducted in the meantime had confirmed that both releasers warranted classification in category 4 via inhalation exposure. Additional hazard statements EUH071 (corrosive to respiratory tract) and EUH029 (contact with water liberates gas) were discussed. There was no proposal from the DS on these, but RAC agreed to add the EUH071 hazard statement as it is relevant for both RP 3:2 and RP 1:1.

STOT Single Exposure

RAC agreed that no classification was warranted for STOT SE.

Skin corrosion / Irritation

Following the comments from the PC and in accordance with CLP, the DS proposed to classify both RP 3:2 and RP 1:1 in category 1B based on read-across to formaldehyde. RAC discussed the evidence and the data available for RP 1:1 which suggested that the substance should be classified in subcategory 1C (based on corrosive effect during 14 day observation after exposure > 4h).

In the discussion, the Commission observer confirmed that a subcategory had to be always assigned as there are potential downstream user consequences (i.e. in transport of chemicals). Two Members expressed concerns about the strictness of the interpretation of the criteria and the need to always provide a sub-category, as in some cases the data might not be available or not convincing enough. RAC agreed to classify RP 1:1 in subcategory 1C. RP 3:2 was classified in subcategory 1B based on corrosive effects during 14 day observation after exposure > 3 min and ≤ 1h.

Eye corrosion / Irritation

RP 3:2 and RP 1:1 cause irreversible eye damage (iris lesions, resp. cornea lesions). In accordance with the CLP Regulation, RAC agreed to classify both substances for Eye Dam. 1 without the hazard statement as it is already covered by the skin corrosion hazard statement.

Skin sensitisation

RAC agreed to classify RP 3:2 and RP 1:1 as Skin Sens. 1A; H317. In the case of RP 3:2 the classification is based on human data and on positive results from three animal studies. In the case of RP 1:1 the animal data were supported by read-across to RP 3:2 and to formaldehyde.

STOT Repeated Exposure

The DS did not propose to classify the releasers for repeated dose exposure assuming that the effects observed after oral exposure were due to corrosivity, and that for inhalation exposure do not warrant classification. However, the effects observed (chronic ulcerative gastritis, peritonitis) for RP 3:2 clearly point to STOT RE 2 for oral exposure and in the absence of other data for RP 1:1, RAC applied a read-across approach. For inhalation exposure RAC applied read-across to formaldehyde (as was done for acute inhalation toxicity), and compared the amount of releasable formaldehyde with the CLP guidance values. It was agreed to classify both releasers in category 2, for effects on the gastrointestinal tract and on the respiratory tract.

Germ Cell mutagenicity

The DS proposed to classify both releasers as Muta 2 based on local genotoxic effects of the hydrolysis product formaldehyde which has a harmonised classification as mutagen in category 2. The Committee discussed the proposal and agreed by simple majority to classify both releasers as Muta 2 based on positive *in vitro* data and on read-across to formaldehyde. Three Members disagreed with this conclusion interpreting the observed effects as local and not having a systemic character. In their view this was not sufficient evidence for mutagenic effects and they indicated a minority position in favour of not classifying RP 3:2 and RP 1:1 for mutagenicity.

Carcinogenicity

No data on the carcinogenicity of the substances were available. Classification as Carc. 1B was proposed by the DS based on local carcinogenic effects of the hydrolysis product

formaldehyde. RAC discussed the relatively rapid rate of hydrolysis in dilute solution (<1h; and thus the actual amount of formaldehyde released) which is dependent on several factors including concentration. The observed skin corrosion effects supported the conclusion that dilution and the rate of hydrolysis is sufficient to induce local carcinogenic effects. RAC agreed that classification in category 1B is warranted.

Toxicity to reproduction

No classification was proposed by the DS. Based on the dose-dependent effects from a one-generation study in rats (increase in post-implantation loses and lower pup viability) the Committee discussed a possible classification in category 1B or 2. Three Members noted that the dose response was very flat and the observed effects were only mild which would point rather to category 2. In addition, the validity of the study was questioned mainly due to inconsistencies between the control group results and the historical control data. RAC did not conclude on classification and asked the DS to provide further details on the study. The discussion was adjourned for completion at RAC 35.

e) Cyproconazole (ISO)

The Chairman reported that cyproconazole was a pesticide active substance, a water-based fungicide used to protect above-ground wood. It has an existing entry in Annex VI to the CLP Regulation for acute toxicity (Acute Tox. 4*; H302 – minimum classification), toxicity to reproduction (Repr. 2; H361d***) and as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The legal deadline for the adoption of an opinion is 17 May 2016.

The Dossier Submitter (IE) proposed to add classification for carcinogenicity (Carc. 2; H351), repeated dose toxicity (STOT RE 2; H373 (liver, oral), M-factors of 10 for both acute and long-term aquatic hazards, to change classification for developmental toxicity to Repr. 1B; H360D, and to confirm Acute Tox. 4 for acute oral toxicity and no classification for all remaining human health hazards.

Acute toxicity

For acute oral toxicity data from several species were available and RAC agreed - contrary to the DS proposal - to classify cyproconazole as Acute Tox. 3; H301 based on the lowest LD50 value in mice.

STOT-Repeated Exposure

Repeated dose toxicity with the liver being the target organ was assessed based on several studies in rats, mice and dogs. Some of the studies showed severe effects whereas some only mild, but the fact that these effects were consistent across the species and via several routes of exposure supports category 2. One RAC Member asked for further clarification about the changes described as fatty changes/vacuoles. The industry representative responded that no specific histochemical stains were used to assess whether the vacuoles contained lipids. RAC agreed to classify cyproconazole in category 2 for repeated dose toxicity with the liver as the target organ. No route of exposure was specified.

Germ Cell mutagenicity

RAC agreed that no classification was warranted for germ cell mutagenicity.

Carcinogenicity

RAC discussed the original DS proposal to classify the substance in category 2 for carcinogenicity based on the results of an 18-month carcinogenicity study in CD-1 mice where liver tumours were observed at the middle and high doses in male mice and at the high dose

in female mice. No tumours were reported in a 2-year rat study. In addition, several mechanistic studies were made available to assess the potential mode of action (MoA) of cyproconazole. It was concluded that the CAR-activation was the main, but not the only MoA, as evidence was provided for a number of key and associated events but not all these events were ruled out in studies with CAR knock-out mice. The DS had assumed additional involvement of cytotoxicity as the MoA and thus proposed category 2. RAC however concluded that there was not sufficient evidence to indicate any other known MoA than CAR-activation as a cause of the liver tumour formation. RAC noted that no adenomas were seen in CAR knock-out mice in the Tamura et al. (2015) study although these negative findings were questioned by some Members due to the short study duration (27 weeks). This study, which was provided during the PC, was further thought to be of limited value due to its design (administration of diethylnitrosamine (DEN) as a liver tumour initiator so as to investigate the promotion stage for hepato-carcinogenicity). Whereas a study with humanized CAR mice was not available, RAC noted that *in vitro* studies showed the absence of cell proliferation upon cyproconazole treatment in human hepatocytes, in contrast to mice hepatocytes. RAC concluded, taking into account all the available data, that cyproconazole does not warrant a classification for carcinogenicity.

Toxicity to reproduction

A proposal for an upgrade of the current classification for developmental toxicity was presented based on clear evidence of adverse effects on development, namely cleft palates and post-implantation loss in two acceptable and one supplementary study in rats and other malformations (e.g. hydrocephalus) in rabbits and rats, at doses that did not cause severe maternal toxicity. The malformations were seen in several litters which gave a stronger indication that it was substance related. In addition, the findings were similar to those observed with other azoles. RAC agreed to upgrade the classification for developmental toxicity and to classify cyproconazole as Repr. 1B. RAC further agreed that no classification is warranted for fertility.

Environment

RAC supported the DS and agreed to classify cyproconazole as Aquatic Acute 1; H400 and considered it relevant to take into account the measured 72-h EbC_{50} value (0.099 mg/L) rather than the estimated nominal ErC_{50} value (0.12 mg/L) for the green algae *Scenedesmus subspicatus* considering the questionable reliability of the latter value. As 0.099 mg/L is between $0.01 < EC_{50} \leq 0.1$ mg/L, the acute M-factor is 10. The 7-days EbC_{50} of 0.059 mg/L obtained from the *Lemna gibba* study of 2007 is considered as supportive to the M-factor of 10. RAC agreed with the DS proposal to classify cyproconazole as Aquatic Chronic 1, H410 based on the lowest long-term aquatic toxicity result which is a 96-h NOEC of 0.021 mg/L for the green algae *Scenedesmus subspicatus*. As this value is between $0.01 < NOEC \leq 0.1$ mg/L, the chronic M-factor is 1, consistent with the new DS proposal following the public consultation.

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) Momfluorothrin (S-1563)

The Chairman welcomed the representative accompanying the ECPA stakeholder observer and reported that momfluorothrin was a biocidal active substance. It has currently no existing entry to Annex VI of the CLP Regulation and the legal deadline for the adoption of an opinion is 17 June 2016.

The Dossier Submitter (UK) proposed to classify for Acute Tox. 4; H302 (oral), STOT SE 2; H371 (CNS), and for environmental hazards – Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M factor of 100 for both. As momfluorothrin is an active substance with no existing harmonised classification, all hazard classes were assessed.

The Committee concurred with the DS and agreed to classify the substance in category 4 for acute oral toxicity based on the LD50 value between 300 and 2000 mg/kg bw in female rats. RAC supported the proposal to classify momfluorothrin as toxic after single exposure in category 2 (STOT SE 2 (CNS); H371) without specifying the route of exposure and also agreed to the harmonisation of environmental hazards including the M-factors as proposed by the DS.

Two long-term GLP carcinogenicity studies in rodents (104-week dietary study in rats and 78-week dietary study in mice) were reported. A dose-related increase in liver tumours was observed in rats, but not in mice. Possible modes of action (MoAs) and the relevance for humans were investigated in a number of *in vitro* and *in vivo* mechanistic studies and the results suggested that the CAR activation is the most plausible MoA. There was also sufficient evidence provided that other MoAs are unlikely. The relevance for humans was investigated in primary rat and human hepatocytes. Although some key events were present in primary human hepatocytes, DNA replication which is the prerequisite for tumour formation did not occur. The DS therefore proposed no classification for carcinogenicity.

RAC Members agreed that there was sufficient evidence ruling out other potential MoAs. As to the CAR-mediated MoA, the Committee noted that no studies with humanized or CAR knock-out animals were available for momfluorothrin. The representative accompanying the ECPA stakeholder observer confirmed that CAR knock-out rats are still under development and that at the moment as an alternative an *in vitro* study with rat hepatocytes in which the CAR gene was knocked down is available from which the involvement of CAR activation can be inferred. One RAC Member asked if ATP-release levels in human hepatocytes had been measured in the *in vitro* tests investigating DNA replication as that would also complement the overall data package. Although this particular data was missing, it was concluded that this was covered by other data. Taking into account all available data, the Committee supported the DS proposal and agreed on no classification for carcinogenicity.

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

g) Methylhydrazine

The Chairman informed RAC that methylhydrazine was mainly used as a solvent, as an organic intermediate and as a rocket propellant. The substance has currently no entry in Annex VI to CLP. The Dossier Submitter from the Netherlands proposed a harmonised classification as Carc. 1B. Legal deadline for adoption of the CLH opinion is 28 April 2016.

The Chairman recalled that during the RAC consultation on the first draft opinion for methylhydrazine in April 2015 other carcinogenic structurally-related, alkylating compounds such as dimethylhydrazines were mentioned, and also that while there was a lack of data in the CLH dossier to confirm this, a genotoxic mode of action for methylhydrazine could not be ruled out. In response, the Dossier Submitter submitted three documents containing additional information related to the carcinogenicity of structurally similar hydrazines. The evaluation of the above information by the Dossier Submitter was then submitted to a targeted public consultation which ended on 31 July 2015. Two comments were provided by two Member states, both in favour of Carc. 1B.

The Rapporteur presented the draft opinion, as revised after the targeted consultation. He stated that there was no direct proof for DNA methylation from methylhydrazine, and that mutagenicity tests were mainly negative. Also the carcinogenicity data provided for methylhydrazine was of limited quality. He therefore concluded that a classification as Carc. 2 is justified. The Committee argued that DNA methylation by methylhydrazine resulting in genotoxicity cannot be sufficiently excluded. Considering carcinogenic potential, Members recognised the deficiencies in the carcinogenicity studies on methylhydrazine, in particular their short duration and debated that read across to the other compounds is necessary to complete on the weight of evidence. Members noted the occurrence of tumours in different organs in the methyhydrazine studies and that several tumour types were also observed for the read-across compounds, which added up to a consistent pattern. RAC therefore agreed that a classification as Carc. 1B (H350) was justified.

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the careful preparation of the opinion and the Committee for their active involvement in the discussions.

h) Salicylic Acid

The Chairman welcomed the representatives of the Dossier Submitter from Industry (NOVACYL S.A.S. and Bayer). He reported that salicylic acid was used as a preservative in the formulation of mixtures, in various industrial uses (intermediate, manufacture of resins, separation of salts, tyre manufacturing), in professional use by workers (in fertilizer formulations, cleaning agents) and in consumer uses (in cosmetics, cleaning agents).

Salicylic acid has no entry in Annex VI to the CLP Regulation. The Dossier Submitter proposed a harmonised classification of the substance as Acute Tox. 4 (H302) and Eye Dam. 1 (H318) and no classification for toxicity to reproduction. The legal deadline for adoption of the CLH opinion is 16 April 2016.

The Chairman recalled that at RAC-33 in June 2015, the Committee had supported the proposal by the DS to classify salicylic acid as Acute Tox. 4 (H302) and Eye Dam. 1 (H318) and not to classify it as toxic for fertility. In addition to the proposal of the DS to not classify the salicylic acid for developmental toxicity, the Rapporteurs had proposed to discuss the Repr. 2 (H361d) option. This resulted in requesting further relevant human epidemiological data as well as a monkey study from the Dossier Submitter to enable assessment of the relevance of findings in animals (rats and monkeys) for humans. The additional information provided by the Dossier Submitter and the Rapporteurs was then submitted to a targeted public consultation which ended on 24 July 2015.

The reproductive toxicity of salicylic acid was assessed by RAC on the basis of the available animal data on salicylic acid itself and using read-across from animal studies on other salicylates and from human epidemiological studies on acetylsalicylate, which the Committee considered to be relevant. For developmental toxicity, RAC discussed the doses of salicylic acid used in animal studies (rat, rabbit) as compared to human exposure in the available epidemiological and case control studies on acetylsalicylic acid in humans. While the representatives of the DS claimed that over 100 years of use of acetylsalicylic acid (aspirin) did not reveal any evidence of developmental effects in humans, some RAC Members remarked that human dose levels in the epidemiological studies were not as high as where there is clear evidence for developmental effects in rats and monkeys, which would justify a classification as Repr. 1B for development. Other Members were of the view that the effects seen in animals had not been seen in humans at therapeutic doses and suggested that classification as Repr. 2 would be more appropriate. Overall, the Committee felt that the evidence available did not provide a clear direction as to whether a classification as Repr. 1B

or 2 for developmental effects was justified. It was agreed to contact the European Medicines Agency (EMA) to clarify the effects of acetylsalicylic acid in humans also at higher than therapeutic doses. Questions to EMA will be drafted and submitted in October for their consideration, after which RAC will be informed.

The Chairman concluded that the discussion of developmental toxicity should be continued at the next RAC-meeting in December (RAC-35), with the view to reaching agreement on this last remaining hazard.

i) α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol; triadimenol (ISO)

The Chairman welcomed the representative from Industry (Bayer Crop Science) and reported that triadimenol was used as a fungicidal seed and foliar spray treatment in agricultural applications within the EU. It currently has no entry in Annex VI to the CLP Regulation. The Dossier Submitter (UK) proposed to classify triadimenol (ISO) as Acute Tox. 4 (H302), as Repr. 2 (H361f) and as toxic to aquatic life with long lasting effects (Aquatic Chronic 2 (H411)).

The Chairman recalled that at RAC-33 in June, the Committee had agreed to the harmonised classification on acute oral toxicity as proposed by the Dossier Submitter. In addition, RAC had also concluded that classification for acute dermal and inhalation toxicity, skin and eye corrosion/irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity and carcinogenicity was not justified. He noted that at RAC-34, the Committee would discuss reproductive toxicity and possible effects on or via lactation, while a discussion of the aquatic hazards would follow in the December meeting only (RAC-35).

The Rapporteurs argued that the developmental effects following exposure to triadimenol (ISO) during gestation and up to weaning, i.e. post-implantation losses in rats and rabbits, decreased litter size at birth and decreased viability on PND 5 and 28 in rats, as well as increased incidences in supernumerary ribs in rats and in skeletal anomalies in rabbits, provided clear evidence of adverse effects on development. Such effects should not be considered as a secondary non-specific consequence of maternal toxicity. The deficiencies in the multi-generation study did not make the evidence on developmental toxicity less convincing and supported the classification of the substance in Repr. 1B for adverse effects on development. Further to this, it was noted by a RAC Member that triadimenol caused also cleft palates similarly to other triazoles and that the severity of this effect also supported classification in Category 1B.

As to fertility, the Rapporteur stated that a dose-related decrease in pregnancy rates was observed in all three generations in the multi-generation study, with weak supporting evidence (decreased fertility index) from a two-generation study testing only lower doses. The decreased pregnancy rates and fertility index were reported in the absence of marked parental toxicity, therefore according to the Rapporteurs the effects could not be considered as a secondary non-specific consequence of parental toxicity.

The Rapporteur proposed classification in category 1B for these effects, which was agreed by the Committee. However, the observed decrease in pregnancy rates could not be assigned to either impairment of sexual function and fertility or to developmental toxicity, because of lack of data in the multi-generation study (exposure during 70-day pre-mating, mating, gestation and lactation periods). According to the CLP criteria if reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity, chemicals with these effects would be classified as reproductive toxicants with a

general hazard statement. Therefore the Committee concluded by consensus that Repro. 1B (H360 without 'F' and 'D') should be assigned to triadimenol (ISO).

As to lactation, the Committee supported the Rapporteurs' conclusion that triadimenol (ISO) may be transferred to milk during breast-feeding. This was based on the significantly reduced viability index on PND 5 seen in several generations in the multi-generation study, together with the information from toxicokinetic studies. Triadimenol (ISO) should therefore be classified for effects on or via lactation with Lact. (H362).

The Chairman thanked the Rapporteur for the careful preparation of the opinion for the human health hazards and referred to the December meeting, for the discussion about the aquatic hazards.

j) Nicotine

The Chairman welcomed the Dossier Submitter's representative from the Netherlands who followed the discussion remotely. He reported that nicotine (ISO) was a naturally occurring alkaloid obtained from the leaves of the tobacco plant and a major constituent in tobacco smoke. It has an existing entry in Annex VI to the CLP Regulation for acute toxicity via oral and dermal routes (Acute Tox. 3*; H301 – minimum classification, Acute Tox. 1; H310) and as Aquatic Chronic 2; H411.

Due to the increased use of E-cigarettes and uncertainties in mixture classification, there is a need to revise the minimum classification. The legal deadline for the adoption of an opinion is 14 October 2016.

The Dossier Submitter (NL) originally proposed to change the minimum classification for acute oral toxicity to Acute Tox. 1; H300, to retain the classification for acute dermal toxicity, to add classification for acute toxicity via inhalation (Acute Tox. 2; H330) and also to define LD50 values (Acute Toxicity Estimates, ATEs) for nicotine.

However based on information related to new acute oral and dermal toxicity studies provided during the Public Consultation, the DS revised their original proposal for acute oral toxicity to Acute Tox. 2; H300 and for acute dermal toxicity to Acute Tox. 2; H310.

The Rapporteur presented the proposal for acute oral toxicity based on data from mice, rats and dogs contained in the CLH report and further information – results from a new acute oral toxicity study in mice - provided during the public consultation. RAC Members pointed out that both main studies – the acute oral toxicity study by Lazutka et al. (1969) in mice and rats and also the new acute oral toxicity study in mice provided during the public consultation had certain limitations and therefore a weight of evidence approach, also considering data from a study in dogs, was necessary to derive the classification. The Members agreed to classify nicotine as Acute Tox. 2 via the oral route; H300 based on the weight of evidence of the available LD50 values and taking metabolic and toxicokinetic differences among species into account. The Acute Toxicity Estimate (ATE) value for oral exposure could not be derived from a single LD50 value and the Committee therefore agreed to apply the default ATE value of 5 mg/kg bw for the classification category 2 oral according to CLP Regulation.

As to acute toxicity via inhalation, the Committee concurred with the DS and agreed to classify nicotine in category 2, using a factor 12 to extrapolate the LC50 value from the available study with 20 min exposure to a 4h exposure time. This resulted in an LC50 value of 0.19 mg/L for rats. This value is also the recommended ATE for nicotine for the classification of mixtures.

RAC agreed with the revised proposal of the DS to classify nicotine in category 2 for the dermal route based on the results of a new study in rabbits submitted during PC. The dermal

LD_{50} of 70.4 mg/kg bw, as reported in the new study, was also agreed as ATE value for nicotine used in mixture classification.

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

7.2 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.

8. Restrictions

8.1 General restriction issues

a) Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

The Secretariat presented the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals (meeting document RAC/34/2015/06). The document had been updated based on comments received during the RAC/SEAC written commenting rounds. RAC agreed on the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals. The Secretariat will make final editorial changes to the document and publish the agreed Framework to ECHA website and the RAC CIRCABC IG.

8.2 Restriction Annex XV dossiers

a) Opinion Development

1) Perfluorooctanic acid (PFOA) – revised draft opinion

The Chairman welcomed the Dossier Submitters' representatives (Germany and Norway), the SEAC Rapporteur (via WebEx) as well as an industry expert accompanying a stakeholder observer. The Chairman reminded the Committee that this dossier had been submitted by Germany and Norway in October 2014. The Dossier Submitters propose a restriction on the manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances. Based on the discussions held at RAC-33 and almost 200 comments received within the public consultation, the Rapporteurs had prepared the revised draft opinion, which was submitted for comments by RAC. Based on the comments received from three RAC Members, the Rapporteurs updated their revised draft opinion, which was made available to the Committee on 2 September.

In presenting their revised draft opinion to RAC, the Rapporteurs explained, the Committee should now focus its discussion on the human health risk assessment, the new concentration limits proposed as well as on the derogations.

With regard to the human health risk characterisation, several Members expressed support for the revised text of the opinion, acknowledging the uncertainties on both the hazard side (a DNEL cannot be reliably derived for some effects that may be more sensitive than the animal

data currently used in the risk characterisation) and the exposure side. An industry expert highlighted that indeed most of the exposure data taken into consideration here is very old data. Since then, there have been a lot of efforts by industry to reduce emissions. One RAC Member suggested mentioning in the opinion that there are also studies showing effect on the immune system. The opinion justification was amended in the meeting to reflect these comments.

With regard to the concentration limits, the Rapporteurs reminded the Committee that the original proposal by the Dossier Submitters was for one concentration limit - 2 ppb - for PFOA and its salts, and the related substances. Based on the comments received during the public consultation, the Dossier Submitters updated their proposal and recommended using six concentration limits. The Rapporteurs, however, considered such a proposal to be overly complex, mainly based on practicality and enforcement issues, and proposed two concentration limits in the RAC opinion – 25 ppb for PFOA and its salts, and 1000 ppb for PFOA-related substances. The Dossier Submitters' representative was concerned that the concentration limit of 1000 ppb will allow intentional use of PFOA-related substances, for example in textiles. The Rapporteurs responded that due to the fact that it is difficult to know the results of proposing 1000 ppb as a concentration limit, they have suggested in the opinion that the Commission might consider a review for this restriction after 5 years from the entry into force. Several Members expressed support for the approach of the Rapporteurs. The Commission observer explained that the need for a review could be described in the text of the justification to the opinion, as the REACH Regulation already provides for possibility to review a restriction, when the need arises. The Rapporteurs and the Committee agreed to delete this clause from the conditions of the restriction and retain the reworded text in the opinion justification.

The Rapporteurs then explained that many requests for derogations had been received during the public consultation and listed those proposed to be included in the RAC opinion (transported isolated intermediates, semiconductor photolithography processes, second-hand articles, recycled articles, photographic coatings and implantable medical devices). The Rapporteurs added that the SEAC Rapporteurs are proposing more derogations based on socio-economic arguments. RAC agreed with the derogations recommended by the Rapporteurs based on their apparently low emissions.

RAC adopted its opinion on the dossier on PFOA, its salts and PFOA-related substances by consensus (with modifications introduced at the meeting). The Rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted RAC opinion and to ensure that the supporting documentation (Background Document and responses to comments from the public consultation) 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 them on the ECHA website and on CIRCABC.

2) Methanol – first draft opinion

The Chairman welcomed an expert accompanying the Cefic stakeholder observer as well as the Dossier Submitter’s representative from Poland, the latter who followed the meeting remotely via WebEx, and the SEAC Rapporteur. The proposed restriction is aimed to prevent misuse of some mixtures containing high concentrations of methanol as an ethyl alcohol surrogate. The scope of the restriction proposal is targeted at windscreen washing fluids and denatured alcohol supplied to the general public. The Committee was informed that the first draft opinion was made available on 13 August and that the RAC commenting round finished on 26 August, with comments received from three RAC Members.

The RAC Rapporteur presented the first draft opinion and summarised the major changes compared to the restriction proposal from Poland. The main changes included the non-lethal effects to be selected as the point of departure instead of lethality. This meant the concentration limit of methanol in windshield washing fluids and in denaturated alcohol was lowered to equal to or greater than 0.1% by weight. It was also agreed to use one similar exposure scenario for both denaturated alcohol and windscreen washing fluid. These changes had been already discussed and agreed in principle at RAC 33.

RAC supported the Forum's advice to include windshield defrosters as a sub-group of windshield washing fluids, this to prevent exclusion of these products by simply optimising the wording of the product claim (product intention) on the product label by changing the term "washing fluid" into "defroster". Both products have similar relevance but cannot be regarded as being covered by the term windshield washing fluids.

RAC advised the Rapporteurs to further refine the wording of the opinion regarding the risks from the alternatives. According to RAC, the conclusions on the suitability of the alternatives should be assessed related to the conditions of misuse.

Finally RAC agreed in principle that the restriction as presented by the Rapporteurs in the first draft opinion is the most appropriate EU wide measure, pending some clarifications regarding the alternatives. The Chairman requested the Rapporteurs to deliver their revised draft opinion on this dossier by end of October 2015 (for adoption at RAC-35).

3) D4/D5– first draft opinion

The Chairman welcomed the Dossier Submitter's representative from UK (following via WebEx) and an external expert accompanying Cefic. He reminded the participants that the restriction dossier on D4/D5 had been submitted by UK in April 2015 and had been considered in conformity by RAC and SEAC in June plenaries. MSC has recently provided an opinion that both substances are vPvB. The restriction proposal is aimed specifically at reducing emissions to the aquatic environment and is targeted at uses that lead to the greatest waste water emissions according to the registration CSRs. The dossier proposes that D4 and D5 shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products (PCPs) that are washed off in normal use conditions. The Chairman informed the Committee that the Rapporteurs had developed the first draft opinion on this dossier, taking into account the discussion on key issues held at RAC-33, which was made available to RAC in mid-August and comments were received from three RAC Members in the following written commenting round.

The Rapporteurs presented the first draft opinion to the Committee. The Committee accepted the recent MSC opinion that D4 and D5 are vPvB and further noted that D4 is classified for relevant environment and human health toxicity endpoints, so fulfilling the T criterion. With regard to the hazards for human health, the Rapporteurs explained that the Dossier Submitter states in the dossier that risks to human health are not the subject of this proposal as the risks to human health from cosmetics are outside of the scope of REACH. The Rapporteurs noted that, according to the Scientific Committee on Consumer Safety (SCCS) draft opinion (2015), aggregated human exposure to D5 via oral and inhalation routes is not safe due to the contribution of body lotion and hair styling aerosols (level of purity of D5 should be >99%). After a brief exchange of views, the Committee agreed that human health risks are outside the scope of the RAC evaluation of this dossier. RAC agreed that the SCCS opinion should be referenced in the RAC opinion.

In relation to the fate and behaviour in the environment, the Rapporteurs agree with the Dossier Submitter that emissions of D4 and D5 to air result in long-range transport to remote regions via the atmosphere and that modelling studies indicate a low potential for subsequent deposition to surface media. The Committee agreed not to analyse further emissions to air (including the evaluation of air-breathing organisms) as this went beyond the scope of the proposed restriction, but to describe them in the opinion as uncertainties.

With regard to Personal Care Products (PCP) as a source of emission to the aquatic environment, the Rapporteurs noted that the proposed restriction groups the different types of products into 'wash-off' and 'leave-on', and that emissions to waste water are estimated by using two emission factors. It was agreed to ask the Dossier Submitter to further consider (including a sensitivity analysis) the emission factors from wash-off and leave-on products (taking into account also the public consultation comments).

With regard to the concentration limit, the Rapporteurs explained that the proposed restriction focuses on the presence of D4 and D5 in the final PCP at a particular concentration limit, regardless of their source, and that a concentration limit of 0.1% w/w is proposed by the Dossier Submitter to prevent intentional use in cosmetics. A few Members expressed support for a lower concentration limit, as the aim should be to minimize emissions as much as possible. Several other Members, however, emphasised that a lower concentration limit could create problems (i.e. with silicon polymers) and additional costs for enforcement. It was agreed not to deviate from the concentration limit proposed by the Dossier Submitter for the time being and to see if any new information comes in within the public consultation.

The Rapporteurs were asked to take the RAC discussion into account in the second draft opinion.

9. Authorisation

9.1 General authorisation issues

a) Continuing review of risk, uncertainty of OC/RMM's and RAC recommendations

The Secretariat presented a set of decision-trees to the Committee describing possible outcomes of RAC and SEAC opinions which would help the Committees to determine additional conditions and monitoring arrangements, as well as justifying the length of the proposed review period. The main aim is to provide a more structured and efficient way to conclude opinions while maintaining consistency, as well as to further develop how SEAC takes RAC's recommendations into consideration.

The proposal was developed for non-threshold substances only and in line with the RAC/SEAC 'common approach' and 'review period' papers. In addition, the Secretariat clarified that the opinion trees do not yet address when and how RAC and SEAC would make recommendations not to grant an authorisation, or situations where the Committees are unable to evaluate the application etc.

RAC discussed the proposal which was in general found to be helpful by Members, but there were still issues for clarification, with one Member noting that the environmental aspects have not been considered in the structure. Other Members reflected that operational conditions and risk management measures needed to be more clearly emphasised in the opinions of RAC and that the decision tree might help to focus attention on this aspect. One representative of a stakeholder organisation appreciated the work done by the Secretariat in providing a set of

rules to be followed in the opinion making process. He also noted that the opinion trees should cover negative opinions describing them in a broader context. The Chairman noted that the proposal was not tabled for agreement at this meeting, but the Secretariat has noted the discussion and will update the document accordingly. Following the discussion at this meeting the Secretariat will launch a consultation with RAC/SEAC Members and the updated version will be presented for agreement at RAC-35.

b) Report from Authorisation Task Force

The Secretariat informed the Committee on the work done so far by the task force, which was established on July 2014. With regard to the low volumes' applications, the EC is preparing a draft implementing act following the finalisation of which the application format for these uses will be completed by the task force.

The Secretariat reminded Members of the workshop on the process of chemicals which will be organised on 23 September by Cefic and Eurometaux in Brussels, asking them to express their interest to participate. In addition, Members were informed about another workshop that will be organised in November by the EC and ECHA with regard to fit-for-purpose for both upstream and downstream user applications.

c) Working Procedure on opinion development

The Secretariat presented a proposal on the revised Working Procedure for RAC and SEAC for developing opinions on Applications for Authorisation. The main changes in the revision concern the steps on the finalisation of the opinion and in particular the part following the possible comments received by the Applicant. Under the current practise following the receipt of comments by the Applicant the Rapporteurs assess the comments and propose either modifications, or no changes in the document, which is followed by a RAC consultation before finalisation either in plenary or by written procedure.

The Secretariat proposed that for cases where the Rapporteurs consider that following the Applicant's comments, no changes to the opinion are necessary, then there will be no consultation with the Committee and the Chairman will adopt the unchanged opinion on the Committee's behalf. In order to improve transparency, an extra step has been added to the process, in which the Rapporteurs will be asked to provide a written justification of their assessment following the Applicant's comments. This will be sent to the European Commission, Member States and the Applicant.

Where changes to the opinion are proposed by the Rapporteurs, the Committee would then be consulted in the usual way and the opinion agreed either by written procedure or at the next plenary meeting.

RAC discussed the proposal, with one Member noting that there is a risk that the Committee's view might be influenced by the Secretariat. However, as noted by the Chairman, the Secretariat's possible influence would on the contrary be minimal given that in such cases there will be no changes in the document already agreed as a draft opinion by the Committee. In addition, he noted that this modification will increase the efficiency of the process in view of the expected peak in the received applications next year, without affecting the transparency of the decision making.

The proposed amendments were agreed by RAC and were then presented by the Secretariat at the SEAC-28 for agreement by SEAC.

d) Update on incoming/future applications for authorisation

The Secretariat updated Members on the forthcoming and expected applications for authorisation, noting an expected peak of about 80 incoming applications in the November 2015 or February 2016 submission windows, which will result to a peak of the workload of the Committee in late spring-summer 2016.

So far the Secretariat has received three new applications in the August 2015 submission window, one of which was submitted in German. The Secretariat explained that in such a case the application would need to be officially translated in English by the European Commission's translation services before being tabled to the Committees. This might take considerable time, however the Secretariat will inform the committee once there is more information on the expected timeline.

9.2 Authorisation applications

a) Authorisation applications – conformity check and the key issues discussion

1. **Six uses of chromium trioxide submitted by LANXESS Deutschland GmbH on behalf of a group of companies (Chromium trioxide 1)**:

   Use 1: Formulation of mixtures

   Use 2: Functional chrome plating

   Use 3: Functional chrome plating with decorative character

   Use 4: Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character

   Use 5: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering

   Use 6: Passivation of tin-plated steel (ETP)

The Rapporteurs provided a brief information to the application for authorisation and presented the draft outcome of the conformity check. The Rapporteurs also presented their first impression of the application, and highlighted some key issues for the attention of the Committee. The Rapporteurs noted that a large variety of workplaces was covered by this application for authorisation but that there was generally a lack of representative descriptions of the tasks, operational conditions, risk management measures, combined exposures and exposure measurements. Thus the applicants will be asked to provide further information and clarifications on all of these issues.

RAC agreed that the application is in conformity and on the Rapporteurs' proposal with regard to the key issues in the application. The Secretariat will inform the applicant about the outcome of the conformity check and about the further information requested by the Committee.

2. **One use of sodium chromate submitted by Dometic GMBH and Dometic Hűtőgépgyártó és Kereskedelmi Zrt. (Sodium chromate 1)**:

Use 1: The use of sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight (Cr 6+) in the cooling solution.

The Rapporteurs provided information on the application for authorisation and presented the draft outcome of the conformity check. The Rapporteurs also presented key issues for the attention of the Committee and proposal of issues for further clarification by the Applicant. Additionally during the discussion RAC advised the Rapporteurs to request the Applicant for clarification on the handling of malfunctioning refrigerators at the end of the their life, on the timelines of the transition/R&D plan and justification for asking for a long review period, the level of the risk reduction after implementation of (future) RMMs, and on potential alternatives used by competitors.

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

3. **One use of sodium dichromate submitted by Boliden Mineral AB (Sodium dichromate 1)**:

   Use 1: The use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores.

The Rapporteurs provided information on the application for authorisation and presented the draft outcome of the conformity check. The Rapporteurs also presented key issues for the attention of the Committee and proposal of issues for further clarification by the Applicant. Additionally, during the discussion, RAC reiterated the importance of requesting the Applicant (as suggested by the Rapporteurs) to clarify if the substance is used in closed or semi closed system.

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

4. **One use of 1,2-dichloroethane submitted by Laboratoires Expanscience (EDC 1)**:

   Use 1: Use as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients

The Rapporteurs provided brief information on the application for authorisation and presented the draft outcome of the conformity check. The Rapporteurs also presented their first impression of the application, highlighting some key issues for the attention of the Committee. In addition, they proposed some issues which would need further clarification by the Applicant, including more details on the quality control laboratory activities, on exposure issues for different working contributing scenarios and on the tonnage and mass balance of EDC used on site.

RAC agreed on the conformity of the application and on the Rapporteurs' proposal with regard to the key issues in the application. The Secretariat will inform the Applicant about the outcome of the conformity check and ask them for further clarifications on the issues requested by the Committee.

b) Authorisation application – final opinion

1. **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

The Chairman briefly introduced the case noting that at the last plenary meeting the Committee had agreed on the draft opinion for this use, which was sent to the Applicants for their possible comments. The Applicants submitted their comments on 6 August 2015.

The Rapporteurs presented to the Committee the Applicants' comments on the draft opinion, as well as their assessment noting that in their view there was no need to modify the opinion. RAC agreed with the Rapporteurs' conclusion.

RAC adopted by consensus the final opinion as presented by the Rapporteurs. The Chairman thanked the Rapporteurs and the Authorisation team for their work on this application for authorisation.

2. **Lead chromate 1**

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

The Chairman briefly introduced the case noting that at the last plenary meeting the Committee had agreed on the draft opinion for this use, which was sent to the Applicant for their possible comments. The Applicant submitted their comments on 30 July 2015.

The Rapporteur summarised to the Committee the Applicant's comments on the draft opinion, as well as their assessment noting that in their view there was no need to modify the opinion. RAC agreed with the Rapporteur's conclusion.

RAC adopted by consensus the final opinion as presented by the Rapporteur. The Chairman thanked the Rapporteur and the Authorisation team for their work on this application for authorisation.

9.3 Appointment of Rapporteurs for authorisation applications (closed session)

The Committee Members expressed their interest in rapporteurships, applying to the pool of Rapporteurs and indicating absence of conflict of interest. Following the Chairman's proposal, RAC agreed to nominate all Members to same pool of Rapporteurs for substances listed form no 16 to no 29 of Annex XIV. The expanded pool of Rapporteurs, as outlined in the amended restricted room document RAC/34/2015/08 rev. 1, was then agreed by RAC.

10. AOB

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 34 7-11 September 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/34/2015**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-34 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 33 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/34/2015/01** and document **RAC/34/2015/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the Q3 - Q4/2015 and Q1/2016 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-34 meeting on CIRCABC.
c) General RAC procedures • Admission new stakeholder organisations ***RAC/34/2015/03 (restricted)*** RAC has agreed on the updated RAC stakeholders' list as proposed by the Secretariat • Co-opted Members ***RAC/34/2015/04 (restricted)*** RAC agreed on the appointment of the co-opted Members as proposed by the Secretariat	**SECR** to publish the updated list of RAC stakeholders on the ECHA website. **SECR** to proceed with the contractual appointment of the new co-opted Members
7. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement without plenary debate • Cyproconazole (ISO) (Acute toxicity – dermal & inhalation routes, STOT SE, Skin / Eye irritation, Skin sensitisation) • Momfluorothrin (S-1563)* (Acute toxicity - all routes, skin/eye/respiratory tract irritation, skin/respiratory sensitisation, STOT SE, STOT RE, mutagenicity, toxicity to reproduction, aquatic hazards) • Medetomidine (aquatic hazards and M-factors)	

- 5-chloro-2-(4-chlorophenoxy)phenol (DCPP) (aquatic hazards and M-factors)

B. Substances with hazard classes for agreement in plenary session

a) Spiroxamine

b) 4,4'-methylenedimorpholine (MBM) *(environmental hazards only)*

c) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)

d) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT)

e) Cyproconazole (ISO)

f) Momfluorothrin (S-1563)*

g) Methylhydrazine

h) Salicylic Acid

i) Triadimenol

j) Nicotine

a) Spiroxamine (2 CLH proposals/opinions)

RAC adopted by consensus the two opinions with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 2 (H361d), STOT RE 2 (H373 (eye))] [RAC-32: M-factors of 100 for both the acute and chronic aquatic classifications; Acute Tox. 4 (H302, H312, H332); Skin Sens. 1 (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) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)

RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4; H302, Acute Tox. 3; H311, Acute Tox. 4; H332, Skin Corr. 1B; H314, Eye Dam. 1, Skin Sens. 1A; H317, STOT RE 2; H373 (GI tract and respiratory tract), Carc. 1B; H350, Muta 2; H341, Aquatic Chronic 2; H411, EUH071]	**The Dossier Submitter** (DS) to provide the original study report for the 1-gen rat study. **Rapporteur** to revise the opinion based on further information from the DS and to forward it to the SECR for the discussion at RAC 35. **SECR** to launch the consultation on the revised draft opinion (toxicity to reproduction) ahead of RAC 35.

d) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT)

RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4; H302, Acute Tox. 4; H332, Skin Corr. 1C; H314, Eye Dam. 1, Skin Sens. 1A; H317, STOT RE 2; H373 (GI tract and respiratory tract), Carc. 1B; H350, Muta 2; H341, Aquatic Chronic 2; H411, EUH071]	**The Dossier Submitter** (DS) to provide the original study report for the 1-gen rat study. **Rapporteur** to revise the opinion based on further information from the DS and to forward it to the SECR for the discussion at RAC 35. **SECR** to launch the consultation on the revised draft opinion (toxicity to

	reproduction) ahead of RAC 35.
e) Cyproconazole (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute toxicity 3; H301, STOT RE 2; H373 (liver)); Repr. 1B; H360D, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=1].	**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.
f) Momfluorothrin (S-1563)*	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, STOT SE 2; H371 (CNS), 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.
h) Methylhydrazine	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B (H350)]	**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.
i) Salicylic acid	
RAC will continue the discussion on developmental toxicity at RAC-35 with the view to adopt the opinion.	**SECR** to contact EMA with regard to studies at high doses. **SECR** to compile a list of questions posed by RAC members. **SECR** to launch a RAC consultation.
j) Triadimenol (ISO)	
RAC agreed on the hazard classes for harmonised classification and labelling as indicated in Table 2 below. RAC will continue examination of the dossier (environment) at RAC-35 in November. [Acute Tox. 4 (H302) agreed at RAC-33]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC-34 and to provide it to SECR.

[Repr. 1B (H360); Lact. (H362)]	
k) Nicotine	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. RAC concluded on ATE values for all three routes of exposure. [Acute Tox. 2; H300, Acute Tox. 2; H310, Acute Tox. 2; H330)]	**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.
7.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCABC confidential.
8. Restrictions	
8.1 General restriction issues	
RAC agreed on the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals (meeting document RAC/34/2015/06)	**SECR** to publish the agreed Framework document on the ECHA website and CIRCABC IG.
7.2 Restriction Annex XV dossiers	
a) Opinion Development	
1. Perfluorooctanoic acid (PFOA) – revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC adopted the opinion on PFOA and its salts by consensus (with modifications introduced at RAC-34).	**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.
2. Methanol – first draft opinion Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed in principle with the restriction proposed in the first draft opinion pending some clarifications	**Rapporteurs** to take the RAC discussion into account in the revised version of the draft opinion (by end of October 2015). **SECR** to open a written commenting round on the revised draft opinion.

regarding the alternatives.	
3. D4/D5 – first draft opinion Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed that D4 is PBT and vPvB and D5 is vPvB. RAC agreed that HH aspects are outside the scope of the RAC evaluation. The SCCS opinion to be reflected in the RAC opinion. RAC agreed not to analyse further emissions to air (including the evaluation of air-breathing organisms), but to describe them in the opinion as uncertainties. RAC agreed to ask the DS to further consider (including sensitivity analysis) the emission factors from wash-off and leave-on products (taking into account the public consultation comments). RAC agreed not to deviate from the DS`s proposed concentration limit (pending the outcome of the public consultation).	**Rapporteurs** to take the RAC discussion into account in the second draft opinion (by end of October 2015). **SECR** to open a written commenting round on the revised draft opinion.
9. Authorisation	
9.1 General authorisation issues	
a) Continuing review of "Risk, uncertainty of OC/RMM's and RAC recommendations"	
b) Report from Authorisation Task Force	
c) Working Procedure on opinion development	
RAC/34/2015/07	RAC Agreed on the Working Procedure amendments as proposed by the Secretariat. SECR to publish the WP on CIRCABC and the ECHA website.
d) Update on incoming/future applications for authorisation	
9.2 Authorisation applications	
a) Authorisation application – conformity check and the key issues discussion	

1. Six uses of chromium trioxide submitted by LANXESS Deutschland GmbH on behalf of a group of companies (Chromium trioxide 1): **Use 1:** Formulation of mixtures **Use 2:** Functional chrome plating **Use 3:** Functional chrome plating with decorative character **Use 4:** Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character **Use 5:** Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering **Use 6:** Passivation of tin-plated steel (ETP) RAC agreed that the application for authorisation Chromium trioxide 1 is in conformity. Regarding the key issues the RAC identified the following: Worker exposure and risk assessment - more detailed description of tasks and Operational Conditions (OCs) are required - further information on the available RMMs is needed as all 6 uses can take place in industrial settings with variable size, production volume, etc. - the workplace context in which the reported exposure measurements were taken needs to be clarified - how the measurement data was subsequently adjusted to take account of the use of the Respiratory Protective Equipment (RPE) needs to be explained - in the combined exposure and risk assessment, clarification is needed on the maximum individual exposure value used in further analyses Man via Environment - supporting data on wastewater discharge and subsequent aquatic and soil releases is needed - additional descriptions of RMMs concerning releases to wastewater and air are needed - additional explanation of the measurement data used to assess local air emissions would be helpful **2. One use of sodium chromate submitted by Dometic GMBH and Dometic Htgépgyártó és Kereskedelmi Zrt. (Sodium chromate 1):** **Use 1:** The use of sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight (Cr 6+) in the	**SECR** to upload to CIRCABC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to inform the applicant about the outcome of the conformity check.

cooling solution. RAC agreed that the application for authorisation sodium chromate 1 is in conformity.	**SECR** to upload to CIRCABC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check.
3. One use of sodium dichromate submitted by Boliden Mineral AB (Sodium dichromate 1): **Use 1**: The use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores. RAC agreed that the application for authorisation sodium dichromate 1 is in conformity.	**SECR** to inform the applicant about the outcome of the conformity check. **SECR** to upload to CIRCABC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to inform the applicant about the outcome of the conformity check.
4. One use of 1,2-dichloroethane submitted by Laboratoires Expanscience (EDC 1): **Use 1:** Use as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients RAC agreed that the application for authorisation EDC1 is in conformity. Regarding the key issues the RAC identified the following: - **Exposure Assessment:** the following should be clarified: – the exposure assessment for quality control laboratory activities; – the assessment of dermal exposure for WCS1, 3 and 4. In addition to the above, RAC considers that further information is needed on: • quality control laboratory activities • clarification of measured workers' exposure levels presented for WCS 1 (especially for sampling activity) • potential sources of exposure to EDC for WCS1 • The input values for assessment of dermal exposure in WCS3 and WCS4 • information related to future changes in the use of EDC • mass balance of EDC	**SECR** to inform the applicant about the outcome of the conformity check. **SECR** to upload to CIRCABC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to inform the applicant about the outcome of the conformity check.
b) Authorisation application – final opinion	
1. Trichloroethylene 2a: **Use 1:** Use of Trichloroethylene in Industrial	Actions:

Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist RAC adopted the final opinion by consensus	**TCE2a use 1** **Rapporteurs** together with SECR to do the final editing of the final opinion. **SECR** to send the final opinion to the European Commission, Member States and the Applicant.
2. Lead chromate 1: **<u>Use 1:</u>** Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection RAC adopted the final opinion by consensus	**Lead chromate 1** **Rapporteurs** together with SECR to do the final editing of the final opinion. **SECR** to send the final opinion to the European Commission, Member States and the Applicant.
9.3 Appointment of (co-)rapporteurs for authorisation applications **RAC/34/2015/08** RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
10. AOB	
11. Action points and main conclusions of RAC-34	
SECR to upload the adopted action points to CIRCABC.	

Table 1: CLH opinions adopted by RAC

(2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1*H*—1,2,4-triazol-1-yl)butan-2-ol; cyproconazole (ISO)

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	650-032-00-X	cyproconazole (ISO); (2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H—1,2,4-triazol-1-yl)butan-2-ol	-	94361-06-5	Repr. 2 Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H361d *** H302 H400 H410	GHS08 GHS07 GHS09 Wng	H361d *** H302 H410			
Dossier submitters proposal	650-032-00-X	cyproconazole (ISO); (2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H—1,2,4-triazol-1-yl)butan-2-ol	-	94361-06-5	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 STOT RE 2 **Modify** Repr. 1B Acute Tox. 4	**Retain** H400 H410 **Add** H351 H373 (liver)(oral) **Modify** H360D H302	**Retain** GHS08 GHS07 GHS09 **Modify** Dgr	**Retain** H410 **Add** H351 H373 (liver)(oral) **Modify** H360D H302		**Add** M=10 M=10	
RAC opinion	650-032-00-X	cyproconazole (ISO); (2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H—1,2,4-triazol-1-yl)butan-2-ol	-	94361-06-5	**Retain** **Aquatic Acute 1** **Aquatic Chronic 1** **Add** **STOT RE 2** **Modify** **Repr. 1B** **Acute Tox. 3**	**Retain** **H400** **H410** **Add** **H373 (liver)** **Modify** **H360D** **H301**	**Retain** **GHS08** **GHS09** **Modify** **GHS06** **Dgr**	**Retain** **H410** **Add** **H373 (liver)** **Modify** **H360D** **H301**		**Add** **M=10** **M=1**	
Resulting Annex VI entry if agreed	650-032-00-X	cyproconazole (ISO); (2*RS*,3*RS*;2*RS*,3*SR*)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H—	-	94361-06-5	Repr. 1B Acute Tox. 3 STOT RE 2 Aquatic Acute 1	H360D H301 H373 (liver) H400	GHS08 GHS06 GHS09 Dgr	H360D H301 H373 (liver) H410		M=10 M=1	

by COM		1,2,4-triazol-1-yl)butan-2-ol			Aquatic Chronic 1	H410					

2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl (Z)-(1R,3R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate; momfluorothrin (S-1563)

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 submitters proposal	xxx-xxx-xx-x	Momfluorothrin (S-1563)*; 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl (Z)-(1R,3R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropane carboxylate *CAS number 609346-29-4	Not assigned	1065124-65-3	Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H371 (CNS) H400 H410	GHS07 GHS08 GHS09 Wng	H302 H371 H410		M = 100 M = 100	
RAC opinion	xxx-xxx-xx-x	Momfluorothrin (S-1563)*; 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl (Z)-(1R,3R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropane carboxylate *CAS number 609346-29-4	Not assigned	1065124-65-3	**Acute Tox. 4** **STOT SE 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H302** **H371 (CNS)** **H400** **H410**	**GHS07** **GHS08** **GHS09** **Wng**	**H302** **H371** **H410**		**M = 100** **M = 100**	
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	Momfluorothrin (S-1563)*; 2,3,5,6-Tetrafluoro-4-(methoxymethyl)benzyl (Z)-(1R,3R)-3-(2-cyanoprop-1-enyl)-2,2-dimethylcyclopropane carboxylate *CAS number 609346-29-4	Not assigned	1065124-65-3	Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H371 (CNS) H400 H410	GHS07 GHS08 GHS09 Wng	H302 H371 H410		M = 100 M = 100	

3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine; nicotine (ISO)

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	614-001-00-4	nicotine (ISO); 3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	Acute Tox. 3 * Acute Tox. 1 Aquatic Chronic 2	H301 H310 H411	GHS06 GHS09 Dgr	H301 H310 H411			
Dossier submitters proposal	614-001-00-4	nicotine (ISO); 3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	**Retain** Acute Tox. 1 **Add** Acute Tox. 2 **Modify** Acute Tox. 1	**Retain** H310 **Add** H330 **Modify** H300	GHS06 GHS09 Dgr	H330 H310 H300 H411			
RAC opinion	614-001-00-4	nicotine (ISO); 3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	**Add** **Acute Tox. 2** **Modify** **Acute Tox. 2** **Acute Tox. 2**	**Add** **H330** **Retain** **H310** **Modify** **H300**	**GHS06** **GHS09** **Dgr**	**H300** **H310** **H330** **H411**			
Resulting Annex VI entry if agreed by COM	614-001-00-4	nicotine (ISO); 3-[(2*S*)-1-methylpyrrolidin-2-yl]pyridine	200-193-3	54-11-5	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Aquatic Chronic 2	H300 H310 H330 H411	GHS06 GHS09 Dgr	H300 H310 H330 H411			

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

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	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	H302 H312 H332 H315 H317 H400 H410	GHS07 GHS09 Wng	H302 H312 H332 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 STOT RE 2 **Modify** Skin Sens. 1B Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Add** H361d H373 **Modify** H317 H302 H312 H332 **Retain** H400 H410	**Add** GHS08 **Retain** GHS07 GHS09	**Add** H361d **Modify** H317 H302 H312 H332 **Retain** 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	**Add** **Repr. 2** **STOT RE 2** **Modify** **Acute Tox. 4** **Acute Tox. 4** **Acute Tox. 4** **Retain** **Skin Sens. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	**Add** **H361d** **H373 (eye)** **Modify** **H302** **H312** **H332** **Retain** **H317** H400 H410	**Add** GHS08	**Add** **H361d** **H373 (eye)** **Modify** **H302** **H312** **H332** **Retain** **H317** H410		**Add** **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	-	118134-30-8	Repr. 2 Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 STOT RE 2	H361d H302 H312 H332 H315 H317 H373 (eye)	GHS08 GHS07 GHS09 Wng	H361d H302 H312 H332 H315 H317 H373 (eye)			

					Aquatic Acute 1 Aquatic Chronic 1	H400 H410		H410		M=100 M=100	

Methylhydrazine

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 submitters proposal	xxx-xxx-xx-x	methylhydrazine	200-471-4	60-34-4	Carc. 1B	H350	GHS08 Dgr	H350			
RAC opinion	xxx-xxx-xx-x	methylhydrazine	200-471-4	60-34-4	**Carc. 1B**	**H350**	**GHS08 Dgr**	**H350**			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	methylhydrazine	200-471-4	60-34-4	Carc. 1B	H350	GHS08 Dgr	H350			

5-chloro-2-(4-chlorophenoxy)phenol (DCPP)

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	605-023-00-5	5-chloro-2-(4-chlorophenoxy) phenol	429-290-0	3380-30-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	605-023-00-5	5-chloro-2-(4-chlorophenoxy) phenol	429-290-0	3380-30-1	**Retain** Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		Add M=10 M=10	
RAC opinion	605-023-00-5	5-chloro-2-(4-chlorophenoxy) phenol	429-290-0	3380-30-1	**Retain** **Aquatic Acute 1** **Aquatic Chronic 1**	H400 H410	GHS09 Wng	H410		**Add** **M=10** **M=10**	
Resulting Annex VI entry if agreed by COM	605-023-00-5	5-chloro-2-(4-chlorophenoxy) phenol	429-290-0	3380-30-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 M=10	

Table 2: CLH dossiers for which selected hazard classes have been agreed by RAC (opinion not adopted)

4,4'-methylenedimorpholine (MBM)

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 submitters proposal	xxx-xxx-xx-x	4,4'-methylenedimorpholine			Carc. 1B Muta. 2 Skin Corr. 1B Skin Sens. 1	H350 H341 H314 H317	GHS08 GHS05 GHS07 Dgr	H350 H341 H314 H317		C ≥ 1.2%	
RAC opinion	xxx-xxx-xx-x	4,4'-methylenedimorpholine									
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	4,4'-methylenedimorpholine									

Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)

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 submitters proposal	xxx-xxx-xx-x	Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)			Carc. 1B Muta. 2 Skin Corr. 1B Skin Sens. 1A Aquatic Chronic 3	H350 H341 H314 H317 H412	GHS08 GHS05 GHS07 Dgr	H350 H341 H314 H317 H412			
RAC opinion	xxx-xxx-xx-x	Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)			**Carc. 1B** **Muta. 2** Repr. 2 **Acute Tox. 4** **Acute Tox. 3** **Acute Tox. 4** **Skin Corr. 1B** **Eye Dam. 1** **Skin Sens. 1A** **STOT RE 2** **Aquatic Chronic 2**	**H350** **H341** H361f **H302** **H311** **H332** **H314** **H318** **H317** **H373 (gastrointestinal tract, respiratory tract)** **H411**	**GHS08** **GHS05** **GHS06** **GHS09** **Dgr**	**H350** **H341** H361f **H302** **H311** **H332** **H314** **H317** **H373 (gastrointestinal tract, respiratory tract)** **H411**	**EUH071** ~~EUH029~~		
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)									

Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1) (HPT)

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 submitters proposal	xxx-xxx-xx-x	Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1)	-	-	Carc. 1B Muta. 2 Skin Corr. 1B Skin Sens. 1A Aquatic Chronic 3	H350 H341 H314 H317 H412	GHS05 GHS07 GHS08 Dgr	H350 H341 H314 H317 H412			
RAC opinion	xxx-xxx-xx-x	Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1)	-	-	**Carc. 1B** **Muta. 2** Repr. 2 **Acute Tox. 4** **Acute Tox. 4** **Skin Corr. 1C** **Eye Dam. 1** **Skin Sens 1A** **STOT RE 2** **Aquatic Chronic 2**	**H350** **H341** H361f **H332** **H302** **H314** **H318** **H317** **H373 (gastrointestinal tract, respiratory tract)** **H411**	**GHS05** **GHS06** **GHS08** **GHS09** **Dgr**	**H350** **H341** H361f **H332** **H302** **H314** **H317** **H373 (gastrointestinal tract, respiratory tract)** **H411**	**EUH071** ~~EUH029~~		
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1)	-	-							

(RS)-4-[1-(2,3-dimethylphenyl)ethyl]-1*H*-imidazole (Medetomidine)

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 submitters proposal	xxx-xxx-xx-x	*(RS)*-4-[1-(2,3-dimethylphenyl)ethyl]-1*H*-imidazole; medetomidine	-	86347-14-0	Acute Tox. 2 Acute Tox. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H300 H330 H336 H400 H410	GHS06 GHS09 Dgr	H410		M = 1 M =100	
RAC opinion[3]	xxx-xxx-xx-x	*(RS)*-4-[1-(2,3-dimethylphenyl)ethyl]-1*H*-imidazole; medetomidine	-	86347-14-0	Acute Tox. 2 Acute Tox. 2 STOT SE 3 **Aquatic Acute 1** **Aquatic Chronic 1**	H300 H330 H336 **H400** **H410**	**GHS06** **GHS09** **Dgr**	H300 H330 H336 **H410**		**M = 1** **M =100**	
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	*(RS)*-4-[1-(2,3-dimethylphenyl)ethyl]-1*H*-imidazole; medetomidine	-	86347-14-0							

[3] This refers only to the proposed environmental hazard classification. HH hazards will be discussed at RAC 35.

Salicylic acid

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 submitters proposal	xxx-xxx-xx-x	salicylic acid	200-712-3	69-72-7	Acute Tox. 4 Eye Dam. 1	H302 H318	GHS07 GHS05 Dgr	H302 H318			
RAC opinion	xxx-xxx-xx-x	salicylic acid	200-712-3	69-72-7	Repr. 1B or 2 **Acute Tox. 4** **Eye Dam. 1**	H360D or H361d **H302** **H318**	GHS08 **GHS07** **GHS05** **Dgr**	H360D or H361d **H302** **H318**			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	salicylic acid	200-712-3	69-72-7							

α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol; triadimenol (ISO)

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 submitters proposal	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol	259-537-6	55219-65-3	Repr. 2 Acute Tox. 4 Aquatic Chronic 2	H361f H302 H411	GHS08 GHS07 GHS09 Wng	H361f H302 H411			
RAC opinion	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol	259-537-6	55219-65-3	**Repr. 1B** **Lact.** **Acute Tox. 4** Aquatic Chronic 2	**H360** **H362** **H302** H411	**GHS08** **GHS07** GHS09 **Dgr**	**H360** **H362** **H302** H411			
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1*H*-1,2,4-triazole-1-ethanol	259-537-6	55219-65-3							

Part III. List of Attendees of the RAC-34 meeting

7-11 September 2015

RAC Members
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
BRANISTEANU Radu
CARVALHO João
COPIN Stephanie
CZERCZAK Slawomir
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HUSA Stine
HÖLZL Christine
ILIE Mihaela
KADIĶIS Normunds
KAPELARI Sonja
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MULLOOLY Yvonne
MURRAY Brendan
NEUMANN Michael
PARIS Pietro
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina

SCHLÜTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SOERENSEN Peter Hammer
SPETSERIS Nikolaos
STAHLMANN Ralf
STASKO Jolanta
TADEO José Luis
TOBIASSEN Lea Stine
UZOMECKAS Zilvinas
VARNAI Veda Marija
Apologies
DI PROSPERO FANGHELLA Paola
KALOGIROU Andreas
PASQUIER Elodie
Absent
TSITSIMPIKOU Christina
Commission observers
MORRIS Alick DG EMPL
PIRSELOVA Katarina DG ENV
RIEPMA Wim DG GROW
SCAZZOLA Roberto DG GROW
Invited expert
ANDREOU Kostas (RAC candidate Member)
BARTHELEMY-BERNERON Johanna (replacing Members Elodie Pasquier)
CHANKOVA-PETROVA Stephanie
MÖLLER Ruth

RAC advisors		**Stakeholders observers**
ESPOSITO Dania (Pietro Paris), (momfluorothrin)		ANNYS Erwin, Cefic
GEOFFROY Laure (Stéphanie Copin)		BARRY Frank, ETUC
LOIKKANEN Jarkko (Riitta Leinonen)		MUNARI Tomaso, EuCheMS
McCABE Laura (Andrew Smith)		ROMANO Dolores, EEB
PECZKOWSKA Beata (Boguslaw Baranski) (spiroxamine, nicotine)		VEROUGSTRAETE Violaine, Eurometaux
PUTS Catheleyne (Marja Pronk) (momfluorothrin)		ROWE Rocky, ECPA
RISSANEN Eeva (Riitta Leinonen)		
STOCKMANN-JUVALA Helene (Tiina Santonen)		**Dossier submitters**
UUKSULAINEN Sanni (Tiina Santonen)		CORRELL MYHRE Ingunn (PFOA), Norway
WOTHE Susann (Urs Schlueter), AfA TCE 2a use 1		VIERKE Lena (PFOA), Germany
		GARD-FLOC´h Arielle (salicylic acid), representing Novacyl
Industry experts		KLAUS Ana-Maria (salicylic acid), Bayer
BOCK Ronald (Cefic, Chemours, PFOA)		
ERLER Steffen (Cefic, Sabic, methanol)		
GARTLAND Kevan (ECPA, Sumitomo, momfluorothrin)		
HAHN Stefan (Cefic, ITEM, MBO, HPT, MBM)		
HENNINGER Kerstin (ECPA, BCS, spiroxamine, triadimenol)		
LLOYD Sara (ECPA, Syngenta, cyproconazole)		
PLOTZKE Kathleen (Cefic, DOW, D4/D5)		

REMOTE PARTICIPANTS
Advisers :
LOSERT Annemarie (Christine Hölzl)
SEAC Rapporteurs
KIISKI Johanna (PFOA)
Dossier submitters
DE dossier submitters:
BIEGEL-ENGLER Annegret (PFOA)
NIEDERSTRASSER Bernd (PFOA)
STAUDE Claudia (PFOA)
NO dossier submitters:
BLOM Cecile (PFOA)
GUTZKOW Bjerve Kristine (PFOA)
KOPANGEN Marit (PFOA)
MORAEUS Olsen Christel (PFOA)
PL dossier submitter:
GODALA Mariusz (methanol)
UK dossier submitters:
CAITENS Andrea (momfluorothrin, triadimenol)
MARTIN Sara (D4/D5)
NL dossier submitters:
MÜLLER Andre (methylhydrazine, nicotine)
AT dossier submitters
KECK Marianne (MBM, MBO, HPT)
PAPARELLA Martin (MBM, MBO, HPT)
Commission
BERTATO Valentina
FERNANDES-de-BARROS Mariana
ROZWADOWSKI Jacek
Van der JAGT Katinka

ECHA staff
BERGES Markus
BLAINEY Mark
BOWMER Tim, Chairman
BROECKAERT Fabrice
DVORAKOVA Dana
ERICSSON Gunilla
HELLSTEN Kati
HENRICSSON Sanna
HONKANEN Jani
JOVER BUSTILLO Vanessa
KANELLOPOULOU Athanasia
KIVELÄ Kalle
KLAUK Anja
KOKKOLA Leila
KOSK-BIENKO Joanna
KOULOUMPOS Vasileios
LEGZDIPA Ilze
LIOPA Elina
LOGTMEIJER Christiaan
LUDBORŽS Arnis
LUSCHÜTZKY Evita
MARQUEZ-CAMACHO Mercedes
MAZZOLINI Anna
MOTTET Denis
MULLER Gesine
NICOT Thierry
NYGREN Jonas
ORISPÄÄ Katja
PILLET Monique
PELTOLA Jukka
PENNESE Daniele
PERAZZOLA Chiara
REGIL Pablo
RODRIGUEZ-IGLESIAS Pilar
ROGGEMAN Maarten
SADAM Diana
SIHVONEN Kirsi
SIMPSON Peter
SMILOVICI Simona
SOSNOWSKI Piotr
SPJUTH Linda

	VAN HAELST Anniek

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-34 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-34 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-34 meeting

ANNEX IV Administrative issues and information items

Annex I (RAC-34)

7 September 2015
RAC/A/34/2015

Final Agenda
34th meeting of the Committee for Risk Assessment

7-11 September 2015

ECHA Conference Centre (Annankatu 18, Helsinki)

7 September starts at 9.00
11 September ends at 11.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/34/2015
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 33 action points, written procedures and update on other ECHA bodies

RAC/34/2015/01
RAC/34/2015/02
For information

b) RAC workplan for all processes

For information

c) General RAC procedures
   - Admission of stakeholder organisations

RAC/34/2015/03 (restricted)
For discussion and agreement

- Co-opted members

RAC/34/2015/04 (restricted)
For discussion and agreement

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

No requests.

Item 6 – Requests under Article 95 (3)

a) 1-methyl-2-pyrrolidone (NMP)

For information

Item 7 – Harmonised classification and labelling (CLH)

7.1 CLH dossiers

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

- Cyproconazole (ISO) (Acute toxicity – dermal & inhalation routes, STOT SE, Skin / Eye irritation, Skin sensitisation)
- Momfluorothrin (S-1563)* (Physical hazards, acute toxicity - all routes, skin/eye/respiratory tract irritation, skin/respiratory sensitisation, STOT SE, STOT RE, mutagenicity, toxicity to reproduction, aquatic hazards)
- Medetomidine (aquatic hazards and M-factors)
- 5-chloro-2-(4-chlorophenoxy)phenol (DCPP) (aquatic hazards and M-factors)

B. Hazard classes for agreement with plenary debate

a) Spiroxamine

b) 4,4'-methylenedimorpholine (MBM) *(environmental hazards only)*

c) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO)

d) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT)

e) Cyproconazole (ISO)

f) Momfluorothrin (S-1563)*

g) Methylhydrazine

h) Salicylic Acid

i) Triadimenol

j) Nicotine

For discussion and adoption

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

RAC/34/2015/05
(Room document)
For agreement

Item 8 – Restrictions

8.1 General restriction issues

a) Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

RAC/34/2015/06
For discussion and agreement

8.2 Restriction Annex XV dossiers

a) Opinion development

1) Perfluorooctanic acid (PFOA) – revised draft opinion

For adoption

2) Methanol – first draft opinion

For discussion

3) D4/D5 – first draft opinion

For discussion

8.3 Appointment of (co-)rapporteurs for restriction dossiers

For information

Item 9 – Authorisation

9.1 General authorisation issues

a) Continuing review of "Risk, uncertainty of OC/RMM's and RAC recommendations"

For discussion

e) Report from Authorisation Task Force

For information

f) Working Procedure on opinion development

RAC/34/2015/07
For discussion and agreement

g) Update on incoming/future applications for authorisation

For information

9.2 Authorisation applications

a) Authorisation application – conformity check and the key issues discussion

1. Six uses of chromium trioxide submitted by LANXESS Deutschland GmbH on behalf of a group of companies (Chromium trioxide 1):

   Use 1: Formulation of mixtures
   Use 2: Functional chrome plating
   Use 3: Functional chrome plating with decorative character
   Use 4: Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character
   Use 5: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering
   Use 6: Passivation of tin-plated steel (ETP)

2. One use of sodium chromate submitted by Dometic GMBH and Dometic Htgépgyártó és Kereskedelmi Zrt. (Sodium chromate 1):

   Use 1: The use of sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight (Cr 6+) in the cooling solution.

3. One use of sodium dichromate submitted by Boliden Mineral AB (Sodium dichromate 1):

   Use 1: The use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores.

4. One use of 1,2-dichloroethane submitted by Laboratoires Expanscience (EDC 1):

   Use 1: Use as process and extracting solvent in the manufacture of plant-derived pharmaceutical bioactive ingredients

For discussion and agreement

b) Authorisation application – final opinion

a. One use 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

b. One use of lead chromate submitted by *Etienne LACROIX* (Lead chromate 1):

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

For discussion and adoption

9.3 Appointment of (co-)rapporteurs for authorisation applications

RAC/34/2015/08
(Restricted room document)
For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-34

Table with Conclusions and Action points from RAC-34

For adoption

Annex II (RAC-34)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-34 meeting.

Document number	Title
RAC/A/34/2015	Final Draft Agenda
RAC/34/2015/01	Report from other ECHA bodies and activities
RAC/34/2015/02	Administrative document
RAC/34/2015/03 Restricted	Revised general approach for admission of accredited stakeholder organisations to RAC and SEAC
RAC/34/2015/04 Restricted	Appointment of co-opted Members to RAC and SEAC
RAC/33/2015/05 Restricted room document	Appointment of Rapporteurs for CLH dossiers
RAC/34/2015/06	General RAC/SEAC procedures: Framework for RAC and SEA in checking conformity and developing opinions on restriction proposals
RAC/34/2015/07	Revised Working Procedure for AfA Opinion Development
RAC/34/2015/08 Restricted room document	Appointment of Rapporteurs for authorisation application

Annex III (RAC-34)

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 31, 32 and/or 33		
Restrictions		
PFOA	Christine BJØRGE	Working for the CA who collaborated with Germany on the preparation of the dossier.
	Stine HUSA	Working for the CA who collaborated with ECHA 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.
	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.
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.
D4/D5 (UK)	Steve DUNGEY	Working for the CA submitting the dossier; directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Andrew SMITH	Working for the CA submitting the dossier; directly involved in the

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Harmonised classification & labelling		
triadimenol (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.
spiroxamine (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.
	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.
	Agnes SCHÜLTE	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
Applications for Authorisation		
Chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this substance - further mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
methylhydrazine (NL)	Betty HAKKERT	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.
	Marja PRONK	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.
4,4'-methylenedimorpholine (MBM) (AT)	Sonja KAPELARI	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.
	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.
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (AT)	Sonja KAPELARI	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.
	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.
Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (AT)	Sonja KAPELARI	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.
	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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
cyproconazole (ISO) (IE)	Brendan MURRAY	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.
momfluorothrin (S-1563)* (UK)	Andrew SMITH	Working for the CA submitting the dossier and was personally involved in the preparation; asked to refrain from voting in the event of a vote on this substance – further mitigation measures may be applied by the Chairman.
	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.
medetomidine (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.
nicotine (ISO) (NL)	Betty HAKKERT	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.
	Marja PRONK	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.
5-chloro-2-(4-chlorophenoxy)phenol (DCPP) (AT)	Sonja KAPELARI	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.
	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 (RAC-34)

Helsinki, 28 August 2015

RAC/34/2015/02

ROOM DOCUMENT

34TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

7 – 11 September 2015

Helsinki, Finland

Concerns:	**Administrative issues and information items**
Agenda Point:	**4a**
Action requested:	**For information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-33 Action Points

The RAC-33 action points due for RAC-34 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
Written procedure for adoption of the minutes of RAC-33	31 August 2015	ongoing

2.2 RAC consultations on dossiers (status by 28 August 2015)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Spiroxamine (tox. to reproduction & STOT RE)	13 August 2015	closed
4,4'-methylenedimorpholine (MBM) (ENV only)	24 August 2015	closed
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (HH part) / (ENV part)	24 August 2015	closed
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (HH part) / (ENV part)	24 August 2015	closed
Cyproconazole (ISO) (HH part) / (ENV part)	13 August 2015 / 17 August 2015	closed
Momfluorothrin (S-1563)*	14 August 2015	closed
Medetomidine (ENV only)	7 August 2015	closed
Methylhydrazine	-	-
Salicylic acid (developmental toxicity)	11 August 2015	closed
Triadimenol (toxicity to reproduction)	3 August 2015	closed
Nicotine (ISO) (extended RAC-c on the revised ODD)	14 August 2015	closed
5-chloro-2-(4-chlorophenoxy)phenol (DCPP)	10 August 2015	closed
Applications for Authorisation		
TCE2a use 1: Members' commenting period following Applicant's comments	24 August 2015	closed
Lead chromate 1: Members'	27 August 2015	closed

commenting period following Applicant's comments		
Restrictions		
Methanol First draft opinion	26 August 2015	closed
D4/D5 First draft opinion	26 August 2015	closed
PFOA Revised draft opinion	27 August 2015	closed

2.3 Other written consultations of RAC (status by 28 August 2015)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-33	6 August 2015	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest for rapporteurship	9 - 22 June 2015	Eight dossiers; volunteers for three dossiers appointed via WP (3 July 2015)
	30 July – 7 August 2015	One dossier; volunteer appointed via WP (21 August 2015)
	30 July – 17 August 2015	Fourteen dossiers; volunteers for four dossiers will be appointed at RAC 34
Applications for Authorisation – no calls		
Restrictions – no calls		

2.5 Written procedures for the appointment of (co-)rapporteurs

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling			
Written procedure for the appointment of (co-) rapporteur(s)	▪ Piperonyl Butoxide ▪ flupyradifurone (ISO) ▪ mesosulfuron-methyl	3 July 2015	Closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.
	▪ Granulated copper ▪ 4,4'-methylenedimorpholine (MBM)	16 July 2015	
	▪ Granulated copper ▪ Flutianil (ISO)	21 August 2015	

Applications for Authorisation			
Appointment of the Rapporteurs for EDC 1 AfA	1,2 dichloroethane (EDC)	-	Rapporteurs appointed
Restrictions – no written procedures			

2.6 Other written procedures

Other written procedures	Deadline	Report on the outcome
AfA: Adoption of the final opinion on the use of trichloroethylene TCE 6	10 August 2015	Closed
AfA: Adoption of the final opinion on the use of trichloroethylene TCE 1	18 August 2015	Closed
AfA: Adoption of the final opinion on the use of trichloroethylene TCE 8	18 August 2015	Closed
AfA: Adoption of the final opinion on the use of trichloroethylene TCE 10	18 August 2015	Closed