RAC/M/35/2015
Final
2 February 2016

Minutes of the 35th Meeting of the Committee for Risk Assessment (RAC-35)

24 November starts at 9.00
27 November breaks at 13.00
1 December resumes at 14:00
4 December ends at 13.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 35th meeting of the Committee for Risk Assessment (RAC-35). Apologies were received from three Members. The Chairman welcomed three new RAC Members and five co-opted RAC Members, the latter as agreed by the Committee at RAC-34. The Chairman also welcomed two invited experts representing the ECHA Management Board's Committee on Conflicts of Interest (COIAC), who attended the agenda point on RAC general procedures.

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. He added that the recordings from RAC-34 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 as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/35/2015), which was adopted by the Committee without change. The Chairman informed that the CLH substance salicylic acid had been postponed until the March 2016 meeting (RAC-36). 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. Sixteen Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of Members at agencies submitting dossiers to RAC but who had not been involved in the preparation. 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. Where Members declared that they had contributed to the preparation of a substance dossier for consideration by RAC, or similar potential conflict, they were asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. 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-34 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points of RAC-34 had been completed, or were on-going. He explained that a report covering the developments in the ECHA Management Board, the Socio-Economic Assessment Committee, Member State Committee, the Forum and the Biocidal Products Committee had been compiled and distributed to RAC as a meeting document (RAC/35/2015/01). 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-34 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman presented the updated RAC work-plan for Q1&Q2/2016, 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

COIAC

The Chairman of the Conflict of Interest Advisory Committee (COIAC), established by the Management Board in 2011, outlined the role of the COIAC and the recommendations provided on request to the Management Board and the Executive Director related to potential Conflict of Interest. The external expert Member of the COIAC gave a presentation on ethics and conflict of interest for holders of public office.

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

None at present.

6. Requests under Article 95 (3)

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

The Chairman presented the results of the first meeting of the Joint Working Group of RAC-Scientific Committee on Occupational Exposure Limits (SCOEL) concerning the Article 95 request to resolve the differences between the Derived No Effect Level (DNEL) and the Occupational Exposure Limit (OEL) for the aprotic solvent 1-methyl-2-pyrrolidone (NMP), which took place in Brussels on 27 October.

A RAC Member of the Joint Working Group then presented an analysis of the SCOEL recommendation and the RAC opinion on NMP in order to identify the points of divergence and especially where convergence of the respective limit values might be achievable by both Committees.

RAC discussed the option to reconsider all available NOAECs and LOAECs for the developmental effects. In so doing, the adversity of the developmental effects could be looked at again. It was noted that it might possibly be justifiable for RAC in this manner to raise the DNEL to some extent, potentially allowing a narrowing of the gap with the OEL. RAC would request similar reconsideration by SCOEL to assess the potential for adjustment of its OEL; in their latest draft recommendation from 2015, this latter is based on respiratory irritation from human volunteer studies. RAC Members of the joint working group felt that consideration needed to be given by SCOEL to systemic and not just local effects. RAC agreed to this proposal, Members requesting that a strictly scientific approach be maintained.

The RAC Members of the Joint Working Group would propose this to SCOEL in order to resolve the differences between the RAC DNEL and SCOEL OEL.

It was also agreed that issues of differing methodology need to be resolved at a later stage, as soon as the second more general Article 95 mandate, regarding the resolution of methodological differences in deriving such reference values, is confirmed (see below)

b) OEL/DNEL methodologies

The Chairman then informed the meeting on the state of play of a second Article 95 request inviting SCOEL and ECHA to set up a joint Task Force of SCOEL and RAC Members to examine and report on ways of converging their respective OEL/DNEL methodologies. He reported that ECHA, having examined the resource issues involved, intended to accept this request in a phased manner and with a detailed work plan (in part to be determined by the RAC/SCOEL Task Force). He noted that the request was challenging and contained an assessment of the respective methodologies for a): determining OEL and DNELs for the inhalation route, b) an analysis of the methodologies for determining threshold and non-threshold carcinogens, bearing SCOEL's 'practical threshold' for some carcinogens in mind and c) the SCOEL 'skin notation' vs the RAC dermal DNEL. This all should be evaluated and assessed in the context of international developments in risk assessment.

7. Harmonised classification and labelling (CLH)

7.1 CLH dossiers

A. Hazard classes for agreement without plenary debate[1] (see section B below for hazard classes from the same substances debated in plenary)

a) Medetomidine (human health hazards): acute dermal toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory/skin sensitisation, germ cell mutagenicity and carcinogenicity

RAC agreed to the proposal by the United Kingdom not to classify for the hazards acute dermal toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory and skin sensitisation, germ cell mutagenicity and carcinogenicity.

b) **Penthiopyrad (ISO):** physical hazards, acute toxicity (all routes of exposure), STOT SE, STOT RE, skin corrosion/irritation, serious eye damage/irritation, respiratory/skin sensitisation, germ cell mutagenicity, aquatic hazards

RAC agreed to the proposal by United Kingdom not to classify for the physical hazards, for acute toxicity for all routes of exposure, specific target organ toxicity after single and after repeated exposure, skin corrosion/irritation, serious eye damage/irritation, respiratory and skin sensitisation and germ cell mutagenicity. RAC also agreed with the Dossier Submitter to classify penthiopyrad (ISO) as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=1 for both hazards.

c) Clethodim (ISO): physical hazards, acute toxicity, STOT SE, serious eye damage / eye irritation, respiratory/skin sensitisation, mutagenicity, carcinogenicity, environmental hazards

RAC agreed to the proposal by the Netherlands not to classify for the physical hazards, for acute dermal and inhalation toxicity, specific target organ toxicity after single exposure,

[1] 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.

serious eye damage/irritation, respiratory sensitisation, germ cell mutagenicity and carcinogenicity. RAC also agreed to classify clethodim (ISO) as Acute Tox. 4 (H302) for the oral route, as Skin Sens. 1 (H317) and as Aquatic Chronic 3 (H412).

d) **2,3-epoxypropyl methacrylate:** acute toxicity (oral and inhalation routes), skin corrosion/irritation, serious eye damage/irritation, skin sensitisation

RAC agreed to the proposal by the Netherlands to classify the substance as Acute Tox. 4 (H302), Skin Corr. 1C (H314) and Eye Dam. 1 (without H318 label), and Skin Sens. 1 (H317). RAC also agreed to remove the classification for acute inhalation toxicity (Acute Tox. 4* - (H332) from Annex VI to CLP.

e) **Hexaflumuron (ISO):** physical hazards, acute toxicity (all routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/irritation, respiratory/skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, aquatic hazards

RAC agreed to the proposal by Portugal not to classify for the physical hazards, for acute toxicity for all routes of exposure, specific target organ toxicity after single exposure, skin corrosion/irritation, serious eye damage/irritation, respiratory and skin sensitisation, germ cell mutagenicity, carcinogenicity and reproductive toxicity. RAC also agreed with the Dossier Submitter to classify Hexaflumuron (ISO) as Aquatic Acute 1 and Aquatic Chronic 1, with M=1000 for the acute and M=10000 for the chronic aquatic hazard.

f) **3,3'-dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea (Complex soap TH 28):** aquatic chronic toxicity

RAC did not agree to the proposal by Germany to remove the classification as Aquatic Chronic 4 (H413) from Annex VI, but decided to retain this classification.

B. Substances with hazard classes for agreement in plenary session

a) Anthraquinone

The Chairman reported that anthraquinone (AQ) was an industrial chemical and a pesticide and that it was mainly used in the paper/pulp industry and as an intermediate for synthesis of other chemicals, including dyestuffs. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 29 July 2016. The DS (Germany) proposed to classify anthraquinone as Carc. 1B (H350).

There had been at least three different production methods for commercial anthraquinone. AQ produced by the Friedel-Crafts process (AQ-FC) and the Diels-Alder reaction (AQ-DA) was essentially free of PAH contaminants and nitroanthracenes, whereas the AQ-OX process-produced AQ contained contaminants such as varying amounts of polycyclic aromatic hydrocarbon (PAH) contaminants, particularly nitroanthracene isomers (NA) which were considered to be mutagenic (9-NA positive/weakly positive in *in vitro* bacterial mutagenicity assays and equivocal/weakly positive in *in vitro* mammalian mutagenicity tests; no *in vivo* mutagenicity assays were available). RAC agreed that there was no data to allow an independent assessment of the relative contribution of the different manufacturing processes and impurities to the mutagenicity and/or carcinogenic potential of anthraquinone.

RAC agreed with no classification for mutagenicity based on a weight of evidence approach as AQ was mostly negative in OECD TG and GLP compliant *in vitro* mutagenicity assays (bacterial mutagenicity tests, mammalian cell mutagenicity assays, clastogenicity assays) and also negative in two *in vivo* micronucleus tests. Another micronucleus study in mice was considered as weakly positive; the male results were unconvincing with a marginal positive result at the highest dose only (4300 mg/kg bw/day) exceeding the limit dose for the assay whereas in females there was a weak response without a clear dose-related response in the range of 300 – 2600 mg/kg bw/day and a positive result in the high dose group (5300 mg/kg bw/day) clearly exceeding the maximum tolerated dose. In addition, there was no data reported for positive controls. The other positive *in vivo* study indicated an increased level of DNA single strand breaks relative to solvent controls but the assay was not validated for *in vivo* mutagenicity and it was not possible to conclude if the 'positive' result was significant.

One RAC Member asked whether the bacterial strains used in the gene mutation tests could explain the observed positive *in vitro* results, but the Rapporteur was of the opinion that the positive results were more likely related to the presence of the impurity in the test substance. The Committee agreed that no classification for mutagenicity of anthraquinone was warranted.

RAC discussed the DS proposal to classify anthraquinone in category 1B for carcinogenicity based on animal data and the associated uncertainties. Two long-term toxicity studies (in the rat and mouse) showed a causal relationship between AQ and an increased combination of benign (liver and kidney adenomas in female rats; kidney adenomas and papilloma and urinary bladder papilloma in male rats; liver adenomas in male mice; hepatic adenomas and thyroid follicular cell adenomas in female mice) and malignant (kidney carcinomas in female rats; hepatic carcinomas and hepatoblastoma in male mice) tumours in two species of animals, an increase in the incidence of tumours in both sexes of two species in well-conducted studies (hepatic tumours in mice and renal tubule tumours in rats), that malignant neoplasms occurred to an unusual degree in two species in one sex (renal tubule carcinomas in female rats and hepatoblastoma in male mice) and that there were strong findings of tumours at multiple sites (renal tubule adenomas and urinary bladder papilloma in male rats; liver adenomas and renal tubule adenomas in female rats; hepatic adenomas and thyroid follicular cell adenomas in female mice).

The mode of action of anthraquinone was not known and the human relevance could not be excluded for any of the target organs. The anthraquinone used in the 2-year NTP studies had been produced via the AQ-OX process (producing the impurity 9-NA) that is not currently in use. The potentially mutagenic impurity, 9-NA, had not been tested for carcinogenicity and, in addition, the metabolites of anthraquinone, 1-OH-AQ and 2-OH-AQ, were reported to be possibly carcinogenic and potentially mutagenic, respectively. RAC concluded that the relative contribution of AQ, its metabolites or the impurity 9-NA to the carcinogenicity potential of anthraquinone could not be ascertained.

A RAC Member asked for clarification on whether the control data on hepatoblastoma in male mice was valid and whether the reported lesions could have actually been hepatocarcinoma. Another RAC Member commented that if present hepatoblastoma would be clearly evident and that their incidence was generally very low.

The overall evidence was considered as clearly in support of classification in category 1B and RAC agreed to classify anthraquinone as Carc. 1B; H350.

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

b), c) and d) cadmium carbonate, cadmium dihydroxide and cadmium dinitrate (as separate substances)

The Chairman welcomed an expert accompanying the Eurometaux stakeholder observer as well as representatives from the Dossier Submitter (Sweden), the latter who followed the meeting remotely. He reported that the three cadmium compounds are used for the production of inorganic and organic compounds and pigments, as laboratory agents, as additives, in batteries/fuels and as components for polymer matrices, plastics and related mixtures.

All three substances were included in the group entry 048-001-00-5 on Annex VI to CLP where they have harmonised classifications as Acute Tox. 4 (minimum classifications for all routes of exposure), Aquatic Acute 1 and Aquatic Chronic 1, with no M-factors set. The legal deadline for the adoption of the opinions is 3 August 2016.

The Chairman stated that the three cadmium compounds were tabled for a first time at a RAC plenary meeting. He reported that the Dossier Submitter (Sweden) proposed separate entries in Annex VI for each compound, which would include the following harmonised classifications: the classifications for acute toxicity and aquatic toxicity transferred from the group entry to the new individual entries without reassessment by RAC (no data in CLH reports), as well as Muta. 1B, Carc. 1B and STOT RE 1 (kidney, bone) to be added to each new entry in accordance with the DS' assessment.

The Rapporteur reported that the nitrate was highly soluble while the carbonate and the hydroxide were slightly soluble only. Nevertheless, it was recognised from the evidence provided in the CLP report that even the less soluble substances would be systemically available. Based on human epidemiology data, RAC concluded that classification as STOT RE 1 with effects on bones and kidneys was justified. The setting of a specific concentration limit for that hazard class was not considered possible as there was a lack of exposure data.

In relation to germ cell mutagenicity, it was recognised that the cadmium cation was sufficiently bioavailable based on the weight of evidence provided by several studies. Further to this, data show that bioavailable Cd^{2+} has the potential to damage the genetic material in somatic and germ cells; RAC was of the opinion that even limited bioavailability of Cd^{2+} would present a mutagenic hazard to germ cells, in particular as there was no basis to assume that low concentrations would lack this hazard. RAC therefore concluded on Muta. 1B (H340) for all three cadmium compounds considered.

In relation to carcinogenicity, animal studies in rats and mice showed that treatment-related tumours of different types occurred at multiple sites, while epidemiological data showed at least some associations between Cd^{2+} exposure and human cancer rates. Based on the overall evidence, RAC therefore concluded on Carc. 1B (H350) for the three cadmium compounds. RAC also agreed to set an SCL of 0.01% for cadmium nitrate, because its bioavailability and carcinogenic potency was considered to be comparable to the other very (water) soluble cadmium compounds for which this SCL had been established. However, it was considered inappropriate to extrapolate estimates of potency from the very soluble cadmium compounds to the less soluble cadmium carbonate and hydroxide, despite the inherent hazards being comparable.

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

e) 2,3-epoxypropyl methacrylate

The Chairman reported that 2,3-epoxypropyl methacrylate (GMA) is an ester of methacrylic acid and glycidol; it is a common monomer used in the creation of epoxy resins. It has an existing Annex VI entry for acute toxicity (minimum classification in category 4 for all routes of exposure) and is classified for Eye Irrit. 2; H319, Skin Irrit. 2; H315 and as Skin Sens. 1; H317. The legal deadline for the adoption of an opinion is 10 September 2016.

The Dossier Submitter (The Netherlands) proposed to revise the existing classification and to add classification for carcinogenicity, mutagenicity and reproductive toxicity (Repr. 1B; H360F, Muta. 2; H341, Carc. 1B; H350) and for specific target organ toxicity after single exposure (STOT SE 1; H370, affected organs: respiratory tract; route of exposure: inhalation).

The proposed classification of GMA is in part based on data on its metabolite glycidol. The Rapporteur presented the results from *in vitro* tests using liver homogenates and nasal tissues, indicating that glycidol is the single metabolite formed. Although the formation of the metabolite is presumed to be slower in humans than in rodents, GMA is expected to transform completely into glycidol and methacrylic acid (MAA) in rodents as well as in man. Furthermore, a comparison of the toxicological profiles for GMA and glycidol showed consistency for several systemic effects (such as effects on fertility and sperm parameters, positive micronucleus tests *in vivo*) but with some differences with regard to local effects: GMA is corrosive and glycidol irritant to skin (where the corrosivity of GMA may prevent exposure to high doses).

Acute toxicity

RAC agreed with the DS proposal to confirm the existing minimum classification for acute oral toxicity (Acute Tox. 4; H302) based on the same range of LD_{50} values for the three tested species. RAC also supported the suggestion by the DS to remove the classification for acute toxicity via inhalation.

RAC discussed acute dermal toxicity and supported the DS proposal to classify GMA in category 3 (Acute Tox. 3; H311) based on the LD_{50} value of 480 mg/kg bw in the rabbit. Although data were poorly reported in this study, consideration was also given to the similar range of toxicity as compared with data on acute oral toxicity in several species (no data on rabbits) and that the rabbit is more sensitive compared to the rat according to repeated dose data.

STOT SE

Specific target organ toxicity after single exposure was discussed based on acute inhalation toxicity studies (in the rat, rabbit, guinea pig and dog) and repeated dose toxicity study (a 2-week study in the rat). Although severe effects on the respiratory tract were observed in a dose relevant for category 1 in the 2-week rat study, the effects were considered to be caused by repeated and not by single exposure. In addition, according to the CLP guidance, classification in STOT SE, categories 1 and 2 are not recommended for severe effects which are the consequence of a corrosive mode of action (MoA). Thus, RAC did not support the DS proposal to classify the substance for STOT SE 1 but recommended classification in STOT SE 3 for respiratory irritation, based on the signs of respiratory irritation in acute toxicity studies. The DS (following the discussion remotely) agreed to the justification and the conclusion on this hazard.

Respiratory Sensitisation

Although RAC recognised that methacrylates are generally associated with asthma, no data were available on GMA or on the sensitising and/or irritant properties of methacrylates. Thus, based on lack of data, RAC decided not to classify GMA for respiratory sensitisation.

STOT RE

The Committee discussed the classification for repeated toxicity and, contrary to the DS's proposal, supported the Rapporteur's conclusion to classify GMA as STOT RE 1; H372 based on effects observed on the respiratory tract (necrosis) in inhalation studies in the rat and rabbit at doses lower than the effective doses after single exposures noting that the effects occurred after repeated rather than single exposure (DS).

Germ cell mutagenicity

The proposal to classify GMA as Muta. 2 was discussed. The Committee noted that there were consistent positive results in all performed *in vitro* tests and a clear mutagenic response on erythrocytes in an oral micronucleus in vivo assay while other *in vivo* studies (one via inhalation and 4 intraperitoneal (i.p.) studies) were negative. In addition, it was recognised that glycidol induced micronuclei *in vivo* and has a harmonised classification as Muta. 2. Whereas not questioning the proposed classification, one RAC Member noted that the RAC decision should only be based on the *in vitro* positive effects supported by the existing data on glycidol. The Committee agreed to classify GMA for Muta. 2.

Carcinogenicity

In the absence of reliable chronic data on the substance itself, the classification proposal for Carc. 1B was based on read-across to the data on the metabolite glycidol. The systemic effects of GMA are expected to be similar to glycidol if high enough glycidol levels can be reached systemically after GMA administration. Glycidol induces multiple tumours in two species (rat and mouse) in both sexes and has a harmonised classification for Carc. 1B. RAC Members supported the use of read-across approach but some questioned whether high enough levels could be reached systemically because of the acutely corrosive effects of GMA which would not exclude a Carc. 2 classification. In the further discussion, also considering that the same organs were affected in repeat dose toxicity studies (as well as effects on fertility and sperm) with both glycidol and GMA, supported by the positive *in vivo* genotoxicity data by the oral route, the Committee agreed with the DS to classify GMA in category 1B for carcinogenicity.

Toxicity to reproduction

The proposal for classification for fertility effects was based on the evidence of a significant decrease in fertility index and reduced sperm motility in rats in an oral TG 422 study with GMA, supported by sperm effects observed in two species (rat and mouse) after intraperitoneal administration of GMA. The Committee also noted that the effects on fertility of GMA showed consistency with glycidol (which has a harmonised classification in cat. 1B for fertility) and that GMA is almost completely metabolised to glycidol in several species including humans, although in different rates. Two RAC Members expressed some reservations e.g. with regard to the quality of the data in the oral study and in the i.p. studies as the results in the highest dose groups (25 and 100 mg/kg bw) differed significantly between the studies. After some discussion, the Committee agreed that there was sufficient evidence for classification of GMA as Repr. 1B; H360F.

No effects on development were observed in the presented studies (rat and rabbit) and RAC agreed that no classification was warranted for developmental toxicity.

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) 3,3'-dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea

The Committee examined in detail a proposal by the Dossier Submitter (Germany) to remove the current classification of Skin Sens. 1 (H317) in Annex VI to the CLP Regulation. This substance is registered under the REACH Regulation but was also previously notified in the UK as a notification of new substances (NONS). Manufacturers/importers have reported variable concentrations of an impurity from the isocyanate family, known to display respiratory and skin sensitisation properties.

The current classification of Skin Sens. 1 (H317) was agreed under the Dangerous Substances Directive 67/548/EC, based on a Buehler test for which limited experimental detail was available, the results of which showed that there was a positive response on first challenge (7/20 animals), but no reactions were seen following a second challenge a week later.

During the RAC consultation and discussion, all Members who provided comments, agreed that, based on the recent local lymph node assay (LLNA) presented in the CLH report, it is justified to remove the classification for skin sensitisation. However, a number of RAC Members stressed that a lower induction concentration was used in the LLNA compared to the Buehler test (10% vs. 25% w/w, respectively). Nevertheless, RAC Members agreed that the LLNA results showed that the substance is not a skin sensitizer up to 10% w/w. They also noted that the results obtained by LLNA should be regarded as more reliable than the results obtained by the Buehler test for which limited information is available.

RAC agreed to remove the classification Skin Sens. 1 (H317) and adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

g) Silver zinc zeolites

The Chairman welcomed an expert accompanying the Eurometaux stakeholder observer as well as representatives from the Dossier Submitter (Sweden) who followed the meeting remotely. He reported that the three silver zinc zeolites presented in the CLH dossier are representatives of a group of antimicrobial biocidal active substances acting through controlled release of Ag^+ ions. Silver zinc zeolites are part of a wider family of other silver containing active substances (called SCAS).

The silver zinc zeolites currently do not have an entry in Annex VI to CLP. The proposed entry in Annex VI is intended to cover all three zeolites in a single group described as:

> *"LTA framework type zeolites which have been surface-modified with both silver and zinc ions at contents Ag^+ 0.5%-6%, Zn^{2+} 5%-16%, and potentially with phosphorus, NH_4^+, Mg^{2+} and/or Ca^{2+} each at level <3%",*

This implies that other zeolites fitting this formula than those three described here would be similarly classified. For this entry, the DS (Sweden) proposed harmonised classifications as Carc. 2 (H351), Repr. 1B (H360D), Skin Irrit. 2 (H315), Eye Dam. 1 (H318), STOT RE 2 (H373), Aquatic Acute 1 (M=100) and Aquatic Chronic 1 (M=100).

The Chairman stated that silver zinc zeolites were tabled for the first time at a RAC plenary meeting. The legal deadline for the adoption of the opinion is 20 October 2016.

He then invited a member of the Secretariat to present background information on substance identity, read-across principles and the data availability for each zeolite in the dossier. This triggered a question from RAC as to whether data from other SCAS would be used. RAC

agreed that as there appeared to be sufficient data on the three substances to support classification, this was not necessary.

The Rapporteur then presented his evaluation of the individual hazards. RAC agreed to the DS proposal of no classification for physical hazards. In relation to acute toxicity and based on data on 2 out of 3 zeolites under consideration, RAC also decided on no classification for all routes of exposure. In relation to specific target organ toxicity after single exposure, RAC did not agree on classification in any of the categories because no toxic effects on specific organs or transient effects were observed that could have justified a classification for STOT SE.

In relation to skin irritation, RAC recognised that different effects could be observed depending on the type of zeolite, ranging from no skin reactions, to severe erythema and oedema which were possibly irreversible at the end of the observation period. The Rapporteur explained that the DS justified these differences on the basis of different contents of Ag^{+} and Zn^{2+} ions and their rates of exchange with the external environment, as well as the type of vehicle used in the studies (distilled water causes far less ions to be released than saline or phosphate buffer solutions). As the DS had proposed a group entry, RAC after some debate accepted classification for Skin Irrit. 2 (H315) for the silver zinc zeolites as a group.

As to eye damage, the Rapporteur reported that among the studies presented in the dossier, there was one study fulfilling the criteria for classification. By contrast, other studies presented showed effects which did not warrant classification according to CLP. The Rapporteur explained that differences among studies might be attributable to the same reasons explained above for the case of skin irritation. Nevertheless, in accordance with the classification criteria and on the basis of the various studies available, the DS proposed a classification as Eye Dam. 1 (H318) which was supported by the Rapporteur and by the other RAC members.

The CLH dossier did not include relevant data on respiratory sensitisation so, no classification was agreed by RAC. In relation to skin sensitisation, negative results were reported in reliable assays performed with each of the three types of zeolites involved. RAC therefore concluded also for this hazard that a classification was not justified.

In relation to specific target organ toxicity after prolonged/repeated exposure, argyria was discussed by RAC; this is a skin and organ pigmentation based on deposits of silver sulphide and selenide that has been observed in humans and in animal studies with silver zinc zeolites. The expert from Eurometaux clarified that on the basis of numerous publications, no link between pigmentation and functional or morphological changes could be established, with the exception of ocular function, namely eye pigmentation. Nevertheless, RAC members noted that some other reported effects as changes in behaviour (hypersensitivity to touch, vocalization, increased activity, aggressive behaviour) or enlargements of Langerhan´s island might be related to silver accumulation in brain or pancreas. As it could be clarified that argyria and other potential effects related to silver deposition appeared at doses above the classification thresholds and that it cannot be considered severe although irreversible, RAC finally agreed not to classify silver zinc zeolites.

As to germ cell mutagenicity, RAC considered classification for this hazard class to be inconclusive based on the lack of reliable studies.

In relation to carcinogenicity, the Rapporteur stated that two studies were available on one of the silver zinc zeolites, one in mice (negative) and one in rats (showing increases in endometrial polyps, pituitary adenomas and leukaemia). For several reasons (e.g. statistically non-significant differences between control and treated animals in the number of tumours per animal, statistically non-significant differences between the incidences of pituitary adenomas and leukaemia reported in exposed and in control animals and between incidences reported for exposed animals and for historical controls, and finally, apparent sex difference in pituitary

tumours that were only adenomas, not carcinomas, incidences mainly within historical control range), RAC decided not to propose classification for carcinogenicity.

Where reproductive toxicity is concerned, there were no relevant effects on fertility in a 2-generation reproductive study in rats treated with AgION Type AK. RAC therefore agreed not to classify for this hazard. By contrast, some developmental toxicity effects were considered as relevant for classification. While the effects on thymus weight of pups were considered related to the systemic toxicity of silver zinc zeolites (as observed in various studies), effects seen in F1 pups (pup mortality and decreased pup weight) were considered sufficient for classification. Furthermore, the slight enlargement of the heart in some pups warranted a classification for developmental toxicity. RAC agreed to classify silver zinc zeolites for Repr. 2 (H361d) rather than for Repr. 1B, as proposed by the DS.

In relation to environmental hazards the Rapporteur argued for a classification as Aquatic Acute 1 and Chronic 1, with separate M-factors of 100 for both hazards following the proposal of the DS. This proposal was based on the toxicity of silver ions released from the silver zinc zeolites while the zinc ions were considered to be a moiety of less toxicity, and a lack of transformation dissolution data according to the Transformation/ Dissolution protocol (T/Dp) (Annex 10 to the UN GHS Purple book) and evidence of rapid environmental transformation. With regard to the latter, the expert from Eurometaux stressed that silver ions bind quickly and strongly to sulphides and that this process happens in water without the need for a sediment phase, the latter being the case for copper (discussed at RAC-31 in December 2014). However, the Rapporteur argued that rapid environmental transformation needs to be demonstrated in all relevant EU waters and this cannot be concluded with the evidence presented in this case. The Eurometaux expert argued that, due to the very low Ag levels, the amount of sulphidic compounds in the water column is presumed to be sufficient to bind all released silver ions into stable insoluble forms, but also acknowledged the need for sufficient evidence that sulphide levels in European waters are high enough to interact with silver. The Committee agreed with the Rapporteur's view that based on the information in the CLH dossier and provided during public consultation no convincing case had been made that silver ions will always rapidly speciate to non-available forms and that further evidence is required demonstrating that this reaction always occurs. The Committee, however, indicated the possibility that this decision regarding speciation and removal to stable insoluble sulphides could be re-considered if further evidence became available in the future.

With regard to the toxicity data selected and the strategy applied for Aquatic Acute and Aquatic Chronic classification of SZZ the Eurometaux expert stressed that the DS did not use the full dataset available for silver and zinc as made available by industry in the REACH Registration dossiers. Additionally, he was of the opinion that the classification scheme was misinterpreted by using the scheme for metal compounds instead of the scheme for metals arguing that silver and zinc are available in the metal form in the zeolite. While silver is more ecotoxic than zinc, he stated that zinc and silver have different dissolution kinetics, the latter being much higher for zinc. In his view the appropriate way to classify SZZ is to compare the release rates from the two metals measured in the T/Dp test with the respective toxicity, applying the summation rule to assess the total ecotoxic potential. However, he recognised that the lack of T/Dp data on the zeolite did not allow this approach to be applied. The expert concluded that, according to the metals classification scheme, the only justified classification at this point in time was Aquatic Chronic 4 based on the lack of 7 and 28 days T/Dp data; with the caveat that this classification would need to be revised if T/Dp information were to become available. The Rapporteur replied that if the guidance for metal compounds was followed, Aquatic Chronic 4 is not applicable and asked for clarity as to why the metals strategy and not that for compounds should be applied in this case. Eurometaux clarified that the term

compound is clearly defined as either salt or oxide and that silver and zinc are available in their metallic form in the SZZ before being released. As a consequence and by taking into account the fact that metals (as opposed to metal compounds) do have their own classification scheme this is considered the only justified interpretation.

The RAC members however, bearing ECHA's advice on substance identity in mind, supported the Rapporteur's view and agreed with the classification and M-factors as proposed by the Rapporteur based on the available information. The Committee agreed to classify the group of silver zinc zeolites as Aquatic 1 and Chronic 1, with M=100 for both hazards, while it was noted that the classification may need to be revised should new data on T/D or evidence of rapid environmental transformation become available.

RAC adopted the opinion by consensus. The Chairman requested the Rapporteurs to reflect the discussion on the application of the metals classification scheme in the opinion and thanked them for their careful preparation of the opinion and the Committee for their active involvement in the consultations and discussions.

h) Hexaflumuron (ISO)

The Chairman reported that Hexaflumuron (ISO) is a biocidal active substance which is used as a termiticide in confined bait stations.

Hexaflumuron (ISO) has no entry in Annex VI to the CLP Regulation; therefore, all hazard classes need to be evaluated. The legal deadline for the adoption of the opinion is 25/05/2016.

The DS (Portugal) proposed to classify the substance as Aquatic Acute 1 (H400) with M=1000 and Aquatic Chronic 1 (H410) with M=10000. Based on the evaluation, the DS also concluded that no classification was justified for any of the human health hazards. The Chairman stated that Hexaflumuron (ISO) was tabled for the first time at a RAC plenary meeting. The aquatic hazards and M-factors and a range of human hazard classes were agreed by RAC through fast-tracking earlier at this meeting.

RAC discussed substance-related haematological effects described in mice and dogs in the context of STOT RE classification and concluded that at relevant dose levels the criteria for classification for STOT RE were not met.

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

i) Penthiopyrad (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer as well as a representative from the Dossier Submitter (United Kingdom) who followed the meeting remotely. He reported that Penthiopyrad (ISO) is a pesticide used as a foliar fungicide on pome fruit, tomato, aubergines, cucurbits, cucumbers, courgettes and cereals.

Penthiopyrad (ISO) has no entry in Annex VI to the CLP Regulation; therefore, all hazard classes need to be evaluated. The legal deadline for the adoption of the opinion is 20 October 2016.

The DS (UK) proposed to classify the substance as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=1 for both. Based on the evaluation, the DS also concluded that no classification was justified for any of the human health hazards.

The Chairman stated that Penthiopyrad (ISO) was tabled for the first time at a RAC plenary meeting. The proposed environmental classification and no classification for a range of human health hazards were agreed by RAC through fast-tracking. The human health hazards to be discussed in plenary are carcinogenicity and reproductive toxicity.

In relation to carcinogenicity and effects on fertility, RAC concluded on no classification.

In relation to developmental effects, RAC concluded that the effects observed in Wistar rats at a limit dose of 1000 mg/kg bw (post-implantation losses and early resorptions) were not sufficiently pronounced to justify a classification for reproductive toxicity in category 2 and therefore recommended no classification.

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

j) Nonadecafluorodecanoic acid (PFDA) and its ammonium and sodium salts

The Chairman reported that PFDA was used in the chemicals industry as a lubricant, wetting agent plasticiser and corrosion inhibitor. The substance and the denoted salts do not have an entry in Annex VI to the CLP Regulation. The DS (Sweden) proposed to classify the substance as Carc. 2 (H351), Repr. 1B (H360Df) and Lact. (H362). The legal deadline for the adoption of the opinion is 29 November 2016.

The Rapporteur proposed that read-across from relevant data on perfluorooctanoic acid and its ammonium salt (PFOA/APFO; [C8]), and perfluorononanoic acid (PFNA; [C9]) and some longer chain perfluorocarboxylic acids (PFCAs; [C11-C12], all of which showed structural and functional similarity to PFDA, was appropriate for the evaluation of the relevant hazards. This approach was supported by RAC.

In relation to carcinogenicity, RAC concluded on Carc. 2 (H351) supported by reading across the data on from APFO/PFOA.

In relation to developmental effects, data of PFDA itself revealed full litter resorption at high dose and reduced foetal weight, though through a non-guideline study and with maternal toxicity, but still providing evidence that adverse developmental effects occurred which were similar to those with PFOA. RAC also recognised that data from PFNA and C11-C12 PFCAs provided further support to the classification. Overall therefore, RAC supported category 1B for developmental effects.

As to effects on fertility, it was acknowledged that data on the substance itself are limited but did show alterations of male parameters similar to PFOA/PFNA/C11-C12 PFCAs with sperm abnormalities, effects on male reproductive organs and altered testosterone levels. Based on this evidence which means an alteration of sexual function and fertility, RAC agreed on a classification in category 2. This resulted in an overall reproductive toxicity classification of PFDA and the denoted salts as Repr. 1B (H360Df).

In relation to effects on or via lactation, it was noted that PFDA was found in human breast milk in several of the available studies; therefore, RAC decided to assign a classification as Lact. (H362), in line with PFOA/PFNA.

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

k) Triadimenol (ENV hazards)

The Chairman welcomed the representative accompanying the ECPA stakeholder observer and reported that the substance is on the agenda for the third time. Industry had been requested to provide additional information on chronic aquatic hazard and had kindly done so. At the last two plenary meetings the Committee discussed and agreed on the classification of the substance for human health related hazards (see the Minutes of RAC-33 and RAC-34). Therefor at RAC-35 the Committee discussed the environmental hazards only.

During the RAC consultation, six RAC Members commented on the environmental part of the draft opinion. Three of them supported the original classification proposed by the Dossier Submitter (UK) and the Rapporteur, Aquatic Chronic 2 (H411), based on a NOEC (growth-weight) of 0.17 mg/L from a Fish Early Life Stage (FELS) test. Three other RAC Members were in favour of a classification as Aquatic Chronic 1 (H410; M=1).

In line with a JRC (2013) report on the adversity of endocrine effects, including the aquatic environment, the observed reduction in vitellogenin (VTG) levels and the associated histopathological changes in the liver at 0.030 mg/L in the Fish Screening Assay (FSA) by Teigeler (2007) were, in isolation, not considered sufficiently adverse by RAC for classification purposes.

The Rapporteur considered the endpoint sex ratio as determined in a Fish Sexual Development Test (FSDT) to be an adverse effect at population level and consequently as relevant in relation to aquatic hazard classification. According to OECD TG 234, the endpoint sex ratio should be determined via gonad histology. Optionally, evaluation and staging of oocytes and spermatogenetic cells may also be determined histologically. The Rapporteur reported that the FSDT by Bomke, (2010), did not fully match the current version of the guideline but was carried out in parallel to its development. Bomke (2010) was evaluated as reliable only with restrictions and several experimental drawbacks have been discovered by the data owner. RAC noted that the tested species fathead minnow (*Pimephales promelas*) was not included in OECD TG 234. It was also considered to be less sensitive to the core endocrine endpoints aromatase inhibition and sex differentiation. The stakeholder expert confirmed that all fish were either males or females based on gonad histology and no undifferentiated or intersex fish were seen. In contrast, the re-evaluation of the sex ratio submitted by one commenting Member State used a discrepancy between phenotypic sex and histological sex to determine undifferentiated or intersex fish and to derive a NOEC of 70.8 µg/L. RAC considered this procedure and the resulting NOEC (i.e. the value that is based on combination of secondary sex characteristics and gonad histology) as not appropriate, and concluded that the sex ratio was not affected up to and including the highest dose tested of 0.17 mg/L.

One RAC Member mentioned that in the case of Tebuconazole the FSDT was used for the assessment of other endpoints. He supported the Rapporteur's proposal and justification. Another RAC Member noted that only endpoints which were included in the CLP guidance should be evaluated and those on endocrine disruption properties should be left out. The Chairman noted that there was no reason not to consider clearly adverse endpoints from well conducted OECD studies designed to examine endocrine disruption in relevant aquatic organisms. He also noted that there was also no reason *a priori* to reject non guideline fish species but that care should be taken, given the variability of the biology of fish reproductive systems to ensure that they were compatible with Guideline species. He noted that there was useful, recent advice on the adversity of effects which at least partly included the aquatic environment, e.g. JRC (2013), concluding that RAC would continue to build experience in such evaluations.

RAC agreed with the proposal by the Dossier Submitter, supported by the Rapporteur, to classify the substance as Aquatic Chronic 2 (H411).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for his work and the Committee for their active involvement in the consultations and discussions.

l) Salicylic acid (developmental toxicity)

The Chairman informed the Committee that the discussion on the CLH dossier of salicylic acid has been removed from the agenda. The ECHA Secretariat made a request to the European Medicines Agency (EMA), as agreed by RAC at the last plenary meeting in September, regarding the information on human toxicity of acetylsalicylic acid. This critical information had however not been received on time for this meeting.

m) 4,4'-methylenedimorpholine (MBM) (human health hazards)

The Chairman welcomed the representative accompanying the Cefic stakeholder observer and reported that 4,4'-methylenedimorpholine (MBM) was a formaldehyde releaser with bactericidal and fungicidal properties and was employed as microbiocide. It has no existing entry to Annex VI of the CLP Regulation and the legal deadline for the adoption of an opinion is 15 March 2016.

The DS (Austria) proposed to classify MBM as Skin Corr. 1B; H314, Skin Sens. 1; H317 with a specific concentration limit of 1.2%, as Carc. 1B; H350 and Muta. 2; H341.

As 4,4'-methylenedimorpholine (MBM) is a biocide with no existing harmonised classification, all hazard classes were assessed. At RAC-34, the Committee agreed that no classification for environmental hazards was warranted.

MBM hydrolyses to formaldehyde (FA) and morpholine. Where data on the substance itself were not available or were considered to be insufficient for classification purposes, read-across to the data on the hydrolysis products was applied.

Acute toxicity

Contrary to the DS proposal not to classify MBM for acute toxicity (presuming that the endpoints were covered by the classification as corrosive), the Rapporteur proposed to classify MBM for acute toxicity (all routes) and this was supported by the Committee. According to the criteria, there is no general disclaimer that classification as corrosive would cover also acute toxicity.

Oral:

Based on the results of an OECD TG study in rats in which the ATE (acute toxicity estimate) value was between 500mg/kg bw and 2000mg/kg bw, the Committee agreed to classify as Acute Tox. 4; H302.

Dermal:

For dermal toxicity no study was available for MBM thus a read-across to FA (dermal LD50 270mg/kg bw) was used applying a factor of 6 for 16.7% of FA released which lead to the corrected LD50 value of 1620mg/kg bw for MBM. This corresponds to category 4 for acute dermal toxicity which was supported by RAC. The representative accompanying the Cefic stakeholder observer noted that the amount of 16.7% of released FA was a calculated value and that the measured value was much lower.

Inhalation:

RAC agreed to classify MBM in category 4 based on read–across to formaldehyde and application of a factor of 6 for 16.7% of FA release.

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 in addition to classification for acute inhalation toxicity due to the corrosive mode of action (MoA) of MBM. The EUH029 hazard statement was not supported as it is not foreseen for substances classified in category 4 for acute toxicity.

STOT single exposure

No classification was proposed by the DS or RAC as the results of acute studies would not justify category 1 or 2 for STOT SE and category 3 would be redundant as the effects are already covered by classification for corrosivity (see below).

Skin corrosion / irritation

RAC concurred with the DS proposal to classify MBM as Skin. Corr. 1B with supportive evidence form read-across to FA for subcategorization which is required for regulatory purpose. No separate studies were available for eye damage, but the effects are covered by labelling for skin corrosion.

Skin sensitisation

RAC concurred with the DS proposal to classify MBM as Skin. Sens. 1 without subcategorization on the basis of read-across to FA and morpholine. The original proposal for setting an SCL was not supported as the application of a correction factor of 6 would result in an SCL in the same range as generic concentration limit. This approach was also supported by the DS.

STOT repeated exposure

The DS did not propose classification for repeated exposure assuming that the effects were already covered by the classification for corrosivity. RAC discussed and agreed on the proposal for STOT RE 2 (oral route) based on a 90-day gavage study in rats with effects at doses of 50mg/kg bw and above with a supporting evidence from a 14-day range study (in the rat, by gavage). No data was available via the dermal route of exposure that would support classification. For inhalation, the same approach as for acute toxicity was applied and the substance was classified as STOT RE 2 based on read-across to FA. RAC agreed on the overall classification in category 2 for repeated toxicity for gastrointestinal tract and respiratory tract.

Germ cell mutagenicity

The Committee supported the DS proposal to classify MBM as Muta 2 based on positive *in vitro* data on MBM and on read-across to FA. Two Members disagreed with this conclusion due to the lack of systemic character of the effects. In their view this was not sufficient evidence for mutagenic effects and they indicated a minority position in favour of not classifying MBM for mutagenicity.

Carcinogenicity

The DS proposal for carcinogenicity 1B was discussed. There was no reliable human data or carcinogenicity studies on MBM available and the DS proposed the classification based on local carcinogenic effects of the hydrolysis product FA which has a harmonised classification as Carc. 1B. Two RAC Members suggested that category 2 might also be considered due to uncertainties on the actual amount of FA released after contact with biological tissues. The DS

informed the Committee about the toxico-kinetic study available for MBM whose results further support the classification, as do the observed skin corrosion effects. The Cefic expert repeated that the calculated value of 16.7% of released FA did not correspond with the measured value which was significantly lower and thus category 2 should be considered.

Other Members were of the opinion that there is sufficient evidence that local carcinogenic effects can be induced. RAC agreed to classify MBM as Carc. 1B.

Toxicity to reproduction

There was no study available on fertility effects of MBM but one OECD 414 study on developmental toxicity (in the rabbit) with non-significant effects and without dose-response. There is only limited data on FA and on morpholine and neither of the two hydrolysis products has a harmonised classification for reproductive toxicity. RAC agreed that no classification for toxicity to reproduction was warranted.

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

n) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (toxicity to reproduction)
o) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (toxicity to reproduction)

The Chairman welcomed the representative accompanying the Cefic stakeholder observer and reported that the two formaldehyde releasers (MBO and HPT) were biocidal active substances. Neither has an existing entry in Annex VI to the CLP Regulation and the legal deadline for the adoption of an opinion for MBO is 15 March 2016 and 11 June 2016 for HPT.

The Dossier Submitter (Austria) proposed to classify MBO and HPT for skin corrosion (Skin. Corr. 1B; H314), skin sensitisation (Skin. Sens. 1A; H317), carcinogenicity (Carc. 1B; H350), mutagenicity (Muta. 2; H341) and as Aquatic Chronic 3; H412.

As MBO and HPT are biocides with no existing harmonised classification, all hazard classes were assessed. This is a second discussion at a RAC plenary meeting; at RAC 34, all hazards for both dossiers were discussed and apart from toxicity to reproduction the Committee agreed on the classification[2].

The discussion on the Rapporteur's proposal to harmonise classification for toxicity to reproduction (fertility) was adjourned at RAC-34 as the original report of the 1-generation study with MBO in rats was requested through the DS to gain a clearer picture of toxicity to reproduction.

Toxicity to reproduction

No classification was proposed by the DS. Based on the original study reports (1-generation study in the rat, developmental study in the rabbit, both with MBO) provided by the DS, the Rapporteur presented two options (classification in category 2 vs. no classification for effects on fertility) based on observed increases in post-implantation loss and pup mortality. This proposal was discussed by the Committee.

Some RAC Members noted that the observed effects qualify for developmental toxicity rather than for fertility effects. Regardless, RAC noted that in the rat study, no clear dose-response

[2] For details please refer to RAC-34 minutes:
http://echa.europa.eu/documents/10162/21961120/rac_34_minutes_en.pdf

for post-implantation losses could be observed and in addition, high mortality rates in three control litters (mainly on Day 2) confounded the results and raised questions on the reliability of the dose-related increase of pup deaths on Day 0/1. Overall the results of the study were found inconclusive.

Based on the detailed analysis of the data from the 1-generation rat study and on the inconclusive rabbit study, RAC agreed that no classification was warranted for either fertility or developmental toxicity.

RAC adopted the opinions by simple majority. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

p) Medetomidine (human health hazards)

The Chairman reported that medetomidine was used as an antifouling agent in biocidal products and, within the EU, as an anaesthetic in veterinary medicine and an analgetic in human medicine. Medetomidine has no entry in Annex VI to the CLP Regulation; therefore, all hazard classes need to be evaluated. The legal deadline for the adoption of the opinion is 20 July 2016.

The DS (UK) proposed to classify the substance as Acute Tox. 2 (H300 and H330), STOT SE 3 (H336), Aquatic Acute 1 (M=1) and Aquatic Chronic 1 (M=100).

The Chairman reminded the Committee that medetomidine was tabled for the second time at a RAC plenary meeting. The proposal for the aquatic classifications and M-factors was already agreed via the fast-track procedure at RAC-34, and for a range of human health hazards, RAC agreed on no classification through fast-tracking at this meeting. The human health hazards to be discussed in plenary are acute oral and inhalation toxicity, STOT SE, STOT RE and reproductive toxicity, with a view to adopt the opinion.

In relation to acute oral and inhalation toxicity, RAC agreed on Acute Tox. 2 in both cases, based on the data from the oral mouse study and the inhalation rat study.

In relation to target organ-specific effects after single exposure, RAC supported the DS proposal for STOT SE (H336) based on the sedation observed. In addition, RAC recognised that already at low doses, exophthalmos as well as opacity and keratitis of the cornea were observed. While opacity and keratitis occurred mainly at the same dose levels causing mortality, exophthalmos could be observed generally also at lower dose levels. RAC therefore concluded that also a classification for STOT SE 1, specifying effects on the eye as target organs was justified (H370 (eyes)).

Where specific target organ toxicity after repeated exposure is concerned, it was raised whether a STOT RE classification in category 1 or 2 had added value where the substance was already classified for acute toxicity. Nevertheless, RAC discussed whether repeated dose toxicity resulting in changes in body weight gain, as well as in high mortality at low doses would be sufficiently covered by the acute toxicity classification. Finally, RAC concluded that STOT RE without specifying target organ(s) is warranted. The dose levels where the most significant toxicity was observed (in the 90-d study) justified a classification of medetomidine as STOT RE 1 (H372).

In relation to reproductive toxicity, no effects on fertility could be observed in a two-generation rat study, even in the presence of significant parental toxicity, so no classification for effects on fertility was proposed. Nevertheless, RAC discussed increased number of early embryonic deaths and reduction in foetal body weight at maternal toxic doses found in fertility

and developmental toxicity studies. However, RAC decided that described effects are not sufficient to justify classification for Repr. 2 (developmental effects) and recommended no classification.

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

q) Clethodim (ISO)

The Chairman reported that clethodim (ISO) is an active substance used in plant protection products and that it has no harmonised classification in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 22 July 2016.

The DS (The Netherlands) proposed to classify the substance as Acute Tox 4; H302, Skin Sens. 1; H317 and Aquatic Chronic 3; H412 and to add the supplemental labelling phrase EUH066 (Repeated exposure may cause skin dryness or cracking).

As clethodim (ISO) is an active substance with no existing harmonised classification, all hazard classes were assessed.

Via fast-track the RAC supported the DS's proposal for acute oral toxicity, skin sensitisation and for environmental hazards, and no classification for a range of human health hazards.

The Committee agreed with the DS that no classification was warranted for skin irritation/corrosion. In addition, RAC supported the proposal from the DS for the supplemental labelling phrase EUH066 based on the results of a rabbit skin irritation study. The observed effects did not meet the classification criteria for Skin irritation category 2 (a mean value of ≥ 2.3 - ≤ 4.0 for erythema or oedema in at least 2/3 of animals) and were reversible within 9 days, but they did cause concern for causing skin dryness, flaking / cracking after repeated exposure.

Repeated dose toxicity after oral exposure was discussed based on the results of six studies in three species (the rat, the mouse and the dog). Across all the studies there were no adverse effects observed and other findings were not sufficient for classification. RAC concurred with the DS that no classification was warranted for STOT RE.

No classification was proposed for developmental toxicity of clethodim based on the results of two developmental toxicity studies – one in the rabbit and one in the rat. In the rabbit, no treatment-related effects were seen. In the rat study, the effects seen in the highest dose group (700mg/kg bw/d) were not considered relevant for classification due to high maternal mortality (20%) and the effects in the next top dose (350mg/kg bw) were not severe enough for classification. RAC also agreed that no classification was warranted for effects on fertility.

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

r) Reaction mass of isomers of benzotriazoles and phenols (Tinuvin 171/571)

The Chairman reported that Tinuvin 171/571 was an industrial chemical with an existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 19 September 2016.

The DS (Germany) proposed to remove the current classification (Aquatic Chronic 2; H411)

based on the new toxicity study on *Daphnia magna*.

The reliability of the bio-concentration test and hence whether the substance should be rather classified in category 4 for aquatic chronic toxicity than completely de-classified was questioned during the public consultation and also pointed out by some RAC Members.

The Committee briefly discussed the duration of bio-concentration test uptake and the validity of the BCF prediction using EPIWIN 4.1. According to the test guideline, the time to reach 80% steady state is predicted to be > 200 d instead of the ca. 30 days in the two bio-concentration tests, and the latter could not be considered valid because the estimated log Kow for two out of 3 isomers was outside the 'training set' for the BCF estimation. Therefore RAC agreed that the weight of evidence provided in the CLH report was not sufficiently robust to allow for de-classification, agreeing instead to down-grade the classification to Aquatic Chronic 4; H413.

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

The Secretariat presented the revised draft working procedures for conformity check and opinion development on Annex XV restriction dossiers to RAC (meeting documents RAC/35/2015/04 and RAC/35/2015/05) and explained that this revision is based on both recommendations made by the Restrictions Efficiency Task Force (REFT) and the experience gained from processing various restriction dossiers. It is in line with the Framework[3] for RAC and SEAC in checking conformity and developing opinions on restriction proposals, which was agreed at RAC-34 and SEAC-28 in September 2015 and published at ECHA's website. Two RAC Members expressed concerns with regard to the new section related to the last three months of the SEAC opinion development, where the SEAC Rapporteurs propose conditions in their opinion that have not been discussed in the context of the already adopted RAC opinion. In such a case, it was explained that the SEAC Rapporteurs may consult the RAC Rapporteurs on such changes and the RAC Chairman may also agree to present this information to the Committee for commenting. To address the concern raised, it will be made clear in the working procedure that such commenting/consultation cannot retrospectively become part of the RAC opinion. With that, RAC agreed with the two working procedures as proposed by the Secretariat.

The Secretariat then presented to RAC the new opinion template for restriction dossiers (room document RAC/35/2015/06), which had been revised based on a) the recommendations of the RETF, b) experience gained from past restriction dossiers and c) the new Annex XV reporting template. The new opinion template had been provided to RAC, SEAC and to the Commission for written commenting prior to RAC-35 and the updated version takes into account the comments received from these parties. RAC took note of and welcomed the proposed

[3] http://echa.europa.eu/web/guest/about-us/who-we-are/committee-for-risk-assessment

template. The Chairman reminded the Committee that the template is considered as a living document and no agreement by the Committee is therefore expected.

8.2 Restriction Annex XV dossiers

a) Opinion Development

1) Methanol – revised draft opinion

The Chairman welcomed an expert accompanying the Cefic stakeholder observer as well as the dossier submitter from Poland, the latter who followed the meeting remotely via WebEx. The restriction proposal is aimed at preventing severe poisoning following misuse of some mixtures containing high concentrations of methanol. 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 Public Consultation ended on 18 September with 10 comments received. The revised draft opinion was made available on 3 November and the RAC commenting round finished on 18 November, with comments received from three RAC Members.

The RAC Rapporteur presented the revised draft opinion and addressed the comments raised by the Committee Members. The case study selected by the Rapporteurs in the revised draft opinion (fatal outcome in 20 year female ingesting 15 ml methanol adulterated whisky (0.08 g/kg bw) (Bennett et al. 1953)) was discussed in detail. Based on the input received from Industry at the end of the Public Consultation and from Committee Members, the Rapporteurs proposed a different case from the same study (severe vision impairment in 34 year female ingesting 50 ml methanol adulterated whiskey (0.26 g/kg bw)) as the point of departure. RAC agreed on the proposal and in the application of an assessment factor of 3 (in line with ECHA Guidance) resulting in a DNEL value of 0.088 g/kg bw. Taking a a 60 kg body weight and a one liter ingestion of a methanol-containing mixture in 24 hours as a realistic worst case scenario, the Rapporteurs proposed a methanol concentration limit of 0.6 % by weight in windshield washing fluids (including windshield defrosters) and denatured alcohol to be protective against methanol-induced severe ocular toxicity and death. RAC agreed on the proposal.

RAC adopted its opinion on the dossier on methanol. 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 Chairman thanked the Rapporteurs for their efficient and thorough handling of this restriction proposal, the Committee Members and the stakeholders for their contributions.

2) D4/D5– revised draft opinion

The Chairman welcomed the Dossier Submitter's representative from the UK (following via WebEx), an external expert accompanying CEFIC and an occasional stakeholder observer (Cosmetics Europe). He reminded the participants that the restriction dossier on D4/D5 had been submitted by UK in April 2015. Both D4 and D5 have vPvB properties (MSC has recently provided an opinion that both substances are vPvB) and based on its CLP classification, D4 can considered to be PBT as well. The restriction proposal is aimed specifically at reducing emissions to the aquatic environment and 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 Rapporteurs presented the second draft opinion to the Committee.

With regard to the emission factors to the aquatic environment, the Rapporteurs proposed that under normal use conditions a rough estimate for an upper bound release rate of 100% ("absolute worst case") and a lower bound release rate of 73% to waste water could be used for all types of wash-off PCPs. For leave-on PCPs, the Rapporteurs recommended a release rate of 2.6% as the upper boundary and 0.1% as lower boundary. The representative of Cosmetics Europe provided some clarifications and expressed concerns regarding the Gouin *et al* study. One RAC Member recommended using a range, rather than a summary statistic for both wash-off and leave-on PCPs (54-93% for wash-off and 0.004-5.8% for leave-on PCPs). In the view of this Member, the proposed 10 year review period is too long and he would suggest 5 years for such substances. The Committee agreed with the emission values for PCPs, as follows – 54-93% for wash-off and 0.1-2.6% for leave-on.

Finally, the Rapporteurs discussed the scope and wording of the restriction. RAC agreed with the proposed concentration limit of 0.1%. Furthermore, it was agreed to consult the Forum on the revised wording of the restriction proposed in the second draft opinion. The Chairman reminded RAC that it is up to the Commission to draft the exact text of the restriction, and that RAC needed to explain the Forum's advice in the opinion.

The Chairman informed RAC that the public consultation on this proposal finishes on 18 December 2015. The Rapporteurs were asked to take the RAC discussion and the public consultation comments into account in the third draft opinion for adoption at RAC 36.

b) Conformity check

1) TDFAs (polyfluorooctyl trialkoxysilanes)

The Chairman welcomed the Dossier Submitters representative from Denmark.

The Dossier Submitter's representative provided a brief introductory presentation. The dossier proposes to restrict the use of:

> *"(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives in mixtures containing organic solvents placed on the market or used in spray products for consumers (aerosol dispensers, hand pump and trigger sprays and mixtures marketed for spray application)".*

The restriction is targeted at mixtures with organic solvents in spray products for supply to the general public. Numerous cases have been reported where consumers have experienced acute pulmonary distress following exposure to waterproofing/impregnation substances in spray products containing fluorinated polymers with free hydroxyl groups. Most of the reported incidents are for aerosol dispensers and only one for pump sprays. However, an assessment of mixtures containing TDFAs and 2-propanol shows a risk that is not controlled for these products applied by both aerosol dispensers and hand pump sprays. TDFAs have also been shown to cause serious acute lung injury in mice exposed to aerosolised mixtures containing TDFAs and organic solvent at certain concentration levels.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter and informed the Committee that they do not consider the dossier to be in conformity due to the shortcomings in hazard assessment (the link of TDFAs to human cases is insufficient) and exposure estimations (exposure model to simulate consumer

exposure should be developed). The Committee agreed. The Chairman informed that SEAC will conclude on the conformity of this dossier at SEAC-29.

If the dossier will be considered not to be in conformity by both Committees, the Secretariat will inform the Dossier Submitter about the reasons of non-conformity.

8.3 Appointment of (co-)rapporteurs for restriction dossiers

The pool of (co-)rapporteurs for the Bisphenol A,4,4'-isopropylidenediphenol restriction proposal (as presented in the restricted meeting document RAC/35/2015/07) was withdrawn from the RAC-35 agenda due to information received from the Dossier Submitter that the dossier will not be submitted. The Registry of Intentions will be updated shortly.

9. Authorisation

9.1 General authorisations issues

a) Continuing review of RAC and SEAC recommendations (opinion trees)

The opinion trees were presented for information at RAC-34 plenary meeting in September 2015. They are intended to help RAC and SEAC to have a structured and consistent way to derive their own opinions and to further develop how SEAC takes RAC's recommendations into consideration. The ECHA Secretariat now presented an updated version of the RAC and SEAC opinion trees. The following is assumed as the starting point: 1) the application for authorisation is in conformity with article 62 of the REACH Regulation, 2) the Normal review period is 7 years, 3) RAC/SEAC do not recommend a longer review period than the one requested by applicant and 4) that for RAC the exposure assessment will generally be of most concern. The Committee discussed in detail the wording of the questions in all of the boxes of the RAC opinion tree and refrained from changing the logic of the questions and conclusion combinations as proposed by the ECHA Secretariat with the exception of one outcome for which additional monitoring could be recommended.

The Committee agreed in principle on the document prepared by the Secretariat. The Secretariat will revise the document in accordance with the plenary discussion and will launch a RAC consultation on the revised document. After the RAC consultation the document will be uploaded to S-CIRCABC and to the ECHA website.

b) Update on incoming/future applications for authorisation and on Workshop on streamlining Applications for Authorisation

The ECHA Secretariat briefed the Committee about the Workshop on streamlining Applications for Authorisation, which took place on 17 November 2015, in Brussels.

The ECHA Secretariat also informed the Committee that 26 applications for authorisation covering 38 uses were received during the November submission window. Conformity of the applications and their key issues will be discussed by the Committee at the next plenary meeting in March 2016.

c) Amendment of the RAC note "Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent

chromium" to include the intrinsic property "Toxic to reproduction" of the Cr(VI) compounds

An ECHA consultant had reviewed the available literature data, focussing on previous reviews and produced a report on the intrinsic property "Toxic to reproduction" of the hexavalent chromium compounds. The secretariat proposed to add these findings to the RAC note "Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent chromium" (RAC/27/2013/06 Rev.1, as agreed in December 2013) as an Amendment to the RAC note. The RAC Rapporteur then presented his views on the draft Ammendment.

The Committee discussed a choice of the available studies, as provided by the ECHA consultant, for the DNEL setting exercise for the inhalatory, dermal and oral routes of exposure. Some RAC Members noted that the most appropriate way to set the DNEL values would be to derive them from the biomonitoring measurements. However, this had not been requested of the consultant.

The Committee agreed in principle on the need for and the outcome of the DNEL values proposed by the ECHA consultant for reproductive toxicity for the various routes of exposure, but it was acknowledged that for some routes (e.g. inhalation) carcinogenicity is probably the primary driver in the risk assessment of the Cr(VI) compounds.

The Secretariat will revise the Amendment to the note in accordance with the plenary discussion and will then launch a RAC consultation, after which, the Note will be uploaded to S-CIRCABC and the ECHA website. In addition the Secretariat will report to the RAC at the next plenary meeting on the scope of the issue of Cr(VI) toxicity to reproduction within the newly received applications for authorisation.

9.2 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues

1. One use of chromium trioxide submitted by *Kromatek Oy* on behalf of a group of companies (**Chromium trioxide - Kromatek**):

Use 1: Use of chromium trioxide in Cr(VI) based functional plating

The Rapporteur provided brief information on the application for authorisation and presented the draft outcome of the conformity check. The Rapporteur noted that this is a downstream user application where site-specific Operational Conditions (OC) and Risk Management measures (RMM) are described. The Applicants are small and medium sized enterprises

The Rapporteur outlined some issues which would need further clarification by the Applicant, including the actual exposure for different working contributing scenarios for which proper use of PPEs is required, as well as information on the training provided to workers. In addition, more details are needed on the methodology used for the submitted measurements of the environmental releases to water.

RAC agreed on the conformity of the application and on the Rapporteur's 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.

2. Two uses of chromium trioxide submitted by *Grohe AG* (**Chromium trioxide - Grohe**):

Use 1: The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also called 'functional plating with decorative character')

Use 2: The use of Chromium Trioxide for pre-treatment step in the electroplating process

The Rapporteurs provided brief information on the application for authorisation, presented the draft outcome of the conformity check and gave their first impression of the application, highlighting some key issues for the attention of the Committee. The application is for two uses of chromium trioxide. Both processes, electroplating and etching, are regarded as similar operational activities. According to the applicant both processes relate to dipping of substrates in baths that contain a specific Cr(VI) solution, and there is no indication that the exposure would be different. Hence, the applicant presented only one exposure scenario, which included both the etching and the electroplating steps, as the exposure information does not differ between the different plants.

. The Rapporteurs noted that there is a lack of detailed information regarding the sampling methodology/protocol for the static measurements and biomonitoring data, such as number of data points to describe the exposure of each activity, measuring method and frequency, as well as location of measurements, etc. The justification for air and water release estimates is lacking and further evidence to substantiate these estimates will be requested.

RAC discussed supported the Rapporteurs' proposal regarding the key issues, in particular the exposure assessment in relation to the OC and RMM applied by the applicants. in the application. RAC agreed on the conformity of the application.The Secretariat will inform the Applicant about the outcome of the conformity check and will ask him for further clarifications on the issues requested by the Committee.

b) First version of the draft opinion:

1. 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.

The Chairman welcomed the Rapporteurs and reported on the state of play of the dossier. At the previous meeting RAC agreed on the conformity of the application and discussed the key issues. The Rapporteurs then presented the first version of the Draft opinion.

RAC considered the level of the risk for workers, but also the uncertainties in the application, the latter triggered by the consideration that the exposure situation needs to be improved in order to limit the risks to workers. The Applicants declared in their application that they have committed to improve the situation in order to comply with upcoming changes in the requirements of the national legislation. RAC was of the opinion that the current RMMs in particular the containment of some activities are not currently adequate in limiting risk to a level as low as reasonably possible.

One Member proposed an addition to the current air measurement method, which could potentially allow taking personal measurements also for short duration tasks (applicants take measurements only for long duration tasks, due to sensitivity-limitations). That would be the

use of direct-reading monitors for aerosols, as these may be correlated with exposure to Cr(VI). RAC noted that the Applicants could potentially adapt the measurement methodology to increase the applicability / sensitivity of personal sampling, and felt that this might provide useful advice to the company. It was agreed that the Applicants should perform more frequent measurements in the future.

RAC Members asked the Rapporteurs to pay attention in the opinion also to dermal exposure and to the toxicity to reproduction endpoint.

RAC agreed to propose that the applicant should improve RMMs, in accordance with the plans they described themselves in the application. RAC also agreed to propose monitoring arrangements with immediate effect, in order to monitor and confirm the reduction of the workplace exposure.

RAC did not provide any advice to SEAC on the length of the review period.

The Committee agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs for their work on the application.

2. 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 Chairman welcomed the Rapporteurs and reported on the state of play of the dossier. At the previous meeting RAC agreed on the conformity of the application and discussed the key issues, as presented by the Rapporteurs. The Rapporteurs presented the first version of the Draft opinion.

RAC asked the Rapporteurs for clarification on differences (relative to frequency and duration of certain tasks) in the Workers contributing scenarios (WCSs) between the two sites included in the application.

RAC discussed if the measurements results are representative taking into account the low number of them. The Rapporteurs pointed out that in this case the exposure values obtained from measured data are of the same order but of a lower magnitude than those from modelled data. The risk calculated via modelled exposure is very possibly an overestimation as the models tend to be quite conservative. The Rapporteurs explained that they were of the opinion that there is consistency between measurements and modelling and the results allow the conclusion to be drawn that the exposures are generally lower than indicated (most are expressed as less-than values).

RAC members expressed concerns that in cases where models overestimate exposure (i.e. the real exposure is well below the minimum limit of the model), SEAC would need to be made aware of this.

RAC members asked the Rapporteurs to pay attention in the opinion also to dermal exposure and to the toxicity to reproduction endpoint.

RAC agreed to propose additional, regular monitoring programs as already mentioned by the Applicant for the review report in order to further reduce uncertainty surrounding the exposures.

RAC did not provide any advice to SEAC on the length of the review period.

The Committee agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs for their work on the application and the Committee for their active participation.

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

   Use 1: process and extracting solvent in fine chemical processes

The Chairman welcomed the Rapporteurs and reported on the state of play of the dossier. At the previous meeting RAC agreed on the conformity of the application and discussed the key issues, as presented by the Rapporteurs. At this meeting, the Rapporteurs presented the first version of the Draft opinion.

RAC concluded that the information on exposures provided by the Applicant appeared in general to be well described and sufficient for the assessment of the use applied for. In addition, RAC agreed that the risk management measures and operating conditions described in the application were generally appropriate and effective in limiting the risk to workers and the general population, although for a state of the art, modern plant, the exposures were higher than expected. However, RAC noted that parts of the operation, in particular tasks such as sampling, maintenance and laboratory work should be better monitored and optimised to reduce exposure of workers. RAC therefore proposed additional working conditions and monitoring arrangements, including monitoring campaigns, closed sampling system and further investigation of potential leakages by the Applicant. RAC did not make any recommendation to SEAC with regard to the review period.

The Committee agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs for their work on the application.

c) Consideration of draft opinions:

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 Chairman welcomed the Rapporteurs and reported on the state of play of the dossier. At the previous meeting RAC agreed on the conformity of the application and discussed the key issues. While no comments were received during the 8-weeks RAC consultation, which ended on 30 September 2015, the public consultation yielded a total number of 118 unique comments on the alternative substances and/or alternative technologies.

The Rapporteurs are currently drafting the first version of the opinion considering: a) the discussion at RAC-34, b) the Applicant's detailed answers to the set of questions sent by the Rapporteurs, c) the outcome of the Rapporteurs' dialogue and d) the trialogue meeting held on 5 and 6 November 2015.

The Rapporteurs expanded on the key issues and presented new information requested by them and received from the applicant just prior to the meeting. The overall impression is that the dossier is still complex and that information is missing. The Rapporteurs will submit the first version of the draft opinion at the beginning of January 2016, which will be closely followed by a RAC consultation.

RAC discussed the available data and the approaches to be taken to reach a conclusion. The Committee discussed the OCs and RMMs described in the application, questioning their representativeness. Since it was an upstream multiple workplace, multiple process application, they considered that representative data on workplace conditions was essential, noting that the range of possible workplace OCs and RMMs is unknown at this point in time.

The Committee therefore discussed an option, i.e. a general approach, of setting a maximum exposure level (e.g. 2 $\mu g/m^3$ for some uses), which is claimed by the applicants to be the representative 8 hours shift exposure. Many RAC Members expressed their concerns regarding high cancer risk levels resulting from the exposure to chromium trioxide at such workplaces, reflecting that the uncertainties seem to be large. However some RAC Members expressed their preference for this general approach in evaluating this application for authorisation covering many downstream users of the substance. It was proposed that it could only be seen as an interim measure coupled to further conditions.

The Committee also acknowledged the fact that the applicants did not consider human exposure via drinking water in the application, but only the air emissions.

The Committee instructed the Secretariat to request that for all uses (1, to 6), the applicants reveal all redacted (blanked-out) data in the recently submitted exposure tables, with the exception of the company names. The Secretariat will also request a description of the RMMs and OCs across the uses 2, 3, 4, 5 from the applicants, i.e. asking them to state how they intend to achieve their proposed maximum exposure concentration of 2 µg/m3 in case this would become a condition in any future authorisation. The Secretariat will request from the applicants corroborative modelling data for Use 1 to support the measured data in the application, and justification of all input parameters used. The Secretariat will request the contextual information concerning the RMM and OCs for the additional measurement data provided for Use 6. The Secretariat will request further information from the applicants on the potential indirect exposure of humans via environment from drinking water for all the uses.

The Chairman thanked the Rapporteurs for their work on the application and the Committee for the fruitful discussion.

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. The expanded pool of Rapporteurs, as outlined in the amended restricted room document RAC/35/2015/10, was then agreed by RAC.

10. AOB

In closing the meeting, the Chairman thanked all of the Committee members, especially the Rapporteurs for their hard work in 2015, noting that thanks to their efforts, the RAC agenda was largely cleared with only a small number of open dossiers being carried forward for completion in 2016. He concluded by thanking the ECHA staff from the Committee's Secretariat and the operational units for their support and dedication.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 35 24-27 November 2015
1-4 December 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/35/2015**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-35 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 34 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/35/2015/01** and document **RAC/35/2015/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the Q1 and Q2/2016 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-35 meeting on S-CIRCABC.
c) General RAC procedures	
7. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement without plenary debate • Medetomidine (human health hazards): no classification for acute dermal toxicity, skin corrosion/irritation, serious eye damage/irritation, respiratory/skin sensitisation, germ cell mutagenicity and carcinogenicity • Penthiopyrad (ISO): no classification for the physical hazards, acute toxicity (all routes of exposure), STOT SE, STOT RE, skin corrosion/irritation, serious eye damage/irritation, respiratory/skin sensitisation, germ cell mutagenicity. Aquatic Acute 1 and Aquatic Chronic 1, with M=1 for both aquatic hazards. • Clethodim (ISO): no classification for the physical hazards, acute dermal and inhalation toxicity, STOT SE, serious eye damage / eye irritation, respiratory sensitisation, germ cell mutagenicity and carcinogenicity. Acute Tox. 4 for the oral route, Skin Sens. 1 and Aquatic Chronic 3. • 2,3-epoxypropyl methacrylate: Acute Tox. 4 (H302), Skin Corr. 1C (H314), Eye Dam. 1 (without H318 label) and Skin Sens. 1 (H317). Removal of Acute Tox. 4* (H332) from Annex VI. • Hexaflumuron (ISO): no classification for the physical hazards, acute toxicity (all routes of exposure), STOT SE, skin corrosion/irritation, serious eye damage/irritation,	

respiratory/skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity. Aquatic Acute 1 and Aquatic Chronic 1, with M=1000 for the acute and M=10000 for the chronic aquatic hazard.

- 3,3'-dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea (Complex soap TH 28): retain Aquatic Chronic 4 (H413) in Annex VI.

B. Substances with hazard classes for agreement in plenary session

a) Anthraquinone
b) Cadmium carbonate
c) Cadmium dihydroxide
d) cadmium dinitrate
e) 2,3-epoxypropyl methacrylate
f) 3,3'dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea
g) Silver zinc zeolite
h) Hexaflumuron (ISO)
i) Penthiopyrad (ISO)
j) Nonadecafluorodecanoic acid (PFDA) and its ammonium and sodium salts
k) Triadimenol (ENV hazards)
~~l)~~ salicylic acid (developmental toxicity) **Item postponed for RAC-36**
m) 4,4'-methylenedimorpholine (MBM) (human health hazards)
n) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (toxicity to reproduction)
o) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (toxicity to reproduction)
p) Medetomidine (human health hazards)
q) Clethodim (ISO)
r) Reaction mass of isomers of benzotriazoles and phenols (Tinuvin 171/571)

a) Anthraquinone

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Carc. 1B (H350)	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

b) Cadmium carbonate

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. STOT RE 1 (H372 (kidney, bone)), Muta. 1B (H340), 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.

Transferred from group entry: Acute Tox. 4* (H302, H312, H332), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410) (no M-factors)	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
c) Cadmium dihydroxide	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. STOT RE 1 (H372 (kidney, bone)), Muta. 1B (H340), Carc. 1B (H350) Transferred from group entry: Acute Tox. 4* (H302, H312, H332), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410) (no M-factors)	**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.
d) Cadmium dinitrate	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. STOT RE 1 (H372 (kidney, bone)), Muta. 1B (H340), Carc. 1B (H350) with SCL=0.01% Transferred from group entry: Acute Tox. 4* (H302, H312, H332), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410) (no M-factors)	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
e) 2,3-epoxypropyl methacrylate	
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), Acute Tox. 3 (H311), ~~Acute Tox. 4 (H332),~~ Skin Corr. 1C (H314), Eye Dam. 1, ~~H318,~~ Skin Sens. 1 (H317), STOT SE 3 (H335), STOT RE 1 (H372) (respiratory tract; inhalation), Muta. 2 (H341), Carc. 1B (H350), Repr. 1B (H360F)	**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) 3,3'-dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. To retain: Aquatic Chronic 4 (H413) To remove: ~~Skin Sens. 1 (H317)~~	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
g) Silver zinc zeolite	

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Repr. 2 (H361d), Skin Irrit. 2 (H315), Eye Dam. 1 (H318), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=100 for both hazards	**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) Hexaflumuron (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Aquatic Acute 1 (H400); M=1000 and Aquatic Chronic 1 (H410); M=10000	**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) Penthiopyrad (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=1 for both hazards	**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.
j) Nonadecafluorodecanoic acid (PFDA) and its ammonium and sodium salts	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Carc. 2 (H351), Repr. 1B (H360Df), Lact. (H362)	**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.
k) Triadimenol (ENV hazards)	
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), Repr. 1B (H360), Lact. (H362), Aquatic Chronic 2 (H411)	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it

	on the ECHA website.
l) Salicylic acid (developmental toxicity)	
Item postponed for RAC-36	
m) 4,4'-methylenedimorpholine (MBM) (human health hazards)	
RAC adopted by simple majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 4; H302, Acute Tox. 4; H312, Acute Tox. 4; H332, EUH071, Skin Corr. 1B; H314, Skin Sens. 1; H317, Muta. 2; H341, STOT RE 2; H373 (GI tract and respiratory tract), 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.
n) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (toxicity to reproduction)	
RAC adopted by simple majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 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	**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.
o) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (toxicity to reproduction)	
RAC adopted by simple majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 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	**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.
p) Medetomidine (human health hazards)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 2 (H300 and H330), STOT SE 1 (H370) (eyes), STOT SE 3 (H336), STOT RE 1 (H372), Aquatic Acute 1 (H400); M=1 and 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.
q) Clethodim (ISO)	

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 4 (H302), Skin Sens. 1 (H317), Aquatic Chronic 3 (H412), EUH 066	**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.
r) Reaction mass of isomers of benzotriazoles and phenols (Tinuvin 171/571)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Aquatic Chronic 4 (H413)	**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 CIRCA BC confidential.
8. Restrictions	
8.1 General restriction issues	
RAC agreed on the revised working procedures for conformity check and opinion development of Annex XV restriction dossiers (RAC/35/2015/05 and RAC/35/2015/04) and discussed the revised opinion template (RAC/35/2015/06).	**SECR** to publish the agreed documents on the ECHA website and CIRCABC IG.
8.2 Restriction Annex XV dossiers	
a) Opinion Development	
1. Methanol – revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC adopted the opinion on methanol by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
2. D4/D5 – second draft opinion	

Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed with the following emission factors: 54-93% for wash-off PCPs and 0.1-2.6% for leave-on PCPs and for a concentration limit of 0.1%. RAC agreed to consult the Forum on the revised wording of the restriction proposed in the second draft opinion.	**Rapporteurs** to take the RAC discussion and the public consultation comments into account in the third draft opinion (by end of January 2016).
b) Conformity check	
1. TDFAs RAC agreed that the dossier does not conform to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter.	**Rapporteurs** to include final editorials in the outcome of the conformity check report and the recommendations. **SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG. **SECR** to inform the dossier submitter on the outcome of the conformity check.
8.2 Appointment of (co-)rapporteurs for restriction dossiers	
Item withdrawn	
9. Authorisation	
9.1 General authorisation issues	
a) Continuing review of RAC and SEAC recommendations (opinion trees)	
SECR presented the document **RAC/35/2015/08**. The Committee discussed and proposed to revise the draft Opinion Trees. RAC agreed in principle on the document.	SECR to revise the draft document in accordance with the plenary discussion. SECR to launch the RAC consultation on the final draft of the document. SECR to upload the document to S-CIRCABC and to the ECHA website.
b) Update on incoming/future applications for authorisation and on Workshop on streamlining Applications for Authorisation	
SECR presented the outcome from the WS "Streamlining Applications for Authorisation" which took place on 17 November 2015 in Brussels. SECR introduced to the Committee applications for authorisation received during the November Submission Window (from 6 to 20 November 2015).	
c) Amendment of the RAC note "Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent chromium" to include the intrinsic property "Toxic to reproduction" of the Cr(VI) compounds	
SECR presented the document **RAC/35/2015/09**. The Committee discussed and proposed to revise the draft	SECR to revise the draft amendment to the RAC note in accordance with the

amendment to the RAC note. RAC agreed in principle on the need for and the outcome of the DNELs proposed for the various routes of exposure.	plenary discussion. SECR to launch the RAC consultation on the draft amendment to the RAC note. SECR to upload the amended document to S-CIRCABC and to the ECHA website. SECR to report to the RAC at the next plenary meeting on the scope of the issue within the newly received applications for authorisation.
9.2 Authorisation applications	
a) Outcome of the conformity check and presentation of the key issues	
3. One use of chromium trioxide submitted by *Kromatek Oy* on behalf of a group of companies (**Chromium trioxide - Kromatek**): **Use 1:** Use of chromium trioxide in Cr(VI) based functional plating RAC agreed on the conformity of the application.	**SECR** to upload to S-CIRCABC the agreed Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
4. Two uses of chromium trioxide submitted by *Grohe AG* (**Chromium trioxide - Grohe**): **Use 1:** The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also called 'functional plating with decorative character') **Use 2:** The use of Chromium Trioxide for pre-treatment step in the electroplating process RAC agreed on the conformity of the application.	**SECR** to upload to S-CIRCABC the agreed Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
b) First version of the draft opinion:	
1. 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. RAC agreed that the RMMs are not appropriate in limiting the risk. RAC agreed to propose general monitoring arrangements. RAC agreed to recommend that the applicant should improve the RMMs for WCS3 as they proposed themselves in the application. RAC did not provide any advice to SEAC on the length	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2*: Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.

of the review period. RAC agreed the draft opinion by consensus.	
2. 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 to propose general monitoring arrangements for presentation at any future review. RAC did not provide any advice to SEAC on the length of the review period. RAC agreed the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2*: Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
3. One use of 1,2-dichloroethane submitted by Laboratoires Expanscience (**EDC 1**): **Use 1:** Process and extracting solvent in fine chemical processes RAC agreed that the described OCs and RMMs are in general appropriate and effective in limiting the risk. RAC agreed to propose additional conditions and monitoring arrangements for the authorisation and the review report. RAC did not provide any advice to SEAC on the length of the review period. RAC agreed on the draft opinion by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline, the RAC Chairman will approve the Final Opinion on behalf of RAC. *Option 2*: Should the Applicant wish to comment, SECR will make the Applicant's comments available on CIRCABC and will inform RAC.
c) Update on the developments in the draft opinions:	
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	**SECR** to request all redacted (blanked-out) data from the applicant in the exposure tables separately for all uses in the application (Uses 1, 2, 3, 4, 5, and 6), with exception of the company names. **SECR** to request from the applicant a description of the RMMs and OCs across the uses 2, 3, 4, 5 to achieve the maximum exposure concentration of 2

plating with decorative character **<u>Use 5:</u>** Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering **<u>Use 6:</u>** Passivation of tin-plated steel (ETP) RAC discussed the available data and the approaches to be taken to conclude on the application for authorisation.	µg/m^3 given by the applicant in case this would be a condition in the authorisation. **SECR** to request from the applicants corroborative modelling data for Use 1 to support the measured data in the application, and all input parameters used. **SECR** to request further information from the applicants on the potential indirect exposure of humans via environment from drinking water for all the uses. **Rapporteurs** to consider the discussion and the information to be received, and to draft the first version of the RAC draft opinions. **SECR** to launch the RAC consultation on the first version of the RAC draft opinions. **Rapporteurs** to consider outcome of the RAC consultation and to draft the second version of the RAC draft opinions for the discussion at RAC-36 plenary meeting in February/March 2016.
9.3 Appointment of (co-)rapporteurs for authorisation applications **RAC/35/2015/10** 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-35	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: Harmonised classification and labelling as adopted by RAC for the denoted substances

9,10-anthraquinone; anthraquinone

Annex VI	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current entry in Annex VI**										
Dossier submitters proposal	TBD	anthraquinone	201-549-0	84-65-1	Carc. 1B	H350	GHS08 Dgr	H350			
RAC opinion	TBD	anthraquinone	201-549-0	84-65-1	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	anthraquinone	201-549-0	84-65-1	Carc. 1B	H350	GHS08 Dgr	H350			

Cadmium carbonate

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	048-001-00-5	cadmium compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), reaction mass of cadmium sulphide with zinc sulphide (xCdS.yZnS), reaction mass of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in this Annex	-	-	Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H332 H400 H410	GHS07 GHS09 Wng	H302 H312 H332 H410			A1
Dossier submitters proposal	TBD	Cadmium carbonate	208-168-9	513-78-0	**Add** Carc. 1B Muta. 1B STOT RE 1	**Add** H350 H340 H372 (kidney, bone)	**Add** GHS08 **Modify** Dgr	**Add** H350 H340 H372 (kidney, bone)			A1
RAC opinion	TBD	Cadmium carbonate	208-168-9	513-78-0	**Add** Carc. 1B Muta. 1B STOT RE 1	**Add** H350 H340 H372 (kidney, bone)	**Add** GHS08 **Modify** Dgr	**Add** H350 H340 H372 (kidney, bone)			A1
Resulting Annex VI entry if agreed by COM	TBD	Cadmium carbonate	208-168-9	513-78-0	Carc. 1B Muta. 1B Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H340 H302 H312 H332 H372 (kidney, bone) H400 H410	GHS07 GHS08 GHS09 Dgr	H350 H340 H302 H312 H372 (kidney, bone) H332 H410			A1

Cadmium hydroxide

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	048-001-00-5	cadmium compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), reaction mass of cadmium sulphide with zinc sulphide (xCdS.yZnS), reaction mass of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in this Annex	-	-	Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H332 H400 H410	GHS07 GHS09 Wng	H302 H312 H332 H410	-	-	A1
Dossier submitters proposal	TBD	Cadmium hydroxide	244-168-5	21041-95-2	**Add** Carc. 1B Muta. 1B STOT RE 1	**Add** H350 H340 H372 (kidney, bone)	**Add** GHS08 **Modify** Dgr	**Add** H350 H340 H372 (kidney, bone)	-	-	A1
RAC opinion	TBD	Cadmium hydroxide	244-168-5	21041-95-2	**Add** Carc. 1B Muta. 1B STOT RE 1	**Add** H350 H340 H372 (kidney, bone)	**Add** GHS08 **Modify** Dgr	**Add** H350 H340 H372 (kidney, bone)	-	-	A1
Resulting Annex VI entry if agreed by COM	TBD	Cadmium hydroxide	244-168-5	21041-95-2	Carc. 1B Muta. 1B Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H340 H302 H312 H332 H372 (kidney, bone) H400 H410	GHS07 GHS08 GHS09 Dgr	H350 H340 H302 H312 H372 (kidney, bone) H332 H410			A1

Cadmium nitrate

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	048-001-00-5	cadmium compounds, with the exception of cadmium sulphoselenide (xCdS.yCdSe), reaction mass of cadmium sulphide with zinc sulphide (xCdS.yZnS), reaction mass of cadmium sulphide with mercury sulphide (xCdS.yHgS), and those specified elsewhere in this Annex	-	-	Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H332 H400 H410	GHS07 GHS09 Wng	H302 H312 H332 H410	-	-	A1
Dossier submitters proposal	TBD	cadmium nitrate	233-710-6	10325-94-7	**Add** Carc. 1B Muta. 1B STOT RE 1	**Add** H350 H340 H372 (kidney, bone)	**Add** GHS08 **Modify** Dgr	**Add** H350 H340 H372 (kidney, bone)	-	-	A1
RAC opinion	TBD	cadmium nitrate	233-710-6	10325-94-7	**Add** Carc. 1B Muta. 1B STOT RE 1	**Add** H350 H340 H372 (kidney, bone)	**Add** GHS08 **Modify** Dgr	**Add** H350 H340 H372 (kidney, bone)	-	Carc. 1B C≥0.01%	A1
Resulting Annex VI entry if agreed by COM	TBD	cadmium nitrate	233-710-6	10325-94-7	Carc. 1B Muta. 1B Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H350 H340 H302 H312 H332 H372 (kidney, bone) H400 H410	GHS07 GHS08 GHS09 Dgr	H350 H340 H302 H312 H372 (kidney, bone) H332 H410		Carc. 1B C≥0.01%	A1

Clethodim (ISO); (5*RS*)-2-{(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl}-5-[(2*RS*)-2-(ethylthio) propyl]-3-hydroxycyclohex-2-en-1-one

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	clethodim (ISO); (5*RS*)-2-{(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl}-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one	-	99129-21-2	Acute Tox. 4 Skin Sens. 1 Aquatic Chronic 3	H302 H317 H412	GHS07 Wng	H302 H317 H412	EUH066		
RAC opinion	TBD	clethodim (ISO); (5*RS*)-2-{(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl}-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one	-	99129-21-2	Acute Tox. 4 Skin Sens. 1 Aquatic Chronic 3	H302 H317 H412	GHS07 Wng	H302 H317 H412	EUH066		
Resulting Annex VI entry if agreed by COM	TBD	clethodim (ISO); (5*RS*)-2-{(1*EZ*)-1-[(2*E*)-3-chloroallyloxyimino]propyl}-5-[(2*RS*)-2-(ethylthio)propyl]-3-hydroxycyclohex-2-en-1-one	-	99129-21-2	Acute Tox. 4 Skin Sens. 1 Aquatic Chronic 3	H302 H317 H412	GHS07 Wng	H302 H317 H412	EUH066		

2,3-epoxypropyl methacrylate

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-123-00-4	2,3-epoxypropyl methacrylate	203-441-9	106-91-2	Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Eye Irrit. 2 Skin Irrit. 2 Skin Sens. 1	H302 H312 H332 H319 H315 H317	GHS07 Wng	H302 H312 H332 H319 H315 H317			D
Dossier submitters proposal	607-123-00-4	2,3-epoxypropyl methacrylate	203-441-9	106-91-2	**Retain** Skin Sens. 1 **Add** Carc. 1B Muta. 2 Repr. 1B STOT SE 1 **Modify** Acute Tox. 4 Acute Tox. 3 Eye Dam. 1 Skin Corr. 1C **Remove** Acute Tox. 4 *	**Retain** H317 **Add** H350 H341 H360F H370 (respiratory tract)(inhalation) **Modify** H302 H311 H318 H314 **Remove** H332	**Add** GHS08 GHS05 GHS06 **Modify** Dgr **Remove** GHS07	**Retain** H317 **Add** H350 H341 H360F H370 (respiratory tract)(inhalation) **Modify** H302 H311 H314 **Remove** H332			**Retain** D
RAC opinion	607-123-00-4	2,3-epoxypropyl methacrylate	203-441-9	106-91-2	**Retain** Skin Sens. 1 **Add** Carc. 1B Muta. 2 Repr. 1B STOT SE 3 STOT RE 1 **Modify** Acute Tox. 4 Acute Tox. 3 Eye Dam. 1 Skin Corr. 1C **Remove** Acute Tox. 4*	**Retain** H317 **Add** H350 H341 H360F H335 H372 (respiratory tract)(inhalation) **Modify** H302 H311 H318 H314 **Remove** H332	**Add** GHS08 GHS05 GHS06 **Modify** Dgr **Remove** GHS07	**Retain** H317 **Add** H350 H341 H360F H335 H372(respiratory tract)(inhalation) **Modify** H302 H311 H314 **Remove** H332			**Retain** D
Resulting	607-123-	2,3-epoxypropyl	203-	106-91-	Carc. 1B	H350	GHS08	H350			**Retain**

Annex VI entry if agreed by COM	00-4	methacrylate	441-9	2	Muta. 2 Repr. 1B Acute Tox. 4 Acute Tox. 3 STOT SE 3 STOT RE 1 Eye Dam. 1 Skin Corr. 1C Skin Sens. 1	H341 H360F H302 H311 H335 H372 (respiratory tract)(inhalation) H318 H314 H317	GHS05 GHS06 Dgr	H341 H360F H302 H311 H335 H372 (respiratory tract)(inhalation) H314 H317			D

3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea

	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	616-094-00-7	3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	406-370-3	58890-25-8	Skin Sens. 1 Aquatic Chronic 4	H317 H413	GHS07 Wng	H317 H413			
Dossier submitters proposal	616-094-00-7	3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	406-370-3	58890-25-8	**Remove** Skin Sens. 1 Aquatic Chronic 4	**Remove** H317 H413	**Remove** GHS07 Wng	**Remove** H317 H413			
RAC opinion	616-094-00-7	3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	406-370-3	58890-25-8	**Retain** Aquatic Chronic 4 **Remove** Skin Sens. 1	**Retain** H413 **Remove** H317	**Remove** GHS07 Wng	**Retain:** H413 **Remove** H317			
Resulting Annex VI entry if agreed by COM	616-094-00-7	3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	406-370-3	58890-25-8	Aquatic Chronic 4	H413		H413			

Reaction mass of: isomers of 2-(2*H*-benzotriazol-2-yl)-4-methyl-(*n*)-dodecylphenol isomers of 2-(2*H*-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 isomers of 2-(2*H*-benzotriazol-2-yl)-4-methyl-(*n*)-tetracosylphenol (Tinuvin 171/571)

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors**	**Notes**
					Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard statement Code(s)**	**Suppl. Hazard statement Code(s)**		
Current Annex VI entry	604-057-00-8	reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol	401-680-5	-	Aquatic Chronic 2	H411	GHS09	H411			
Dossier submitters proposal	604-057-00-8	reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol	401-680-5	-	**Remove** Aquatic Chronic 2	**Remove** H411	**Remove** GHS09	**Remove** H411			
RAC opinion	604-057-00-8	reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol	401-680-5	-	**Modify** Aquatic Chronic 4	**Modify** H413	**Remove** GHS09	**Modify** H413			
Resulting Annex VI entry if agreed by COM	604-057-00-8	reaction mass of: isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-dodecylphenol isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-5,6-didodecyl-phenol. n = 5 or 6 isomers of 2-(2H-benzotriazol-2-yl)-4-methyl-(n)-tetracosylphenol	401-680-5	-	Aquatic Chronic 4	H413		H413			

Silver zinc zeolites

Annex VI	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current entry in Annex VI**										
Dossier submitters proposal	TBD	Silver zinc zeolite (Zeolite, LTA1 framework type, surface-modified with silver and zinc ions) This entry covers LTA framework type zeolite which has been surface-modified with both silver and zinc ions at contents Ag^+ 0.5%-6%, Zn^{2+} 5%-16%, and potentially with phosphorus, NH_4^+, Mg^{2+} and/or Ca^{2+} each at level <3%	-	13032 8-20-0	Carc. 2 Repr. 1B Skin Irrit. 2 Eye Dam. 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H360D H315 H318 H373 H400 H410	GHS08 GHS05 GHS09 Dgr	H351 H360D H315 H318 H373 H410		M=100 M=100	
RAC opinion	TBD1	Silver zinc zeolite (Zeolite, LTA1 framework type, surface-modified with silver and zinc ions) This entry covers LTA framework type zeolite which has been surface-modified with both silver and zinc ions at contents Ag^+ 0.5%-6%, Zn^{2+} 5%-16%, and potentially with phosphorus, NH_4^+, Mg^{2+} and/or Ca^{2+} each at level <3%	-	13032 8-20-0	Repr. 2 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H315 H318 H400 H410	GHS08 GHS05 GHS09 Dgr	H361d H315 H318 H410		M=100 M=100	
Resulting Annex VI entry if agreed by COM	TBD	Silver zinc zeolite (Zeolite, LTA1 framework type, surface-modified with silver and zinc ions) This entry covers LTA framework type zeolite which has been surface-modified with both silver	-	13032 8-20-0	Repr. 2 Skin Irrit. 2 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H361d H315 H318 H400 H410	GHS08 GHS05 GHS09 Dgr	H361d H315 H318 H410		M=100 M=100	

		and zinc ions at contents Ag^+ 0.5%-6%, Zn^{2+} 5%-16%, and potentially with phosphorus, NH_4^+, Mg^{2+} and/or Ca^{2+} each at level <3%									

Hexaflumuron (ISO); 1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	hexaflumuron (ISO); 1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea	401-400-1	86479-06-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1000 M=10000	
RAC opinion	TBD	hexaflumuron (ISO); 1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea	401-400-1	86479-06-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1000 M=10000	
Resulting Annex VI entry if agreed by COM	TBD	hexaflumuron (ISO); 1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea	401-400-1	86479-06-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1000 M=10000	

Penthiopyrad (ISO); (*RS*)-*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide

Annex VI	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current entry in Annex VI**										
Dossier submitters proposal	TBD	Penthiopyrad (ISO); (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide	-	183675-82-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	
RAC opinion	TBD	Penthiopyrad (ISO); (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide	-	183675-82-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	Penthiopyrad (ISO); (RS)-N-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)pyrazole-4-carboxamide	-	183675-82-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	

Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	2,2,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-nonadecafluorodecanoic and its ammonium and sodium salts	206-400-3		Carc. 2 Repr. 1B Lact.	H351 H360Df H362	GHS08 Dgr	H351 H360Df H362			
RAC opinion	TBD	nonadecafluorodecanoic acid [1]; ammonium nonadecafluorodecanoate [2]; sodium nonadecafluorodecanoate [3]	206-400-3 [1]; 221-470-5 [2]; - [3]	335-76-2 [1]; 3108-42-7 [2]; 3830-45-3 [3]	Carc. 2 Repr. 1B Lact.	H351 H360Df H362	GHS08 Dgr	H351 H360Df H362			
Resulting Annex VI entry if agreed by COM	TBD	nonadecafluorodecanoic acid [1]; ammonium nonadecafluorodecanoate [2]; sodium nonadecafluorodecanoate [3]	206-400-3 [1]; 221-470-5 [2]; - [3]	335-76-2 [1]; 3108-42-7 [2]; 3830-45-3 [3]	Carc. 2 Repr. 1B Lact.	H351 H360Df H362	GHS08 Dgr	H351 H360Df H362			

4,4’-methylene-dimorpholine (MBM)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	4,4'-methylenedimorpholine	227-062-3	5625-90-1	Carc. 1B Muta. 2 Skin Corr. 1B Skin Sens. 1	H350 H341 H314 H317	GHS08 GHS07 GHS05 Dgr	H350 H341 H314 H317		C ≥ 1.2%	
RAC opinion	xxx-xxx-xx-x	4,4'-methylenedimorpholine	227-062-3	5625-90-1	Carc. 1B Muta. 2 Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 Skin Corr. 1B Skin Sens. 1 STOT RE 2	H350 H341 H302 H312 H332 H314 H317 H373 (gastrointestinal tract, respiratory tract)	GHS08 GHS07 GHS05 Dgr	H350 H341 H302 H312 H332 H314 H317 H373 (gastrointestinal tract, respiratory tract)	EUH071		
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	4,4'-methylenedimorpholine	227-062-3	5625-90-1	Carc. 1B Muta. 2 Acute Tox. 4 Acute Tox. 4 Acute Tox. 4 STOT RE 2 Skin Corr. 1B Skin Sens. 1	H350 H341 H302 H312 H332 H373 (gastrointestinal tract, respiratory tract) H314 H317	GHS08 GHS07 GHS05 Dgr	H350 H341 H302 H312 H332 H373 (gastrointestinal tract, respiratory tract) H314 H317	EUH071		

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current 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 Acute Tox. 4 Acute Tox. 3 Acute Tox. 4 STOT RE 2 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1A Aquatic Chronic 2	H350 H341 H302 H311 H332 H373 (gastrointestinal tract, respiratory tract) H314 H318 H317 H411	GHS08 GHS06 GHS05 GHS09 Dgr	H350 H341 H302 H311 H332 H373 (gastrointestinal tract, respiratory tract) H314 H317 H411	EUH071		
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2)			Carc. 1B Muta. 2 Acute Tox. 4 Acute Tox. 3 Acute Tox. 4 STOT RE 2 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1A Aquatic Chronic 2	H350 H341 H302 H311 H332 H373 (gastrointestinal tract, respiratory tract) H314 H318 H317 H411	GHS08 GHS06 GHS05 GHS09 Dgr	H350 H341 H302 H311 H332 H373 (gastrointestinal tract, respiratory tract) H314 H317 H411	EUH071		

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current 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	GHS08 GHS05 GHS07 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 Acute Tox. 4 Acute Tox. 4 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1A STOT RE 2 Aquatic Chronic 2	H350 H341 H302 H332 H314 H318 H317 H373 (gastrointestinal tract, respiratory tract) H411	GHS08 GHS05 GHS07 GHS09 Dgr	H350 H341 H302 H332 H314 H317 H373 (gastrointestinal tract, respiratory tract) H411	EUH071		
Resulting Annex VI entry if agreed by COM	xxx-xxx-xx-x	Reaction products of paraformaldehyde with 2-hydroxypropylamine (ratio 1:1)	-	-	Carc. 1B Muta. 2 Acute Tox. 4 Acute Tox. 4 STOT RE 2 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1A Aquatic Chronic 2	H350 H341 H302 H332 H373 (gastrointestinal tract, respiratory tract) H314 H318 H317 H411	GHS08 GHS05 GHS07 GHS09 Dgr	H350 H341 H302 H332 H373 (gastrointestinal tract, respiratory tract) H314 H317 H411	EUH071		

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current 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	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 1 STOT SE 3 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H300 H330 H370 (eye) H336 H372 H400 H410	GHS08 GHS06 GHS09 Dgr	H300 H330 H370 H336 H372 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	Acute Tox. 2 Acute Tox. 2 STOT SE 1 STOT SE 3 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H300 H330 H370 (eye) H336 H372 H400 H410	GHS08 GHS06 GHS09 Dgr	H300 H330 H370 H336 H372 H410		M=1 M=100	

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	xxx-xxx-xx-x	triadimenol (ISO); α-tert-butyl-β-(4-chlorophenoxy)-1H-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)-1H-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)-1H-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			

Part III. List of Attendees of the RAC-35 meeting

24-27 November 2015 and 1-4 December 2015

RAC Members
ANDREOU Kostas (2nd week only)
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
BRANISTEANU Radu (1st week only)
CARVALHO João
CHANKOVA-PETROVA Stephka
CHIURTU Elena (co-opted member) (1st week only)
COPIN Stephanie
CZERCZAK Slawomir
DI PROSPERO FANGHELLA Paola (2nd week only)
DUNAUSKIENĖ Lina
DUNGEY Stephen (1st week only)
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HUSA Stine
ILIE Mihaela (1st week only)
JANKOWSKA Elzbieta (co-opted member)
KADIĶIS Normunds
KAPELARI Sonja
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MOELLER Ruth

MULLOOLY Yvonne (1st week only)
NORTHAGE Christine (co-opted member)
MURRAY Brendan (2nd week only)
NEUMANN Michael
PARIS Pietro
PASQUIER Elodie (1st week only)
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SOERENSEN Peter Hammer
SPETSERIS Nikolaos (1st week only)
STAHLMANN Ralf
STASKO Jolanta
TADEO José Luis
TOBIASSEN Lea Stine
TSITSIMPIKOU Christina (1st week only)
UZOMECKAS Zilvinas
VAN DER HAAR Rudolf (co-opted member)
VARNAI Veda Marija
VIEGAS Susana (co-opted member)

Apologies		**Invited experts**
HÖLZL Christine		HENÖKL Thomas (general RAC procedures)
KALOGIROU Andreas		
SCHLUETER Urs		
Commission observers		**Stakeholders observers**
HEIDORN Christian DG ENV (1st week only)		ANNYS Erwin, Cefic
MORRIS Alick DG EMPL (1st week only)		BARRY Frank, ETUC
ROZWADOWSKI Jacek DG GROW (1st week only)		VEROUGSTRAETE Violaine, Eurometaux
SCAZZOLA Roberto DG GROW (2nd week only)		WAETERSCHOOT Hugo, Eurometaux (agenda item silver zinc ENV only)
		ROWE Rocky, ECPA (2nd week only)
RAC advisors		VAN EGMOND Roger (Cosmetics Europe, occasional stakeholder for D4/D5)
ESTEVEZ Jorge (Miguel Sogorb) (CLH silver zinc zeolite, cadmium compounds) (2nd week only)		
LOIKKANEN Jarkko (Riitta Leinonen) (CLH medetomidine)		**Stakeholder apologies**
McCABE Laura (Andrew Smith) (CLH cadmium compounds, clethodim, hexaflumuron) (2nd week only)		DEN HAAN Klaas (Concawe)
PARTOSCH Falko (Ralf Stahlmann) (1st week only)		MUNARI Tomaso (EuCheMS)
ROMOLI Debora (Pietro Paris) (CLH penthiopyrad) (2nd week only)		ROMANO Dolores (EEB)
STOCKMANN-JUVALA Helene (Tiina Santonen)		
SUUTARI Tiina (Riitta Leinonen) (2nd week only)		**Consultant:**
UUKSULAINEN Sanni (Tiina Santonen) (1st week only)		BRESCIA Susy (AfA Cr(VI)) (1st week only)

Industry experts		
DUCROT Virginie (ECPA, Bayer CropScience, triadimenol) (2nd week only)		FIORE Karine (1st week only)
ERLER Steffen (Cefic, SABIC, methanol) (1st week only)		KRAJNC Karmen (1st week only)
FREZ William (Cefic, University of Michigan), MBM/MNO/HPT) (2nd week only)		**Dossier submitters:**
GALE Eric (ECPA, LKC Switzerland Ltd, penthiopyrad) (2nd week only)		
KÄCH Francine (Cosmetics Europe, L´Oreal, D4/D5) (1st week only)		Austria:PAPARELLA Martin (MBM, MBO, HTP) (2nd week only)
LOMBAERT Noömi (Eurometaux, IZA/ICdA, cd compounds) (2nd week only)		The Netherlands: MÜLLER Andre (2,3-epoxypropyl methacrylate, clethodim)
PLOTZKE Kathleen (Cefic, DOW, D4/D5) (1st week only)		Poland: MARIUSZ Godala (methanol) (1st week only)
RAFFRAY Mark (Eurometaux, Precious metals consortium, silver zinc zeolite) (2nd week only)		Sweden:
REMOTE PARTICIPANTS		BIRGANDER Pernilla (silver zinc zeolite) (2nd week only)
RAC members:		CEDERBERG Håkan (PFDA, cadmium compounds) (2nd week only)
BRANISTEANU Radu (2nd week only)		HAHLBECK Edda (silver zinc zeolite) (2nd week only)
DUNGEY Steve (2nd week only)		HENRIKSSON Erika Witasp (PFDA, cadmium compounds) (2nd week only)
PASQUIER Elodie (2nd week only)		ÖSTERWALL Christoffer (silver zinc zeolite) (2nd week only)
SCHLUETER Urs		UK:
Adviser/invited expert :		CAITENS Andrea (medetomidine, penthiopyrad)
LOSERT Annemarie (Christine Hölzl)		MARTIN Sara (D4/D5) (1st week only)
SEAC Rapporteurs (AfA and restriction)		
ALEXANDRE Joao (1st week only)		**Commission observers:**
COGEN Simon (1st week only)		BERTATO Valentina (1st week only)
CSERGO Robert (1st week only)		GARCIA-JOHN Enrique (1st week only)
DOUGHERTY Gary (1st week only)		RIEPMA Wim (1st week only)
FANKHAUSER Simone (1st week only)		STRECK Georg (1st week only)

ECHA staff	PENNESE Daniele
BERGES Markus	PERAZZOLA Chiara
BLAINEY Mark	PILLET Monique
BOWMER Tim, Chairman	REGIL Pablo
BROECKAERT Fabrice	RHEINBERGER Christoph
DVORAKOVA Dana	RODRIGUEZ-IGLESIAS Pilar
ERICSSON Gunilla	SADAM Diana
HELLSTEN Kati	SIMPSON Peter
HENRICSSON Sanna	SMILOVICI Simona
HONKANEN Jani	SOSNOWSKI Piotr
JOVER BUSTILLO Vanessa	SOTIRIOS Kiokias
KANELLOPOULOU Athanasia	TSIFOUTIS Vasileios
KIVELÄ Kalle	VAN HAELST Anniek
KLAUK Anja	
KOKKOLA Leila	
KOSK-BIENKO Joanna	
KOULOUMPOS Vasileios	
LEGZDIPA Ilze	
LUSCHÜTZKY Evita	
MARQUEZ-CAMACHO Mercedes	
MAZZOLINI Anna	
MERKOURAKIS Spyridon	
MOTTET Denis	
MULLER Gesine	
NICOT Thierry	
NYGREN Jonas	
ORISPÄÄ Katja	
O´OROURKE Regina	
PELTOLA Jukka	

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-35 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-35 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-35 meeting

ANNEX IV Administrative issues and information items

Annex I (RAC-35)

24 November 2015
RAC/A/35/2015

Final Agenda
35th meeting of the Committee for Risk Assessment

24 November - 4 December 2015

ECHA Conference Centre (Annankatu 18, Helsinki)

24 November starts at 9.00
27 November breaks at 13.00
1 December resumes at 14:00
4 December ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/35/2015
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 35 action points, written procedures and update on other ECHA bodies

RAC/35/2015/01
RAC/35/2015/02
(room document)

For information

b) RAC workplan for all processes

For information

c) General RAC procedures

For information

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)

- Medetomidine (human health hazards): skin and eye corrosion/irritation, respiratory /skin sensitisation, mutagenicity and carcinogenicity
- Penthiopyrad (ISO): aquatic acute toxicity, aquatic chronic toxicity; all human health hazards (=no classification) except carcinogenicity and developmental toxicity
- Clethodim (ISO): physical hazards, acute toxicity, STOT SE, serious eye damage / eye irritation, respiratory / skin sensitisation, mutagenicity, carcinogenicity, environmental hazards
- 2,3-epoxypropyl methacrylate: acute toxicity (oral and inhalation routes), serious eye damage, eye corrosion, skin sensitisation
- hexaflumuron (ISO): physical hazards, acute toxicity (dermal route), skin damage /eye irritation, skin sensitisation, environmental hazards
- 3,3'dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea: environmental hazards

B. Hazard classes for agreement with plenary debate

a) anthraquinone

b) cadmium carbonate

c) cadmium dihydroxide

d) cadmium dinitrate

e) 2,3-epoxypropyl methacrylate

f) 3,3'dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea

g) silver zinc zeolite

h) hexaflumuron (ISO)

i) penthipyorad (ISO)

j) nonadecafluorodecanoic acid (PFDA) and its ammonium and sodium salts

k) triadimenol (ENV hazards)

~~l) salicylic acid (developmental toxicity)~~

m) 4,4'-methylenedimorpholine (MBM) (human health hazards)

n) Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (toxicity to reproduction)

o) Reaction product of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (toxicity to reproduction)

p) medetomidine (human health hazards)

q) clethodim (ISO)

r) Reaction mass of isomers of benzotriazoles and phenols (Tinuvin 171/571)

For discussion and adoption

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

AC/35/2015/03
(restricted room document)
For agreement

Item 8 – Restrictions

8.1 General restriction issues

a) Revision of the restriction process

RAC/35/2015/04
RAC/35/2015/05
For discussion and agreement
RAC/35/2015/06
(room document)
For information and discussion

8.2 Restriction Annex XV dossiers

a) Opinion development

1) Methanol – revised draft opinion

For adoption

2) D4/D5 – revised draft opinion

For discussion

b) Conformity check

1) TDFAs

For agreement

8.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/35/2015/07
(restricted document)
For agreement

Item 9 – Authorisation

9.1 General authorisation issues

a) Continuing review of RAC and SEAC recommendations (opinion trees)

RAC/35/2015/08
For discussion and agreement

b) Update on incoming/future applications for authorisation and on Workshop on streamlining Applications for Authorisation

For information

c) Amendment of the RAC note "Application for Authorisation: Establishing a reference dose-response relationship for carcinogenicity of hexavalent chromium" to include the intrinsic property "Toxic to reproduction" of the Cr(VI) compounds

RAC/35/2015/09
For discussion and agreement

9.2 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues

1. One use of chromium trioxide submitted by *Kromatek Oy* on behalf of a group of companies (**Chromium trioxide - Kromatek**):

Use 1: Use of chromium trioxide in Cr(VI) based functional plating

2. Two uses of chromium trioxide submitted by *Grohe AG* (**Chromium trioxide - Grohe**):

Use 1: The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also called 'functional plating with decorative character')
Use 2: The use of Chromium Trioxide for pre-treatment step in the electroplating process

b) First version of the draft opinion:

1. 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.

2. 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.

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

   Use 1: process and extracting solvent in fine chemical processes

For discussion and agreement

c) Consideration of draft opinions:

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)

For information and discussion

9.3 Appointment of (co-)rapporteurs for authorisation applications

RAC/35/2015/10 (restricted room document)

For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-35

Table with Conclusions and Action points from RAC-35

For adoption

Annex II (RAC-35)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-35 meeting.

Document number	Title
RAC/A/35/2015	Final Draft Agenda
RAC/A/2015 Restricted	Draft outline agenda
RAC/35/2015/01	Report from other ECHA bodies
RAC/35/2015/02 Room document	Administrative issues
RAC/35/2015/03 Restricted	Appointment of Rapporteurs for CLH dossiers
RAC/35/2015/04_a RAC/35/2015/04_b	WP for conformity check of restriction dossiers – TC_clean WP for conformity check of restriction dossiers – TC_track changes
RAC/35/2015/05_a RAC/35/2015/05_b	WP on opinion development of restrictions_clean WP on opinion development of restrictions_track changes
RAC/35/2015/06_a Room document RAC/35/2015/06_b Room document	Revised template for opinion restriction_clean Revised template for opinion restriction_track changes
RAC/35/2015/07 Restricted	Appointment of rapporteurs restriction
RAC/35/2015/08	AfA – draft Note – opinion trees
RAC/35/2015/09	Amendment carcinogenicity dose response Cr(VI) - repro
RAC/35/2015/10	Appointment of rapporteurs authorisation

ANNEX III (RAC-35)

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 PREVIOUS RAC PLENARY MEETING(S)		
Restrictions		
D4/D5 (UK)	Steven 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 preparation of 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.
1-methyl-2-pyrrolidone (NMP)	Marja PRONK	Working for the CA previously 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
	Betty HAKKERT	Working for the CA previously submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
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.
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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		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.
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.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DECLARATIONS		
TDFAs (DK)	Lea Stine TOBIASSEN	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
	Peter Hammer SØRENSEN	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.
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement in previous relevant dossiers: asked to refrain from voting in the event of a vote on this substance – the Chairman to consider further mitigation measures as necessary.
Cr(IV) dose-response	Andrew SMITH	Working for the CA who collaborated with ECHA on the preparation of the note.
Harmonised classification & labelling		
anthraquinone (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.
cadmium carbonate cadmium dihydroxide cadmium dinitrate (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSON	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
clethodim (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.
2,3-epoxypropyl methacrylate (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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.
3,3'dicyclohexyl-1,1'methylenebis(4,1-phenylene)diurea (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.
Reaction mass of: isomers of benzotriazoles & phenols (Tinuvin 171/571) (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.
silver zinc zeolite (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSON	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier. The Chairman to consider further mitigation measures as necessary.
hexaflumuron (ISO) (PT)	João CARVALHO	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
penthipyorad (ISO) (UK)	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.
nonadecafluorodecanoic acid (PFDA) and its ammonium and sodium salts (SE)	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSON	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier. The Chairman to consider further mitigation measures as necessary

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Annex IV (RAC-35)

Helsinki, 20 November 2015

RAC/35/2015/02

ROOM DOCUMENT

35TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

24 – 27 November 2015
1 – 4 December 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-34 Action Points

The RAC-34 action points due for RAC-35 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-34	20 November 2015	ongoing

2.2 RAC consultations (status by 20 November 2015)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
4,4'-methylenedimorpholine (MBM) (HH only)	10 November	closed
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (MBO) (toxicity to reproduction)	28 October 2015	closed
Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (HPT) (toxicity to reproduction)	28 October 2015	closed
medetomidine (HH only)	26 October 2015	closed
triadimenol (ENV only)	2 November 2015	closed
Nonadecafluorodecanoic acid (PFDA) and its amonium and sodium salts	29 October 2015	closed
penthipyorad (ISO)	2 November 2015	closed
hexaflumuron (ISO)	28 October 2015	closed
silver zinc zeolite	2 November 2015	closed
Reaction mass of: isomers of benzotriazoles and phenols (Tinuvin 171/571)	27 October 2015	closed
3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea	29 October 2015	closed
2,3-epoxypropyl methacrylate	2 November 2015	closed
clethodim (ISO)	29 October 2015	
cadmium carbonate	16 October 2015	closed
cadmium dihydroxide		
cadmium dinitrate		

Subject / document	Deadline	Status / follow-up
Application for Authorisation		
EDC 1: Members' consultation on application	30 September 2015	closed
Sodium chromate 1: Members' consultation on application	30 September 2015	closed
Sodium dichromate 1: Members' consultation on application	30 September 2015	closed
Chromium trioxide 1: Members' consultation on application	30 September 2015	closed
EDC 1: Members' consultation on the draft opinion	11 November 2015	closed
Sodium chromate 1: Members' consultation on the draft opinion	11 November 2015	closed
Sodium dichromate 1: Members' consultation on the draft opinion	11 November 2015	closed
Chromium trioxide-Kromatek: Members' consultation on conformity	18 November 2015	closed
Chromium trioxide-Grohe: Members' consultation on conformity	18 November 2015	closed
Chromium trioxide-Kromatek: Members' consultation on application	4 January 2016	ongoing
Chromium trioxide-Grohe: Members' consultation on application	4 January 2016	ongoing
Restrictions		
D4/D5 Second draft opinion	18 November 2015	closed
Methanol Revised draft opinion	18 November 2015	closed
TDFAs conformity check	16 November 2015	closed

2.3 Other written consultations of RAC (status by 20 November 2015)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-34	26 October 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	12 – 26 October 2015	25 CLH intentions / submitted dossiers – 12 volunteers
Applications for Authorisation – no calls		

Restrictions		
Call for expression of interest for rapporteurship for BPA in tab water	24 September - 23 October 2015	2 volunteers

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)	▪ Dibutylbis(pentane-2,4-dionato-O,O')tin ▪ Dioctyltin dilaurate ▪ P-cymene ▪ Imidacloprid (ISO) ▪ Ethylene oxide ▪ 2,2 dibromo-2-cyanoacetamide (DBNPA) ▪ Azamethiphos (ISO) ▪ Octhilinone (ISO) ▪ 1,4 dioxane ▪ Chlorphenapyr (ISO) ▪ Transfluthrin (ISO) ▪ Terpineol ▪ XTJ 568 ▪ Piperonyl butoxide ▪ Dodecyl methacrylate	13 November 2015	Closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.
Applications for Authorisation			
Appointment of the Rapporteurs for Chromium trioxide-Kromatek and Chromium trioxide-Grohe	chromium trioxide	-	Rapporteurs appointed
Restrictions – no written procedures			

2.6 Other written procedures

Other written procedures	Deadline	Report on the outcome