RAC/M/30/2014
Final
10 November 2014

Minutes of the 30th Meeting of the Committee for Risk Assessment (RAC-30) 8 – 12 September 2014

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 30th meeting of the Committee for Risk Assessment (RAC). Apologies were received from two members. The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting and informed members that the draft opinions of the following applications for authorisation were adopted via a written procedure earlier in the summer and therefore were removed from the agenda:

- uses 1 and 2 of the DEHP2a, DEHP2b and DEHP2c applications, and
- use 2 of DBP2.

The Agenda (RAC/A/30/2014) was adopted. The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. Thirteen members and two invited experts declared potential conflicts of interest, each to specific agenda items. In the event of a vote, these members were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Report from other ECHA bodies and activities

a) Report on RAC-29 action points, written procedures and other ECHA bodies

The Chairman informed the Committee that all action points of RAC-29 had been completed, or were on-going; noting that the publication of one adopted CLH opinion had been delayed but that this would be finalised and uploaded to the ECHA website as soon as possible. The summary of all consultations, calls for expression of interest in rapporteurships and written procedures is available in a meeting document on CIRCABC (see Annex IV). He also informed the Committee that the final minutes of RAC-29 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 9 September, and thanked those members who had provided comments on the draft.

b) RAC work plan for all processes

The Chairman presented the updated RAC work-plan for 2014 and Q1/2015, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances.

The Secretariat then gave a presentation on the potential impact of **Authorisations** expected in 2015 and 2016 and on how the Committee will manage to evaluate the steeply increased number of applications. A range of possible efficiency measures for dealing with authorisation applications was discussed, including amongst others: a reduction of the number of meetings at which a dossier would be tabled to a default of one full plenary discussion, with more difficult dossiers being tabled at 2 and only in exceptional cases 3 meetings; a key-issues paper was proposed for consideration at the conformity check of each application to give the Rapporteurs guidance from the Committee at the earliest possible moment; the possibility of setting up a risk management/exposure assessment working group to support the evaluations was discussed, and it was proposed to make access to document for members and rapporteurs as easy as possible bearing in mind the need for security and confidentiality. Some suggestions were made as to the evaluation of dossiers in the future, relating to: efficient grouping of similar dossiers, the level of scrutiny applied, more use of standard phrases and possible introduction of checklists of Operational Conditions and Risk management Measures.

The Secretariat agreed to continue to seek support for the members and the Committee in their work. Members expressed a desire to see some of the proposed changes already in place by the onset of the main set of applications on trichloroethylene in December/March. The Secretariat indicated that it would prepare a paper for the next meeting and would recommend appropriate changes to the relevant Committee working procedures.

c) General RAC procedures

The Chairman informed the Committee that in order to make working on the applications for authorisation easier for the members, the Secretariat had changed the way to handle encryption of the application files. The Secretariat would grant the members the same privileges as the Rapporteurs. This meant that member-encryption would now also allow commenting on and printing of documents; the Secretariat would no longer continue with separate encryption for Rapporteur's documents.

Members were informed that these changes will be implemented by the next date upon which a new application for authorisation will be uploaded for their attention.

The Secretariat also reminded the members about the declaration of confidentiality they have signed as members and when they obtained the passwords for the applications for authorisation encryption.

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

a) Tetrapropylphenol (TPP)

The Chairman informed the Committee about a new mandate from the ECHA Executive Director, based on a note from the Commission. The Committee is requested to review that part of the CLH proposal on tetrapropylphenol (TPP) related to setting of Specific Concentration Limits (SCLs), as originally submitted by Chevron Oronite SAS in February 2013 and adopted by RAC at its 27th meeting.

The Rapporteur summarised the mandate and the foreseen time plan for the preparation of the opinion pursuant to Art. 77(3)(c). Discussion and agreement on the opinion is scheduled for RAC 31.

b) Consumer exposure to benzene contained in natural gas

The Chairman informed the Committee about another new mandate from the Executive Director, based on a note from the Commission. Accordingly, the Committee is requested to

draw up an opinion on the consumer-related risk assessment contained in the RIVM Report 601352002/2013 "Risk assessment of an increased concentration limit of benzene in natural gas". The Rapporteur summarised the mandate and the foreseen time plan for the preparation of the opinion pursuant to Art. 77(3)(c) and in accordance with the RAC Framework relating to such requests. Plenary discussion and adoption of the opinion by RAC are foreseen for RAC-31.

6. Harmonised classification and labelling (CLH)

6.1 CLH dossiers

a) Methanol

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and a representative of the Dossier Submitter (DS). He reported that methanol is used in a variety of industrial applications, including waste water treatment, while its primary use is as a fuel. It has an existing Annex VI entry as a highly flammable liquid and minimum classifications for acute toxicity via all routes of exposure and STOT SE 1. The Dossier Submitter (Italy) proposed to add classification for developmental toxicity (Repr. 1B; H360D). The legal deadline for adoption of the CLH opinion is 28 April 2015.

The Rapporteur presented the DS proposal which was mainly based on effects in rats and mice as well as evidence of tail abnormalities from a study in rabbits and reduced pregnancy duration in Macaque monkeys. The rodent studies clearly showed severe developmental toxicity.

The discussion of the rodent studies focused on two main issues: 1) low potency of methanol-induced developmental toxicity effects in rodents and 2) the metabolic differences between rodents and humans which, according to the Rapporteur, did not enable a direct extrapolation to humans. The Rapporteur presented a comparison of the dose-metrics of blood methanol concentrations in humans *vs* rodents. It was noted that based on the comparison, significant developmental toxicity meeting the classification criteria would only be anticipated at doses which are expected to result in significant acute toxicity.

Studies in two non-rodent species (rabbits and Macaque monkeys, with metabolic pathways for methanol that are more similar to humans) were reported in the proposal. However, the rabbit study was not considered to be of adequate quality for drawing conclusions on developmental toxicity. Although it was agreed that the findings in Macaques were not adequate for classification, the doses used in the study were low (up to 1800 ppm) and resulted in low blood concentrations even at the highest dose. Industry responded that the monkeys did not tolerate a higher dose (2700 ppm) in a pilot study. The DS noted that it has not been proven that the developmental effects observed in rodents cannot affect humans and suggested that is a sufficient justification for the proposed classification.

In the discussion it was noted that known polymorphism in alcohol dehydrogenases in human populations would lead to more efficient metabolism of methanol in some populations.

Based on insufficient evidence for the relevance to humans of the findings in rodents, RAC agreed that no classification for developmental toxicity is warranted for methanol. RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee for their participation in the discussion.

b) Chloralose

The Chairman welcomed the Rapporteur and reported that Chloralose is used as a rodenticide in a slurry formulation and is presented as ready-to-use bait, at a concentration of 4 % (w/w). The substance currently has a harmonised classification in Annex VI of the CLP Regulation.

The Rapporteur informed members that the DS's (Portugal) proposal was to replace in the current entry Acute Tox. 4* (H302) with Acute Tox. 4 (H302), to maintain Acute Tox. 4* (H332), and to add STOT SE 3 (H336), Aquatic Acute 1 (H400) with M-factor of 10, and Aquatic Chronic 1 (H410) with M-factor of 10.

The Rapporteur presented the draft opinion and proposed to classify the substance for acute oral toxicity as Acute Tox. 3 (H301) and further proposed to provide no recommendation regarding acute inhalation toxicity because the single study on rats available was inconclusive for classification purposes. In addition, it was not known whether this study or other data led to the current classification of Chloralose for acute inhalation toxicity. The Rapporteur justified classification of the substance in STOT SE 3 (H336) based on available human data and also supported the DS's proposed classification on environmental effects. RAC members expressed their agreement with the assessment of the Rapporteur and the opinion was adopted by consensus.

In conclusion, the Chairman thanked the Rapporteur for presenting the case and the Committee for their participation.

c) N,N dimethylacetamide (DMAC)

The Chairman welcomed the Rapporteur and reported that DMAC is mainly used as a solvent and a reaction catalyst in the production of agrochemicals, pharmaceuticals and fine chemicals. It has a current entry in Annex VI of the CLP Regulation for toxicity to reproduction (Repr. 1B; H360D) with a Specific Concentration Limit (SCL) of 5% and for Acute toxicity 4 via dermal and inhalation routes. DMAC was identified by MSC as a SVHC. The DS (Netherlands) proposed to remove the SCL, therefore the general concentration limit (GCL ≥ 0,3%) would apply.

The Rapporteur presented the Dossier Submitters proposal for the revision of the SCL. According to the data provided (12 reprotox. studies in rat, mouse and rabbit, via oral and inhalation exposure) and in accordance with the Guidance for setting SCLs (November 2013), DMAC is a medium potency Cat 1B developmental toxicant and there are no modifying factors that would affect the potency group, therefore the GCL of 0.3% should apply.

RAC members supported the proposal and agreed to the removal of the SCL for toxicity to reproduction. RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee members for their participation in the discussion.

d) Acetochlor

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He noted that the pesticide active substance Acetochlor (ISO) was being tabled for a first plenary discussion and that it already had an entry in Annex VI to the CLP Regulation where it is classified as Acute Tox. 4* (H332), STOT SE 3 (H335), Skin Irrit. 2 (H315), Skin Sens. 1 (H317), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). The Dossier Submitter (Spain) had proposed the following modifications to the entry, namely as harmonised classifications as Carc. 2 (H351), Acute Tox. 4 (H302), Acute Tox. 4 (H332), STOT RE 2 (H373 (liver, kidney)), Skin Sens. 1 B (H317), M-factor =1000 for Aquatic Acute 1 and M=100 for Aquatic Chronic 1.

The Chairman informed the Committee about the state of play regarding the opinion development; the legal deadline for the adoption of the opinion is 4 June 2015.

The Rapporteur presented the draft opinion and reported that the DS' proposal for acute oral toxicity (Acute Tox. 4) was based on the lowest reported oral LD50 value (1929 mg/kg) in female rats. The other LD50 values were >2000 mg/kg, thus beyond the upper classification

limit. Since the data showed that there were 2/5 deaths at doses greater than 2000 mg/kg and because an independent calculation of the LD50 using the same data resulted in a value for female rats which was >2000 mg/kg, RAC concluded that no classification was warranted for acute oral toxicity.

The DS proposal for serious eye damage / eye irritation, was no classification. During RAC consultation, reservations had been expressed because eye irritation would also be expected where severe skin lesions had been observed in dermal irritation studies. However, based on the negative data from an acceptable eye irritation study, RAC concluded that no classification for eye irritation was warranted.

As to skin sensitisation, the Rapporteur reported that during RAC consultation the view was expressed that it was not possible to rule out classification as Skin Sens 1A because the possibility for a high response at lower induction concentrations of acetochlor than tested (100% and 10% in the Buehler and GPMT studies, respectively) cannot be excluded. Therefore RAC agreed on Skin Sens. 1 without sub-categorisation.

In relation to specific target organ toxicity after repeated exposure, the DS proposal was to classify for STOT RE 2 (H373; liver, kidney). RAC agreed that the kidney findings in the animal studies indicated that this organ should be included in the classification. However, findings in the liver should be considered as supportive only whereas the evidence for testicular toxicity in dogs was considered relevant for consideration of a classification for reproductive toxicity (fertility) only. Therefore, RAC concluded that acetochlor should be classified as STOT RE 2 (H373; kidney).

In relation to mutagenicity, RAC agreed with the DS proposal that based on the data presented in the dossier, no classification for germ cell mutagenicity was warranted.

In relation to carcinogenicity, the DS' proposal to classify as Carc. 2 (H351) was mainly based on evidence of nasal tumours in rats and to a lesser extent on lung and uterus tumours in mice. Human relevance of the nasal tumours (based on MoA) was then discussed. The Rapporteur presented the pathways associated with the metabolism of acetochlor in detail. The mechanism for the formation of nasal olfactory epithelial tumours was determined to be local cytotoxicity secondary to quinone imine formation. The data showed that human liver microsomes were capable of the EMA pathway which is involved in formation of the toxic intermediates. Since it was clear that tumours were formed in animals, RAC agreed that classification for carcinogenicity was warranted. Although it was considered reasonable to assume that nasal tumours could form in humans by a similar mechanism, there was uncertainty concerning the quantitative differences and therefore RAC concluded that classification of the substance as Carc. 2 (H351) was warranted. One RAC member stated that he would reserve the option of preparing a minority opinion, depending on the final wording in the opinion on this hazard class.

In relation to reproductive toxicity, the Rapporteur disagreed with the DS who had proposed no classification. Instead, the Rapporteur argued for classification as Repr. 2 (H361f) based on findings in the testes of dogs in the repeated dose toxicity studies and findings in a 2-generation study in rats. As the question about the testicular effects could not be concluded due to time constraints, the Chairman decided to return to the topic at the next RAC meeting in December 2014. He also indicated that at RAC-31, the chronic aquatic hazard would need to be completed.

e) Iodomethane

The Chairman welcomed the Rapporteurs and the expert accompanying the ECPA stakeholder observer and reported that iodomethane is used in the EU as an industrial and pharmaceutical

methylating agent and as an intermediate in pharmaceutical and pesticide manufacture. The substance currently has a harmonised classification in Annex VI of the CLP Regulation.

The Rapporteur informed members of the Committee that the DS's (United Kingdom) proposal was to remove the classification of Carc. 2 (H351) based on two carcinogenicity studies conducted after the current classification had been adopted (a 104 week inhalation study in rats and a 78 week feeding study in mice).

The Rapporteur presented the draft opinion. With regard to germ cell mutagenicity, RAC concluded, consistent with the conclusion of the dossier submitter, that no classification was required for this hazard class.

Concerning the classification for carcinogenicity, options to remove or to retain the current classification of iodomethane as Carc. 2 (H351) were presented. The Committee agreed that the evidence of tumours in organs other than the thyroid was weak and therefore the substance should not be considered as a multiple organ carcinogen.

The Rapporteur noted that the original classification was not based on thyroid tumours. The evidence for iodomethane exposure related thyroid tumour formation was not questioned by RAC. The discussion focused on both qualitative and quantitative differences in thyroid function between humans and rodents. The mechanism for tumourigenicity appeared to involve an increase in serum iodide concentration leading to decreased thyroid hormone levels and consequently increased thyroid stimulating hormone (TSH) levels, with the resultant chronic stimulation of the follicular cells of the thyroid eventually leading to tumour development. The thyroid was also a target organ for iodomethane in dogs.

RAC noted that in 1999, at a meeting of the Commission Group of Specialised Experts, some Experts had indicated that an increase of TSH in humans does not pose a significant concern regarding potential thyroid carcinogenesis in humans. However, taking into account more recent data on effects of prolonged TSH simulation in humans and on trends towards increasing thyroid cancer rates in humans, it was considered that the lack of significance to humans of the thyroid tumours seen in the animal studies was not adequately shown. The members considered that the conditions for non-classification (according to the CLP Regulation) were not met and agreed on retaining Carc. 2.

It was noted that the conclusions of the EU Specialised Experts from 1999 on how to deal with rodent thyroid tumours in the classification for carcinogenicity might need to be revisited.

The opinion was adopted by consensus. In conclusion, the Chairman thanked the Rapporteurs for presenting the case.

f) Heptadecafluorononanoic acid and its sodium and ammonium salts (PFNA)

The Chairman reported that PFNA (375-95-1) was primarily used as a processing aid for fluoropolymer manufacture, most notably for polyvinylidene fluoride. PFNA is also used as a lubricating oil additive, surfactant for fire extinguishers, cleaning agent, textile antifouling finishing agent, polishing surfactant, and in liquid crystal display panels.

He noted that the substance had no entry in Annex VI to the CLP Regulation. He reported that the Dossier Submitter (Sweden) had proposed the following harmonised classifications: Carc. 2 (H351), Repr. 1B (H360D), STOT RE 1 (H372 (liver)), Acute Tox. 4 (H302), Acute Tox. 4 (H332), Eye Dam. 1 (H318) and Lact. (H362).

The Rapporteur informed the plenary that the classification proposal was largely based on a read-across from ammonium pentadecafluorooctanoate (APFO), the ammonium salt of the homologue perfluorooctanoic acid (PFOA) for which RAC had adopted an opinion in 2012. The Committee agreed to this approach on grounds of structural similarity and physico-chemical

properties. Based on the read-across of the data from APFO, RAC agreed to the harmonised classifications, including Carc. 2, as proposed by the Dossier Submitter. However, it was decided to add thymus and spleen as target organs to the hazard statement for STOT RE 1, due to adverse effects on these organs observed in repeated dose toxicity studies with both APFO and PFNA. For the reproductive toxicity classifications, data from studies using PFNA was used (as described below), in addition to read-across from APFO.

With regard to reproductive toxicity, the Committee recognised that for APFO and PFOA, the conclusion had been no classification for fertility due to insufficient evidence from a 2-generation study. However, for PFNA three studies were available. One study showed small reductions in sperm motility and sperm count in the epididymis of F0 males. In this study, the test material was S-111-S-WB and the possibility was raised that components other than PFNA might have been more potent and therefore contributed to the findings to a greater extent than PFNA. However, CEFIC clarified that it was a mixture comprising 78% C6-C18 (mainly C9 as well as C8 and C7) and therefore relevant. In other studies, following PFNA treatment, an increase of serum testosterone level and decreased serum estradiol levels was seen in rats. Furthermore, with APFO, an increased frequency of spermatogenic cells with apoptotic features was seen in rats and increased frequency of abnormalities in sperm morphology and vacuolated cells in the seminiferous tubules of 129/sv wild-type (mPPARα) and PPARα-humanized (hPPARα) as well as reduced plasma testosterone concentrations in mice. The proposal for the classification of PFNA, PFN-S and PFN-A as Repr. 2 (H361f) was further supported by a human study of a group of 105 young adult men reporting for military draft in Denmark showing that higher serum concentrations of perfluoroalkyl acids (PFAAs) was significantly associated with reduced numbers of normal spermatozoa. RAC concluded that taken together, the effects seen with APFO together with the effects observed in the studies where PFNA was a component were sufficient to warrant classification as Repr. 2 for adverse effects on sexual function and fertility.

As to developmental effects, two developmental toxicity studies on effects of PFNA in mice were considered by the Committee. The studies demonstrated that exposure of mice to PFNA during gestation resulted in reduced pup viability, pup body weight gain, delays puberty as well as onset of eye opening, and also induced full litter resorptions/loss at high doses. In general, the developmental toxicity findings following exposure to PFNA in mice were similar to those seen with APFO. Therefore, RAC agreed to classify PFNA as Repr. 1B (H360D).

RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee members for their participation in the discussion.

g) Copper compounds (human health hazards)

Tribasic copper sulphate, Copper oxychloride, Copper powder (copper flakes coated with aliphatic acid), Copper thiocyanate, Bordeaux mixture, Basic copper carbonate, Copper (II) oxide, Copper (II) hydroxide, Copper (I) oxide (dicopper oxide), Copper sulphate pentahydrate

The Chairman welcomed the experts accompanying the EUROMETAUX and CEFIC stakeholder observer as well as representatives from the Dossier Submitter (France) who followed the plenary discussion via remote connection. The Chairman reported that opinions needed to be adopted for ten copper compounds, the deadline for adoption being 17 June 2015. The substances were used as active substances in biocides and plant protection products; accordingly all hazard classes would have to be evaluated and discussed. While only three copper compounds had an existing Annex VI entry (dicopper oxide, copper thiocyanate and copper sulphate pentrahydrate), the Dossier Submitter had proposed a range of harmonised classifications both in relation to human health and the aquatic hazards.

The Chairman clarified that at the RAC-30 plenary meeting, only the human health hazards would be discussed, while a debate about the aquatic hazards was foreseen for RAC-31 in December 2014.

The Rapporteur presented the draft opinion. In relation to most of the copper compounds, the evaluation of the hazard classes acute toxicity (all routes), STOT SE, skin corrosion/irritation, eye damage/irritation and skin sensitisation, the classification proposals were agreed for these hazard classes as shown in Table 2 of the Annex. Some further discussion on eye damage/irritation for dicopper oxide and the coated copper flakes as well as acute inhalation toxicity for copper dihydroxide and the coated copper flakes took place.

In relation to dicopper oxide, RAC recognised that persistent eye effects were observed in various animals and classification as Eye Dam. 1 (H318) was considered more appropriate than Eye Irrit. 2 (DS proposal). As to eye effects of the coated copper flakes, RAC agreed to classify as Eye Irrit. 2 (H319) following correct application of the classification criteria to the corneal opacity findings.

With regard to the acute inhalation toxicity of copper dihydroxide, the Committee agreed to classify as Acute Tox. 2 (H330) based on the lowest available LC_{50} of 0.5 mg/l observed in a whole-body study. An independent recalculation using the lethality scores in this study showed that the actual LC_{50} was < 0.5 mg/l. While a nose-only study reported an LC_{50} value within the range of 0.205 < LC_{50} <1.08 m/l, the lethality scores were similar to the whole-body study and no large differences in LC_{50} values should be expected. In relation to the coated copper flakes, it was clarified that the coated flakes have to be considered as a specific form of copper. The aliphatic acid coating was considered very unlikely to contribute to the toxicity. One Industry expert noted that the differences seen in the two acute inhalation toxicity studies could be explained by the different particle size of the material tested and that the negative Leuschner study (2011) used material more representative of what is currently on the market. The Rapporteur replied that this did not negate the results from the positive study (Wesson 2001), so Acute Tox. 3 (H331) was proposed. The Committee agreed to this classification.

For the endpoints of STOT RE, carcinogenicity, mutagenicity and reproductive toxicity, the dossier submitter proposed no classification based on read-across from negative studies using mainly copper sulphate pentahydrate.

In relation to mutagenicity and reproductive toxicity, it was agreed that read-across from the most soluble copper compound, copper sulphate pentahydrate, was valid for seven other copper compounds. Some members felt that copper thiocyanate should be excluded from this read across due to the potential toxicity of the anion. It was noted that for the thiocyanate anion, there were no data in the dossier reflecting its toxic properties. Therefore, the information available in the CLH report did not allow for a conclusion on whether read-across was appropriate for this copper compound.

In relation to STOT RE and carcinogenicity, it was recognised that the information available in the CLH report did not allow for a conclusion on whether read-across was appropriate, particularly for the inhalation route as differences in particle size and solubility may for instance impact local toxicity. No classification was therefore concluded based on lack of data.

The Chairman summarised the conclusions taken by the Committee and thanked the Rapporteur for the presentation of the arguments and the RAC members for the careful discussion.

6.2 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.

7. Restrictions

7.1 Restriction Annex XV dossiers

a) Opinion development

1) Cadmium and its compounds in paints – 4th version of the draft opinion

The Chairman welcomed the DS representatives (ECHA) and the SEAC Rapporteurs, who joined the meeting. The Chairman reminded the Committee that this was a technical amendment to an existing restriction at the request of the Commission. The Chairman stressed that the discussion should focus on the main elements presented by the Rapporteurs in order to adopt the opinion at this meeting. Following the end of the public consultation in June 2014, the RAC Rapporteurs had not made any changes to the draft opinion. The Commission restated their position that the proposed restriction was the most appropriate route to proceed with the amendment of the restriction proposal.

After the presentation on the draft opinion by the RAC Rapporteurs, with the support of the members, the Chairman concluded that RAC adopted its opinion on Cadmium and its compounds in paints by consensus.

The Secretariat will forward the adopted opinion and its supporting documentation to SEAC, and publish the adopted opinion and its supporting documentation on the ECHA website. The Chairman thanked the Rapporteurs for their presentation of the arguments and the Committee for their participation in the discussion.

2) Cadmium and its compounds in artist paints – 1st version of the draft opinion

The Chairman welcomed the DS representatives (Sweden, remotely), the SEAC Rapporteur and an industry expert accompanying the Eurometaux stakeholder observer. He introduced the topic by informing the Committee that over 600 comments had already been received in the public consultation, many from artists who are against the proposed restriction but there was also some support expressed. He then asked the RAC Rapporteurs to present their first version of the RAC opinion. Their presentation focused on the proposal that RAC would base its opinion on the relevant EFSA assessments (2009, 2012), with a focus on kidney effects as they indicated at the previous meeting in June.

Members restated their concerns as already expressed at RAC 29 regarding the need for caution when translating exposure to risks as well as the uncertainties in the assumptions contained in the proposal. RAC questioned the severity of the kidney effects and whether they were actually adverse effects and asked the Rapporteurs to instead focus on assessing the bone fractures and breast cancer cases. Some members suggested that the EFSA opinion needs to be looked at in more detail, as well as dealing with any discrepancies with a previous WHO opinion. There was support for using the EFSA report as the starting point for the opinion (i.e. using the principle that any further exposure to Cd should be avoided) but with further explanation/justification.

With regard to the 'humans via the environment' exposure scenario proposed by the DS, RAC discussed the use of release factors of 1% or 5% concluding there was some evidence for

using 5%, but either factor could be used. RAC also discussed the 1/8 volume of the brushes assumed to be full of paint at the end of a painting session, which is not based on modelling but on a calculation by the DS. RAC observed that oil based colours would have in general a lower release to waste water in comparison to the water based paints, due to different methods applied to clean brushes and palettes (involving solvents such as turpentine). Paint residues generated from the cleaning with solvents could also be treated differently (as hazardous waste) by painters. Among the water based paints, acrylics need specific handling due to their fast-drying properties and they may not provide the same release as the other water based paints.

It was felt that the average concentration of Cd in the paints needed further consideration as the main evidence in the dossier results from measurements made in Sweden which are then assumed to be applicable to the whole EU.

There was continued support from RAC for the Gustafsson study (2013) as a good basis for the relevant part of the exposure assessment. The Rapporteurs were advised by RAC to focus on the plausibility of the exposure scenario in the light of the uncertainties in the underlying assumptions. Some members felt that the significance of risks should also be considered. The Committee also agreed that it would be appropriate to examine alternative risk management options, e.g. labelling[1].

RAC also discussed the question about the long term sludge protection effect and industry committed to submit further information on this via the Public Consultation.

Furthermore, industry informed the Committee that they have extensive EU-wide biomonitoring data that show that the current exposure of Cd to the general population is not exceeding health limits in EU while Cd levels in soil are decreasing; industry confirmed this information was submitted to the public consultation.

In summary, the Chairman requested the Rapporteurs to take the RAC-30 discussions and the comments received from the public consultation into account in the revised draft opinion (due by end of October 2014). He then requested RAC members to come forward as volunteers to support the Rapporteurs in the opinion development, especially to help analyse the bone and breast cancer effects.

3) Chrysotile - 1st version of the draft opinion

The Chairman informed the Committee of the state of play regarding the opinion development on the amendment of the derogation to an existing restriction designed to phase out the last uses (two companies) of Chrysotile in the EU. Subject to final public consultation comments, RAC was invited to agree on the main elements as proposed by the RAC Rapporteurs.

The Rapporteurs then presented the first version of the draft opinion to RAC, expressing their support for the proposed risk management option 2 (i.e. derogation with a fixed end date) but proposing to remove the explicit opportunity for another review after 2025. RAC debated the need for another review as alternatives are still in the testing phase and asked the Rapporteurs to keep to the original wording of the restriction but to include a concern for not allowing a review in the justification of the opinion. Regarding the proposal by the Rapporteurs to delete the reference to the maximum level by the German Authorities and keep to the exposure and corresponding risk level, RAC preferred a dual approach (i.e. both national standards as well as the limit value). RAC also supported the Rapporteurs in terms of the grading of RMOs. The Rapporteurs were asked to provide more justification on RMO4.

[1] The Secretariat notes that such an option was not contained in the DS proposal.

In general, stakeholder comments related to the shortening of the end date or removing the derogation (a total ban on asbestos). One stakeholder restated their questions on why the effects of the whole lifecycle of asbestos (including outside EU) are not taken into account in the opinion development and why importing asbestos fibres is not registered according to Article 2(7) of REACH Regulation. The Secretariat responded that RAC's mandate only covers an EU wide action and the exemption from the obligation to register asbestos is due to the fact that asbestos is a mineral, therefore it is exempted based on Annex V (7) of REACH Regulation. The Commission observer pointed out the appropriate role of the Committee i.e. RAC should focus on assessing the risks of the proposed restriction. It was furthermore pointed out, that the concerns raised by the stakeholder observers will be discussed more in detail in other fora, such as the REACH Committee.

The Chairman gave then the floor to the CEFIC expert to answer detailed questions addressed to him by members and to provide RAC with information on the procedures for exposure measurement and inspection by the German authorities. In addition, the CEFIC expert restated that Dow had made a voluntary commitment to the German authorities to stop import of fibres from 2017; the two years were needed to ensure the quality of stocks were sufficient for any further internal usage.

In summary, the Chairman concluded that the Rapporteurs should take the RAC-30 discussions and the comments received from the public consultation into account in the revised draft opinion (due by end of October 2014).

4) Isopropylidenediphenol (Bisphenol A) – first plenary discussions on the key issues document

The Chairman welcomed the DS representative (France) and the SEAC Rapporteurs, who joined the meeting. The Chairman introduced the topic by informing the Committee that the restriction dossier submitted by France passed the conformity check in June. The Committee is expected to provide sufficient feedback to enable the Rapporteurs to formulate a first draft opinion.

The RAC Rapporteurs presented the key issues regarding the human health hazard assessment.

Several members stressed that there are large differences on various aspects between the restriction proposal and opinions on bisphenol A among other European bodies (EFSA and SCOEL), which results in different orders of magnitude in the risk characterisation. Concerns were expressed that differences in the selection of key studies should not result in a deviating opinion of RAC.

Several members expressed the view that to allow for an independent assessment by RAC, a more detailed justification for the selection of the key studies per endpoint would be needed, including a discussion on negative results in studies that assessed the same endpoints as well as information on study reliability.

A discussion followed on each of the four endpoints identified in the restriction proposal.

Regarding the female reproductive system, one member voiced agreement with the shortcomings of the study by Rubin et al. (2001) as presented in the EFSA opinion of 2006: the study did not specify whether the ovarian cycle was longer or shortened and it is therefore difficult to conclude based on this study that there is a disruption of the cycles.

Regarding the mammary gland, members agreed with the Rapporteur that the connection between the observed changes and an increased susceptibility for cancers merits further assessment. A member mentioned that EFSA's draft opinion did not base its conclusion for this endpoint on the study by Moral et al. (2008), but on a weight of evidence.

The industry stakeholder and some members stressed the importance of including the US FDA/NCTR (Delclos et al. 2014) subchronic toxicity study also in the assessment of the mammary gland changes and the effects on the female reproductive system.

With respect to the effects on brain and behaviour, members noted they needed a more detailed discussion on the available studies; there is a large amount of data regarding effects on brain and behaviour but that the data is not consistent. Several members and the industry stakeholder supported the conclusion in EFSA's draft opinion of 2014 that due to methodological shortcomings in the evaluated studies the effects were not considered likely when using a WoE approach.

Concerning the evaluation of the critical effects on metabolism and obesity, RAC supported the conclusion of the Rapporteurs that the studies are not sufficiently convincing to set a NOAEL.

The Chairman then opened the discussion on the selection of Assessment Factors (AF). Several members were of the opinion that it was too premature to discuss the AF LOAEL to NAEL extrapolation. Members did not support the use of an Assessment Factor of 10 for intraspecies differences for workers. Regarding the interspecies AF, it was stressed that the species need to be considered as well as the evidence on toxicokinetics. Reference to the draft EFSA opinion of 2014 was made in this respect.

The Rapporteur presented the key issues identified in the exposure assessment, mainly highlighting oral bioavailability data, the assumptions regarding dermal absorption rates and flux, and the biomonitoring data.

Several members were of the opinion that further assessment was needed on dermal absorption. A member questioned the reliability of the Biedermann study, and considered 27% dermal absorption to be very conservative. It was highlighted that biomonitoring simulation experiments with thermal paper were carried out by Ehrlich et al. (2014) and Porras et al. (2014) and provide important information which needs to be compared with results from exposure modelling.

An NGO Stakeholder stated that the authors of the US FDA/NCTR (Delclos et al. 2014) subchronic toxicity study had recognized contamination of their controls. Therefore the results of the low dose exposure of this study should be considered with caution. The Stakeholder also stated that given that the health effects of BPA included in the restriction dossier were endocrine mediated, BPA should be considered by default a non-threshold substance.

The Chairman stressed that the March plenary meeting is reserved to discuss the technical details and the final streamlining of draft opinion, thus agreement needs to be reached in RAC on most of the issues at the next plenary meeting, scheduled for the end of November. The severity of effects needs to be discussed and RAC expressed the need for a better analysis of the selection of key studies, also taking into account negative studies in the weight of evidence. The severity of effects needs to be discussed, and a reasoned selection of AFs needs to be presented where appropriate for each endpoint separately. A comparison with other opinions such as from EFSA needs to be made. Lastly, further analysis of dermal absorption is needed and the exposure assessment in general needs to be strengthened to be ready for agreement.

5) Ammonium salts – first plenary discussions on the key issues document

The Chairman welcomed the dossier submitter representatives (France). He reminded the participants that this restriction dossier, submitted within Article 129 of the REACH Regulation (safeguard clause), had passed the conformity check in RAC and SEAC in June 2014. The RAC initial commenting round on the dossier finished on 11 July with no comments received from the Committee members.

The RAC Rapporteurs presented the key issues document to RAC. With regard to the human health hazard assessment, they recommended the Committee to focus on the released ammonia as a hazardous substance (and not on the ammonium salts), as well as on acute/sub-acute exposure (rather than on chronic exposure). They suggested to focus on respiratory tract irritation, as in their view there was not sufficient evidence in the dossier of *de-novo* genesis of respiratory tract sensitisation and induction of asthma. The Rapporteurs, however, recommended RAC to further consider hyper responsiveness and asthma in particularly sensitive population groups in the context of this hazard assessment. They also expressed the view that odour threshold, and resulting annoyance, is not considered harmful to health. The Rapporteurs then listed the key studies described in the dossier and explained the derivation of the DNEL.

With regard to the exposure assessment, the Rapporteurs pointed out that the main factor affecting exposure is the relative humidity (RH), with cellulose insulation loading rate also playing a potential role. The Rapporteurs were interested in knowing whether RAC supported the current approach proposed by the dossier submitter that the loading rate for testing compliance depends on the thickness and density of the used material. The Rapporteurs were generally satisfied with the approach of the dossier submitter that a RH of 90% in the living area is not justified even for the worst case scenario as the single maximum value recorded in the French study was 80% RH. They were interested whether RAC agrees that a value closer to the 95% percentile RH (67%) should be used, i.e. 70% RH. One RAC member pointed out that RH depends on season and weather conditions and asked whether the French data covers different seasons. The Rapporteurs agreed to investigate the issue further and try to find more data.

The Rapporteurs also sought the opinion of RAC whether the existing evidence justifies the claim that ammonia gas released from the cellulose insulation was the probable origin of the health effects seen in the recorded cases; whether RAC considers that a group entry is acceptable; and whether RAC supports the conclusion of the Rapporteurs that it is not possible at this point in time to define a concentration limit in cellulose insulation above which the salts should not be added. The Committee agreed with all the Rapporteurs' conclusions. The Secretariat provided input on how the structure of ammonium salts may impact their behaviour upon hydration. RAC agreed with the general conclusion that a group entry is justified considering the similar "stability behaviour" of the inorganic ammonium salts used in these cellulose applications as well as the current approach that a "safe" concentration limit of ammonium salts cannot be established.

Finally, the Rapporteurs informed the Committee that the Commission had been asked to clarify why the current Construction Product Regulation (CPR) cannot serve as an alternative legislative framework than REACH so as to regulate the cellulose insulation treated with ammonium salts. The Commission then explained that the CPR mainly aims to harmonise the test methods performed on products and to ensure that the product performances reached and declared by manufacturers are calculated using the same test methods. The prohibition or limitation of certain components in construction products is not the main aim of the CPR but left to be regulated by MSs or other EU legislation (e.g. REACH).

RAC agreed on the main elements presented by the Rapporteurs. The Chairman informed that the Rapporteurs will need to deliver their first draft opinion on this dossier by the end of October (to be discussed at RAC-31).

b) Conformity check

1) Methanol - outcome of conformity check

The Chairman welcomed the dossier submitter representatives (Poland) and the SEAC Rapporteurs. The Chairman reminded the Committee that the dossier on methanol was submitted by Poland to ECHA on 1 August 2014. The conformity check process was launched in RAC and SEAC on 14 August and the Committees were expected to reach a conclusion on conformity.

The representative of the dossier submitter provided an introductory presentation on the proposal to restrict methanol. The proposed restriction is aimed to prevent poisoning cases in consumers resulting from oral exposure to methanol or mixtures containing methanol such as windshield washing fluids and technical ethanol used as a fuel for touristic appliances or as a cleaning agent.

The RAC Rapporteurs then presented the outcome of the RAC conformity check and recommended that the dossier should be considered not in conformity. The RAC Rapporteur stated that more information is needed to allow an independent assessment of the hazards, more information is needed on the substance uses within the scope of the proposal other than the misuse of windshield fluids containing methanol, and more information is needed to assess the risks arising from these uses and the effectiveness of the proposed restriction.

Several members voiced support to the Rapporteurs' conclusions. In addition, some members recommended further information on the non-lethal effects of methanol, consideration of a non-DNEL approach to the lethal effects and on the risks arising from consumer exposure to non-lethal oral doses.

The Chairman concluded that the Committee supported the Rapporteurs' conclusion for non-conformity.

2) DecaBDE - outcome of conformity check

The Chairman welcomed the DS representatives (ECHA) as well as the Norwegian representatives (who followed the discussions remotely) and the SEAC Rapporteurs. He informed the participants that the restriction dossier on decaBDE had been submitted by ECHA on 1 August 2014, on request by the Commission. The Norwegian Environment Agency has collaborated with ECHA in the preparation of the restriction dossier. DecaBDE was identified as an SVHC and included in the Candidate List as PBT/vPvB. DecaBDE exhibits a widespread occurrence in the environment and in wildlife. This bromine saturated diphenyl ether debrominates in the environment to lower homologues which are PBTs/vPvBs or act as precursors to substances with PBT/vPvB properties. In addition to PBT/vPvB concerns, other potential impacts of exposure to decaBDE may result in neurotoxicity in mammals, including humans. The proposal focuses on the hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles.

The RAC commenting round finished on 25 August with no comments received from the RAC members. The representative of the DS provided a presentation on the main elements proposed in the dossier. The RAC Rapporteur then presented the outcome of the conformity check and the recommendations to the DS and informed the Committee that the dossier is in conformity from the RAC point of view.

The Committee agreed that the dossier conforms to the Annex XV requirements. The Chairman informed that SEAC will conclude on the conformity of this dossier at SEAC-24 next day. If the dossier will be considered in conformity by both Committees, the public consultation on the dossier will be launched on 17 September.

7.2 Appointment of Rapporteurs for restriction dossiers

The Secretariat presented the proposed Rapporteurs for the restriction dossiers Grill lighters fluids and fuels for decorative lamps labelled R65 or H304 (to be submitted by ECHA), and Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) (to be submitted by United Kingdom), as outlined in the meeting document RAC/30/2014/04 RESTRICTED.

The agreement on the appointment of Rapporteurs will follow later in 2014. RAC took note of the pool of Rapporteurs for the restriction dossiers which will be submitted to ECHA in the first half of 2015.

8. Authorisation

8.1 General authorisations issues

a) RAC and SEAC working procedure "fit-for–purpose" applications for authorisation

The Chairman invited the Secretariat to give an oral update on the streamlined AfA approach for special cases and the task force that has been established to help develop this approach. The task force was initiated at the CARACAL meeting on 8-9 July where the Commission agreed with the Member States that a task force would be set up with representatives from ECHA, the European Commission, RAC, SEAC and Member State Competent Authorities. An initial meeting of the task force took place on 26 August via teleconference, mainly to discuss the organisation of the work and to have a first exchange of views on how applications for low volume and spare parts uses could be dealt with. The task force's first set of recommendations would be on the agenda for the next CARACAL meeting, which will take place on 12-13 November. The representative of the Secretariat also informed the Committee about the "Lessons Learned on Applications for Authorisation" workshop/conference planned for the beginning of next year.

8.2 Authorisation applications

The Chairman announced that the discussion on the first version of the draft opinions would take place in an observed session, i.e. with Stakeholder Observers present. However, in the unlikely event that confidential business information needed to be discussed, he would close the session as a precaution. He reminded the participants, including Stakeholder Observers of the need to keep the discussions on the applications confidential.

Please note that the sequence in which the applications are described in the minutes may differ to that in which dossiers were handled and agreed in the Committee. This is due to the similarities in several of the uses between applications, which were thus discussed in a consecutive order.

a) Authorisation application on phthalates – 3rd version of the RAC draft opinions (applications submitted within the August 2013 submission window)

1. One use of DEHP submitted by DEZA a.s. (DEHP 2c):

   Use 3 Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

NOTE: *Due to the similarities of the applications, DEHP2c use 3 was discussed together with DBP2 use 3.*

The Chairman informed the Committee of the state of play regarding the DEHP2c use 3 application and invited the Rapporteurs to present the main conclusions of the second version of the draft opinion. It was noted that the DEHP2c use 3 application did not include any information on the production of capacitors, therefore the authorisation (if granted) should not cover the production of capacitors and that this should be reflected in the opinion/justification.

The Rapporteurs mentioned that the applicant had used different DNELs for the different uses in the DEHP2c application, but that for use 3 the RAC reference DNELs[2] had been used. The Rapporteurs concluded that the exposure was adequately described and assessed by the applicant. According to the Rapporteurs' assessment, the highest combined RCR for DEHP for both routes of exposure of workers was 0.10. Therefore, they proposed to RAC that the risk is adequately controlled.

The discussion continued on the combined exposure to DPB and DEHP as the applicant provided a combined risk assessment and had indicated that these substances are used in the same mixture. The Secretariat noted that as the applicant had submitted separate applications for DEHP and DBP, formally RAC should provide an opinion on the risks from the use of DEHP and DBP separately.

RAC members supported the Rapporteurs' conclusion that risks for workers from this use of DEHP are adequately controlled. On request by some members a statement was added to the justification to the opinion, clarifying that in assessing the risk arising from the use of DEHP in ceramic sheets and printing pastes for production of lambda sensor elements RAC cannot address exposure to DEHP from other uses (i.e., background consumer exposure) and exposure to other phthalates in the same mixture (including DBP for which the applicant provided a combined risk assessment).

The Chairman concluded that RAC considered that the risk is adequately controlled and there is no need to recommend additional conditions and monitoring arrangements. In addition, RAC agreed that there is no need to advise SEAC on the length of the review period.

RAC agreed with the draft opinion by consensus. The Chairman thanked the Rapporteurs and the ECHA Authorisation team for their work on the application for authorisation.

2. One use of DBP submitted by DEZA a.s. (DBP 2):

   Use 3 Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

The Chairman informed the Committee of the state of play regarding the opinion development and invited the Rapporteurs to present key issues. Due to the similarities in the applications, this use was discussed together with the DEHP2c use 3.

On DBP2 use 3 the Rapporteurs presented the main conclusion of the draft opinion separately for the Exposure Scenario: Lambda sensors (ES 1) and the Exposure Scenario 2: Capacitors (ES 2).

Concerning ES 2 the Rapporteurs concluded that the exposure of the workers is adequately described, but they found that the combination of Worker Contributing Scenarios proposed by the Applicant required further justification. Therefore, they based their assessment on a more plausible combined exposure. The highest combined RCR for workers for both routes was 0.59, which results in the conclusion that for this specific use of DBP the risk is adequately controlled. RAC supported the Rapporteurs' conclusions.

[2] See RAC/24/2013/08 rev. 2, agreed at Helsinki, 12 April 2013.

For ES 1 (lambda sensors) the Rapporteurs applied the same approach as for the ES 2 and they proposed more plausible combination of the Worker Contributing Scenarios than the Applicant. According to the Rapporteurs the assessment of the highest combined RCR for workers for both routes was 0.95. Therefore, they proposed to RAC the conclusion that the risk is adequately controlled. RAC members supported the Rapporteurs' conclusion but they asked to add to the justification of the opinion clear arguments on why the estimated exposure for workers was considered by RAC as conservative and most likely overestimating the actual exposure. The Chairman proposed to move relevant text concerning overestimation from the Annex I of the draft opinion which was accepted by RAC. In addition, some members asked for a clear statement that RAC could not address potential exposure to DBP from other uses (i.e., background consumer exposure). RAC agreed with the additional text proposed by the Rapporteurs which in addition to background consumer exposure considered that RAC cannot address exposure to other phthalates in the same mixture, including DEHP for which the applicant provided a combined risk assessment (See above discussion on DEHP2c.).

The Chairman concluded that for both exposure scenarios RAC supported the conclusions that the risk is adequately controlled and there is no need to recommend additional conditions and monitoring arrangements. In addition, RAC agreed that there is no need to advise SEAC on the review period.

RAC agreed with the draft opinion by consensus. The Chairman thanked the Rapporteurs and the Authorisation team for their work on the application for authorisation.

b) Authorisation application – 2nd outline RAC draft opinions (applications submitted within the November 2013 submission window)

1. The use of diarsenic trioxide submitted by Boliden Kokkola Oy (Diarsenic trioxide 1):

   Use 1 Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process

2. The use of diarsenic trioxide submitted by Nordenhamer Zinkhütte GmbH (Diarsenic trioxide 2):

   Use 1 Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process

Due to similarities in the applications for Diarsenic trioxide 1 (Boliden Kokkola Oy) and 2 (Nordenhamer Zinkhütte GmbH), the cases were presented and discussed together. The Chairman invited the RAC Rapporteurs to present the cases and main conclusions of the draft opinions.

RAC members asked for clarification which type of information is required from them by SEAC in case of an application for authorisation for the use of a non-threshold substance based on the Socio-economic route. The Rapporteur was of the opinion that SEAC needs an estimation of number of cancer cases and was supported by the Secretariat. RAC however expressed a preference to communicate (individual) cancer risk levels, not cancer cases.

RAC members pointed out that in this case the risks for workers are on a similar (relatively high) level compared to the risk form exposure of man via environment (also supported by the biomonitorig data). However, the low number of workers involved prevented it from resulting in higher estimated numbers of cancer cases.

Some RAC members considered that the exposures could be considered high in case workers do not use Personal Protection Equipment (PPE) and suggested for future cases that the exposure should always be presented with and without PPE.

The Rapporteurs informed RAC that, they had presented the worst case scenario for workers and that the applicant had informed them that the workers always use PPE (gloves). However, RPE is not required under all workers contributing scenarios. Furthermore, tasks are not always performed for a full 8 hours which is not considered in the risk assessment.

The Chairman concluded that taking into consideration the above mentioned arguments RAC agreed that the Operational Conditions (OC) and Risk Management Measures (RMM) appeared to be appropriate in reducing the risk as proposed by the Rapporteurs and the applicant and given some of the uncertainties in the exposure assessment that a short review period should be recommended to SEAC and the Commission.

In the event of a future application to review this authorisation, the Committee requested a better description of the tasks of workers and an improved risk estimate for both workers and man via the environment as a condition.

RAC agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs and the Authorisation team for their work on the application for authorisation.

3. Two uses of diarsenic trioxide submitted by Linxens France (Diarsenic trioxide 3):

   Use 1 Formulation of diarsenic trioxide into a mixture

   Use 2 Industrial use of diarsenic trioxide as processing aid in gold electroplating

The Chairman informed the Committee of the state of play regarding the opinion development and invited the Rapporteurs to present the key issues.

Following the Rapporteurs' presentation, RAC members discussed differences in the exposure values between two uses. They commented that for better understanding of the process a more precise description of the uses would be helpful. Moreover, they preferred to see exposure data presented with and without Personal Protection Equipment (PPE). Some of the members were of the opinion that biomonitoring data should be used to verify model calculations. The Rapporteurs replied that differences in exposure values were due to the different character of the uses (formulation and industrial use), different time period and frequency of tasks and different concentration of the substance used. The biomonitoring data confirmed that there is no high exposure and the working instructions for workers obliged them to use gloves all the time. A presentation of the exposure data without PPE would not provide any useful information for the risk assessment.

Furthermore some RAC members pointed out that the (presumed) cancer cases are an illustrative estimate for the purposes of the SEA only.

The Commission asked RAC to provide in the justification a list of the identified uncertainties but to avoid duplication of the information submitted in the application.

The Chairman concluded that the current OC and RMM are appropriate in reducing the risk, so there is no need to recommend additional conditions or monitoring arrangements. In addition, RAC agreed that there is no need to advise SEAC on the length of the review period.

RAC agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs and the Authorisation team for their work on the application for authorisation.

4. Six uses of lead sulfochromate yellow (C.I. pigment yellow 34) and lead chromate molybdate sulphate red (C.I. pigment red 104) submitted by DCC Maastricht B. V. OR (Lead chromate pigments 2):

   Use 1 Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use

   Use 2 Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)

   Use 3 Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking

   Use 4 Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use

   Use 5 Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use

   Use 6 Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking

The Chairman invited the Rapporteurs to present the second version of the draft opinions.

The Committee expressed its appreciation for the extensive work completed by the Rapporteurs on evaluating the exposure assessment. Several RAC Members raised questions regarding the effectiveness of the personal protective equipment (which seemed to offer unusually high levels of protection), other risk reduction measures described for the different uses in the application for authorisation, as well as combined exposure. RAC agreed that RMM are appropriate for reducing the risk of Chromium.

The Committee also discussed the length of the review period as a recommendation to SEAC but did not come to a conclusion at this time.

Two members queried the exposure to lead noting that the reference values used by the applicant are different from the reference values used in the RAC restriction on lead in consumer products, examined earlier by the Committee and asked for further development of the opinion with respect to lead in the workplace.

The Chairman requested the Rapporteurs to modify the second version of the RAC Draft Opinions according to the discussion both in the plenary meeting as well as in the break-out group and to submit the third version of the RAC Draft Opinions, which would then be launched for a RAC Consultation.

c) Authorisation application – 1st outline version of RAC draft opinions (applications submitted within the February 2013 submission window)

1. Two uses of HBCDD submitted by INEOS Styrenics Netherlands B.V., INEOS Styrenics Ribecourt SAS, INEOS Styrenics Wingles SAS, Synthos Dwory 7 spóka z organiczon odpowiedzialnoci spóka komandytowo-akcyjna, Synthos Kralupy a.s., StyroChem Finland Oy, Monotez SA, RP Compounds GmbH, Synbra Technology bv, Sunpor Kunststoff GmbH, Dunastyr Polystyrene Manufacturing C. Co. Ltd, versalis SpA and Unipol Holland bv (HBCDD 1):

Use 1 Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications).
Use 2 Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications.

The Chairman informed the Committee of the state of play regarding the opinion development for the two uses of HBCDD applied for and reminded members that as agreed at RAC 29, the Secretariat is in contact with Commission services in order to clarify the relevance of human health exposure assessment (specifically for workers) in the context of PBT substances; these discussions are still ongoing. However, he noted that RAC needed to proceed with this dossier without delay and had therefore been requested by the Commission to justify in the opinion why worker exposure had not been considered.

The RAC Rapporteurs then presented the first draft outline of the opinion documents to RAC. The Rapporteurs noted that due to the PBT nature of the substance, RAC cannot readily translate emission estimates into impacts. In addition to the uncertainties of emission estimates (CSR exposure modelling), the impact assessment does not address actual distribution of releases and impact dependency on initial concentrations in the receiving compartments. The Committee was informed that these gaps most likely could not be solved in the near future and that the emission amount alone is an improper indicator for the remaining risk/impact.

The Chairman opened the floor for discussion and the Rapporteurs provided further clarifications to members in particular on the Voluntary Emission Control Action Program (VECAP) which lies at the heart of the calculation of emissions. In particular, the Rapporteurs mentioned that the emission data provided by the applicants is based on the assumption that all applicants are in compliance with the voluntary VECAP standards, however there is no actual measurement data provided in the application to validate that standard. Furthermore, not all of the applicants seem to be in compliance with this standard.

RAC agreed, noting that this information had been previously requested in writing, with the suggestion of the Rapporteurs to seek further clarification from the applicants on the methodology and data underpinning the emission factors described in the VECAP scheme. In addition, a sensitivity analysis of reported emissions estimates for Use 1 and 2 would need to be undertaken by the applicants.

The Chairman concluded that the Rapporteurs would take the discussions into account in the first versions of the RAC draft opinions.

d) Authorisation application - outcome of the conformity check

1. Trichloroethylene 5

The Chairman welcomed the RAC Rapporteurs, the Authorisation Team, as well as the SEAC Rapporteurs. He informed the Committee that the aim of this session was to agree on the outcome of the conformity check of the Trichloroethylene 5 (TCE 5) application for authorisation, which was submitted in the May submission window by one applicant applying for one substance and two uses. The Public Consultation for the application has been launched on 13 August 2014 and will end on 8 October 2014.

The Rapporteurs provided brief information on the application for authorisation and presented the outcome of the draft conformity report. The Chairman summarised the agreement of the Committee with the application being in conformity. The first outline draft opinion should be received by the Secretariat by 5 November 2014. A Rapporteurs' dialogue has been set for middle of October, whereas a Trialogue discussion with the applicants may take place in early November.

2. Diarsenic trioxide 4

The Chairman informed the Committee that the aim of this session was to agree on the outcome of the conformity check of the Diarsenic trioxide 4 application for authorisation, which was submitted outside the submission window by 1 applicant applying for 1 substance and 1 use.

The Rapporteur gave some brief information on the application and presented the outcome of the draft conformity check. Members asked the Secretariat and the Rapporteur to clarify during the trialogue with the Applicant the number of workers exposed to the substance.

The Chairman concluded that RAC agreed by consensus that the application conforms with requirement of REACH.

8.3 Appointment of Rapporteurs for authorisation applications (closed session)

RAC agreed on the renewed pool of Rapporteurs for the applications for authorisation process without discussion.

The Chairman appointed Rapporteurs for the upcoming nine applications (TCE 1, 2a, 2b, 3, 4, 6, 8, 9, 10) for authorisation on the uses of trichloroethylene.

9. AOB

Update on Guidance activities

The Chairman informed the Committee that an update on Guidance activities was made available to the members via CIRCABC.

In closing the meeting, the Chairman thanked all the participants and the Secretariat for their patience and dedication during the one week meeting, noting the volume of work that had been agreed and adopted and the progress made.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 30 8 – 12 September 2014

(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/30/2014**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-30 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 29 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/30/2014/01** and document **RAC/30/2014/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the 2014 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-30 meeting on CIRCABC.
c) General RAC procedures SECR presented the update on the 2014 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-30 meeting on CIRCABC.
5. Requests under Article 77 (3) (c)	
a) Tetrapropylphenol (TPP)	**Rapporteur** to prepare the 1st draft opinion. **SECR** to launch the RAC consultation prior to the RAC-31 meeting. **Rapporteur** to revise the draft opinion based on the comments received.
b) Consumer exposure to benzene contained in natural gas	**SECR** to upload the 1st draft opinion onto CIRCABC. **SECR** to launch RAC consultation on the 1st draft opinion. **Rapporteur** to revise the opinion in accordance with the comments received during RAC consultation.
6. Harmonised classification and labelling (CLH)	
1. CLH dossiers a) Methanol b) Chloralose	

c) N,N dimethylacetamide (DMAC)

d) Acetochlor

e) Iodomethane

f) Heptafluorononanoic acid and its sodium and ammonium salts (PFNA)

g) Copper dossiers *(human health hazards)*

1. Tribasic copper sulphate
2. Copper oxychloride
3. Copper powder (copper flakes coated with aliphatic acid)
4. Copper thiocyanate
5. Bordeaux mixture
6. Basic copper carbonate
7. Copper (II) oxide
8. Copper (II) hydroxide
9. Copper (I) oxide
10. Copper sulphate pentahydrate

a) Methanol	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [no classification for toxicity to reproduction]	**Rapporteur** to revise the opinion in accordance with the discussions at RAC-29 and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
b) Chloralose	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3 (H301), STOT SE 3 (H336), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to the SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
c) N,N dimethylacetamide (DMAC)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Remove the SCL of 5% for toxicity to reproduction (Repr. 1B; H360D); a GCL of 0,3% will apply]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **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) Acetochlor	

RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H332); Skin Irrit. 2 (H315); Skin Sens. 1 (H317); STOT SE 3 (H335); Carc. 2 (H351); STOT RE 2 (H373 (kidney)); M=1000 for Aquatic Acute 1]	**Rapporteurs** to revise the opinion in accordance with the discussions in RAC. **SECR** to launch RAC consultation on the revised draft opinion.
e) Iodomethane	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Retain the current classification for carcinogenicity, Carc. 2; H351]	**Rapporteur** to revise the opinion in accordance with the discussions in RAC. **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) Heptadecafluorononanoic acid and its sodium and ammonium salts (PFNA)	
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); Acute Tox. 4 (H332); Eye Dam. 1 (H318)]; STOT RE 1 (H372 (liver, thymus, spleen)); Carc. 2 (H351); Repr. 1B (H360Df); Lact. (H362)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **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.
g) Copper compounds (human health hazards)	
1. Tetracopper hexahydroxide sulphate and hydrate (tribasic copper sulphate) RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H302)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to include an evaluation of the aquatic hazards in the draft opinion. **SECR** to launch RAC consultation on the aquatic hazards. **Rapporteur** to revise the opinion in accordance with the comments received during RAC consultation. **SECR** to schedule the draft opinion for discussion at the RAC-31B plenary meeting.
2. Dicopper chloride trihydroxide (copper oxychloride RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 3 (H301) and Acute Tox. 4 (H332)]	See Tetracopper hexahydroxide sulphate and hydrate
3. Copper flakes (coated with aliphatic acid) RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H302), Acute Tox. 3 (H331) and Eye Irrit. 2 (H319)]	See Tetracopper hexahydroxide sulphate and hydrate

4. Copper thiocyanate RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [EUH032]	See Tetracopper hexahydroxide sulphate and hydrate
5. Bordeaux mixture RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H332) and Eye Dam. 1 (H318)]	See Tetracopper hexahydroxide sulphate and hydrate
6. Copper(II)carbonate – copper(II)hydroxide (1:1)) (basic copper carbonate) RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H302), Acute Tox. 4 (H332) and Eye Irrit. 2 (H319)]	See Tetracopper hexahydroxide sulphate and hydrate
7. Copper (II) oxide RAC agreed on the harmonised classification and labelling as indicated in Table 2 below.	See Tetracopper hexahydroxide sulphate and hydrate
8. Copper (II) hydroxide RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H302), Acute Tox. 2 (H330) and Eye Dam. 1 (H318)]	See Tetracopper hexahydroxide sulphate and hydrate
9. Copper (I) oxide RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H302), Acute Tox. 4 (H332) and Eye Dam. 1 (H318)]	See Tetracopper hexahydroxide sulphate and hydrate
10. Copper sulphate pentahydrate RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4 (H302) and Eye Dam. 1 (H318)]	See Tetracopper hexahydroxide sulphate and hydrate
6.2 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.
7. Restrictions	
7.1 Restriction Annex XV dossiers	
a) Opinion Development	
1. Cadmium and its compounds in paints – 4th	**Rapporteurs** to make final editorial

version of the draft opinion Rapporteurs presented the 4th version of the RAC draft opinion. RAC adopted the opinion on the proposed restriction by consensus.	changes to the adopted RAC opinion. **Rapporteurs** 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. Cadmium and its compounds in artist paints – 1st version of the draft opinion Rapporteurs presented the 1st version of the RAC draft opinion. RAC discussed the main elements proposed in the draft opinion and information received from the dossier submitter.	**Rapporteurs** to take the RAC-30 discussions and the comments received from the public consultation into account in the revised draft opinion (due by end of October 2014.) **Members** to come forward as volunteers to support the Rapporteurs in the opinion development.
3. Chrysotile - 1st version of the draft opinion Rapporteurs presented the 1st version of the RAC draft opinion. RAC discussed the main elements proposed in the draft opinion.	**Rapporteurs** to take the comments into account into the revised draft opinion due by end of October 2014. **Rapporteurs** to ensure that the supporting documentation (BD and RCOM) with the revised draft opinion.
4. Isopropylidenediphenol (Bisphenol A) – first plenary discussions on the key issues document Rapporteurs presented and RAC discussed the key issues document for the RAC opinion.	**Rapporteurs** to take the RAC discussion into account in the 1st version of the draft opinion (by 31 October 2014). **SECR** to open a written commenting round on this version.
5. Ammonium salts – first plenary discussions on the key issues document Rapporteurs presented and RAC discussed the key issues document for the RAC opinion.	**Rapporteurs** to take the RAC discussion into account in the first draft opinion (by 31 October 2014). **SECR** to open a written commenting round on this version.
b) Conformity check	
1. Methanol - outcome of conformity check RAC agreed that the dossier does not conform to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload on CIRCA BC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
2. DecaBDE – outcome of conformity check RAC agreed that the dossier conforms to the Annex XV	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload on CIRCABC.

requirements and took note of the recommendations to the dossier submitter.	**SECR** to inform the dossier submitter on the outcome of the conformity check.
7.2 Appointment of (co-)rapporteurs for restriction dossiers RAC took note of the pools of the proposed (co-)rapporteurs for the Grill lighters fluids and fuels for decorative lamps labelled R65 or H304 and Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) restriction dossiers.	
8. Authorisation	
8.1 General authorisation issues	
a) RAC and SEAC working procedure "fit-for–purpose" applications for authorisation	Information item – no action needed.
8.2 Authorisation applications	
a) Authorisation application on phthalates – 3rd version of the RAC draft opinions (applications submitted within the August 2013 submission window)	
3. Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a): Use 1 Formulation of DEHP in compounds, dry-blends and Plastisol formulations Use 2 Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles The draft opinions were adopted via written procedure on 28 August.	**SECR** to inform SEAC about the adoption of the Draft Opinions. **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinions. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinions on behalf of RAC. **SECR** to send the Opinions to the Commission, the Member States and the Applicant. **SECR** to publish the Opinions on the ECHA website.
4. Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b): Use 1 Formulation of DEHP in compounds, dry-blends and Plastisol formulations Use 2 Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles The draft opinions were adopted via written procedure on 28 August.	**SECR** to inform SEAC about the adoption of the Draft Opinions. **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinions. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinions on behalf of RAC. **SECR** to send the Opinions to the Commission, the Member States and the Applicant. **SECR** to publish the Opinions on the

	ECHA website.
5. Three uses of DEHP submitted by DEZA a.s. (DEHP 2c): Use 1 Formulation of DEHP in compounds, dry-blends and Plastisol formulations Use 2 Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles Use 3 Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements The draft opinions on uses 1 and 2 were adopted via written procedure on 28 August. The draft opinion on use 3 was adopted.	**SECR** to inform SEAC about the adoption of the Draft Opinions. **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinions. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinions on behalf of RAC. **SECR** to send the Opinions to the Commission, the Member States and the Applicant. **SECR** to publish the Opinions on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure. **SECR** to send the Opinions to the Commission, the Member States and the Applicant. **SECR** to publish the Opinions on the ECHA website.
6. The third use of DBP submitted by DEZA a.s. (DBP 2): Use 2 Use in propellants Use 3 Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements The draft opinion on use 2 was adopted via written	**SECR** to inform SEAC about adoption of the Draft Opinions **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to

procedure on 3 September. The draft opinion on use 3 was adopted.	comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure. **SECR** to send the Opinions to the Commission, the Member States and the Applicant. **SECR** to publish the Opinions on the ECHA website.
b) Authorisation application – 2nd version of RAC draft opinions (applications submitted within the November 2013 submission window)	
1. The use of diarsenic trioxide submitted by Boliden Kokkola Oy (Diarsenic trioxide 1): Use 1 Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process The draft opinion on this use was agreed by consensus. RAC decided to recommend a short review period and in the case of reapplication to request the applicant to improve the exposure assessment to both workers and man via the environment.	**Rapporteurs** and **SECR** to make editorial changes in the draft opinion to reflect RAC discussion and conclusions. **SECR** to inform SEAC about adoption of the Draft Opinions **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the

	Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.
2. The use of diarsenic trioxide submitted by Nordenhammer Zinkhütte GmbH (Diarsenic trioxide 2): Use 1 Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process The draft opinion on this use was agreed by consensus. RAC decided to recommend a short review period and request applicant to improve exposure assessment to both workers and man via environment.	**Rapporteurs** and **SECR** to do editorial changes in the draft opinion to reflect RAC discussion and conclusions. **SECR** to inform SEAC about adoption of the Draft Opinions **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR.

	SECR to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.
3. Two uses of diarsenic trioxide submitted by Linxens France (Diarsenic trioxide 3): Use 1 Formulation of diarsenic trioxide into a mixture Use 2 Industrial use of diarsenic trioxide as processing aid in gold electroplating The draft opinions on two uses were agreed by consensus.	**SECR** to inform SEAC about adoption of the Draft Opinion **SECR** to send the Applicant the Draft Opinion (after SEAC agreement) with a request to indicate his intention to submit comments on the Draft Opinion. *Option 1*: Should the Applicant not wish to comment or fails to comment by the deadline (2 months), the RAC Chairman to approve the Final Opinion on behalf of RAC. **SECR** to send the Opinion to the Commission, the Member States and the Applicant. **SECR** to publish the Opinion on the ECHA website. *Option 2:* Should the Applicant wish to comment, SECR to make the Applicant's comments available on CIRCABC and to inform RAC. **SECR** to invite the co-rapporteurs to provide their views on the comments. **Co-rapporteurs** to preview the Applicant's comments and to prepare a draft version of the Final Opinion taking into account the Applicant's comments, and to send it to SECR. **SECR** to organise written commenting in RAC. **Co-rapporteurs** to revise the draft Final Opinion. **SECR** to initiate the adoption of the Final Opinion at the RAC plenary meeting or via written procedure.
4. Six uses of lead sulfochromate yellow (C.I. pigment yellow 34) and lead chromate molybdate sulphate red (C.I. pigment red 104) submitted by DCC Maastricht B. V. OR (Lead chromate pigments 2): Use 1 Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use Use 2 Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating	**Co-rapporteurs** to consider plenary discussion and to prepare the third version of the RAC draft opinions. **SECR** to upload to CIRCABC the third version of the RAC draft opinions. **SECR** to launch the RAC Consultation on the third version of the RAC Draft Opinions.

etc.) Use 3 Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking Use 4 Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use Use 5 Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use Use 6 Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking RAC agreed that risk management measures are appropriate for reducing the risk. However, these substances shall not be used manually; higher level of automatisation is required.	
c) Authorisation application – 1st outline version of RAC draft opinions (application submitted within February 2013 submission window)	
1. Two uses of HBCDD submitted by INEOS Styrenics Netherlands B.V., INEOS Styrenics Ribecourt SAS, INEOS Styrenics Wingles SAS, Synthos Dwory 7 spóka z organiczon odpowiedzialnoci spóka komandytowo-akcyjna, Synthos Kralupy a.s., StyroChem Finland Oy, Monotez SA, RP Compounds GmbH, Synbra Technology bv, Sunpor Kunststoff GmbH, Dunastyr Polystyrene Manufacturing C. Co. Ltd, versalis SpA and Unipol Holland bv (HBCDD 1): Use 1 Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications). Use 2 Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications.	**RAC** agreed that the emissions' estimates are difficult to translate into impact. **SECR** to seek further clarifications from applicants on the emission factors (data and methodology) described in VECAP scheme. **Rapporteurs** to include sets of conditions of use 1, in case no sufficient information on VECAP emission factors is timely provided by the Applicant. **Rapporteurs** to consider the plenary discussion and to prepare the first versions of the RAC draft opinions by **26 September**. **SECR** to upload to CIRCABC the first version of the RAC draft opinions and to launch a 3 week RAC consultation on the first draft version of the RAC draft opinions.
d) Authorisation application – outcome of conformity check	
1. Trichloroethylene 5 RAC agreed on conformity of the application.	**SECR** to upload to CIRCA BC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
2. Diarsenic trioxide 4 RAC agreed on the conformity of the application	**SECR** to upload to CIRCA BC the adopted Conformity Report.

	SECR to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.
8.3 Appointment of (co-)rapporteurs for authorisation applications	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
9. AOB	
10. Action points and main conclusions of RAC-30	**SECR** to upload the adopted action points to CIRCA BC.

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

N,N-dimethylacetamide (DMAC)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	616-011-00-4	*N,N*-dimethylacetamide	204-826-4	127-19-5	Repr. 1B Acute Tox. 4* Acute Tox. 4*	H360D *** H332 H312	GHS08 GHS07 Dgr	H360D *** H332 H312		Repr. 1B; H360D: C ≥ 5 %	
Dossier submitters proposal	616-011-00-4	*N,N*-dimethylacetamide	204-826-4	127-19-5						**Remove** Repr. 1B; H360D: C ≥ 5 %	
RAC opinion	616-011-00-4	*N,N*-dimethylacetamide	204-826-4	127-19-5						~~Repr. 1B;~~ ~~H360D: C ≥ 5 %~~	
Resulting Annex VI entry if agreed by COM	616-011-00-4	*N,N*-dimethylacetamide	204-826-4	127-19-5	Repr. 1B Acute Tox. 4* Acute Tox. 4*	H360D *** H332 H312	GHS08 GHS07 Dgr	H360D *** H332 H312			

Perfluorononan-1-oic acid and its sodium and ammonium salts

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	607-718-00-9	perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts	206-801-3 [1]; - [2]; - [3]	375-95-1 [1]; 21049-39-8 [2]; 4149-60-4 [3]	Carc. 2 Repr. 1B STOT RE 1 Acute Tox. 4 Acute Tox. 4 Eye Dam. 1 Lact.	H351 H360D H372 (liver) H302 H332 H318 H362	GHS05 GSH07 GSH08 Dgr	H351 H360D H372 (liver) H302 H332 H318 H362			
RAC opinion	607-718-00-9	perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts	206-801-3 [1]; - [2]; - [3]	375-95-1 [1]; 21049-39-8 [2]; 4149-60-4 [3]	**Carc. 2 Repr. 1B Lact. Acute Tox. 4 Acute Tox. 4 STOT RE 1 Eye Dam. 1**	**H351 H360Df H362 H302 H332 H372 (liver, thymus, spleen) H318**	**GHS05 GSH07 GSH08 Dgr**	**H351 H360Df H362 H302 H332 H372 (liver, thymus, spleen) H318**			
Resulting Annex VI entry if agreed by COM	607-718-00-9	perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts	206-801-3 [1]; - [2]; - [3]	375-95-1 [1]; 21049-39-8 [2]; 4149-60-4 [3]	Carc. 2 Repr. 1B Lact. Acute Tox. 4 Acute Tox. 4 STOT RE 1 Eye Dam. 1	H351 H360Df H362 H302 H332 H372 (liver, thymus, spleen)	GHS05 GSH07 GSH08 Dgr	H351 H360Df H362 H302 H332 H372 (liver, thymus,			

						H318		spleen) H318			

Iodomethane

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	602-005-00-9	methyl iodide; iodomethane	200-819-5	74-88-4	Carc. 2 Acute Tox. 4* Acute Tox. 3* Acute Tox. 3* STOT SE 3 Skin Irrit. 2	H351 H312 H331 H301 H335 H315	GHS06 GHS08 Dgr	H351 H312 H331 H301 H335 H315			
Dossier submitters proposal	602-005-00-9	methyl iodide; iodomethane	200-819-5	74-88-4	**Remove** Carc. 2	**Remove** H351	**Remove** GHS08	**Remove** H351			
RAC opinion	602-005-00-9	methyl iodide; iodomethane	200-819-5	74-88-4	**Carc. 2**	**H351**	**GHS08**	**H351**			
Resulting Annex VI entry if agreed by COM	602-005-00-9	methyl iodide; iodomethane	200-819-5	74-88-4	Carc. 2 Acute Tox. 4* Acute Tox. 3* Acute Tox. 3* STOT SE 3 Skin Irrit. 2	H351 H312 H331 H301 H335 H315	GHS06 GHS08 Dgr	H351 H312 H331 H301 H335 H315			

Methanol

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	603-001-00-X	methanol	200-659-6	67-56-1	Flam. Liq. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT SE 1	H225 H331 H311 H301 H370**	GHS02 GHS06 GHS08 Dgr	H225 H331 H311 H301 H370 **		* STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	
Dossier submitters proposal	603-001-00-X	methanol	200-659-6	67-56-1	**Add** Repr. 1B	**Add** H360D	-	**Add** H360D			
RAC opinion	603-001-00-X	methanol	200-659-6	67-56-1							
Resulting Annex VI entry if agreed by COM	603-001-00-X	methanol	200-659-6	67-56-1	Flam. Liq. 2 Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT SE 1	H225 H331 H311 H301 H370**	GHS02 GHS06 GHS08 Dgr	H225 H331 H311 H301 H370 **		* STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	

Chloralose

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram ,Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	605-013-00-0	chloralose (INN); (R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose; glucochloralose; anhydroglucochloral	240-016-7	15879-93-3	Acute Tox. 4* Acute Tox. 4*	H332 H302	GHS07 Wng	H332 H302			
Dossier submitters proposal	605-013-00-0	chloralose (INN); (R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose; glucochloralose; anhydroglucochloral	240-016-7	15879-93-3	**Retain** Acute Tox. 4* **Add** STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1 **Modify** Acute Tox. 4 (oral)	**Retain** H332 **Add** H336 H400 H410	**Retain** GHS07 Wng **Add** GHS09	**Retain** H332 **Add** H336 H410		**Add** M=10 (acute) M=10 (chronic)	C
RAC opinion	605-013-00-0	chloralose (INN); (R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose; glucochloralose; anhydroglucochloral	240-016-7	15879-93-3	**Acute Tox. 3** **STOT SE 3** **Aquatic Acute 1** **Aquatic Chronic 1**	**H301** **H336** **H400** **H410**	**GHS06** **GHS09** **Dgr**	**H301** **H336** **H410**		**M=10 (acute)** **M=10 (chronic)**	C
Resulting Annex VI entry if agreed by COM	605-013-00-0	chloralose (INN); (R)-1,2-O-(2,2,2-trichloroethylidene)-α-D-glucofuranose; glucochloralose; anhydroglucochloral	240-016-7	15879-93-3	Acute Tox. 4* Acute Tox. 3 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H332 H301 H336 H400 H410	GHS06 GHS09 Dgr	H332 H301 H336 H410		M = 10 M = 10	

Table 2: Dossiers where the harmonised classification and labelling was agreed by RAC, i.e. the opinion has not yet been adopted

Acetochlor (ISO)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-037-00-6	acetochlor (ISO); 2-chloro-*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	Acute Tox.4 * STOT SE 3 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H332 H335 H315 H317 H400 H410	GHS07 GHS09 Wng	H332 H335 H315 H317 H410			
Dossier submitters proposal	616-037-00-6	acetochlor (ISO); 2-chloro-*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	**Retain** STOT SE 3 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 Acute Tox. 4 STOT RE 2 **Modify** Acute Tox. 4 (inhalation) Skin Sens. 1B	**Retain** H335 H315 H400 H410 **Add** H351 H302 H373 (liver, kidney)	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H335 H315 H410 **Add** H351 H302 H373 (liver, kidney)		**Add** M = 1000 (acute) M = 100 (chronic)	
RAC opinion	616-037-00-6	acetochlor (ISO); 2-chloro-*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1	**Carc. 2** **Acute Tox. 4** **STOT RE 2** **STOT SE 3** **Skin Irrit. 2** **Skin Sens. 1** Repr. 2 Aquatic Acute 1 Aquatic Chronic 1	**H351** **H332** **H373 (kidney)** **H335** **H315** **H317** H361f H400 H410	**GHS07** **GHS08** **GHS09** **Wng**	**H351** **H332** **H373 (kidney)** **H335** **H315** **H317** H361f H410		M=1000 (acute) M=100 (chronic)	

Resulting Annex VI entry if agreed by COM	616-037-00-6	acetochlor (ISO); 2-chloro-*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide	251-899-3	34256-82-1							

Tetracopper hexahydroxide sulphate; [1]
Tetracopper hexahydroxide sulphate hydrate [2]

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-RST-00-Y	tetracopper hexahydroxide sulphate; [1] tetracopper hexahydroxide sulphate hydrate [2]	215-582-3	1333-22-8 [1] 12527-76-3 [2]	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 2	H302 H400 H411	GHS07 GHS09 Wng	H302 H410		M=10 (acute)	
RAC opinion	029-018-00-7	tetracopper hexahydroxide sulphate; [1] tetracopper hexahydroxide sulphate hydrate [2]	215-582-3	1333-22-8 [1] 12527-76-3 [2]	**Acute Tox. 4** Aquatic Acute 1 Aquatic Chronic 2	**H302** H400 H411	**GHS07** GHS09 **Wng**	**H302** H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-018-00-7	tetracopper hexahydroxide sulphate; [1] tetracopper hexahydroxide sulphate hydrate [2]	215-582-3	1333-22-8 [1] 12527-76-3 [2]							

Dicopper chloride trihydroxide

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-017-00-1	dicopper chloride trihydroxide	215-572-9	1332-65-6	Acute Tox. 4 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 2	H332 H301 H400 H411	GHS06 GHS09 Dgr	H332 H301 H410		M=10 (acute)	
RAC opinion	029-017-00-1	dicopper chloride trihydroxide	215-572-9	1332-65-6	**Acute Tox. 4** **Acute Tox. 3** Aquatic Acute 1 Aquatic Chronic 2	**H332** **H301** H400 H411	**GHS06** GHS09 **Dgr**	**H332** **H301** H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-017-00-1	dicopper chloride trihydroxide	215-572-9	1332-65-6							

Copper flakes (coated with aliphatic acid)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-RST-01-Y	copper flakes (coated with aliphatic acid)	231-159-6	7440-50-8	Acute Tox. 3 Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H400 H410	GHS06 GHS09 Dgr	H331 H302 H410		M=10 (acute)	
RAC opinion	029-019-01-X	copper flakes (coated with aliphatic acid)	231-159-6	7440-50-8	**Acute Tox. 3** **Acute Tox. 4** **Eye Irrit. 2** Aquatic Acute 1 Aquatic Chronic 1	**H331** **H302** **H319** H400 H410	**GHS06** GHS09 **Dgr**	**H331** **H302** **H319** H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-019-01-X	copper flakes (coated with aliphatic acid)	231-159-6	7440-50-8							

Copper thiocyanate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	615-004-00-3	salts of thiocyanic acid, with the exception of those specified elsewhere in this Annex	-	-	Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* Aquatic Chronic 3	H332 H312 H302 H412	GHS07 Wng	H332 H312 H302 H412	EUH032		A
Dossier submitters proposal	029-RST-00-Y	copper thiocyanate	214-183-1	1111-67-7	Aquatic Acute 1 Aquatic Chronic 2	H400 H411	GHS09 Wng	H410	EUH032	M=10 (acute)	
RAC opinion	029-015-00-0	copper thiocyanate	214-183-1	1111-67-7	Aquatic Acute 1 Aquatic Chronic 2	H400 H411	GHS09 Wng	H410	**EUH032**	M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-015-00-0	copper thiocyanate[3]	214-183-1	1111-67-7							

[3] New entry

Bordeaux mixture

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-RST-00-Y	bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide	-	8011-63-0	Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 2	H332 H318 H400 H411	GHS07 GHS05 GHS09 Dgr	H332 H318 H410		M=10 (acute)	
RAC opinion	029-022-00-9	bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide	-	8011-63-0	**Acute Tox. 4** **Eye Dam. 1** Aquatic Acute 1 Aquatic Chronic 2	**H332** **H318** H400 H411	**GHS07** **GHS05** GHS09 **Dgr**	**H332** **H318** H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-022-00-9	bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide	-	8011-63-0							

Copper(II) carbonate – copper(II) hydroxide (1:1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-RST-00-Y	copper(II) carbonate--copper(II) hydroxide (1:1)	235-113-6	12069-69-1	Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 2	H332 H302 H319 H400 H411	GHS07 GHS09 Wng	H332 H302 H319 H410		M=10 (acute)	
RAC opinion	029-020-00-8	copper(II) carbonate--copper(II) hydroxide (1:1)	235-113-6	12069-69-1	**Acute Tox. 4** **Acute Tox. 4** **Eye Irrit. 2** Aquatic Acute 1 Aquatic Chronic 2	**H332** **H302** **H319** H400 H411	**GHS07** GHS09 **Wng**	**H332** **H302** **H319** H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-020-00-8	copper(II) carbonate--copper(II) hydroxide (1:1)	235-113-6	12069-69-1							

Copper(II) oxide

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-016-00-6	copper(II) oxide	215-269-1	1317-38-0	Acute Tox. 2 Aquatic Acute 1 Aquatic Chronic 1	H330 H400 H410	GHS06 GHS09 Dgr	H330 H410		M=10 (acute)	
RAC opinion	029-016-00-6	copper(II) oxide	215-269-1	1317-38-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-016-00-6	copper(II) oxide	215-269-1	1317-38-0							

Copper dihydroxide; copper(II) hydroxide

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	029-021-00-3	copper dihydroxide; copper(II) hydroxide	243-815-9	20427-59-2	Acute Tox. 2 Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H302 H318 H400 H410	GHS06 GHS05 GHS09 Dgr	H330 H302 H318 H410		M=10 (acute)	
RAC opinion	029-021-00-3	copper dihydroxide; copper(II) hydroxide	243-815-9	20427-59-2	**Acute Tox. 2** **Acute Tox. 4** **Eye Dam. 1** Aquatic Acute 1 Aquatic Chronic 1	**H330** **H302** **H318** H400 H410	**GHS06** **GHS05** GHS09 **Dgr**	**H330** **H302** **H318** H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-021-00-3	copper **dihydroxide**; copper(II) hydroxide	243-815-9	20427-59-2							

Dicopper oxide; copper (I) oxide

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	029-002-00-X	dicopper oxide; copper (I) oxide	215-270-7	1317-39-1	Acute Tox 4* Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410			
Dossier submitters proposal	029-002-00-X	dicopper oxide; copper (I) oxide	215-270-7	1317-39-1	**Retain** Aquatic Acute 1 **Add** Acute Tox. 4 Eye Irrit. 2 **Modify** Acute Tox. 4 (oral) Aquatic Chronic 2	**Retain** H400 **Add** H332 H319 **Modify** H411	**Retain** GHS07 GHS09 Wng	**Retain** H410 **Add** H332 H319		**Add** M=100 (acute)	
RAC opinion	029-002-00-X	dicopper oxide; copper (I) oxide	215-270-7	1317-39-1	**Acute Tox. 4** **Acute Tox. 4** **Eye Dam. 1** Aquatic Chronic 2	**H332** **H302** **H318** H411	**GHS07** **GHS05** GHS09 **Dgr**	**H332** **H302** **H318** H410		M=100 (acute)	
Resulting Annex VI entry if agreed by COM	029-002-00-X	dicopper oxide; copper (I) oxide	215-270-7	1317-39-1							

Copper sulphate pentahydrate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	029-004-00-0	Copper sulphate	231-847-6	7758-98-7	Acute Tox. 4* Eye Irrit. 2 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H319 H315 H400 H410	GHS07 GHS09 Wng	H302 H319 H315 H410			
Dossier submitters proposal	029-023-00-4	Copper sulphate pentahydrate	231-847-6	7758-99-8	Acute Tox. 4 Eye Dam. 1 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 2	H302 H318 H315 H400 H411	GHS07 GHS05 GHS09 Dgr	H302 H318 H315 H411		M=10 (acute)	
RAC opinion	029-023-00-4	Copper sulphate pentahydrate	231-847-6	7758-99-8	**Acute Tox. 4** **Eye Dam. 1** ~~Skin Irrit. 2~~ Aquatic Acute 1 Aquatic Chronic 2	**H302** **H318** ~~H315~~ H400 H411	**GHS07** **GHS05** GHS09 **Dgr**	**H302** **H318** ~~H315~~ H410		M=10 (acute)	
Resulting Annex VI entry if agreed by COM	029-023-00-4	Copper sulphate pentahydrate[4]	231-847-6	7758-99-8							

[4] New entry

Part III. List of Attendees of the RAC-30 meeting

8-12 September 2014

RAC members		
BARANSKI Bogusław		SCHULTE Agnes
BIRO Anna		SMITH Andrew
BJORGE Christine		SOGORB Miguel
BRANISTEANU Radu		SOERENSEN Peter
CARVALHO João		SPETSERIS Jolanta
CZERCZAK Slawomir		STASKO Jolanta
Di PROSPERO FANGHELLA Paola		STOLZENBERG Hans-Christian
DUNAUSKIENĖ Lina		TADEO José Luis
DUNGEY Stephen		UZOMECKAS Zilvinas
GRUIZ Katalin		Van der HAGEN Marianne
GUSTAFSON Anne-Lee		VARNAI Veda Marija
HAKKERT Betty		VIVIER Stephanie
ILIE Mihaela		RUPPRICH Norbert
JENSEN Frank		SANTONEN Tiina
KADIĶIS Normunds		SCHLÜTER Urs (8-9.9.)
KAPELARI Sonja		SCHULTE Agnes
KORATI Safia		SMITH Andrew
LEINONEN Riitta		SOGORB Miguel
LUND Bert-Ove		SOERENSEN Peter
MENARD Anja		SPETSERIS Jolanta
MULLOOLY Yvonne		STASKO Jolanta
MURRAY Brendan		STOLZENBERG Hans-Christian
NEUMANN Michael		TADEO José Luis
PARIS Pietro		UZOMECKAS Zilvinas
PASQUIER Elodie		Van der HAGEN Marianne
PRONK Marja		VARNAI Veda Marija
RUCKI Marian		VIVIER Stephanie
RUPPRICH Norbert		
SANTONEN Tiina		
SCHLÜTER Urs		

Advisers to the RAC members		**Industry experts**
CLAUSEN Henning (adviser to Peter Hammer Soerensen)		BEYER Dieter (Cefic, bisphenol A)
ESPOSITO Dania (adviser to Pietro Paris)		DELBEKE Katrien (Eurometaux, copper compounds)
GERAETS Liesbeth (adviser to Betty Hakkert and CLH adviser for copper compounds)		ERLER Steffen (Cefic, methanol CLH)
KOPONEN Milja (adviser to Tiina Santonen)		KRONENBERG Joel (ECPA, acetachlor)
NIEMELÄ Helena (adviser to Riitta Leinonen)		MACKIE Carol (Cefic, copper compounds)
PAPPONEN Hinni (adviser to Riitta Leinonen)		NETTERSHEIM Rolf (Cefic, Chrysotile)
PECZKOWSKA Beata (adviser to Boguslaw Baranski and CLH adviser for PFNA)		ROSE Patrick (ECPA, iodomethane)
RISSANEN Eeva (adviser to Riitta Leinonen)		SMOLDERS Erik (Eurometaux, cadmium in artist paints)
ROTHER Dag (adviser to Agnes Schulte and Urs Schlueter, and the restriction adviser for ammonium salts)		
STOCKMANN-JUVALA Helene (adviser to Tiina Santonen)		**Commission observers**
		GARCIA JOHN Enrique (DG ENTR)
Stakeholders observers		SCAZZOLA Roberto (DG ENTR)
ANNYS Erwin, CEFIC		
BARRY Frank, ETUC		**Dossier submitters**
BUONSANTE Vito, ClientEarth		CAVALIERI Luisa (FR, ammonium salts)
MUNARI Tomaso, EuCheMS		FIORE Karine (BPA)
REGO Laura, ECEAE		MANTOVANI Alberto (IT, methanol CLH)
ROHDE Arlean, CONCAWE		
ROMANO Dolores, EEB		**Excuses**
ROWE Rocky, ECPA		LOSERT Annemarie (via Webex)
VEROUGSTRAETE Violaine, Eurometaux		TSITSIMPIKOU Christina
WAETERSCHOOT Hugo, Eurometaux		MORRIS Alick (GD EMPL-SANCO)

ECHA staff
ATLASON Palmi
BERGES Markus
BLAINEY Mark
BOWMER Tim, Chairman
BROECKAERT Fabrice
DVORAKOVA Dana
HENNIG Philip
JOVER BUSTILLO Vanessa
HONKANEN Jani
KANELLOPOULOU Athanasia
KARJALAINEN Ari
KIOKIAS Sotirios
KIVELÄ Kalle
KLAUK Anja
KOKKOLA Leila
KOSK-BIENKO Joanna
KOSTIKA Xenia
LAPENNA Silvia
LOGTMEIJER Christiaan
LUDBORŽS Arnis
LUSCHÜTZKY Evita
MARQUEZ-CAMACHO Mercedes
MAZZOLINI Anna
MERKOURAKIS Spyridon
MOSSINK Jos
MOTTET Denis
NICOT Thierry
NYGREN Jonas
ORISPÄÄ Katja
PELTOLA Jukka
PERAZZOLA Chiara
REGIL Pablo
RODRÍGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
SADAM Diana
SOSNOWSKI Piotr
STOYANOVA Evgenia
VAINIO Matti
VAN HAELST Anniek
SEAC members
BRIGNON Jean-Marc (DEHP 2c –use 3)
COGEN Simon (Trichloroethylene 5)
CSERGO Robert (Cadmium and its compounds, methanol)
DANTINNE Catheline (DBP 2 uses 2 and 3)
FURLAN Janez (Diarsenic trioxide)
GEORGIOU Stavros (Diarsenic trioxide 4, Bisphenol A)
GRANDI Silvia (Methanol restriction)
KRAJNC Karmen (Trichloroethylene 5)
PALOTAI Zoltan (Chrysotile)
SCHUCHTAR Endre (DecaBDE)
SIMON Franz-Georg (Cadmium and its compounds)
SLETTEN Thea (Bisphenol A)
THIELE Karen (DecaBDE)
SEAC adviser
JONGENEEL Rob (Cees Luttikhuizen adviser for ammonium salts)
Participants at the CLH copper compounds evening session 11.9.2014
HAMMERSCHMIDT Chad (Eurometaux expert)
LOFT Steve (Eurometaux expert)
REMOTE PARTICIPANTS
RAC members:
LOSERT Annemarie (8-12.9.9)
SCHLUETER Urs (10-12.9.)
Advisers :
RUSSO Maria Teresa (adviser to Paola di Prospero)

IT dossier submitters:		**EFSA :**
CATONE Tiziana (methanol CLH)		ISTACE Fréderique
FR dossier submitters:		
LECOQ Pierre (ammonium salts)		
TERENDIJ Carline (BPA restriction)		***Remote participants at the CLH copper compounds evening session 11.9.2014***
SE dossier submitters:		**FR dossier submitters:**
CARLSSON Mattias (cadmium in artist paints)		CHION Béatrice (CLH copper compounds evening session 11.9.2014)
CEDERBERG Inger (cadmium in artist paints)		DELENTDECKER Chloé (CLH copper compounds evening session 11.9.2014)
HENRIKSSON Witasp Erika (PFNA)		GOUZE Marie-Estelle (CLH copper compounds evening session 11.9.2014)
IVARSSON Jenny (cadmium in artist paints)		LORI Julia (CLH copper compounds evening session 11.9.2014)
PARKMAN Helena (cadmium in artist paints)		POULSEN Véronique (CLH copper compounds evening session 11.9.2014)
VIRDARSSON Jenny (cadmium in artist paints)		**Advisers :**
WARHOLM Margareta (cadmiumin artist paints)		LUIT Richard (adviser to Marja Pronk) – CLH copper compounds evening session 11.9.2014
		VERSCHOOR Anja (adviser to Marja Pronk) - CLH copper compounds evening session 1.9.2014
NO dossier submitters:		
BAUMBUSCH Angelika (DecaBDE)		
KOPANGEN Marit (DecaBDE)		
ÖYSTEIN Fotland Tor (DecaBDE)		
PL dossier submitters:		
GODALA Mariusz (methanol restriction)		
MAJKA Jerzy (methanol restriction)		
Commission observers:		
BORRAS Anna		
FERNANDES-de-BARROS Mariana		
LUVARA Giuseppina		
ROZWADOWSKI Jacek		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-30 meeting

ANNEX II List of documents submitted to the members of the Committee for Risk Assessment for the RAC-30 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-30 meeting

ANNEX IV Administrative issues and information items

8 September 2014
RAC/A/30/2014

Final Agenda
30th meeting of the Committee for Risk Assessment

8-12 September 2014

ECHA Conference Centre (Annankatu 18, Helsinki)

8 September starts at 9:00
12 September: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/30/2014
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 29 action points, written procedures and other ECHA bodies

RAC/30/2014/01
RAC/30/2014/02 (room document)
For information

b) RAC workplan for all processes

For information

c) General RAC procedures

For discussion

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

a) Tetrapropylphenol (TPP)

b) Consumer exposure to benzene contained in natural gas

For discussion

Item 6 – Harmonised classification and labelling (CLH)

6.1 CLH dossiers

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

(a) Acetochlor: Acute Tox. (dermal, inhalation), Skin Corr./Irrit., STOT SE, M-factors for Aquatic Acute 1 and Aquatic Chronic 1

(b) Copper compounds

1. Copper(II) carbonate – copper(II) hydroxide (1:1): Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE
2. Bordeaux mixture: Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE
3. Dicopper oxide: Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Skin Sens., STOT SE
4. Copper dihydroxide: Acute Tox. (oral, dermal), Eye Dam./Irrit., Skin Corr./Irrit., Skin Sens., STOT SE
5. Copper flakes (coated with aliphatic acid): Acute Tox. (oral, dermal), Skin Corr./Irrit., Skin Sens., STOT SE
6. Dicopper chloride trihydroxide: Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE
7. Copper sulphate pentahydrate: Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE
8. Copper thiocyanate: EUH032, Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE
9. Copper(II) oxide: Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE
10. Tetracopper hexahydroxide sulphate [1], Tetracopper hexahydroxide sulphate hydrate [2]: Acute Tox. (oral, dermal, inhalation), Skin Corr./Irrit., Eye Dam./Irrit., Skin Sens., STOT SE

For agreement

B. Opinions for adoption / opinions with hazard classes for agreement with plenary debate

h) Methanol

i) Chloralose

j) N,N dimethylacetamide (DMAC)

k) Acetochlor

l) Iodomethane

m) Heptafluorononanoic acid and its sodium and ammonium salts (PFNA)

n) Copper dossiers *(human health hazards)*

1. Tribasic copper sulphate
2. Copper oxychloride
3. Copper powder (copper flakes coated with aliphatic acid)
4. Copper thiocyanate
5. Bordeaux mixture
6. Basic copper carbonate
7. Copper (II) oxide
8. Copper (II) hydroxide
9. Copper (I) oxide
10. Copper sulphate pentahydrate

For discussion/adoption

6.2 Appointment of RAC Rapporteurs for CLH dossiers

RAC/30/2014/03 (restricted room document)

For agreement

Item 7 – Restrictions

7.1 Restriction Annex XV dossiers

a) Opinion development

1) Cadmium and its compounds in paints – 4th version of the draft opinion

For adoption

2) Cadmium and its compounds in artist paints – 1st version of the draft opinion

For discussion

3) Chrysotile - 1st version of the draft opinion

For discussion/agreement

4) Isopropylidenediphenol (Bisphenol A) – first plenary discussions on the key issues document

For discussion

5) Ammonium salts – first plenary discussions on the key issues document

For discussion

b) Conformity check

1) Methanol - outcome of conformity check

For agreement

2) DecaBDE – outcome of conformity check

For agreement

7.2 Appointment of Rapporteurs for restriction dossiers

RAC/30/2014/04 (restricted document)
For information

Item 8 – Authorisation

8.1 General authorisation issues

a) RAC and SEAC working procedure "fit-for–purpose" applications for authorisation

For discussion

8.2 Authorisation applications

b) Authorisation application on phthalates – 3rd version of the RAC draft opinions (applications submitted within the August 2013 submission window)

1. One use of DEHP submitted by DEZA a.s. (DEHP 2c):

   Use 3 Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

   For agreement

2. One use of DBP submitted by DEZA a.s. (DBP 2):

   Use 3 Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

   For agreement

c) Authorisation application – 2nd version of RAC draft opinions (applications submitted within the November 2013 submission window)

1. The use of diarsenic trioxide submitted by Boliden Kokkola Oy (Diarsenic trioxide 1):

Use 1 Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process

For discussion/agreement

2. The use of diarsenic trioxide submitted by Nordenhamer Zinkhütte GmbH (Diarsenic trioxide 2):

Use 1 Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process

For discussion/agreement

3. Two uses of diarsenic trioxide submitted by Linxens France (Diarsenic trioxide 3):

Use 1 Formulation of diarsenic trioxide into a mixture

Use 2 Industrial use of diarsenic trioxide as processing aid in gold electroplating

For discussion/agreement

4. Six uses of lead sulfochromate yellow (C.I. pigment yellow 34) and lead chromate molybdate sulphate red (C.I. pigment red 104) submitted by DCC Maastricht B. V. OR (Lead chromate pigments 2):

Use 1 Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use

Use 2 Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)

Use 3 Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking

Use 4 Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use

Use 5 Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use

Use 6 Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking

For discussion/agreement

d) Authorisation application – 1st outline version of RAC draft opinions (applications submitted within the February 2013 submission window)

1. Two uses of HBCDD submitted by INEOS Styrenics Netherlands B.V., INEOS Styrenics Ribecourt SAS, INEOS Styrenics Wingles SAS, Synthos

Dwory 7 spóka z organiczon odpowiedzialnoci spóka komandytowo-akcyjna, Synthos Kralupy a.s., StyroChem Finland Oy, Monotez SA, RP Compounds GmbH, Synbra Technology bv, Sunpor Kunststoff GmbH, Dunastyr Polystyrene Manufacturing C. Co. Ltd, versalis SpA and Unipol Holland bv (HBCDD 1):

Use 1 Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications).
Use 2 Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications.

For discussion

e) Authorisation application – outcome of the conformity check
   1. Trichloroethylene 5
   2. Diarsenic trioxide 4*

For agreement

** Additional dossier received after the last submission window*

8.3 Appointment of Rapporteurs for authorisation applications

RAC/30/2014/05 (restricted room document)
For agreement

Item 9 – AOB

Item 10 – Action points and main conclusions of RAC-30

Table with Conclusions and Action points from RAC-30

For adoption

ANNEX II (RAC-30)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-30 meeting.

Document number	**Title**
RAC/A/30/2014	Final Draft Agenda
RAC/30/2014/01	Report from other ECHA bodies and activities
RAC/30/2014/02 Room document	Administrative document
RAC/30/2014/03 Room document Restricted	Appointment of RAC Rapporteurs for CLH dossiers
RAC/30/2014/04 Restricted	Appointment of Rapporteurs for restriction dossiers
RAC/30/2014/05	Appointment of Rapporteurs for authorisation applications

ANNEX III (RAC-30)

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

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
ALREADY DECLARED AT RAC 27, 28 and/or 29		
RESTR: Cadmium in Artist paints (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; 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
DECLARED AT RAC 30		
Art. 77(3)(c): Consumer exposure to benzene contained in natural gas (*risk assessment*)	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.
CLH: Copper compounds (10 dossiers) FR	Elodie PASQUIER	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
CLH: Methanol IT	Paola DI PROSPERO FANGHELLA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
		mitigation measures applied.
CLH: Chloralose PT	João CARVALHO	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
CLH: N,N dimethylacetamide (DMAC) 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.
CLH: Iodomethane UK	Andrew SMITH	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
CLH: Heptadecafluorononanoic acid and its sodium and ammonium salts (PFNA) 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.
RESTR: Ammonium salts (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
RESTR: Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
	Tiina SANTONEN	Being involved in a study on BPA performed by her employer
RESTR: DecaBDE (ECHA)	Marianne van der HAGEN	Working for the CA who collaborated with ECHA on the preparation of the dossier.
	Christine BJØRGE	Working for the CA who collaborated with ECHA on the preparation of the dossier.
RESTR: 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.

RAC advisers

AP/Dossier / DS	RAC member adviser	Reason for potential CoI / Working for
RESTR: Methanol (FI & PL)	Helena NIEMELA	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.
	Hinni PAPPONEN	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.

ANNEX IV (RAC-30)

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-29 Action Points

The RAC-29 action points due for RAC-30 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-29	26 August	Adopted
AfA: DEHP 4 uses 1 and 2	13 August	Agreed by majority
AfA: DEHP 2a, 2b, 2c uses 1 and 2	28 August	Use 1: Agreed by consensus Use 2: Agreed by majority
AfA: DBP 2 use 2	3 September	Agreed

2.2 Written dossier consultations (status by 2 September 2014)

Subject / Document	Deadline	Status / follow-up
CLH: Acetochlor (ISO)	5 August 2014	Closed
CLH: Copper substances (human health HCs)	28 July 2014	Closed
CLH: Iodomethane	7 August 2014	Closed
CLH: N,N – dimethylacetamide (DMAC)	30 July 2014	Closed
CLH: Heptadecafluorononanoic acid and its sodium and ammonium salts (PFNA)	25 July 2014	Closed
AfA: DBP 2, use 2	1 August 2014	Closed
AfA: DBP 2, use 3	5 August 2014	Closed
AfA: DEHP 2c, use 3	5 August 2014	Closed
AfA: Diarsenic trioxide 1	25 July 2014	Closed
AfA: Diarsenic trioxide 2	25 July 2014	Closed

AfA: Diarsenic trioxide 3, use 1	25 July 2014	Closed
AfA: Diarsenic trioxide 3, use 2	25 July 2014	Closed
AfA: Lead chromate pigments 2	21 August 2014	Closed
AfA: TCE 5 (conformity)	20 August 2014	Closed
AfA: TCE 5 (application)	1 October 2014	Open
AfA: Diarsenic trioxide 4 (conformity)	20 August 2014	Closed
AfA: Diarsenic trioxide 4 (application)	1 October 2014	Open
REST: Ammonium salts	26 August 2014	Closed
REST: Bisphenol A	2 September 2014	Closed
REST: Cadmium and its compounds in paints	18 August 2014	Closed
REST: Cadmium and its compounds in artists' paints	22 August 2014	Closed
REST: Chrystotile	22 August 2014	Closed
REST: DecaBDE (conformity)	25 August 2014	Closed
REST: Methanol (conformity)	25 August 2014	Closed

2.3 Other written consultations of RAC (status by 2 September 2014)

Other written consultations	Deadline	Status / follow-up
RAC consultation on the draft minutes of RAC-29	31 July 2014	Closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
CLH: Call for expression of interest for rapporteurship	30 July – 8 August 2014	Volunteers for two dossiers; appointment via WP
	18 – 29 August 2014	Volunteer for one dossier; the appointment will be done at RAC 30
Restriction: call for expression of interest for rapporteurship for Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Grill lighters fluids and fuels for decorative lamps labelled R65 or H304	10 July - 15 August 2014	Three volunteers for D4/D5 and two volunteers for grill lighter fluids and lamp oils

2.5 Written procedures for appointment of Rapporteurs

Appointment RAP	For Substance	Deadline	Outcome
CLH: Written procedure for appointing of Rapporteur(s)	▪ S-methoprene; Isopropyl (2E,4E,7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate ▪ Carboxin (5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide) ▪ Silthiofam (4,5-Dimethyl-2-trimethylsilanyl-thiophene-3-carboxylic acid allylamide) ▪ Triadimenol (ISO)	11 August 2014	Closed No comments were received from RAC members on the recommendation of the Chairman; the RAC Rapporteurs were appointed with tacit agreement.
	▪ 3,3'-dicyclohexyl-1,1'-methylenebis(4,1-phenylene)diurea (Complex soap TH 28) ▪ Fipronil (ISO)	20 August 2014	Closed No comments were received from RAC members on the recommendation of the Chairman; the RAC Rapporteurs were appointed with tacit agreement.
Art. 77(3)(c) request	▪ Revision of the CLH proposal for setting Specific Concentration	29 August 2014	Closed No comments were

Appointment RAP	For Substance	Deadline	Outcome
	Limits (SCLs) for tetrapropylphenol (TPP) submitted by Chevron Oronite SAS in February 2013		received from RAC members on the recommendation of the Chairman; the RAC Rapporteur was appointed with tacit agreement.
	▪ RAC opinion on the consumer-related risk assessment contained in the RIVM report "Risk assessment of an increased concentration limit of benzene in natural gas"	31 August 2014	Closed No comments were received from RAC members on the recommendation of the Chairman; the RAC Rapporteur was appointed with tacit agreement.

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