RAC/M/31/2014

12 February 2015

Minutes of the 31st Meeting of the Committee for Risk Assessment (RAC-31) 25-27 November 2-4 December 2014

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 31st meeting of the Committee for Risk Assessment (RAC-31). Apologies were received from four members (at the RAC-31 A part of the meeting) and from nine members (at the RAC-31 B part of the meeting). The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting and reminded the meeting participants that RAC-31 is one meeting spread over two weeks, informing them that the meeting would be suspended on Thursday 27th November in the afternoon and reopened on Tuesday 2nd December at 09:00. The following agenda items had been added to the Final Draft Agenda:

- Authorisation: DEHP 2c (use 3) and DBP 2 (use 3) (AP 8.2.e)
- Mode of Action (MoA) Workshop (AP 6.3)

The Agenda (RAC/A/31/2014) was thus 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. Fifteen members and one invited expert 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. For any newly arrived members, the request for declarations was repeated at the start of the second week. 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-30 action points, written procedures and other ECHA bodies

The Chairman informed the Committee that all action points of RAC-30 had been completed, or were on-going. The summary of all consultations, calls for expression of interest in rapporteurships and written procedures is available in the usual meeting document on CIRCABC (see Annex IV). He also informed the Committee that the final minutes of RAC-30 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website on 13 November 2014, 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 Q1&Q2/2015, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances. He informed members that they could find the expected schedules for Restriction

and Authorisation dossiers in the work plan. In addition, the scheduling and the endpoints to be considered for each Harmonised Classification and Labelling (CLH) dossier for the next two meetings ahead are given in the relevant section, including those for human health and the environment.

c) General RAC procedures

The Secretariat provided a presentation on the revised Working Procedure on the appointment of rapporteurs for all processes, i.e. Applications for Authorisation, Restriction and CLH. The revision aims to increase the efficiency and harmonize and streamline all three processes. The Working Procedure, as outlined in the amended document RAC/31/2014/03 rev.1, was agreed by RAC.

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

a) Phenol, dodecyl-, branched Tetrapropenylphenol (TPP)

The Chairman welcomed a representative of the Dossier Submitter (Chevron Oronite SAS). He reported that based on a note from the Commission, RAC received a mandate from the ECHA Executive Director requesting the Committee to review that part of the CLH proposal on Tetrapropenylphenol (TPP) related to setting of Specific Concentration Limits (SCLs), as originally submitted by Chevron Oronite SAS in February 2013 and adopted by RAC in December 2013 (CLH-O-0000003405-79-03/F).

Chevron Oronite SAS claimed that RAC in its opinion had not considered their SCL proposal (1.5%) for toxicity to reproduction adequately; more specifically that RAC had not properly assessed the dataset provided in accordance with Article 10 of the CLP Regulation. Chevron Oronite had no objection to the adopted classification (Repr. 1B; H360F).

The mandate requested the Committee to assess the scientific validity of the method used by Chevron Oronite SAS for calculating the SCL for toxicity to reproduction, suitability of the studies brought forward by the company and the compatibility of the proposal with the current ECHA guidance on setting SCLs vs. GCLs for reproductive toxicity.

The Rapporteur prepared a draft opinion addressing the three aspects as specified in the mandate.

The Dossier Submitter representative summarised in a brief presentation the Chevron Oronite's view and justification for the use of the 'limit dose' method used for their calculation of the SCL.

The Rapporteur then summarised the background for the calculation of specific concentration limits as set both in the CLP Regulation and in the Guidance on the application of the CLP criteria; version 4. Firstly, the method chosen by Chevron Oronite SAS is recommended against by the Guidance (Section VI.5.1.1.4), as it would result in an individual SCL for each substance. The Members considered that this would indicate a precision that could not be expected from standard reproductive toxicity studies. The approach taken by Chevron Oronite SAS to establish a SCL for TPP is also based on the assumption that a dose where no effect is seen in animals, i.e. supported as they claimed by the reproduction studies with TPP containing UVCB's, would be safe for humans. This assumption was not considered correct by the Committee, as such an approach would require the application of assessment factors or some sort of safety margin.

Several RAC members underlined that it should be the potency of a substance/mixture which would trigger the adaptation of a general concentration limit and potentially lead to the setting of a SCL. In this context another RAC member reminded the Committee that the original aim

of the Guidance was to cover most of the mixtures by the general concentration limit. This was confirmed by the representative of the Commission.

In a further exchange of views it was noted that whereas the Guidance leaves room for the use of methods other than the recommended 'ED10' method for setting a SCL, such an approach always needs to be fully justified and should only be used "in exceptional circumstances" as stated in Art. 10(1), third paragraph of the CLP regulation, which goes on to say that it should be based on 'adequate, reliable and conclusive scientific information'.

The Committee agreed that these conditions had not been fulfilled in the approach taken by Chevron Oronite SAS for setting a SCL for TPP. The Committee concluded that the studies on TPP itself were sufficient for the classification as well as for deriving the GCL and confirmed the conclusions of the Rapporteur and the earlier adopted opinion which was to apply a general concentration limit of 0.3 % for toxicity to reproduction of Tetrapropenylphenol (TPP). In the discussion, members supported the analysis of the Rapporteur, thus retaining the general concentration limit (GCL) for TPP as adopted at RAC 27 in December 2013.

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

b) Consumer exposure to benzene contained in natural gas

The Chairman welcomed a representative from RIVM in the Netherlands who followed the plenary discussion via remote connection, regarding RIVM letter report 601352002/2013. The Chairman clarified that the Committee was requested to draw up an opinion on the consumer-related risk assessment referring to cooking and heating, which was contained in the RIVM Report 601352002/2013 "*Risk assessment of an increased concentration limit of benzene in natural gas*" under a mandate from the Executive Director of ECHA in accordance with REACH Art. 77(3c) and based on a note from the Commission. He reminded the Committee that the Rapporteur had already summarised the mandate and the time plan for the preparation of the opinion at RAC-30 in September; and that it was intended for discussion and adoption at this meeting.

The Rapporteur reported that the use of benzene is restricted to prevent risks to human health. In Annex XVII to REACH the presence of benzene in natural gas is indicated as a mass fraction (0.1 percent comparable with 1 g benzene in 1000 g natural gas). It is proposed to change this to the same unit as set for gases in other European legal frameworks. In those other frameworks maximum levels are indicated as a volume fraction (0.1 percent comparable with 1 litre benzene in 1000 litres natural gas). According to RIVM, it is unlikely that this conversion would cause health hazards in typical situations of human exposure to benzene via natural gas. This is demonstrated in their report for various exposure scenarios, including the use of natural gas at home in the kitchen and for household heating.

In particular, the RIVM letter report concluded that consumer exposure to benzene present in natural gas at a concentration greater than 0.1% (w/w) but below 0.1% (v/v) during regular use of natural gas as fuel for cooking and heating does not represent a risk for consumers that is not adequately controlled.

The Rapporteur confirmed that for the exposure scenarios referring to cooking and heating (domestic uses), a volume-based, increased concentration limit would still ensure adequate control of the risks for consumers. He pointed out that the conclusion was valid for the exposure conditions as described in the RIVM report. However, it could not be verified whether risks from exposure scenarios which are based on assumptions, conditions and equipment differing from those described in the report, e.g. as it may be the case in other Member states,

still provide adequate control, because relevant information was missing in the RIVM report. RAC members confirmed this view; as an example for differing assumptions, RAC members asked whether in case of lighting for heating without a pilot flame, risks could be adequately controlled.

The Committee was informed that as stated in the RIVM report, most benzene concentrations in natural gas are below the limit of 0.1% (w/w). Occasionally, benzene concentrations would exceed this limit with concentrations up to 0.42 % (w/w). This would occur for natural gas from small fields. However, this natural gas with a higher concentration of benzene is subsequently diluted with natural gas from other sources; this means that consumer exposure to high benzene content in natural gas is limited due to dilution. It was assessed by RIVM that a benzene concentration of 0.1% (w/w) in natural gas overall reflects a worst case situation for Dutch consumers. As to the situation for consumers in other EU Member States, it is stated in the report that this worst case assumption would also hold for natural gas transported outside the Netherlands, as it would be diluted even further during transport and mixed with other sources. As to the question about risks in case of lighting for heating without a pilot flame, the rapporteur explained that the exposure due to that scenario was probably comparable to a single lighting for cooking per day.

RAC agreed with the conclusions presented by the Rapporteur, that consumer exposure to benzene present in natural gas at a concentration greater than 0.1% (w/w) but below 0.1% (v/v) during regular use of natural gas as fuel for cooking and heating as described in the RIVM report does not represent a risk for consumers that is not adequately controlled. The Committee 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.

6. Harmonised classification and labelling (CLH)

6.1 CLH dossiers

A. Hazard classes for agreement without plenary debate

a) Pirimicarb (ISO): Acute toxicity (oral, dermal, inhalation)

b) Fluopyram (ISO): Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Eye corrosion/irritation, Skin sensitisation, Aquatic Acute, Aquatic Chronic

c) Thiacloprid (ISO): Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Eye corrosion/irritation, Skin sensitisation, Aquatic Acute, Aquatic Chronic

d) Triflumizole: Acute toxicity (oral, dermal, inhalation), STOT SE, Skin corrosion/Irritation, Eye corrosion/irritation, Respiratory tract irritation, Skin sensitisation, Respiratory sensitisation, Aquatic Acute, Aquatic Chronic

e) Pencycuron (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Skin corrosion/irritation, Eye corrosion/irritation, Respiratory sensitisation, Skin sensitisation, STOT RE

The above hazard classes were all agreed by RAC (see further below for additional information on each substance).

B. Substances with hazard classes for agreement in plenary session

a) Acetochlor (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that the pesticide active substance Acetochlor (ISO) 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 reminded that Acetochlor (ISO) was being tabled for a second plenary discussion; legal deadline for adoption of the CLH opinion is 4 June 2015. At the Committee meeting in September 2014 (RAC-30), RAC already agreed to classify the substance as Carc. 2 (H351), Acute Tox. 4 (H332), STOT RE 2 (H373, kidney), STOT SE 3 (H335), Skin Irrit. 2 (H315) and Skin Sens. 1 (H317). RAC also agreed to classify Acetochlor (ISO) as Aquatic Acute 1 (H400) with an M-factor of 1000. At RAC-31b, the remaining hazards, i.e. Aquatic Chronic and reproductive toxicity, were to be completed with the view to the adoption of the opinion. As to the former, RAC agreed to classify Acetochlor (ISO) as Aquatic Chronic 1 (H410) with an M-factor of 100.

With regard to reproductive toxicity, the Chairman reported that ECHA had sought further input from parties concerned and therefore a targeted public consultation on the reproductive toxicity of Acetochlor (ISO) had been conducted in September 2014. Three comments were received from stakeholders, which were taken into consideration by the Rapporteur in the revised draft opinion.

The Rapporteur in his presentation, consistent with the view presented at RAC 30, argued for classification as Repr. 2 (H361f), based on severe effects in the testes of dogs in the repeated dose toxicity studies and supported by findings in a 2-generation study in rats, where slight but statistically significant reductions in the numbers of live pups and implantations (in the presence of significant maternal toxicity) as well as in ovary and (absolute, but not relative) testis weights were observed. However, the significant findings in dogs occurred only in the 1 year studies (and not after 90-119 days treatment), but in one of the studies in the presence of evidence for significant (in particular) kidney toxicity. RAC therefore discussed whether or not the testicular findings in dogs were likely to be secondary to chronic renal failure. In the discussion RAC noted that there was no clear mechanistic link between the renal findings and testicular toxicity. The IND representative argued that some of the data were consistent with uraemic syndrome in the dogs and pointed to the discrepancy between the renal findings in the two 12 month studies in dogs. RAC noted that testis weight along with brain weight were normally stable and therefore reductions in testis weight should be given more serious consideration than most other organs, especially when accompanied by notable histopathological findings. It was also noted that no significant new information relevant to the reproductive toxicity data classification had been contributed either from the targeted public consultation or the subsequent review of the slides from the dog studies reported by Industry. RAC agreed that on the weight of evidence, a Repr.2 classification for adverse effects on sexual function and fertility (H360f) was the most appropriate.

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

b) 3,7-dimethylocta-2,6-dienenitrile (Geranonitril)

The Chairman welcomed the Rapporteurs and reported that geranonitril was mainly used as a fragrance component (current use is unknown). It has no current entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 25 May 2015. The Dossier Submitter (Germany) proposed to classify geranonitril as mutagenic, Muta. 1B; H340.

The Rapporteur presented the Dossier Submitter's proposal based on the potential of the substance to induce chromosomal damage in somatic and germ cells. This is based on the results of studies in mice and supported by positive results from *in vitro* test.

RAC members supported the proposal and agreed to the proposed classification of geranonitril as a mutagen in category 1B. RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee members for their comments.

c) Chlorsulfuron (ISO)

The Chairman reported that Chlorsulfuron (ISO) was a pesticide active substance which had been approved in 2009 for Annex I listing under Council Directive 91/414/EEC. The substance was discussed for the first time at a RAC plenary meeting; legal deadline for adoption of the CLH opinion is 18 August 2015.

The Chairman clarified that the substance was listed in Annex VI to CLP with harmonised classifications as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set. The Dossier Submitter from Poland proposed a review of the CLH, namely Aquatic Acute 1 (H400) with M=1000 and Aquatic Chronic 1 (H410), with M=100. As to health hazards, no proposals had been made by the Dossier Submitter, so no further hazards were available for RAC evaluation.

The Rapporteur presented the draft opinion. He reported that various RAC members had raised issues pertaining to the Boeri study (2002) and the Douglas *Lemna* study (1988). In particular, the ErC50 and NOEC in the *Lemna* study had been based on nominal concentrations in the CLH report and, following RAC members comments, the Rapporteur recalculated them based on the geometric mean of the initially measured concentration and 1/2 LOQ (as per ECHA guidance). The recalculated ErC50 and NOEC lead to higher M-factors, i.e. acute M-factor 10000 and chronic M-factor 1000. The Rapporteur showed both options but proposed the M-factors in accordance with the original proposal by the Dossier Submitter, i.e. acute M-factor = 1000 and chronic M-factor = 100.

RAC agreed with the Rapporteur's and Dossier Submitter's proposal for the M-factors and 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) Pirimicarb (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. The Chairman reported that Pirimicarb is an active substance authorised in the EU and used exclusively as an insecticide. The substance was discussed for the first time at a RAC plenary meeting; legal deadline for adoption of the CLH opinion is 31 October 2015.

The Chairman clarified that Pirimicarb already had an entry in Annex VI to the CLP Regulation where it is classified as Acute Tox. 3* (H301), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). The Dossier Submitter from the United Kingdom proposed to classify the substance as Carc. 2 (H351), Acute Tox. 3 (H331), Skin Sens. 1B (H317), to remove the minimum

classification for Acute Tox. 3* (H301), and to add M-factors of 10 and 100 for Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), respectively.

The RAC discussed harmonised classification as Skin Sens. 1 (H317) vs. Skin Sens. 1B (H317), Carc. 2 (H351) vs. no classification, M-factors for aquatic toxicity, as proposed by the Dossier Submitter.

After a short discussion on skin sensitisation, RAC agreed that there is not sufficient evidence to classify the substance in any sub-category (1A or 1B). RAC therefore agreed to classify Pirimicarb as Skin Sens. 1 (H317), without sub-categorisation.

On carcinogenicity, the Rapporteur presented a summary of the available studies and various arguments in favour or not of the classification of Pirimicarb in category 2. Pirimicarb induces an increase in the incidence of lung adenomas in female C57 black mice, a strain with a low background incidence of lung adenomas. No mechanistic data could dismiss the possible human relevance of these tumours, although RAC recognised that Pirimicarb is not a genotoxic substance. However, a number of RAC Members expressed their view that the high number of different tumours in various and sometimes unexpected organs (brain, mammary gland) in the rat gives sufficient evidence for classification of the substance as Carc. 2 (H351).
With regard to the environmental classification, the Rapporteurs presented a proposal by the Dossier Submitter to introduce an M-factor of 10 for the aquatic acute toxicity and 100 for the aquatic chronic toxicity. The Committee agreed on the proposal.

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.

e) Benzovindiflupyr (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer, and the Dossier Submitter (France) and EFSA representatives, who were both following via WebEx. The Chairman noted that Benzovindiflupyr currently has no entry in the harmonised classifications in Annex VI to the CLP Regulation. The substance is proposed for use as a fungicide in the EU (not yet approved under EC Reg.1107/2009) and is manufactured inside and outside of the EU. The Dossier Submitter proposed to classify Benzovindiflupyr as Acute Tox. 3 (H301), Acute Tox. 3 (H331), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M-Factors of 100 for both acute and chronic effects.

The Chairman reminded the Committee that, as Benzovindiflupyr is a new active substance in the meaning of the pesticides Regulation, the CLH opinion development for this dossier is aligned with the EFSA peer review process. Additional information by the Dossier Submitter, as requested under the EFSA process, was received very late in the development of the RAC opinion. However it had been possible for the Rapporteurs to make a proper assessment and this is reflected in the draft opinion presented to the RAC.

The Chairman invited the Rapporteurs to present the second version of the draft opinion document, as revised after the RAC consultation. A representative from EFSA informed RAC that there will be an expert working group meeting in January to discuss the aspects related to potential endocrine disruptor (ED) properties of Benzovindiflupyr. The Chairman, after consultation with the Secretariat, clarified that under the CLP regulation the ED properties are considered in the context of mode of action assessment for various endpoints such as reproductive toxicity and STOT RE, however they do not constitute a separate classification hazard.

During the discussion, RAC members supported the assessment of the Rapporteurs and agreed on the proposed classification for Benzovindiflupyr. Following the evaluation of the data presented on the CMR and STOT-RE properties of the substance, RAC agreed that no

classification is warranted for Benzovindiflupyr for these endpoints. RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee members for their comments.

f) Fluopyram (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer and presented a brief background on the dossier. He noted that Fluopyram is a fungicide and is a new substance in the meaning of Regulation (EC) No 1107/2009. Preparations of Fluopyram are proposed for use in the areas of agriculture, horticulture and viticulture. The substance has no entry in the harmonised classifications in Annex VI to the CLP Regulation. The Dossier Submitter (Germany) proposed the evaluation of the following hazard classes: Carc. 2 (H351) and Aquatic Chronic 2 (H411).

The environmental part of the draft opinion document, as well as several endpoints for which no classification was proposed were agreed via a fast-track and RAC supported the Rapporteur's and the Dossier Submitter's proposal. The Chairman then invited the Rapporteur to present the human health part of the second version of the draft opinion document, as revised after the RAC consultation.

With regard to single and repeated dose exposures (STOT SE and STOT RE), as well as for germ cell mutagenicity, RAC agreed that no classification is warranted. The discussion continued on carcinogenicity, focusing on the mode of action of the CAR activation in thyroid and liver tumours and whether this is relevant to humans or not. Following a thorough consideration of the data presented, RAC agreed that the proposed classification for carcinogenicity is not warranted for Fluopyram, noting that the presented mechanism in this case is not likely to be relevant to humans.

The Rapporteur continued with the proposal related to reproductive toxicity. The ECPA stakeholder provided clarifications on the teratogenicity studies. RAC agreed with the proposal of the Dossier Submitter that no classification for reproductive toxicity is warranted.

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

g) Tert-butyl hydroperoxide (TBHP)

The Chairman welcomed a representative from the Dossier Submitter (Netherlands) who followed the plenary discussion via remote connection. The Chairman reported that TBHP was used in the chemical industry primarily as a starting material and as reactive ingredient. The substance was discussed for the first time at a RAC plenary meeting; the legal deadline for adoption of the CLH opinion is 3 August 2015.

The Chairman clarified that TBHP had no harmonised classification in Annex VI to CLP. The Dossier Submitter from the Netherlands proposed to classify the substance in category 2 for germ cell mutagenicity, Muta. 2 (H341), based on the positive results in two dominant lethal mutation assays performed by the intraperitoneal route, which provided evidence for local mutagenicity of TBHP.

The Rapporteur who presented the case proposed to agree with Dossier Submitter to classify TBHP as Muta.2 (H341). During the debate in RAC, however, it was argued whether a classification as Carc. 2 (H351) was more appropriate, based on the local genotoxicity observed. But since carcinogenicity was not addressed in the CLH report, RAC could not give an opinion on this endpoint due to lack of data.

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.

h) Thiacloprid (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that thiacloprid (ISO) is mainly used in the EU as an insecticidal plant protection product in the form of foliar spray applications for professional use. The substance has no current entry in Annex VI of the CLP Regulation and the legal deadline for the adoption of an opinion is 3 August 2015. The Dossier Submitter (UK) proposed to classify the substance for acute toxicity (Acute Tox. 3; H301, Acute Tox. 4; H332), carcinogenicity (Carc. 2; H351) and toxicity to reproduction (Repr. 2; H361f) and for environmental hazards as Aquatic Acute 1; H400 with M factor =100 and Aquatic Chronic 1; H410 with M factor =100.

As thiacloprid (ISO) is an active substance with no existing harmonised classification, all hazard classes were assessed. The Committee agreed on no classification for acute toxicity via the dermal route, skin/eye corrosion/irritation and skin sensitisation. For acute toxicity via the oral and inhalation routes and environmental hazards, the Committee supported the original Dossiers Submitters proposal. These hazard classes were agreed via the fast track agreement.

Carcinogenicity, mutagenicity (no classification), toxicity to reproduction, STOT SE (STOT SE; H336 – narcotic effects, proposed by the Rapporteur), STOT RE (no classification) were discussed in the plenary.

A short discussion was held on the Rapporteur's proposal to classify the substance as STOT SE 3 for narcotic effects based on the data in acute toxicity studies and in acute neurotoxicity studies in rats. The expert accompanying the ECPA stakeholder observer noted that the observed effects were due to nicotinergic effect on the muscle nACh receptors and not due to central nervous system depression and therefore the classification should not be warranted. The Rapporteur noted that nACh receptors were located also in the central nervous system and there was no data to conclude on the MoA of the observed effects in animals. The RAC members supported the Rapporteur's proposal based on the clear symptoms observed in the absence of lethality meeting the classification criteria in animals.

The Committee supported the conclusion on no classification for mutagenicity and STOT RE.

Where carcinogenicity is concerned, in the CLH report, 3 tumour types were reported in 2 different species; malignant uterine adenocarcinoma in rats, mostly benign ovarian luteomas in mice and thyroid tumours in rats. Firstly, RAC discussed the human relevance of thyroid tumours. The Dossier Submitter proposed that the mechanism of thyroid tumours, which occurred mostly in males, was UDPGT induction. The UDPGT induction mediated thyroid tumours are considered as not relevant to humans in the CLP guidance. Induction of UDPGT was expected to lead to decrease in serum T4 and T3 levels and a compensatory increase in TSH that would result in thyroid hyperplasia and tumours. One member was of the opinion that it could be concluded that the thyroid tumours were not relevant to humans, while it was pointed out by another RAC member that it should not be concluded that any thyroid tumours were not relevant to humans. Several RAC members were of the opinion that the sequence of events of the proposed MoA was not sufficiently demonstrated and other MoAs could not be excluded, especially because the substance was shown to affect the hormonal balance in general. One RAC member added that the evidence for UDPGT-mediated MoA was not as conclusive as in other cases in which RAC had agreed that this MoA had been demonstrated. The IND representative commented that despite the T3 and T4 levels were increased at some time points in the 13-week rat study, they were within the historical control ranges. One RAC member was of the opinion that internal controls were more relevant and the hormone levels

of historical controls should not be given too much weight. RAC concluded that the relevance of the observed thyroid tumours to humans could not be excluded in this particular case. As there were also other tumour types, RAC did not conclude on whether these tumours alone would warrant a classification but decided to conclude on classification after assessing all evidence for carcinogenicity.

RAC next discussed whether the malignant uterine tumours occurred above the Maximum Tolerable Dose as suggested by IND. After getting a clarification from IND that the reported decrease in body weight indicated a decrease in body weight as compared to control animals, but within the group reflected a decrease in body weight gain, RAC agreed unanimously that there were no signs of any severe systemic toxicity and that MTD was not exceeded. In addition, RAC was of the opinion that the ovarian tumours in mice did not co-occur with severe systemic toxicity. Regarding the single malignant ovarian tumour, IND commented that luteomas were always benign and the histopathological analysis of the tumour was perhaps performed before the definition of luteoma was set. Uterine tumours in rats and the ovarian tumours in mice were considered as of human relevance and the hormonal imbalance was considered as a plausible MoA of non-genotoxic thiacloprid.

Based on all available evidence, RAC concluded to classify thiacloprid in category 2 for carcinogenicity.

Finally, RAC discussed reproductive toxicity. It was questioned whether dystocia should be considered as an adverse effect on sexual function and fertility or on development or whether it should not be specifically considered under either of these subdivisions but rather under reproductive toxicity in general without a specification. In order to be able to conclude on this, RAC requested for a detailed presentation of the exposure periods in all dystocia studies. RAC also asked for a more detailed presentation of the reproductive and maternal toxicity data for all individual studies relevant for the hazard class. Due to the large number of studies and further details requested, RAC did not conclude on the classification for reproductive toxicity; the Chairman noted that this will be tabled again at RAC 32 in March for agreement.

i) Triflumizole

The Chairman welcomed an expert accompanying the ECPA stakeholder observer as well as a representative from the Dossier Submitter (the Netherlands) who followed the plenary discussion via remote connection. The Chairman reported that Triflumizole was a fungicide mainly used on fruiting vegetables and ornamentals. The substance was discussed for the first time at a RAC plenary meeting; legal deadline for adoption of the CLH opinion is 17 September 2015.

The Chairman clarified that Triflumizole had no harmonised classification in Annex VI to CLP. The Dossier Submitter (NL) proposed to classify the substance as Repr. 1B (H360D), Acute Tox. 4 (H302), STOT RE 2 (H373; liver), Skin Sens. 1 (H317), Aquatic Acute 1 (H400, M-factor of 1) and Aquatic Chronic 1 (H410, M-factor of 1).

As Triflumizole is a plant protection product with no existing harmonised classification, all hazard classes need to be assessed. The Committee agreed on no classification for STOT SE, Skin/Eye irritation, Skin/Eye corrosion, Respiratory tract irritation and Respiratory sensitisation. For Skin sensitisation, Acute toxicity via oral route and Environmental toxicity hazard classes, the Committee supported the original Dossier Submitter's proposal. These hazard classes were agreed via the fast track agreement.

CMR hazards and STOT RE were discussed at the plenary. The Committee concurred with the Dossier Submitter on no classification for mutagenicity and carcinogenicity based on negative results from the studies performed. Also no classification for effects on sexual function and fertility was agreed.

In the discussion, RAC supported the Dossier Submitter proposal for specific target organ toxicity after repeated exposure (STOT RE 2; H373) based on liver effects observed in 28-day repeated dose toxicity study, a 2-year study in rats and 90-day repeated dose toxicity studies in rats and mice. It was argued that although in some studies the effects were seen slightly above the guidance values in CLP, the consistency of effects seen in several studies were considered to support classification as STOT RE 2 for effects on liver.

RAC discussed the proposed classification for developmental toxicity and agreed to classify triflumizole as Repr. 1B; H360D based on clear adverse effects in rat (oral exposure) in a developmental toxicity study (reduced number of live foetuses at birth, increased number of late resorptions and death, as well as reduced foetal weights). In a rabbit developmental toxicity study there was a decreased survival rate after 24 hours. Several members supported the conclusion and confirmed that the observed effects across a number of studies, occurring together with only slight to moderate maternal toxicity, were *per se* sufficient for the classification even without additional comparison with other azole substances (e.g. letrozole).

The expert accompanying the ECPA stakeholder observer did not dispute the aromatase inhibition effects of triflumizole, but noted that there might have been different mechanisms in different species that could override these effects; e.g. the rat is considered to be more sensitive to estrogen depletion compared to humans. She further explained the decrease in 24-hour survival rate in rabbits with the stress caused upon the pups when being separated from the dam. As a further argument, the expert mentioned several azole substances which were used as therapeutic drugs (mentioned but not further developed in the dossier) also during pregnancy without any reported adverse effects and referred to epidemiological studies, which had however not been provided to RAC. This was argued against by several RAC members who said that the use of azole medications is contraindicated in pregnant women.

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.

j) Diisobutyl phthalate (DIBP)

The Chairman welcomed a representative from the Dossier Submitter (Germany) who followed the plenary discussion via remote connection. The Chairman reported that DIBP was used as a plasticiser. The substance was discussed for the first time at a RAC plenary meeting; legal deadline for adoption of the CLH opinion is 9 September 2015.

The Chairman clarified that DIBP already had an entry in Annex VI to the CLP Regulation where it is classified as Repr. 1B (H360Df) with specific concentration limits of 25% for developmental effects and 5% for effects on sexual function and fertility. The Dossier Submitter from Germany proposed to remove the SCL, and to apply the generic concentration limits (GCLs) instead, in view of new study results and the revised method of deriving an SCL for reproductive toxicity, which was implemented through Version 3.0 of ECHA's *Guidance on the Application of the CLP Criteria* (November 2012).

The proposal to remove the SCL and to apply the GCL was shared by the Committee: It was concluded that application of the GCL of 0.3% for developmental effects and of 3% for fertility effects was justified. 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.

k) Dicyclohexyl phthalate (DCHP)

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. The Chairman reported that DCHP was a common plasticizer ingredient in the production of

nitrocellulose, ethyl cellulose, chlorinated rubber, polyvinyl acetate, polyvinyl chloride, and other polymers resins and it is also used in paper finishes and makes printing ink water-resistant (HSDB 2013). The substance was discussed for the first time at a RAC plenary meeting; legal deadline for adoption of the CLH opinion is 18 August 2015.

The Chairman clarified that DCHP had no harmonised classification in Annex VI to CLP. The Dossier Submitter from Sweden proposed the following CLH: Repr. 1B (H360FD) and Skin Sens. 1 (H317).

The Rapporteurs presented the draft opinion, which proposed classifications as Skin Sens. 1 (consistent with the Dossier Submitter's proposal) and Repr. 1B (H360Df). Related to the skin sensitisation property, RAC concludes that DCHP should be classified as a Skin Sens. 1 since the SI from the second experiment in the key study were higher than those indicted in the OECD Test Guideline 442B as borderline. In the discussion on the reproductive toxicity classification, RAC agreed that the atrophy of the testes seen in pre-pubertal animals as well as reduced AGD and increased incidence of areola mammae in male pups was severe enough to justify classification as Repr. 1B for developmental toxicity (H360D). These effects were reported in the absence of marked maternal toxicity. The adverse effects observed in male reproductive organs including testicular tubular atrophy and atrophic tubules in the prostate occur after *in utero* exposure and are considered as supportive evidence of developmental effects. The findings were consistent with an anti-androgenic effect which is relevant to humans. However, the effects on the testes were only seen in animals exposed *in utero* and the effects on spermatids and prostate were not considered pronounced enough to justify classification for fertility effects. The expert accompanying the Cefic stakeholder observer argued that the reduced AGD was not considered as an adverse effect and that developmental effects seen following *in utero* exposure to DCHP were weaker than those observed for other phthalates, such as DBP or DBHP.RAC decided to adopt classifications for DCHP as Skin Sens. 1 (H317) and Repr. 1B (H360D) and agreed that as there had been no proposal from the DS with regards to Specific or generic Concentration Limits it was appropriate not to evaluate this.

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.

l) Pencycuron (ISO)

The Chairman welcomed a representative from the Dossier Submitter (Netherlands) who followed the plenary discussion via remote connection. The Chairman reported that Pencycuron (ISO) was an active substance for herbicidal use, which has been included in Annex I to Directive 91/414/EEC. The substance was discussed for the first time at a RAC plenary meeting; legal deadline for adoption of the CLH opinion is 8 October 2015.

The Chairman clarified that the substance had no harmonised classification in Annex VI to CLP. Therefore, RAC was requested to review all hazard classes including those for which no classification was proposed by the Dossier Submitter. The Dossier Submitter (The Netherlands) proposed a harmonised classification as Aquatic Chronic 1 (H410), with M=1, while they did not consider a classification for human health hazards appropriate.

The Rapporteurs presented the draft opinion. They proposed not to classify for any human health hazards apart from developmental toxicity upon which they evaluated to ascertain whether the classification would be warranted or not. In this connection, RAC discussed the decreases in pup body weights in F1 and F2 generations that were the most pronounced in the F2 generations during postnatal day 21 (PND21) and that did not co-occur with any significant decrease in maternal body weight in the F2 generations. It was proposed that the effect was due to dietary exposure of the pups as the decrease in pup body weight was more pronounced

towards the PND21 when the pups had already started to eat. However, as there were already decreases in pup body weight before the pups started to eat, it could not be concluded that the effect was due to exposure via diet. In addition, RAC did not have data on milk production of dams or on substance in milk. Taken together, RAC concluded that the evidence was not sufficient to justify classification for developmental or for lactation effects.

As to the aquatic hazards, RAC agreed with the Rapporteur to classify Pencycuron (ISO) as Aquatic Chronic 1 (H410) with M=1 as proposed by the Dossier Submitter, but also decided to classify as Aquatic Acute 1 (H400) with M=1, based on a study provided during public consultation that was not included in the CLH report.

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.

m) and n) E-glass microfibres and glass microfibres of representative composition

The Chairman welcomed the representatives from the Dossier Submitter (France) who followed the plenary discussion via remote connection. The Chairman reported that both microfibers were designed for high- and ultra-high-purity filtration of air and liquids. Applications include filtration for the general ventilation of buildings, hospital clean rooms, industrial and research laboratories, nuclear power plants and high-purity filtration and are not for use in household insulation. The only non-filtration application is for specialised insulation (e.g. in aircraft) and for battery separator media.

E-glass microfibres and glass microfibres of representative composition were discussed for the first time at a RAC plenary meeting although their classifications were already agreed at TC C&L (2007) with slightly different substance identifications; legal deadline for adoption of the CLH opinions is 13 August 2015.

The Chairman clarified that while both microfibres were characterised by their chemical composition and physical shape (length, diameter, aspect ratio), a range of substance identity issues needed to be clarified in the dossier and as a result, the submission and public consultation had then been repeated and the opinion development process re-started earlier this year.

Neither glass microfibres nor E-glass microfibres of representative composition had an entry in Annex VI to CLP. The Dossier Submitter from France proposed the following CLH:

- Glass microfibers of representative composition: Carc. 2; H351 (with note R)
- E-glass microfibers of representative composition: Carc. 1B; H350i (with note R)

The Rapporteur recommended to classify both substances in accordance with the Dossier Submitter's proposal, but also argued for reflecting the inhalation route in the hazard statement for glass microfibers; he also questioned the applicability of Note R.

RAC agreed to classify E-glass microfibers as proposed. It was confirmed to include the inhalation route in the hazard statement (H350i) as it could not reasonably be assumed that other routes of exposure were relevant.

In relation to the glass microfibers, it was noted that the data provided were of low quality, while overall insufficient evidence was provided in the dossier in order to unambiguously decide whether Carc. 1B could be justified. Based on the evidence provided and the classification criteria, the Committee concluded to classify glass microfibers of representative composition as Carc. 2; also in this case the inhalation route was included in the hazard

statement (H351 (inhalation)), as it could not be reasonably assumed that other routes of exposure were relevant.

Finally the Committee discussed whether any of the Notes A, Q and R should be assigned to both substances. It was concluded that Note A needed to be assigned to maintain consistency with the Annex VI entries for other fibres, including for refractory ceramic fibres. As to Note R, the Secretariat clarified that Note R referred to fibre diameters (Length Weighted Geometric Mean Diameter (LWGMD) less than two standard geometric errors greater than 6 µm) and not the length which were outside the scope of the entries. Note R refers to bulk Man Made Mineral Fibres (MMMF) whereas glass microfibres are specifically manufactured as fibres with a diameter of less than 3 µm. It was therefore not considered relevant to apply this note to either substance. Note Q was not considered appropriate because the available evidence showed that the fibres produced carcinogenicity via the routes of exposure described in the note Q. It was therefore agreed that it was not relevant to include exemption conditions for both glass microfibres.

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

o) Copper dossiers (environmental hazards)

Tetracopper hexahydroxide sulphate, Dicopper chloride trihydroxide, Copper flakes (coated with aliphatic acid), Copper thiocyanate, Bordeaux mixture, Copper (II) carbonoate – Copper (II) hydroxide (1 :1), Copper (II) oxide, Copper (II) hydroxide, Copper (I) oxide, Copper sulphate pentahydrate

The Chairman welcomed the experts accompanying the EUROMETÁUX, Cefic and ECPA stakeholder observers as well as representatives from the Dossier Submitter (France) who followed the plenary discussion via remote connection. The Chairman reported that the deadline for adoption was 17 June 2015. The substances are used as active substances in biocides and plant protection products; accordingly all hazard classes would have to be evaluated and discussed. Only three copper compounds had an existing Annex VI entry (dicopper oxide, copper thiocyanate and copper sulphate pentahydrate).

The Chairman noted that the substances were to be discussed for the second time at a RAC plenary meeting; at RAC-30 in September 2014, the Committee had already agreed on the human health hazard classifications as displayed in the classification tables annexed to these minutes. The Chairman clarified that following the debate on the aquatic hazards at this RAC meeting it is the aim to adopt the opinions.

The Rapporteur presented generic issues considered relevant for the evaluation of all copper compounds and copper flakes for their environmental hazards such as 'rapid removal', data selection and aggregation as well as the dissolution/transformation protocol data on water solubility. He then provided a detailed overview of the data available for classification purposes. Consideration was first given to the concept of rapid environmental transformation and removal of copper ions from the water column. While the information presented in the CLH dossiers provided a useful insight into key fate pathways in a model shallow lake system, it was noted by the Rapporteur that on the basis of the available information there was not sufficient evidence that copper (II) ions are rapidly and irreversibly removed from the water column. The Rapporteur's view was supported by several Committee members. During the discussion it was further emphasised that sediment is relied on as a permanent sink. Members questioned whether this was so and did not consider that it adequately covered: systems with sand or gravel substrates, high turbulence, water columns deeper that 3m, the oxidation state of surface layers, or high levels of existing contamination by metals. In addition, it was noted

that in comparison, rapid degradation for organic substances does not include sequestration by particulate matter (or other fate pathways such as volatility); instead it relies on mineralisation to CO_2 and water.

In addition to that, an advisor to a RAC member stressed that the results reported from full 7 and 28 days Transformation/Dissolution (T/D) tests (at a loading of 1 mg Cu/L) showed an increase of the soluble copper ions from day 7 to day 28. He further concluded that this contradicts any kind of transformation to insoluble forms.

Eurometaux commented that the modelling results derived with the TICKET-Unit World Model (TICKET-UWM) should be considered as supporting information to field, mesocosm and laboratory studies and reminded that the latter should be the basis for discussion within a Weight of Evidence approach. The rapporteur noted that the choice of the model is open to question with regard to the extent of Cu binding to particles and their settling velocity – further noting that 70% removal was not achieved in 28d in one of the field studies. The Rapporteur considered that the overall evidence of information presented in the CLH dossier was not considered representative for diverse environments.

One Stakeholder expert reminded that not only partition but also precipitation and speciation need to be considered on a case-by-case basis (and referred to the CLP guidance). The expert continued that according to the guidance for organic substances, rapid degradation of organic substances, is an intrinsic property that is also influenced by abiotic factors such as nutrients, pH and temperature. The Stakeholder expert raised a concern that all relevant information should be considered in a weight of evidence approach. For copper, information on the long term fate of copper ions from field evidence (lakes and rivers) as well as laboratory experiments are available and not all data were considered by the rapporteur. The Chairman reminded the meeting that all the information provided by the end of the public consultation would be considered and the RAC opinion was intended to be adopted.

A further factor considered by RAC was the risk and exposure based nature of the proposed model in the context of a hazard-based classification system.

The Committee agreed with the Rapporteur's view that no convincing case had been made that copper (II) ions will always rapidly speciate to non-available forms, and in particular that this process had been not been demonstrated to be irreversible under relevant environmental conditions. Therefore the Committee agreed that <u>for the purposes of classification</u>, Copper (II) ions are not subject to rapid environmental transformation.

The second part of the presentation focused on the data selected and the metals classification strategy applied for Aquatic Acute and Chronic hazard classification. The Rapporteur explained that the toxicity data in the CLH report were grouped in three pH bands (5.5-6.5; 6.5-7.5 and 7.5-8.5) and that there is a trend of increasing toxicity with lower pH. The dossier submitter's proposal for acute classification was based on the acute toxicity value of 29 µg/L at pH 5.5-6.5. However, the Rapporteur considered other data presented in the CLH report and proposed an LC_{50} value based on the geometric mean of survival studies at the lowest pH range (*Pimephales promelas larvae*, pH range 5.5-6.5, 8.1 µg Cu/L) considering that this was the most sensitive species in the acute tests. While this was supported by one RAC member, another proposal was to apply the lowest LC_{50} value of 4.4 µg Cu/L, since the two studies were not performed under exactly comparable conditions (differences in water hardness). Eurometaux explained that these studies were rejected in the REACH registration dossiers and the voluntary Risk Assessment Report prepared by Industry under the Existing Substance Regulation (Council Regulation (EEC) No 793/93) (ESR) due to the sensitivity of the tested early life stages of the species to acidic conditions. Eurometaux therefore questioned the reliability (acceptance) of these "larvae - early life stage tests" as a basis for acute environmental classification in accordance to the OECD Guideline 203, stressing further that

there are more than 250 LC_{50} values available for fish, covering the 3 pH groups, and more data points for *P. promelas* at higher pHs, to be used in a Weight of Evidence Approach. In the course of the discussion it was clarified that a microcosm study performed by the US EPA (Zischke et al., 1983) showed that *P. promelas* can survive at low pH which clearly indicates that the studies should not be considered invalid for <u>acute</u> endpoints.

In relation to the large dataset available, Eurometaux asked for clarification as to why the SSD approach was not used. The Rapporteur replied that while an SSD is possible, such an approach could risk masking effects on particularly sensitive groups due to abiotic factors such as pH in this type of case. It was also mentioned that the dataset presented contains an insufficient number of species and too few major taxonomic groups to justify the application of an SSD. The Chairman noted that the SSD approach was not included in the CLH dossier and normally RAC evaluates information that is included in the proposal or provided during the public consultation (PC). The Chairman concluded that on this basis RAC agrees on using the LC_{50} value of 8.1 µg Cu/L to derive the aquatic acute classification.

In relation to the chronic dataset, the Rapporteur presented the possible options to derive the chronic classification by using either the most sensitive chronic NOEC of 7.4 µg Cu/L for the pH range 6.5 to 7.5 (reported for *Ceriodaphnia dubia*), or available chronic NOEC values from two studies conducted with *O.mykiss,* or to apply the surrogate approach. The Rapporteur clarified that the preference of RAC was to use the chronic data which overrides the rather simplistic surrogate approach. However, there is evidence for some fish species which are more sensitive in the lowest pH-range and for which no data were presented in the current case. As a consequence and following the CLP guidance, the Rapporteur questioned the adequacy of the chronic data and concluded that the classification strategy should be a comparison of the surrogate approach with the classification based on available chronic data and to select the more stringent outcome. The Rapporteur proposed to include the chronic NOEC for *C. dubia* as the most reliable endpoint in this comparison to calculate the chronic ERV. An expert mentioned that the *O. Mykiss* NOEC of 1.7 µg/L was based on a test, carried out with a pesticide formulation and not the pure substance. The rapporteur proposed to use the Daphnia and surrogate approach for the fish. One Stakeholder expert did not agree with using the surrogate approach but supported the use of the *C. dubia* value and again consideration of the SSD was suggested. While Eurometaux argued that a conclusion based on the surrogate approach would go against the classification criteria for such a data rich substance and not in line with previous assessment for metals or the guidance, RAC considered that the acute data took precedence over inadequate chronic data, so using the surrogate approach was indeed justified. The Secretariat clarified the reasoning behind the chosen approach and referred to an example in the CLP guidance which is analogous to the current case.

The Committee furthermore agreed:

- That all copper compounds were considered readily soluble for classification purposes;
- The classification strategy applied for copper flakes should follow the one for metals given that the flakes are considered to be a specific form of the metal copper;
- To use only solubility data to classify copper compounds but 7 and 28 days T/D data provided during PC for the classification of copper flakes.

Based on the decisions taken, RAC concluded on the following classifications:

- <u>Copper flakes (coated with aliphatic acid):</u> Acute Tox. 4 (H302), Acute Tox. 3 (H331), Eye Irrit. 2 (H319), Aquatic Acute 1 (M=100)[1], Aquatic Chronic 1 (M=100)[1]

[1] After adoption of the opinion, the Secretariat became aware of an error in the calculation of the M-factors in the opinion for ***copper flakes***; accordingly, M=100 is not correct, but instead M=10 would be appropriate for both the acute and the chronic aquatic classification.

- Copper (II) oxide: Aquatic Acute 1 (M=100), Aquatic Chronic 1 (M=100)
- Copper (I) oxide; dicopper oxide: Acute Tox. 4 (H302), Acute Tox. 4 (H332), Eye Dam. 1 (H318), Aquatic Acute 1 (M=100), Aquatic Chronic 1 (M=100)
- Copper (II) hydroxide, copper dihydroxide: Acute Tox. 4 (H302), Acute Tox. 2 (H330), Eye Dam. 1 (H318); Aquatic. Acute 1 (M=10), Aquatic Chronic 1 (M=10)
- Copper (II) carbonate -- copper (II) hydroxide (1:1): Acute Tox. 4 (H302), Acute Tox. 4 (H332), Eye Irrit. 2 (H319), Aq. Ac. 1 (M=10), Aq. Chr. 1 (M=10)
- Dicopper chloride trihydroxide: Acute Tox. 3 (H301), Acute Tox. 4 (H332), Aquatic Acute 1 (M=10), Aquatic Chronic 1 (M=10)
- Copper thiocyanate: EUH032, Aquatic Acute 1 (M=10), Aquatic Chronic 1 (M=10)
- Copper sulphate pentahydrate: Acute Tox. 4 (H302) and Eye Dam. 1 (H318), Aquatic Acute 1 (M=10), Aquatic Chronic 1 (M=10)
- Tetracopper hexahydroxide sulphate [1], tetracopper hexahydroxide sulphate hydrate [2]: Acute Tox. 4 (H302), Aquatic Acute 1 (M=10), Aquatic Chronic 1 (M=10)
- Bordeaux mixture, reaction products of copper sulphate with calcium dihydroxide: Acute Tox. 4 (H332), Eye Dam. 1 (H318), Aquatic Acute 1 (M=10), Aquatic Chronic 1 (M=10)

RAC adopted all ten opinions by consensus. The Chairman thanked the Rapporteur and the ad-hoc group members for the presentation of the arguments, the Committee members for their participation in the discussions and the Industry experts for their contributions.

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.

6.3 Mode of Action/Human Relevance Framework Workshop

The Secretariat informed RAC on a recent workshop entitled "*Mode of Action and Human Relevance Framework in the context of Classification and Labelling (CLH) and regulatory assessment of biocides and pesticides*". The workshop was organised by ECHA in collaboration with EFSA and was attended by participants from MSCAs, industry representatives from the pesticides sector, academia, EFSA and ECHA. Several RAC members had participated and one held a presentation on the "*Challenges of MoA/HRF under CLH*". The workshop agenda, final report and presentations are available on the ECHA website at (http://echa.europa.eu/en/view-article/-/journal_content/title/workshop-on-mode-of-action-and-human-relevance-framework-under-clh-bp-and-ppp-regulations).

The Secretariat mentioned that under CLH, hazard classes are compared with the classification criteria (carcinogenicity but also toxicity to reproduction) as laid down in CLP. Case studies presented at the workshop demonstrated that presenting hazard information on key events within MoA analysis in a structured manner allows a more efficient and consistent assessment by the Committee. There was strong support at the workshop that the guidance and templates as developed by WHO/IPCS could provide useful tools for weight of evidence analysis and transparent documentation of MoA/HRF. WHO/IPCS templates are now available on ECHA the website at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. ECHA and EFSA will facilitate their uptake for use in biocides and PPP active substances hazard assessment and under the CLH process respectively (including for industrial chemicals). Additional workshops were recommended to follow up on the practical use and implementation as appropriate of the existing guidance for MoA.

The meeting was informed by the Secretariat of other potential initiatives in support of RAC evaluations on e.g. specific MoA expert consultations (e.g. ECHA-EFSA-JRC cooperation), monitoring international decisions and consensus under other regulatory frameworks, WHO/IPCS template integration and examples already dealt with by RAC and published in CLH opinions etc. In particular, in relation to the discussion on Fluopyram, the Chairman proposed that the Secretariat provide an analysis of CAR-mediated MoA leading to liver carcinogenicity that have been addressed so far by RAC.

7. Restrictions

7.1 General restriction issues

a) Review of the restriction process – update from the Task Force

The Secretariat provided an update from the Restrictions Efficiency Task Force. The RETF was set up following the CARACAL meeting of November 2013 in order to conduct a discussion among MSs, ECHA's Committees and the Secretariat, and the Commission and make recommendations for improving the efficiency of the restriction process. The RETF has agreed on the key observations and recommendations within the following topics: the opinion making procedures in the Committees, the extent of analysis required (dossiers and opinions), the challenges in preparing proposals, the scope and targeting, the proportionality and technicalities (Annex XV format, guidance). ECHA and the Commission intend to hold workshops in 2015 to discuss the implementation of recommendations with the MSs and to monitor the implementation of the recommendations by the relevant parties. It is proposed to report back to the Management Board and CARACAL at the end of 2015 on implementation and to monitor resources used for future restriction proposals.

7.2 Restriction Annex XV dossiers

a) Opinion development

1) Cadmium and its compounds in artist paints – revised draft opinion

The Chairman welcomed the Dossier Submitter representatives (Sweden, remotely), the SEAC Rapporteur and an industry expert accompanying the Eurometaux stakeholder observer. The Chairman informed the Committee on the state of play regarding the opinion development on placing on the market and use of cadmium and its compounds in artists' paints. The public consultation had resulted in 666 comments received from artists, industry, Member States, non-governmental organisations, a large majority being against the restriction proposal.

The Rapporteurs then presented their revised draft opinion to RAC, with a conclusion that the restriction is not supported. However, they pointed out that they had no information to contradict the EFSA opinion that cadmium input into the food chain needs to be reduced.

RAC agreed with the above conclusions by the Rapporteurs; given the very small and uncertain impact (48 bone fractures and 13 breast cancer incidents per year in 150 years), the effects proposed by the Dossier Submitter are considered to be less relevant to the conclusion of the EFSA opinion. Additionally, the uncertainties for the predictions were not quantifiable but definitely high, therefore a quantitative reliable and scientific evaluation of the risk reduction capacity was not possible.

It was recognised by RAC that the release factor of 5 % is not a reliable figure (although more plausible than the default of 1%) and adds significantly to the uncertainties of the assessment. RAC also considered that the cadmium content differs between different types of artists' paints

and also within individual types of paints, and that based on the available data it was not possible to evaluate whether or not a differentiation between sale to the general public or only to professionals would have a significant impact on the exposure. Finally, RAC concluded in terms of its effectiveness in reducing the risks from cadmium in artists' paints alone, this restriction is not considered to be the most appropriate EU wide measure to address the negligible level of risks.

Following some modifications to the justification text of the opinion, RAC adopted its opinion on Cadmium in artists' 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) Chrysotile - revised draft opinion

The Chairman welcomed the Dossier Submitter representatives (ECHA), the SEAC Rapporteur and an industry expert accompanying the Cefic stakeholder observer. The Chairman informed the Committee on the state of play regarding the opinion development to amend of the derogation to an existing restriction designed to phase out the last uses (two companies) of Chrysotile in the EU. RAC was invited to adopt the opinion as proposed by the Rapporteurs.

The Rapporteurs then presented the revised draft opinion to RAC, restating their support for the proposed risk management option 2 (i.e. derogation with a fixed end date). RAC discussed again the possibility for another review after 2025, but concluded no changes to the restriction proposed in the ECHA dossier.

The Commission observer asked for additional technical clarification on the wording of the justification on why import of long fibres (for quality assurance purposes) would still be needed, although Dow had made a voluntary commitment to the German authorities to stop import of fibres from 2017. They also asked for more clarification on the low risks.

After clarifying questions regarding the wording of the justification, the Chairman concluded that RAC adopted its opinion on Chrysotile 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.

After the RAC adoption, one stakeholder representative restated their position from RAC 30 regarding the amendment of the derogation, where they would have preferred the RMO4 (i.e. the end the current derogation immediately).

3) Isopropylidenediphenol (Bisphenol A) – first draft opinion

The Chairman welcomed an expert accompanying Cefic stakeholder observer and the Dossier Submitter representatives (France) who joined the meeting in person and/or followed the discussion remotely via WebEx. The Chairman also welcomed the SEAC Rapporteurs and informed the Committee of the state of play regarding the opinion development. Five detailed comments were received from RAC-members on the first draft opinion.

The RAC rapporteurs then presented the first draft opinion regarding the human health hazard assessment. The rapporteurs noted that robust effects are seen for female reproductive toxicity at doses of 50 mg/kg bw/day and above, and thus it was not considered a sensitive endpoint compared to the effects of BPA on the mammary gland. The rapporteurs considered the evidence for effects on brain and behaviour as well as effects on metabolism and obesity

not sufficiently convincing to set a NOAEL. Therefore, it was proposed that the focus of the hazard assessment should be on the mammary gland effects and that this endpoint should be taken forward in the risk assessment. RAC supported this approach. Several members were of the view that although the information regarding effects on brain and behaviour as well as metabolism and obesity does not appear to allow setting of a NOAEL, there is an indication of possible effects of BPA.

The discussion then focussed on the key oral and subcutaneous studies for mammary gland effects. The study quality, the nature of the observed effects, the nomenclature used to describe pathological findings, the consistency of the effects across studies, their adversity and the dose-response of the effects were debated.

Several members did not support the view of the rapporteur that based on the oral administration studies from Betancourt et al (2010), Jenkins et al (2009), Moral et al (2008), Tharp et al (2012) and Delclos et al (2014), an overall NOAEL of 25 µg/kg bw/day can be identified for effects on the development of the mammary gland.

Several members and an industry stakeholder observer stressed the importance of the US/FDA/NCTR (Delclos et al 2014) subchronic toxicity GLP-compliant study which used a high number of doses and animals per dose. It was also clarified after some discussion that this study was in fact complete and the results fully available for evaluation. They also considered that the recognized contamination in the serum of the control animals was not sufficient reason to dismiss the lack of effects at the 5 dose levels between 2.5 and 2700 µg/kg bw/day. It was also noted that other studies evaluated, such as the study by Moral et al (2008) had not measured the exposure levels in animals. It was furthermore pointed out that EFSA (2014) considered in its draft opinion that the study by Delclos et al (2014) was robust. An NGO stakeholder observer was of the view that it is not correct to assume contamination in studies that did not measure exposure levels.

One member reminded the Committee that the studies selected by the rapporteur as key studies were those with positive effects and that the absence of effects in the multi-generation studies should not be forgotten. One member was of the view that the effects seen do not appear to be consistent. Some studies are indicative of mammary gland proliferation, whereas others such as Moral et al (2008) and Delclos et al (2014) do not give evidence of proliferation.

The Chairman summarised that at the one end of the spectrum there are the low dose effects from the study of Moral et al (2008) and on the other end there is the Delclos et al (2014) study with no low dose effects. The question is what an adequate point of departure for DNEL setting would then be, bearing in mind the effects on the mammary gland.

A group of 9 RAC members, industry stakeholder, the DS and several ECHA staff participated in an ad-hoc working group to further discuss the studies that reported mammary gland effects and to discuss possibilities to determine an adequate point of departure for DNEL setting for this effect. The group considered that at this stage, RAC cannot determine an adequate NOAEL for mammary gland effects. They therefore recommended to RAC that a comparison would be needed with the final EFSA opinion which is foreseen to be adopted mid-December 2014. In the interim, the group recommended to take a three point approach forward for the establishment of the NOAEL for mammary gland changes, covering the whole spectrum, i.e. a DNEL derived from the NOAEL of 25 µg/kg bw/day from the study by Moral et al (2008), an intermediate NOAEL of about 200 µg/kg/d, based on an overall interpretation of the Moral and Tharpe data, and a DNEL derived from the NOAEL of 840 µg/kg bw/day based on the study by Delclos et al (2014)."

The RAC members agreed with the recommendations of the group as a positive way forward, emphasizing the need to take the revised EFSA TDI into account. The RAC Rapporteurs then presented their analysis of the exposure assessment. The discussion focussed on the use of

probabilistic versus simple deterministic modelling and the added value of data from biomonitoring for reasonable worst case exposure estimates for workers and the general population.

Several members considered that the probabilistic modelling was perhaps not needed and considered that simplification would be helpful, whereas another member voiced support for the use of the Monte Carlo approach as statistically sound. Several members were of the opinion that both the exposure estimates from the available biomonitoring data and the estimates from modelling should be considered in the exposure assessment and that the estimates should be compared with each other. The three exposure scenarios in the percutaneous absorption flow model were discussed and reflected upon against the available biomonitoring data. Some members expressed the view that the scenario using an absorption flow of 0.022 µg/cm2/h from the study by Demierre et al (2012) and a contact surface of 6 cm2 using the percutaneous absorption flow model would result in an underestimation of the reasonable worst case exposure for workers. One member was of the view that the dose in the study by Demierre et al (2012) was too low to determine flux accurately and requested a more thorough assessment of the study of Marquet et al (2011) from this perspective. An industry stakeholder observer questioned the validity of the assumption of 100% systemic bioavailability from the dermal route, referring to a recent dermal toxicokinetic study in human volunteers by the US NTP (Thayer *et al*, not published) indicating 11-15% bioavailability.

The Chairman concluded that the main elements of the human health and exposure assessment still warrant further discussion. To facilitate agreement in RAC, a face-to-face consultation with RAC members will be organised 29 January 2015 with the aim to have concrete proposals for the setting of the point of departure for DNEL setting for the effects on mammary gland, a reasoned selection of AFs, input parameters for the exposure modelling, and appropriate risk estimates.

The Rapporteurs were requested to update their first draft opinion in advance of the meeting in January, taking into account the discussion in RAC 31, the final EFSA opinion, as adopted mid-December and all studies received during the public consultation.

The Chairman stressed again that the March plenary meeting is reserved to discuss the technical details and the final streamlining of the draft opinion.

4) Ammonium salts – first draft opinion

The Chairman welcomed the Dossier Submitter representatives (France) and the SEAC rapporteurs. He reminded the participants that this restriction dossier has been submitted under Article 129 of the REACH Regulation (safeguard clause). The substances in the scope of the restriction proposal are inorganic ammonium salts that are used as additives in cellulose insulation for their flame retardant properties. The first draft opinion of RAC and the background document were uploaded on CIRCABC on 31 October and comments were received from three RAC members in the following written consultation.

The RAC Rapporteurs presented the first draft opinion to the Committee. With regard to the human health hazard assessment, they reminded the members that at RAC-30 it was agreed to focus on acute/sub-acute irritation to the respiratory tract and eyes, as there was insufficient evidence of *de-novo* genesis of respiratory tract sensitization and induction of asthma. It was, however, agreed to consider hyper responsiveness and asthma in particularly sensitive population groups. It was also concluded at RAC-30 that odour threshold, and resulting annoyance, is not considered harmful to health. The Rapporteurs then reminded the Committee of the key studies described in the dossier and explained the derivation of DNEL by the Dossier Submitter, adding that the Rapporteurs support the Dossier Submitter's proposal for the DNEL derivation. RAC agreed with the Rapporteurs on this.

With regard to the exposure assessment, the Rapporteurs noted that the key factors affecting exposure emission from insulation are loading rate (density and thickness) and the moisture content (Relative Humidity). The Rapporteurs pointed out that there is no information available on stabilisation of ammonium salts and insufficient information on the moisture content in order to set an ammonium concentration limit or moisture concentration for the insulation material. RAC therefore agreed at RAC-30 to the Dossier Submitter's proposal that emission is correlated to the loading rate in the foreseen use (i.e. building requirements of the MSs). They further specified that restriction (and compliance) is based on demonstrating emissions below 3ppm when the material is tested under worst case conditions (90% RH). The Rapporteurs explained that the exposure assessment to demonstrate the risk is based on the least stable material (greatest emitting insulation) from the samples tested. They informed the Committee that the Dossier Submitter had updated the exposure calculations based on the worst case conditions in attic (90% RH and highest insulation loading rate in the EU) and the worst case RH of 70% in the living area. Risk is demonstrated based on the worst emitting material found on the French market (least stabilised material tested). The Dossier Submitter has also calculated levels in the living area based on the results of the most stable insulation material tested. RAC agreed with the risk characterisation and the fact that there is a demonstrated risk linked to the exposure to ammonia emissions, as evidenced by the reported incidents in France, in the houses insulated with the use of ammonium based cellulose material.

The Secretariat has informed RAC of a latest PC comment -submitted by a flame retarder manufacturer - that provides some information on the potential stabilisation of ammonium blends. The COM observer was interested to know who would be responsible for complying with the conditions of the restriction (the person who applies the mixture into the panel, or the professional installing the panel). The Rapporteurs responded that the producer will be responsible for testing the panel and ensuring that it meets the requirements. The COM observer also questioned the analytical method proposed in the dossier (as this testing method is related to volatile organic compounds). The observer from Cefic explained that the same test chamber and conditions can be used, but the methods to analyse the results are different. A short discussion took place on whether to mention the analytical method in the text of the Annex XVII entry. The COM observer pointed out that normally the analytical methods are not included in the texts of Annex XVII entries.

RAC agreed on the main conclusions presented by the Rapporteurs and expressed their general support to this restriction proposal. A need for liaison of the Secretariat and Rapporteurs with the Forum to clarify the issue of testing methods (in view of the final forum advice) was agreed. The Chairman informed that the Rapporteurs will need to deliver their revised draft opinion on this dossier by the beginning of February (to be discussed and adopted at RAC-32 in March 2015).

5) DecaBDE – key issues document

The Chairman welcomed the representative of the Dossier Submitter (ECHA) as well as representatives from Norway (who had collaborated with ECHA in the preparation of the restriction dossier) as well as the SEAC Rapporteurs to the meeting. He informed the participants that the restriction dossier on decaBDE focuses on the hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles. DecaBDE occurs widely in the environment and in wildlife. In addition to PBT/vPvB concerns, other potential impacts of exposure to decaBDE may result in neurotoxicity in mammals, including humans.

The Rapporteurs presented the key issues document to RAC. With regard to the human health it was considered not to be the main focus of the dossier, but they suggested that

developmental neurotoxicity data for decaBDE and other PBDE congeners could be used as a supporting (unquantified) line of argument. One member agreed to help the Rapporteurs on the evaluation of the neurotoxic effects. According to the Rapporteurs, the exposure assessment has significant uncertainties based on the stakeholder input and emissions, and the Rapporteurs proposed to use data from the decaBDE monitoring program (and elsewhere if available), and back-calculate the emissions to sludge. Furthermore, RAC discussed whether the major alternative identified by the stakeholders (EBP, currently subject to substance evaluation and for which the risks have not yet been confirmed) would pose a relatively lower hazard than decaBDE. In addition RAC supported the Rapporteurs in considering that the transformation rate of decaBDE is a relevant issue to be included in the opinion.
In summary, RAC agreed on the main elements presented by the Rapporteurs. The Chairman informed that the Rapporteurs will need to deliver their first draft opinion on this dossier by end of January 2015 (to be discussed at RAC-32).

b) Conformity check

1) Perfluorooctanic acid (PFOA) – outcome of conformity check

The Chairman welcomed the Dossier Submitter representatives (Germany and Norway) and the SEAC Rapporteurs. He reminded the Committee that the dossier on Perfluorooctanoic acid (PFOA) had been submitted jointly by Germany and Norway on 17 October 2014. The conformity check was launched in RAC and SEAC on 30 October and the Committees are expected to reach a conclusion on conformity at this meeting.

The representative of the Dossier Submitters provided an introductory presentation on the proposal to restrict PFOA. PFOA is one important representative of the substance group of per- and polyfluorinated substances (PFASs). The hazard profile of PFOA is well known: PFOA is a PBT-substance, which may cause severe and irreversible adverse effects on the environment and human health. PFOA has a harmonised classification in Annex XV of the CLP Regulation as Carc. 2, Repr. 1B and STOT RE 1 (liver). Due to its PBT and CMR properties, PFOA and its ammonium salts (APFO) have been identified as substances of very high concern under REACH. The Dossier Submitters propose a restriction on manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances.

The RAC Rapporteurs then presented the outcome of the conformity check and the recommendations to the Dossier Submitter and informed the Committee that the dossier can be considered in conformity from the RAC point of view. The Rapporteurs mentioned that more clarity would be needed with regard to the concentration limit chosen (2 ppb) as well as with the proposed application time of the restriction (18 months after entry into force).

The COM observer expressed concern with regard to the wide scope of the restriction (also in terms of the numbers of potential substances covered) and the fact that no exemptions have been proposed. The Rapporteurs and the Secretariat emphasised that the public consultation on the Annex XV report will hopefully bring more clarity on this.

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-25 later this week. If the dossier will be considered in conformity by both Committees, the public consultation on the Annex XV report will be launched on 17 December 2014.

7.3 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),
- Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) (to be submitted by United Kingdom) and
- dimethyl formamide (to be submitted by Italy),

all as outlined in meeting document RAC/31/2014/06 RESTRICTED.

RAC agreed on the appointment for Rapporteurs as proposed in the recommendation. RAC was informed that Poland has not resubmitted its dossier on Methanol within 60 days after receiving the reasons for non-conformity. Instead, they will make a new entry in the RoI and submit it as a new dossier in 2015. As it will be a new dossier, we would need to appoint the rapporteurs again. RAC agreed to appoint the same rapporteurs, provided that they are available.

8. Authorisation

8.1 General authorisations issues

Revision of Working procedures

The Secretariat provided a presentation on the revised Working Procedure for RAC and SEAC for developing opinions on Applications for Authorisation. The main changes in the revision concern increase of efficiency at the stage of opinion development. Hence, a discussion on the key issues will follow the Committee's agreement on conformity of the application at its first plenary discussion. The second new item added to the working procedure is a trialogue meeting, between the Committees' Rapporteurs and the applicant (and which has already been carried out for almost all applications for authorisation received up to now, but had not been included in the current procedure). The third new item in the working procedure is an option to 'A-list' non-controversial draft opinions without plenary debate following the SEAC (and RAC) consultations prior to the third plenary meeting (fourth if conformity and key issues is included). Criteria for the 'A-listing' of the draft opinions will be presented by the Secretariat at the next SEAC plenary meeting in March 2015.

In general, SEAC members supported the revised Working Procedure, which simplifies and facilitates the opinion development and emphasized the importance for assistance from ECHA with regard to the key issues. Several members were of the view that the key issues should be identified by the rapporteurs with the help of the Secretariat (and not the other way round, as was originally proposed by the Secretariat).

Several members emphasised the efficiency of the discussions during the plenary meetings and other members supported reducing the number of the plenary discussions per application. One member expressed the view that the conformity check should be discontinued. The Secretariat responded that this is a requirement set by the REACH Regulation (Article 64).

A few members and stakeholder observers were concerned about the new revision and how it will affect transparency. The Secretariat responded that the public versions of the documents are published on the ECHA webpage. The Working Procedure, with additional modification introduced during the meeting as outlined in the amended document RAC/31/2014/07 rev.1, was agreed by RAC and SEAC.

RAC Reference values (DNEL's and Carcinogenicity dose-response)
The Chairman reminded the Committee about the ongoing work on the carcinogenicity dose-response relationships for three new substances on Annex XIV of the REACH Regulation (2,2'-dichloro-4,4'-methylenedianiline (MOCA); formaldehyde, oligomeric products with aniline (technical MDA); 1,2-dischloroethane (EDC)), and the setting of DNELs for one, which is toxic

to reproduction (bis(2-methoxyethyl)ether), also known as diglyme. At the beginning of October 2014, the ECHA consultant submitted a first report on each of these substances. Four RAC Members volunteered to act as Rapporteurs and following a written commenting round, the contractor modified the draft report. The Chairman then invited a representative of the ECHA contractor to present the modified draft report.

The Rapporteurs then provided comments for further improvements of the draft report. Specifically, for technical MDA the Rapporteur requested further explanation of the key study description, noting also that the T25 calculations need to be better underpinned. To enable comparison with the registration dossiers, a stepwise presentation of the calculations in the draft report would help understanding. He further noted that the absorption assumptions need to be firmed up in line with ECHA Guidance. The Rapporteur requested improvement of the discussion on the shape of the dose-response curve. He also requested clarification on the carcinogenic potential of oligomers.

The Rapporteur on MOCA noted that the second version of the draft report was an improvement; the critical study seemed to be adequately described, although one member suggested that this needed further attention. She also noted that SCOEL and DECOS (NL) data were taken into account in the draft report.

The Rapporteur for Diglyme requested that the critical studies be present in the draft report. He specifically asked that the use of internal systemic dose be addressed for the sake of comparison and noted some mismatches between numbers in the main body of the text and the annexes.

The Rapporteur for EDC reported that the genotoxicity of the substance seems to be adequately considered in the draft report and also noted that it had improved in comparison to the first version. RAC was informed that short and long-term studies on carcinogenicity done by the industry were expected, including Work on the Mode of Action of EDC and would become available later in 2015. It was noted by the Chairman that the Note on EDC was required for adoption at RAC 32 in March, to allow industry sufficient time to use the RAC DNEL. The Commission representative reminded the Committee that with respect to the Article 95 of the REACH Regulation, the SCOEL opinion on EDC needs to be properly addressed.

8.2 Authorisation applications

a) Authorisation application – 3rd RAC draft opinion (applications submitted within the November 2013 submission window)

1. 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 fourth version of the draft opinions, which, at the request from the previous meeting, had been further developed as to the lead part.

Following the comments submitted by the members during the RAC consultation, the Committee, having reviewed all the options presented, agreed to use an EFSA set of values as the most appropriate, when evaluating lead exposure-related risks at the workplace.

RAC considered that the exposure levels without RPE/PPE are high. However, with proper use of RPE/PPE, seem to be appropriate in reducing the risk from exposure to chromium and lead. Yet, RAC noted that some of the factors for the effectiveness of RPE/PPE might not be achieved in practice and had reservations about the intensity of use and overreliance on RPE/PPE reported in the workplace. Therefore RAC recommended additional conditions and monitoring arrangements and reviewed their application to the downstream users of the applicant.

The Committee agreed by consensus with the draft opinions. The Rapporteurs together with the Secretariat will finalise the editorial checking of the draft opinions. The Secretariat will send the combined RAC and SEAC draft opinions to the Applicant for their possible comments.

The Chairman thanked the Rapporteurs for their extensive and valuable work on this complicated application for authorisation.

b) Authorisation application – 2nd version of RAC draft opinions (applications submitted within the February 2014 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 welcomed the Rapporteurs and their advisors and reported on the state of play of the dossier since the last plenary discussion.

The RAC and SEAC Consultations on the first draft of the opinions were launched on 10 October 2014 and ended on 29 October 2014. A Rapporteurs' second and third dialogues took

place in October and November, and the Rapporteurs prepared the second version of the draft opinions.

In addition, following the request from the Committee agreed at RAC-30 plenary meeting, the applicants have been asked to provide further clarifications on the emission factors (data and methodology) mentioned in the application. These clarifications together with asensitivity analysis of the reported emissions estimates have been received; however the view of the Rapporteurs was that not all concerns were adequately addressed.

The Chairman then invited the Rapporteurs to present the second version of the draft opinion documents. In their presentation, the Rapporteurs noted that there were several open issues with regard to the exposure assessment in the application.

Following the members' discussion, RAC confirmed that based on the information provided by the applicant, the uncertainties in the exposure assessment were too high to conclude on the remaining risk. The available information was not sufficient to determine whether the operating conditions and risk management measures described in the application reduce the remaining risk to the extent that it is practically and technically possible. Nevertheless, RAC formulated additional conditions and monitoring arrangements in the event that an authorisation would be granted. These are listed in the draft opinions.

RAC agreed on the draft opinions by consensus. The Rapporteurs together with the Secretariat will finalise the editorial checking of the draft opinions. The Secretariat will send the draft opinions to the Applicants for their possible comments.

c) Authorisation application – 1st outline RAC draft opinion (applications submitted within the May 2014 submission window)

1. The use of diarsenic trioxide submitted by Yara France (Diarsenic trioxide 4):

   Use 1 Use of diarsenic trioxide as a processing aid for the removal of carbon dioxide in synthesis gas formed in the production of ammonia

The Chairman briefly introduced the case and then he invited the Rapporteur to present the first version of the draft opinion.

The Rapporteur informed the committee that in her opinion, the exposure assessment is acceptable for impact assessment. In recent years the applicant has made substantial improvement in reducing risk for workers and for humans via environment but further progress is necessary. Therefore, she recommended to RAC to set appropriate monitoring conditions in the opinion.

During the further discussion the members raised some concerns regarding the appropriateness of the biomonitoring results. They mentioned that Arsenic background levels in urine can vary significantly depending on dietary habits, and also that the values below the detection limit were unexpected. They also pointed out that worker's Arsenic levels will normally vary per day, as Arsenic is rapidly excreted. The members were interested to know whether the Applicant had performed any monitoring of the levels of Arsenic in people living next to the plant. Furthermore, members asked the Rapporteur to clarify in the opinion whether a) the background exposure to arsenic has been excluded from the biomonitoring and whether the biomonitoring included the use of personal protective equipment and whether its results were adjusted taking into account its assumed effectiveness.

Although the overall estimated lung cancer cases for workers were at a very low level, the RAC members asked the Rapporteur to stress in the opinion that in some Workers Contributing Scenarios the excess of cancer risk for individual workers was at a high level.

The Committee asked the Rapporteur and the ECHA Secretariat to rephrase the proposed monitoring conditions to consider the current occupational health legislation and following discussion on the authorisation of use of lead chromate pigments to rephrase question 6 of the justification of the draft opinion.

The Rapporteur revised the opinion, which was then revisited by RAC, the members agreeing with the proposed changes.

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

2. Two uses of trichloroethylene submitted by Vlisco Netherlands BV (Trichloroethylene 5):

   Use 1 Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth

   Use 2 Use of trichloroethylene as a solvent in a process to recover and purify resin from process water

The Chairman welcomed the Rapporteurs and reported on the state of play of the dossier. No comments had been received during the public consultation, which took place from 13 August until 8 October. No RAC Members had commented on the application for authorisation during the RAC consultation from 6 August until 1 October.

The Rapporteurs presented the first version of the draft opinion on the application for authorisation. They acknowledged that the applicant had used the carcinogenicity dose-response relationship, as agreed by the Committee at an earlier stage. The Committee agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk. RAC was informed that the applicant had indicated that they intended to introduce local exhaust ventilation at a particular point in the process to further reduce exposures and this was noted in the opinion; no conditions or monitoring arrangement were recommended. The Committee briefly discussed the length of the review period to be advised to SEAC, and concluded that this would not be necessary. The draft opinion was agreed by consensus. The Rapporteurs together with the Secretariat will finalise the editorial checking of the draft opinions. The Secretariat will send the combined RAC and SEAC draft opinions to the Applicant for their possible comments.

The Chairman thanked the Rapporteurs for their work in the development of the RAC draft opinion.

d) Authorisation applications - outcome of the conformity check and presentation of key issues

A total of 12 applications for the authorisation of trichloroethylene (TCE) were presented by their respective rapporteurs for agreement of conformity and to discuss any key issues. It was noted that all the applicants had used the reference values (dose response curves) published by RAC.

All 12 applications were found by RAC to conform with the requirements of REACH and the applicants will be informed accordingly.

1. Trichloroethylene 1:

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

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

2. Trichloroethylene 2a:

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

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

   Use 3 Use of Tricholoroethylene in packaging

   Use 4 Use of Tricholoroethylene in formulation

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

The RAC Rapporteurs provided brief information on the application for authorisation and presented the draft outcome of the conformity check. With regard to uses 1, 3 and 4, the Rapporteurs estimated that the draft opinions could be agreed well in advance of the 10 month AfA deadline. It was also noted that uses 3 and 4 are linked to the uses 1 and 2 of the TCE 2b application. Uses 2 and 5 are more specific and thus the Rapporteurs estimated that there is also a possibility for RAC to agree on the draft opinion well in advance of the 10 month AfA deadline.

3. Trichloroethylene 2b:

   Use 1 Use of Trichloroethylene in formulation

   Use 2 Use of Trichloroethylene in packaging

The RAC Rapporteurs provided a brief overview of the application and presented the draft outcome of the conformity check. The Rapporteurs also presented their first impression of the application, highlighting some key issues for the attention of the committee. The uses applied for are linked to uses 3 and 4 of the TCE 2a application. The Rapporteurs estimated that there is a possibility for RAC to agree on the draft opinions for this application well in advance of the 10 month AfA deadline.

4. Trichloroethylene 3:

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

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

5. Trichloroethylene 4:

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

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

6. Trichloroethylene 6:

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

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

7. Trichloroethylene 7:

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

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

8. Trichloroethylene 8:

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

Due to the similarity of the use the conformity of the applications for authorisation TCE cases 8, 9 and 10 were discussed together. The Rapporteur gave some brief information on the application and presented the outcome of the draft conformity check and key issues to be clarified with the Applicants. She stated that, in her opinion, it should be possible to agree draft opinions on TCE 8 and 9 well in advance of the 10 month AfA deadline. Due to quality of the application more discussion may be needed on AFA TCE 10.

9. Trichloroethylene 9:

   Use 1 Industrial use as a process chemical in caprolactam purification

Due to the similarity of the use the conformity of the applications for authorisation TCE cases 8, 9 and 10 were discussed together.

10. Trichloroethylene 10:

    Use 1 Use as an extraction solvent in caprolactam production

Due to the similarity of the use the conformity of the applications for authorisation TCE cases 8, 9 and 10 were discussed together.

11. Trichloroethylene 11:

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

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

12. Trichloroethylene 12:

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

The RAC Rapporteurs provided brief information on the application for authorisation and presented the draft outcome of the conformity check. They noted that this is an 'upstream' or 'umbrella' applications covering many workplaces.

e) Authorisation applications – adoption of the RAC final opinions

1. On the use of bis (2-ethylhexyl) phthalate (DEHP 2c) submitted by DEZA a.s.

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

The Chairman presented to the Committee the Applicant's comments on the draft opinion. RAC agreed with the Rapporteurs' and the Secretariat's conclusion that the Applicant's comments were such that no changes needed to be made to the opinion.

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

2. On the use of dibutyl phthalate (DBP 2) submitted by DEZA a.s.

Use 3: Industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

The Chairman presented to the Committee the Applicant's comments on the draft opinion. RAC agreed with the Rapporteurs' and the Secretariat's conclusion that the Applicant's comments were such that no changes needed to be made to the opinion.

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

8.3 Appointment of Rapporteurs for authorisation applications (closed session)

The Committee members during the plenary meeting expressed their interest for rapporteurship; they applied to the pool of rapporteurs and indicated absence of conflict of interest. Following the Chairman's proposal, RAC agreed the names of all members volunteering for chromate dossiers to be appointed to every substance from No. 16 to No. 22 of Annex XIV. The pool of rapporteurs, as outlined in the amended restricted room document RAC/31/2014/08 rev 1, was agreed by RAC.

9. AOB

a) Report from the 3rd preparatory seminar on Chromates

This item of the agenda was not discussed.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 31 25-27 November and 2-4 December 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/31/2014**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-31 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 30 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/31/2014/01** and document **RAC/31/2014/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the Q1 and Q2/2015 work plan for RAC covering the Classification and Labelling, Restriction and Authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-31 meeting on CIRCABC.
c) General RAC procedures SECR presented the revised working procedure for the appointment of rapporteurs covering the Classification and Labelling, Restriction and Authorisation processes. RAC agreed on the revised working procedure **RAC/31/2014/03.**	**SECR** to upload the revised working procedure on CIRCABC.
5. Requests under Article 77 (3) (c)	
a) Tetrapropenylphenol (TPP) **RAC adopted the opinion by consensus.**	**Rapporteur** to revise the opinion in accordance with the discussion. **SECR** to make an editorial check of the opinion in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
b) Consumer exposure to benzene contained in natural gas **RAC adopted the opinion by consensus.**	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it

	on the ECHA website.

6. Harmonised classification and labelling (CLH)

A. Hazard classes for agreement without plenary debate

a) Pirimicarb (ISO): Acute toxicity (oral, dermal, inhalation)
b) Fluopyram (ISO): Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Eye corrosion/irritation, Skin sensitisation, Aquatic Acute, Aquatic Chronic
c) Thiacloprid (ISO): Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Eye corrosion/irritation, Skin sensitisation, Aquatic Acute, Aquatic Chronic
d) Triflumizole: Acute toxicity (oral, dermal, inhalation), STOT SE, Skin corrosion/Irritation, Eye corrosion/irritation, Respiratory tract irritation, Skin sensitisation, Respiratory sensitisation, Aquatic Acute, Aquatic Chronic
e) Dicyclohexyl phthalate (DCHP): Skin sensitisation
f) Pencycuron (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Skin corrosion/irritation, Eye corrosion/irritation, Respiratory sensitisation, Skin sensitisation, STOT RE, Aquatic Acute, Aquatic Chronic

B. Substances with hazard classes for agreement in plenary session

a) Acetochlor
b) 3,7-dimethylocta-2,6-dienenitrile (Geranonitril)
c) Chlorsulfuron (ISO)
d) Pirimicarb (ISO)
e) Benzovindiflupyr (ISO)
f) Fluopyram (ISO)
g) Tert-butyl hydroperoxide (TBHP)
h) Thiacloprid (ISO)
i) Triflumizole
j) Diisobutyl phthalate (DIBP)
k) Dicyclohexyl phthalate (DCHP)
l) Pencycuron (ISO)
m) E-glass microfibres of representative composition
n) Glass microfibres of representative composition
o) Copper dossiers (environmental hazards)
    1. Tetracopper hexahydroxide sulphate [1], tetracopper hexahydroxide sulphate hydrate [2], tribasic copper sulphate
    2. Dicopper chloride trihydroxide, copper oxychloride
    3. Copper flakes (coated with aliphatic acid)
    4. Copper thiocyanate
    5. Bordeaux mixture
    6. Copper (II) carbonate – copper (II) hydroxide (1:1), basic copper carbonate

7. Copper (II) oxide 8. Copper (II) hydroxide, copper dihydroxide 9. Copper (I) oxide, dicopper oxide 10. Copper sulphate pentahydrate	
a) Acetochlor	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2 (H351), Repr. 2 (H361f), Acute Tox. 4 (H332), Skin. Irrit. 2 (H315), STOT SE 3 (H335), Skin Sens. 1 (H317), STOT RE 2 (H373; kidney), Aquatic Acute 1 (H400; M=1000), Aquatic Chronic 1 (H410; M=100)]	**Rapporteur** to revise the opinion in accordance with the discussions in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
b) 3,7-dimethylocta-2,6-dienenitrile (Geranonitril)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Muta. 1B (H340)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
c) Chlorsulfuron (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [M(acute)=1000, M(chronic)=100]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
d) Pirimicarb (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2 (H351), Acute Tox. 3 (H301 and H331), Skin Sens. 1 (H317), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=100)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
e) Benzovindiflupyr (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Acute Tox. 3 (H301 and H331), Aquatic Acute 1 (H400; M=100), Aquatic Chronic 1 (H410; M=100)]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
f) Fluopyram (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Chronic 2 (H411)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
g) Tert-butyl hydroperoxide (TBHP)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Muta. 2 (H341)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
h) Thiacloprid (ISO)	
RAC agreed on hazard classes for the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 3 (H301), Acute Tox. 4 (H332), Carc. 2 (H351), STOT SE 3 (H336), Aquatic Acute 1 (H400; M=100), Aquatic Chronic 1 (H410; M=100)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR for the discussion at RAC 32. **Rapporteur** to re-structure the presentation on toxicity to reproduction in order to facilitate the discussion. **Rapporteur** with the support of **the SECR** to summarise the data on a study by study basis including data on maternal toxicity and any information on exposure prior to pregnancy.
i) Triflumizole	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, Skin Sens 1 (H317), Repr. 1B (H360D), STOT RE 2 (H373; liver), Aquatic Acute 1 (H400; M=1), Aquatic Chronic 1 (H410; M=1)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
j) Diisobutyl phthalate (DIBP)	
RAC adopted by consensus the opinion with a proposal	**Rapporteur** to revise the opinion in

for the harmonised classification and labelling as indicated in Table 1 below. [removal of SCL; generic concentration limits of 0.3% (D) and 3% (f) to apply to Repr. 1B (H360Df)]	accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
k) Dicyclohexyl phthalate (DCHP)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1 (H317) without sub-categorisation, Repr. 1B (H360D)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
l) Pencycuron (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1 (H400; M=1), Aquatic Chronic 1 (H410; M=1)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
m) E-glass microfibres of representative composition	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B (H350i), Note A; no Note R, no Note Q]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
n) Glass microfibres of representative composition	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2 (H351)(inhalation), Note A; no Note R, no Note Q]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
o) Copper compounds (environmental hazards)	

• RAC agreed by consensus that Copper (II) ions are not subject to rapid environmental transformation for the purposes of C&L • RAC agreed by consensus with the selection of acute data for P. promelas as described in the opinion • RAC agreed by consensus to use the *C. dubia* NOEC for the chronic ERV alongside the low *O. mykiss* NOEC at pH 8 plus the surrogate method for the fish trophic group • RAC agreed by consensus that all copper compounds must be regarded as readily soluble for classification purposes • On the basis of the CLH report, RAC agreed by consensus to use only solubility data for classification	
1. Tetracopper hexahydroxide sulphate [1], tetracopper hexahydroxide sulphate hydrate [2], tribasic copper sulphate 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), 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 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.
2. Dicopper chloride trihydroxide, copper oxychloride 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), Acute Tox. 4 (H332), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	See Tetracopper hexahydroxide sulphate and hydrate
3. Copper flakes (coated with aliphatic acid) 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. 3 (H331), Eye Irrit. 2 (H319), Aquatic Acute 1 (H400; M=100)[2], Aquatic Chronic 1 (H410; M=100)[2]]	See Tetracopper hexahydroxide sulphate and hydrate
4. Copper thiocyanate RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [EUH032, Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	See Tetracopper hexahydroxide sulphate and hydrate
5. Bordeaux mixture RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	See Tetracopper hexahydroxide sulphate and hydrate

[2] After adoption of the opinion, the Secretariat became aware of an error in the calculation of the M-factors in the opinion for ***copper flakes***; accordingly, M=100 is not correct, but instead M=10 would be appropriate for both the acute and the chronic aquatic classification.

[Acute Tox. 4 (H332), Eye Dam. 1 (H318), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	
6. Copper (II) carbonate – copper (II) hydroxide (1:1), basic copper carbonate 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 and H332), Eye Irrit. 2 (H319), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	See Tetracopper hexahydroxide sulphate and hydrate
7. Copper (II) oxide RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1 (H400; M=100), Aquatic Chronic 1 (H410; M=100)]	See Tetracopper hexahydroxide sulphate and hydrate
8. Copper (II) hydroxide, copper dihydroxide 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. 2 (H330), Eye Dam. 1 (H318), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	See Tetracopper hexahydroxide sulphate and hydrate
9. Copper (I) oxide, dicopper oxide 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 and H332), Eye Dam. 1 (H318), Aquatic Acute 1 (H400; M=100), Aquatic Chronic 1 (H410; M=100)]	See Tetracopper hexahydroxide sulphate and hydrate
10. Copper sulphate pentahydrate 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), Eye Dam. 1 (H318), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)]	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.
6.3	
7. Restrictions	
7.1 General restriction issues	

a) Review of the restriction process – update from the Task Force	
7.2 Restriction Annex XV dossiers	
a) Opinion Development	
1. Cadmium and its compounds in artist paints – revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC agreed on the opinion on Cadmium and its compounds in artists' paints by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs,** together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
2. Chrysotile - revised draft opinion Rapporteurs presented and RAC discussed the revised draft of the RAC opinion. RAC agreed on the opinion on Chrysotile by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs,** together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and CIRCABC IG.
3. Isopropylidenediphenol (Bisphenol A) – first draft opinion Rapporteurs presented the first draft opinion and RAC discussed the main elements proposed in the draft opinion. SECR to organise a RAC-face to face consultation on the first draft opinion by the end of January 2015 to agree on the main elements of the hazard and exposure assessment. SECR to invite EFSA to participate in the RAC face-to-face consultation.	**Rapporteurs** to take the RAC discussions into account in the revised version of the draft opinion (by end of January 2015). **Rapporteurs** to ensure the supporting documentation (BD and RCOM) with the revised draft opinion.
4. Ammonium salts – first draft opinion Rapporteurs presented and RAC discussed the first	**Rapporteurs** to take the RAC discussion into account in the revised draft opinion (by end of January 2015).

draft opinion.	
5. DecaBDE – 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 end of January 2015).
b) Conformity check	
1. Perfluorooctanoic acid (PFOA) – outcome of conformity check RAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
7.3 Appointment of (co-)rapporteurs for restriction dossiers	
RAC agreed on the Recommendations of the Chair for the (co-) rapporteurs for the restriction dossiers on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5), Grill lighters fluids and fuels for decorative lamps labelled R65 or H304 and dimethyl formamide.	
8. Authorisation	
8.1 General and procedural application for authorisation issues	
RAC and SEAC agreed on the Working Procedure, with additional modification introduced during the meeting as outlined in the amended document RAC/31/2014/07 rev.1.	**SECR** to publish the agreed Working Procedure on ECHA website.
Presentation on the dose-response relationship for carcinogenicity setting exercise for 3 new substances on Annex XIV of the REACH Regulation: - 2,2'-Dichloro-4,4'-methylenedianiline (MOCA), - Formaldehyde, oligomeric reaction products with aniline (technical MDA) and, - 1,2-Dischloroethane, and the DNEL setting exercise for reprotoxic new substance on the Annex XIV of the REACH Regulation: - Bis(2-methoxyethyl)ether (diglyme).	Information item – no action needed.
8.2 Authorisation applications	
a) Authorisation application – 3rd RAC draft opinion (applications submitted within the November 2013 submission window)	
1. 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	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions.

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 RAC agreed on the draft opinions by consensus.	**SECR** to send the draft opinions to the applicant for commenting.
b) Authorisation application – 2nd version of RAC draft opinions (applications submitted within the February 2014 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 on the draft opinions by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.
c) Authorisation application – 1st outline RAC draft opinion (applications submitted within the May 2014 submission window)	

1. The use of diarsenic trioxide submitted by Yara France (Diarsenic trioxide 4): **Use 1:** Use of diarsenic trioxide as a processing aid for the removal of carbon dioxide in synthesis gas formed in the production of ammonia RAC agreed on the draft opinions by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.
2. Two uses of trichloroethylene submitted by Vlisco Netherlands BV (Trichloroethylene 5): **Use 1:** Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth **Use 2:** Use of trichloroethylene as a solvent in a process to recover and purify resin from process water RAC agreed on the draft opinions by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting
d) Authorisation application – outcome of conformity check and presentations of key issues	
1. Trichloroethylene 1: **Use 1:** Trichloroethylene used as degreasing solvent in the manufacture of polyethylene separators for lead-acid batteries RAC agreed on conformity of the application.	**SECR** to upload to CIRCABC the adopted Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check. **SECR** to send the updated Conformity Report to the Applicant.

2. Trichloroethylene 2a: **Use 1:** Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist **Use 2:** Industrial use as process chemical (enclosed systems) in Alcantara Material production **Use 3**: Use of tricholoroethylene in packaging **Use 4**: Use of tricholoroethylene in formulation **Use 5:** Use of Trichloroethylene as Extraction Solvent for Bitumen in Asphalt Analysis 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.
3. Trichloroethylene 2b: **Use 1**: Use of Trichloroethylene in formulation **Use 2**: Use of tricholoroethylene in packaging 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.
4. Trichloroethylene 3: **Use 1:** Use of trichloroethylene as a processing aid in the biotransformation of starch to obtain betacyclodextrin 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.
5. Trichloroethylene 4: **Use 1:** Use of trichloroethylene (TCE) as a process solvent for the manufacturing of modules containing hollow fibre gas separation membranes 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.
6. Trichloroethylene 6: **Use 1:** Trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries 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.
7. Trichloroethylene 7: **Use 1:** Use of tricholoroethylene-containing vulcanising and bonding agents for endless connections and repair of chloroprene rubber transportation belts in underground hard coal	**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

mining RAC agreed on the conformity of the application	Report to the Applicant.
8. Trichloroethylene 8: **<u>Use 1</u>**: Industrial use as an extraction solvent for the purification of caprolactam from caprolactam oil RAC agreed on the 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.
9. Trichloroethylene 9: **<u>Use 1:</u>** Industrial use as a process chemical in caprolactam purification 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.
10. Trichloroethylene 10: **<u>Use 1:</u>**Use as an extraction solvent in caprolactam production 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.
11. Trichloroethylene 11: **<u>Use 1:</u>** Use of trichloroethylene as solvent in the synthesis of vulcanization accelerating agents for fluoroelastomers RAC agreed on the 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.
12. Trichloroethylene 12: **<u>Use 1:</u>** Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems 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.
e) Authorisation applications – adoption of the RAC final opinions	
1. On the use of bis (2-ethylhexyl) phthalate (DEHP 2c) submitted by DEZA a.s. **<u>Use 3:</u>** Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements 2. On the use of dibutyl phthalate (DBP 2) submitted by DEZA a.s.	**Rapporteurs** together with **SECR** to do the final editing of the final opinions. **SECR** to send the final opinions to the European Commission, Member States and the Applicant.

<u>Use 3</u>: Industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements RAC agreed on the final opinions by consensus	
8.3 Appointment of (co-)rapporteurs for authorisation applications RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
9. AOB	
a) Report from the 3rd preparatory seminar on Chromates	
10. Action points and main conclusions of RAC-31	**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

E-glass microfibres of representative composition

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	TBD	e-glass microfibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following representative composition (% given by weight): SiO2 50.0- 56.0%, Al2O3 13.0-16.0%, B2O3 5.8-10.0%, Na2O <0.6%, K2O <0.4%, CaO 15.0-24.0%, MgO <5.5%, Fe2O3 <0.5%, F2 <1.0%. Process: typically produced by flame attenuation and rotary process.]	-	-	Carc. 1B	H350i	GHS08 Dgr	H350i			R
RAC opinion	TBD		-	-	**Carc. 1B**	**H350i**	GHS08 Dgr	**H350i**			**A**
Resulting Annex VI entry if agreed by COM	TBD		-	-	Carc. 1B	H350i	GHS08 Dgr	H350i			A

Glass microfibres of representative composition

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	TBD	glass microfibres of representative composition; [Calcium-aluminium-silicate fibres with random orientation with the following composition (% given by weight): SiO2 55.0-60.0%, Al2O3 4.0-7.0%, B2O3 8.0-11.0%, ZrO2 0.0-4.0%, Na2O 9.5-13.5%, K2O 0.0-4.0%, CaO 1.0-5.0%, MgO 0.0-2.0%, Fe2O3 <0.2%, ZnO 2.0-5.0%, BaO 3.0-6.0%, F2 <1.0%. Process: typically produced by flame attenuation and rotary process.]	-	-	Carc. 2	H351	GHS08 Wng	H351			R
RAC opinion	TBD		-	-	**Carc. 2**	**H351 (inhalation)**	GHS08 Wng	**H351 (inhalation)**			**A**
Resulting Annex VI entry if agreed by COM	TBD		-	-	Carc. 2	H351 (inhalation)	GHS08 Wng	H351 (inhalation)			A

Benzovindiflupyr (ISO); *N*-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide

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	TBD	benzovindiflupyr (ISO); *N*-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide	-	1072957-71-1	Acute Tox. 3 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H331 H301 H400 H410	GHS06 GHS09 Dgr	H331 H301 H410		M=100 M=100	
RAC opinion	TBD	benzovindiflupyr (ISO); *N*-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide	-	1072957-71-1	**Acute Tox. 3 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1**	**H301 H331 H400 H410**	**GHS06 GHS09 Dgr**	**H301 H331 H410**		**M= 100 M= 100**	

Resulting Annex VI entry if agreed by COM	TBD	benzovindiflupyr (ISO); *N*-[9-(dichloromethylene)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methyl-1*H*-pyrazole-4-carboxamide	-	1072957-71-1	Acute Tox. 3 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H301 H331 H400 H410	GHS06 GHS09 Dgr	H301 H331 H410		M= 100 M= 100	

Tert-butyl hydroperoxide

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	TBD	tert-butyl hydroperoxide	200-915-7	75-91-2	Muta. 2	H341	GHS08 Wng	H341			
RAC opinion	TBD	tert-butyl hydroperoxide	200-915-7	75-91-2	**Muta. 2**	**H341**	**GHS08 Wng**	**H341**			
Resulting Annex VI entry if agreed by COM	TBD	tert-butyl hydroperoxide	200-915-7	75-91-2	Muta. 2	H341	GHS08 Wng	H341			

Geranonitril; 3,7-dimethylocta-2,6-dienenitrile

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 Annex VI entry	**No current Annex VI entry**										
Dossier submitters proposal	TBD	3,7-dimethylocta-2,6-dienenitrile	225-918-0	5146-66-7	Muta. 1B	H340	GHS08 Dgr	H340			
RAC opinion	TBD	3,7-dimethylocta-2,6-dienenitrile	225-918-0	5146-66-7	**Muta. 1B**	**H340**	**GHS08 Dgr**	**H340**			
Resulting Annex VI entry if agreed by COM	TBD	3,7-dimethylocta-2,6-dienenitrile	225-918-0	5146-66-7	Muta. 1B	H340	GHS08 Dgr	H340			

Fluopyram (ISO); N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide

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	TBD	fluopyram (ISO); N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide		658066-35-4	Carc. 2 Aquatic Chronic 2	H351 H411	GHS08 GHS09 Wng	H351 H411			
RAC opinion	TBD	fluopyram (ISO); N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide		658066-35-4	**Aquatic Chronic 2**	**H411**	**GHS09**	**H411**			
Resulting Annex VI entry if agreed by COM	TBD	fluopyram (ISO); N-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]ethyl}-2-(trifluoromethyl)benzamide		658066-35-4	Aquatic Chronic 2	H411	GHS09	H411			

Pencycuron (ISO); 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea

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	TBD	pencycuron (ISO); 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea	266-096-3	66063-05-6	Aquatic Chronic 1	H410	GHS09 Wng	H410		M=1	
RAC opinion	TBD	pencycuron (ISO); 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea	266-096-3	66063-05-6	**Aquatic Acute 1 Aquatic Chronic 1**	**H400 H410**	**GHS09 Wng**	**H410**		**M=1 M=1**	
Resulting Annex VI entry if agreed by COM	TBD	pencycuron (ISO); 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea	266-096-3	66063-05-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	

Dicyclohexyl phthalate

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	TBD	dicyclohexyl phthalate	201-545-9	84-61-7	Repr. 1B Skin Sens. 1	H360DF H317	GHS07 GHS08 Dgr	H360DF H317			
RAC opinion	TBD	dicyclohexyl phthalate	201-545-9	84-61-7	**Repr. 1B** **Skin Sens. 1**	**H360D** **H317**	**GHS07** **GHS08** **Dgr**	**H360D** **H317**			
Resulting Annex VI entry if agreed by COM	TBD	dicyclohexyl phthalate	201-545-9	84-61-7	Repr. 1B Skin Sens. 1	H360D H317	GHS07 GHS08 Dgr	H360D H317			

Triflumizole (ISO); (1E)-*N*-[4-chloro-2-(trifluoromethyl)phenyl]-1-(1Himidazol-1-yl)-2-propoxyethanimine

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	TBD	triflumizole (ISO); (1E)-N-[4-chloro-2-(trifluoromethyl)phenyl]-1-(1H-imidazol-1-yl)-2-propoxyethanimine	-	68694-11-1	Repr. 1B Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H302 H373 (liver) H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360D H302 H373 H317 H410	-	 M=1 M=1	
RAC opinion	TBD	triflumizole (ISO); (1E)-N-[4-chloro-2-(trifluoromethyl)phenyl]-1-(1H-imidazol-1-yl)-2-propoxyethanimine	-	68694-11-1	**Repr. 1B** **Acute Tox. 4** **STOT RE 2** **Skin Sens. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	**H360D** **H302** **H373 (liver)** **H317** **H400** **H410**	**GHS08** **GHS07** **GHS09** **Dgr**	**H360D** **H302** **H373** **H317** **H410**		 **M=1** **M=1**	
Resulting Annex VI entry if agreed by COM	TBD	triflumizole (ISO); (1E)-N-[4-chloro-2-(trifluoromethyl)phenyl]-1-(1H-imidazol-1-yl)-2-propoxyethanimine	-	68694-11-1	Repr. 1B Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H360D H302 H373 (liver) H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H360D H302 H373 (liver) H317 H410		 M=1 M=1	

Chlorsulfuron (ISO); 2-chloro-*N*-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulphonamide

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 state-ment Code(s)		
Current Entry	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulphonamide	265-268-5	64902-72-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulphonamide	265-268-5	64902-72-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		**Add:** M = 1000 M = 100	
RAC opinion	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulphonamide	265-268-5	64902-72-3	**Aquatic Acute 1** **Aquatic Chronic 1**	**H400** **H410**	**GHS09** **Wng**	**H410**		**M = 1000** **M = 100**	
Resulting Annex VI entry if agreed by COM	613-121-00-4	chlorsulfuron (ISO); 2-chloro-N-[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl] benzenesulphonamide	265-268-5	64902-72-3	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H400 H410		M = 1000 M = 100	

Pirimicarb (ISO); 5,6-dimethyl-2-dimethylamino- pyrimidin-4-yl N,N-dimethylcarbamate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram,Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Entry	006-035-00-8	pirimicarb (ISO); 5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	Acute Tox. 3 * Aquatic Acute 1 Aquatic Chronic 1	H301 H400 H410	GHS06 GHS09 Dgr	H301 H400 H410			
Dossier submitters proposal	006-035-00-8	pirimicarb (ISO); 5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	**Modify:** Acute Tox. 3 **Add:** Carc. 2 Acute Tox. 3 Skin Sens. 1B **Retain:** Aquatic Acute 1 Aquatic Chronic 1	 **Add:** H351 H331 H317 **Retain:** H400 H410	 **Add:** GHS08 **Retain:** GHS06 GHS09 Dgr	 **Add:** H351 H331 H317 **Retain:** H301 H410		**Add:** M=10 M=100	
RAC opinion	006-035-00-8	pirimicarb (ISO); 5,6-dimethyl-2-dimethylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	**Carc. 2** **Acute Tox. 3** **Acute Tox. 3** **Skin Sens. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	**H351** **H331** **H301** **H317** **H400** **H410**	**GHS06** **GHS08** **GHS09** **Dgr**	**H351** **H331** **H317** **H301** **H410**		**M=10** **M=100**	
Resulting Annex VI entry if agreed by COM	006-035-00-8	pirimicarb (ISO); 5,6-dimethyl-2-dimehylamino-pyrimidin-4-yl N,N-dimethylcarbamate	245-430-1	23103-98-2	Carc. 2 Acute Tox. 3 Acute Tox. 3 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H331 H301 H317 H400 H410	GHS06 GHS08 GHS09 Dgr	H351 H331 H301 H317 H410		M=10 M=100	

Diisobutyl phthalate

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	607-623-00-2	diisobutyl phthalate	201-553-2	84-69-5	Repr. 1B	H360Df	GHS08 Dgr	H360Df		Repr. 1B; H360Df: C ≥ 25 % Repr. 2; H361f: 5 % ≤ C < 25 %	
Proposal for RAC	607-623-00-2	diisobutyl phthalate	201-553-2	84-69-5						Removal of SCLs	
RAC opinion	607-623-00-2	diisobutyl phthalate	201-553-2	84-69-5						**Removal of SCLs**	
Resulting Annex VI entry if agreed by COM	607-623-00-2	diisobutyl phthalate	201-553-2	84-69-5	Repr. 1B	H360Df	GHS08 Dgr	H360Df			

Acetochlor (ISO); 2-chloro-*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl) acetamide

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	**Modify:** Acute Tox. 4 (inhalation) Skin Sens. 1B **Retain:** STOT SE 3 Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 **Add:** Carc. 2 Acute Tox. 4 STOT RE 2	**Retain:** H335 H315 H400 H410 **Add:** H351 H302 H373 (liver, kidney)	**Retain**:GHS 07 GHS09 Wng **Add:** GHS08	**Retain:** H335 H315 H410 **Add:** H351 H302 H373 (liver, kidney)		**Add**: M=1000 M=100	
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** **Repr. 2** **Acute Tox. 4** **STOT SE 3** **STOT RE 2** **Skin Irrit. 2** **Skin Sens. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	**H351** **H361f** **H332** **H335** **H373 (kidney)** **H315** **H317** **H400** **H410**	**GHS07** **GHS08** **GHS09** **Wng**	**H351** **H361f** **H332** **H335** **H373 (kidney)** **H315** **H317** **H410**		**M=1000** **M=100**	

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	Carc. 2 Repr. 2 Acute Tox. 4 STOT SE 3 STOT RE 2 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H361f H332 H335 H373 (kidney) H315 H317 H400 H410	GHS07 GHS08 GHS09 Wng	H351 H361f H332 H335 H373 (kidney) H315 H317 H410		 M=1000 M=100	

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 state-ment 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	
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 1**	**H302 H400 H410**	**GHS07 GHS09 Wng**	**H302 H410**		**M=10** **M=10**	
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]	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M=10 M=10	

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	
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 1**	**H332** **H301** **H400** **H410**	**GHS06** **GHS09** **Dgr**	**H332** **H301** **H410**		**M=10** **M=10**	
Resulting Annex VI entry if agreed by COM	029-017-00-1	dicopper chloride trihydroxide	215-572-9	1332-65-6	Acute Tox. 4 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H332 H301 H400 H410	GHS06 GHS09 Dgr	H332 H301 H410		M=10 M=10	

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 M=1	
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=100**[3] **M=100**	
Resulting Annex VI entry if agreed by COM	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=100[3] M=100	

[3] After adoption of the opinion, the Secretariat became aware of an error in the calculation of the M-factors in the opinion for ***copper flakes***; accordingly, M=100 is not correct, but instead M=10 would be appropriate for both the acute and the chronic aquatic classification.

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 State-ment Code(s)	Pictogram ,Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard stateme nt 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	**Modify:** Aquatic Chronic 2 **Add:** Aquatic Acute 1	**Modify:** H411 **Add:** H400	**Add:** GHS09	**Modify:** H410	**Retain:** EUH032	 **Add:** M=10	
RAC opinion	029-015-00-0	copper thiocyanate	214-183-1	1111-67-7	**Aquatic Acute 1** **Aquatic Chronic 1**	**H400** **H410**	**GHS09**	**H410**	**EUH032**	**M=10** **M=10**	
Resulting Annex VI entry if agreed by COM	029-015-00-0	copper thiocyanate	214-183-1	1111-67-7	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	EUH032	 M=10 M=10	

Bordeaux mixture; reaction products of copper sulphate with calcium dihydroxide

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	
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 1	H332 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H332 H318 H410		M=10 M=10	
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	Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H332 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H332 H318 H410		M=10 M=10	

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	
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 1**	**H332** **H302** **H319** **H400** **H410**	**GHS07** **GHS09** **Wng**	**H332** **H302** **H319** **H410**		**M=10** **M=10**	
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	Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H319 H400 H410	GHS07 GHS09 Wng	H332 H302 H319 H410		M=10 M=10	

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 state-ment 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 M=1	
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=100** **M=100**	
Resulting Annex VI entry if agreed by COM	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=100 M=100	

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 M=1	
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** **M=10**	
Resulting Annex VI entry if agreed by COM	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 M=10	

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 State-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard state-ment 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	**Modify:** Acute Tox. 4 (oral) **Add:** Acute Tox. 4 Eye Irrit. 2 **Retain:** Aquatic Acute 1 Aquatic Chronic 1	 **Add:** H332 H319 **Retain:** H400 H410	 **Retain:** GHS07 GHS09 Wng	 **Add:** H332 H319 **Retain:** H410		**Add:** M=100 M=1	
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 Acute 1** **Aquatic Chronic 1**	**H332** **H302** **H318** **H400** **H410**	**GHS07** **GHS05** **GHS09** **Dgr**	**H332** **H302** **H318** **H410**		 **M=100** **M=100**	
Resulting Annex VI entry if agreed by COM	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 Acute 1 Aquatic Chronic 1	H332 H302 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H332 H302 H318 H410		 M=100 M=100	

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	**Modify:** Acute Tox. 4 Eye Dam. 1 Aquatic Chronic 2 **Remove:** Skin Irrit. 2 **Retain:** Aquatic Acute 1	**Modify:** H318 H411 **Remove:** H315 **Retain:** H400	**Add:** GHS05 **Retain:** GHS07 GHS09 Dgr	**Modify:** H318 H410 **Remove:** H315		**Add:** M=10	
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 1**	**H302** **H318** ~~H315~~ **H400** **H410**	**GHS07** **GHS05** **GHS09** **Dgr**	**H302** **H318** ~~H315~~ **H410**		**M=10** **M=10**	
Resulting Annex VI entry if agreed by COM	029-023-00-4	Copper sulphate pentahydrate	231-847-6	7758-99-8	Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H302 H318 H410		M=10 M=10	

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

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

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

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

[4] Where a classification/labelling element is highlighted in yellow, this is to indicate that RAC has not yet agreed on the underlying hazard, but will discuss it further.

Part III. List of Attendees of the RAC-31 A meeting

25-27 November 2014

RAC members
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
CARVALHO João
CZERCZAK Slawomir
Di PROSPERO FANGHELLA Paola
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
ILIE Mihaela
JENSEN Frank
KADIĶIS Normunds
KAPELARI Sonja
KORATI Safia
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MULLOOLY Yvonne
NEUMANN Michael
PARIS Pietro
PASQUIER Elodie
PRONK Marja (25-26.11.)
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLÜTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SOERENSEN Peter
STASKO Jolanta
STOLZENBERG Hans-Christian
TADEO José Luis
TSITSIMIPIKOU Christina
UZOMECKAS Zilvinas
VARNAI Veda Marija
VIVIER Stephanie
Advisers to the RAC members
ESPOSITO Dania (adviser to Pietro Paris)
PAPPONEN Hinni (adviser to Riitta Leinonen)
PECZKOWSKA Beata (adviser to Boguslaw Baranski and adviser for Article 77(3) request on benzene
VÄÄNÄNEN Virpi (adviser to Tiina Santonen)
ROUSSELLE Christophe (adviser to Elodie Pasquier)
Commission observers
HEIDORN Christian (DG ENV)
LUVARA Giuseppina (DG ENTR)
MORRIS Alick (DG EMPL)
SAARIKOSKI Sirkku (DG EMPL)

Stakeholders observers		**Excuses**
ANNYS Erwin, Cefic		BRANISTEANU Radu
BARRY Frank, ETUC		LOSERT Annemarie
ROHDE Arlean, CONCAWE		MURRAY Brendan
ROMANO Dolores, EEB		SPETSERIS Nikolaos
VEROUGSTRAETE Violaine, Eurometaux		
Industry experts		**ECHA staff**
NETTERSHEIM Rolf (Cefic, Chrysotile)		
BEYER Dieter (Cefic, bisphenol A)		BERGES Markus
Van ASSCHE Frank (Eurometaux, cadmium in artists paints)		BLAINEY Mark
		BOWMER Tim, Chairman
Invited experts		DVORAKOVA Dana
HÖLZL Christine (prospective RAC member)		JOVER BUSTILLO Vanessa
KALOGIROU Andreas (prospective RAC member)		KANELLOPOULOU Athanasia
Van der HAGEN Marianne (rapporteur for Chrysotile)		KIOKIAS Sotirios
RUMSBY Paul (contractor for general AfA issues)		KIVELÄ Kalle
		KLAUK Anja
Dossier submitters		KOKKOLA Leila
Norwegian dossier submitters:		KOSK-BIENKO Joanna
FOTLAND Öystein Tor (DecaBDE)		KOSTIKA Xenia
MYHRE Ingunn Correll (PFOA)		KOULOUMPIS Vasileios
MYHRE Oddvar (DecaBDE)		LOGTMEIJER Christiaan
German dossier submitters:		LUDBORŽS Arnis
VIERKE Lena (PFOA)		MARQUEZ-CAMACHO Mercedes
French dossier submitters:		MAZZOLINI Anna
Cavalieri Luisa (ammonium salts)		MOSSINK Jos
Rousselle Christophe (bisphenol A)		MOTTET Denis

ORISPÄÄ Katja		**REMOTE PARTICIPANTS**
PENNESE Daniele		**Advisers :**
PERAZZOLA Chiara		McDERMOTT Michelle (adviser to Yvonne Mullooly)
REGIL Pablo		Van der HAGEN Marianne (adviser to Christine Bjørge
SIMPSON Peter		ROTHER Dag (adviser to Agnes Schulte
RODRÍGUEZ IGLESIAS Pilar		
ROGGEMAN Maarten		**Dossier submitters**
SADAM Diana		**DE dossier submitters:**
SOSNOWSKI Piotr		NIEDERSTRASSER Bernd (PFOA)
STOYANOVA Evgenia		STARKE Sue Martina (PFOA)
VAINIO Matti		STAUDE Claudia (PFOA)
VAN HAELST Anniek		
		FR dossier submitters:
SEAC members		LECOQ Pierre (ammonium salts)
BOUSTRAS George (chrysotile)		PERNELET-JOLY Valerie (BPA)
BRIGNON Jean-Marc (PFOA)		REDAELLI Matteo (BPA)
COGEN Simon (Trichloroethylene)		
CSERGO Robert (Cadmium and its compounds in artists paints)		**NL dossier submitters:**
D´AMICO Flaviano (ammonium salts)		MÜLLER Andre (Art 77 benzene)
FANKHAUSER Simone (Lead chromates pigments)		
FIORE-TARDIEU Karine (Lead chromates pigments)		**NO dossier submitters:**
FURLAN Janez (Diarsenic trioxide,trichloroethyle)		BLOM Cecile (PHOA)
GEORGIOU Stavros (Diarsenic trioxide 4, Bisphenol A)		GUTZKOW B Kristine (PFOA)
KIISKI Johanna (PFOA)		HOFER Tim (DecaBDE)
KRAJNC Karmen (Trichloroethylene)		HAUG Line Småstuen (PFOA)
LUTTIKHUIZEN Cees (ammonium salts)		HUSA Stine (PFOA)
PALOTAI Zoltan (Chrysotile)		KOPANGEN Marit (PFOA, DecaBDE)
SCHUCHTAR Endre (DecaBDE)		TOLFSEN Christina Charlotte (DecaBDE)
SIMON Franz-Georg (Cadmium and its compounds in artists paints)		
SLETTEN Thea (Bisphenol A, trichloroethylene)		
STOYANOVA-LAZAROVA Elina		
THIELE Karen (DecaBDE, HBCDD)		
THORS Åsa (HBCDD)		

SE dossier submitters:		
CARLSSON Mattias (cadmium in artist paints)		
CEDERBERG Inger (cadmium in artist paints)		
IVARSSON Jenny (cadmium in artist paints)		
PARKMAN Helena (cadmium in artist paints)		
VIRDARSSON Jenny (cadmium in artist paints)		
WARHOLM Margareta (cadmiumin artist paints)		
Commission observers:		
BERTATO Valentina		
FERNANDES-de-BARROS Mariana		
GARCIA JOHN Enrique		
PIRSELOVA Katarina		
ROZWADOWSKI Jacek		
STRECK Georg		
EFSA :		
ISTACE Fréderique		

RAC SEAC Joint session
Tuesday 25 November 2014

List of the SEAC participants

SEAC members
ALEXANDRE João
ALEXANDROPOULOU Ionna
BOUSTRAS George
BRIGNON Jean-Marc
COGEN Simon
CSERGŐ Robert
DALTON Marie
DANTINNE Catheline
D'AMICO Flaviano
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GOLOVACIOVA Ilona
GRANDI Silvia (via WEBEX)
KIISKI Johanna
KRAJNC Karmen
LUTTIKHUIZEN Cees
MEXA Alexandra
NARROS SIERRA Adolfo
NICOLAIDES Leandros
PALOTAI Zoltán
SCHUCHTAR Endre

SIMON Franz Georg
SLETTEN Thea Marcelia
SMILGIUS Tomas
STOYANOVA-LAZAROVA Elina Velinova
THIELE Karen
THORS Åsa
Advisors & Experts
BERNHEIM Theresa (advisor to K. Thiele)
CASTELLI Stefano (advisor to F. D'Amico)
CAVALIERI Luisa (advisor to K. Fiore)
FEAYAERTS Jean-Pierre (advisor to S. Cogen, via WEBEX)
JONGENEEL Rob and LUIT Richard (advisors to C. Luttikhuizen)
KAJIC Silva (Invited Expert, HR)
LESTANDER Dag (Advisor to Å. Thors, via WEBEX)
VERHOEVEN Julia (advisor to C. Luttikhuizen, via WEBEX)
Stakeholder observers
BUONASANTE Vito (CLIENT EARTH)
JANOSI Amaya (Cefic)
MUSU TONY (ETUC)
SANTOS Tatiana (EEB)
WAETERSCHOOT Hugo (EUROMETAUX)
Representative of the European Commission
BENGYUZOV Manol (DG ENTR)
GALLEGO Mateo (DG ENV)

Part III. List of Attendees of the RAC-31 B meeting

2-4 December 2014

RAC members		
BARANSKI Bogusław		STAŠKO Jolanta
BIRO Anna		TSITSIMIPIKOU Christina
BJORGE Christine		UZOMECKAS Zilvinas
BRANISTEANU Radu		VARNAI Veda Marija
CARVALHO João		VIVIER Stephanie
CZERCZAK Slawomir		
Di PROSPERO FANGHELLA Paola		
DUNAUSKIENĖ Lina		
DUNGEY Stephen		
GRUIZ Katalin		
GUSTAFSON Anne-Lee		
KADIĶIS Normunds		
KAPELARI Sonja		
KORATI Safia		
LEINONEN Riitta		
LUND Bert-Ove		
MENARD Anja		
MURRAY Brendan		
NEUMANN Michael		
PARIS Pietro		
PASQUIER Elodie		
PRONK Marja (2-3.12.))		
RUCKI Marian		
RUPPRICH Norbert		
SANTONEN Tiina (2.12.)		
SCHULTE Agnes		
SMITH Andrew		
SOGORB Miguel		
SOERENSEN Peter		

Advisers to the RAC members		**Commission observers**
CATONE Tiziana (adviser to Paola di Prospero, and bensovindiflupyr)		SCAZZOLA Roberto (DG ENTR)
HENNING Ian Clausen (adviser to Peter Hammer Soerensen)		
RISSANEN Eeva (adviser to Riitta Leinonen)		**Invited experts**
ROMOLI Debora (adviser to Pietro Paris, and pirimicarb, fluopyram, friflumizole)		MARTIN Barbara (José Tadeo´s adviser)
VEGA Milagros (adviser to Joao Carvalho, and benzovindiflupyr)		STAHLMANN Ralf (prospective RAC member)
Stakeholders observers		**Dossier submitters**
ANNYS Erwin, Cefic		NAUFAL Ziad (TPP) Chevron Oronite
BARRY Frank, ETUC		
Den HAAN Klaas, CONCAWE		**Excuses**
ROWE Rocky, ECPA		**RAC members:**
WAETERSCHOOT Hugo, Eurometaux		HAKKERT Betty
		ILIE Mihaela
Industry experts		JENSEN Frank
DELBEKE Katrien (Eurometaux, copper compounds)		LOSERT Annemarie
MACKIE Carol (Cefic, copper compounds)		MULLOOLY Yvonne
HENNINGER Kerstin (ECPA, thiacloprid)		SCHLÜTER Urs
HOARE Andy (ECPA, copper compounds)		SPETSERIS Nikolaos
LLOYD Sara (ECPA, benzovindiflupyr, pirimicarb)		STOLZENBERG Hans-Christian
MARTENS Mark (ECPA, acetochlor)		TADEO José Luis
TESH Sheila (ECPA, triflumizole)		
TINWELL Helen (ECPA, fluopyram)		**Stakeholders:**
		TAYLOR Katy (ECEAE)

ECHA staff		**Dossier submitters:**
BERGES Markus		**FR dossier submitters:**
BLAINEY Mark		CAVELIER Adeline (benzovindiflupyr)
BOWMER Tim, Chairman		LUCIOT Marie (benzovindiflupyr)
BROECKAERT Fabrice		MICHEL Cécile (benzovindiflupyr, e-glass)
DVORAKOVA Dana		TERENDIJ Carline (e-glass fibres)
HENNIG Philip		
JOVER BUSTILLO Vanessa		**NL dossier submitter:**
HONKANEN Jani		MÜLLER André (TBHP, pencycuron, triflumizole)
KANELLOPOULOU Athanasia		
KARJALAINEN Ari		
KIVELÄ Kalle		
KLAUK Anja		
KOKKOLA Leila		
KOSK-BIENKO Joanna		
KOSTIKA Xenia		
LAPENNA Silvia		
LUDBORŽS Arnis		
LUSCHÜTZKY Evita		
MAZZOLINI Anna		
MOSSINK Jos		
NYGREN Jonas		
PERAZZOLA Chiara		
REGIL Pablo		
RODRÍGUEZ IGLESIAS Pilar		
SOSNOWSKI Piotr		
VAN HAELST Anniek		
REMOTE PARTICIPANTS		
RAC members:		
HAKKERT Betty		
LOSERT Annemarie		
SMITH Andrew (4.12.)		
Advisers:		
LUIT Richard (adviser to Marja Pronk)		
EFSA:		
COURT MARQUES Danièle		
ISTACE Fréderique		
PARRA MORTE Juan		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-31 meeting

ANNEX II List of documents submitted to the members of the Committee for Risk Assessment for the RAC-31 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-31 meeting

ANNEX IV Administrative issues and information items

25 November 2014
RAC/A/31/2014

Final Agenda
31th meeting of the Committee for Risk Assessment

25-27 November
2-4 December 2014

ECHA Conference Centre (Annankatu 18, Helsinki)

25 November starts at 9:00
27 November ends at 16:00
2 December starts at 9.00
4 December ends at 18:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/31/2014
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 30 action points, written procedures and other ECHA bodies

RAC/31/2014/01
RAC/31/2014/02 (room document)
For information

b) RAC workplan for all processes

For information

c) General RAC procedures

RAC/31/2014/03
For discussion/agreement

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

a) T

a) Tetrapropenylphenol (TPP)

For discussion/agreement

b) Consumer exposure to benzene contained in natural gas

For discussion/agreement

Item 6 – Harmonised classification and labelling (CLH)

6.1 CLH dossiers

A. Hazard classes for agreement without plenary debate

a) Pirimicarb (ISO): Acute toxicity (oral, dermal, inhalation)

b) Fluopyram (ISO): Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Eye corrosion/irritation, Skin sensitisation, Aquatic Acute, Aquatic Chronic

c) Thiacloprid (ISO): Acute toxicity (oral, dermal, inhalation), Skin corrosion/irritation, Eye corrosion/irritation, Skin sensitisation, Aquatic Acute, Aquatic Chronic

d) Triflumizole: Acute toxicity (oral, dermal, inhalation), STOT SE, Skin corrosion/Irritation, Eye corrosion/irritation, Respiratory tract irritation, Skin sensitisation, Respiratory sensitisation, Aquatic Acute, Aquatic Chronic

e) Dicyclohexyl phthalate (DCHP): Skin sensitisation

f) Pencycuron (ISO): Acute toxicity (oral, dermal, inhalation), STOT SE, Skin corrosion/irritation, Eye corrosion/irritation, Respiratory sensitisation, Skin sensitisation, STOT RE

B. Substances with hazard classes for agreement in plenary session

a) Acetochlor
b) 3,7-dimethylocta-2,6-dienenitrile (Geranonitril)
c) Chlorsulfuron (ISO)
d) Pirimicarb (ISO)
e) Benzovindiflupyr (ISO)
f) Fluopyram (ISO)
g) Tert-butyl hydroperoxide (TBHP)
h) Thiacloprid (ISO)
i) Triflumizole
j) Diisobutyl phthalate (DIBP)
k) Dicyclohexyl phthalate (DCHP)

l) Pencycuron (ISO)

m) E-glass fibres of representative composition

n) Glass fibres of representative composition

o) Copper dossiers (environmental 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 (co-)rapporteurs for CLH dossiers

RAC/31/2014/04 (restricted room document)

For agreement

Item 7 – Restrictions

7.1 General restriction issues

a) Review of the restriction process – update from the Task Force

RAC/31/2014/05

For information and discussion

7.2 Restriction Annex XV dossiers

a) Opinion development

1) Cadmium and its compounds in artist paints – revised draft opinion

For adoption

2) Chrysotile - revised draft opinion

For adoption

3) Isopropylidenediphenol (Bisphenol A) – first draft opinion

For discussion

4) Ammonium salts – first draft opinion

For discussion

5) DecaBDE – key issues document

For discussion

b) Conformity check

1) Perfluorooctanic acid (PFOA) – outcome of conformity check

For agreement

7.3 Appointment of (co-)rapporteurs for restriction dossiers

RAC/31/2014/06 (restricted document)
For agreement

Item 8 – Authorisation

8.1 General authorisation issues

RAC/31/2014/07
For discussion and agreement

8.2 Authorisation applications

b) Authorisation application – 3rd RAC draft opinion (applications submitted within the November 2013 submission window)

1. 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):

   i. Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use
   ii. Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)
   iii. Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking
   iv. Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use
   v. Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use
   vi. Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking

For agreement

f) Authorisation application – 2nd version of RAC draft opinions (applications submitted within the February 2014 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):
    i. Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications).
    ii. Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications.

For discussion/agreement

g) Authorisation application – 1st outline RAC draft opinion (applications submitted within the May 2014 submission window)

a. The use of diarsenic trioxide submitted by Yara France (Diarsenic trioxide 4):
    i. Use of diarsenic trioxide as a processing aid for the removal of carbon dioxide in synthesis gas formed in the production of ammonia

For discussion/agreement

b. Two uses of trichloroethylene submitted by Vlisco Netherlands BV (Trichloroethylene 5):
    i. Use of trichloroethylene as a solvent for the removal and recovery of resin from dyed cloth
    ii. Use of trichloroethylene as a solvent in a process to recover and purify resin from process water

For discussion/agreement

h) Authorisation applications – outcomes of the conformity check and presentation of key issues

13. Trichloroethylene 1:

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

14. Trichloroethylene 2a:

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

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

<u>Use 3</u>: Use of tricholoroethylene in packaging

Use 4: Use of tricholoroethylene in formulation

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

15. Trichloroethylene 2b:

Use 1: Use of Trichloroethylene in formulation

Use 2: Use of tricholoroethylene in packaging

16. Trichloroethylene 3:

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

17. Trichloroethylene 4:

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

18. Trichloroethylene 6:

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

19. Trichloroethylene 7:

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

20. Trichloroethylene 8:

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

21. Trichloroethylene 9:

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

22. Trichloroethylene 10:

Use 1: Use as an extraction solvent in caprolactam production

23. Trichloroethylene 11:

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

24. Trichloroethylene 12:

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

For agreement

i) Authorisation applications – adoption of the RAC final opinions

3. On the use of bis(2-ethylhexyl) phthalate (DEHP 2c) submitted by DEZA a.s.

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

4. On the use of dibutyl phthalate (DBP 2) submitted by DEZA a.s.

Use 3: Industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

For adoption

8.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)

RAC/31/2014/08 (restricted room document)

For agreement

Item 9 – AOB

a) Report from the 3rd preparatory seminar on Chromates

Item 10 – Action points and main conclusions of RAC-31

Table with Conclusions and Action points from RAC-31

For adoption

ANNEX II (RAC-31)

Documents submitted to the members of the Committee for Risk Assessment for the RAC-31 meeting.

Document number	**Title**
RAC/A/31/2014	Final Draft Agenda
RAC/31/2014/01	Report from other ECHA bodies and activities
RAC/31/2014/02 Room document	Administrative document
RAC/31/2014/03	General RAC procedures (WP-appointment raps)
RAC/31/2014/04 Room document Restricted	Appointment of RAC Rapporteurs for CLH dossiers
RAC/31/2014/05	General restriction issues – update from the task Force
RAC/31/2014/06 Restricted	Appointment of Rapporteurs for restriction dossiers
RAC/31/2014/07	General authorisation issues
RAC/31/2014/08 Room document Restricted	Appointment of Rapporteurs for authorisation applications

ANNEX III (RAC-31)

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, 29 and/or 30		
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.
RESTR: Bisphenol A (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Tiina SANTONEN	Being involved in a study on BPA performed by her employer
RESTR: DecaBDE (ECHA)	Christine BJØRGE	Working for the CA who collaborated with ECHA on the preparation of the dossier.
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.

New dossiers

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
NEW		
RESTR: PFOA	Christine BJØRGE	Working for the CA who collaborated with Germany on the preparation of the dossier.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Hans-Christian STOLZENBERG	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: 3,7-dimethylocta-2,6-dienenitrile (Geranonitrile) (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Hans-Christian STOLZENBERG	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Agnes SCHÜLTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Chlorsulfuron (ISO) (PL)	Boguslaw BARANSKI	Working for the CA submitting the

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
		dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Tert-butyl hydroperoxide (TBHP) (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: Glass fibres of representative composition (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: E-glass fibres of representative composition (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Thiacloprid (ISO) (UK)	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Triflumizole (ISO) (NL)	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Pirimicarb (ISO) (UK)	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
		dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Benzovindiflupyr (ISO) (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Fluopyram (ISO) (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Hans-Christian STOLZENBERG	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Agnes SCHÜLTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
CLH: Diisobutyl phthalate (DIBP) (DE)	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Hans-Christian STOLZENBERG	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Agnes SCHÜLTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC member	Reason for potential CoI / Working for
CLH: Dicyclohexyl phthalate (DCHP) (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.
CLH: Pencycuron (ISO) (NL)	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

RAC advisers

AP/Dossier / DS	RAC member adviser	Reason for potential CoI / Working for
CLH: Copper compounds (10 dossiers) FR	Christophe ROUSSELLE	Working for the CA submitting the dossier and being personally involved in the preparation of the dossier.

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Helsinki, 19 November 2014

RAC/31/2014/02

ROOM DOCUMENT

31ST MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

25-27 November
2-4 December 2014

Helsinki, Finland

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

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-30 Action Points

The RAC-30 action points due for RAC-31 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-30	7 November 2014	Adopted

2.2 Written dossier consultations (status by 19 November 2014)

Subject / Document	Deadline	Status / follow-up
Art. 77(3)(c): Tetrapropenylphenol (TPP) - setting of Specific Concentration Limits (SCLs) for Tetrapropenylphenol (TPP) as proposed by Chevron Oronite SAS	29 October 2014	Closed
Art. 77(3)(c): Consumer exposure to benzene contained in natural gas (RIVM report)	17 October 2014	Closed
CLH: Acetochlor (ISO) – revised ODD	4 November 2014	Closed
CLH: Copper substances (ENV HCs)	5 November 2014	Closed
CLH: 3,7-dimethylocta-2,6-dienenitrile (Geranonitril)	22 September 2014	Closed
CLH: Chlorsulfuron (ISO)	20 October 2014	Closed
CLH: Pirimicarb (ISO)	24 October 2014	Closed
CLH: Benzovindiflupyr (ISO)	30 October 2014	Closed
CLH: Fluopyram (ISO)	30 October 2014 / 3 November 20174 (HH)	Closed
CLH: Tert-butyl hydroperoxide (TBHP)	30 October 2014	Closed
CLH: Thiacloprid (ISO)	3 November 2014	Closed
CLH: Triflumizole (ISO)	24 October 2014	Closed
CLH: Diisobutyl phthalate (DIBP)	29 September 2014	Closed
CLH: Dicyclohexyl phthalate (DCHP)	22 October 2014	Closed

Subject / Document	Deadline	Status / follow-up
CLH: Pencycuron (ISO)	31 October 2014	Closed
CLH: E-glass fibres of representative composition	31 October 2014	Closed
CLH: Glass fibres of representative composition	31 October 2014	Closed
AfA: Trichloroethylene 5 (application)	1 October 2014	Closed
AfA: Diarsenic trioxide 4 (application)	1 October 2014	Closed
AfA: Lead chromate pigments 2 (model DO)	27 October 2014	Closed
AfA: Trichloroethylene 1 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 1 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 2a (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 2a (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 2b (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 2b (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 3 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 3 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 4 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 4 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 6 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 6 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 7 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 7 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 8 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 8 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 9 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 9 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 10 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 10 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 11 (conformity)	12 November 2014	Closed

Subject / Document	Deadline	Status / follow-up
AfA: Trichloroethylene 11 (application)	5 January 2015	Ongoing
AfA: Trichloroethylene 12 (conformity)	12 November 2014	Closed
AfA: Trichloroethylene 12 (application)	5 January 2015	Ongoing
REST: Ammonium salts	21 November 2014	Open
REST: Bisphenol A	17 November 2014	Closed
REST: Cadmium and its compounds in artists' paints	17 November 2014	Closed
REST: Chrysotile	17 November 2014	Closed
REST: DecaBDE	21 November 2014	Open
REST: PFOA (conformity)	10 November 2014	Closed

2.3 Other written consultations of RAC (status by 17 November 2014)

Other written consultations	Deadline	Status / follow-up
RAC consultation on the draft minutes of RAC-30	22 October 2014	Closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
CLH: Call for expression of interest for rapporteurship	22 – 31 October 2014	Volunteers for five dossiers; appointment via WP
Restriction: call for expression of interest for rapporteurship for N,N-dimethylformamide; dimethyl formamide restriction proposal	23 October - 5 November 2014	No volunteers

2.5 Written procedures for appointment of (co-)rapporteurs

Appointment (co-)RAP	For Substance	Deadline	Outcome
CLH: Written procedure for appointing of (co-)rapporteur(s)	▪ momfluorothrin ▪ hexythiazox (ISO) ▪ penfluen ▪ N-(hydroxymethyl)acrylamide	17 November 2014	Closed No comments were received from RAC members on the

Appointment (co-)RAP	For Substance	Deadline	Outcome
	(NMA) ▪ 1,2-dihydroxybenzene; pyrocatechol		recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.

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