RAC/M/36/2016
Final
13 May 2016

Minutes of the 36th Meeting of the Committee for Risk Assessment (RAC-36)

29 February started at 14.00
4 March suspended at 12.00
8 March resumed at 14:00
10 March ended at 13.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 36th meeting of the Committee for Risk Assessment (RAC-36), the first of 2016. Apologies were received from three Members. The Chairman also welcomed one invited expert representing one RAC Member who was unable to attend.

The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. He added that the recordings form the 35th meeting had already been destroyed. The Chairman noted that the minutes would be published on the ECHA website and would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/36/2016), which was adopted by the Committee without change. 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. No points were raised under any other business.

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. Seven Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of Members at agencies submitting dossiers to RAC but who had not been involved in the preparation. In the event of a vote, these Members were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. Where Members declared that they had contributed to the preparation of a substance dossier for consideration by RAC, or similar potential conflict, they were asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Report from other ECHA bodies and activities

a) Report on RAC-35 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points of RAC-35 had been completed or were on-going. He explained that a report covering the developments in the ECHA Management Board, the Socio-Economic Assessment Committee, Member State Committee, the Forum and the Biocidal Products Committee had been compiled and distributed to RAC as a meeting document (RAC/36/2015/01). The summary of all consultations, calls for expression of interest in rapporteurships and written procedures is available in the usual meeting document on CIRCABC (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-35 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website, and thanked those Members who had provided comments on the draft.

b) Feedback from the Commission on RAC Applications for authorisation opinions

A European Commission observer from DG GROW gave a brief presentation on the Commission's experience in processing the Application for authorisation opinions which were adopted in RAC in 2015. He noted that the responsibility for drafting Commission proposals for authorisation decisions lay with DG GROW and DG Environment, with the former in the lead. The draft decision is then subject to an inter-service consultation, discussion and vote in the REACH Committee and finally World Trade Organisation consultation.

The need for evidence-based, factual opinions was emphasised and he noted that clear analysis and conclusions were required to produce high quality opinions. Conditions proposed by RAC or SEAC and monitoring arrangements proposed by RAC, needed to be carefully and consistently written, as once included in the decision, they became legal requirements of the authorisation.

He reflected that the RAC opinions and discussions have continuously improved in terms of structure, analysis and presentation during the last year. However there is still room for improvement in order for the documents to be more independently readable and self-explanatory.

The Chairman thanked the European Commission's representative for this update and proposed that such useful feedback at regular intervals would help the Committee in their work.

c) RAC work-plan for all processes

The Chairman presented the updated RAC work-plan for Q2&Q3/2016, covering the three processes of restriction, authorisation and harmonised classification and labelling of substances. He informed Members that they could find the expected schedules for Restriction and authorisation dossiers in the work plan. In addition, the scheduling and the endpoints to be considered for each harmonised classification and labelling (CLH) dossier for the next two meetings ahead are given in the relevant section, including those for human health and the environment.

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

There are no items under this agenda point currently.

6. Requests under Article 95 (3)

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

The Chairman informed the Committee about a draft paper which had been developed by the RAC Members of the joint Working Group on NMP (WG), taking into account the discussion at RAC-35 to reconsider all available NOAECs and LOAECs for the developmental effects of NMP and re-analyse their adversity.

A RAC Member of the WG presented the main aspects of the paper and summarised the discussion and exchange of views with the Scientific Committee on Occupational Exposure

Limits (SCOEL) so far. The aim of the RAC paper was to reach a common view and get the endorsement of the Committee for the line to take in further discussions with SCOEL. The first element discussed was the choice of critical adverse health effect. The RAC Members of the WG had made a thorough re-analysis of the studies used for the RAC 2014 opinion on NMP. RAC discussed and endorsed the proposal to consider all inhalation studies (incl. those using a single dose) in the discussion with SCOEL aimed at an overall NOAEC. While two RAC Members pointed out that the reduced birth weight effect was of a relatively low severity and reversible, the Committee acknowledged the fact that although the 5% decrease in birth weight might be seen as only slight, it was observed during the whole lactation period, (up until day 21) thus could not be considered as quickly reversible and in addition it was observed across oral and dermal studies and therefore was consistent. The paper also questioned the respiratory irritation effect mainly relied on by SCOEL to derive its iOEL but raised an area for potential compromise with reproductive toxicity effects as the relevant Point of Departure (PoD).

In the follow-up discussion, a RAC Member clarified the approach taken by SCOEL who had taken both local and systemic effects into consideration when deriving an OEL for NMP. It was also confirmed by the DG EMPL observer that the 2015 SCOEL recommendation on NMP was currently in draft form and had been revised in reaction to the joint mandate / request from the Commission.

The Committee supported the proposed approach and the Chairman thanked the RAC Members of the WG for the work done so far.

b) OEL-DNEL methodology request

The Chairman informed the meeting on the state of play of the second Article 95 request on OEL/DNEL methodology and that ECHA had accepted the request in a phased manner and with a detailed work plan. He presented the mandate and draft work plan to RAC as well as ECHA's project team and the names of the RAC Members who had volunteered for the joint RAC-SCOEL task force. In the subsequent discussions, it was confirmed by the Commission that only industrial chemicals as regulated by REACH and OSH legislation should be the focus. The concern was raised that this could become a large research project which due to historical differences between the two legislations could be difficult to complete within the revised timeline allocated by COM. It was then clarified in the discussions that the mandate was specifically to identify areas of convergence and divergence between the approaches to setting reference values under the two legislations, and to advise the Commission accordingly. RAC reviewed and endorsed the draft work plan and then agreed to appoint the Members volunteering to the joint task force. The Chairman noted that the draft work plan would be immediately forwarded to the SCOEL secretariat for their consideration and thanked the appointed RAC Members of the task force for their commitment to the upcoming work.

7. Harmonised classification and labelling (CLH)

7.1 CLH dossiers

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

RAC reviewed an A-listing of hazard classes for a range of substances and agreed these without plenary debate. The details of each substance are given below in section B.

B. Substances with hazard classes for agreement in plenary session

a) Amisulbrom (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer as well as a representative from EFSA who followed the meeting remotely. He reported that Amisulbrom (ISO) is a pesticide active substance which is used as a fungicide on grapes and potatoes within the EU.

Amisulbrom (ISO) has no entry in Annex VI to the CLP Regulation; therefore, all hazard classes need to be evaluated.

The Dossier Submitter (UK) proposed to classify Amisulbrom (ISO) as Eye Irritant 2 (H319), Carc. 2 (H351), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=10 for both aquatic hazards (based on the surrogate approach).

The legal deadline for the adoption of the opinion is 29 May 2016.

The Chairman recalled that the following hazard classes had been agreed at this meeting by RAC through the fast-track procedure: no classification for the physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, respiratory and skin sensitisation, STOT SE, STOT RE, germ cell mutagenicity, reproductive toxicity (fertility), aspiration hazard in addition to Aquatic Acute 1 (H400) with M=10 and Aquatic Chronic 1 (H410) with M=10. He reported that the hazards to be discussed in plenary were eye corrosion/irritation, carcinogenicity and developmental toxicity.

In relation to eye damage/irritation, the Rapporteur reported that there was a lack of effects on cornea and iris as well as an absence of conjunctival oedema. Also, the conjunctival erythema was of low severity. Yet there were no plausible explanations supporting the interpretation that the short intermittence was a proof of reversibility and the re-occurrence not substance-related. RAC then discussed whether the criteria for serious eye damage were fulfilled, and whether the weight of evidence would indicate severe eye effects. Because of the absence of effects on cornea and iris as well as the low grade erythema observed, it was concluded that this was not the case, and that Amisulbrom (ISO) should be classified as Eye Irrit. 2 (H319).

In relation to carcinogenicity, the Rapporteur reported that Amisulbrom (ISO) induced tumor formation in rats and mice. He proposed that the substance was not genotoxic and that the tumor profile might lower the level of concern; however, the histopathological changes concurrent with toxicity, enzymatic induction, liver gene expression and cell proliferation indicated that the process was not simply adaptive. While the first two key events in the phenobarbital-like mode of action (PB-like MoA) (as defined in Elcombe, 2014) resembled the behavior of phenobarbital, the intrinsic potential of enzymatic induction was lower for Amisulbrom (ISO). He concluded that the tumor profile corroborated the uncertainties such as

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

the role of excessive toxicity seen in female rats and the fact that other MoAs were not strongly dismissed, and suggested a weak case for Category 2.

RAC then discussed whether the reduced body weight gains seen in the rat studies where related to lower food consumption as result of poor palatability or related to toxicity of the substance. Based on the data available, this could not be sufficiently clarified. The expert accompanying the ECPA Stakeholder observer presented the CAR-mediated MoA as the only relevant cause of the tumour formation but RAC questioned whether other MoA have been convincingly excluded. Additionally, the expert stated that the MoA was similar to PB and therefore irrelevant to humans. Consequently, Amisulbrom (ISO) should not be considered as a human carcinogen. RAC then considered that the contribution of other MoA than CAR could ultimately not be dismissed as the mechanistic data provided in the CLH report were not sufficiently robust and that a classification into category 2 (H351) would be justified. This was finally agreed by RAC.

In relation to developmental toxicity, RAC Members were of the view that the cleft palates observed in HAN Wistar rats were not attributable to Amisulbrom (ISO), but had a genetic cause attributable to the strain used. It was therefore decided not to propose a classification for developmental toxicity.

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

b) Chlorocresol

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. He reported that Chlorocresol is a biocidal active substance which is under revision in various product types.

Chlorocresol already has an existing entry in Annex VI to CLP, where it is classified as Acute Tox. 4 * (H302), Acute Tox. 4 * (H312), Eye Dam. 1 (H318), Skin Sens. 1 (H317) and Aquatic Acute 1 (H400), no M-factor being set. The legal deadline for the adoption of the opinion is 12 November 2016.

The Dossier Submitter (France) proposed to retain the classifications as Eye Dam. 1 (H318) and Aquatic Acute 1 (H400), to add Skin Irrit. 2 (H315), STOT SE 3 (H335), Aquatic Chronic 3 (H412), to amend the current classifications to Acute Tox. 4 (H302, oral) and Skin Sens. 1B (H317) based on data, and to remove Acute Tox. 4 * (H312) from the entry in Annex VI.

The legal deadline for the adoption of the opinion is 12 November 2016.

The Chairman recalled that the following hazard classes had been already agreed at this meeting by RAC through the fast-track procedure: Acute Tox. 4 (H302), no classification for acute toxicity for the dermal and the inhalation route, Skin Sens. 1B (H317), STOT SE 3 (H335), Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 3 (H412).

He then reported that the only remaining hazard to be discussed in plenary was skin corrosion/irritation.

The Rapporteur reported that the studies available showed diverging while mostly corrosive effects, i.a. severe necrosis at the site of contact and to the epidermal layer. Based on the severity of the effects, RAC concluded that classification as Skin Corr. 1C (H314) was justified.

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) Flutianil (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that Flutianil (ISO) is a thiazolidine fungicide. It is a new active substance under the plant protection products Regulation.

Flutianil (ISO) has no entry in Annex VI to the CLP Regulation; therefore, all hazard classes needed to be evaluated. The Dossier Submitter (UK) proposed to classify Flutianil (ISO) as Repr. 2 (H361d) and as Aquatic Chronic 1 (H410), with M=100.

The legal deadline for the adoption of the opinion is 10 November 2016.

The Chairman recalled that the following hazard classes had been agreed by RAC through the fast-track procedure: no classification for the physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, respiratory and skin sensitisation, STOT SE, STOT RE, germ cell mutagenicity, aspiration hazard in addition to Aquatic Chronic 1 (H410) with M=100. He reported that the hazards to be discussed in plenary were carcinogenicity and developmental toxicity.

In relation to carcinogenicity, the Rapporteur reported that Flutianil (ISO) was not genotoxic. In addition, he stated that there was not sufficient evidence of a carcinogenic effect in rats and mice; therefore, he did not propose classification for carcinogenicity. The other RAC Members concurred with his proposal and the substance was not classified for carcinogenicity.

In relation to effects on sexual function and fertility, RAC was of the opinion that the results of repeated toxicity and carcinogenicity studies on mice, rats and dogs did not provide clear, unequivocal evidence of adverse effects meeting the classification criteria, particularly when evaluated jointly with the negative results of the two-generation reproduction study in rats. Therefore, RAC did not consider classification justified.

In relation to developmental effects, RAC Members were of the view that the properly conducted developmental studies in rats and rabbits had not provided clear evidence of development toxicity of Flutianil, thus not warranting classification for that hazard.

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

d) Pyroxsulam (ISO)

The Chairman welcomed the representative accompanying the ECPA stakeholder observer and reported that pyroxsulam was a pesticide active substance used as herbicide. It has no existing entry in Annex VI to the CLP Regulation and the legal deadline for the adoption of an opinion is 20 November 2016.

The Dossier Submitter (UK) proposed to classify pyroxsulam (ISO) as a skin sensitiser (Skin. Sens. 1; H317) and for environmental hazards as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 100 for both hazards. As pyroxsulam (ISO) is a pesticide active substance with no harmonised classification, it was subject to the C&L process in accordance with Article 36(2) of CLP and all hazard classes needed to be assessed.

RAC agreed to the Dossier Submitter's proposal to classify pyroxsulam (ISO) as Skin. Sens. 1; H317 based on the positive results from a GPMT (Guinea Pig Maximisation Test) with an intradermal induction of 5% pyroxsulam based on the method of Magnusson and Kligman and on the proposed environmental classification as Aquatic Acute 1; H400 based on the smallest acute toxicity results measured in *Lemna gibba* and Aquatic Chronic 1; H410 with an M-factor of 100 for both endpoints.

One comment from the public consultation had suggested classification as a carcinogen in category 2 based on some evidence for slightly increased tumour incidence in male F344 rats (lymphocyte leukaemia) and an increase in hepatocellular adenoma incidence in male mice carcinogenicity and this was discussed by the Committee.

The Committee concluded that the effects observed in animal studies (rat and mouse) were not treatment related nor was the type of neoplasm in the particular strain of rat considered relevant for human hazard assessment in this case. In both studies only one sex (male) was affected and the tumours occurred at similar levels to the background incidence. The mouse liver tumours presented a borderline case at the highest tested dose of 1000 mg/kg bw/day but the overall evidence was insufficient to classify for carcinogenicity. RAC agreed that no classification was warranted for carcinogenicity of pyroxsulam.

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

e) Isoeugenol

The Chairman reported that isoeugenol was used as a fragrance and flavouring agent in numerous non-food and food products and as an anaesthetic for fish. Isoeugenol is a mixture of two diastereomers and the CLH proposal covered the racemic mixture and both isomers (i.e. 2-methoxy-4-((E)prop-1-enyl)phenol and 2-methoxy-4-((Z)prop-1-enyl)phenol).

It has no existing entry in Annex VI to the CLP Regulation and the legal deadline for the adoption of an opinion is 9 December 2016.

The Dossier Submitter (the Netherlands) proposed to classify isoeugenol as Skin. Sens. 1A; H317 and to apply the generic concentration limit (GCL) of 0.1% should apply.

The Committee agreed with the proposed classification on the basis of the results from the LLNA (Local Lymph Node Assays), GPMT (Guinea Pig maximisation Test by Magnusson and Kligman) and Buehler assays, which are the officially accepted animal test methods which enable sub-categorisation. The subcategorization was further supported by the results of human study data from HRIPT (Human Repeat Insult Patch Tests), HMT (Human Maximisation Tests) and ROAT (Repeated Open Application Tests).

The discussion focused on setting a specific concentration limit (SCL) for skin sensitisation which generally applies to the most potent skin sensitisers classified in subcategory 1A. For isoeugenol the animal data showed that it is a strong skin sensitiser with some results even indicating extreme potency (GPMT study studies showing an incidence of sensitisation of ≥ 100% with an intradermal induction dose below of 0.15 % w/v). In the weight of evidence assessment which took into account the animal studies as well as data from humans, RAC Members supported setting an SCL of 0.01%. This would automatically trigger supplemental labelling EUH208 ('Contains isoeugenol. May produce an allergic reaction') for mixtures not classified as a skin sensitiser but containing isoeugenol at 1/10 of the SCL.

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) Epsilon-Metofluthrin

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that epsilon-Metofluthrin is a biocidal active substance which is manufactured and formulated into biocidal products outside of the EU.

Epsilon-Metofluthrin has no entry in Annex VI to the CLP Regulation; therefore, all hazard classes need to be evaluated. The legal deadline for the adoption of the opinion is 4 December 2016.

The Dossier Submitter (UK) proposed to classify epsilon-Metofluthrin as Acute Tox. 3 (H301), Acute Tox. 4 (H332), STOT RE 2 (H373; inhalation), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with M=100 for both aquatic hazards.

The Chairman recalled that the following hazard classes had been agreed during the ongoing meeting by RAC through the fast-track procedure: no classification for the physical hazards, acute toxicity (dermal route), skin corrosion / irritation, serious eye damage / eye irritation, respiratory and skin sensitisation, germ cell mutagenicity, reproductive toxicity, aspiration hazard, in addition to Acute Tox. 4 (H332), Aquatic Acute 1 (H400) with M=100 and Aquatic Chronic 1 (H410) with M=100. He reported that the hazards to be discussed in plenary were acute oral toxicity, STOT SE, STOT RE and carcinogenicity.

In relation to acute oral toxicity, the Rapporteur proposed a classification as Acute Tox. 3 (H301) based on 20% mortality at 100 mg/kg in rats and at 60 mg/kg bw in mice (gavage in corn oil), on an LD_{50} by inhalation estimated to be 275 mg/kg bw (estimated internal dose) and an LD_{50} (oral) expected to be lower. Finally the LD_{50} for the oral route (corn oil) was considered to be below 300 mg/kg bw. The expert accompanying the ECPA stakeholder observer noted that the testing of the substance in corn oil meant testing a mixture so that the mice study would not be valid as deriving an LD_{50} from that study was not admissible. The Rapporteur responded that according to the ECHA guidance, testing of a liquid substance using corn oil as a vehicle was allowed, so the study would be valid. Overall, the weight of evidence would count in deriving a classification, as done in other cases. RAC agreed to this and decided to propose classification of epsilon-Metofluthrin as Acute Tox. 3 (H301).

In relation to STOT RE, the Rapporteur suggested that based on the available data there was no justification for classification for the oral route. This view was shared by RAC. For the inhalation route, the Rapporteur reported that in a 28-day study in rats, no effects were seen at or below 0.1 mg/l while at the highest dose (0.2 mg/l), tremors during or immediately after exposure occurred equally in both sexes; in addition, rats started to die already in the first week of exposure (after day 3), which suggested that the criteria for STOT RE 2 were met, with no target organ to be identified (as is the practice when the reason for STOT RE classification is lethality). This view was contested by some RAC Members who argued that STOT RE would not be the correct classification while the classification for acute inhalation toxicity would already cover the observed deaths. On the other hand, it could not be shown that the tremors observed were symptoms of an effect later causing the deaths , thus justifying a classification for STOT SE as the tremors could be seen as the manifestation of a (repeated) acute effect. Other RAC Members supported the Rapporteur by clarifying that an acute toxicity classification should be assigned where deaths occurred after treatment no longer than 48 h, that the difference with typical dose levels for acute effects were pronounced enough to be covered by a STOT RE classification and that the criteria would allow that the occurrence of deaths justified a STOT RE classification as well. These findings were acknowledged by the Committee and the classification as STOT RE 2 (H373)(inhalation) was agreed, although the target organ or effect were still to be agreed. RAC also discussed classification for neurotoxic effects in either STOT SE or STOT RE. No conclusion was reached.

RAC decided to postpone the discussion about specific target organ toxicity to the next RAC meeting in June, as well as the discussion about carcinogenicity.

g) 2-methylisothiazol-3(2*H*)-one (MIT) and h) Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1) (C(M)IT/MIT)

The Chairman welcomed two experts accompanying the Cefic stakeholder observer, as well as representatives from the French and Slovenian Dossier Submitters who followed the meeting remotely. He reported that MIT(ISO) and C(M)IT/MIT are both biocidal active substance which are used in a wide range of product types.

The Chairman stated that both substances were tabled for the first time at a RAC plenary meeting. The legal deadline for the adoption of the opinion for C(M)IT/MIT is 14 October 2016 and for MIT (ISO) it is 5 January 2017.

Aquatic hazards for MIT and C(M)IT/MIT

As to aquatic hazards, the Chairman reported that MIT (ISO) currently has no harmonised classification. The Dossier Submitter proposed to classify it as Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with M=1.

By contrast, C(M)IT/MIT does have an existing entry in Annex VI where it is classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

In relation to the aquatic hazards, the Rapporteur presented the proposed classification for both substances as both belong to the group of isothiazolinones with a similar mode of action in algae cells.

- For MIT (ISO), the Rapporteur argued for a classification as Aquatic Acute 1 and Chronic 1, with separate M-factors of 10 for acute hazards of 1 for long-term hazards, following the proposal of the DS.
- For C(M)IT/MIT the proposal was to retain the existing harmonised classification as Aquatic Acute 1 and Chronic 1 but adding separate M-factors of 100 to both hazard classes, as proposed by the DS.

In relation to aquatic toxicity the Rapporteur stressed the reasons to base the classification on a shorter time point from the algal tests than the standard one (i.e. 72 hrs or 96 hrs) on the fact that the strongest adverse effects (and thus, the lowest acute and chronic toxicity endpoints) were shown at 24 hrs and at 48 hrs for MIT and C(M)IT/MIT, respectively. He further justified the use of these endpoints based on the fact that the specific growth rate meets the criteria and therefore the validity of the test. Finally, the Rapporteur concluded that both substances are considered not rapidly degradable in the aquatic environment for classification purposes.

During the discussion one RAC Member agreed with the conclusion on rapid degradation but stressed the need for consistency in the choice of time point from the algal tests (24 hrs for MIT versus 48 hrs for C(M)IT/MIT) to present acute and chronic toxicity. While he did not express any preference on either time point for the acute classification he stressed the need to ensure consistency between both substances. In relation to chronic toxicity he proposed to use the 72 hrs toxicity endpoint instead based on the consideration that the high initial toxicity on algae declines with time as the substance is depleted. Therefore, use of an endpoint from a time period less than 72 hrs to derive the long-term hazard classification is considered too conservative. However, despite these comments several RAC Members agreed with the Rapporteurs' proposal on the choice of the shorter time point of 24 hrs (for MIT) and 48 hrs (for C(M)IT/MIT) for both acute and chronic classification based on the specific effect of both substances on algae.

In addition, a RAC Member also commented on the current proposal to classify MIT based initial measured concentrations whereas for C(M)IT/MIT mean measured concentrations are used and pointed towards the current inconsistency on which the classification for both substances is based. He stressed that while the toxicity declines with time, it appears to be too conservative to base the classification of C(M)IT/MIT on mean measured concentrations and therefore suggested to use initial measured concentrations taking into consideration the test substance depletion caused by algal uptake. This would result in an M-factor of 10 for both 24 hrs acute and 72 hrs chronic endpoints, respectively. The Rapporteur replied that mean measured concentrations are preferred using the same arguments as brought up by the RAC Member. However, while for C(M)IT/MIT measured concentrations for every 24 hrs are available this was not the case for MIT and the classification is therefore based on initial measured concentrations. The Rapporteur's view was supported by another RAC Member who stressed that the preference of using mean measured concentrations should be clearly stated in the opinion as well as the fact that these were not available for MIT.

The Committee finally agreed with the Rapporteur's proposal to classify MIT as Acute 1 with an M-factor of 10 and Chronic 1 with an M-factor of 1 and C(M)IT/MIT as Acute 1 and Chronic 1 with M-factors of 100 for both hazards, but recommended that the opinion should include a discussion on how the classification would be affected if the 72 hrs endpoint for chronic effects were chosen. With regard to the choice of concentrations, the Chairman concluded that based on the RAC decision of using initial measured concentrations for classifying MIT and mean measured concentrations for classifying C(M)IT/MIT, other isothiazolinones would have to be treated based on their own merits as no consistent approach was followed for these two substances at issue.

Human health hazards of (C(M)IT/MIT)

As to human health hazards, the Dossier Submitter (France) proposed to classify C(M)IT/MIT as Acute Tox. 3 (H301), Acute Tox. 2 (H330 and H310), Skin Corr. 1C (H314) with an SCL of 0.5% and as Skin Sens. 1A (H317) with an SCL of 15 ppm (0.0015%).

The Chairman recalled that the following hazard classes had been agreed during the ongoing meeting by RAC through the fast-track procedure: no classification for the physical hazards, and STOT SE, Acute Tox. 3 (H301), Acute Tox. 2 (H310), Acute Tox. 2 (H330) and the supplemental hazard statement EUH071 ("Corrosive to the respiratory tract"). He reported that the hazards to be discussed in plenary were skin corrosion and skin sensitisation.

In relation to skin irritation, the Rapporteur proposed classification as Skin Corr. 1C (H314) with an SCL of 0.6 % (confirming its current listing on Annex VI of CLP), based on 2 out of 3 studies available. He pointed out that category 1A and 1B could not strictly be excluded as none of the two studies investigated an exposure duration less than 4 hours. On the other hand study 3 (1 hour and 4 hour exposures) only indicated skin irritation, the overall evidence therefore supporting 1C. This classification proposal was agreed by RAC, while there was some discussion about the substance identity. The expert accompanying the Cefic stakeholder observer clarified that the 3:1 ratio of C(M)IT and MIT in the reaction mass was fixed and determined by the production process, and that the classification proposal related to the standard concentration of the reaction mass of 14% in water. The Rapporteur indicated that it was technically possible to produce the substance at concentrations up to 56%, i.e. >14%, which may necessitate a more severe classification than category 1C.

The Committee agreed to classify the substance on the basis of the available data and, as it is the normal practice for substances adopted by RAC, not to refer to its purity in the name. The discussion on the substance identity and marketed concentration would be included in the

opinion. The Secretariat will investigate with the Commission whether additional details can be added in the Annex VI entry.

In relation to skin sensitisation, the Rapporteur proposed to classify C(M)IT/MIT as a strong sensitiser, because the results of the available LLNA studies showed the EC3 value to be 0.003 % (i.e. < 2 %) inducing a Stimulation Index (SI) of 3. This proposal was agreed by the Committee. In relation to SCL setting, the Rapporteur recalled that the most relevant human data were reviewed by the TC C&L in 1997-98, resulting in an SCL of 15 ppm (i.e. 0.0015 %), while there was no further information available to RAC that could challenge this value. He also pointed out that according to revised ECHA guidance, a default of 10 ppm could be used for strong sensitisers. The Committee noted that there were no convincing scientific arguments to change the SCL from the current 15 to 10 ppm, so it was agreed to retain the SCL of 15 ppm.

Human health hazards of (MIT)

As to human health hazards, the Dossier Submitter (Slovenia) proposed to classify MIT (ISO) as Acute Tox. 3 (H301), Acute Tox. 3 (H311), Acute Tox. 2 (H330), Skin Corr. 1B (H314), Skin Sens. 1A (H317) with an SCL of 0.06% (i.e. 600 ppm), Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with M=1 and to assign the supplemental hazard statement EUH071 ("Corrosive to the respiratory tract").

The Chairman recalled that the following hazard classes had been agreed during the ongoing meeting by RAC through the fast-track procedure: Acute Tox. 3 (H301), Acute Tox. 3 (H311), Acute Tox. 2 (H330), Skin Corr. 1B (H314) and the supplemental hazard statement EUH071. He reported that the hazards to be discussed in plenary were skin sensitisation and developmental toxicity. In addition there would also need to be some discussion on the proposed aquatic hazard classification.

In relation to developmental toxicity, the Rapporteur proposed no classification based on the evaluation of three studies: the first study on Sprague-Dawley rats provided no treatment-related external, visceral or skeletal malformations or variations in foetuses. The second study on Wistar rats showed delayed ossification, which he attributed to the reduced bodyweight gain of the dams, while the observation of dilated cerebral ventricles would still need to be discussed. One RAC Member noted that there were actually no plausible reasons to explain the dilatation of ventricles, unless there was a decrease in the surrounding brain tissue. Another RAC Member proposed that the observed effects were actually artefacts, as it was not very probable that only a single endpoint was affected, while the findings were also observed in controls. He concluded that there may have been problems with the methodology. This view was shared by other RAC Members, and no classification was agreed by the Committee.

In relation to skin sensitisation, the Rapporteur proposed to classify MIT (ISO) as a strong sensitiser. Firstly, the animal data supported category 1A, with consistent human clinical data supporting the results from the animal studies. Secondly, there was a relatively high and substantial incidence of reactions among consumers that use cosmetics and household products containing MIT, the scale of this having increased over recent years. The Rapporteur's arguments were acknowledged by RAC, and Skin Sens. 1A (H317) was agreed for MIT (ISO).

In relation to SCL setting, the Rapporteur proposed to set an SCL of 15 ppm, taking into account that Scientific Committee on Consumer Safety (SCCS) had previously recommended 15 ppm[i] and that this was consistent with the potency and the SCL for C(M)IT/MIT that has just been agreed by RAC. He pointed out that an SCL should be set to protect non-sensitised individuals and mentioned that epidemiological and other data showed that MIT (ISO) had the

potential to induce skin sensitisation at concentrations < 100 ppm, while 2 ROATs showed that the elicitation threshold was < 50 ppm. On the other hand, there was not a single robust case of < 50 ppm causing induction. Therefore 15 ppm was sufficiently protective. The expert accompanying the Cefic stakeholder observer mentioned that an additional LLNA study was available (not in CLH report) which showed that the potency of MIT (ISO) was strong, but not extreme. He noted that the EC3 value of this study was 1.55%. The Committee was of the view that in a weight of evidence approach which already contained extensive data, an additional study could not reasonably be expected to outweigh the existing studies, and that based on the arguments provided by the Rapporteur, an SCL of 15 ppm (0.0015%) was agreed. It was finally noted that EU208 would apply automatically to mixtures containing a sensitising substance in a concentration ≥ 1/10 of the SCL as defined in Annex II to CLP, which meant in this case at concentrations ≥ 1.5 ppm / 0.0015%.

Conclusion for MIT and C(M)IT/MIT

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

h) Salicylic acid

The substance has no Annex VI entry in the CLP Regulation. The legal deadline for adoption of the opinion is 16 April 2016. Salicylic acid has a very wide range of industrial and professional uses. The Dossier submitter (NOVACYL S.A.S.) proposed to classify salicylic acid as harmful via the oral route of exposure (Acute Tox. 4; H302) and as causing serious eye damage (Eye Dam. 1; H318). At the RAC-33 plenary meeting the Committee agreed to classify the substance as harmful via the oral route of exposure (Acute Tox. 4; H302) and as causing serious eye damage (Eye Dam. 1; H318). Since then the subject of the discussions in the Committee is developmental toxicity of the substance. After the discussion of the Rapporteurs' evaluation of the developmental toxicity at the RAC-33 and the RAC-34 plenary meetings, as well as consideration of the results of the additional public consultation on the reproductive toxicity, and the subsequent RAC consultation, the Rapporteurs proposed to classify the substance as toxic to the reproductive system in Category 2 (Repr. 2; H361d: Suspected of damaging the unborn child).

At the RAC-33 plenary meeting the RAC Members requested the Dossier Submitter to make a developmental toxicity study on monkeys available to RAC. The RAC Members requested the Rapporteurs to evaluate the available information concerning the possible effects of the substance on *ductus arteriosus* with relevance to humans.

At the plenary discussion at RAC-34, some RAC Members remarked that human dose levels in the available epidemiological studies (as equivalent dose levels of Salicylic acid) were not as high as the doses at which there was clear evidence for developmental effects in rats and monkeys, the latter providing data which would justify a classification as Repr. 1B for development. Other RAC Members were of the view that the effects seen in animals had not been seen in humans at therapeutic doses (of acetylsalicylate) and suggested that classification as Repr. 2 would be more appropriate. Following the plenary discussion at RAC-34 the Committee felt that the evidence available did not provide a clear direction as to whether a classification as Repr. 1B or 2 for developmental effects was justified. RAC agreed to contact the European Medicines Agency (EMA) to clarify the effects of acetylsalicylic acid (ASA) in humans also at higher than therapeutic doses. Questions to EMA were drafted and submitted as agreed in October 2015 for their consideration.

Between RAC-34 and RAC-36 ECHA received various responses from EMA, including an expert statement and two references. Additional publications from two RAC Members were also brought to the attention of the Committee, as well as an expert statement provided by the Dossier submitter. A RAC consultation was launched on the documentation provided. On the recommendation of EMA, one of their working group Members with specific expertise in this field was invited by the Secretariat to attend the discussion at RAC-36 and provide input as needed.

Based on the available data sets of animal studies on salicylic acid (positive rat and monkey studies and negative rabbit study) and epidemiological data on ASA in humans, the RAC Members, expressed their views in favour of classification either as Repr. 1B; H360D or Repr. 2; H361d. A number of RAC Members, in favour of category 1B, noted that the available animal data on rats and monkeys clearly suggest that the data on the substance fulfils the criteria for 1B ("May damage the unborn child") and that the human data on ASA should not negate these findings. A number of RAC Members, by contrast noted that the available human epidemiological data on ASA, although rather contradictory and with only a few reported exposures at higher doses, nevertheless demonstrate no clear evidence of malformations in humans. Thus, these Members suggested classifying the substance as Category 2, ("Suspected of damaging the unborn child").

The external expert explained to the Committee the rationale behind the use restriction of ASA containing medicines (Aspirin etc.) during the third trimester of pregnancy. She explained that in modern medicine it is not considered as being a major teratogen, but may have some potential for teratogenic effect. She also referred to a recent study from 2016, which showed an increase of sub-chronic hematoma after daily dosage of 81 mg/kg bw to pregnant women, with an increased risk of miscarriages. As other effects she mentioned that prostaglandin inhibitors in general, including ASA, could have other adverse effects on foetuses, especially on their renal development and during the third trimester on the circulation developments.

The Industry Dossier Submitter criticised the monkey study used in the evaluation noting the absence of a control group and the rather low number of animals used, leading to inconclusive results. They also noted that the effects seen in the study in rats might be irrelevant to humans due to difference in metabolism of the substance; it takes place in the stomach in rats and in the liver in humans.

Regarding the available information on plasma levels of ASA in humans, some RAC Members noted that plasma levels of ASA in women during pregnancy seemed to be lacking and that such data is in any case not relevant for the hazard assessment (in contrast to a typical risk assessment). However, a number of RAC Members expressed their appreciation of having the plasma levels of the substance presented and noted the relevance for humans of the doses and blood concentrations experienced in the animal experiments, stating them as being helpful in understanding the weight of evidence.

After an extensive discussion of the available data, the Committee was divided more or less evenly between Repr. 1B and Repr. 2 and a vote was required. There were 19 RAC Members who voted in favour of Repr. 2; H361d and 12 who were in favour of Repr. 1B; H360D. As those in the minority did not wish to provide a minority opinion and were prepared to accept the views of the majority, the Committee was able to adopt its opinion as Repr. 2, H361d by consensus.

The Chairman gave a special word of thanks to the Rapporteurs for their clear presentation of the case, to the Committee Members for their active involvement with interventions from over 20 Members and to the invited expert for her contribution. He also thanked the Industry

Dossier Submitter and their accompanying expert for their constructive contribution to the debate.

7.2 Appointment of RAC Rapporteurs for CLH dossiers

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

8. Restrictions

8.1 General restriction issues

a) Carcinogenicity dose-response relationship development for cobalt salts

The agenda item was introduced by the secretariat explaining that this investigation was part of a Commission request to explore the future risk management of the cobalt salts, either under Annex XIV or restriction. The Chairman invited the ECHA Contractor to present a draft report on the carcinogenicity dose-response relationship for cobalt (II) salts. The ECHA Contractor presented a review of the relevant scientific literature he could identify in the given framework and the registration data related to carcinogenicity of the five cobalt (II) salts (cobalt (II) sulphate, cobalt dichloride, cobalt dinitrate, cobalt (II) carbonate and cobalt diacetate) and identified the most adequate studies for the quantitative risk assessment, as well as an assessment of the mode of action of the substances considering ECHA's previous analysis, and the derivation of the relevant dose-response curves for the five cobalt (II) salts.

The Committee discussed the approach taken by the ECHA Contractor as presented. One Committee Member suggested some sympathy for the proposed threshold mechanism but pointed out the 4 mutagenicity studies using the intra-peritoneal (i.p.) route (an exposure route that could not be dismissed as irrelevant) gave a consistent picture that would indicate a genotoxic effect. . Another Committee Member stated that the i.p. route cannot be dismissed as irrelevant because first pass effects, which can obscure genotoxic effects, are circumvented by this route. The i.p route was still requested for the genotoxicity endpoint under REACH, and should be considered. A further Committee Member recommended assessing the quality of the i.p. studies to confirm the reliability of the results. The Member recommended these studies should be further looked at to ensure there would be no future surprises. Another Member could not accept the threshold approach proposed due to the lack of an actual threshold being demonstrated. An industry stakeholder also raised the point that cobalt was an essential element which in their view indicated a threshold mechanism and that due to tissue essentiality and background levels of cobalt in all tissues, the cancer dose-response curve cannot cross the origin of the graph. However, one RAC Member questioned if the essentiality was relevant for an inhalation exposure.

Eurometaux asked whether there is some check of consistency in the instructions for ECHA contractors in assessing the literature to derive dose-response/DNELs; following bottom-up or top-down approaches and checking only secondary literature vs. primary studies can impact the derivation of the value.

RAC recommended taking forward the non-threshold approach as a mode of action for carcinogenicity of the cobalt (II) salts, acknowledging a lack of substance-specific evidence on the threshold and the 4 i.p. studies as the main reason.

The Committee requested the ECHA Contractor to consider the discussion, to update the draft report and to submit it to the Secretariat together with the draft RAC note for discussion at the next plenary meeting.

8.2 Restriction Annex XV dossiers

a) Opinion Development

1) D4/D5– third draft opinion

The Chairman welcomed the Dossier Submitter's representative from the UK (following via WebEx), an expert accompanying Cefic, an occasional stakeholder observer (Cosmetics Europe) and their accompanying expert. He reminded the participants that the restriction dossier on D4/D5 had been submitted by UK in April 2015. Both D4 and D5 have very persistent very bioaccumulative (vPvB) properties (the ECHA's Members State Committee has recently provided an opinion that both substances are vPvB) and based on its CLP classification, D4 can be considered to be PBT as well. The restriction proposal is aimed specifically at reducing emissions to the aquatic environment and the dossier proposes that D4 and D5 shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions. The Committee was informed that the public consultation on the proposal ended on 18 December 2015 with 32 comments received. The third draft opinion was made available on 4 February 2016 and comments were received from five RAC Members in the following written commenting round.

The Rapporteurs presented the third draft opinion to the Committee. The main changes concerned revised supply tonnage estimates and how this affects the emission calculations (the RAC estimate being wider than that of the Dossier Submitter). With regard to the "reality check" calculations (estimates of emissions based on influent monitoring data), RAC acknowledged that overall these calculations broadly corroborate the emissions assessments of both RAC and the Dossier Submitter, but did not consider that these data provide conclusive evidence that emissions of D5 or wastewater can be explained solely by uses in wash-off PCPs. The Dossier Submitter reiterated their view that emissions of D4/D5 to the environment are likely to be as a result of their use in wash-off PCPs, rather than use in leave-on PCPs. In addition, the committee discussed the potential for releases of D4/D5 from wipe-based PCPs that are inappropriately disposed by flushing, rather than in solid waste. Whilst RAC considered that this type of disposal was reasonably foreseeable the representative of Cosmetics Europe reported that these types of products no longer commonly contain D4/D5 in the EU. Further discussion took place on the precise wording of the proposal with RAC preferring a wording that referred to "*cosmetic products that are used or disposed with water intended for consumer or professional use*" to the Dossier Submitter's original proposal. The secretariat noted that although the wording of the proposal has been modified throughout the opinion making process it was never the intention to modify the scope of the proposed restriction but rather to reflect the feedback received from the Forum and other stakeholders to ensure that the intended scope was clear and enforceable. With regard to the proposed transitional period, RAC recommended that the restriction should come into force preferably 18 months after the publication in the Official Journal, in line with the RAC opinions on the restriction of the PBT substances decaBDE and PFOA. The representative of Cosmetics Europe highlighted that such a short transitional period would mean that industry would need to recall

products from the shelves. The Secretariat pointed out that SEAC could propose a different transitional period based on socio-economic arguments. The Dossier Submitter intends to discuss a possible monitoring programme with industry to help inform future risk management considerations, and asked RAC Members to contact their Competent Authorities to gauge interest in joining a steering group.

RAC adopted its opinion on the dossier on D4/D5 by consensus. The Rapporteurs were requested, together with the Secretariat, to make final editorial changes to the adopted RAC opinion and to ensure that the supporting documentation (Background Document and responses to comments from the public consultation) is in line with the adopted RAC opinion. The Chairman thanked the Rapporteurs for their efficient and thorough handling of this restriction proposal, the Committee Members and the stakeholders for their contributions.

9. Authorisation

9.1 General authorisation issues

a) Capacity building

1. DNEL setting for the reprotoxic properties of 1-bromopropane

The Chairman invited the ECHA Contractor's representative to present a draft report on the DNEL setting for the reprotoxic properties of 1-bromopropane. The ECHA Contractor acknowledged the existence of an adequate database of available studies, primarily by inhalation, consisting of three in depth reviews, reporting guideline studies and published investigations. He presented the studies proposed for the selection of the most sensitive endpoint for DNEL derivation and invited the Committee to discuss a number of open questions provided in the presentation.

The RAC Members also exchanged views about the most sensitive species to be used in the DNEL derivation. The RAC Rapporteur acknowledged the draft report and asked the Committee Members for their views on the use of an extrapolation factor of 2 as used by the ECHA Contractor instead of default factor of 6. Some RAC Members spoke in favour of a factor of 3. In the DNEL derivation exercise, RAC Members also requested the ECHA Contractor to use the more recent scientific publications available. They also discussed a dermal absorption value.

The Committee supported the assessment factor of 3 for extrapolation from LOAEC to NOAEC.

In light of the discussion in Committee, the ECHA Contractor was requested to update the draft report and to submit it to the Secretariat together with the draft RAC note for discussion at the next plenary meeting. The ECHA Contractor was requested to: evaluate whether the EFSA value for dermal absorption of 75% might be appropriate instead of 100%; to provide a comparison between the NTP report and Lui *et. al.* study to better substantiate the selection of the key study; to further consider whether the assessment factor of 2 might be appropriate for duration of exposure (one Member noted that a publication by Mangelsdorf may provide useful information on which assessment factor to use) and finally, to provide further supporting argumentation for the conclusions regarding genotoxicity (threshold vs non-threshold effect).

2. DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP)

The Chairman invited the ECHA Contractor's representative to present a draft report on the DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP). The ECHA Contractor proposed read-across from dipentylphthalate (DPP) as most appropriate from among the molecules with comparable structures, consisting also of diisobutylphthalate (DIBP) and dibutylphthalate (DBP). The RAC Rapporteur considered the arguments presented to select DPP over DBP as the main weakness in the draft report as both DPP and DBP appeared to be suitable substances for read-across. However, she noted that the latter is more potent, and its choice may be too conservative.

During the debate, the approach taken by the ECHA Contractor was broadly supported and the RAC Members shared his view that an assessment factor is not needed, since the exposure in the chosen study covered the whole developmental period of species (rats).

The Committee requested the ECHA Contractor to consider the discussion at the Committee, to update the draft report and to submit it to the Secretariat together with the draft RAC note for discussion at the next plenary meeting.

3. Carcinogenicity dose-response relationship development for Aluminium and Zirconium Refractory Ceramic Fibres (Al-RCF and Zr-RCF)

The Chairman invited the ECHA Contractor to present a draft report on the carcinogenicity dose-response relationship development for aluminium and zirconium refractory ceramic fibres (RCF). The RAC Rapporteur noted that there are different approaches, such as the practical threshold approach taken by SCOEL, or the rat inhalation approach and asbestos potency approach, used by different scientific and regulatory bodies. The ECHA Contractor has taken only one of these. He suggested that all the other approaches should be described and assessed in the draft report as to why they were not taken forward.

During the discussion the RAC Members debated on the different existing approaches used in the carcinogenicity assessment for RCF.

RAC further requested that other (alternative) approaches should be documented, their main steps and conclusions in the assessment clearly described and critically discussed in the draft report by the ECHA contractor, i.e. main toxicological approaches taken up by other bodies, such as practical threshold approach taken by SCOEL, rat inhalation approach, asbestos potency approach. Finally, the ECHA Contractor was requested to consider the discussion and to update the draft report and to submit it to the Secretariat for the next plenary meeting, together with the draft RAC note.

b) Update on incoming/future applications for authorisation

The ECHA Secretariat informed the Committee that during the February submission window (8-22 February 2016) ECHA had received 28 new applications for authorisation on 43 uses of substances of very high concern: 13 applications for uses of chromium(VI) compounds, eight for uses of 1,2-dichloroethane (EDC), six for uses of bis(methoxyethyl) ether (Diglyme) and finally one application for uses of oligomeric reaction products of formaldehyde with aniline (Technical MDA).

9.2 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues for 27 applications

i) Key issues

1. **Sodium dichromate-Brenntag (SD_Brenntag)**
2. **Potassium dichromate-Brenntag (PD_Brenntag)**
3. **Dichromium tris(chromate)-Henkel (DtC_Henkel)**
4. **Strontium chromate-Akzo Nobel (SC_Akzo)**
5. **Potassium hydroxyoctaoxodizincatedichromate-PPG (PH_PPG)**

RAC noted that the five applications for authorisation above were submitted by the same consortium (CCST) and bore strong similarities; they were therefore considered together for the purpose of discussing key issues. Four uses have been applied for: formulation (in all five applications for authorisation), surface treatment (in three applications for authorisation), painting and coating (in two applications for authorisation) and electrolytic passivation of tin plated steel (in 1 application for authorisation).

It was noted that for this latter use a review period of four years had been requested, while for the rest 12 years. The Rapporteur explained that each of these upstream applications has 1 to 10 Applicants, covers from 50 to several hundred sites, 500 to 15 000 workers and 100 to 1 000 T/year of each substance. In a detailed overview, the Rapporteur informed the Committee on each use.

The Committee then discussed the following aspects which along with other more technical issues will form the basis for questions to the Applicants.

- RAC noted that the uses were very broad and while the necessity to aggregate similar processes or "use-cases" is understood, it was considered important that the Applicant would provide an improved description of the processes covered, the tasks involved, and the risk management measures (RMMs) and operational conditions (OCs) per Worker Contributing Scenario (WCS).
- Furthermore, RAC wished to receive substantial clarification regarding the representativeness and relevance of the measured data, including contextual information such as OCs and RMMs present at the workplaces corresponding to the measured data. RAC also noted that the degree to which the measured data is representative for the many other workplaces potentially covered by the applications needs to be clearly justified.
- The Committee, as it has done in other cases, reiterated that additional modelling could help to support measured exposure data.

6. **Sodium dichromate-Akzo Nobel (SD_Akzo)**
7. **Sodium dichromate-Solvay (SD_Solvay)**
8. **Sodium dichromate-Arkema (SD_Arkema)**
9. **Sodium dichromate-Ercros (SD_Ercros)**
10. **Sodium dichromate-Electroquimica (SD_ELECTRQUIMICA)**
11. **Sodium dichromate-Kemira (SD_Kemira)**
12. **Sodium dichromate-Caffaro Brescia (SD_Caffaro)**

RAC noted that the seven applications above were submitted by the same consortium (Sodium Dichromate authorisation Consortium) and bore strong similarities; they were therefore considered together for the purpose of discussing key issues.

Use 1: use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of **sodium chlorate** [Caffaro = sodium chlorite], with or without subsequent production of chlorine dioxide or sodium chlorite (all 7 applicants).

Use 2: use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of **potassium chlorate** (additional use by Akzo Nobel only).

The Rapporteur provided an overview of the applications and noted that inhalation exposure assessment was based on pooled measured air monitoring data and modelling at 9 out of 12 sites (in 6 countries).

The Rapporteur outlined some of the issues which would need further clarification by the Applicant, including the worker exposure assessment: e.g. the representativeness of the relatively sparse air monitoring data, the input data for the supporting modelled exposure estimates, the descriptions of the workers tasks, and dermal exposure assessment. For the OCs and RMMs implemented for workers more specific information was considered necessary per site. More specific information is also needed for exposure to Humans via the Environment.

13. Chromium trioxide-Federal-Mogul Friedberg (CT_Friedberg)

14. Chromium trioxide-Federal-Mogul Valvetrain (CT_Valvetrain)

15. Chromium trioxide-Federal-Mogul Burscheid (CT_Burscheid)

RAC noted that the three applications above were submitted by the same concern (Federal Mogul (FM)) and also bore strong similarities; they were therefore considered together for the purpose of discussing key issues.

The scope of these applications concerning functional (hard) chrome plating of parts for gasoline and diesel engines is narrow and well defined and the three Applicants are downstream users of chromium trioxide. The substance is used at three sites by FM Burscheid, one site by Friedberg and three sites by Valvetrain. Total quantities of the substance used across the sites vary between from 100 to 1,000 t/year in the case of FM Burscheid and FM Friedberg, and 10 to 100 t/year at FM Valvetrain. The number of exposed workers also varies, i.e. more than 100 at FM Burscheid and below 100 each at FM Friedberg and FM Valvetrain.

The Committee noted the Applicant's description of manual and automatic plating operations that take place with a variety of RMMs, including local exhaust ventilation (LEV), closed systems with no LEV or partly closed systems with "good natural ventilation".

The Rapporteurs focussed on the effectiveness of the above RMMs and RAC noted different and rather high general ventilation rates used by the Applicant, and indicated their intention to ask the Applicants to provide more detailed explanations. Further information was also considered necessary on: the ventilation systems connected to the manual and automated plating systems, the tasks carried out by workers, the potential for combined exposure and on how access to the plating lines during use is controlled. The Rapporteurs then presented the additional further details of the questions they propose to ask to the Applicants.

16. Chromic acid-Bosch (CA_Bosch)

This application covers the "*hard chrome plating for gasoline and diesel injection applications*", the scope is narrow and well defined. The Applicant is a downstream user of acids generated from chromium trioxide and their oligomers at two sites in Germany (Bamberg site has two

operation lines, Homburg site – one line). The total quantity of the substance is less than 10 tonnes/year and the number of exposed workers is less than 100.

The Committee noted that according to the Applicant, at one of the sites, a state-of-the-art, double-shell protection system is in operation. The Rapporteurs indicated some uncertainties related to the exposure assessment and the RMMs in place, and presented the additional questions they proposed to put to the Applicant.

17. Chromium trioxide-Circuit Foil Luxembourg (CT_Circuit)

18. Arsenic acid-Circuit Foil Luxembourg (AsA_Circuit)

These two applications were made by the same downstream User for the industrial use of arsenic acid and chromium trioxide for the treatment of copper foil used in the manufacture of printed circuit boards at one site. The Rapporteurs explained that less than 50 workers may be exposed and the quantity used per year is respectively 1 to 10 t of arsenic acid and 10-100 t of Cr(VI). The rapporteurs pointed out some missing information on the combined exposure of workers, and the need for further clarity on the RMMs in place, including the use of Personal Protective Equipment (PPE). They would require a more comprehensive description of the tasks performed by the workers and the organisation of the work. For two of the Worker Contributing Scenarios (WCS), the worker exposure assessment is based on modelled data only and for other two WCS the exposure assessment is based on a small number of measurements whereas the exposure for one WCS is estimated by qualitative assessment. The Rapporteurs informed RAC that their questions to the applicant would be based on the above key issues and that they also intended to request: supporting documentation on releases to air and waste water as well as clarification on the impact assessment for indirect exposure of humans via the environment.

19. Chromium trioxide and dichromium tris(chromate)-Nexter Mechanics (CT_DtC_Nexter)

The scope of this application is narrow, well defined and concerns hard chromium and black chromium plating for the manufacture of armament parts (Uses 1 to 3), and the use of chromium trioxide and dichromium tris(chromate) in qualified mixtures for the conversion coating of welded mechanical structures and associated parts of armoured vehicles (Use 4). Uses 1 to 3 are performed at one site and Use 4 at two sites. The quantities of chromium trioxide for Uses 1 to 3 are below 1 t/year, while Use 4 is below 100 kg/year at one site, and below 1 t/year at the other. The use of dichromium tris(chromate) takes place only in quantities below 10 kg/year. The Applicant is a downstream user of the substances and the total number of exposed workers is <10. It was noted that the size of the parts involved may be very large.

The Committee discussed the representativeness of the available exposure data, noting that it was largely based on modelling, supported by some stationary measurements. The Rapporteurs informed RAC of the RMMs, including LEV in place for Uses 1 to 3 and noted that the plating processes are open and manual. Control of access to the baths and use of RPE were discussed. RAC asked whether mist suppressants were used.

Similarly, the Rapporteurs presented Use 4 concerning 'chromate conversion coating' by a) spraying in a closed and automated cabin and b) automated, immersion of parts in open baths. RAC briefly discussed the key issues in a similar manner to Uses 1-3 above.

The RAC Rapporteurs indicated some uncertainties related to the exposure assessment and RMMs in place, and finally presented the additional questions to be asked to the Applicants to reduce these uncertainties.

20. Chromium trioxide-Praxair (CT_Praxair)

This is a downstream user application of a narrow scope covering four sites (for use 1) and one site (for use 2).

Use 1: Industrial spraying or brush application of chromium trioxide mixtures for the coating of metallic articles subject to harsh environment, to ensure high temperature corrosion & oxidation resistance, as well as anti-fouling properties or lubricity at high temperature, for automotive, aviation, power generation machinery, Oil and Gas and marine applications. Use 1 appears to be a bridging application with a requested review period of 7 years.

Use 2: Industrial spraying of chromium trioxide mixtures for the coating of metallic articles subject to harsh environment to ensure either a low temperature-cured coating for corrosion protection, or a high temperature corrosion & oxidation resistance with reduction of surface roughness or with a high temperature adhesive, for aviation, power generation machinery, Oil and Gas and marine applications.

Spraying may be automated or manual. The Applicant has provided air measurements from personal samplers, supported by modelling data and information on combined exposure. Likewise, measured data was provided to cover environmental emissions to the atmosphere.

The Rapporteurs pointing out that further information would be needed specifically on sampling and analytical methods used for air measurements for workers exposure. The representativeness of the exposure measurements, the cleaning process for brush application, the selection of the assigned protection factor value (APF-value) for respiratory protective equipment and the number of humans exposed via the environment, were all briefly discussed. Finally, RAC asked for clarification about the proportion of manual spraying and whether it is a full-time task.

21. Potassium dichromate-Sofradir (PD_Sofradir)

This is a downstream user application of a narrow scope covering two sites (one use per site). The current production was developed under laboratory clean-room conditions and the current quantity used is < 1 tonne per year and < 15 workers per use are potentially exposed; the intention is to increase capacity if the authorisation is granted.

Use 1: Industrial use of potassium dichromate-based mixtures during the steps of initial and final etching of CZT layers (cadmium zinc telluride) during the production of opto-electronic components gathering readout and an infrared detecting circuit with the MCT technology (mercury cadmium telluride).

Use 2: Industrial use of potassium dichromate based mixture during the etching of both InSb substrate sides during the production of opto-electronic components gathering readout and an infrared detecting circuit with the InSb technology (indium antimonide).

The Rapporteurs provided information on the laboratory setting and the use of hoods or fume cupboards as RMMs They intended to request clarification on air emissions, on the estimation of exposure of man via environment (MvE) and on dermal exposure assessment related to toxicity to reproduction.

22. Sodium dichromate-Lanxess (SD_Lanxess)

The Rapporteur presented this downstream user application for authorisation for the use of sodium dichromate in industrial cooling systems and focussed on the Operational Conditions (OCs) and RMM (RMMs). The quantity used per year is low, covering one site with three cooling plants (in closed outdoor systems). RAC considered the difficulties of exposure monitoring is such a situation and the Rapporteur outlined some issues which would need further clarification by the Applicant.

23. Ammonium dichromate-Micrometal (AD_Micrometal)

Ammonium dichromate is used as a photosensitizer in a lithography process for the etching of metal surfaces in the automated manufacturing of high-precision, micro-structured metal strips in large quantities. The Applicant is a downstream user of ammonium dichromate and the scope of the application is narrow and well defined. The substance is used at one site and the total quantity is less than 1 tonne/year. The number of workers potentially exposed is 10-100.

The Rapporteurs noted that they intended to request clarification on the tonnage used, further information on the containment of the process, specific RMMs, clarifications on work organisation and tasks, including maintenance. It was noted that modelling data might help to complement the measured exposure data in the context of RAC's evaluation.

24. Chromium trioxide-Cromomed (CT_Cromomed)

The Rapporteur provided brief information on the application for authorisation which concerns functional or hard chrome plating of large to very large parts in an open, mainly manual electroplating process, noting that this is a downstream user application, covering five sites in two countries. RAC discussed the exposure assessment included in the application, noting that it was similar to another application; the Chairman reminded the Committee that each application shall be assessed on its own merits.

The Rapporteur then outlined some issues which would need further clarification by the Applicant, including worker exposure assessment (i.e. how many workers, which tasks, under which conditions) and risk level for workers. In addition, more information is considered necessary on the exposure assessment to humans via the environment.

25. Chromium trioxide-Rimex Metals (CT_Rimex)

This application concerns the use of chromium trioxide as an oxidising and hardening agent in the manufacture of coloured stainless steel. The application covers one site where 10-100 tonnes of chromium trioxide is used per year and less than 50 workers are potentially exposed.

The Rapporteurs then presented an overview of the OCs and RMMs as well as the air monitoring dataset data provided by the Applicant. RAC was also informed that the rapporteurs had further questions regarding: previous monitoring and biomonitoring data, supporting exposure modelling and that they would need a better understanding of containment and the Applicant's assurances with regards to improving LEV.

26.EDC-BASF (EDC_BASF)

The Rapporteur presented the application for authorisation, noting that this is a downstream use application with a well-defined, narrow scope of using EDC as an extraction agent. The Applicant needs 60 tonnes of EDC per year to replace losses (mainly – off-gas incineration). Up to 35 workers may be exposed. The process takes place in a closed system and in the Rapporteur's view the site-specific OC and RMM were sufficiently described.

The Rapporteur outlined some minor issues which may need further clarification by the Applicant, including some aspects on the worker exposure assessment.

27.Diglyme-Novartis (Diglyme_Novartis)

The Rapporteur presented the application for authorisation, noting that this is a downstream user application with a well-defined, narrow scope for the use of Diglyme as a solvent in the manufacture of an active pharmaceutical ingredient. The Applicant uses 1-10 tonne of diglyme per year. The process takes place in a closed system and in the Rapporteur's view the site-specific OC and RMM were adequately described. The Applicant is asking for 7 years review period needed to implement an alternative.

The Rapporteur outlined some issues which would need further clarification by the Applicant, including some aspects on the exposure assessment including some background information on workplace measurements. In addition, clarifications would be needed on the number of potentially exposed workers, as well as the general population.

General discussion on the key-issues of the 27 applications.

In each of the 27 applications for which key-issues were considered by RAC, the proposals of the rapporteurs for questions to the Applicants were supported by the Committee. It was emphasised that the questions should be clear and to the point, focussing on necessary information for the evaluation.

The Chairman noted that the purpose of holding an extended key issues discussion had been to provide the whole Committee but especially the 20 rapporteurs involved with a broad overview of the very varied chromate applications. The particular focus had been to address and discuss common problems in both upstream and downstream applications. He expressed the hope that this would ensure consistency in opinion drafting and set the scene for the next meeting when many of these applications would be tabled for agreement.

As several RAC Members expressed their wish for support from the Secretariat on environmental issues, an evening-session on environmental risk assessment in the context of authorisations was organised in the 2nd week of the plenary meeting.

An industry stakeholder representative requested guidance for Applicants on what is the minimum data expected to be included in the applications. The Secretariat replied that the opinion trees used as part of the key issues presentation on each dossier were due for publication. They are intended to explain how RAC and SEAC reach their recommendations on applications for authorisations and how they intend to maintain consistency. Secondly, a check-list intended as an *aide memoire* for rapporteurs in evaluating applications was nearing completion and would soon be published to also provide Applicants with information on the Committee's approach to evaluation, so allowing them to better anticipate what would be required. It was stressed that not all of the items on the check-list would be needed in every case.

ii) Conformity check

Following the key issues presentations above, the secretariat presented a list of draft conformity agreements for the 27 applications for authorisation.

RAC agreed on the conformity of the applications. The Committee also discussed the key issues identified by the Rapporteurs in the applications. The Secretariat will inform the Applicants about the outcome of the conformity checks and will request further clarifications on the issues identified and discussed by the Committee.

b) First version of the draft opinion:

In each case, the Chairman welcomed the Rapporteurs and reported on the state of play of the opinion development process. At previous RAC meetings the Committee had agreed on the conformity of these applications and discussed the key issues. The Rapporteurs then prepared draft opinions, which went for a RAC consultation before the plenary. Based on the comments made by the RAC Members, the Rapporteurs had modified the draft opinions and presented the updated versions to the Committee.

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

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

RAC considered that the information provided related to exposure is sufficient for risk characterisation. However, RAC considered that the implemented RMM and existing OC in particular for the workplace were not appropriate and effective in limiting the exposures and the risk to workers, noting that the residual risks were relatively high. For addressing the identified uncertainties in engineering and administrative controls, RAC recommended specific additional conditions and monitoring arrangements for the application and for any subsequent review report. These are described in detail in the opinion and include among others the regular monitoring of Cr(IV) concentration in workplace air, as well as further organisational measures aiming to a reduction of the Cr(IV) exposure. Given that RAC was able to recommended specific conditions, the Committee did not as a result provide any advice to SEAC on the length of the review period.

The Committee agreed the draft opinion by consensus. The Chairman thanked the Rapporteur for his work on the application.

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

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

   Use 2: The use of chromium trioxide for pre-treatment step in the electroplating process

RAC considered that OC and RMM were appropriate and effective in limiting the exposure and the risk to workers. RAC recommended additional monitoring arrangements for the application

and the review report as described in the opinion. RAC did not provide any advice to SEAC on the length of the review period.

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

c) Second version of the draft opinion:

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

   Use 1: Formulation of mixtures

   Use 2: Functional chrome plating

   Use 3: Functional chrome plating with decorative character

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

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

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

The Chairman informed the Committee that the information requested of the Applicants by RAC has been submitted to the extent that it had allowed the Rapporteurs to proceed with drafting the opinions but that questions remained. The Rapporteurs had developed the draft opinions for Uses 1, 2 and 6, which were presented to RAC.

Use 1: Formulation of mixtures

RAC noted uncertainties related to the description of OC and RMM, and their ability to adequately limit the risk to workers. According to the SEA, the number of sites performing chromium trioxide formulation is up to 30 in the EU. The exposure assessment is based on measured data (8 measurements from 6 companies, including both large and small formulators and representing 20% of maximum number of companies), but the variation between the measurements is high (range of means 0.1 - 10 $\mu g/m^3$). According to the Applicant, the number of measurements is limited, since the exposures (as 8 hour time weighted average) have been well within prevailing national occupational exposure limits.

RAC proposed to use the Applicant's own combined worker exposure estimate of 0.5 $\mu g/m^3$ as an 8-hour time weighted average, resulting in an excess risk of 2×10^{-3} and the Applicant's estimate of general population exposure at the local scale as a basis of further analyses by SEAC. However, RAC noted that these values had been proposed by the Applicant in their CSR and their use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC of a safe or acceptable exposure level for this non-threshold substance.

RAC recommended additional conditions and monitoring arrangements for the application and for the review report as described in the opinion.

RAC agreed on the draft opinion on Use 1. However, the Committee did not agree on recommendations to SEAC on the review period and this issue is still pending.

Use 2: Functional chrome plating

The Committee also discussed the draft opinion on the Use 2 in the application. RAC concluded that there were uncertainties in the exposure assessment to workers arising mainly from the

lack of clear information on the OC, applied RMM, and the exposure values provided for specific sites. The applicant had provided recently measured, mean personal sampling values covering 23 functional chrome plating sites to RAC, all with open, manual operations using LEV. RAC noted that the application potentially covered >1000 sites of unknown geographical distribution. These exposure values ranged from 0.1 to 20 µg/m^3, of which 21 out of 23 were below 2 µg/m^3, i.e. the value considered by the Applicant as a representative exposure level for this application. RAC noted the uncertainties associated with this exposure estimate and pointed out that the Applicant's own data and the literature data provided, while supportive in general, do indicate a wide range of exposure levels, including some an order of magnitude higher than the above. The Committee concluded that, these data might be suitable for human health impact assessment by SEAC but it should be noted that RAC's assessment of Cr(VI) exposure in this application is still ongoing. RAC recommended to SEAC to use the applicant's exposure estimate of 2 µg/m^3 in the human health impact assessment calculations as a starting point. There were some uncertainties identified in relation to the Applicant's claims that wastewater releases are "negligible"; RAC considered that the indirect exposure of man via the environment calculated by the Applicant could be used for risk characterisation and impact assessment. Due to time constraints, the Committee had to suspend the discussions, the Chairman noting that it would be tabled again at RAC 37 in May/June.

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

RAC considered that the combined exposure estimate proposed by the Applicant was a reasonable estimate of exposure. RAC considered that OC and RMM were appropriate and effective in limiting the exposures and the risk to workers. The Committee recommended additional conditions and monitoring arrangements for the application and the review report as described in the opinion. Considering this outcome, RAC gave no specific advice to SEAC regarding the length of the review period, noting that the Applicant had requested 4 years in this case.

RAC agreed on the draft opinion on the Use 6 by consensus.

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

9.3 Appointment of Rapporteurs for authorisation applications (closed session)

The Committee Members expressed their interest in rapporteurships, applying to the pool of Rapporteurs and indicating absence of conflict of interest. The expanded pool of Rapporteurs, as outlined in the amended restricted room document RAC/36/2016/06, was then agreed by RAC.

10. AOB

18 March 2016

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 36 29 February – 04 March 2016
8-10 March 2016

(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/36/2016**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-36 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 35 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/36/2015/01** and document **RAC/36/2015/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b)Feedback from the Commission on RAC opinions	
c) RAC work plan for all processes SECR presented the update on the Q2 and Q3/2016 work plan for RAC covering the Classification and Labelling, Restriction and authorisation processes.	**SECR** to upload the presentation to non-confidential folder of the RAC-36 meeting on S-CIRCABC.
6. Requests under Article 95 (3)	
a) 1-methyl-2-pyrrolidone (NMP)	
A RAC-Member of the joint RAC-SCOEL working group on NMP presented a draft approach with the view to agree on a common way forward for RAC and SCOEL on a joint opinion. RAC discussed and supported the proposed approach to reconsider the available NOAECs and LOAECs for developmental effects and to take into account recent and previous papers using PBPK and benchmark dose modelling.	**SECR** to forward the RAC-proposal (RAC 36/2016/03) to SCOEL Secretariat for their consideration at the next plenary meeting of SCOEL, which takes place from 8 to 10 March. The next steps will be agreed following a response from SCOEL with the intention to agree on a joint RAC-SCOEL opinion as soon as possible.
7. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement without plenary debate • Amisulbrom (ISO): no classification for the physical hazards, no classification for acute toxicity (all routes of exposure), no classification for skin corrosion / irritation, no	

classification for respiratory and skin sensitisation, no classification for STOT SE, no classification for STOT RE, no classification for germ cell mutagenicity, no classification for toxicity to reproduction (effects on fertility), no classification for aspiration hazard, Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with M=10

- Chlorocresol: Acute Tox. 4 (H302), no classification for acute toxicity for the dermal and the inhalation route, Skin Sens. 1B (H317), STOT SE 3 (H335), Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 3 (H412)
- Flutianil (ISO): no classification for the physical hazards, no classification for acute toxicity (all routes of exposure), no classification for skin corrosion / irritation, no classification for eye damage / irritation, no classification for respiratory and skin sensitisation, no classification for STOT SE and STOT RE, no classification for germ cell mutagenicity, no classification for aspiration hazard, no classification for acute aquatic toxicity, Aquatic Chronic 1 (H410) with M=100
- Pyroxsulam (ISO): no classification for the physical hazards, no classification for acute toxicity (all routes of exposure), no classification for skin corrosion / irritation, no classification for eye damage / irritation, Skin Sens. 1 (H317), no classification for STOT SE, no classification for STOT RE, no classification for germ cell mutagenicity, no classification for toxicity to reproduction, no classification for aspiration hazard, Aquatic Acute 1 (H400) with M=100, Aquatic Chronic 1 (H410) with M=100
- Epsilon-metofluthrin: no classification for the physical hazards, Acute Tox. 4 (H332), no classification for acute toxicity for the dermal route, no classification for skin corrosion / irritation, no classification for eye damage / irritation, no classification for respiratory and skin sensitisation, no classification for germ cell mutagenicity, no classification for toxicity to reproduction, no classification for aspiration hazard, Aquatic Acute 1 (H400) with M=100, Aquatic Chronic 1 (H410) with M=100
- 2-methylisothiazol-3(2*H*)-one (MIT): no classification for the physical hazards, Acute Tox. 3 (H301), Acute Tox. 3 (H311), Acute Tox. 2 (H330), EUH071, Skin Corr. 1B (H314), no classification for eye damage / irritation, no classification for germ cell mutagenicity, no classification for carcinogenicity, no classification for toxicity to reproduction (effects on fertility), no classification for aspiration hazard
- Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1) (C(M)IT/MIT): no classification for the physical hazards, Acute Tox. 3 (H301), Acute Tox. 2 (H310), Acute Tox. 2 (H330), EUH071, no classification for STOT SE

B. Substances with hazard classes for agreement in plenary session

i) Amisulbrom (ISO)

j) Chlorocresol

k) Flutianil (ISO)

l) Pyroxsulam (ISO)

m) Isoeugenol

n) Epsilon-metofluthrin

o) 2-methylisothiazol-3(2*H*)-one (MIT)

p) Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1) (C(M)IT/MIT)

q) Salicylic acid

a) Amisulbrom (ISO)

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

Eye Irrit. 2 (H319), Carc. 2 (H351), Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with M=10	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
b) Chlorocresol	
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. 1B (H317), STOT SE 3 (H335), Skin Corr. 1C (H314), Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 3 (H412)	**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) **Flutianil (ISO)**	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Aquatic Chronic 1 (H410) with 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.
d) **Pyroxsulam (ISO)**	
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, Aquatic Acute 1; H400 with M=100, Aquatic Chronic 1; H410 with M=100	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
e) Isoeugenol	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Skin. Sens. 1A (H317), with an SCL of 0,01%	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
f) **Epsilon-metofluthrin**	

RAC agreed on the harmonised classifications as indicated in Table 2 below. Acute Tox, 3 (H301), Acute Tox. 4 (H332), Aquatic Acute 1 (H400) with M=100, Aquatic Chronic 1 (H410) with M=100	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **RAC** to continue the discussions at RAC-37
g) **2-methylisothiazol-3(2H)-one (MIT)**	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 3 (H301), Acute Tox. 3 (H311), Acute Tox. 2 (H330), EUH071, Skin Corr. 1B (H314), Skins. 1A (H317) with SCL=0.0015% (15 ppm), Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with 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.
h**) Reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (C(M)IT/MIT)**	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 3 (H301), Acute Tox. 2 (H310), Acute Tox. 2 (H330), EUH071, Skin Corr. 1C (H314) with an SCL of 0.6%, Skin Sens. A (H317) with SCL=0.0015% (15 ppm), Aquatic Acute 1 (H400) with M=100, Aquatic Chronic 1 (H410) with 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.
i) **Salicylic acid**	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 4; H302, Eye Dam. 1; H318 (agreed at RAC-33) Repr. 2; H361d	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
7.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCA BC confidential.
8. Restrictions	

8.1 General restriction issues	
a) Carcinogenicity dose-response relationship development for cobalt salts - **RAC/36/2016/05** The ECHA Contractor presented a draft report on dose-response relationship and DNEL development for cobalt salts. The Committee discussed the approach taken by the ECHA contractor. RAC recommends providing further information regarding the quality of the studies on genotoxicity, as listed in the report. RAC recommends taking forward the non-threshold approach as a mode of action for carcinogenicity of the cobalt salts, pointing out the lack of substance-specific evidence on the threshold as the main reason for taking this approach.	The ECHA Contractor to consider the discussion at the Committee, to update the draft report and to submit it to SECR together with the draft Committee's note for the discussion at the next plenary meeting RAC-37.
8.2 Restriction Annex XV dossiers	
a) Opinion Development	
1. D4/D5 – third draft opinion The Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on D4/D5 restriction proposal by consensus (with modifications introduced at RAC-36).	**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 S-CIRCABC IG.
9. Authorisation	
9.1 General authorisation issues	
a) Capacity building	
1. DNEL setting for the reprotoxic properties of 1-bromopropane The ECHA Contractor presented a draft report on DNEL setting for the reprotoxic properties of 1-bromopropane. The Committee discussed the approach taken by the ECHA contractor.	**ECHA Contractor** to consider the discussion at the Committee, to update the draft report and to submit it to SECR together with the draft Committee's note for the discussion at the next plenary meeting RAC-37. - Evaluate whether EFSA value for dermal absorption (75%) might be appropriate instead of 100%.

	- Provide a comparison between the NTP report and Lui *et. al.* to better substantiate the selection of the key study. - An AF of 2 might be appropriate for duration of exposure (Mangelsdorf publication may provide useful information on which AF to use). - Use an AF of 3 for extrapolation from LOAEC to NOAEC - Further support the conclusions regarding genotoxicity (threshold vs non-threshold effect)
2. DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP) The ECHA Contractor presented a draft report on DNEL setting for the reprotoxic properties of DIPP. The Committee discussed the approach taken by the ECHA contractor.	**ECHA Contractor** to consider the discussion at the Committee, to update the draft report and to submit it to SECR together with the draft Committee's note for the discussion at the next plenary meeting RAC-37.
3. Carcinogenicity dose-response relationship development for Al-RCF and Zr-RCF The ECHA Contractor presented a draft report on carcinogenicity dose-response development for Al-RCF and Zr-RCF. The Committee discussed the approach taken by the ECHA contractor.	**ECHA Contractor** to consider the discussion at the Committee, to update the draft report and to submit it to SECR for the discussion at the next plenary meeting RAC-37; if possible together with the draft Committee's note. Other (alternative) approaches should be documented, their main steps and conclusions in the assessment clearly described and critically discussed in the draft report by the ECHA contractor: main toxicological approaches taken up by other bodies: practical threshold approach [taken by SCOEL], rat inhalation approach, asbestos potency approach.
b) Update on incoming/future applications for authorisation	
SECR introduced to the Committee applications for authorisation received during the February Submission Window (from 8 to 22 February 2016).	
9.2 Authorisation applications	

a) Outcome of the conformity check and presentation of the key issues	
1. Sodium dichromate-Brenntag (SD_Brenntag) **2. Potassium dichromate-Brenntag (PD_Brenntag)** **3. Dichromium tris(chromate)-Henkel (DtC_Henkel)** **4. Strontium chromate-Akzo Nobel (SC_Akzo)** **5. Potassium hydroxyoctaoxodizincatedichromate-PPG (PH_PPG)** **6. Sodium dichromate-Akzo Nobel (SD_Akzo)** **7. Sodium dichromate-Solvay (SD_Solvay)** **8. Sodium dichromate-Arkema (SD_Arkema)** **9. Sodium dichromate-Ercros (SD_Ercros)** **10. Sodium dichromate-Electroquimica (SD_ELECTRQUIMICA)** **11. Sodium dichromate-Kemira (SD_Kemira)** **12. Sodium dichromate-Caffaro Brescia (SD_Caffaro)** **13. Chromium trioxide-Federal-Mogul Friedberg (CT_Friedberg)** **14. Chromium trioxide-Federal-Mogul Valvetrain (CT_Valvetrain)** **15. Chromium trioxide-Federal-Mogul Burscheid (CT_Burscheid)** **16. Chromic acid-Bosch (CA_Bosch)** **17. Chromium trioxide-Circuit Foil Luxembourg (CT_Circuit)** **18. Arsenic acid-Circuit Foil Luxembourg (AsA_Circuit)**	**SECR** to upload to S-CIRCABC the agreed Conformity Reports. **SECR** to inform SEAC about the outcome of the Conformity checks. **SECR** to send the updated Conformity Reports to the Applicants.

19. Chromium trioxide and dichromium tris(chromate)-Nexter Mechanics (CT_DtC_Nexter) **20. Chromium trioxide-Praxair (CT_Praxair)** **21. Potassium dichromate-Sofradir (PD_Sofradir)** **22. Sodium dichromate-Lanxess (SD_Lanxess)** **23. Ammonium dichromate-Micrometal (AD_Micrometal)** **24. Chromium trioxide-Cromomed (CT_Cromomed)** **25. Chromium trioxide-Rimex Metals (CT_Rimex)** **26. EDC-BASF (EDC_BASF)** 27. **Diglyme-Novartis (Diglyme_Novartis)** RAC agreed on the conformity of 27 applications for authorisation. RAC discussed the key issues in the 27 applications for authorisation and provided advice to the Rapporteurs.	
b) First version of the draft opinion:	
1. **Chromium trioxide_Kromatek** **Use 1:** Use of chromium trioxide in Cr(VI) based functional plating RAC agreed on the draft opinion RAC considers that OCs and RMMs are not sufficient for limiting the exposures and the risk to workers. RAC recommends additional conditions and monitoring arrangements for the application and the review report as described in the opinion. RAC gives no specific advice to SEAC to reduce the proposed review period.	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
2. **Chromium trioxide_Grohe** **Use 1:** The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

called 'functional plating with decorative character') **Use 2:** The use of Chromium Trioxide for pre-treatment step in the electroplating process RAC agreed on the draft opinions. RAC considers that OCs and RMMs are appropriate and effective in limiting the exposures and the risk to workers. RAC recommends additional monitoring arrangements for the application and the review report as described in the opinion. RAC gives no specific advice to SEAC regarding a length of the review period.	
c) Second version of the draft opinion:	
1. Six uses of chromium trioxide submitted by LANXESS Deutschland GmbH on behalf of a group of companies **(Chromium trioxide 1):** **Use 1:** Formulation of mixtures **Use 2:** Functional chrome plating **Use 3:** Functional chrome plating with decorative character **Use 4:** Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character **Use 5:** Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering **Use 6:** Passivation of tin-plated steel (ETP) **Use 1:** RAC agreed on the draft opinion. RAC notes significant uncertainties related to the description of OCs and RMMs and their ability to adequately limit the risk to workers. RAC proposes to use the Applicant's estimate of combined exposure level of 0.5 µg/m^3 as 8 h average, resulting in excess risk of 2×10^{-3} as a basis of further analyses by SEAC. This value is proposed by the Applicant in the CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as a safe or acceptable exposure level for this non-threshold substance. RAC proposes to use the Applicant's estimate on general population exposure at the local scale for further analysis by SEAC. RAC recommends additional conditions and monitoring	**Rapporteurs** to consider plenary discussions and additional support of the RAC Members in drafting of the draft opinions on Uses 1 to 5. **Rapporteurs** together with **SECR** to do the final editing of the agreed draft opinion on Use 6.

arrangements for the application and the review report as described in the opinion. <u>However, RAC did not yet agree on any recommendation for SEAC with regards to the review period.</u> **<u>Use 2:</u>** No further agreement on this use. **<u>Use 6:</u>** RAC agreed on the draft opinion. RAC considers that the combined exposure estimate proposed by the Applicant is a reasonable estimate of exposure. RAC considers that OCs and RMMs are generally appropriate and effective in limiting the exposures and the risk to workers. RAC recommends additional conditions and monitoring arrangements for the application and the review report as described in the opinion. RAC gives no specific advice to SEAC regarding a length of the review period.	
9.3 Appointment of (co-)rapporteurs for authorisation applications **RAC/36/2016/09** RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
10. AOB	
11. Action points and main conclusions of RAC-36 Taken care of agenda item by agenda item during the meeting.	
SECR to upload the adopted action points to CIRCA BC.	

Table I: Adopted opinions with hazard classes proposed for harmonisation by RAC

Salicylic acid

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 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 submitter's proposal	TBD	salicylic acid	200-712-3	69-72-7	Acute Tox. 4 Eye Dam. 1	H302 H318	GHS07 GHS05 Dgr	H302 H318 Dgr			
RAC opinion	TBD	salicylic acid	200-712-3	69-72-7	**Repr. 2** **Acute Tox. 4** **Eye Dam. 1**	**H361d** **H302** **H318**	**GHS08** **GHS07** **GHS05** **Dgr**	**H361d** **H302** **H318**			
Resulting Annex VI entry if agreed by COM	TBD	salicylic acid	200-712-3	69-72-7	Repr. 2 Acute Tox. 4 Eye Dam. 1	H361d H302 H318	GHS08 GHS07 GHS05 Dgr	H361d H302 H318			

MIT (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 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 submitter's proposal	TBD	2-methylisothiazol-3(2H)-one	220-239-6	2682-20-4	Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H311 H301 H314 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H330 H311 H301 H314 H317 H410	EUH071	Skin Sens 1A: ≥ 0.06% M=10 M=1	
RAC opinion	TBD	2-methylisothiazol-3(2H)-one	220-239-6	2682-20-4	**Acute Tox. 2** **Acute Tox. 3** **Acute Tox. 3** **Skin Corr. 1B** **Skin Sens. 1A** **Aquatic Acute 1** **Aquatic Chronic 1**	**H330** **H311** **H301** **H314** **H317** **H400** **H410**	**GHS05** **GHS06** **GHS09** **Dgr**	**H330** **H311** **H301** **H314** **H317** **H410**	**EUH071**	**Skin Sens 1A;** **H317 : ≥ 0.0015%** **M=10** **M=1**	
Resulting Annex VI entry if agreed by COM	TBD	2-methylisothiazol-3(2H)-one	220-239-6	2682-20-4	Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H311 H301 H314 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H330 H311 H301 H314 H317 H410	EUH071	Skin Sens 1A; H317 : ≥ 0.0015% M=10 M=1	

C(M)IT/MIT

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 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	613-167-00-5	reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Skin Corr. 1B Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H311 H301 H314 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H331 H311 H301 H314 H317 H410		Skin Corr. 1B; H314 : C ≥ 0.6% Skin Irrit. 2; H315: 0.06% ≤ C < 0.6% Eye Irrit. 2; H319: 0.06% ≤ C < 0.6% Skin Sens. 1; H317: C ≥ 0.0015%	
Dossier submitter's proposal	613-167-00-5	reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Modify** Acute Tox. 3 Acute Tox. 2 Acute Tox. 2 Skin Corr. 1C Skin Sens. 1A	**Retain** H301 H314 H317 H400 H410 **Modify** H310 H330	**Retain** GHS05 GHS06 GHS09 Dgr	**Retain** H301 H314 H317 H410 **Modify** H310 H330	**Add** EUH071	**Retain** Eye Irrit. 2; H319: 0.06% ≤ C < 0.6% **Add** M=100 M=100 **Modify** Skin Corr. 1C; H314 : C ≥ 0.6% Skin Irrit. 2; H315: 0.06% ≤ C < 0.6% Skin Sens. 1A; H317: C ≥ 0.0015%	
RAC opinion	613-167-00-5	reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	**Acute Tox. 2** **Acute Tox. 2** **Acute Tox. 3** **Skin Corr. 1C** **Skin Sens. 1A** **Aquatic Acute 1** **Aquatic Chronic 1**	**H330** **H310** **H301** **H314** **H317** **H400** **H410**	**GHS05** **GHS06** **GHS09** **Dgr**	**H330** **H310** **H301** **H314** **H317** **H410**	**EUH071**	**Skin Corr. 1C; H314 : C ≥ 0.6% Skin Irrit. 2; H315: 0.06% ≤ C < 0.6%** **Eye Irrit. 2; H319: 0.06%**	

										≤ C < 0.6% Skin Sens. 1A; H317: C ≥ 0.0015% M=100 M=100	
Resulting Annex VI entry if agreed by COM	613-167-00-5	reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	-	55965-84-9	Acute Tox. 2 Acute Tox. 2 Acute Tox. 3 Skin Corr. 1C Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H301 H314 H317 H400 H410	GHS05 GHS06 GHS09 Dgr	H330 H310 H301 H314 H317 H410	EUH071	Skin Corr. 1C; H314 : C ≥ 0.6% Skin Irrit. 2; H315: 0.06% ≤ C < 0.6% Eye Irrit. 2; H319: 0.06% ≤ C < 0.6% Skin Sens. 1A; H317: C ≥ 0.0015% M=100 M=100	

Chlorocresol

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 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	604-014-00-3	chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	Acute Tox. 4 * Acute Tox. 4 * Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1	H302 H312 H318 H317 H400	GHS05 GHS07 GHS09 Dgr	H302 H312 H318 H317 H400			
Dossier submitter's proposal	604-014-00-3	chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	**Retain** Eye Dam. 1 Aquatic Acute 1 **Add** Skin Irrit. 2 STOT SE 3 Aquatic Chronic 3 **Modify** Acute Tox. 4 Skin Sens. 1B **Remove** Acute Tox. 4 *	**Retain** H318 H400 **Add** H315 H335 H412 **Modify** H302 H317 **Remove** H312	GHS05 GHS07 GHS09 Dgr	**Retain** H318 H400 **Add** H315 H335 H412 **Modify** H302 H317 **Remove** H312		**Add** M=1	
RAC opinion	604-014-00-3	chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	**Acute Tox. 4 Skin Corr. 1C Skin Sens. 1B STOT SE 3 Aquatic Acute 1 Aquatic Chronic 3**	**H302 H314 H317 H335 H400 H412**	**GHS07 GHS05 GHS09 Dgr**	**H302 H314 H317 H335 H412**		**M=1**	
Resulting Annex VI entry if agreed by COM	604-014-00-3	chlorocresol; 4-chloro-m-cresol; 4-chloro-3-methylphenol	200-431-6	59-50-7	Acute Tox. 4 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1B STOT SE 3 Aquatic Acute 1 Aquatic Chronic 3	H302 H314 H318 H317 H335 H400 H412	GHS07 GHS05 GHS09 Dgr	H302 H314 H317 H335 H410		M=1	

Flutianil (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 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 submitter's proposal	TBD	flutianil (ISO); (2Z)-{[2-fluoro-5-(trifluoromethyl)phenyl]thio}[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile	Not assigned	958647-10-4	Repr. 2 Aquatic Chronic 1	H361d H410	GHS08 GHS09 Wng	H361d H410		M=100	
RAC opinion	TBD	flutianil (ISO); (2Z)-{[2-fluoro-5-(trifluoromethyl)phenyl]thio}[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile	Not assigned	958647-10-4	**Aquatic Chronic 1**	**H410**	**GHS09 Wng**	**H410**		**M=100**	
Resulting Annex VI entry if agreed by COM	TBD	flutianil (ISO); (2Z)-{[2-fluoro-5-(trifluoromethyl)phenyl]thio}[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene]acetonitrile	Not assigned	958647-10-4	Aquatic Chronic 1	H410	GHS09 Wng	H410		M=100	

Isoeugenol

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitter's proposal	TBD	isoeugenol; [1] (E)-2-methoxy-4-(prop-1-enyl)phenol; [2] (Z)-2-methoxy-4-(prop-1-enyl)phenol [3]	202-590-7 [1] 227-678-2 [2] 227-633-7 [3]	97-54-1 [1] 5932-68-3 [2] - [3]	Skin Sens. 1A	H317	GHS07 Wng	H317			
RAC opinion	TBD	isoeugenol; [1] (E)-2-methoxy-4-(prop-1-enyl)phenol; [2] (Z)-2-methoxy-4-(prop-1-enyl)phenol [3]	202-590-7 [1] 227-678-2 [2] 227-633-7 [3]	97-54-1 [1] 5932-68-3 [2] - [3]	**Skin Sens. 1A**	**H317**	**GHS07 Wng**	**H317**		**C ≥ 0,01%**	
Resulting Annex VI entry if agreed by COM	TBD	isoeugenol; [1] (E)-2-methoxy-4-(prop-1-enyl)phenol; [2] (Z)-2-methoxy-4-(prop-1-enyl)phenol [3]	202-590-7 [1] 227-678-2 [2] 227-633-7 [3]	97-54-1 [1] 5932-68-3 [2] - [3]	Skin Sens. 1A	H317	GHS07 Wng	H317		C ≥ 0,01%	

Pyroxsulam (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitter's proposal	TBD	Pyroxsulam	610-007-6	422556-08-9	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		 M=100 M=100	
RAC opinion	TBD	Pyroxsulam	610-007-6	422556-08-9	**Skin Sens. 1** **Aquatic Acute 1** **Aquatic Chronic 1**	**H317** **H400** **H410**	**GHS07** **GHS09** **Wng**	**H317** **H410**		 **M=100** **M=100**	
Resulting Annex VI entry if agreed by COM	TBD	Pyroxsulam	610-007-6	422556-08-9	Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	GHS07 GHS09		 M=100 M=100	

Amisulbrom (ISO)

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	**No current Annex VI entry**										
Dossier submitter's proposal	TBD	amisulbrom (ISO); 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide	-	348635-87-0	Carc. 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H319 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H319 H410		 M=10 M=10	
RAC opinion	TBD	amisulbrom (ISO); 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide	-	348635-87-0	**Carc. 2** **Eye Irrit. 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H351** **H319** **H400** **H410**	**GHS08** **GHS07** **GHS09** **Dgr**	**H351** **H319** **H410**		 **M=10** **M=10**	
Resulting Annex VI entry if agreed by COM	TBD	amisulbrom (ISO); 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide	-	348635-87-0	Carc. 2 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H319 H400 H410	GHS08 GHS07 GHS09 Dgr	H351 H319 H410		 M=10 M=10	

Table II: Draft CLH opinions with hazard classes agreed by RAC

Epsilon-metofluthrin

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) No 1272/2008)

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (1R,3R)-2,2-dimethyl-3-[(1Z)-prop-1-en-1-yl]cyclopropanecarboxylate; Epsilon-metofluthrin	-	240494-71-7	Acute Tox. 3 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H301 H332 H373 (inhalation) H400 H410	GHS07 GHS08 GHS09 Wng	H301 H332 H373 (inhalation) H410		M=100 M=100	
RAC opinion	TBD	2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (1R,3R)-2,2-dimethyl-3-[(1Z)-prop-1-en-1-yl]cyclopropanecarboxylate; Epsilon-metofluthrin	-	240494-71-7	***Acute Tox. 3*** ***Acute Tox. 4*** STOT SE 1 STOT RE 2 ***Aquatic Acute 1*** ***Aquatic Chronic 1***	***H301*** ***H332*** H370 (target organ) (route) H373 (target organ) (route) ***H400*** ***H410***	**GHS06** GHS08 **GHS09** **Dgr**	**H301** **H332** H370 (target organ) (route) H373 (target organ) (route) **H410**		**M=100** **M=100**	
Resulting Annex VI entry if agreed by COM	TBD	2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (1R,3R)-2,2-dimethyl-3-[(1Z)-prop-1-en-1-yl]cyclopropanecarboxylate; Epsilon-metofluthrin	-	240494-71-7							

Part III. List of Attendees of the RAC-36 meeting

29 February – 4 March 2016 and 8-10 March 2016

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

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

Apologies	**Invited experts**
COPIN Stephanie	DEWHURST Ian (Health&Safety Executive UK) DNEL (1st week only)
GRUIZ Katalin	LARSEN Poul Bo (DHI) cobalt salts (1st week only)
HÖLZL Christine (maternity leave)	LOSERT Annemarie (replacement for RAC Member Christine Hölzl) (2nd week only)
	NIELSEN Brian Svend (DHI) cobalt salts (1st week only)
Commission observers	
HEIDORN Christian DG ENV (1st week only)	**Stakeholders observers**
MORRIS Alick DG EMPL (1st week only)	ANNYS Erwin, Cefic
ROZWADOWSKI Jacek DG GROW (1st week only)	BARRY Frank, ETUC
RAC advisors	VEROUGSTRAETE Violaine, Eurometaux (1st week only)
ESPOSITO Dania (Pietro Paris) (1st week only)	ROWE Rocky, ECPA (2nd week only)
LOIKKANEN Jarkko (Riitta Leinonen) (1st week only)	VAN EGMOND Roger (Cosmetics Europe, occasional stakeholder for D4/D5)
McCABE Laura (Andrew Smith) (CLH MIT/C(M)IT) (2nd week only)	
PECZKOWSKA Beata (Boguslaw Baranski) (CLH flutianil, epsilon-metofluthrin)	**Stakeholder apologies**
ROMOLI Debora (Pietro Paris) (CLH amisulbrom, C(M)IT/MIT, MIT) (2nd week only)	MUNARI Tomaso (EuCheMS)
STOCKMANN-JUVALA Helene (Tiina Santonen) (2nd week only)	ROMANO Dolores (EEB)
SUUTARI Tiina (Riitta Leinonen) (2nd week only)	**Dossier submitters**
UUKSULAINEN Sanni (Tiina Santonen)	BARD Denis (salicylic acid) (1st week only)
WOTHE Susann (Urs Schlueter) (1st week only)	GARD-FLOC´H Arielle (salicylic acid) (1st week only)

Industry experts		**Adviser/invited expert :**
BEVAN Ruth (Eurometaux, UK Interdepartmental Group on Health Risks from Chemicals (IGHRC), AI-RCF, An-RCF (1st week only)		LOSERT Annemarie (Christine Hölzl) (1st week only)
BOWEN Damian (Ecpa, JSC/Otsuka Agrio, flutianil) (2nd week only)		**SEAC Rapporteurs (AfA)**
DANZEISEN Ruth (Eurometaux, CDI, Cobalt salts (1st week only)		COGEN Simon (1st week only)
EARL Lesley (Ecpa, Envigo/Nissan Chemicals Europe/Japan, amisulbrom) (2nd week only)		CSERGO Robert (1st week only)
GARTLAND Kevan (Ecpa, Sumitomo, epsilon-metofluthrin) (2nd week only)		GEORGIOU Stavros (1st week only)
KÄCH Francine (Cosmetics Europe, L´Oreal, D4/D5) (1st week only)		FANKHAUSER Simone (1st week only)
HARDT Susanne (Cefic, Lanxess Deutschland GmbH, chlorocresol)		JONES Derrick (1st week only)
HINDLE Stuart (Cefic, Dow Europe GmbH, MIT, C(M(IT/MIT) (2nd week only)		KIISKI Johanna (1st week only)
LÄPPLE Florian (Cefic, Thor, MIT) (2nd week only)		KRAJNC Karmen (1st week only)
MEHTA Tina (Ecpa, Dow Agro Sciences, pyroxsulam) (2nd week only)		LUIT Richard (1st week only)
PLOTZKE Kathleen (Cefic, DOW, D4/D5) (1st week only)		SCHLUCHTAR Endre (1st week only)
		Dossier submitters:
REMOTE PARTICIPANTS		**France**
RAC Members:		PRINTEMPS Nathalie (C(MI/MIT)
COPIN Stephanie		
DUNGEY Steve (2nd week only)		**Netherlands**
GUSTAFSON Anne-Lee (1st week only)		GERAETS Liesbeth (isoeugenol)
HAKKERT Betty (2nd week only)		
SCHLUETER Urs		**UK**
Ex-RAC Member (co-rapporteur)		MARTIN Sara (D4/D5) (1st week only)
TADEO José Luis (2nd week only)		

Slovenia		
HUMAR-JURIC Tatjana (MIT)		
CEBASEK Petra (MIT)		
van der GEEST Bert (MIT)		
FATUR Tanja (MIT)		
Consultants		
KOVAL Ira (AI-RCF)		
BARENTSEN Helma (AI-RCF)		
PELGROM Sylvia (AI-RCF)		
Commission observers:		
BERTATO Valentina (1st week only)		
GARCIA-JOHN Enrique (1st week only)		
RIEPMA Wim (1st week only)		
LUVARA Giuseppina (1st week only)		
EFSA		
COURT MARQUES Daniele		
ISTACE Frederique		

ECHA staff	PENNESE Daniele
BERGES Markus	PERAZZOLO Chiara
BLAINEY Mark	PILLET Monique
BOWMER Tim, Chairman	PREVEDOUROS Konstantinos
BROECKAERT Fabrice	REGIL Pablo
CHLEBUS Marek	RHEINBERGER Christoph
DVORAKOVA Dana	RODRIGUEZ-IGLESIAS Pilar
ERICSSON Gunilla	ROGGEMAN Maarten
HENRICSSON Sanna	SADAM Diana
KANELLOPOULOU Athanasia	SIHVONEN Kirsi
KARJALAINEN Ari	SIMPSON Peter
KIVELÄ Kalle	SMILOVICI Simona
KLAUK Anja	SOSNOWSKI Piotr
KOKKOLA Leila	SPJUTH Linda
KOSK-BIENKO Joanna	STOYANOVA Evgenia
KOULOUMPOS Vasileios	
LINNA Risto	
LIOPA Elina	
LOGTMEIJER Christiaan	
LOUKOU Christina	
LUSCHÜTZKY Evita	
MARQUEZ-CAMACHO Mercedes	
MAZZEGA SBOVATA Silvia	
MERKOURAKIS Spyridon	
MOTTET Denis	
MULLER Gesine	
NYGREN Jonas	
ORISPÄÄ Katja	
O´ROURKE Regina	
PELTOLA Jukka	

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-36 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-36 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-36 meeting

ANNEX IV Administrative issues and information items

Annex I (RAC-36)

29 February 2016
RAC/A/36/2016

Final Agenda

36th meeting of the Committee for Risk Assessment

29 February - 10 March 2016

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 29 February starts at 14.00
Friday 4 March breaks at 13.00
Tuesday 8 March resumes at 14.00
Thursday 10 March ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/36/2016
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC 35 action points, written procedures and update on other ECHA bodies

RAC/36/2016/01

RAC/36/2016/02
Room document

For information

b) Feedback from the Commission on RAC opinions

For information and discussion

c) RAC workplan for all processes

For information

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

No requests.

Item 6 – Requests under Article 95 (3)

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

RAC/36/2016/03
Restricted document
For discussion/agreement

b) OEL-DNEL methodology request

For information

Item 7 – Harmonised classification and labelling (CLH)

7.1 General CLH issues

a) Update on CLP activities

For information

7.2 CLH dossiers

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

- Amisulbrom (ISO): physical hazards, health hazards (Acute toxicity - all routes of exposure, Skin corrosion / irritation, Respiratory or skin sensitisation, STOT SE, STOT RE, Germ cell mutagenicity), aquatic hazards
- Chlorocresol: health hazards (Acute toxicity - all routes of exposure, STOT SE), aquatic hazards
- Flutianil (ISO): physical hazards, health hazards (Acute toxicity – all routes of exposure, STOT SE, Skin corrosion / irritation, Serious eye damage / eye irritation, Skin sensitisation), aquatic hazards
- Pyroxsulam (ISO): physical hazards, health hazards (Acute toxicity – all routes of exposure, Skin corrosion / irritation, Serious eye damage / eye irritation, Respiratory or skin sensitisation, STOT SE, STOT RE, Germ cell mutagenicity, Toxicity to reproduction, Aspiration hazard), aquatic hazards
- Epsilon-metofluthrin: physical hazards, health hazards (Acute toxicity – dermal an inhalation routes of exposure, Skin corrosion / irritation, Serious eye damage / eye irritation, Respiratory or skin sensitisation, Germ cell mutagenicity, Toxicity to reproduction, Aspiration hazard, aquatic hazards
- 2-methylisothiazol-3(2*H*)-one (MIT): physical hazards, health hazards (acute toxicity via oral route of exposure, respiratory sensitisation, STOT RE, carcinogenicity, germ cell mutagenicity, toxicity to reproduction)

- Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1) (C(M)IT/MIT): physical hazards, health hazards (Acute toxicity – oral route of exposure, STOT SE, EUH071), aquatic hazards

B. Hazard classes for agreement with plenary debate

r) Amisulbrom (ISO)

s) Chlorocresol

t) Flutianil (ISO)

u) Pyroxsulam (ISO)

v) Isoeugenol

w) Epsilon-metofluthrin

x) 2-methylisothiazol-3(2*H*)-one (MIT)

y) Reaction mass of 5-chloro-2-methyl-2*H*-isothiazol-3-one and 2-methyl-2*H*-isothiazol-3-one (3:1) (C(M)IT/MIT)

z) Salicylic acid

For discussion and adoption

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

RAC/36/2016/04
Restricted room document
For agreement

Item 8 – Restrictions

8.1 General restriction issues

a) Carcinogenicity dose-response relationship development for cobalt salts

RAC/36/2016/05
For discussion

b) Report from the Restrictions workshop held in Brussels on 19-20 January 2016

For information

8.2 Restriction Annex XV dossiers

a) Opinion development

1) D4/D5 – revised draft opinion

For adoption

8.3 Appointment of (co-)rapporteurs for restriction dossiers

For information

Item 9 – Authorisation

9.1 General authorisation issues

b) Capacity building

1. DNEL setting for the reprotoxic properties of 1-bromopropane
2. DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP)
3. Carcinogenicity dose-response relationship development for Al-RCF and Zr-RCF

For discussion

b) Update on incoming/future applications for authorisation

For information

9.2 Authorisation applications

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

1. Sodium dichromate-Brenntag (SD_Brenntag)
2. Potassium dichromate-Brenntag (PD_Brenntag)
3. Dichromium tris(chromate)-Henkel (DtC_Henkel)
4. Strontium chromate-Akzo Nobel (SC_Akzo)
5. Potassium hydroxyoctaoxodizincatedichromate-PPG (PH_PPG)
6. Sodium dichromate-Akzo Nobel (SD_Akzo)
7. Sodium dichromate-Solvay (SD_Solvay)
8. Sodium dichromate-Arkema (SD_Arkema)
9. Sodium dichromate-Ercros (SD_Ercros)
10. Sodium dichromate-Electroquimica (SD_ELECTRQUIMICA)
11. Sodium dichromate-Kemira (SD_Kemira)
12. Sodium dichromate-Caffaro Brescia (SD_Caffaro)
13. Chromium trioxide-Federal-Mogul Friedberg (CT_Friedberg)
14. Chromium trioxide-Federal-Mogul Valvetrain (CT_Valvetrain)
15. Chromium trioxide-Federal-Mogul Burscheid (CT_Burscheid)
16. Chromic acid-Bosch (CA_Bosch)
17. Chromium trioxide-Circuit Foil Luxembourg (CT_Circuit)
18. Arsenic acid-Circuit Foil Luxembourg (AsA_Circuit)
19. Chromium trioxide and dichromium tris(chromate)-Nexter Mechanics (CT_DtC_Nexter)
20. Chromium trioxide-Praxair (CT_Praxair)
21. Potassium dichromate-Sofradir (PD_Sofradir)
22. Sodium dichromate-Lanxess (SD_Lanxess)
23. Ammonium dichromate-Micrometal (AD_Micrometal)
24. Chromium trioxide-Cromomed (CT_Cromomed)
25. Chromium trioxide-Rimex Metals (CT_Rimex)
26. EDC-BASF (EDC_BASF)

27. Diglyme-Novartis (Diglyme_Novartis)

For discussion and agreement

d) First version of the draft opinion:

1. Chromium trioxide-Kromatek

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

2. Chromium trioxide-Grohe

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

For discussion and agreement

e) Second version of the draft opinion:

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

Use 1: Formulation of mixtures

For discussion and agreement

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

For discussion

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

For discussion and agreement

9.3 Appointment of (co-)rapporteurs for authorisation applications

RAC/36/2016/06
Restricted room document
For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-36

Table with Conclusions and Action points from RAC-36

For adoption

Annex II (RAC-36)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-36 meeting.

Document number	Title
RAC/A/36/2016	Final Draft Agenda
RAC/A/2016 Restricted	Draft outline agenda
RAC/36/2016/01	Report from other ECHA bodies
RAC/36/2016/02 Room document	Administrative issues
RAC/36/2016/03 Restricted	Request under Article 95(3) 1-methyl-2-pyrrolidone (NMP)
RAC/36/2016/04 Restricted	Appointment of Rapporteurs for CLH dossiers
RAC/36/2016/05	Carcinocenicity dose-response relationship development for cobalt salts
RAC/36/2016/06 Restricted	Appointment of Rapporteurs authorisation

ANNEX III (RAC-36)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLÜTER	Institutional & personal involvement
Restrictions		
D4/D5 (UK)	Steve DUNGEY	Working for the CA submitting the dossier; directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Andrew SMITH	Working for the CA submitting the dossier; directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Harmonised classification & labelling		
n.a.	-	-
Article 95(3) requests		
1-methyl-2-pyrrolidone (NMP)	Marja PRONK	Working for the CA previously submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Betty HAKKERT	Working for the CA previously submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
Restrictions		
No new dossiers		
Applications for Authorisation		
n.a.		
Harmonised classification & labelling		
Amisulbrom (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.
Chlorocresol (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.
Flutianil (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.
Pyroxsulam (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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Isoeugenol (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.
Epsilon-methofluthrin (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.
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) ; C(M)IT/MIT (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.
2-methylisothiazol-3(2H)-one (MIT) (SI)	Anja MENARD – SRPCIC	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

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Annex IV (RAC-36)

Helsinki, 23 February 2016

RAC/36/2016/02

ROOM DOCUMENT

36TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

29 February – 4 March 2016
7 – 11 March 2016

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-35 Action Points

The RAC-35 action points due for RAC-36 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-35	1 February 2016	closed

2.2 RAC consultations (status by 23 February 2016)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Amisulbrom (ISO)	29 January 2016	closed
Chlorocresol	10 January 2016	closed
Flutianil (ISO)	24 January 2016	closed
Pyroxsulam	8 February 2016	closed
Isoeugenol	17 January 2016	closed
Epsilon-methofluthrin	29 January 2016	closed
2-methylisothiazol-3(2H)-one (MIT)	29 January 2016	closed
Reaction mass 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) ; C(M)IT/MIT	24 January 2016	closed
Salicylic acid	16 April 2016	closed
Draft common template for PPP Assessment Reports (DAR) to be submitted to EFSA and CLH reports to be submitted to ECHA	12 February 2016	closed
Application for Authorisation		
27 applications received on the November 2015 submission window: Members' consultation on conformity	10 February 2016	closed
27 applications received on the November 2015 submission window: Members' consultation on application	23 March 2016	**ongoing**
Chromium trioxide-Kromatek: Members' consultation on the draft opinion	12 February 2016	closed

Subject / document	Deadline	Status / follow-up
Chromium trioxide-Grohe: Members' consultation on the draft opinion	15 February 2016	closed
Restrictions		
D4/D5 Third draft opinion	17 February 2016	closed

2.3 Other written consultations of RAC (status by 23 February 2016)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-35	15 January 2016	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
URGENT Call for expression of interest for rapporteurship	12 – 20 January 2016	6 CLH dossiers
Call for expression of interest	4 - 15 February 2016	22 CLH dossiers
Applications for Authorisation – no calls		
Restrictions – no calls		

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

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling			
Written procedure for the appointment of (co-) rapporteur(s)	▪ Branched hexatriacontane (or Alkane 4) ▪ Mandestrobin ▪ pyridate (ISO) ▪ 2-bromo-2-(bromomethyl)pentanedinitrile ▪ asulam-sodium (ISO) ▪ empenthrin (ISO); (E)-(RS)-1-ethynyl-2-methylpent-2-enyl-	28 January 2016	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
	(1R,3RS)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate		
Written procedure for the appointment of (co-) rapporteur(s)	▪ phenyl bis(2,4,6-trimethylbenzoyl)-phosphine oxide ▪ nitric acid ... % ▪ nickel (II) sulphide ▪ nickel bis(sulfamidate)|nickel sulfamate ▪ Trinickel Disulphide ▪ PMDRBO (Citriol) ▪ Isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea ▪ Sodium N-(hydroxymethyl)glycinate ▪ 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	25 February 2016	Ongoing
Applications for Authorisation			
Appointment of the Rapporteurs for November 2015 submission window	chromium trioxide	-	Rapporteurs appointed for most applications. Co-rapporteur for CCST consortium applications pending
Restrictions – no written procedures			

2.6 Other written procedures

Other written procedures	Deadline	Status / follow-up
None		

[i] Scientific Committee on Consumer Safety (SCCS) 2009. Opinion on the mixture of 5-chloro-2-methylisothiazolin-3(2H)-one and 2-methylisothiazoline-3(2H)-one. Adopted at its 5th plenary meeting on 8 December 2009.