RAC/M/37/2016

Final

Adopted 23 August 2016

Amended 11 October 2016 (point 8.a)

Minutes of the 37th Meeting of the Committee for Risk Assessment (RAC-37)

23 May	**started at 14.00**
27 May	**suspended at 13.00**
30 May	**resumed at 14:00**
3 June	**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 37th meeting of the Committee for Risk Assessment (RAC-37). Apologies were received from four 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 36th 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/37/2016), 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. Fifteen 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 if necessary. 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-36 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points from the previous meeting RAC-36 had been completed or were on-going. He explained that the usual 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/37/2016/01). The summary of all consultations, calls for expression of interest in rapporteurships and written procedures is also available in the usual meeting document on CIRCABC (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-36 had been adopted via written procedure and were uploaded to CIRCABC and on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman presented the updated RAC work-plan for Q3&Q4/2016, 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 that the draft paper, developed by the RAC Members of the joint Working group on NMP (RAC/36/2016/03 restricted), and agreed in principle at RAC-36, was shared immediately thereafter with the Scientific Committee on Occupational Exposure Limits (SCOEL) Members for their consideration. No response to this proposal has been received to date. On 31th March 2016, SCOEL/OPIN/2016-119 (2016) was published, in which SCOEL reconfirmed their view on the OEL (40 mg/m3). Due to the different views on the science reflecting the hazardous properties of NMP between RAC and SCOEL (such as the critical effect underpinning the Health Based Limit Value recommended by each Committee) and the different methodology applied, the Secretariat has proposed to SCOEL to proceed with a short joint opinion, introducing the mandates and summarizing the conclusion, and having the SCOEL and RAC-opinion annexed. Annex II to this document (RAC/37/2016/03 restricted) was tabled at RAC-37 to re-assess the RAC-analysis, taking into account the SCOEL opinion of March 2016.

The Commission observer thanked all RAC Members and expressed appreciation for the in-depth analysis and evaluation. Furthermore, the Commission observer informed the Committee that the three Commission Services (DG EMPL, DG GROW and DG ENV) would shortly request the RAC and SCOEL Working Group to reconvene, preferably by the end of June and to re-open the discussions in order to reach a compromise on a common DNEL/OEL value for NMP and to develop a joint RAC-SCOEL opinion.

The Committee supported the re-assessment of NMP prepared by the RAC Members of the working group, reconfirming their view of RAC-36 and taking into account the SCOEL opinion of March 2016.

The Chairman thanked the RAC Members of the joint Working Group for their work. The Secretariat will forward the RAC-assessment to the Commission and the SCOEL Secretariat.

b) OEL-DNEL methodology request

The Chairman noted that the mandate to create a Task Force with SCOEL for the comparative critical assessment of REACH DNEL and OEL methodologies a) for the inhalation route and b) for dermal route, including 'skin notation' and dermal DNEL was distributed to RAC Members in December 2015.

He informed the Committee that the draft work plan, endorsed at RAC-36 as a starting point for the Task force, was forwarded to the SCOEL secretariat at the end of February for their consideration. However no further movement regarding the proposed work-programme had taken place since then.

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 form 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) Acetaldehyde, ethanal

The Chairman reported that acetaldehyde, ethanal was an industrial chemical used in various processes for example in the production of acetic acid, cellulose acetate, pyridine derivatives, perfumes, paints (aniline dyes), plastics and synthetic rubber. It has an existing entry in Annex VI to the CLP Regulation as Flam. Liq. 1; H224, Eye Irrit. 2; H319, STOT SE 3; H335, Carc. 2; H351. The legal deadline for the adoption of an opinion is 21 December 2016.

The Dossier Submitter (the Netherlands) proposed, to modify carcinogenicity classification to Carc. 1B; H350, and to add harmonised classification for mutagenicity (Muta. 1B; H340) and to retain the remaining existing hazard classes.

The Chairman noted that the dossier was tabled for discussion but not for agreement at this meeting (see below). It was pointed out that acetaldehyde is an endogenous compound in humans.

The DS proposal for classification for mutagenicity was based on a weight of evidence analysis that included many *in vitro* studies and tests for genotoxicity in a variety of *in vivo* somatic and germ cell test systems. The Committee discussed the positive evidence from the *in vitro* studies in mammalian cells and the *in vivo* somatic cell tests (e.g. micronucleus assays); members felt that this justified at least a category 2 classification for germ cell mutagenicity. It was noted that although acetaldehyde can be detoxified readily, detoxification in humans is subject to polymorphic metabolism and some individuals are more prone to its toxicity than others. It was agreed that further information should be sought on the toxicologically relevant polymorphism involving mitochondrial ALDH2; aldehyde dehydrogenase).

The data relating to systemic circulation and especially effects on germ cells were considered to be more problematic to assess. Two studies in germ cells were available, both employing the intra-peritoneal exposure route to ensure the gonads were exposed to as high a dose as possible, one (an SCE test) giving a positive result, the other (a Micronucleus test) a negative result. The Rapporteurs noted that there was no direct evidence to show that acetaldehyde can reach the germ cells, testes or ovaries after exposure via physiological routes. The acceptability of the SCE study design was also considered.

[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.

Regarding carcinogenicity, the DS had proposed to upgrade the current harmonised classification (Carc. 2; H351) to category 1B, based on tumour findings in the same studies in the rat and the hamster that had been considered already during the previous TC-C&L classification agreement.

The Committee discussed the data and noted that in spite of some data gaps, tumours occurred in rats and hamsters after inhalation exposure at concentrations that were poorly tolerated and caused local irritation. Tumours occurred in both species exclusively in organs of the respiratory tract i.e. at the site of exposure. Chronic oral administration was not associated with an increased tumour incidence in rats. Members also pointed out that the mutagenic potential of acetaldehyde to somatic cells now should also be taken into account when assessing carcinogenicity.

A targeted public consultation will be launched seeking additional information on mode of action of acetaldehyde, in particular, studies that could elucidate the influence of acetaldehyde dehydrogenase (ALDH2) polymorphism on the physiological levels of acetaldehyde. This will also enable consultation on the revised RCOM table.

b) 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 reported that epsilon-metofluthrin was tabled for a second discussion at a RAC plenary and recalled that the following hazard classes had been agreed during the previous meeting: 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. 3 (H301), 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 at the RAC-37 plenary were STOT SE, STOT RE and carcinogenicity.

The Rapporteur explained that the substance induced neurotoxicity further to acute exposure. By inhalation, serious signs of neurotoxicity occurred in a poorly reported acute study, as well as tremor in the repeat dose toxicity (RDT) study at non-lethal doses after single exposure. In addition, mortality occurred in an RDT study at lower doses than in the acute studies, suggesting a classification as STOT RE 2 when epsilon-metofluthrin was inhaled. On the other hand, there was no indication of long-term functional or histological effects on the nervous system in RDT studies, suggesting that the addition of the nervous system as a target for STOT RE was not appropriate.

During the discussions in RAC, it was clarified that the neurotoxicity effects were acute effects, justifying the classification for STOT SE 1 (H370) with effects on the nervous system. This was agreed by the Committee. In relation to repeated dose toxicity, it was generally recognised that deaths occurred within dose ranges qualifying for STOT RE and taking at least several days of treatment, thus justifying classification. One member expressed a minority opinion arguing that the deaths were covered by the acute toxicity and that STOT RE was not warranted. The

Committee concluded by majority to assign STOT RE 2 (H373) in addition to STOT SE 1 (H370; nervous system).

As to carcinogenicity, RAC discussed whether the mode of action related to liver tumours observed in rats is relevant to humans. Based on the detailed analysis of the Rapporteur, the Committee confirmed that CAR activation was the most plausible mechanism behind liver tumour formation in the rat. This mode of action (MoA) was considered by RAC to be relevant to humans, but it was also recognised that last key event in this MoA (the induction of hepatocellular proliferation, something which is a prerequisite for tumour formation) was not observed in human cells. Based on these findings, RAC concluded that a classification for carcinogenicity was not justified. It was finally noted that the findings and the conclusions drawn were consistent with the close structural analogue momfluorothrin also evaluated by RAC.

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

c) Phosmet (ISO)

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that Phosmet (ISO) is an insecticide and acaricide used as an active substance in plant protection products. The legal deadline for the adoption of an opinion is 31 January 2017.

Phosmet (ISO) has an existing entry in Annex VI to CLP, where it is classified as Acute Tox. 4* (H302), Acute Tox. 4* (H312), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=100 for the aquatic hazard. During the evaluation of Phosmet (ISO) by TC C&L, no final conclusion was reached on the classification regarding acute oral and inhalation toxicity in the human hazard assessment. Also, there was no discussion on the repeated dose toxicity at that time.

The Dossier Submitter (Spain) proposed do retain Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with M=100 for the acute and to add M=10 for the chronic aquatic hazard, to modify to Acute Tox. 3 (H301), to remove Acute Tox. 4* (H312) and to add Acute Tox. 4 (H332) and STOT RE 1 (H372; nervous system). For the hazards germ cell mutagenicity, carcinogenicity and reproductive toxicity, Spain concluded on no classification.

The Chairman recalled that the following hazard classes had already been agreed through the fast-track procedure: Acute Tox. 3 (H301), Acute Tox. 4 (H332) and no classification for acute dermal toxicity, germ cell mutagenicity, carcinogenicity and developmental reproductive toxicity. He pointed out that the hazard classes STOT SE vs. STOT RE, reproductive toxicity (fertility) and the aquatic hazards are foreseen for plenary discussion.

In relation to specific target organ toxicity, the Rapporteur proposed STOT SE 1 with effects on the nervous system in the draft opinion, instead of STOT RE as proposed by the DS. The Rapporteur proposed that based on available animal studies with Phosmet (ISO), the evidence might not be strong enough to trigger STOT RE, in particular it could not be confirmed whether neurotoxic effects could be present following repeated doses. The discussions focussed on whether the case for STOT SE 1 could be made based on acute poisoning through cholinesterase inhibition. It was confirmed by RAC that the effects seen were not covered by an acute toxicity classification, thus a classification for STOT SE 1 (H370) with effects on the nervous system was considered to be justified.

In relation to effects on fertility, the results of a 2-generation study in CD rats (dietary study, Meyer & Walberg 1990) were discussed. It was recognized that there was a reduced mating, fertility and gestation index at 80 ppm and 300 ppm, and that most pronounced effects occurred on fertility. The Industry expert noted that the effects seen were secondary effects to

neurotoxicity. Several RAC Members noted that the neurotoxic effects had to be considered as although potentially secondary due to behaviour, they were still specific effects on fertility, therefore justifying a classification as Repr. 2 (H361f). This was agreed by RAC.

In relation to the acute aquatic hazard, RAC decided to follow the Dossier Submitter's proposals and to classify Phosmet (ISO) as Aquatic Acute 1 (H400), based on the lowest aquatic acute toxicity value from the results of three trophic levels (*Daphnia magna* EC_{50} = 0.00211 mg/L < 1 mg/L), and to assign an acute M-factor of 100, based on the criterion of: 0.001 mg/L < EC_{50} = 0.00211 mg/L ≤ 0.01 mg/L. In relation to the chronic aquatic hazard, the Rapporteur reported that the DS proposed the substance to be rapidly degradable, which would imply a chronic M-factor of 10. The Rapporteur mentioned that the CLH report did not include information on the ecotoxicity of the degradation products nor did it include information on ultimate degradation to support a conclusion of the substance as being rapidly degradable. Instead, some toxicity data on aquatic invertebrates (short-term) for some degradation products was provided but was not deemed to be representative.

RAC that the information on the ecotoxicity of the degradation products provided is not adequate to consider Phosmet (ISO) as rapidly degradable. Consequently, the chronic M-factor should be 100 rather than 10.

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) Pinoxaden (ISO)

The Chairman welcomed the representative accompanying the ECPA stakeholder observer and reported that pinoxaden (ISO) was a pesticide active substance used as a grass-weed control herbicide. It has no existing entry in Annex VI to the CLP Regulation and the legal deadline for the adoption of an opinion is 14 March 2017.

The DS (UK) proposed to classify pinoxaden (ISO) as Acute Tox 4; H332, Skin Irrit 2; H315, Eye Irrit 2; H319, STOT SE 3; H335, Skin Sens 1A; H317, Aquatic Acute 1; H400, M-factor = 1 and Aquatic Chronic 3; H412. As pinoxaden (ISO) was a pesticide with no current harmonised classification it was subject to the C&L process in accordance with Article 36(2) of CLP and all hazard classes had to be assessed.

The Chairman recalled that several hazard classes had already been agreed through the fast-track procedure during the ongoing meeting. No classification was agreed for: for the physical hazards,, acute dermal toxicity, serious eye damage / eye irritation and aspiration hazards. Additionally, Acute Tox. 4; H332, Skin Sens. 1A; H317 and Aquatic Acute 1; H400 with M=1, Aquatic Chronic 3; H412 were agreed without plenary debate. He pointed out that all remaining hazard classes are foreseen for plenary discussion at RAC-37, including acute oral toxicity. This latter endpoint was initially agreed through the fast-track procedure based on the findings in an acute oral toxicity study with rats, but was reconsidered when discussing STOT RE (see below).

<u>Skin irritation / corrosion</u>

The Committee discussed the DS proposal for skin irritation; no substance related skin irritation was noticed in animal studies but the available human information at the workplace suggest some evidence of skin irritation or reaction to pinoxaden exposure. However, the clinical signs were not considered specific to skin irritation and the Members noted that the MoA was not known. RAC agreed to no classification for skin irritation.

<u>Respiratory sensitisation and respiratory tract irritation (STOT RE; H335)</u>

The DS proposed not to classify pinoxaden for respiratory sensitisation. Instead, proposed respiratory irritation (STOT SE 3; H335) based on data on workers (covering the period 2010 – 2013 only) and supportive information from the acute inhalation study in rats. During the public consultation, a proposal to classify for respiratory sensitisation was made.

During the plenary discussion some RAC Members expressed the view that the available data should be considered insufficient for a classification (e.g. due to absence of any objective measurements), while others requested further consideration of classification as a respiratory sensitizer. Further details of the human data (including the 3 cases with asthma-like symptoms and a diagnosed case of occupational asthma; additional information on effects observed in the employees affected before 2010) were requested from the industry representative. The conclusion on this hazard was therefore postponed to the next plenary meeting in September.

Germ cell mutagenicity

The DS proposed no classification based on *in vitro* and *in vivo* guideline studies. Although clastogenic activity was indicated in two positive *in vitro* chromosome aberration tests it did not show this activity in the *in vivo* micronucleus test. The Committee concurred with the DS and agreed to no classification for germ cell mutagenicity.

Carcinogenicity

The Committee discussed the carcinogenicity data (gavage studies in the rat and the mouse, a dietary carcinogenicity study in the mouse and two mechanistic studies in mice). Although very rare tumours (leiomyosarcoma) in the non-glandular stomach in rats were observed in both sexes in one study (in the absence of general toxicity in female rats), RAC noted that there was no dose response observed and concluded that most likely the tumours were not treatment-related. The Committee agreed to no classification for carcinogenicity.

STOT RE

No classification was proposed by the DS for repeated dose toxicity based on the available repeated dose toxicity studies in the rat, mouse and dog. During the public consultation severe maternal toxicity seen in pregnant rabbits in developmental toxicity studies was considered as supportive for a STOT RE classification. The Committee discussed the data; some Members pointed out that the effects apart from mortality did not fulfil the criteria for the repeated dose toxicity (STOT RE). In a dose-range finding developmental study, 25% mortality occurred at day 1 or 2 after exposure to 1000 mg/kg and at Day 5 or 6 after exposure to 700 mg/kg. Mortality was also observed in other short-term studies. The Committee concluded that classification for acute toxicity via oral route of exposure would be more appropriate. Based on scientific judgement, RAC estimated that 50% mortality would likely occur at an oral dose ≤ 2000 mg/kg, which fits into category 4 for acute toxicity. Overall, RAC agreed to classify pinoxaden as Acute Tox. 4; H302.

Toxicity to reproduction

The Committee agreed to the DS proposal for no classification for fertility. They then discussed the results of one out of two main developmental toxicity studies in rabbits where very rare malformations (diaphragmatic hernia) occurred at 100 and 30 mg/kg bw/day and reduced foetal weight (11%) at 100 mg/kg bw/day (Altman 2003b). While some Members thought that the effects could be the result of a genetic influence, others were of the view that this could be excluded since it had been investigated in specific studies. In addition, other developmental effects such as increased post-implantation losses were reported in other studies. RAC agreed to classify pinoxaden as Repr. 2; H361d.

The Committee will resume the discussion on respiratory irritation / sensitisation of pinoxaden

at RAC-38.

e) Quizalofop-P-tefuryl

The Chairman welcomed an expert accompanying the ECPA stakeholder observer. He reported that Quizalofop-P-tefuryl is a herbicide which is manufactured outside the EU, but is used in the EU to control a range of annual and perennial grass weeds in a range of broad-leaved field crops. The legal deadline for the adoption of an opinion is 28 January 2017.

Quizalofop-P-tefuryl has an existing entry in Annex VI to CLP, where it is classified as Acute Tox. 4* (H302), Muta 2 (H341), Repr. 1B (H360Df), STOT RE 2 (H373), Aquatic Acute 1 (H400) and Aquatic Chronic (H410) with no M-factors set. The Dossier Submitter (United Kingdom) proposed to retain Aquatic Acute 1 and Aquatic Chronic 1, adding M=1 for both hazards, to add Carc. 2 (H351) and Skin Sens. 1B (H317), to modify to Acute Tox. 4 (H302) and Repr. 2 (H361fd) and to remove STOT RE 2 (H373) and Muta. 2 (H341).

The Chairman recalled that the following hazard classes had already been agreed through the fast-track procedure: no classification for the physical hazards, for acute dermal and inhalation toxicity, for skin corrosion / irritation, for serious eye damage / eye irritation, for respiratory sensitisation, for germ cell mutagenicity and for aspiration hazards. The Committee agreed to Acute Tox. 4 (H302), Aquatic Acute 1 (H400) with M=1 and Aquatic Chronic 1 (H410) with M=1, without plenary debate. He pointed out that the hazard classes: skin sensitisation, STOT single vs. STOT RE, carcinogenicity and reproductive toxicity (both fertility and development) are foreseen for plenary discussion at RAC-37.

As to specific target organ toxicity after single exposure (STOT SE), the Rapporteur clarified that the effects seen after single oral exposure (no adverse effects were observed after dermal and inhalation exposure) to Quizalofop-P-tefuryl were not target-organ related, but in general related to acute toxicity. As there was no clear evidence of specific effects on a target organ or tissue that were independent of mortalities, and no definitive signs of respiratory tract irritation or narcotic effects, the Rapporteur proposed and the Committee agreed no classification for STOT SE.

Regarding specific target organ toxicity after repeated exposure (STOT RE), some RAC Members argued that the effects seen in repeated dose studies were a reflection of acute toxicity and as such covered by the acute toxicity classification. Other RAC Members noted that mortality was seen after repeated exposure in several studies (and at very high incidences in some studies), without a plausible explanation and occurring at later points in time and were hence not attributed to acute toxicity. According to some Members, these mortalities would justify classification for STOT RE as lethality is mentioned in the CLP criteria. In addition, there were effects on the liver (e.g. liver necrosis) which could not be completely explained by peroxisome proliferation, a significant decrease in level of haemoglobin and haematocrit in males (30%/27% respectively), increased bilirubin (200%), urea nitrogene (61%) and creatine (29%), as well as myocardial lesions (the latter considered to explain some of the deaths observed in mice). Based on these evidence, RAC agreed to retain the classification of Quizalofop-P-tefuryl as STOT RE 2 (H373).

In relation to skin sensitisation, the Rapporteur explained there was a negative Buehler test and a Guinea Pig Maximisation Tests (Denton 1998; OECD 406; GLP) that showed equivocal results. Upon first challenge, technical quizalofop-P-tefuryl elicited a positive response in 12 out of 20 animals, but only after 48 hours, and with a positive response observed also in the vehicle control group (5/20). There were no clearly positive responses indicative of skin sensitisation in any of the test animals following re-challenge. Given the inconclusive results and doubtful

validity of the study, no classification for skin sensitisation was proposed by the Rapporteur and this conclusion was shared by the Committee.

In relation to carcinogenicity, it was recognised that a range of tumours was formed in rats, namely increased incidences of hepatocellular adenomas and carcinomas, Leydig cell tumours and kidney squamous cell carcinoma. In the absence of mechanistic information on the MoA behind these tumours (although PPARα involvement was claimed for some of them), human relevance could not be excluded. With the evidence of increased tumours seen only in one species (rats) and Quizalofop-P-tefuryl not proven to be genotoxic in *in vitro* and *in vivo* studies, classification in category 2 was considered more appropriate than category 1B by the Committee.

In relation to reproductive toxicity, RAC recognized that fertility effects in a 2-generation study as well as the testicular effects seen in repeat dose toxicity studies in rats were observed at dose levels inducing reduced body weight, reduced food consumption and liver hyperthrophy, most probably related to induction of rat hepatic PPARα. None-the-less, there is some evidence from studies in experimental animals of an adverse effect on sexual function and fertility and RAC concluded that Quizalofop-P-tefuryl warranted classification for fertility as Repr. 2 (H361f) acknowledging that the evidence was not sufficiently convincing to place the substance in category 1.

In relation to developmental effects, the Rapporteur reported that the assessment was based on the results of a two-generation reproduction toxicity study (1993a) in rats, which was confirmed by other study results. The adverse developmental effects were mainly seen at dose levels either lethal to maternal organisms or at dose levels initiating serious metabolic alterations leading to disturbances in lipid and testosterone/estrogen metabolism through activation of PPARα receptors. However, the data provided evidence that Quizalofop-P-tefuryl affects the development of animals and RAC was therefore of the opinion that Quizalop-P-tefuryl warranted classification as cat. 2 for developmental effects rather than cat. 1B, thus providing an overall reproductive toxicity classification as Repr. 2 (H361d).

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) S-methoprene

The Chairman welcomed the representative accompanying the ECPA stakeholder observer and reported that S-methoprene was a biocidal active substance (insecticide). It has no existing entry in Annex VI to the CLP Regulation and the legal deadline for the adoption of an opinion is 14 January 2017.

The DS (Ireland) proposed to classify S-methoprene as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 1 for both hazards. As S-methoprene was a biocide with no current harmonised classification it was subject to the C&L process in accordance with Article 36(2) of CLP and all hazard classes had to be assessed.

The Chairman recalled that the following hazard classes had already been agreed through the fast-track procedure during the ongoing meeting: no classification for the physical hazards, for acute toxicity (all routes of exposure), for skin corrosion / irritation, for serious eye damage / eye irritation, for respiratory and skin sensitisation, for STOT SE and STOT RE, for germ cell mutagenicity and for aspiration hazard. In addition, Aquatic Acute 1 (H400) with M=1 and Aquatic Chronic 1 (H410) with M=1 were agreed without plenary debate. He pointed out that the hazard classes carcinogenicity and reproductive toxicity (both fertility and development) are foreseen for plenary discussion at RAC-37.

Some additional ecotoxicology studies referring to soil and sediment toxicity and some degradation studies were submitted during the PC, but the results of these did not affect CLH classification. The Committee agreed to the DS proposal to classify S-methoprene for aquatic hazards.

The Committee discussed the data on carcinogenicity and on toxicity to reproduction. For carcinogenicity, the Committee concurred with the DS proposal for no classification based on two studies (2 year study in the rat and 18 months study in the mouse) which did not show any treatment-related tumours at any dose (top doses were 5000ppm and 2500ppm in rats and mice, respectively). RAC however noted that in both studies the maximum tolerable dose had not been reached. The reporting of the studies in the CLH report was lacking in detail and that this had hampered independent verification of the study results.

RAC discussed toxicity to reproduction on the basis of three studies (two in the rat and one in the rabbit) provided by the DS. All three studies were poorly reported in the CLH report which was pointed out by several RAC Members in the discussion. The statistically significant increase in the post-implantation loss with an incidence of 14% (compared to 7% of controls) was observed in the rat study at the highest dose only (1000 mg/kg bw/day) but no dose-response relationship was observed. Significant foeto-lethality observed in rabbits at 1000 mg/kg bw/day was seen concurrently with maternal toxicity. On this basis, RAC Members supported the proposal for no 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.

g) Sodium hypochlorite, solution … % Cl active

The Chairman welcomed an expert accompanying the Cefic stakeholder observer and a representative from the Dutch Dossier Submitter who was following the meeting via remote connection. He reported that sodium hypochlorite is manufactured by the absorption of chlorine in ca. 21% caustic soda solution. He pointed out that sodium hypochlorite is used mainly in chemical synthesis, for cleaning, disinfection and sanitation in household, for municipal water and sewage disinfection and for bleaching.

The legal deadline for the adoption of an opinion is 24 February 2017.

Sodium hypochlorite has an existing entry in Annex VI to CLP, where it is classified as Skin Corr. 1B (H314) and Aquatic Acute 1 (H400), with no M-factor set, and additionally labelled as EUH031. The Dossier Submitter's (Netherlands) proposal refers to a change of the aquatic classification, namely to classify for Aquatic Acute 1 (H400) with M=100 and Aquatic Chronic 1 (H410) with M=10.

The Rapporteur informed the Committee that in the CLH report, the proposed acute M-factor of 100 was based on lowest LC_{50} values between 0.001 and 0.01 mg/L, while the chronic M-factor of 10 was based on non-rapid degradation and the lowest chronic NOEC values between 0.001 and 0.01 mg/L.

Concerning the M-factor for acute aquatic classification, RAC decided to place more scientific emphasis on the newer, GLP-compliant studies (Gallagher *et al*.) rather than older, non-standard methods (such as Taylor, 1993; Williams *et al*., 2003, etc.). As such, an M-factor of 10, corresponding to acute toxicity values between 10-100 µg/L, was adopted.

The Committee agreed to assign an additional classification as Aquatic Chronic 1 (H410) based on the chronic data available and discussed the justification for the M-factor. While it was recognised that 99% of the substance was immediately mineralised in water, the role of abiotic

degradation for the consideration of rapid degradability appeared to be unclear. The Secretariat clarified that the degradation decision scheme in the CLP Guidance was developed for organic chemicals, implying that points a. (ready biodegradability) and b. (simulation testing) had to be considered irrelevant for inorganic chemicals such as sodium hypochlorite. Rather, the actual rate of mineralisation/ transformation and the relevance of environmental conditions should be considered and a weight of evidence approach applied. RAC then concluded that for classification purposes of sodium hypochlorite, the high rate of transformation was key and that therefore a lower M-factor was justified than proposed by the Dossier Submitter, namely M=1 for the chronic aquatic hazard. It was considered that by-products of chlorination (usually called disinfection by-products created when chorine reacts with organic matter), while relevant for a risk assessment, were generally not relevant for harmonised classification.

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

h) 4-tert-butylphenol

The Chairman welcomed an expert accompanying the Cefic stakeholder observer, as well as two representatives from the Norwegian Dossier Submitter who followed the meeting via remote connection. He reported that the major use of 4-tert-butylphenol is as a monomer in chemical synthesis, e.g. for the production of polycarbonates, phenolic resins, epoxy resins etc. The substance is also hydrogenated to the corresponding cyclic alcohol. According to ECHA's dissemination web site, typical products are adhesives, sealants, coatings and paints, thinners and paint removers.

4-tert-butylphenol is tabled for a first discussion at a RAC plenary meeting; the legal deadline for the adoption of an opinion is 26 April 2017.

4-tert-butylphenol has an existing entry in Annex VI to CLP, where it is classified as: Repr. 2 (H361f), Skin Irrit. 2 (H315), Eye Dam. 1 (H318). The Dossier Submitter (Norway) proposed to add a harmonised classification as Acute Chronic 1 (H410) with M=1.

The Rapporteur informed the Committee that they supported the DS' proposal to classify for Aquatic Chronic 1 based on a 128-d NOEC of 0.0096 mg/L for fathead minnow *P. promelas,* and that they also supported the conclusion of rapid degradability for this substance. The Rapporteur noted that a study prepared in Poland (Demska-Zakęs, 2005; a 28-d semi-static ecotoxicity study with juvenile fish) which was made available to RAC after the public consultation was a non-TG study using non-standard species. While supporting the aquatic chronic 1 classification, it was not possible to consider this study in the RAC opinion, as it was not available in English translation, it had not been submitted during public consultation and it was not a peer reviewed publication (University thesis).

In relation to a study based on OECD Test Guideline 301A (Dissolved Organic Carbon (DOC) Die-Away test), it was recognized that 4-tert-butylphenol can be considered readily biodegradable, based on DOC removal, the fact that the substance is not highly adsorptive (estimated K_{OC} = 500 – 2000), achieving almost complete removal by 21d and on the finding that the 10-day window was met (80% degradation after 14d). Two other ready biodegradation studies, while not achieving the pass threshold in one case, or the 10 day window in the other were seen as generally supportive of rapid degradation. Therefore, the Committee concluded on a chronic M-factor of 1 for 4-tert-butylphenol.

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

i) Isoproturon (ISO)

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. He reported that herbicides containing Isoproturon (ISO) are used in agriculture for the control of a range of mono- and dicotyledonous weeds in cereals. Isoproturon (ISO) is also a biocidal active substance listed in Regulation 1062/2014. Products are used as film preservatives and construction material preservatives. Isoproturon (ISO) is tabled for a first discussion at a RAC plenary meeting; the legal deadline for the adoption of an opinion is 4 May 2017.

Isoproturon (ISO) has an existing entry in Annex VI to CLP, where it is classified as Carc. 2 (H351), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with single M-factor of 10 for both aquatic hazard classes. The Dossier Submitter (Germany) proposed while retaining the other existing hazard classes to add the following hazard classes: Repr. 2 (H361f) and STOT RE 2 (H373; blood, oral) and to add a separate chronic M-factor of 10.

The Chairman recalled that the environmental hazard classes had already been agreed through the fast-track procedure during the ongoing meeting.

In relation to specific target organ toxicity, blood toxicity was observed in three animal species, although RAC noted that the substance does not seem very potent. One RAC Member recognised that the molecular structure of the substance suggests that it causes blood toxicity, which in the longer term results in anaemia. RAC supported classification of in Category 2 as STOT RE 2 (H373; blood), without specification of the route.

Regarding carcinogenicity the Rapporteurs acknowledged the existing entry in Annex XIV of the CLP Regulation. Since carcinogenicity was not included in the CLH Report by the Dossier Submitter, the endpoint was not a part of the public consultation and not discussed by RAC.

Concerning the reproductive toxicity effects on fertility, the Rapporteurs noted methodological and reporting deficiencies in several of the studies, the observed effects were insufficient to draw a firm conclusion on the classification of the substance. The effects on fertility occurred together with other toxic effects, namely reduced body weight gain and feed consumption, but they did not appear to be due to a secondary non-specific consequence of the other toxic effects. Some RAC Members acknowledged retarded spermatogenesis occurring only in F1 generation male rats. Overall, RAC Members agreed that the observed retarded spermatogenesis is insufficient to classify the substance for its effects on fertility.

In relation to developmental toxicity, the Rapporteurs acknowledged the five teratogenicity studies conducted in rats and two teratogenicity studies conducted in rabbits. In these studies embryo-/foetotoxicity has been observed from 100 mg/kg bw/day (rat) and 160 mg/kg bw/day (rabbit) and included increase in resorptions, reduced foetal weight, and incomplete ossification. Retarded ossification has been observed also in one supplementary study on rats with statistical significance at 200 mg/kg bw/d. One study in rats showed a dose-related increase in resorptions with statistical significance at 500 mg/kg bw/d; however, female rats showed also abnormal clinical signs as excessive urination and lethargy at that dose level. Two other studies showed reduced foetal weight, but only at doses also showing reduced maternal weight. The Rapporteurs concluded that the available teratology studies do not provide any findings to justify classification of Isoproturon for developmental toxicity. The Committee agreed with the conclusion of the Rapporteurs that the criteria for harmonised classification of Isoproturon for its effects on development were not met.

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

j) Isobutyl methacrylate

The Chairman reported that isobutyl methacrylate is used as a monomer for polymerisation or intermediate in synthesis of other chemicals and the CLP proposal is tabled for a first discussion at a RAC plenary meeting; the legal deadline for the adoption of an opinion is 3 March 2017.

Isobutyl methacrylate has an existing entry in Annex VI to CLP, where it is classified as Flam. Liq. 3 (H226), STOT SE 3 (H335), Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), Skin Sens. 1 (H317) and as Aquatic Acute 1 (H400), with no M-factor set. The Dossier Submitter (Germany) proposed to modify Skin Sens. 1 to Skin Sens. 1B and to remove the existing harmonised classifications for eye irritation and aquatic acute toxicity from Annex VI to CLP.

In relation to eye irritation, RAC recognised that none of the conditions for classification as Eye Irrit. 2 are fulfilled and agreed with the DS to **recommend the removal of this classification from Annex VI to CLP**.

In relation to skin sensitisation, the LLNA test presented in the dossier showed a positive response and RAC and classification as Skin Sensitization 1 was agreed. The test data included a derived EC3 of 41.4%, thus allowing assessment of potency. According to the CLP criteria, a value of EC3 >2 is associated with a moderate potency corresponding to sub-category 1B, which RAC agreed.

In relation to the aquatic hazards, RAC considered that isobutyl methacrylate was rapidly degradable and not bioaccumulative. Horberg (1995) on algal toxicity was considered to be invalid. RAC concluded that isobutyl methacrylate should not be classified for aquatic acute toxicity based on the lowest acute endpoints (72-hour initial measured E_rC_{50} = 16 mg/L for *Pseudokirchneriella subcapitata*).

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

7.2 Appointment of RAC Rapporteurs for CLH dossiers

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

8. Restrictions

General restriction issues

a) Capacity building - Carcinogenicity dose-response relationship setting for cobalt salts

The Chairman invited the ECHA Contractor to present the draft report on the carcinogenicity dose-response relationship for five cobalt (II) salts (cobalt (II) sulphate, cobalt dichloride, cobalt dinitrate, cobalt (II) carbonate and cobalt diacetate). The Contractor highlighted in his presentation the revisions made, taking into account the discussion of RAC-36 concerning the evaluation of the results and the quality of the intra-peritoneal studies in relation with the genotoxicity effect, the identification of the cobalt salts as non-threshold carcinogens for the inhalation route and the identification of the dose-response relationship as applicable to the respirable fraction of the compounds.

The Committee discussed the updated report. The Committee agreed that the identification of the substances as non-threshold carcinogens needed to be reinforced, based on the lack of substance-specific evidence for a threshold mode of action and the uncertainties regarding the other mechanisms involved.

The relevance of the i.p. studies had been questioned by the other expert assessments, based on shortcomings of the studies, as well as on the relevance or not of the exposure route. The contractor concluded and the Committee agreed that these studies are relevant indications for a genotoxic potential of water soluble cobalt salts in vivo, and that the i.p. route is relevant. Less emphasis is now put on the K-ras mutations in lung tissue in the report. Also, the threshold calculation was now omitted from the report.

It was emphasised that the dose-response relationships described in the report are related to the respirable fraction of an aerosol, because the animals in the NTP (1998) were exposed to cobalt sulphate particles with a MMAD (Mass Median Aerodynamic Diameter) in the range of 1 µm – 3 µm, and the lung tumours from which the BMDL10 level was derived were located in the deeper part of the lung. The appropriateness of using a linear dose-response approach is further highlighted in the report.

In relation to the BMDL10, industry experts stated that this approach inherently assumes a non-linear dose-response and then the consultant extrapolated back by a "one hit" assumption (linear dose-response). This is questionable, especially for an essential element. Industry expert states that industry does not support the use of i.p. studies to inform cobalt's dose-response relationship by the inhalation route.

RAC agreed on the note on carcinogenicity dose-response relationship of water soluble cobalt salts. The Secretariat will consult with the Rapporteur and the Consultant on the wording concerning the mode of action as suggested in the discussion. The Secretariat will consider further actions in discussion with the Commission.

b) Update on Forum restriction projects

The Secretariat presented the revised Working Procedure of the Forum for the elaboration of the Forum advice, the Forum Guide on Enforceability of Restriction Proposals, a methodology to recommend analytical methods, a compendium of Analytical methods and the REF-4 Project on Restrictions.

8.1 Restriction Annex XV dossiers

a) Conformity check

1) TDFAs – outcome of the conformity check and presentation of the key issues

The Chairman welcomed the Dossier Submitters representative from Denmark.

The Dossier Submitter's representative provided a brief update on the main changes in the resubmitted dossier. The dossier proposes to restrict the use of:

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

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

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter and informed the Committee that they consider the dossier to be in conformity. The Committee agreed and the Chairman informed that SEAC will conclude on the conformity of this dossier at its 31st meeting.

If the dossier will be considered to be in conformity by both Committees, the Secretariat will inform the Dossier Submitter and launch a public consultation on 15 June 2016.

2) Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) – outcome of the conformity check and presentation of the key issues

The Chairman welcomed the Dossier Submitters' representatives from ECHA and Denmark.

The Dossier Submitters' representative (ECHA) provided a brief introductory presentation on the dossier. The dossier proposes a restriction on articles containing the four phthalates (Diisobutyl phthalate (DIBP); Dibutyl phthalate (DBP); Benzyl butyl phthalate (BBP) and Bis(2-ethylhexyl) phthalate (DEHP)) for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes. A previous restriction proposal on the four phthalates was submitted by Denmark in 2011 and RAC and SEAC adopted opinions not supporting the proposal. The four phthalates were included in Annex XIV of REACH (the Authorisation List). Applications for authorisation were received only for certain uses of DEHP and DBP. The current proposal from ECHA and Denmark builds on the previous restriction proposal and takes into account the applications for authorisation that have been submitted and granted. The new proposal presents: additional information and assessment covering the hazard, new information on exposure (especially DEMOCOPHES biomonitoring data), additional data on costs and trends in substitution, and a review of new information on benefits.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitters and informed the Committee that they consider the dossier to be in conformity. The Committee agreed on the conformity of the dossier.

The Commission observer requested that articles defined as electric and electronic equipment in Directive 2011/65/EU (RoHS) are excluded from the scope. She drew the Committee's attention to the "Common Understanding Paper" prepared by the Commission and endorsed by the Member States on the interface between REACH and RoHS. The four phthalates that are the subject of the current restriction dossier are all listed in Annex II of RoHS (restricted substances) and the simplest way to avoid duplications and/or inconsistencies is to exclude electric and electronic equipment from the scope of the proposed restriction. She suggested that this should be made clear when a public consultation on the proposal is launched.

In addition, the Commission observer highlighted the importance of providing a clear justification in the Committee opinion on the following topics: the need to consider DIBP use in toys and

childcare articles, the enforceability of the restriction, and the contribution of food contact materials to exposure from the four phthalates.

In addition to the conformity discussions, the Rapporteurs presented their key issues to the Committee to assist them in preparing their first opinion. The selection of points of departure in relation to those considered in a previous restriction proposal was discussed, as were the anti-androgenic effects, which were considered of high importance. In relation to scope, they pointed out that one derogation proposed in the restriction text related to industrial and agricultural workplaces seemed contradictory and needed clarification; one NGO observer questioned why a derogation was proposed for such workplaces. The Committee agree that the issues identified by the Rapporteurs were the most important issues for opinion making.

The Chairman informed that SEAC will conclude on the conformity of this dossier at SEAC-31. If the dossier will be considered to be in conformity by both Committees, the Secretariat will inform the Dossier Submitters and launch a public consultation on 15 June 2016.

9. Authorisation

9.1 General authorisations 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, guideline studies and published investigations. However, he noted that very limited human evidence for reproductive toxicity is available; neurological effects predominate among the available data. The only developmental study on rat shows reduced skull ossification and increased bent ribs. One of the reproductive toxicity study on rat demonstrate reductions in fertility, litter size, foetal weight, implantations, impact on sperm quality, reproductive organ / tissue weights, as well as increases in oestrous cycle length, retained elongated spermatids, ovarian cysts. Specific investigations on rat and mouse provide evidence of reversibility: reductions in fertility, litter size, foetal weight, impact on sperm quality (count, motility, morphology), maturing ovarian follicles / ova, reproductive organ / tissue weights, as well as increases in oestrous cycle length, retained elongated spermatids, pup mortality, including cross fostering. The ECHA Contractor noted that there is a good degree of consistency of these findings. NOAECs / BMDLs typically are between 100 to 300 ppm (500 – 1500 mg/m^3) in rats and mice. In one mouse study (Liu *et al*.), however, LOAEC is 50 ppm based on sperm counts, sperm motility and abnormal sperm in 3 strains.

Considering the plenary discussion at RAC-36, the ECHA Contractor proposed to introduce the following changes: dermal absorption value of 10%, most of dermal dose lost by evaporation; genotoxicity statement expanded to clarify assumption of non-genotoxic mode of action; detailed comparison of Liu study with NTP results in mice without an obvious explanation for different results. He stated that the results of the Liu study cannot be dismissed, but they are out of line with the rest of the database; and finally DNELs now proposed on rat reproduction study BMD_L of 190 ppm corresponding to 950 mg/m^3. As the second option the ECHA Contractor proposed to use slightly lower BMD_L of 150 ppm from the second generation.

The ECHA Contractor asked the Committee for further guidance in developing the draft RAC note on setting of DNEL values for the reproductive toxicity of 1-bromopropane. The first question

concerned the use of the Liu *et al*. mouse data versus rat reproduction data with a focus on having no reproduction study in mice, and whether sperm parameter changes relate to reproductive outcome. The second question was on the use of the lowest BMD_L from rat reproduction study from the second generation.

The Committee discussed the draft report, and gave advice on further improvements. Specifically, RAC recommended that the Contractor tabulate a summary of the relevant results, including the significance and reversibility of the effects, to provide a comprehensive overview of the available data and facilitate an agreement on the most appropriate starting point for DNEL derivation. The Committee requested the ECHA Contractor to consider the plenary discussion, to update the draft report and to submit it to SECR together with the draft Committee's note for the discussion and agreement at RAC-38 in September.

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.

The ECHA Contractor provided the following arguments supporting a choice of DPP for read-across of DIPP. DPP has two side chains of five carbon atoms as DIPP and the same molecular weight. Key physico-chemical properties, such as vapour pressure, water solubility and $LogP_{ow}$, of DIPP and DPP, which are important in determining toxicity, are very similar. Ideally, potency information on DPP and the other two candidates would be important but the database is insufficient. By contrast, DIBP has side chains with four carbons, hence it has smaller molecular weight than DIPP, even though both substances have branched side chains. Key physico-chemical properties between DIBP and DPP are similar, but the $LogP_{ow}$ is significantly different. The third read-across candidate DBP has side chains with four carbon atoms; it has smaller molecular weight than DIPP.

The ECHA Contractor in his presentation also summarised reprotoxicity data for DPP. The effects of the substance are testis atrophy in mature rats at high doses with immature, pre-pubertal rats being more sensitive. Fertility affected in mice from 760 mg/kg bw/d. The following observations had been recorded in rat developmental studies with prenatal assessments: effects on foetal testosterone levels from 33 mg/kg bw/d; down-regulation of some foetal testis genes involved in steroidogenesis and sexual differentiation from 11 mg/kg bw/d (though this has not been considered adverse at this dose in the absence of biochemical, functional or morphological changes); and mild testis atrophy from 33 mg/kg bw/d; as well as descent of testes in the inguinal area delayed at 300 mg/kg bw/d. The following developmental studies in rat with postnatal assessments have been found: reduced AGD on PND_2 from 100 mg/kg bw/d; nipple retention on PND_{13} from 300 mg/kg bw/d; hypospadia from 300 mg/kg bw/d, and other malformation of the male reproductive and urogenital tract from 100 mg/kg bw/d.

The ECHA Contractor proposed a value of 11 mg/kg bw/d (from exposure during gestation days 8-18 or 14-18) as NOAEL of based on reductions in foetal testosterone, down-regulation of foetal testis genes, and mild foetal testis atrophy at 33 mg/kg bw/d. The value is taken from the three studies (Hannas *et al*., 2011; 2012; Gray *et al*. 2016).

The Committee discussed the draft report, and recommended that the selection of phthalates for read-across to DIPP be strengthened. It was recommended to take a more holistic approach and assess the effects of a wider selection of phthalate compounds (e.g. based on reduced foetal testosterone). Additionally RAC highlighted the need for consistency between the report on DNEL setting for the reprotoxic properties of DIPP and the ECHA/Denmark restriction proposal on phthalates (DIBP, DBP, BBP, DEHP). The Committee requested the ECHA Contractor to consider the plenary discussion, to update the draft report and to submit it to SECR together with the draft Committee's note for the discussion and agreement at RAC-38 in September.

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 ECHA Contractor in the introduction mentioned that studies with experimental animals demonstrated increased incidence of mesothelioma and/or lung cancer and/or pulmonary fibrosis in two species (rats, hamsters) upon exposure to RCF by inhalation, intrapleural, intraperitoneal or intratracheal instillation. Available epidemiological data did not demonstrate an association between occupational RCF exposure and increased incidence of mesothelioma, lung cancer or pulmonary fibrosis in humans; this piece of information has been last updated in 2012). A number of international authorities have derived limit values for RCFs. However, only four have based them on the calculated excess cancer risks due to RCFs exposure. There is no consensus on the method of calculation of excess cancer risks from RCFs exposure between the authorities. Most authorities used the results from two rat inhalation bioassays (studies of Mast *et al*., 1995a,b) as a starting point for excess cancer risk calculations. Based on the results of the previous RAC meeting, it has been agreed to present a detailed overview of existing evaluations in order to obtain the range of the established limit values with corresponding excess cancer risks. The ECHA Contractor also presented a summary table with different regulatory outcomes by the following national and international organisations: ACGIH, AGS (DE), DECOS (NL), EPA Canada, ANSES (FR), HSE (UK), IARC, NIOSH (USA), Safe Work Australia and SCOEL (EU). Both non-threshold and threshold approaches have been used by different regulatory bodies to determine safe exposure limits for RCF. The ECHA Contractor summarised that the set limit values vary between 0.1 and 1 fibres/ml, excess cancer risks vary between 0.07 and 4 per 1,000 for exposure to 0.1 fibres/ml; three out of four evaluations used rat inhalation bioassay data. The highest excess cancer risks derived by AGS use the results of intraperitoneal test to compare the potency of RCFs with the potency of crocidolite asbestos and use epidemiologic asbestos data corrected for relative potency to calculate excess cancer risks from RCFs exposure. The lowest excess cancer risks are derived by DECOS; however, no original reporting is available. Excess cancer risks derived by NIOSH and France are comparable (0.5 per 1,000 vs. 0.15-0.24 per 1,000 at exposure level of 0.1 fibres/ml, using linear extrapolation). Estimates derived by NIOSH and ANSES make use of well-documented models and use substance-specific inhalation assay data. The ECHA Contractor proposed therefore to use them as the most realistic excess cancer risks estimates. If these estimates are used as a starting point, acceptable cancer risks of 4 per 1,000 can be calculated for exposure levels of 0.8-2.7 fibres/ml, using linear extrapolation. The SCOEL value of 0.3 fibres/ml would then correspond to excess cancer risk of 0.45-1.5 per 1,000.

The Committee discussed the following key issues: (1) mode of action of RCFs, (2) setting of the inhalation studies, (3) dose-response relationship in humans, and, finally, (4) intraperitoneal testing and its suitability to determine carcinogenicity for the substance. The industry expert accompanying Eurometaux, clarified that a significant increase in lung tumour incidence had

only been observed in the Mast *et al*. (1995a) study, which was a single dose MTD study, and that this had subsequently been explained by the excessive dose given and particle contamination of the test material, leading to an overload effect. Regarding the epidemiology studies, he mentioned the negative findings found in a recent paper by Gerazime *et al*. (2015) and in the update of the Cincinatti study. He also drew attention to the negative results in two standard regulatory *in vitro* tests for genotoxicity that had been conducted on RCF. This all added to the weight of evidence that RCFs are not directly genotoxic and that any carcinogenic activity of RCFs would have a threshold, meaning that a safe exposure level can be determined. The application of a linear model for calculation of cancer risk may therefore not be appropriate. He suggested that calculation of a DNEL, based either on the NOAEL for lung cancer (DNEL = 2.17 f/ml) or on the NOAEL for pulmonary fibrosis (DNEL = 0.48 f/ml) would be a better approach.

The Committee discussed the approach taken by the ECHA contractor and requested them to consider the points raised, to update the draft report and to submit it to the Secretariat. RAC agreed to await regulatory developments with these substances before proceeding further with reference values.

b) Applications for authorisation received in the May submission window

The ECHA Secretariat informed the Committee that during the May submission window (6-20 May 2016) ECHA had received 22 new applications for authorisation on 30 uses of substances of very high concern: 15 applications for uses of chromium(VI) compounds, 5 for uses of 1,2-dichloroethane (EDC), and finally, 1 each for the use of bis(methoxyethyl) ether (Diglyme) and for uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA).

9.2 Authorisation applications

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

RAC agreed on conformity of 29 applications for authorisation and discussed the key issues in each case, providing advice to the teams of Rapporteurs.

1. Chromium trioxide - SNECMA

This is a downstream user application for the industrial use of a chromium trioxide-based surface treatment mixture applied on safety-critical rotating components of commercial and military aircraft engines, whose failure endangers airworthiness. The annual volume of the substance used is 60 kg. The applicant requested a 10 year review period.

2. Chromium trioxide - MTU Aero Engines AG

This is a downstream user application for the two uses of chromium trioxide. The first use covers functional chrome plating for aerospace applications for civil and military uses, comprising coating of new components for aircraft engines as well as maintenance, repair and overhaul work on aircraft engine components. Annual volume of the substance used for this use is 0.35 tonnes. The applicant requested a 15 years review period for the use.

The second use the applicant has applied for concerns surface treatment (unrelated to functional chrome plating) in a similar sector to the above. The annual volume of the substance used for this use is <100kg. The applicant requested a 15 years review period for the use.

3. Chromium trioxide - ABLOY Oy

This is a downstream user application by one applicant for one use of chromium trioxide in the electroplating of mechanical and electro-mechanical cylinders, cams and padlocks, electro-mechanical lock cases and architectural hardware. The application covers one production site with the exposure of 30 workers. The total annual tonnage used is currently < 1 tonne, but foreseen to increase to 1.3 tonnes. The applicant requested a review period of 12 years.

4. Chromium trioxide - HOOGOVENS Court Roll Surface Technologies V.O.F.

This is a downstream user application submitted on behalf of 8 applicants for one use of chromium trioxide for functional chrome plating of work rolls used in the steel and aluminium industry. The application covers 11 production sites (and one additional site to start shortly). The total annual tonnage used is ca. 35 tonnes. The applicants requested a review period of 12 years.

5. Chromium trioxide - TOPOCROM GmbH

This is a downstream user application by one applicant for one use of chromium trioxide for functional chrome plating in closed reactor systems for the establishment of adjustable hemispherical surface structures. The total annual tonnage used is 30 tonnes. The applicant requested a review period of 15 years.

6. Chromium trioxide - FN HERSTAL S.A.

This is a downstream user application for two uses of chromium trioxide. The first covers the industrial use of chromium trioxide in the hard chromium coating of military small- and medium-caliber firearms barrel bores and auxiliary parts subject to thermal, mechanical and chemical stresses, in order to provide hardness, heat resistance and thermal barrier properties, as well as corrosion resistance, adhesion and low friction properties. The annual volume of the substance used is 5 tonnes. The applicant requested a 12 years review period for the use.

The second concerns the industrial use of chromium trioxide in the hard chromium coating of civilian firearms barrel bores and auxiliary parts subject to thermal, mechanical and chemical stresses, in order to provide a low friction coefficient as well as heat, corrosion and wear resistance properties. The annual volume of the substance used for this use is 1 tonne. The applicant requested a 7 years review period for the use.

7. Chromium trioxide - GERHARDI KUNSTOFFTECHNIK GmbH

The Secretariat presented the key issues in the application for authorisation from Gerhardi KUNSTOFFTECHNIK GmbH (submitted on behalf of 12 applicants). It is a downstream user application for one use of chromium trioxide for plating on plastics for automotive applications (PoPAA). The application covers 22 different production sites, and the total annual tonnage used is 560 tonnes. The applicant requested the review period of 12 years.

8. Chromium trioxide; Potassium dichromate; Sodium dichromate - SOURIAU SAS

The Secretariat presented the key issues in the application for authorisation from Souriau SAS (submitted on behalf of consortium of six connector manufacturers). It is a downstream user application for three uses of a mixture of the substances for conversion coating of connectors (1, conversion coating of cadmium coated rectangular connectors; 2, conversion coating and passivation of circular and rectangular connectors; 3, etching of composite connectors). The application covers six sites in three countries; in total one hundred workers are potentially exposed and the annual tonnage used is ca. 15 tonnes. The applicant requested review periods of 12, 7 and 4 years respectively for the three uses.

9. Chromium trioxide - HAPOC GmbH and Co. KG

This is an **upstream** user application for four uses of chromium trioxide. The first covers use in dissolved and solid form to produce aqueous solutions of any composition for industrial application, i.e. formulation. As stated in the application by the applicant, the largest quantity used at the operating site is a few kilograms a year; the planned total quantity is a maximum of 1,000 tonnes a year, and the applicant requested a 25 year review period for the use.

The second concerns use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow, in category III. As stated in the application by the applicant, the minimum quantity used at the operating site is less than one tonne a year; the potential total quantity at the operating site is several 100 tonnes a year, and the applicant requested a 12 year review period for the use.

The third use the applicant has applied for concerns use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow, in category II. As stated on by the applicant, the minimum quantity used at the operating site is less than one tonne a year; the potential total quantity at the operating sites is over 100 tonnes a year, and the applicant requested a 17 year review period for the use.

The fourth use the applicant has applied for concerns use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow, in category I. As stated in the application by the applicant, the minimum quantity used at the operating site is less than one tonne a year; the potential total quantity at the operating site is several 100 tonnes a year, and the applicant requested a 25 year review period for the use.

The categories mentioned above associate each of the uses with a maximum cancer risk level; uses 2 to 4 are similar in practical terms but each has a different risk level assigned by the applicant (4:10000, 4:1000 and 2:100 respectively). RAC discussed this application only in the context of conformity, noting that this risk category approach needed to be considered carefully.

10. Ammonium dichromate - VECO BV

This is a downstream application for the use of ammonium dichromate as the photosensitive constituent of a polyvinyl alcohol photolithographic lacquer system. The annual volume of the substance used is 40 kg and the applicant requested a 7 years review period.

11. Potassium dichromate - GENTROCHEMA BV

This is an upstream user application for the two uses of potassium dichromate.

The first use covers the formulation of mixtures with an annual volume of 100 tonnes at 1 to 10 sites. The applicant requested a 12 year review period for this use.

The second concerns the use of potassium dichromate for the surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic films. The annual volume of the substance indicated is 100 tonnes across more than 100 sites and the applicant requested a 12 year review period for this use.

12. Sodium dichromate - GENTROCHEMA BV

This is an upstream application for three uses of sodium dichromate.

The first use covers the formulation of mixtures. The annual volume of the substance indicated is 1,300 tonnes at 1 to 10 sites and the applicant requested a 12 year review period for the use.

The second concerns the use of sodium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic films. The annual volume of the substance indicated is 1,300 tonnes at more than 100 sites and the applicant requested a 12 year review period for this use.

The third concerns the use of sodium dichromate for the electrolytic passivation of tin-plated steel for the packaging industry. The annual volume of the substance indicated is 1,300 tonnes at 1 to 10 sites and the applicant requested a 4 year review period for the use. This can be considered as a bridging application.

13. Sodium dichromate - TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH

This is a downstream application for the use of sodium dichromate as a corrosion inhibitor in ammonia absorption deep cooling systems of a methanol synthesis plant.

The annual tonnage used is < 1 tonne at one site and the applicant requested a 21 year review period for this use.

14. Sodium dichromate - JACOBS DOUWE EGBERTS DE GmbH

This is a downstream application for the use of sodium dichromate as a corrosion inhibitor in ammonia absorption deep cooling systems as applied in the industrial production of freeze dried products such as coffee, herbs, spices and comparable products.

The annual tonnage used is < 1 tonne at five sites and the applicant requested a 20 year review period for the use.

15. EDC - BASF SE

This is an application for two uses of EDC as a solvent and crystallisation medium in the synthesis of 1) the plant protection product bentazone (ISO) as manufacturer, and 2) the biocide flocoumafen (ISO) as both manufacturer and importer. The annual volume of the substance used is up to 250 tonnes for use 1 and 1-10 tonnes for use 2. The applicant requested at least a 12 year review period years for both uses. During the discussion the RAC Members have been informed about the workers' exposure assessment based on both measurements, or modelled data. RAC

16. EDC - ELI LILLY

This is a downstream user application for the use of EDC as a reaction medium and a solvating agent in mediating subsequent chemical transformation reactions leading to the manufacture of an Active Pharmaceutical Ingredient, Raloxifene Hydrochloride. The annual volume of the substance used is 100-250 tonnes and the applicant requested a 12 year review period.

During the discussion the RAC Members have been informed about the workers' exposure assessment based on both measurements, or modelled data.

17. EDC - DOW ITALIA S.R.L.

This is a downstream user application for the use of EDC as a sulphonation, swelling agent of polystyrenedivinylbenzene copolymer beads in the production of strong acid cation exchange resins. The annual volume of the substance used is <50 tonnes and the applicant requested a 15 year review period. During the discussion the RAC Members have been informed about the workers' exposure assessment based on both measurements, or modelled data.

18. EDC - LANXESS Deutschland GmbH

This is a downstream user application for two uses of EDC as: 1) a swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins and 2) a swelling agent and reaction medium during the phthalimidomethylation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of anion exchange and chelating resins. The annual volume of the substance used is <100 tonnes and the applicant requested a 4 year review period for use 1 and 12 years for use 2. During the discussion the RAC Members have been informed about the workers' exposure assessment based on both measurements, or modelled data.

19. EDC - H&R OLWERKE SCHINDLER GmbH

It is a downstream user application for the use of EDC as a solvent and anti-solvent of the feedstock and intermediate product streams in the combined de-waxing and de-oiling of refining of petroleum vacuum distillates for the production of base oils and hard paraffin waxes. The annual volume of the substance used is 10-100 tonnes and the applicant requested a 20 year review period. During the discussion the RAC Members have been informed about the workers' exposure assessment based on both measurements, or modelled data.

20. EDC - GRUPA LOTOS S.A.

This is a downstream user application for the use of EDC as an extraction solvent in the de-waxing of petroleum vacuum distillates and de-asphalted oil and de-oiling of slack wax for the production of base oils and paraffinic waxes. The annual volume of the substance used is 10-100 tonne sand the applicant requested a 20 year review period.

During the discussion the RAC Members have been informed about the workers' exposure assessment based on both measurements, or modelled data.

21. EDC - GE HEALTHCARE Bio-Sciences AB

This is a downstream user application for the use of EDC as an emulsifying solvent in the manufacture of porous particles for beaded chromatography and cell culture media. The annual volume of the substance used is 30 tonnes and the applicant requested a 12 year review period.

22. Diglyme - ROCHE DIAGNOSTIC GmbH

This is a downstream user application for the use of Diglyme as a process chemical in the manufacture of one specific type of bead, used in the immunodiagnostic assays market. The annual volume of the substance used is 8 tonnes, expected to rise to 11 tonnes/year and the Applicant requested a 12 year review period. During the discussion RAC Members were informed about the risk characterisation ratio (RCR), as estimated by the applicant in the Chemical Safety Report (CSR). RAC Members were informed of the similarities of this downstream application to the Diglyme_LIFE TECHNOLOGIES A.S application for authorisation, from which the Applicant has purchased the technology to produce this specific type of bead.

23. Diglyme - LIFE TECHNOLOGIES A.S.

This is a downstream user application for the use of Diglyme as a process chemical in the manufacture of beads, which are mono-sized particles used in biomolecular research and in the in-vitro immunodiagnostic assays market. The annual volume of the substance used is 11 tonnes, which is expected to rise to 34 tonnes/year and the Applicant requested a 12 year review period. During the discussion the RAC Members have been informed about the risk characterisation ratio (RCR), as estimated by the applicant themselves in the Chemical Safety Report (CSR).

24. Diglyme - BRACCO IMAGING S.P.A.

This is a downstream user application for the use of Diglyme as a processing aid in the purification of 5-amino-2,4,6-triiodoisophthalic acid dichloride by precipitation. The annual volume of the substance used is 200-300 t and the Applicant requested a 12 year review period.

25. Diglyme - MAFLON S.P.A.

This is a downstream user application for the use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity. The annual volume of the substance used is 10- 100 tonnes and the Applicant requested a 12 year review period.

26. Diglyme - ACTON TECHNOLOGIES Limited

This is a downstream user application for the two uses of:

1. bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes). The annual volume of the substance used is 20 tonnes and the applicant requested a 12 year review period.

2. bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural

integrity (downstream user processes). The annual volume of the substance used is 10 tonnes. The Applicant requested 12 years long review period.

27. Diglyme - ISOCHEM

This is a downstream user application for the use of Diglyme as a process solvent in the manufacturing of an intermediate for an active pharmaceutical ingredient (API). Annual volume of the substance used is 22 to 35 tonnes and the applicant requested 12 year review period. RAC Members were informed about the risk characterisation ratio (RCR), as estimated by the applicant in their Chemical Safety Report (CSR).

28. Technical MDA - POLYNT COMPOSITES France

This is a downstream user application for two uses:

1. Formulation of an epoxy resin hardener containing technical MDA. The annual volume of the substance used is ca. 30 tonnes and the Applicant requested a 12 year review period.

2. Industrial use of an epoxy resin hardener containing technical MDA aimed at immobilising spent ion exchange resins in a high containment matrix. The annual volume of the substance used is ca. 30 tonnes and the Applicant requested a 12 year review period.

29. EDC - EURENCO

This is a downstream user application for the industrial use of 1,2-Dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an energetic oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives. The annual volume of the substance used is ca. 3 tonnes and the Applicant requested 4 year review period.

b) Agreement on Draft Opinions

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

   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)

A RAC consultation was held on the draft opinions on all five uses from 2 to 9 May 2015. The Chairman informed the Committee that the legal deadline for the agreement on the RAC draft report on this application for authorisation was 23 May 2016. On 26 April 2016 the applicant

was informed about the postponement of the agreement on the draft opinions and that they will receive the draft opinions by 30 June 2016.

Summary of RAC-36 discussions:

The Committee agreed on the draft opinion on the Use 6.

RAC also agreed in principle on Use 1, noting significant uncertainties related to the description of Operational Conditions (OC) and Risk Management Measures (RMM) and their ability to adequately limit the risk to workers. RAC proposed to use the Applicant's estimate of combined exposure level of 0.5 μg/m^3 as 8 h average, resulting in an excess risk of 2×10^{-3} as a basis of further analyses by SEAC. This value was proposed by the Applicant in their CSR. RAC proposed to use the Applicant's estimate on general population exposure at the local scale for further analysis by SEAC. RAC then recommended additional conditions and monitoring arrangements for the application and the review report as described in the opinion. However, RAC did not at that time agree on any recommendation to SEAC with a bearing on the review period.

RAC also discussed the draft opinion on the Use 2 and concluded that there were uncertainties in the exposure assessment to workers arising mainly from the lack of clear information on the OC, and RMM applied, 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 at that time 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 at that time 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 until the RAC-37 plenary meeting. Draft opinions on Uses 3, 4 and 5 were not discussed during RAC-36.

RAC-37 discussions:

Use 1: Formulation of mixtures

During the discussion at RAC 37, one RAC Member noted the high variability of the available measured data supplied by the Applicant. In addition to the agreement reached at RAC-36 on the RAC draft opinion on the Use 1, the Committee agreed to give no advice to SEAC regarding the length of the review period.

Use 2: Functional chrome plating

The Committee also discussed the draft opinion on the Use 2. During the discussion Members expressed an increased level of confidence in the opinion, as drafted by the Rapporteurs. One RAC Member noted that it is necessary to state clearly that the Cr(VI) concentration of 2 μg/m^3 proposed by the applicant leads to a significant risk at the workplace and that in their opinion, even concentration of 0.5 μg/m^3 are associated with a relatively high risk. The member also pointed to the lack of a clear link between the proposed risk management measures (RMMs) and the exposures at the workplace. The Chairman responded that the size of the relative risks

was not the main issue in RAC's evaluation but whether the operational conditions and risk management measures were appropriate and effective in limiting the risks.

RAC concluded that there are considerable uncertainties in the broad Exposure Scenario provided. RAC would have expected to receive at least exposure data clearly linked to specific operational conditions (OCs), RMMs for representative sites with the justification as to how these can represent the applicant's claims. RAC noted the applicants' intentions to address these issues by the sunset date.

RAC proposed to use the applicants' estimate based on maximum combined exposure level for 8 hours of 2 μg/m^3, resulting in excess life-time lung cancer risk of 8 × 10^{-3} as the basis of further analyses by SEAC. Finally, RAC requested to modify the sentence beginning "Whilst monitoring campaigns are essential…" etc. by removing "below those provided in chapter 10 of the CSR."

Reflecting uncertainty concerns with the scope of the application for this use, RAC agreed to recommend to SEAC that the length of the review period should "not be longer than seven years" and agreed on the draft opinion on the Use 2.

Use 3: Functional chrome plating with decorative character

RAC again noted considerable uncertainties in the Exposure Scenario provided and reiterated the need to provide exposure data clearly linked to specific OCs, RMMs for representative sites with the justification as to how these can represent the applicant's claims. RAC noted the applicants' intentions to address these issues by the sunset date. RAC proposed to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 μg/m^3, resulting in excess life-time lung cancer risk of 8 × 10^{-3} as the basis of further analyses by SEAC. Finally, RAC requested to modify the sentence beginning "Whilst monitoring campaigns are essential…" etc. by removing "below those provided in chapter 10 of the CSR."

In this case, RAC gave no advice to SEAC regarding the length of the review period and agreed on the draft opinion on Use 3 as proposed by the Rapporteurs.

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

RAC again noted the considerable uncertainties in the Exposure Scenario provided, which covered surface treatment by immersion in baths, spray painting and also machining of finished parts. RAC proposed to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 μg/m^3, resulting in excess life-time lung cancer risk of 8 × 10^{-3} as the basis of further analyses by SEAC. Reflecting uncertainty concerns with the scope of the application for this use, in particular with regard to surface treatment by spraying and its associated activities, RAC agreed to recommend to SEAC that the length of the review period "should not be longer than seven years". RAC agreed on the draft opinion on Use 4.

Use 5: Surface treatment (except passivation of tin-plated steel (Use 6, ETP)) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to Functional chrome plating or Functional chrome plating with decorative character)

RAC again noted considerable uncertainties in the Exposure Scenario provided, which covered surface treatment by immersion in baths, spray painting and also machining of finished parts. RAC was informed by the Rapporteurs that the applicant had altered the conditions for respiratory protection in relation to spray painting and coating to reduce potential exposure times for this activity.

RAC proposed to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 μg/m^3, resulting in excess life-time lung cancer risk of 8 × 10^{-3} as the basis of further analyses by SEAC.

RAC gave no advice to SEAC regarding the length of the review period. RAC agreed on the draft opinion on Use 5.

Note on all Lanxess Deutschland GmbH uses described above: the exposure values for chromium trioxide proposed by the Applicant in their CSRs and their use in Socio-Economic analysis should not be seen as an endorsement by RAC of safe or acceptable exposure levels for workers or the environment.

2. **Sodium dichromate - Akzo Nobel**
3. **Sodium dichromate - Solvay**
4. **Sodium dichromate - Arkema**
5. **Sodium dichromate - Ercros**
6. **Sodium dichromate - Electroquimica**
7. **Sodium dichromate - Kemira**
8. **Sodium dichromate - Caffaro Brescia**

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 and agreeing draft opinions.

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 Brescia = 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 Rapporteurs presented their draft opinions on the applications. The Rapporteurs considered that RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. However, at the applicant's site there is room for improvement of the OCs/RMMs to even further reduce the exposure. The Rapporteurs further noted that the monitoring of exposure is not or not sufficiently developed, thus proposed specific conditions for reporting requirements.

RAC supported the Rapporteurs conclusions, however some debated the need to have specific conditions for the review report. RAC concluded that for any subsequent authorisation review report, the Applicant should provide additional occupational exposure measurements representative for all tasks, the number of workers that are potentially exposed and sites to demonstrate that the RMMs and OCs are still appropriate and effective in limiting the risks. RAC gave no specific advice to SEAC in relation to the review period. The Committee agreed the draft opinion by consensus. The Chairman thanked the Rapporteurs for their work on the application and the Committee for fruitful discussions.

9. **Chromium trioxide - Federal-Mogul Friedberg**

10. Chromium trioxide - Federal-Mogul Valvetrain

11. Chromium trioxide - Federal-Mogul Burscheid

RAC noted that the three applications above were submitted by the same corporation (Federal Mogul (FM)) and also bore strong similarities; they were therefore considered together for the purpose of discussing and agreeing on the draft opinions.

The Chairman reminded the Committee that the scope of the application CT_Valvetrain is narrow and well-defined. 20 tonnes of the substance are used annually (corresponding to 10 tonnes Cr(VI)) across the three sites operated by the Applicant (Orleans, Barsinghausen and Blumberg). 55 workers in total are potentially exposed to the substance and the Applicant had requested a 12 years review period.

According to the measured data provided, the concentration of Cr(VI) in the air varied between 0.05 μg/m^3 and 1.02 μg/m^3. RAC recommended that Applicant should implement regular campaigns of occupational exposure measurements.

The scope of the application CT_Burscheid is narrow and well-defined. 360 tonnes of the substance are used annually (corresponding to 180 tonnes Cr(VI)) across the three sites operated by the Applicant (Burscheid, Dresden and Garennes). In total 122 workers are potentially exposed to the substance and the Applicant requested a 12 years review period.

The scope of the application CT_Friedberg is narrow and well-defined. 120 tonnes of the substance are used annually (corresponding to 60 tonnes Cr(VI)) on the one site operated by the Applicant (Friedberg). 71 workers in total are exposed to the substance. The Applicant requested a 12 years review period.

RAC concluded that RMMs and OCs for all three cases are appropriate in limiting the risk, and agreed on the draft opinion as proposed by the Rapporteurs. However, RAC recommended that Applicant should implement regular campaigns of occupational exposure measurements. In addition, RAC agreed to offer no advice to SEAC regarding the length of the review period in all three cases.

12. Chromic acid-Bosch

The Chairman reminded the Committee that the substance is used on two sites operated by the Applicant: a) Bamberg with one unit consisting of two lines for hard chrome plating of parts in gasoline fuel injectors using 30 t of diluted chromic acid per year containing 7.5 t of CrO_3 and b) Homburg with one line for the coating of valve seats for common rail fuel injectors (CRIN) for truck diesel engines using 1.5 t of diluted chromic acid per year containing 375 kg of CrO_3. There are 26 workers involved in the operations with the substance at the Bamberg site, and 12 workers involved at the Homburg site. The size of the general population concerned is estimated at 10,000. The Applicant requested a 27 years review period.

RAC noted that RMMs and OCs are appropriate in limiting the risk, and agreed on the draft opinion as proposed by the Rapporteurs. RAC made no recommendations on conditions or monitoring arrangements. In addition, RAC agreed to offer no advice to SEAC regarding the length of the review period.

13. Chromium trioxide-Circuit Foil Luxembourg

14. Arsenic acid-Circuit Foil Luxembourg

These two applications were submitted by the same downstream user Circuit Foil Luxembourg 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 copper foil is processed through a sequence of chemical and electrochemical steps. A protective chemical conversion coating with chromium trioxide is applied to prevent corrosion to both surfaces of the foil during storage or lamination. Arsenic acid is used as adjuvant that prevents the formation of hydrogen during the electrochemical reactions.

In total, 49 workers are potentially exposed. The quantity used per year is 3.25 tonnes of arsenic acid and 15.80 tonnes of Cr(VI). In both uses the review period requested was 12 years.

In both applications the Applicant described the exposure values obtained from measured and modelled data.

The exposure scenarios included all relevant processes and are comprised 5 Worker Contributing Scenarios (WCS) and 1 Environmental Contribution Scenario (ECS).

The assessment for inhalation exposure is based on a qualitative assessment (WCS1), on measuring (one static measurement for WCS2 and one personal measurement for WCS3) and on modelling (WCS4 and WCS5) using ART 1.5. On RAC´s request for further data the applicant provided modelled data for WCS2 and WCS3. The modelled data (which did not take Respiratory protective Equipment into account) are comparable to the measured data. However, RAC notes that only for 2 WCS modelled and measured data are available. In addition, the applicant provided biomonitoring data of Cr(VI) in blood or urine and biomonitoring data of inorganic arsenic and total arsenic in urine. According to the applicant, the biomonitoring data is mainly used to assess whether workers were following the instructions for safety and health.

Following a request for clarification, a further assessment at the local scale based on EUSES modelling was provided for Cr(VI) and at the local and regional scales based on EUSES modelling arsenic acid. In addition, upon RAC's request the applicant provided an assessment for dermal exposure to arsenic acid based on qualitative assessment (WCS1) and on modelling (WCS 2–5), using ECETOC TRA 3.0.

Nonetheless, the RMMs appear to be appropriate and effective in limiting the risks to workers and the general population. However, the strategy for monitoring worker exposure and environmental releases is not considered to be sufficiently developed. RAC considers that the exposure assessment should be supplemented with additional monitoring data to increase its reliability. Additional monitoring should be representative of all tasks with potential for chromium trioxide and arsenic acid exposure.

RAC gave no specific advice to reduce the proposed review period. The Committee agreed the draft opinion by consensus with additional monitoring arrangements for the review report as proposed by the Rapporteurs.

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

The Chairman reminded the Committee that the application 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 and 2 are 500 kg/year, for the Use 3 300 kg/year, while Use 4 is performed across the two sites operated by the Applicant (Tulle and Roanne). 40 kg/year of chromium trioxide are used at Tulle site, and below 562 kg/year of the same substance at the Roanne site. 1 kg/year of

dichromium tris(chromate) is used at the Roanne site. The applicant is a downstream user of the substances and the total number of potentially exposed workers less than 10. It was noted that the size of the parts involved may be very large. The Applicant requested a 12 year review period for the Use 1, and seven years for Uses 2, 3 and 4.

For Use 4, RAC Members noted that the modelled data gave higher exposure values than the available monitoring data. One RAC Member noted that there is no local exhaust ventilation at the Tulle site, and that natural ventilation only is in place. The Member doubted the efficacy of the natural ventilation during the cold season of the year.

On the Uses 1, 2 and 3, RAC noted that the RMMs and OCs are appropriate in limiting the risk, and agreed on the draft opinions as proposed by the Rapporteurs. RAC recommended that the Applicants should implement regular campaigns of occupational exposure measurements. In addition, RAC agreed to offer no advice to SEAC regarding a length of the review period.

On the Use 4, RAC also noted that RMMs and OCs are appropriate in limiting the risk, and agreed on the draft opinions as proposed by the Rapporteurs and following the plenary discussion. In addition, RAC agreed to offer no advice to SEAC regarding a length of the review period.

16. Chromium trioxide - Praxair

This is an application for two uses of 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 (=use 1) and 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 (=use 2).

The application covers 5 sites (use 1) and 2 sites (use 2), the total volume of the substance used annually is respectively 0.4 0.07 tonnes. The number of workers potentially exposed is 43 (use 1) and 26 (use 2). The Applicant requested the review period of 12 years (use 1), 7 years (use 2) respectively.

All tasks represented by WCSs are well described. 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, model data was provided to cover environmental emissions to the atmosphere supported by a limited amount of measurement data.

Some uncertainties were however noted with regard to the actual effectiveness of the respiratory protection, which in the case the manual spraying task is the main barrier to exposure. Thus monitoring arrangements (air measurements and biomonitoring) for the manual spraying tasks were recommended in order to reduce such uncertainty.

The Committee was of the opinion that RMMs and OCs are appropriate in limiting the risk and gave no advice to SEAC regarding the length of the review period. RAC agreed on the draft opinion by consensus.

17. Potassium dichromate - Sofradir

This is a downstream application covering two sites (one use per site). The current production was developed under laboratory clean-room conditions and the current quantity used is below 1 tonne per year and less than 15 workers per use are potentially exposed; the intention is to

increase capacity if the authorisation is granted, at least until the envisaged alternatives will be implemented. The Applicant requested a review period of 7 years (use 1) and 4 years (use 2).

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 Applicant has reported only a limited amount of measured data for worker's inhalation exposure, which however are below or at a relatively low LOD (limit of detection), hence for worker exposure monitoring arrangements for the review report were proposed. It was further noted that indirect exposure to humans via the environment as calculated by the Applicant contained uncertainties related to the lack of measurements of emissions to the air), hence for the air releases monitoring arrangements for the authorisation were proposed.

The Committee considered that RMMs and OCs described in the application were appropriate and effective in limiting the risk to workers. RAC gave no advice to SEAC regarding the length of the review period. The Committee adopted the draft opinion by consensus.

18. Sodium dichromate - Lanxess

The Rapporteur presented the draft opinion on this downstream user application for authorisation for the use of sodium dichromate in industrial cooling systems and focussed on the OCs and RMM RMMs in place. The quantity used per year is low, covering one site with three cooling plants (in closed outdoor systems). According to the Rapporteur's assessment, RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC gave no advice to SEAC regarding the length of the review period. RAC made no recommendations on conditions or monitoring arrangements. The Committee agreed the draft opinion by consensus.

19. Ammonium dichromate - 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 substance is used at one site and the total quantity is 200 to 300 kg/year. The number of workers potentially exposed is 22. The Applicant requested 12 years long review period.

RAC noted that concerning worker exposure, the application contains very limited measured data consisting of 4 samples, collected using static sampling methodology. The modelling with ECETOC TRA submitted upon RAC's request for additional information was considered by the Rapporteurs as unsuitable, due to the use of inappropriate input parameters. Modelled dermal exposure also provided following RAC's request was dismissed as inappropriate by RAC Rapporteurs for the same reasons.

It was not clear to RAC where the potential sources of emission from this process were in relation to the few air samples that were reported. RAC concluded that due to uncertainties regarding the RMMs, and related to the representativeness of the measured data for workers' exposure, the appropriateness and effectiveness of RMMs and OCs in limiting the risk for workers has not been demonstrated by the applicant. RAC agreed on the draft opinion as proposed by the

Rapporteurs, except that, reflecting the uncertainties with regard to containment in the application, RAC proposed to modify the condition for the workplace monitoring; it has to be done as soon as the authorisation is granted / enters into effect, and annually thereafter. In addition, RAC agreed to offer no advice to SEAC regarding the length of the review period.

20. Chromium trioxide - Cromomed

The Rapporteurs presented their proposal for draft opinion on a downstream user application for authorisation for the use of chromium trioxide in functional chrome plating. The application covers five locations. According to the Rapporteurs' assessment, the RMMs and OCs described in the application are appropriate in limiting the exposure and the risk to workers sufficiently. However there is room for improvement. RAC agreed on the draft opinion as proposed by the Rapporteurs. In addition, RAC proposed monitoring arrangements to support and improve RMMs and agreed to offer no advice to SEAC regarding a length of the review period. The Committee agreed the draft opinion by consensus.

21. Chromium trioxide - Rimex Metals

The Rapporteurs presented the draft opinion on this application for authorisation for the use of chromium trioxide as an oxidising and hardening agent in the manufacture of coloured stainless steel. The application covers one site with 27 workers potentially exposed. According to the Rapporteurs' assessment, the RMMs and OCs described in the application are appropriate in limiting risks. RAC agreed on the draft opinion as proposed by the Rapporteurs and recommended additional conditions and monitoring arrangements. RAC also agreed to offer no advice to SEAC regarding the length of the review period. The Committee agreed the draft opinion by consensus.

22. EDC - BASF

The Rapporteurs 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 process takes place in a closed system and in the Rapporteurs' view the site-specific OC and RMM were sufficiently described.

RAC considered that the OCs and RMM were appropriate and effective in limiting the exposure and the risk to workers. RAC did not recommend any additional monitoring arrangements for the application, nor for the review report. RAC did not provide any advice to SEAC on the length of the review period. The Committee agreed on the draft opinion by consensus.

23. Diglyme - Novartis

The Rapporteurs 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 process takes place in a closed system and in the Rapporteurs' view the site-specific OCs and RMM were adequately described.

RAC considered that adequate control of the risk has been demonstrated. RAC did not recommend any additional monitoring arrangements for the application, nor for the review report. RAC did not provide any advice to SEAC on the length of the review period. The Committee agreed on the draft opinion by consensus.

c) Discussion of applications

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

The above five applications for authorisation were submitted by the same consortium (CCST) and bore strong similarities, therefore they were considered together for discussion at this plenary meeting. Four uses have been applied for: formulation (by all five applicants), surface treatment (by three applicants), painting and coating (by two applicants) and electrolytic passivation of tin plated steel (by one applicant).

The Rapporteurs presented the state of play, noting that the draft opinions were in preparation, as well as their first assessment of these five applications for authorisation. The Committee discussed the points raised by the Rapporteurs, and provided feedback in view of the trialogue meeting and of the preparation of the draft opinions.

RAC reiterated that the uses are broad and that the Applicants would need to provide improved descriptions of the processes covered, the tasks involved, as well as the RMMs and OCs per WCS. Photos of the machining process would be also welcomed for a better understanding of this process.

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. Moreover, it could be beneficial to use the available measurement data as input to the ART model.

Lastly, RAC highlighted that information that is to be considered in the evaluation of each of these five applications would have to be provided by the Applicants, and it is not sufficient to refer to previous, similar applications for authorisation.

The Rapporteurs will consider the advice and guidance given by RAC Members and will prepare the draft opinions for consultation with RAC Members, also taking in to consideration the Applicants' answers to a second set of questions and the outcome of the trialogue meeting scheduled for 21 June 2016. A consultation with RAC Members on the draft opinion will be held during the summer period.

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/37/2016/09, was then agreed by RAC.

10. AOB

None.

3 June 2016

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 37 23–27 May 2016
30 May-3 June 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/37/2016**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-37 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 36 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/37/2016/01** and document **RAC/37/2016/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the 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-37 meeting on CIRCABC.
6. Requests under Article 95 (3)	
a) 1-methyl-2-pyrrolidone (NMP)	
RAC agreed with the assessment of the RAC Members of the joint RAC-SCOEL working group to resolve the differences in scientific opinion as regards exposure levels for N-Methyl-2-pyrrolidone (NMP).	**SECR** to forward the RAC-assessment to COM and the SCOEL Secretariat (DG EMPL)
7. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement without plenary debate • Phosmet (ISO): Acute Tox. 3 (H301), Acute Tox. 4 (H332), no classification for acute dermal toxicity, no classification for germ cell mutagenicity, no classification for carcinogenicity, no classification for developmental reproductive toxicity • Pinoxaden (ISO): no classification for the physical hazards, no classification for acute dermal toxicity, Acute Tox. 4 (H332), Eye Irrit. 2 (H319), Skin Sens. 1A (H317), no classification for aspiration hazard, Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 3 (H412) • Quizalofop-p-tefuryl: no classification for the physical hazards, Acute Tox. 4 (H302), no classification for acute dermal and inhalation toxicity, no classification for skin corrosion	

/ irritation, no classification for serious eye damage / eye irritation, no classification for respiratory sensitisation, no classification for germ cell mutagenicity, no classification for aspiration hazard, Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 1 (H410) with M=1

- S-methoprene: no classification for the physical hazards, no classification for acute toxicity (all routes of exposure), no classification for skin corrosion / irritation, no classification for serious eye damage / eye 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, Aquatic Acute 1 (H400) with M=1, Aquatic Chronic 1 (H410) with M=1
- Isoproturon (ISO): Aquatic Acute 1 (H400) with M=10, Aquatic Chronic 1 (H410) with M=10

B. Substances with hazard classes for agreement in plenary session

a) Acetaldehyde, ethanal

b) Epsilon-metofluthrin

c) Phosmet (ISO)

d) Pinoxaden (ISO)

e) Quizalofop-P-tefuryl

f) S-methoprene

g) Sodium hypochloride, solution … % Cl active

h) 4-tert-butylphenol

i) Isoproturon (ISO)

j) Isobutyl methacrylate

a) Acetaldehyde, ethanal

RAC discussed the proposal for the harmonised classification and labelling as indicated in Table 2 below. RAC asked for further clarification on the Mode of Action. The final conclusion on the dossier has been postponed and RAC will conclude on harmonised C&L at the next RAC plenary meeting (September 2016).	**SECR** to launch a targeted public consultation on the Mode of Action and the revised RCOM table. **Rapporteurs** to revise the opinion in accordance with the discussion in RAC and comments received during the targeted PC, as necessary and to provide it to the SECR. **SECR** to table the dossier for discussion and agreement at RAC 38.

b) Epsilon-metofluthrin

RAC adopted by majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. At RAC-37: STOT SE 1 (H370; nervous system), STOT RE 2 (H373) At RAC-36: Acute Tox. 3 (H301), Acute Tox. 4 (H332), Aquatic Acute 1 (H400; M=100), Aquatic Chronic 1 (H410; 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 Rapporteur. **SECR** to forward the adopted opinion and its annexes (including one minority opinion) to COM and publish it on the ECHA website.

c) Phosmet (ISO)

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 3 (H301), Acute Tox. 4 (H332), STOT SE 1 (H370; nervous system), Repr. 2 (H361f), Aquatic Acute 1 (H400; M=100), Aquatic Chronic 1 (H410; 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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
d) Pinoxaden (ISO)	
RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. Acute Tox. 4; H332, Acute Tox. 4; H302, Eye Irrit. 2; H319, Skin Sens. 1A; H317, Repr. 2; H361d, Aquatic Acute 1; H400, M=1, Aquatic Chronic 3; H412	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to launch a RAC consultation on the revised draft opinion for the hazard classes respiratory irritation / sensitisation. **IND** to provide any further clarification on the cases of workers exposed to Pinoxaden. **Rapporteurs** to revise the draft opinion and provide it to the SECR for the discussion and agreement at RAC 38.
e) Quizalofop-P-tefuryl	
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), STOT RE 2 (H373), Carc. 2 (H351), Repr. 2 (H361fd), Aquatic Acute 1 (H400; M=1), Aquatic Chronic 1 (H410; M=1)	**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) S-methoprene	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=1	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
g) Sodium hypochlorite, solution … % Cl active	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=1)	**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) 4-tert-butylphenol	
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; M=1)	**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 Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
i) Isoproturon (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. STOT RE 2 (H373; blood), Aquatic Acute 1 (H400; M=10), Aquatic Chronic 1 (H410; M=10)	**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.
j) Isobutyl methacrylate	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Skin Sens. 1B (H317)	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
7.2 Appointment of RAC (co-)rapporteurs for CLH dossiers	
RAC appointed the new (co-)rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)rapporteurs to CIRCABC confidential.
8. Restrictions	
8.1 General restriction issues	
a) Capacity building - Carcinogenicity dose-response relationship setting for cobalt salts	
The ECHA Contractor presented the updated draft report on carcinogenicity dose-response relationship setting for cobalt salts.	**SECR** to request the consultant to update the agreed note in accordance with the discussion in RAC-37.

RAC agreed on the note on the carcinogenicity dose-response relationship setting for cobalt salts.	**SECR** to publish the note on the ECHA website.
8.2 Restriction Annex XV dossiers	
a) Conformity check	
1) TDFAs – outcome of the conformity check and presentation of the key issues RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter. The Rapporteurs presented and RAC discussed the key issues for the RAC opinion.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC IG. **SECR** to inform the dossier submitter on the outcome of the conformity check.
2)Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) – outcome of the conformity check and presentation of the key issues RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter. The Rapporteurs presented and RAC discussed the key issues for the RAC opinion.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC IG. **SECR** to inform the dossier submitter on the outcome of the conformity check.
9. Authorisation	
9.1 General authorisation issues	
a) Capacity building	
1. DNEL setting for the reprotoxic properties of 1-bromopropane ECHA Contractor presented a revised draft report on DNEL setting for the reprotoxic properties of 1-bromopropane. The Committee discussed the draft report by the ECHA Contractor. The Committee gave advice to the ECHA Contractor on further improvements of the draft report. Specifically, RAC recommended the contractor to summarise the relevant study results in table form, including the significance and reversibility of the effects, to provide a comprehensive overview of the available data and facilitate an agreement on the most appropriate starting point for DNEL derivation.	**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 and agreement at RAC-38.
2. DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP) ECHA Contractor presented a revised draft report on DNEL setting for the reprotoxic properties of DIPP.	**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

The Committee discussed the draft report by the ECHA Contractor. The Committee recommended the ECHA Contractor to strengthen the selection of phthalates for read-across to DIPP. It was recommended to take a more holistic approach and assess the effects of a wider selection of phthalate compounds (e.g. reduced foetal testosterone). Additionally RAC highlighted the need for consistency between the report on DNEL setting for the reprotoxic properties of DIPP and the restriction proposal on phthalates (DIBP, DBP, BBP, DEHP).	for the discussion and agreement at RAC-38.
3. Carcinogenicity dose-response relationship development for Al-RCF and Zr-RCF 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, which presented an overview of the methodology and conclusions of other International and National bodies. RAC agreed to await regulatory developments with these substances before proceeding with reference values.	**ECHA Contractor** to consider the discussion at the Committee, to update the draft report and to submit it to SECR.
b) Applications for authorisation received in the May submission window	
SECR introduced to the Committee applications for authorisation received during the May Submission Window (from 6 to 20 May 2016).	
9.2 Authorisation applications	
a) Outcome of the conformity check and presentation of the key issues	
1. Chromium trioxide_SNECMA **2. Chromium trioxide_MTU** **3. Chromium trioxide_ABLOY** **4. Chromium trioxide_HOOGOVENS Court Roll Surface Technologies** **5. Chromium trioxide_TOPOCROM GmbH** **6. Chromium trioxide_FN HERSTAL S.A.** **7. Chromium trioxide_GERARDHI KUNSTOFFTECHNIK GmbH** **8. Chromium trioxide; Potassium dichromate; Sodium dichromate_SOURIAU SAS**	**SECR** to upload to CIRCABC the agreed Conformity Reports. **SECR** to inform SEAC about the outcome of the Conformity checks. **SECR** to inform the applicants about the outcome of the conformity checks.

9. Chromium trioxide_HAPPOC **10. Ammonium dichromate_VECO BV** **11. Potassium dichromate_GENTROCHEMA BV** **12. Sodium dichromate_GENTROCHEMA BV** **13.Sodium dichromate_TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH** **14. Sodium dichromate_JACOBS DOUWEE EGBERTS DE GmbH** **15. EDC_BASF SE** **16. EDC_ELI LILLY S.A.** **17. EDC_DOW ITALIA S.R.L.** **18. EDC_LANXESS Deutschland GmbH** **19. EDC_H&R OLWERKE SCHINDLER GmbH** **20. EDC_GRUPPA LOTOS S.A.** **21. EDC_GE HEALTHCARE Bio-Sciences** **22. Diglyme_ROCHE DIAGNOSTIC GmbH** **23. Diglyme_LIFE TECHNOLOGIES A.S.** **24. Diglyme_BRACCO IMAGING S.P.A.** **25. Diglyme_MAFLON S.P.A.** **26. Diglyme_ACTON TECHNOLOGIES Limited** **27. Diglyme_ISOCHEM** **28. Technical MDA_POLYNT COMPOSITES France** **29. EDC_EURENCO**	

RAC agreed on conformity of 29 applications for authorisation. RAC discussed the key issues in the 29 applications for authorisation and provided advice to the Rapporteurs.	
b) Agreement on Draft Opinions	
1 Chromium trioxide 1 (5 uses) (CT_Lanxess) <u>Use 1</u> In addition to the agreement reached at RAC-36 on the RAC draft opinion on Use 1, the Committee agreed to give no advice to SEAC regarding the length of the review period. <u>Use 2</u> RAC agreed on the draft opinion on Use 2 as proposed by the Rapporteurs. RAC notes considerable uncertainties in the Exposure Scenario provided; especially, RAC would have expected to receive at least exposure data clearly linked to specific OCs, RMMs for representative sites with the justification as to how these can represent the applicant's claims. RAC notes the applicants' intentions to address the issues by the sunset date. • RAC proposes to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 µg/m^3, resulting in excess life-time lung cancer risk of 8×10^{-3} as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in their CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as safe or acceptable level for this non-threshold substance. • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • Reflecting uncertainty concerns with the very wide scope of the application for this use, RAC agreed to recommend to SEAC that the length of the review period should "*not be longer than seven years*". <u>Use 3</u> RAC agreed on the draft opinion on Use 3 as proposed by the Rapporteurs. RAC notes considerable uncertainties in the Exposure Scenario provided;	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions on the Uses 1, 2, 3, 4, 5 and 6. **SECR** to send the draft opinions to the Applicants for commenting.

especially, RAC would have expected to receive at least exposure data clearly linked to specific OCs, RMMs for representative sites with the justification as to how these can represent the applicant's claims. RAC notes the applicants' intentions to address the issues by the sunset date. • RAC requested to modify the sentence beginning "Whilst monitoring campaigns are essential…etc." by removing "*below those provided in chapter 10 of the CSR.*" • RAC proposes to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 µg/m^3, resulting in excess life-time lung cancer risk of 8×10^{-3} as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as safe or acceptable level for this non-threshold substance. • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • RAC gave no advice to SEAC regarding the length of the review period. <u>Use 4</u> RAC agreed on the draft opinion on Use 4. RAC notes considerable uncertainties in the Exposure Scenario provided, especially RAC would have expected to receive at least exposure data clearly linked to specific OCs, RMMs for representative sites with the justification as to how these can represent the applicant's claims. RAC notes the applicants' intentions to address the issues by the sunset date. • RAC requested to modify the sentence beginning "Whilst monitoring campaigns are essential…etc." by removing "*below those provided in chapter 10 of the CSR.*" • RAC proposes to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 µg/m^3, resulting in excess life-time lung cancer risk of 8×10^{-3} as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by	

RAC as safe or acceptable level for this non-threshold substance. • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • Reflecting uncertainty concerns with the scope of the application for this use, in particular with regard to surface treatment by spraying and its associated activities, RAC agreed to recommend to SEAC that the length of the review period "*should not be longer than seven years*". <u>Use 5</u> RAC agreed on the draft opinion on Use 5. RAC notes considerable uncertainties in the Exposure Scenario provided, especially RAC would have expected to receive at least exposure data clearly linked to specific OCs, RMMs for representative sites with the justification as to how these can represent the applicant's claims. RAC notes the applicants' intentions to address the issues by the sunset date. • RAC requested to modify the sentence beginning "Whilst monitoring campaigns are essential…etc." by removing "*below those provided in chapter 10 of the CSR.*" • RAC proposes to use the applicants' estimate on maximum combined exposure level for 8 hours of 2 μg/m^3, resulting in excess life-time lung cancer risk of 8×10^{-3} as the basis of further analyses by SEAC. It should be noted that this value is proposed by the applicant in CSR and its use for socio-economic purposes by SEAC should not be seen as an endorsement by RAC as safe or acceptable level for this non-threshold substance. • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • RAC gave no advice to SEAC on the length of the review period. <u>Use 6</u> RAC had previously agreed this use at its 36th meeting.	

2. Sodium dichromate-Akzo Nobel (2 uses) (SD_Akzo) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
3. Sodium dichromate-Solvay (1 use) (SD_Solvay) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
4. Sodium dichromate-Arkema (1 use) (SD_Arkema) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
5. Sodium dichromate-Ercros (1 use) (SD_Ercros) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicants for commenting.
6. Sodium dichromate-Electroquimica (1 use) (SD_ELECTRQUIMICA) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

7. Sodium dichromate-Kemira (1 use) (SD_Kemira) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinions to the Applicant for commenting.
8. Sodium dichromate-Caffaro Brescia (1 use) (SD_Caffaro) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
9. Chromium trioxide-Federal-Mogul Friedberg (1 use) (CT_Friedberg) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended that the Applicant implement regular campaigns of occupational exposure measurements. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.
10. Chromium trioxide-Federal-Mogul Valvetrain (1 use) (CT_Valvetrain) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended that the Applicant implement regular campaigns of occupational exposure measurements. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.
11. Chromium trioxide-Federal-Mogul Burscheid (1 use) (CT_Burscheid) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended that the Applicant implement regular campaigns of occupational exposure measurements. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.

12. Chromic acid-Bosch (1 use) (CA_Bosch) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC made no recommendations on conditions or monitoring arrangements RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
13. Chromium trioxide-Circuit Foil Luxembourg (1 use) (CT_Circuit) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.
14. Arsenic acid-Circuit Foil Luxembourg (1 use) (AsA_Circuit) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended monitoring arrangements for review reports. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.
15. Chromium trioxide and dichromium tris(chromate)-Nexter Mechanics (4 uses) (CT_DtC_Nexter) <u>Uses 1-3</u> RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC recommended that the Applicants need to implement regular campaigns of occupational exposure measurements. RAC agreed to offer no advice to SEAC on the length of the review period. <u>Use 4</u> RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinions as proposed by the Rapporteurs and following the plenary discussion. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.

16. Chromium trioxide-Praxair (2 uses) (CT_Praxair) <u>Use 1 & 2:</u> RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion. RAC recommended monitoring arrangements for the authorisation and for the review reports. RAC gave no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.
17. Potassium dichromate-Sofradir (2 uses) (PD_Sofradir) <u>Use 1 & 2:</u> RAC is of the opinion that RMMs and OCs are appropriate in limiting the risks. RAC agreed on the draft opinion. RAC recommended monitoring arrangements for the authorisation and for the review reports. RAC gave no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicants for commenting.
18. Sodium dichromate-Lanxess (1 use) (SD_Lanxess) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC agreed on the draft opinion as proposed by the Rapporteur. RAC made no recommendations on conditions or monitoring arrangements. RAC agreed to offer no advice to SEAC on the length of the 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.
19. Ammonium dichromate-Micrometal (1 use) (AD_Micrometal) Due to uncertainties regarding the RMMs, and related to the representativeness of the measured data for workers' exposure, RAC is of the opinion that the appropriateness and effectiveness of RMMs / OCs in limiting the risk for workers has not been demonstrated by the applicant. RAC agreed on the draft opinion as proposed by the Rapporteurs, except that, reflecting the uncertainties with regard to containment in the application, RAC proposes to modify the condition for the workplace monitoring – it is to be performed as soon as authorisation has been granted / enters into effect, and annually thereafter. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
20. Chromium trioxide-Cromomed (1 use) (CT_Cromomed)	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

RAC is of the opinion that RMMs and OCs are appropriate in limiting the risks to workers, however there is room for improvements. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended to propose monitoring arrangements for the application. RAC had no advice to SEAC on the length of the review period.	**SECR** to send the draft opinion to the Applicant for commenting.
21. Chromium trioxide-Rimex Metals (1 use) (CT_Rimex) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risks. RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC recommended additional conditions and monitoring arrangements. RAC agreed to offer no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
22. EDC-BASF (1 use) (EDC_BASF) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risks. RAC made no recommendations on conditions or monitoring arrangements for the application or the review period. RAC had no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
23. Diglyme-Novartis (Diglyme_Novartis) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the risk appears to be adequately controlled. RAC made no recommendations on conditions or monitoring arrangements. RAC had no advice to SEAC on the length of the review period.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
c) Orientation discussion of applications	
1. Sodium dichromate-Brenntag (3 uses) (SD_Brenntag, CCST consortium) **2. Potassium dichromate-Brenntag (2 uses) (PD_Brenntag, CCST consortium)** **3. Dichromium tris(chromate)-Henkel (2 uses) (DtC_Henkel, CCST consortium)** **4. Strontium chromate-Akzo Nobel (2 uses) (SC_Akzo, CCST consortium)**	**Rapporteurs** to consider plenary discussions and prepare the Draft Opinions for the applied uses for a consultation with RAC Members. The Draft Opinions will be tabled for discussion for agreement at RAC 38.

5. Potassium hydroxyoctaoxodizincatedichromate-PPG (2 uses) (PH_PPG, CCST consortium)	
9.3 Appointment of (co-)rapporteurs for authorisation applications **RAC/37/2016/09** 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-37	
SECR to upload the adopted action points to CIRCABC.	

Table 1: CLH dossiers for which RAC adopted an opinion

Note: where hazard classes of an existing entry were not proposed to be changed by the Dossier Submitter, these are highlighted in grey colour

S-methoprene; isopropyl (2*E*,4*E*,7*S*)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	isopropyl (2*E*,4*E*,7*S*)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate; S-methoprene	-	65733-16-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	
RAC opinion	TBD	isopropyl (2*E*,4*E*,7*S*)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate; S-methoprene	-	65733-16-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	isopropyl (2*E*,4*E*,7*S*)-11-methoxy-3,7,11-trimethyldodeca-2,4-dienoate; S-methoprene	-	65733-16-6	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	

Phosmet (ISO); *S*-[(1,3-dioxo-1,3-dihydro-2*H*-isoindol-2-yl)methyl] *O,O*-dimethyl phosphorodithioate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard stateme nt Code(s)		
Current Annex VI entry	015-101-00-5	phosmet (ISO); S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate	211-987-4	732-11-6	Acute Tox. 4 * Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H302 H312 H400 H410	GHS07 GHS09 Wng	H302 H312 H410		M=100	
Dossier submitter's proposal	015-101-00-5	phosmet (ISO); S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate	211-987-4	732-11-6	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Acute Tox. 4 STOT RE 1 **Modify** Acute Tox. 3 **Remove** Acute Tox. 4 *	**Retain** H400 H410 **Add** H332 H372 (nervous system) **Modify** H301 **Remove** H312	**Retain** GHS09 **Add** GHS06 GHS08 **Modify** Dgr **Remove** GHS07	**Retain** H410 **Add** H332 H372 (nervous system) **Modify** H301 **Remove** H312		**Retain** M=100 **Add** M=10	
RAC opinion	015-101-00-5	phosmet (ISO); S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-dimethyl phosphorodithioate	211-987-4	732-11-6	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 Acute Tox. 4 STOT SE 1 **Modify** Acute Tox. 3 **Remove** Acute Tox. 4 *	**Retain** H400 H410 **Add** H361f H332 H370 (nervous system) **Modify** H301 **Remove** H312	**Retain** GHS09 **Add** GHS06 GHS08 **Modify** Dgr **Remove** GHS07	**Retain** H410 **Add** H361f H332 H370 (nervous system) **Modify** H301 **Remove** H312		**Retain** M=100 **Add** M=100	
Resulting Annex VI entry if agreed by COM	015-101-00-5	phosmet (ISO); S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl] O,O-	211-987-4	732-11-6	Repr. 2 Acute Tox. 4 Acute Tox. 3 STOT SE 1 Aquatic Acute 1	H361f H332 H301 H370 (nervous system)	GHS08 GHS06 GHS09 Dgr	H361f H332 H301 H370 (nervous system)		M=100 M=100	

		dimethyl phosphorodithioate			Aquatic Chronic 1	H400 H410		H410			

Quizalofop-p-tefuryl (ISO); (+/-) tetrahydrofurfuryl (*R*)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-373-00-4	Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	200509-41-7	Acute Tox. 4 * Muta. 2 Repr. 1B STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H302 H341 H360Df H373 ** H400 H410	GHS07 GHS08 GHS09 Dgr	H302 H341 H360Df H373 ** H410			
Dossier submitter's proposal	607-373-00-4	Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	200509-41-7	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 Skin Sens. 1B **Modify** Acute Tox. 4 Repr. 2 **Remove** STOT RE 2 * Muta. 2	**Retain** H400 H410 **Add** H351 H317 **Modify** H302 H361fd **Remove** H373** H341	**Retain** GHS07 GHS08 GHS09 **Add** Wng **Remove** Dgr	**Retain** H410 **Add** H351 H317 **Modify** H302 H361fd **Remove** H373 ** H341		**Add** M=1 M=1	
RAC opinion	607-373-00-4	Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	200509-41-7	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 **Modify** Repr. 2 Acute Tox. 4 STOT RE 2 **Remove** Muta. 2	**Retain** H400 H410 **Add** H351 **Modify** H361fd H302 H373 **Remove** H341	**Retain** GHS07 GHS08 GHS09 **Add** Wng **Remove** Dgr	**Retain** H410 **Add** H351 **Modify** H361fd H302 H373 **Remove** H341		**Add** M=1 M=1	
Resulting Annex VI entry if agreed by COM	607-373-00-4	Quizalofop-P-tefuryl; (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenyloxy]propionate	414-200-4	200509-41-7	Carc. 2 Repr. 2 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H361fd H302 H373 H400 H410	GHS07 GHS08 GHS09 Wng	H351 H361fd H302 H373 H410		M=1 M=1	

Sodium hypochlorite, solution ...%Cl active

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	017-011-00-1	sodium hypochlorite, solution ... % Cl active	231-668-3	7681-52-9	Skin Corr. 1B Aquatic Acute 1	H314 H400	GHS05 GHS09 Dgr	H314 H400	EUH031		B
Dossier submitter's proposal	017-011-00-1	sodium hypochlorite, solution ... % Cl active	231-668-3	7681-52-9	**Retain** Aquatic Acute 1 **Add** Aquatic Chronic 1	**Retain** H400 **Add** H410	**Retain** GHS09	**Add** H410 **Remove** H400		**Add** M=100 M=10	
RAC opinion	017-011-00-1	sodium hypochlorite, solution ... % Cl active	231-668-3	7681-52-9	**Retain** Aquatic Acute 1 **Add** Aquatic Chronic 1	**Retain** H400 **Add** H410	**Retain** GHS09	**Add** H410 **Remove** H400		**Add** M=10 M=1	
Resulting Annex VI entry if agreed by COM	017-011-00-1	sodium hypochlorite, solution ... % Cl active	231-668-3	7681-52-9	Skin Corr. 1B Aquatic Acute 1 Aquatic Chronic 1	H314 H400 H410	GHS05 GHS09 Dgr	H314 H410	EUH031	M=10 M=1	B

4-tert-butylphenol

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	Repr. 2 Skin Irrit. 2 Eye Dam. 1	H361f H315 H318	GHS08 GHS05 Dgr	H361f H315 H318			
Dossier submitter's proposal	604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	**Add** Aquatic Chronic 1	**Add** H410	**Add** GHS09	**Add** H410		**Add** M=1	
RAC opinion	604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	**Add** Aquatic Chronic 1	**Add** H410	**Add** GHS09	**Add** H410		**Add** M=1	
Resulting Annex VI entry if agreed by COM	604-090-00-8	4-tert-butylphenol	202-679-0	98-54-4	Repr. 2 Skin Irrit. 2 Eye Dam. 1 Aquatic Chronic 1	H361f H315 H318 H410	GHS08 GHS05 GHS09 Dgr	H361f H315 H318 H410		M=1	

Isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	006-044-00-7	isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	Carc. 2 Aquatic Acute 1 Aquatic Acute 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=10	
Dossier submitter's proposal	006-044-00-7	isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Repr. 2 STOT RE 2	**Retain** H400 H410 **Add** H361f H373 (oral, blood)	**Retain** GHS09 Wng	**Retain** H410 **Add** H361f H373 (oral, blood)		**Retain** M=10 **Add** M=10	
RAC opinion	006-044-00-7	isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2	**Retain** H400 H410 **Add** H373 (blood)	**Retain** GHS09 Wng	**Retain** H410 **Add** H373 (blood)		**Retain** M=10 **Add** M=10	
Resulting Annex VI entry if agreed by COM	006-044-00-7	isoproturon (ISO); 3-(4-isopropylphenyl)-1,1-dimethylurea	251-835-4	34123-59-6	Carc. 2 STOT RE 2 Aquatic Acute 1 Aquatic Acute 1	H351 H373 (blood) H400 H410	GHS08 GHS09 Wng	H351 H373 (blood) H410		M=10 M=10	

Isobutyl methacrylate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling				
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	Specific Conc. Limits, M-factors	Notes
Current Annex VI entry	607-113-00-X	isobutyl methacrylate	202-613-0	97-86-9	Flam. Liq. 3 STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1	H226 H335 H315 H319 H317 H400	GHS02 GHS07 GHS09 Wng	H226 H335 H315 H319 H317 H400			D
Dossier submitter's proposal	607-113-00-X	isobutyl methacrylate	202-613-0	97-86-9	**Modify** Skin Sens. 1B **Remove** Eye Irrit. 2 Aquatic Acute 1	**Retain** H317 **Remove** H319 H400	**Retain** GHS07 Wng **Remove** GHS09	**Retain** H317 **Remove** H319 H400			
RAC opinion	607-113-00-X	isobutyl methacrylate	202-613-0	97-86-9	**Modify** Skin Sens. 1B **Remove** Eye Irrit. 2 Aquatic Acute 1	**Retain** H317 **Remove** H319 H400	**Retain** GHS07 Wng **Remove** GHS09	**Retain** H317 **Remove** H319 H400			
Resulting Annex VI entry if agreed by COM	607-113-00-X	isobutyl methacrylate	202-613-0	97-86-9	Flam. Liq. 3 STOT SE 3 Skin Irrit. 2 Skin Sens. 1B	H226 H335 H315 H317	GHS02 GHS07 Dgr	H226 H335 H315 H317			D

Epsilon-metofluthrin; 2,3,5,6-tetrafluoro-4-(methoxymethyl)benzyl (1*R*,3*R*)-2,2-dimethyl-3-[(1*Z*)-prop-1-en-1-yl]cyclopropanecarboxylate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier 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. 4 Acute Tox. 3 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H301 H373 (inhalation) H400 H410	GHS06 GHS08 GHS09 Dgr	H332 H301 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. 4 Acute Tox. 3 STOT SE 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H301 H370 (nervous system) H373 H400 H410	GHS06 GHS08 GHS09 Dgr	H332 H301 H370 (nervous system) H373 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	Acute Tox. 4 Acute Tox. 3 STOT SE 1 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H332 H301 H370 (nervous system) H373 H400 H410	GHS06 GHS08 GHS09 Dgr	H332 H301 H370 (nervous system) H373 H410		M=100 M=100	

Table 2: CLH dossiers for which RAC agreed on specified hazard classes

Note:

- where hazard classes of an existing entry were not proposed to be changed by the Dossier Submitter, these are highlighted in grey colour
- where hazard classes were agreed while the opinion has not yet been adopted, these are highlighted in **bold**
- where hazard classes still need to be agreed by RAC, these are highlighted in yellow colour

Acetaldehyde; ethanal

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	605-003-00-6	acetaldehyde; ethanal	200-836-8	75-07-0	Flam. Liq. 1 Eye Irrit. 2 STOT SE 3 Carc. 2	H224 H319 H335 H351	GHS02 GHS07 GHS08 Dgr	H224 H319 H335 H351			
Dossier submitter's proposal	605-003-00-6	acetaldehyde; ethanal	200-836-8	75-07-0	**Add** Muta. 1B **Modify** Carc. 1B	**Add** H340 **Modify** H350	**Retain** GHS08 Dgr	**Add** H340 **Modify** H350			
RAC opinion	605-003-00-6	acetaldehyde; ethanal	200-836-8	75-07-0	**Retain** Carc. 2 **Add** Muta. 2	**Retain** H351 **Add** H341	**Retain** GHS08 Dgr	**Retain** H351 **Add** H341			
Resulting Annex VI entry if agreed by COM	605-003-00-6	acetaldehyde; ethanal	200-836-8	75-07-0							

Pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7*H*-pyrazolo [1,2-*d*][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate

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

	Index No	**International Chemical Identification**	**EC No**	**CAS No**	**Classification**		**Labelling**			**Specific Conc. Limits, M-factors**	**Notes**
					Hazard Class and Category Code(s)	**Hazard statement Code(s)**	**Pictogram, Signal Word Code(s)**	**Hazard state-ment Code(s)**	**Suppl. Hazard statement Code(s)**		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate	-	243973-20-8	Acute Tox. 4 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1A STOT SE 3 Aquatic Acute 1 Aquatic Chronic 3	H332 H315 H319 H317 H335 H400 H412	GHS07 GHS09 Wng	H332 H315 H319 H317 H335 H412		M=1	
RAC opinion	TBD	pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate	-	243973-20-8	**Retain** **Acute Tox. 4** **Eye Irrit. 2** **Skin Sens. 1A** **Aquatic Acute 1** **Aquatic Chronic 3** **Add** **Acute Tox. 4** **Repr. 2** **Modify** Resp. Sens. & / or STOT SE 3 **Remove** **Skin Irrit. 2**	**Retain** **H332** **H319** **H317** **H400** **H412** **Add** **H302** **H361d** **Modify** H334 & / or H335 **Remove** **H315**	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** **H332** **H319** **H317** **H410** **Add** **H302** **H361d** **Modify** H334 & / or H335 **Remove** **H315**		**M=1**	
Resulting Annex VI entry if agreed by COM	TBD	pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-	-	243973-20-8							

		9-yl 2,2-dimethylpropanoate									

Part III. List of Attendees of the RAC-37 meeting

23-27 May 2016 and 30 May-3 June 2016

RAC Members
BARANSKI Bogusław
BIRO Anna
BJORGE Christine
BRANISTEANU Radu (2nd week only)
CARVALHO João
CHANKOVA-PETROVA Stephka
CHIURTU Elena (co-opted Member)
CZERCZAK Slawomir
DE LA FLOR TEJERO Ignacio
DI PROSPERO FANGHELLA Paola (2nd week only)
DUNAUSKIENĖ Lina
DUNGEY Stephen (2nd week only)
GRUIZ Katalin
GUSTAFSON Anne-Lee (2nd week only)
HUSA Stine
ILIE Mihaela (1st week only)
JANKOWSKA Elzbieta (co-opted Member)
KADIĶIS Normunds
KAPELARI Sonja
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MOELLER Ruth
MULLOOLY Yvonne
MURRAY Brendan (2nd week only)
NEUMANN Michael (2nd week only)
PARIS Pietro
PASQUIER Elodie (1st week only)
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLUETER Urs
SCHULTE Agnes
SMITH Andrew (2nd week only)
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)
Apologies
ANDREOU Kostas
COPIN Stephanie (maternity leave)
HAKKERT Betty
HÖLZL Christine (maternity leave)

Invited experts
DEWHURST Ian (Health&Safety Executive UK) DNEL (1st week only)
KOVAL Ira (AI.RCF AfA)
LARSEN Poul Bo (DHI) cobalt salts (1st week only)
LOSERT Annemarie (replacement for RAC Member Christine Hölzl) (2nd week only)
Commission observers
LUVARA Giuseppina DG GROW (1st week only)
RAC advisors
BISEGLIE Sara (Pietro Paris) (1st week only)
LOIKKANEN Jarkko (Riitta Leinonen)
PAPPONEN Hinni (Riitta Leinonen) (1st week only)
PECZKOWSKA Beata (Boguslaw Baranski) (CLH Quizalofop-P-tefuryl)
ROMOLI Debora (Pietro Paris) (2nd week only)
SONNENBURG Anna (Ralf Stahlmann) (CLH Acetaldehyde)
STOCKMANN-JUVALA Helene (Tiina Santonen) (2nd week only)
SULGA Marius (Lina Dunauskiene) (CLH Quizalofop-P-tefuryl)
SUUTARI Tiina (Riitta Leinonen) (2nd week only)
UUKSULAINEN Sanni (Tiina Santonen)
VEGA Milagros (Joao Carvalho) (CLH Isoproturon)

Stakeholders observers
ANNYS Erwin, Cefic
BARRY Frank, ETUC (2nd week only)
DEN HAAN Klaas, Concawe
JANOSI Amaya, Cefic (replacing the regular Cefic stakeholder observer 25-27 May)
VEROUGSTRAETE Violaine, Eurometaux (1st week only)
ROMANO Dolores (1st week only)
ROVIDA Constanza, ECOPA (occasional stakeholder observer 24 May)
ROWE Rocky, ECPA (2nd week only)
Stakeholder apologies
MUNARI Tomaso (EuCheMS)
Dossier submitters
WINTHER Toke (TDSAs)

Industry experts		**RAC advisers**
DANZEISEN Ruth (Eurometaux, CDI, Cobalt salts (1st week only)		CASIMIRO Elsa (Joao Carvalho) (1st week only)
FOSTER John (Ecpa, Arysta, CLH quizalafop-p-terfuryl)		LOSERT Annemarie (Christine Hölzl) (1st week only)
GARTLAND Kevan (Ecpa, Sumitomo, CLH epsilon-metofluthrin) (2nd week only)		McCABE Laura (Andrew Smith) (2nd week only)
HARRISON Paul (Eurometaux, IEH Consulting, AI and Zr RCFs AfA) (1st week only)		**SEAC adviser**
LLOYD Sara (Ecpa, Syngenta, CLH pinoxaden) (2nd week only)		BÖHLEN Elmar (SEAC member Philipp Hennig, Chromium VI) (1st week only)
ROTH Thomas (Ecpa, Gowen, CLH phosmet)		**RAC expert**
VAN VELTHOVEN Martijn (Cefic, Unilever, sodium hypochlorite)		ALTMANN Dominik (Umweltbundesamt, 4-tert butylphenol)
WARREN Simon (Ecpa, Task Force and Adama, CLH isoproturon)		
WEEKS Jason (Ecpa, JNCC, CLH s-methoprene)		**SEAC Rapporteurs (AfA and restriction)**
		ALEXANDRE Joao (1st week only)
REMOTE PARTICIPANTS		COGEN Simon (1st week only)
RAC Members:		FANKHAUSER Simone (1st week only)
BRANISTEANU Radu (1st week only)		HENNIGG Philipp (1st week only)
DUNGEY Steve (1st week only)		KAJIC Silva (1st week only)
HAKKERT Betty		KRAJNC Karmen (1st week only)
HÖLZL Christine (2nd week only)		NICOLAIDES Leandros (1st week only)
PASQUIER Elodie (2nd week only)		SCHLUCHTAR Endre (1st week only)
PRONK Marja (Friday of 2nd week only)		
SCHLUETER Urs (1st week only)		
SMITH Andrew (1st week only)		

Dossier submitters:	**ECHA staff**
	BERGES Markus
Denmark	BLAINEY Mark
FOCK Lars (TDFAs and phthalates) (1st week only)	BOWMER Tim, Chairman
	BROECKAERT Fabrice
Netherlands	CHLEBUS Marek
ZWEERS Patrick (CLH sodium hypochlorite)	CLENAGHAN Conor
	DVORAKOVA Dana
Norway	ERICSSON Gunilla
CORRELL Myhre Ingunn (CLH 4-tert-butylphenol)	HENRICSSON Sanna
LARSEN Ann Kristin (CLH 4-tert-butylphenol)	KANELLOPOULOU Athanasia
	KARJALAINEN Ari
Commission observers:	KIVELÄ Kalle
BERTATO Valentina	KLAUK Anja
FERNANDES de BARROS Mariana	KOKKOLA Leila
GARCIA-JOHN Enrique	KOSK-BIENKO Joanna
HEIDORN Christian (1st week only)	KOULOUMPOS Vasileios
RIEPMA Wim	LIOPA Elina
LUVARA Giuseppina (2nd week only)	LOGTMEIJER Christiaan
ROZWADOWSKI Jacek	LOUKOU Christina
	LUSCHÜTZKY Evita
EFSA	MARQUEZ-CAMACHO Mercedes
PARRAMORTE Juan (2nd week only)	MERKOURAKIS Spyridon
STURMA Jürgen (2nd week only)	MOTTET Denis
	MULLER Gesine
	NICOT Thierry
	NYGREN Jonas
	ORISPÄÄ Katja
	O´ROURKE Regina
	PELTOLA Jukka
	PENNESE Daniele

PERAZZOLA Chiara		
PILLET Monique		
PREVEDOUROS Konstantinos		
REGIL Pablo		
RHEINBERGER Christoph		
RODRIGUEZ-IGLESIAS Pilar		
ROGGEMAN Maarten		
SADAM Diana		
SIHVONEN Kirsi		
SIMOES Ricardo		
SIMPSON Pete		
SMILOVICI Simona		
SOSNOWSKI Piotr		
SOTIRIOS Kiokias		
SPJUTH Linda		
STOYANOVA Evgenia		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-37 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-37 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-37 meeting

ANNEX IV Administrative issues and information items

Annex I (RAC-37)

23 May 2016
RAC/A/37/2016

Final Agenda

37th meeting of the Committee for Risk Assessment

23 May – 3 June 2016

ECHA Conference Centre (Annankatu 18, Helsinki)

23 May starts at 14.00
27 May breaks at 13.00
30 May resumes at 14.00
3 June ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/37/2016
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 36 action points, written procedures and update on other ECHA bodies

RAC/37/2016/01

RAC/37/2016/02
Room document

For information

b) 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/37/2016/03
Restricted document
For discussion and agreement

b) OEL-DNEL methodology request

For information

Item 7 – Harmonised classification and labelling (CLH)

7.1 CLH dossiers

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

k) Phosmet (ISO)

acute toxicity (all routes), germ cell mutagenicity, carcinogenicity, reproductive toxicity (developmental effects)

l) Pinoxaden (ISO)

physical hazards, acute toxicity (all routes), serious eye damage / eye irritation, aspiration hazard, environmental hazards

m) Quizalofop-p-tefuryl

physical hazards, acute toxicity (all routes), skin corrosion/irritation, serious eye damage / eye irritation, respiratory sensitisation, germ cell mutagenicity, environmental hazards

n) S-methoprene

physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, respiratory / skin sensitisation, STOT RE, germ cell mutagenicity, aspiration hazard, environmental hazards

o) Isoproturon (ISO)

environmental hazards

B. Hazard classes for agreement with plenary debate

p) Acetaldehyde, ethanal

q) Epsilon-metofluthrin

r) Phosmet (ISO)

s) Pinoxaden (ISO)

t) Quizalofop-P-tefuryl

u) S-methoprene

v) Sodium hypochloride, solution … % Cl active

w) 4-tert-butylphenol

x) Isoproturon (ISO)

y) Isobutyl methacrylate

For discussion and adoption

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

RAC/37/2016/04
Restricted room document
For agreement

Item 8 – Restrictions

8.1 General restriction issues

a) Capacity building - Carcinogenicity dose-response relationship setting for cobalt salts

RAC/37/2016/05
For discussion/agreement

b) Update on Forum restriction projects

For information

8.2 Restriction Annex XV dossiers

a) Conformity check

1) TDFAs – outcome of the conformity check and presentation of the key issues

2) Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) – outcome of the conformity check and presentation of the key issues

For agreement

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 setting for aluminium and zirconium refractory ceramic fibres (Al- and Zr RCFs)

RAC/37/2016/06
RAC/37/2016/07
RAC/37/2016/08
For discussion and/or agreement

b) Applications for authorisation received in the May submission window

For information

c) Forum project on enforcement of authorisations

For information

d) Report on the AfA Task Force Activities

For information

9.2 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues
   1. Chromium trioxide_SNECMA
   2. Chromium trioxide_MTU
   3. Chromium trioxide_ABLOY
   4. Chromium trioxide_HOOGOVENS Court Roll Surface Technologies
   5. Chromium trioxide_TOPOCROM GmbH
   6. Chromium trioxide_FN HERSTAL S.A.
   7. Chromium trioxide_GERARDHI KUNSTOFFTECHNIK GmbH
   8. Chromium trioxide; Potassium dichromate; Sodium dichromate_SOURIAU SAS
   9. Chromium trioxide_HAPPOC
   10. Ammonium dichromate_VECO BV
   11. Potassium dichromate_GENTROCHEMA BV
   12. Sodium dichromate_GENTROCHEMA BV
   13. Sodium dichromate_TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH
   14. Sodium dichromate_JACOBS DOUWEE EGBERTS DE GmbH
   15. EDC_BASF SE
   16. EDC_ELI LILLY S.A.
   17. EDC_DOW ITALIA S.R.L.
   18. EDC_LANXESS Deutschland GmbH
   19. EDC_H&R OLWERKE SCHINDLER GmbH
   20. EDC_GRUPPA LOTOS S.A.
   21. EDC_GE HEALTHCARE Bio-Sciences
   22. Diglyme_ROCHE DIAGNOSTIC GmbH
   23. Diglyme_LIFE TECHNOLOGIES A.S.
   24. Diglyme_BRACCO IMAGING S.P.A.
   25. Diglyme_MAFLON S.P.A.
   26. Diglyme_ACTON TECHNOLOGIES Limited
   27. Diglyme_ISOCHEM
   28. Technical MDA_POLYNT COMPOSITES France
   29. EDC_EURENCO

For discussion and agreement

b) Agreement on Draft Opinions
   1. Chromium trioxide 1 (5 uses) (CT_Lanxess)
   2. Sodium dichromate-Akzo Nobel (2 uses) (SD_Akzo)
   3. Sodium dichromate-Solvay (1 use) (SD_Solvay)

4. Sodium dichromate-Arkema (1 use) (SD_Arkema)
5. Sodium dichromate-Ercros (1 use) (SD_Ercros)
6. Sodium dichromate-Electroquimica (1 use) (SD_ELECTRQUIMICA)
7. Sodium dichromate-Kemira (1 use) (SD_Kemira)
8. Sodium dichromate-Caffaro Brescia (1 use) (SD_Caffaro)
9. Chromium trioxide-Federal-Mogul Friedberg (1 use) (CT_Friedberg)
10. Chromium trioxide-Federal-Mogul Valvetrain (1 use) (CT_Valvetrain)
11. Chromium trioxide-Federal-Mogul Burscheid (1 use) (CT_Burscheid)
12. Chromic acid-Bosch (1 use) (CA_Bosch)
13. Chromium trioxide-Circuit Foil Luxembourg (1 use) (CT_Circuit)
14. Arsenic acid-Circuit Foil Luxembourg (1 use) (AsA_Circuit)
15. Chromium trioxide and dichromium tris(chromate)-Nexter Mechanics (4 uses) (CT_DtC_Nexter)
16. Chromium trioxide-Praxair (2 uses) (CT_Praxair)
17. Potassium dichromate-Sofradir (2 uses) (PD_Sofradir)
18. Sodium dichromate-Lanxess (1 use) (SD_Lanxess)
19. Ammonium dichromate-Micrometal (1 use) (AD_Micrometal)
20. Chromium trioxide-Cromomed (1 use) (CT_Cromomed)
21. Chromium trioxide-Rimex Metals (1 use) (CT_Rimex)
22. EDC-BASF (EDC_BASF)
23. Diglyme-Novartis (Diglyme_Novartis)

For discussion and agreement

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

For discussion

9.3 Appointment of (co-)rapporteurs for authorisation applications

RAC/37/2016/09
Restricted room document
For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-37

Table with Conclusions and Action points from RAC-37

For adoption

Annex II (RAC-37)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-37 meeting.

Document number	Title
RAC/A/37/2016	Final Draft Agenda
RAC/A/2016 Restricted	Draft outline agenda
RAC/37/2016/01	Report from other ECHA bodies
RAC/37/2016/02 Room document	Administrative issues
RAC/37/2016/03 Restricted	Request under Article 95(3) 1-methyl-2-pyrrolidone (NMP)
RAC/37/2016/04 Restricted	Appointment of Rapporteurs for CLH dossiers
RAC/37/2016/05	Carcinocenicity dose-response relationship development for cobalt salts
RAC/37/2016/06	DNEL setting for the reprotoxic properties of 1-bromopropane
RAC/37/2016/07	DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP)
RAC/37/2016/08	Carcinogenicity dose-response relationship setting for aluminium and zirconium refractory ceramic fibres (AI- and Zr RCFs)
RAC/37/2016/09 Restricted	Appointment of Rapporteurs authorisation

ANNEX III (RAC-37)

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: asked to refrain from voting in the event of a vote on this substance - the Chairman may apply further mitigation measures as necessary.
Applications by Circuit Foil Luxembourg on chromium trioxide and arsenic acid	Ruth MOELLER	Institutional involvement: asked to refrain from voting in the event of a vote on this substance - the Chairman may apply further mitigation measures as necessary.
Restrictions		
n.a.	-	-
Harmonised classification & labelling		
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.
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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Restrictions		
TDFAs	Peter Hammer SOERENSEN	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.
	Lea Stine TOBIASSEN	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.
Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP)	Peter Hammer SOERENSEN	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.
	Lea Stine TOBIASSEN	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.
Harmonised classification & labelling		
Acetaldehyde, ethanol **Sodium hypochlorite, solution … % CL active (NL)**	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.
	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.
S-methoprene (IE)	Brendan MURRAY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Yvonne MULLOOLY	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
Phosmet (ISO) (ES)	Ignacio de la Flor TEJERO	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.
Pinoxaden (ISO) **Quizalofop-P-tefuryl** **(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; directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - the Chairman may apply further mitigation measures as necessary.
Quizalofop-P-tefuryl (UK)	Andrew SMITH	Working for the CA submitting the dossier and directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - the Chairman may apply further mitigation measures as necessary.
4-tert-butylphenol (NO)	Christine BJØRGE	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.
	Stine HUSA	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 - the Chairman may apply further mitigation measures as necessary.
Isoproturon (ISO) **Isobutyl methacrylate (DE)**	Agnes SCHULTE	Working for the CA submitting the dossier and directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - the Chairman may apply further mitigation measures as necessary.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

o0o

Helsinki, 19 May 2016

RAC/37/2016/02

ROOM DOCUMENT

37TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

23- 27 May 2016
30 May – 3 June 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-36 Action Points

The RAC-36 action points due for RAC-37 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-36	12 May 2016	closed

2.2 RAC consultations (status by 17 May 2016)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Acetaldehyde, ethanal	26 April 2016	closed
Epsilon-metofluthrin	n.a.	n.a.
Phosmet (ISO)	27 April 2016	closed
Pinoxaden (ISO)	25 April 2016	closed
Quizalofop-P-tefuryl	25 April 2016	closed
S-methoprene	18 April 2016	closed
Sodium hypochloride, solution … % Cl active	28 April 2016	closed
4-tert-butylphenol	21 April 2016	closed
Isoproturon (ISO)	18 April 2016	closed
Isobutyl methacrylate	26 April 2016	closed
Application for Authorisation		
27 applications received on the November 2015 submission window: Members' consultation on application	23 March 2016	closed
29 applications received on the February 2016 submission window: Members' consultation on application	22 June 2016	**ongoing**
29 applications received on the February 2016 submission window: Members' consultation on	10 May 2016	closed

Subject / document	Deadline	Status / follow-up
conformity		
19 draft opinions on 12 applications for authorisation from November 2015 submission window	9 May 2016	closed
14 draft opinions on 11 applications for authorisation from November 2015 submission window	10 May 2016	closed
Restrictions		
-		

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

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-36	22 April 2016	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest for rapporteurship	22 March – 1 April 2016	2 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)	▪ halosulfuron-methyl (ISO); methyl 3-chloro-5-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-1-methyl-1H-pyrazole-4-carboxylate ▪ cyflumetofen (ISO); 2-methoxyethyl (RS)-2-(4-tert-	11 April 2016	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
	butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-o-tolyl)propionate		)rapporteurs were appointed with tacit agreement.
Written procedure for the appointment of (co-) rapporteur(s) and the establishment of an ad hoc working group	▪ glyphosate (ISO); N-(phosphonomethyl)glycine	15 April 2016	Closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)rapporteurs were appointed with tacit agreement.
Applications for Authorisation			
Appointment of the Rapporteurs for February 2016 submission window	Cr(VI) compounds EDC Diglyme Technical MDA	-	Rapporteurs appointed for most applications. Co-rapporteur for PD_Gentrochema and SD_Gentrochema applications pending
Restrictions – no written procedures			

2.6 Other written procedures

Other written procedures	Deadline	Status / follow-up
Written procedure on the Terms of Reference for the AWHG on glyphosate (ISO)	2 May 2016	approved