RAC/M/38/2016
Final
29 November 2016

Minutes of the 38th Meeting of the Committee for Risk Assessment (RAC-38)

6 September started at 09.00
9 September suspended at 13.30
13 September resumed at 09.00
16 September 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 38th meeting of the Committee for Risk Assessment (RAC-38). Apologies were received from one Member. The Chairman introduced three new RAC members who were appointed at the ECHA Management Board meeting on 23 June 2016. He also offered warmest congratulations to the 18 RAC members on their reappointment at the same Management Board meeting, noting that many were first appointed at RAC 1 in 2008, and thanked them for their willingness to continue the work of RAC.

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 37th 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/38/2016), 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. Fourteen Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of 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 also asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Report from other ECHA bodies and activities

a) Report on RAC-37 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-37 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/38/2016/01). 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-37 had been adopted as usual 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 Q4/2016-Q1/2017, covering the three processes of Restriction, Authorisation and Harmonised Classification and Labelling of substances. He informed Members that they could find the expected schedules for Restriction and Authorisation dossiers in the work plan. In addition, the scheduling and the endpoints to be considered for each Harmonised Classification and Labelling (CLH) dossier for the next two meetings ahead are given in the relevant section, including those for human health and the environment.

c) Annual update of RAC accredited stakeholders' list

RAC discussed and agreed on the annual update of the Committee's list of accredited stakeholder organisations.
There was no change to the current stakeholder organisations regarded as regular or occasional observers and all retained their respective status. Four new organisations interested in the work of RAC were added as "occasional observers". The new stakeholders will be informed by the Secretariat about RAC's decision. The updated list of stakeholders will be published on ECHA's website and be applied with immediate effect following the end of the RAC-38 plenary meeting.

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 noted that the joint RAC/SCOEL working group had first met in Brussels in October 2015. He mentioned that at RAC-37 the Committee had supported the re-assessment of NMP (doc RAC/37/2016/03 restricted) prepared by the RAC Members of the joint RAC/SCOEL working group, reconfirming their view expressed at RAC-36 and taking into account the SCOEL recommendation of 30 March 2016 (SCOEL/OPIN/2016-119 N-Methyl-2-Pyrrolidone). At the further request of the Commission (DG ENTR, DG ENV and DG EMPL), the RAC and SCOEL working group members re-convened in Brussels (22 July and 23 August) to discuss.

The Secretariat informed RAC that detailed meeting discussions at the July meeting had resulted in a request to further examine the scientific evidence on: respiratory irritation and chemosensory effects (SCOEL), the PBPK modelling used in the derivation of OELs or DNELs (by RAC and SCOEL) and further explanation of the nature and adversity with regards to developmental effects (RAC).

At the August-meeting it was concluded that the differing views of the members of the respective Committees on the hazardous properties of NMP, were largely based on their expert judgment and that in reviewing the information for a second time, all relevant effects had been taken into account. The RAC/SCOEL WG members agreed that respiratory irritation is in principle suitable as a point of departure for deriving workplace DNEL's and OEL's; likewise, developmental effects can also be used. In the case of NMP however, as documented in their respective opinions, RAC and SCOEL place a different emphasis on the importance of each of these effects as a point of

departure. SCOEL favoured respiratory irritation, while RAC remained convinced of the developmental effects as the leading point of departure.

The minutes of the August-meeting will form the basis for the RAC-SCOEL joint opinion, expressing both deviating interpretations, but also listing down the areas in common within the opinion development.

b) OEL-DNEL methodology request

The Committee was informed that a proposed work-programme on the comparative critical assessment of REACH-DNEL and SCOEL-OEL methodologies for the inhalation and dermal routes had been forwarded to SCOEL in February 2016 but that no further movement regarding the proposed work-programme had taken place since then.

The Committee was informed however, that the Task Force had met twice over the summer (as described above under agenda point 6.a.1 NMP) and that the work performed by the ECHA contractor (RAC/38/2016/05) on OELs and DNELs by the inhalation route was introduced and briefly discussed by the joint Task Force.

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 the A-listing of hazard classes for a range of substances and following the usual scrutiny according to the relevant Committee procedure, had agreed these without plenary debate. The details for each substance are given below in section B.

B. Substances with hazard classes for agreement in plenary session

a) Acetaldehyde, ethanal

The Chairman reminded the Committee that the harmonised classification of the substance was discussed previously at RAC-37. Acetaldehyde, is an industrial chemical used 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 retain the existing hazard classes, to modify carcinogenicity classification to Carc. 1B; H350 and to add harmonised classification for mutagenicity (Muta. 1B; H340).

Following the discussions in RAC-37, a targeted public consultation was launched seeking additional information on the mode of action of acetaldehyde, in particular, studies that could elucidate the influence of acetaldehyde dehydrogenase (ALDH2) polymorphism on the physiological levels of acetaldehyde.

The DS proposal for the classification of mutagenicity is based on positive in vitro data (gene mutation tests, chromosome aberration tests and MN (micronucleus) tests), positive in vivo data on somatic cells via inhalation and intra peritoneal (i.p.) route in rats and mice and on the positive in vivo data in germ cells (positive sister chromatid exchange test in the mouse spermatogonial cells via i.p. route).

The Committee agreed that there was clear evidence for mutagenicity of acetaldehyde in somatic cells; the effects in germ cells were however questioned. Acetaldehyde occurs endogenously; it

[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.

is very reactive and therefore the i.p. route of exposure might not be relevant. Based on this evidence, the Committee agreed on Muta. 2 (H341).

The DS proposed to upgrade the existing classification of Carc. 2; H351 to category 1B based on the existing data in the rat and the hamster (available already during the previous classification).

The Committee discussed the data and noted that tumours occurred in two species (rat and hamster, the latter being less sensitive to tumorigenic events in general) and in both sexes and with a convincing dose-response in terms of tumour incidences. Members also indicated that the mutagenic properties of acetaldehyde need to be taken into account when assessing carcinogenicity. Comparison with formaldehyde was suggested bearing in mind that acetaldehyde is less potent compared to formaldehyde. RAC Members, who took part in the discussion on the carcinogenicity endpoint disagreed with the view of the Rapporteurs to classify the substance as category 2 carcinogen. Some RAC Members noted that the inflammation/irritation observed at the exposure levels in rats (750 ppm) is not severe enough to disregard the results of the tests. Other RAC Members concluded that tests on rats clearly demonstrate adenocarcinomas. Although incident rate in hamsters is not so high when compared to rats, the results of the studies on rats with respect to toxicokinetics are highly relevant to humans. The Committee agreed to classify acetaldehyde as Carc. 1B (H350).

b) Pinoxaden (ISO)

The Chairman welcomed the representative accompanying the ECPA stakeholder observer and reported that pinoxaden (ISO) is 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) is 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 Committee had discussed the proposal already at RAC-37 and agreed on classification and labelling for the following hazards: Acute Tox. 4; H332, Acute Tox. 4; H302, Eye Irrit. 2; H319, Skin Sens. 1A; H317, Repr. 2; H361d and on environmental hazards - Aquatic Acute 1; H400, M=1 and Aquatic Chronic 3; H412.

<u>Respiratory irritation / sensitisation</u>

The DS proposal to classify for respiratory irritation (STOT SE 3; H335) was based on reported respiratory symptoms in workers' and on supportive information from an acute inhalation study in rats. During the public consultation, one MS requested RAC to consider the classification of pinoxaden as a respiratory sensitiser on the basis of its categorisation as a strong skin sensitiser. After the public consultation, further details on health effects in the workforce from the synthesis and formulation of pinoxaden were provided by industry upon request from RAC. The main question raised by RAC during the RAC-37 discussion was whether the observed effects in humans were related to an irritation and/or an allergic mode of action. RAC noted that it could not be excluded on the basis of the available data, that the observed irritation effects are also related to sensitising properties of pinoxaden. However, no objective measurements or immunological tests appeared to be available from the affected workers. The evidence for RAC was thus limited to respiratory irritation, confirmed by the acute toxicity study by inhalation in rats and the positive mouse LLNA skin sensitisation test. On this basis, some RAC Members

expressed the view that the available data should be considered insufficient for classification (e.g. due to absence of any objective measurements), while others requested further consideration of classification as a respiratory sensitiser. Overall, no conclusion had been reached by the Committee and further clarification and details on the human data were requested from the industry representative. The conclusion on this hazard was therefore postponed to the next plenary meeting in September and industry offered to provide further specifics on the aforementioned workers.

This additional information showed that there were 38 adverse respiratory incidents reported in 23 individuals (among 306 workers manufacturing pinoxaden) in the period of 2004-2016. Eleven out of the 23 individuals had reported symptoms of respiratory tract irritation. For the remaining 9 individuals it appears that respiratory hypersensitivity was predominant, although two had pre-existing asthma. The reported symptoms had a clinical character of an allergic reaction accompanied in some cases by effects on the skin and the eyes. For some workers only one incidence is reported, or a few incidences over several others. The symptoms noted varied from coughing, sneezing, wheezing, shortness of breath and tight chest. However, based on the reporting, only in very few cases has it been indicated how long the reactions/symptoms lasted in those affected individuals and which were the exposure concentrations, which could be helpful in the assessment.

Regarding exposure, the symptoms occurred after relatively low level exposure (0.3 – 0.5 mg/m^3 and ≤ 0.1 mg/m^3 after implementation of very strict control measures). Two of the individuals were relocated but information about the others is lacking. There was no information on individual exposure levels or medical history for the human cases.

RAC noted that during the period of 2004 – 2016, the manufacturers occupational exposure limit (OEL) value had been lowered from 10 mg/m^3 to 0.1 mg/m^3. According to the industry representative, this reduction was implemented following incidents which occurred during handling and bagging of high quantities of technical pinoxaden.

In addition to the data on synthesis and formulation workers, a case was reported through the manufacturer's product surveillance system of military cadets crawling on exercise through a field freshly treated with pinoxaden. Seven out of 45 cadets showed symptoms (such as wheeze, facial swelling, swelling of the throat without skin reactions, and bronchospasm) and were treated with steroids and adrenalin. According to the industry representative, prior treatment of the field with other plant protection or other agricultural products was not reported, nor was the previous medical history or possible exposure to pinoxaden of the cadets.

Overall, RAC concluded that although there were some evidence that pinoxaden could have a respiratory sensitisation potential, it was not considered sufficient to fulfil the criteria for classification for respiratory sensitisation and thus, pinoxaden did not warrant classification. Based on the reported respiratory tract irritation symptoms, RAC agreed to classify pinoxaden as respiratory irritant (STOT SE 3; H335).

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

c) 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone ("BDMBP")

The Chairman reported that BDMBP was an industrial chemical which is used as a photosensitive agent in printing inks, pigmented coatings and photopolymers for imaging applications. BDMBP already has an entry in Annex VI to CLP where it is classified as Aquatic Acute 1 and Aquatic Chronic 1, with no M-factors set. The Dossier Submitter (BASF SE) proposed a harmonised

classification as Repr. 2 (H361d). The legal deadline for the adoption of an opinion is 16 March 2017.

The Rapporteur clarified that the one-generation reproduction study in which relevant effects were seen was of good quality. Further to this, stillbirths and postnatal mortality were statistically significant, i.e. severe effects which were relevant for humans. The Committee agreed with this, also recognising that the maternal effects observed were not considered as directly causing the developmental effects. RAC concurred with the Rapporteur and proposed classification as Repr. 1B (H360D) for developmental effects.

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

d) Spirodiclofen (ISO): 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate

The Chairman welcomed an expert accompanying the ECPA stakeholder observer as well as representatives of the Dossier Submitter (Netherlands) who followed the discussions remotely. He reported that Spirodiclofen (ISO) is an active substance used in plant protection products, specifically an insecticide/acaricide belonging to the chemical class of keto/enols or tetronic acids, acting as an inhibitor of lipid biosynthesis, mainly against mites.

The Chairman clarified that Spirodiclofen currently does not have an entry in Annex VI to CLP and that therefore all hazard classes needed to be evaluated during the CLH process. The Dossier Submitter (Netherlands) proposed a harmonised classification as Repr. 2 (H361f), Carc. 1B (H350), Skin Sens. 1B (H317), STOT RE 2 (H373) and Aquatic Chronic 1 (H410; M=10). The legal deadline for the adoption of an opinion is 27 February 2017.

RAC agreed on the following hazards via the fast-track procedure: no classification for the physical hazards, acute toxicity (all routes), skin corrosion / irritation, serious eye damage / eye irritation, respiratory sensitisation, STOT SE, germ cell mutagenicity, aspiration hazards and hazardous to the ozone layer. Also Skin Sens. 1B (H417) and Aquatic Chronic 1 (H410) with an M-factor of 10 were agreed through fast-track.

The Rapporteur clarified that the evaluation of STOT-RE was based on repeated dose toxicity studies of spirodiclofen in mice, rats and dogs, on combined chronic toxicity/carcinogenicity in mice and rats and on 2-generation reproductive toxicity, acute neurotoxicity and sub-chronic immunotoxicity studies in rats. He explained that effects were observed in the adrenals, haematology and liver. The Rapporteur proposed to classify as STOT RE 2 based on effects observed in the haematology and liver in the dog studies, but left it open as to whether a target organ should be specified. Other RAC members agreed that the dog was the most sensitive species. However, it was questioned whether the liver effects were sufficiently severe to warrant a classification; some members would have preferred to see increased liver enzymes in blood and diffused necrosis in the liver, in particular as necrotic effects are subject to the classification criteria. It was recognised that spirodiclofen caused effects on all endocrine organs in all experimental species while a specific target organ could not exclusively be identified. RAC agreed on a classification as STOT RE 2 (H373), with no target organ to be specified.

As to **carcinogenicity**, the Rapporteurs reported that there were tumours in three organs (liver, testis and uterus), two species and two sexes. Liver tumours were observed in both male and female mice whereas testicular (Leydig cells) and uterus tumours were observed in male and female rats, respectively. RAC discussed which relevant (pre)neoplastic lesions occurred in at least two species. In dogs, no tumours were observed after one year of dosing but Leydig cells and the liver were also affected. Concern was particularly expressed about the observed uterine

tumours in rats considering the hormonal disrupting properties of the substance. Overall, based on the historical control data for these tumours, statistical significance and general toxicity of spirodiclofen, they should be considered for classification. The two other tumour types were of less clear significance or relevance for deciding on the category for carcinogenicity.

RAC additionally questioned the rationale for the dose selection in some studies and the statistical analysis in others since dose-effect relationship may have been masked. Data were not detailed enough in the CLH report whereas some key organs may have not been examined in the OECD studies. For these reasons, RAC requested that the original study reports be checked. Overall, RAC could not conclude due to lack of details on key studies presented in the CLH report. It was agreed that the Secretariat would contact the manufacturer for further details on the key studies.

As to **reproductive toxicity** and effects on sexual function and fertility, the Rapporteur explained that there was evidence that spirodiclofen affects reproductive and endocrine organs in dogs, rats and mice, the dog being the most sensitive species. He reported that the histopathological changes in reproductive organs did not affect the reproductive function in the 2-gen rat study where effects occurred together with general toxicity. He considered that Repr. 1B was not supported as the effects seen were not sufficiently pronounced and occurred at doses also showing some general (parental) toxicity in mice and rats and that the evidence was sufficient for classification as Repr. 2 (H361f). Some members asked whether the decrease in the weight of the uterus at low doses could be underpinned by histopathological findings in dogs. Other members wondered whether the findings in rats and mice were relevant to humans, having in mind that if they were not, only the dog studies would need to be considered for classification, justifying a classification as Repr. 1B (H360F). However, also in this case no data were available to convincingly show the relevance of the findings in rats and mice to humans. One RAC member indicated that the top dose calculation in one of the studies possibly contained an error, and requested access to the original data for this reason.

The Chairman noted the general lack of relevant data in the process and requested the ECPA representative, who agreed to contact the manufacturer of spirodiclofen for access to the study reports on carcinogenicity and reproductive toxicity. He closed the discussion by stating that RAC would need to continue and finalise the debate on spirodiclofen at the December meeting.

e) Pyrocatechol

The Chairman welcomed the representative accompanying the Cefic stakeholder observer and reported that pyrocatechol was a major intermediate for the synthesis of agrochemicals; as well as an intermediate for perfumes, cosmetics and aromas. It is also used in various areas such as: anticorrosion agent; antioxidant for rubber, olefins and polyofins, polyurethanes; therapeutic agent; bonding agents; tanning agent, synthetic tannins or photography; catalysts. It has an existing entry in Annex VI to the CLP Regulation – minimum classification for acute toxicity via oral and dermal routes of exposure (Acute Tox. 4*; H302, Acute Tox. 4*; H312) and as Skin Irrit. 2; H315 and Eye Irrit. 2; H319. The legal deadline for the adoption of an opinion is 4 March 2017.

The DS (FR) proposed to retain classification for Eye and Skin irritation, modify acute toxicity (Acute Tox. 3; H301, Acute Tox. 3; H311) and to add harmonised classification for mutagenicity (Muta. 2; H341) and carcinogenicity (Carc. 2; H351).

The Chairman recalled that acute toxicity via inhalation (Acute Tox. 3; H311) was agreed through the fast-track procedure. The Committee agreed to the DS proposal to classify pyrocatechol in category 3 for acute oral toxicity with an ATE of 300 mg/kg bw based on two rat studies. RAC supported the DS proposal to classify pyrocatechol as Muta. 2 based on the positive

in vivo micronucleus data supported by the observations in cultured mammalian cells. No data were available to assess mutagenic potential in germ cells, therefore category 1 was not considered.

Carcinogenicity

The Rapporteurs presented the data on carcinogenicity. The tumours were observed in rats (several strains) and mice (B6C3F1 and Balb/c) with the (glandular) stomach being the main target organ. Benign tumours were observed at doses on or above 0.2% (0.8% in the majority of cases); malignant tumours at doses of 0.4% and 0.8% with a dose-response evident. The original DS proposal was based on assumption that irritancy might be the predominant MoA and thus category 2 would be more appropriate.

RAC however was of the opinion that the MoA is not known and it is probable that different MoAs (local genotoxicity, irritancy) might be involved in tumorigenesis. A severe ulceration observed in the rat carcinogenicity study could point towards a gastrin mode of action as one of the possibilities. In addition, formation of semiquinone radicals would suggest that oxidative DNA damage might be one of MoAs too. The mutagenic property of the substance, and consequently the possible contribution of a genotoxic MoA, further supported classification as category 1B.

It was noted that glandular stomach tumours in the rat are very rare. In addition, there were other sites of tumorigenesis, namely the pancreas, the oesophagus, the tongue and the lungs.

The expert accompanying the Cefic stakeholder observer expressed his view that the pancreas tumours were adenomas (not carcinomas) and were observed in the highest dose (with 0.8% of statistical significance which is considered as very low). He also referred to a mouse study mentioned in the IARC monograph where no tumorigenesis had been observed after dermal route of exposure. RAC took note of this information, however negative results of the dermal study would not affect the interpretation of the effects on the glandular stomach. He further noted that pyrocatechol was a natural substance occurring in food and smoke; the effects observed occurred only at extremely high doses (also above the ATE) and therefore he doubted the human relevance.

The Committee agreed to classify pyrocatechol as category 1B (Carc. 1B; H350) based on the occurrence of malignant and benign tumours in two species and in both sexes consistently across the doses and bearing in mind the mutagenic potential of pyrocatechol.

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) Mesosulfuron-methyl

RAC agreed on the environmental classification of the substance via the fast-track procedure as Aquatic Acute 1; H400, M=100 and Aquatic Chronic 1; H410, M=100. The human health hazards of the substance will be discussed at RAC-39.

g) Tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2H-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate

D-trans-tetramethrin; (1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropane-carboxylate

The Chairman welcomed an expert accompanying the ECPA stakeholder observer as well as a representative of the Dossier Submitter (Germany) who was following the discussions remotely.

He reported that both Tetramethrin and d-trans-tetramethrin were used as active substances in biocidal and plant protection products.

The Chairman clarified that neither of the substances currently has an entry in Annex VI to CLP and that therefore all hazard classes needed to be evaluated. The Dossier Submitter (Germany) proposed a harmonised classification as Acute Tox. 4 (H332), Carc. 2 (H351), STOT SE 2 (H371, nervous system, inhalation), Aquatic Acute 1 (H400; M=100) and Aquatic Chronic 1 (H410; M=100) for both substances. The legal deadline for the adoption of the opinions is 4 April 2017.

RAC agreed on the following hazards via the fast-track procedure: no classification for the physical hazards, acute toxicity (dermal and inhalation route), skin corrosion / irritation, serious eye damage / eye irritation, respiratory and skin sensitisation, STOT RE, germ cell mutagenicity, reproductive toxicity (fertility and development; lactation), aspiration hazards and hazardous to the ozone layer. Also Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) with an M-factor of 100 for both hazards were agreed through fast-track for both Tetramethrin (ISO) and d-trans-tetramethrin. Due to their close structural similarities, read-across was applied between the two substances.

The hazard classes acute oral toxicity, STOT SE and carcinogenicity were discussed in plenary.

For acute oral toxicity, the Rapporteurs proposed category 4 both for Tetramethrin (ISO) and for d-tetramethrin, based on the results from a mouse study for d-tetramethrin. RAC agreed that read-across should be consistently applied for all hazard classes, and that therefore both substances be classified in the same way, i.e. in category 4.

For STOT SE it was discussed whether a category 2 classification specifying effects on the nervous system, via the inhalation route, could be justified for both substances. The expert accompanying the ECPA stakeholder observer clarified that Tetramethrin was acting through a pyrethroid mode of action. RAC recognised that the neurotoxic effects seen in rats (tremors) as well as the respiratory symptoms are likely attributed to this mode of action, thus justifying a classification as STOT SE 2 (H371 (nervous system)).

As to carcinogenicity, the Rapporteur reported that incidences of interstitial cell tumours in the testis could be observed in rats above the historical control levels. He clarified that there were nine known modes of action applying to Leydig cell tumours, and with the available data it was not possible to rule out all modes of action with relevance to humans. In accordance with the criteria, RAC decided to classify both Tetramethrin substances as Carc. 2 (H351).

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

h) Maleic anhydride

The Chairman reported that maleic anhydride was mainly used for synthesizing e.g. unsaturated polyester resins, coatings, pharmaceuticals, pesticides, lubricating-oil additives and foodstuff additives. It has an existing entry in Annex VI to the CLP Regulation - minimum classification for acute toxicity via oral route of exposure (Acute Tox. 4*; H302) as well as classifications for skin corrosion (Skin. Corr. 1B; H314), skin sensitisation (Skin. Sens. 1; H317) and respiratory sensitisation (Resp. Sens. 1; H334) and the legal deadline for the adoption of an opinion is 18 May 2017.

The DS (AT) proposed to retain the classification for acute toxicity (remove the asterisk), to modify the classification for skin sensitisation (to Skin. Sens. 1A; H317) and to add classification for toxicity after repeated exposure (STOT RE 1; H372 (respiratory system), STOT RE 2; H373

(kidney)), for eye damage (Eye Dam. 1; H318) and a supplementary labelling statement EU H071 ('Corrosive to the respiratory tract').

The Chairman recalled that acute oral toxicity (Acute Tox. 4; H302) and subcategorization of skin sensitisation to category 1A were agreed through the fast-track procedure. In addition to the proposed sub-categorisation of skin sensitisation and in accordance with the PC comments (supported subsequently also by the DS), the Committee agreed upon setting a specific concentration limit (SCL) of 0.001% based on extreme potency (EC3 < 0.2 % - LLNA test).

In accordance with Annex II 1.2.6 of the CLP Regulation, the Committee agreed upon addition of the labelling statement EU H071 'Corrosive to the respiratory tract'.

RAC supported the proposal to classify the substance for toxicity after repeated exposure (STOT RE 1; H372 (respiratory system) (inhalation)) based on clear evidence from a 28-day study in rat. Classification as STOT RE 2 (kidney) was not supported as the two categories cannot be applied simultaneously. In addition, the observed kidney effects were of questionable severity and potency and therefore not considered relevant for the classification in STOT RE 1.

The Committee discussed the proposed classification and labelling for serious eye damage and agreed on the classification in category 1 (Eye Dam. 1; H318). As the substance is already classified for skin corrosion (Skin. Corr. 1B; H314), the substance should also be classified as Eye Dam. 1 (H318). Regarding labelling, since (H314) 'causes severe skin burns and eye damage' already covers the concerns, H318 'causes serious eye damage' is made redundant and was not applied. This approach was confirmed by the Secretariat and is supported by the Commission, who also clarified that classification but not labelling with H318 applies if Skin Corr. 1/1A/1B/1C is warranted and that it is irrelevant whether or not there are animal data showing that Eye Dam. 1 is warranted.

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

i) Succinic anhydride

The Chairman reported that succinic anhydride was used as a monomer for the production of resins. It has an existing entry in Annex VI to the CLP Regulation - minimum classification for acute toxicity via oral route of exposure (Acute Tox. 4*; H302) as well as classifications for eye irritation (Eye Irrit. 2; H319) and for STOT SE (STOT SE 3; H335) and the legal deadline for the adoption of an opinion is 30 March 2017.

In accordance with Annex II 1.2.6 of the CLP Regulation, the Committee agreed upon addition of the labelling statement EU 071 "Corrosive to the respiratory tract".

The DS did not evaluate STOT SE. However this endpoint was open for commenting during the public consultation of the CLH report and consequently this endpoint was evaluated by RAC. RAC noted that there was no information available on the rationale for the current STOT SE 3 classification. With reference to the CLP guidance and taking into account the corrosive properties of succinic anhydride as well as the fact that succinic anhydride has sensitising properties that will cause respiratory sensitisation (i.e. a more severe effect on the respiratory system as compared to the current classification for irritation of the respiratory tract), RAC concluded that the current classification in STOT SE 3 should be considered superfluous.

The Committee discussed the proposed classification and labelling for serious eye damage and agreed on the classification in category 1 (Eye Dam. 1; H318). In line with the rationale for the previous decision taken for the maleic anhydride, RAC agreed that labelling with H318 is redundant.

The DS (AT) proposed to retain the classification for acute toxicity (remove the asterisk) and to add classification for respiratory sensitisation (Resp. Sens. 1; H334), skin sensitisation (Skin. Sens. 1; H317), eye damage (Eye Dam. 1; H318) and for skin corrosion (Skin. Corr. 1; H314).

The Chairman recalled that acute oral toxicity (Acute Tox. 4; H302) and skin sensitisation (Skin. Sens. 1; H317) were agreed through the fast-track procedure.

Respiratory sensitisation

The DS proposal for respiratory sensitisation in category 1 was mainly based on a weight of evidence assessment, including read-across to maleic anhydride which has a common functional group and belongs to the same chemical class – mono-cyclic anhydrides – which are known respiratory sensitisers at workplaces. Also, the DS concluded that succinic anhydride as well as acid anhydrides are positive in LLNA. RAC considered the available data in a WoE determination and concluded that succinic anhydride has a potential to be a respiratory sensitiser at a "high" exposure level. This was based on the fact that cyclic anhydrides are well known workplace respiratory sensitisers, the demonstration of IgE (immunoglobulin E) in sera of rats exposed via the intradermal route to succinic anhydride protein conjugates and a positive LLNA test in mice (showing that succinic anhydride can trigger a biologically relevant immunologic response). It was also noted that QSAR's predicted respiratory sensitisation for succinic anhydride. The Committee agreed that there was not sufficient evidence for sub-categorisation and proposed to classify the substance as Resp. Sens. 1; H 334.

Skin corrosion

The proposal to classify succinic anhydride for skin corrosion (Category 1) was mainly based on data from an *in vitro* skin corrosion test, EpiDerm™, (using reconstructed human epidermis), the effects seen in an in vivo acute dermal toxicity test and on read-across of this property from maleic anhydride (Category 1A agreed above). The EpiDerm™ test is conclusive for skin corrosion. According to the DS, the classification was also supported by the effects observed in an acute dermal toxicity study in rat. However, the absence of more serious skin effects in the *in vivo* test was noted by RAC. It was considered that the vehicle chosen (corn oil) in order to apply the anhydride might have attenuated a corrosive effect of succinic anhydride as well as the lower dose, the use of the rat etc. as compared to the standard acute dermal *in vivo* skin corrosion/irritation test in the rabbit. RAC members agreed on the proposed classification for skin corrosion (Category 1). RAC noted that in general more weight should be given on *in vivo* data (if available) if considered relevant for assessment of skin corrosion/irritation, than on *in vitro* data.

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

7.3 Appointment of RAC Rapporteurs for CLH dossiers

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

8. Restrictions

8.1 Restriction Annex XV dossiers

a) Conformity check

1) N,N-dimethylformamide; dimethyl formamide (DMF)

The Chairman welcomed the Dossier Submitter's representative from Italy. He informed the participants that the restriction dossier had been submitted by Italy on 15 June 2016. The conformity check was launched on 17 August and the RAC commenting round finished on 22 August (there was one comment received from a RAC member, in support of the Rapporteurs).

DMF is an aprotic solvent able to dissolve a wide range of substances and used in many applications in the chemical industry, e.g. in the manufacturing of fine chemicals, pharmaceuticals, polymers, textiles, non-metallic mineral products, perfumes and fragrances.

The Dossier Submitter provided an introductory presentation on the dossier. The dossier proposes a restriction on the uses of the substance on its own or in mixtures in a concentration equal to or greater than 0.3%. The proposal is to use DNEL values for long-term inhalation exposure (3.2 mg/m^3) and a DNEL for long-term dermal exposure (0.79 mg/kg bw/day) developed in accordance with REACH Guidance R.8 as a condition of the restriction.

The Rapporteurs presented the outcome of the conformity check and informed the Committee that they do not consider the dossier to be in conformity due to the lack of information on the hazard data, making an independent assessment of the hazard information impossible. Furthermore, descriptions of the exposure situations for all identified uses in the proposed scope were not included.

The Committee highlighted that more detailed information on the available studies on repeated dose toxicity and toxicity to reproduction is needed. In addition, a more detailed description of the severity of effects would be needed to justify the Point of Departure for the DNEL and to characterise the potential health impact.

It was pointed out that the REACH registrants in their chemical safety reports had used the Indicative Exposure Limit (iOEL) value for DMF established by the Scientific Committee on Occupational Exposure Limits in 2009 at 15 mg/m^3(8hr time weighted average) as the DNEL for inhalation. Noting this, RAC advised that a clear and transparent justification for any choice of DNEL is very important considering the likely comparison of the DNEL with the iOEL. In all respects the Committee agreed that clear descriptions of the studies and of the diversity of the reproductive and other effects would be needed to facilitate an independent evaluation.

The Committee agreed that the dossier does not conform to the Annex XV requirements and also agreed with the recommendations to the Dossier Submitter as presented by the Rapporteurs.

The Chairman mentioned that the Dossier Submitter will be informed about the reasons for non-conformity and about the further steps and actions to be taken.

b) Opinion development

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

The Chairman welcomed the RAC Rapporteurs and the dossier submitter representatives from Denmark. He informed the participants that the dossier was submitted in February 2016 (within the 60 days resubmission window after concluded not in conformity by RAC and SEAC in November 2015.) The restriction proposal proposes a restriction on the use of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)-silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives in mixtures containing organic solvents placed on the market or used in spray products for consumers (aerosol dispensers, hand pump and trigger sprays and mixtures marketed for spray application). The restriction is targeted at mixtures with organic solvents in spray products for supply to the general public. TDFAs have 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 and RAC discussed the draft opinion for the first time. Overall, the RAC Rapporteurs considered that the risks to consumers from the use of impregnating aerosol sprays containing TDFAs and 2-propanol are not adequately controlled when used under worse case conditions. This is not the case for pump and trigger sprays although it was highlighted that exposure may occur also from these products. The RAC Rapporteurs considered that the scope of the proposal is clear but suggested some amendment to the proposed legal text to provide clarity to the focus of the restriction proposal. Furthermore, the RAC Rapporteurs supported the view that any necessary action to address risks associated with TDFAs should be implemented in all Member States and considered that a restriction is an appropriate risk management measure addressed at consumers, which will specifically reflect the particular concerns of the use of TDFAs and solvents in mixtures sold in spray products.

In general, based on the data provided, RAC members supported the use of DNELs, NOAEC and AFs as proposed by the Rapporteurs but were not yet convinced that TDFAs is the cause of observed clinical cases. RAC, therefore, requested industry to provide a) further testing data on the analysis of the product Magic Nano and b) any relevant inhalation toxicity testing data on this or similar formulated products which might help to better understand the role of the substance as well as the solvents used and thereby support RAC's evaluation of the case.

Additionally, RAC supported the use of CONSEXPO and/or Sprayexpo for the subsequent exposure estimates. The Chairman concluded that the plausibility of the link between identified hazard and TDFAs/solvents in spray products will be further considered at RAC-39. In addition, to improve participation in the public consultation process and provision of essential information on critical issues identified by RAC, ECHA will set up a consultation targeted at manufacturers and companies formulating such products as well as trade associations.

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 Submitter's representatives from ECHA and Denmark, an industry expert accompanying the Cefic regular stakeholder observer and the SEAC Rapporteurs. He informed the participants that the dossier had been submitted in April 2016 and had been considered in conformity by RAC in June 2016. 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.

The Rapporteurs presented their first draft opinion. With regard to the scope of the proposed restriction, the Rapporteurs explained to the Committee that the restriction is limited to the four phthalates in Annex XIV whose sunset date has passed and is targeted at articles, focussing on those that present a risk via critical routes of exposure. The proposal is targeted at human health as the primary concern. DEHP, DBP, DIBP and BBP are all classified as Repr. 1B and were grouped in view of common physicochemical properties, common anti-androgenic MoA and similar use. The Committee agreed with the Rapporteurs that the proposed targeting and grouping of the substances is justified.

In relation to the hazard, the Committee agreed to change the DNEL for DIBP based on read-across from DBP and, depending on the outcome of the PC, to use the previously established DNELs for the other three substances. The Committee also decided to address other effects

(e.g., immunological, metabolic, neurodevelopmental) and other uncertainties related to the DNELs in the uncertainty analysis, but also acknowledged that this could be reconsidered depending on the outcome of the PC and proposed that SEAC takes these into account in the SEA. Several members asked for more information on human health effects, other than reproductive effects, to be included in the Background document. The Chairman noted substantial agreement in the Committee with regard to the DNEL's as discussed.

Regarding exposure, RAC agreed to base the risk assessment on biomonitoring data. Exposure modelling is considered as supportive evidence of the contribution of articles in the scope of the proposed restriction to exposure and risk. The Rapporteurs recommended to use DEMOCOPHES data for children and DEMOCOPHES data in combination with data from Myridakis et al. (2015) for mothers. For infants, there is not enough biomonitoring data available.

With regard to risk characterisation, some members and an industry expert requested clarification regarding the proportion of the overall exposure arising from articles not in the scope of the restriction and therefore the risk reduction capacity of the proposed restriction. The Dossier Submitter clarified that the future exposure was estimated with and without the restriction and that with the restriction, RCRs would be below 1 in most MSs, while without the restriction there would still be significant risk. One member saw the proposed restriction as a sensible step forward to reduce rather than to eliminate exposure and drew parallels with the restriction dossier on Nonylphenol ethoxylates. The Committee agreed on the RCRs and that there is a risk that needs to be addressed. RAC also agreed that the need for an EU wide action is justified, however, whether the risk can best be addressed by a restriction was still open to discussion and it was agreed to continue this further at RAC-39.

The Committee briefly discussed the contribution of DIBP in toys and childcare articles as well as food contact materials to overall exposure. RAC agreed that there is potentially a risk from DIBP in toys and childcare articles that needs to be addressed.

The Rapporteurs were asked to take the discussion into account in the preparation of the second draft opinion. At the next RAC-39 plenary meeting, the Committee is expected to discuss the conditions of the restriction proposal as well as derogations, effectiveness of the proposed restriction in reducing the identified risks, risk reduction capacity of alternatives, and practicality and monitorability of the proposed restriction.

8.2 Appointment of RAC Rapporteurs for restriction dossiers (closed session)

RAC agreed in the closed session on the updated pool of Rapporteurs for the restriction dossiers on Diisocyanates and on Lead and its compounds (as stated in the restricted room document RAC/38/2016/07). Furthermore, interested members were invited to volunteer for the pool of (co-)Rapporteurs for restriction proposal on Diisocyanates as there are not enough candidates in the pool to appoint both Rapporteur and (co-)Rapporteur positions.

9. Authorisation

9.1 General authorisations issues

a) Correspondence with the Commission (DG GROW, DG ENV) on Authorisations

The Chairman informed the Committee that ECHA received two letters from the Commission regarding the authorisation procedure (RA/38/2016/11) and regarding the risk management recommendations in ECHA opinions on applications for authorisations (RAC/38/2016/11). The representative of the Commission observer introduced the content of the letters to RAC.

After presentations, RAC discussed aspects related to the opinion development process for applications for authorisation. The Secretariat mentioned that some of the issues were covered by the AfA Task Force and a written consultation on the AfA Task Force practical guide will be launched for RAC and SEAC members during the second half of September 2016. At the next plenary meeting, the Secretariat will briefly report on the progress made by the AfA Task Force i.e. the state of play of the practical guide.

The Chairman reported that the second letter above, concerning three RAC opinions on which the Commission had requested clarifications, would be assessed by the Secretariat in consultation with the Rapporteurs and that on this basis explanatory notes would be prepared, i.e. without reopening the dossiers in Committee. RAC would be informed of the outcome.

b) Outcome of the Authorisation Rapporteurs workshop held the afternoon before RAC 38.

On Monday 5th September a preparatory workshop for the RAC Rapporteurs involved in authorisations was held at ECHA to discuss several aspects of the Committee's evaluations, mainly of downstream applications. They agreed that when requesting additional clarification, applicants should be approached as early as possible in the process and that requests should be restricted to what is strictly essential of the Committee's evaluation. The need for clear measured data supporting Risk Management Measures and contextual information supporting those measurements. The importance and need to explain uncertainties clearly in the opinions was also highlighted. The Rapporteurs agreed that in line with recent requests from the Commission, any conditions applied should be as specific as possible, in particular where exposure control is concerned.

The discussion then focussed on what kind of measured inhalation data could be considered as representative of using stationary and personal samples, possibly supported by modelling for different scales and complexity of workplaces, or multiple workplaces.

The issue of how to treat a situation where there is a direct emission (without apparent RMMs in place) of a SVHC to the environment was discussed.

The final part of the workshop focused on two issues:

i. acceptable levels of risk; the participants considered that this was a policy issue, the subject of a broad societal dialogue and while RAC could contribute to such a discussion, it would need to be requested in the usual way in the form of a mandate.

ii. with regard to describing the perception of high or low risk in drafting authorisation opinions, it was agreed that, bearing the applicants obligations under REACH and OHS legislation to minimise exposure, it is advisable not to use qualifying statements in relation to the level of risk in RAC opinions.

RAC expressed its appreciation for this contribution from the Rapporteur's workshop and the Chairman note that these issues would be tabled for discussion in plenary at some point in the near future.

c) Health outcomes predicted by reference dose-response relationships for carcinogenic substances

Based on recurring discussions on several different applications for authorisation, RAC noted that because of differences in the nature of the data for different carcinogenic substances, dose-response relationships will estimate the excess risk of quite different health outcomes. The dose-response relationship for Cr(VI) exposure (via inhalation) estimates the excess risk of a fatal

health outcome (e.g. fatal lung cancer), whilst the dose response relationship for trichloroethylene (TCE) estimates the excess risk of the incidence of kidney cancer, which may or may not prove to be fatal. Where dose-response relationships are used by applicants to estimate the total burden of disease within a population (i.e. number of fatal and non-fatal cases in workers), RAC reminds applicants that the relative number of fatal and non-fatal cases associated with a particular exposure level should be estimated using an appropriate approach and reported separately. The appropriate approach will be different dependent on if the dose-response relationship estimates the excess risk of a fatal health outcome (additional non-fatal cases) or the excess risk of developing a particular cancer (non-fatal cases as a proportion of the total cases). The basis for each dose-response relationship is included in the documentation describing each reference dose-response relationship reported on the ECHA website.

d) horizontal issues arising from evaluations of authorisation dossiers

In the context of several authorisation dossiers, the RAC discussed dermal exposure and the use of modelling, in particular Riskofderm and EUSES. The Committee was reminded that the Riskofderm model was more specifically designed for assessing dermal exposure and has been used in many authorisation cases in the past; therefore, for the sake of consistency, a case could possibly be made for using it more extensively. However, it was decided that further discussion was needed on this aspect and members had further questions with regard to alternative models as used by the Applicants. It was agreed that ECHA would organise an evening seminar on dermal exposure assessment at the next RAC meeting. The Chairman clarified that when alternative models are used (or requested by RAC) to analyse sensitivity, it would be better to present all the resulting outcomes to SEAC.

a) Capacity building

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

The Chairman invited the ECHA Contractor's representative to present the revised draft report on the DNEL setting for the reprotoxic properties of 1-bromopropane. The ECHA Contractor explained that the update concerns the addition of a tabulated summary of the relevant results, including the significance and reversibility of the effects and a comprehensive overview of the available data, in order to facilitate a RAC agreement on the most appropriate starting point for DNEL derivation. The Committee agreed to use a LOAEC of 50 ppm based on mouse sperm effects (Liu et al, 2009) as the point of departure and an assessment factor of 3 (1 for study duration and 3 for LOAEC to NOAEC extrapolation) for DNEL derivation. The Committee requested the contractor to modify the note on the DNEL setting for reprotoxic properties of 1–bromopropane accordingly. The agreed note will be published on the ECHA website, taking into account the proposed changes.

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

The Chairman invited the ECHA Contractor's representative to present the revised draft report on the DNEL setting for the reprotoxic properties of DIPP. The update on DIPP concerns mainly the justification of the selection of phthalates for read across to DIPP. A more holistic approach was taken in this read-across, including similarity in structure, physicochemical properties, and several key male developmental effects (including e.g. reduced foetal testosterone). This approach is consistent with the approach taken in the restriction proposal by ECHA and Denmark on four phthalates (DIBP, DBP, BBP, DEHP). The Committee discussed the draft report by the

ECHA Contractor. The Committee agreed on the note on the DNEL setting for reprotoxic properties of DIPP. The agreed note will be published on the ECHA website.

9.2 Authorisation applications

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

1. Diglyme_Merck

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the application for authorisation. In the presentation of the case, the Secretariat outlined issues which would need further clarification by the applicants and asked the Committee for comments and further suggestions.

RAC agreed on the conformity of this application for authorisation. The Committee also discussed the key issues identified by the Rapporteurs in the applications. The Secretariat will inform the applicants about the outcome of the conformity check and, where needed, will request further clarifications on the issues identified and discussed by the Committee.

b) Agreement on Draft Opinions

1. Chromium trioxide_SNECMA (1 use) (CT_Snecma)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by the downstream user 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 <100kg across four sites in the EU, <20 workers being potentially exposed. Spraying (of the work solution) is involved in all four applicant's sites; in addition brushing is used as a mode of application at one industrial site. The Applicant requested a 10 year review period.

The exposure assessment provided by the Applicant was based on measured data as well as on results of modelling. Worker exposure assessment contained some uncertainty due to the absence of workplace air measurement data for all the applicant's sites. The Rapporteurs concluded that the RMMs and OCs described in the application were appropriate and effective in limiting the risk to workers and the general population.

RAC agreed by consensus on the draft opinion with modifications related to the consistency of the RMMs and OCs across the sites. RAC decided to recommend additional conditions and monitoring arrangements for the review report only. RAC also agreed to give no advice to SEAC on the length of the review period.

2. Chromium trioxide_MTU (2 uses) (CT_MTU)

The Rapporteurs presented the draft opinions on the application for authorisation submitted by the downstream user for the two uses of chromium trioxide. The first Use covered 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 used for this Use is 0.35 tons, 15 workers potentially exposed. The second Use the Applicant applied for concerned surface treatment (unrelated to functional chrome plating) in a similar sector to the above. Annual volume for this Use is <100kg tonnes; < 50 workers are potentially exposed. The Applicant requested a 15 years review period for both Uses.

For both Uses exposure assessment provided by the Applicant was based on the measured data as well as on the results of modelling. Worker exposure assessment contained some uncertainty

due to the limited or absent workplace air measurement data for all the worker contributing scenarios, available measurement data was provided mostly with limited contextual information. The Rapporteurs concluded that overall RMMs and OCs described in the application are appropriate and effective in limiting the risks of workers but that the implemented RMMs could be further reviewed.

RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC decided to recommend additional conditions and monitoring arrangements for review reports and gave no advice to SEAC on the length of the review period.

3. Chromium trioxide_ABLOY (1 use) (CT_Abloy)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream user for the use of chromium trioxide in electroplating of mechanical and electro-mechanical cylinders, cams and padlocks, electro-mechanical lock cases and architectural hardware. The annual volume of the substance used is currently <1 tonne, but foreseen to increase. The application covers one site with <50 workers exposed. The Applicant requested a 12 year review period.

RAC agreed by consensus on the draft opinion with modifications related to the conditions. It was agreed that air monitoring is to be required for tasks undertaken by outsourced workers. The Committee was of the opinion that RMMs and OCs are appropriate in limiting the risk and decided to recommend additional conditions and monitoring arrangements for review reports only. RAC agreed to give no advice to SEAC on the length of the review period.

4. Chromium trioxide_HOOGOVENS Court Roll Surface Technologies (1 use) (CT_Hoogovens)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by eight applicants (downstream users) for the use of chromium trioxide for functional chrome plating of work rolls used in the steel and aluminium industry. The annual volume of the substance used is <50 tonnes. The application covers 11 (+1 to start shortly) sites with ca. 200workers exposed. The Applicants requested a 12 year review period.

RAC agreed by consensus on the draft opinion with modifications related to the consistency of the RMMs and OCs across the sites. It was agreed that biomonitoring will not be set as a condition. The Committee was of the opinion that RMMs and OCs are appropriate in limiting the risk and decided to recommend additional conditions and monitoring arrangements for review reports. RAC agreed to give no advice to SEAC on the length of the review period.

5. Chromium trioxide_TOPOCROM GmbH (1 use) (CT_Topocrom)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream user for the use of chromium trioxide for functional chrome plating in closed reactor systems for the establishment of adjustable hemispherical surface structures. The annual volume of the substance used is <50 tonnes. The application covers one site with ca. 25 workers exposed. The Applicant requested a 15 year review period.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. The Committee was of the opinion that RMMs and OCs are appropriate in limiting the risk and decided to recommend additional conditions and monitoring arrangements for review reports. RAC agreed to give no advice to SEAC on the length of the review period.

6. Chromium trioxide_FN HERSTAL S.A. (2 uses) (CT_Herstal)

The Rapporteurs presented the draft opinions on the application for authorisation submitted by the downstream user for two Uses of chromium trioxide concerning the industrial use of chromium trioxide in the hard chromium coating of military small- and medium-caliber firearms barrel bores and auxiliary parts The annual volume of the substance used for this Use is 1 tonne and <50 workers are potentially exposed. The Applicant requested a 7 years review period for the Use 2.

For both Uses exposure assessment was based solely on the modelled data and therefore contained uncertainties due to the absence of workplace air measurement data, and a sufficient exposure assessment. The Rapporteurs concluded that RMMs and OCs described in the application are appropriate and effective in limiting the risks of workers at Herstal site. However RAC noted that effectiveness of implemented RMMs at the site of Erith should be further improved to reduce exposure to Cr(VI) both for workers and for the general population.

RAC agreed by consensus on the both draft opinions as proposed by the Rapporteurs. However, specifically for Use 1 RAC acknowledged differences in OCs and RMMs between the two Applicants' sites where the substance is used, i.e. that these are not appropriate and effective in limiting the risks at the Erith site. RAC agreed to offer no advice to SEAC on the length of the review period in both draft opinions.

7. Chromium trioxide_GERHARDI KUNSTSTOFFTECHNIK GmbH (1 use) (CT_Gerhardi)

The Rapporteurs presented a draft opinion for one Use for plating on plastics for automotive applications (PoPAA).

The application covers twelve companies operating at twenty-two sites in four countries; the total volume of chromium trioxide used annually is <1000 tonnes and the number of workers potentially exposed varies widely depending on the activity. The Applicant requested a review period of 12 years.

The process involves surface functional plating treatment with decorative character. Automotive plastic parts are prepared by pre-treatment (etching) followed by deposition of metallic chromium (amongst other metals) to improve surface appearance, level of corrosion protection and to enhance durability. Automatic plating lines are in operation at all sites. There are no manual plating baths.

The production process is an open system. Potential occupational exposure to Cr(VI) may occur during the plating, etching and decanting tasks as well as during maintenance and handling of waste.

RAC was of the opinion that it was improbable that a non-combined exposure would exist and therefore more detailed conditions should be included in the opinion. To this end, RAC recommended to address specifically RMMs related to hierarchy of control, segregation and/or confinement of the plating baths, maintenance and efficiency of the local and general ventilation systems and respiratory protection equipment for some worker contributing scenarios.

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.

8. Chromium trioxide; Potassium dichromate; Sodium dichromate_SOURIAU SAS (3 opinions) (CT_PD_SD_Souriau)

The Rapporteurs presented the draft opinion on an application for three industrial Uses – use of a mixture containing hexavalent chromium compounds for the conversion of cadmium coated connectors in order to achieve a higher level of performances than the requirements of international standards as well as to withstand harsh environments and high safety applications (such as in the military, aeronautic, aerospace, mining, offshore and nuclear industries or for the application in safety devices for road vehicles, rolling stock and vessels) (=Use 1), use of a mixture containing hexavalent chromium compounds in conversion coating and passivation of connectors in order to meet the requirements of international standards (=Use 2) and use of a mixture containing chromium trioxide for the etching of composite connectors used by industries subject to harsh environments, to mainly ensure adhesive deposit to meet the requirements of international standards (=Use 3).

The application covers six sites in three countries. The Uses, the parts treated, the operating conditions and risk management measures are similar. The total volume of a mixture used annually is ca. 15 tonnes and the number of workers potentially exposed is 100. The Applicant requested a review period of 12 years (Use 1), 7 years (Use 2) and 4 years (Use 3) respectively.

In Uses 1 and 2, a mixture containing Cr(VI) compounds is used for the conversion of cadmium-coated circular and rectangular connectors which are used, for example, in safety devices for road vehicles, rolling stock and vessels. Dipping of articles in Cr(VI)-containing treatment baths can be an automated or a manual process, depending on the treatment line configuration. Manual dipping is performed at all sites, on a regular basis or only for sample production. Addition of liquid hexavalent chromium to bath can also be automated using a closed pumping system.

In Use 3, mixtures containing chromium trioxide are used for the etching of composite connectors, in order to ensure the surface preparation of substrates prior to their surface treatment. These are high performance connectors, intended to withstand severe atmospheric and mechanical conditions (humidity, temperature, vibrations, corrosive atmosphere) and concerns mainly aeronautics sector.

The production process is characterised as an open system. Potential for occupational exposure to Cr(VI) may exist during specific tasks, reflecting dipping, sampling and adjustment of baths. Dipping of articles in Cr(VI)-containing treatment bath is an automated process in Use 3, while addition of solid chromium trioxide to the bath is a manual task.

RAC noted that there were uncertainties in the exposure estimates for the workers, because of the relatively small monitoring dataset available.

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. The Committee recommended additional monitoring arrangements for review reports. RAC agreed on the draft opinion by consensus.

9. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC)

RAC noted an oral update by the Rapporteurs on the progress of the opinion development on the application for authorisation CT_HAPOC.

10. Ammonium dichromate_VECO BV (1 use) (AD_Veco)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by the downstream user 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 <100 kg, and ca. 25 workers potentially exposed. The applicant requested a 7 years review period.

The Rapporteur concluded that description of the tasks of the workers was adequately clarified in written responses from the applicant. She also concluded that exposure assessment contained some uncertainties due to the absence of any workplace air measurement data, exposure estimation based solely on modelling, control of worker exposure mainly relied on administrative measures (good housekeeping practice, training and skills of workers). The Rapporteur noted that existing RMMs at the applicant's site were not considered appropriate and effective in limiting the risks of workers since they included mainly administrative measures and PPE in controlling exposure during predominantly manual tasks under open process conditions. In the absence of any workplace air measurement data, the effectiveness of implemented RMMs in limiting the risks to workers were not convincingly demonstrated.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteur. RAC was of the opinion that RMMs and OCs were not appropriate in limiting the risk. RAC decided to recommend additional monitoring arrangements based on relevant standard methodologies or protocols to be performed as soon as the authorisation is granted. Biomonitoring should be continued.

11. Sodium dichromate_TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH (1 use) (SD_Total)

The Rapporteur presented the draft opinion on this downstream user application for authorisation for the use of sodium dichromate as a corrosion inhibitor in ammonia absorption deep cooling systems of a methanol synthesis plant. The quantity used per year is less than one tonne, covering one site in closed outdoor systems. According to the Rapporteur's assessment, the 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.

12. Sodium dichromate_JACOBS DOUWEE EGBERTS DE GmbH (1 use) (SD_Jacobs)

The Rapporteur presented the draft opinion on this downstream user application for authorisation for the use of sodium dichromate 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 quantity used per year is less than one tonne, covering five sites in closed indoor 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.

13. EDC_BASF SE (2 uses) (EDC_BASF_2)

The Chairman invited the Rapporteurs to present the RAC draft opinions. The Rapporteurs presented the draft opinions on the application for authorisation submitted by the downstream user for the industrial uses of EDC as solvent and crystallisation medium in the synthesis of the

EU pesticide Bentazone (ISO) (use 1) as solvent and of the EU biocide Flocoumafen (ISO) (use 2).

The annual volume of the substance used is up to 250 tonnes (use 1) and up to 10 tonnes (use 2). Ca. 10 workers are potentially exposed on both uses and the applicant requested a 12 years review period for both uses.

There were no major points of discussion for this application and the draft opinions were subsequently agreed by consensus as proposed by the Rapporteurs. RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population and proposed additional conditions and monitoring arrangements for the review report only. Finally, RAC agreed to offer no advice to SEAC on the length of the review period.

The Chairman thanked the Rapporteurs for their work on the application.

14. EDC_ELI LILLY S.A. (1 use) (EDC_Eli_Lilly)

The Chairman invited the Rapporteurs to present the RAC draft opinion.

The Rapporteurs presented the draft opinions on the application for authorisation for the manufacture of an active pharmaceutical ingredient. The annual volume of the substance used is between 100 to 250 tonnes and <50 workers are potentially exposed on both uses and the applicant requested a 12 years review period.

The draft opinion was agreed by consensus as proposed by the Rapporteur. In particular, RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC did not propose any additional conditions and monitoring arrangements for the authorisation nor the review report. Finally, RAC agreed to offer no advice to SEAC on the length of the review period. The Chairman thanked the Rapporteur for their work on the application.

15. EDC_DOW ITALIA S.R.L. (1 use) (EDC_Dow)

The Chairman invited the Rapporteurs to present the RAC draft opinion. There were no major points of discussion for this application and the draft opinion was subsequently agreed by consensus, as proposed by the Rapporteurs. In particular, RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. Furthermore, RAC did not propose any additional conditions and monitoring arrangements for the authorisation. In case of a review report, the applicants should include all sources of release to the air (including fugitive emissions) in the exposure assessment. Also, RAC agreed to offer no advice to SEAC on the length of the review period. The Chairman thanked the Rapporteurs for their work on the application.

16. EDC_LANXESS Deutschland GmbH (2 uses) (EDC_Lanxess)

The Chairman invited the Rapporteurs to present the RAC draft opinion. There were no major points of discussion for this application and the draft opinion was subsequently agreed by consensus as proposed by the Rapporteurs. In particular, RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. Furthermore, RAC did not propose any additional conditions and monitoring arrangements for the authorisation. In case of a review report, the applicants should include regular occupational exposure measurements including all

sources of release to the air (also fugitive emissions) in the exposure assessment. Also, RAC agreed to offer no advice to SEAC on the length of the review period.

The Chairman thanked the Rapporteurs for their work on the application.

17. EDC_H&R OLWERKE SCHINDLER GmbH (1 use) (EDC_Olwerke)

There were no major points of discussion for this application and the draft opinion was subsequently agreed by consensus as proposed by the Rapporteurs. In particular, RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. In addition, RAC did not propose any additional conditions and monitoring arrangements for the authorisation. However, in case of a review report, the Rapporteurs proposed additional conditions as listed in the opinion. Finally, RAC agreed to offer no advice to SEAC on the length of the review period.

The Chairman thanked the Rapporteurs for their work on the application.

18. EDC_GRUPPA LOTOS S.A. (1 use) (EDC_Lotos)

There were no major points of discussion for this application and the draft opinion was subsequently agreed by consensus as proposed by the Rapporteurs. In particular, RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. Furthermore, RAC did not propose any additional conditions and monitoring arrangements for the authorisation. However, in case of a review report, the Rapporteurs proposed additional conditions as listed in the opinion. Finally, RAC agreed to offer no advice to SEAC on the length of the review period.

The Chairman thanked the Rapporteurs for their work on the application.

19. EDC_GE HEALTHCARE Bio-Sciences (1 use) (EDC_Bio-Sciences)

The Rapporteurs highlighted that the Applicants had not submitted any WCS in the application, and what was provided following the request of the Rapporteurs was not judged as sufficient.

In particular, RAC agreed that while the implemented risk management measures and operational conditions are appropriate and effective in limiting the risk to workers, they are <u>not</u> appropriate and effective in limiting the risk to the general population. Therefore, they recommended additional conditions and monitoring arrangements for the authorisation and the review report as listed in the opinion. Also, RAC agreed to offer no advice to SEAC on the length of the review period. Following an intervention by the EC observer, it was agreed to remove the word "improve" from the conditions' text in the draft opinion. The draft opinion was agreed by consensus as proposed by the Rapporteurs.

The Chairman thanked the Rapporteurs for their work on the application.

20. Technical MDA, POLYNT COMPOSITES France (2 uses) (MDA_Polynt)

[*please note that the detailed minutes for this case will be made available after the Applicant has been informed post RAC consultation and agreement by Written Procedure*]

This application concerns a downstream application for two uses of technical MDA (Formaldehyde, oligomeric reaction products with aniline) and was tabled for a full discussion, the opinion not being ready for agreement at this meeting. The first use concerns formulation of an epoxy resin hardener containing technical MDA (tMDA). The hardener, containing

approximately 36% (w/w) of tMDA, is produced in >20 batches per year. The second use concerns the industrial use of an epoxy resin hardener containing tMDA at different sites using a mobile unit in a process designed to immobilise spent ion exchange resins in a high containment matrix.

The draft opinion will be subject of a RAC consultation and agreement is foreseen either via written procedure, or at the next plenary.

21. EDC_EURENCO (1 use) (EDC_Eurenko)

[*please note that the detailed minutes for this case will be available after the Applicant has been informed post RAC consultation and agreement by Written Procedure*]

This application concerns a downstream 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, used to increase the energetic performance of propellants and explosives. It is described as a relatively open process with many manual operations.

The final draft will be the subject of a RAC consultation consultations and then agreement is foreseen via written procedure, or at the next plenary.

22. Sodium dichromate-Brenntag (3 uses) (SD_Brenntag)
23. Potassium dichromate-Brenntag (2 uses) (PD_Brenntag)
24. Dichromium tris(chromate)-Henkel (2 uses) (DtC_Henkel)
25. Strontium chromate-Akzo Nobel (2 uses) (SC_Akzo)
26. Potassium hydroxyoctaoxodizincatedichromate-PPG (2 uses) (PH_PPG)

The above five applications for authorisation were prepared 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 Chairman introduced the state of play of the applications for authorisation. At the previous meeting, the Committee discussed the draft opinions and received guidance from the Committee. A Trialogue has been held on 21 June 2016, where the Rapporteurs reiterated their request to the Applicants for more measurement data, contextual information to the measurement data, and further information in particular on improved descriptions of the processes covered, the tasks involved, as well as the RMMs and OCs per WCS. The Rapporteurs prepared the draft opinions, which went for consultation with RAC Members during the summer. Based on the comments received from Members the Rapporteurs have updated the draft opinions. The draft opinions were tabled for agreement at this plenary meeting.

The Chairman invited the Rapporteurs to present the RAC draft opinions.

The Rapporteurs explained that, in response to their questions, the Applicants had provided during and following the Trialogue, amongst other contextual information to the measurement data, additional modelling and literature data, which were considered by the Rapporteurs when preparing the draft opinions for consultation with RAC Members.

The discussion on the cases covering formulation, paints and coatings and surface treatment mainly focused on the uncertainties in the exposure assessment, the broad exposure scenarios and their validation, as well as the OCs and RMMs. RAC confirmed that the OCs and RMMs described in the application do not limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation. These included improved

exposure scenarios without delay and their validation with air monitoring data for workers; monitoring of emissions to the environment and conditions related to the review report as listed in the opinions.

In addition to the conditions and monitoring arrangements mentioned above for these three uses, RAC proposed to include specific conditions for the use on formulation (on waste management); on the use on paints and coatings (regarding biomonitoring, access control, physical segregation and appropriate RPE) and on the use on surface treatment (regarding waste management and control of exposure during decanting and weighing of solids).

Regarding the use on passivation of tin-plated steel, RAC confirmed that the operational conditions and risk management measures described in the application do limit the risk, provided that the risk management measures and operational conditions as described in the application and the suggested conditions and monitoring arrangements are adhered to.

With regard to the advice to SEAC on the length of the review period, RAC's recommendation were as follows: no advice to SEAC for the uses on formulation and on Passivation of tin-plated steel; a review period of no longer than 7 years for the uses on paints and coatings and surface treatment.

As general remarks common on all uses, RAC considered that the applicant's assessment of the exposure, of humans via the environment is based on a series of default assumptions that are likely to result in a significant overestimate of health impacts. The re-use of the estimated additional statistical fatal cancer cases outside of the socioeconomic analysis was strongly advised against. RAC further noted that the uncertainties in the applicant's assessment should be addressed in any review report.

The draft opinions were agreed by consensus. The Chairman thanked the Rapporteurs for their work on the applications.

27. Potassium dichromate GENTROCHEMA BV (2 uses) (PD_Gentrochema)
28. Sodium dichromate GENTROCHEMA BV (3 uses) (SD_Gentrochema)

RAC noted an oral update by the Rapporteurs on the progress of the opinion development on the applications for authorisation PD_Gentrochema and SD_Gentrochema.

b) Adoption of Final Opinion

1. Chromium trioxide-Kromatek (1 use) (CT_Kromatek)

The Chairman introduced the state of the application for authorisation. At the previous meeting, RAC discussed and agreed by consensus on the second version of the RAC draft opinion. The draft opinion was sent to the Applicants, who made their comments on the document.

The Rapporteur assessed the comments from the Applicants, proposing no changes in the document given that the Applicants' comments where referring to SEAC and not to RAC issues. The draft opinion together with the comments of the Applicants and the Rapporteur's suggestion for no modifications went for a RAC consultation, with no comments from RAC Members.

The final opinion was adopted by consensus. The opinion will be sent to the Applicants, European Commission and Member States following the adoption at SEAC.

The Chairman thanked the Rapporteur and Secretariat for their work on the application.

2. Six Uses of chromium trioxide submitted by LANXESS Deutschland GmbH on behalf of a group of companies:

The Chairman introduced the state of the application for authorisation. At the previous meetings, RAC discussed and agreed by consensus the six RAC draft opinions. The draft opinions were sent to the Applicants, who made their comments on the documents.

The Rapporteurs carefully considered the Applicants' comments, noting that there were many comments on the review period and on the process in general. The Rapporteurs were of the opinion that the Applicants' comments contained no new clarifications related to the RAC evaluation of the application. However, they proposed to introduce minor clarifications in the RAC opinions. The draft final opinions together with the comments by the Applicants were sent for RAC consultation prior to the plenary meeting.

The RAC Rapporteurs presented these proposed changes to the final opinions, and responses to the Applicants' comments. As there were no questions by Members, the final opinions were adopted by consensus. The opinions will be sent to the Applicants, the European Commission and the Member States following the adoption at SEAC.

The Chairman thanked the Rapporteurs and Secretariat for their work on the application.

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/38/2016/10, was then agreed by RAC.

10. AOB

None.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC-38 6–9 September 2016
13-16 September 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/38/2016**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-38 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 37 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/38/2016/01** and document **RAC/38/2016/02.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes SECR presented the update on the Q4/2016 and Q1-2/2017 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-38 meeting on S-CIRCABC.
c) Annual update of RAC accredited stakeholders' list. **SECR** presented document **RAC/38/2016/03.** **RAC** agreed on the updated list.	**SECR** to publish the document on ECHA's website.
7. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate • Spirodiclofen (ISO): physical hazards, acute toxicity (all routes), skin corrosion / irritation, serious eye damage / eye irritation, respiratory sensitisation, skin sensitisation, STOT SE, germ cell mutagenicity, aspiration hazards, aquatic hazards and M-factors (acute and chronic) • Maleic anhydride: acute toxicity, skin sensitisation • Succinic anhydride: acute toxicity, skin sensitisation	

- D-trans-tetramethrin:

  physical hazards, acute toxicity (dermal and inhalation), skin corrosion / irritation, serious eye damage / eye irritation, respiratory and skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, aspiration hazard, aquatic hazards and M-factors (acute and chronic)

- Tetramethrin (ISO):

  physical hazards, acute toxicity (dermal and inhalation), skin corrosion / irritation, Serious eye damage / eye irritation, respiratory and skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, aspiration hazard, aquatic hazards and M-factors (acute and chronic)

- Mesosulfuron-methyl:

  aquatic hazards and M-factors (acute and chronic)

B. Substances with hazard classes for agreement in plenary session

a) Acetaldehyde, ethanal
b) Pinoxaden (ISO)
c) 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone
d) Spirodiclofen
e) Pyrocatechol
f) Mesosulfuron-methyl
g) Tetramethrin (ISO)
h) D-trans-tetramethrin
i) Maleic anhydride
j) Succinic anhydride

a) Acetaldehyde, ethanal

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Carc. 1B (H350), Muta. 2 (H341)	**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 EC and publish it on the ECHA website.

b) Pinoxaden (ISO)

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. RAC 38: STOT SE 3 ; H335 Agreed already at RAC 37:	**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.

Acute Tox. 4; H332, Acute Tox. 4; H302, Eye Irrit. 2; H319, Skin Sens. 1A; H317, Repr. 2; H361d, Aquatic Acute 1; H400 with M=1, Aquatic Chronic 3; H412	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
c) 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Repr. 1B (H360D)	**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.
d) Spirodiclofen (ISO)	
RAC agreed on the harmonised classification and labelling as indicated in Table 2 and below. Skins Sens. 1B (H317), STOT RE 2 (H373), Aquatic Chronic 1 (H410) with M=10	The **manufacturer** to provide data on specific areas identified during the discussion on carcinogenicity and reproductive toxicity, as requested by **RAC**. **RAC** to revisit the open points during RAC consultation and at RAC-39 in December.
e) Pyrocatechol	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 3; H301, Acute Tox. 3; H311, Muta. 2; H341, Carc. 1B; H350	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
f) Mesosulfuron-methyl	
RAC agreed on the harmonised classification and labelling as indicated in Table 2 and below. 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. **Rapporteurs** to provide the draft opinion (human health part) to the SECR. **SECR** to launch a RAC consultation prior to RAC 39.
g) Tetramethrin (ISO)	
RAC adopted <u>by consensus</u> 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. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur.

Acute Tox. 4 (H302), STOT SE 2 (H371 (nervous system) (inhalation)), Carc. 2 (H351), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with an M-factor of 100 for both aquatic hazards	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
h) D-trans-tetramethrin	
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 SE 2 (H371 (nervous system) (inhalation)), Carc. 2 (H351), Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with an M-factor of 100 for both aquatic hazards	**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) Maleic anhydride	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 4; H302, Skin. Sens. 1A; H317, SCL: 0,001%, STOT RE 1; H372 (respiratory system) (inhalation), Eye Dam. 1; H318, EU H071	**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) Succinic anhydride	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Acute Tox. 4; H302, Skin. Sens. 1; H317, Eye Dam. 1; H318, Skin. Corr. 1; H314, Resp. Sens. 1; H334	**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.
7.3 Appointment of RAC (co-)Rapporteurs for CLH dossiers	
RAC appointed the new (co-)Rapporteurs for CLH dossiers.	**SECR** to upload the list of appointed (co-)Rapporteurs to CIRCA BC confidential.
8. Restrictions	
8.1 Restriction Annex XV dossiers	
a) Conformity check	
1)N,N-dimethylformamide; dimethyl formamide (DMF) – outcome of the conformity check and presentation of the key issues RAC agreed that the dossier does not conform to the Annex XV requirements.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG. **SECR** to inform the dossier submitter on the outcome of the conformity check.

RAC took note of the recommendations to the dossier submitter.	
1) TDFAs Rapporteurs presented and RAC discussed the RAC first draft opinion. The plausibility of the link between the identified hazards, the clinical cases and TDFAs/solvents in spray products will be further considered at RAC-39. RAC supported in principle the use of DNELs, NOAEC and AFs as proposed by the Rapporteurs. RAC requested industry to provide further testing data on the analysis of Magic Nano. RAC supported the use of CONSEXPO for and/or sprayexpo for the subsequent exposure estimates.	**Rapporteurs** to take the discussion into account in the second draft opinion.
2) Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) The Rapporteurs presented and RAC discussed the first draft opinion. RAC considered the proposed grouping of the four substances as justified. RAC agreed to change the DNEL for DIBP based on additional information (0.0083 mg/kg/d) and to use the previously established DNELs for the other three substances[2]. RAC agreed to address other effects (immunological, metabolic, neurodevelopmental) in the uncertainty analysis and SEA. RAC agreed to base the risk assessment on biomonitoring data with exposure modelling as	**Rapporteurs** to take the discussion into account in the second draft opinion.

[2] ECHA (2012a). Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC): Opinion on an Annex XV dossier proposing restrictions on four phthalates and the associated Background document. Opinion available at http://echa.europa.eu/documents/10162/58050be8-f7be-4b55-b106-76dda4989dd6, Background document at http://echa.europa.eu/documents/10162/3bc5088a-a231-498e-86e6-8451884c6a4f

ECHA (2013b). Authorisation, establishing reference DNELs for DEHP. Agenda Point: 7 a) i. DNEL setting (DEHP). 24th meeting of the committee for risk assessment RAC/24/2013/08 rev. 2). Available at: http://echa.europa.eu/documents/10162/13579/rac_24_dnel_dehp_comments_en.pdf

ECHA (2013c). Authorisation, establishing reference DNELs for DBP, Helsinki, 12 April 2013. 24th meeting of the committee for risk assessment, Agenda Point: 7 a) i. DNEL setting (DBP). RAC/24/2013/09_rev 2. Available at: http://echa.europa.eu/documents/10162/13579/rac_24_dnel_dbp_comments_en.pdf

ECHA (2013d). Application for Authorisation: Establishing Reference DNELs for BBP. RAC/26/2013/07 Rev.1, Helsinki, 12 September 2013. Agreed at RAC-26. Available at: http://echa.europa.eu/documents/10162/13579/rac_26_reference_dnels_bbp_en.pdf

supportive evidence of articles contribution to exposure and risk, i.e. as proposed by the DS. **RAC agreed on the RCRs and that there is a risk that needs to be addressed.** RAC agreed that there is risk of DIBP in toys and childcare articles that needs to be addressed. RAC agreed that the need for EU-wide action is justified. Whether the risk can best be addressed by a restriction will be considered at RAC-39.	
8.2 Appointment of RAC (co-)Rapporteurs for restriction dossiers	
RAC agreed on the updated pool of Rapporteurs for the restriction dossiers as stated in the restricted room document **RAC/38/2016/07**.	**RAC** members to volunteer for the pool of (co-)Rapporteurs for restriction proposal on diisocyanates.
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 agreed on the note on the DNEL setting for reprotoxic properties of 1–bromopropane.	**SECR** to update the agreed note in accordance with RAC-38. **SECR** to publish the agreed note on the ECHA website.
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. The Committee discussed the revised draft report by the ECHA Contractor. The Committee agreed on note on the DNEL setting for reprotoxic properties of DIPP.	**SECR** to update the agreed note in accordance with RAC-38. **SECR** to publish the agreed note on the ECHA website.
9.2 Authorisation applications	
a) Outcome of the conformity check and presentation of the key issues	
1. Diglyme_Merck RAC agreed on conformity of the application for authorisation. RAC discussed the key issues in the application for authorisation and provided advice to the Rapporteurs.	**SECR** to upload to S-CIRCABC the agreed Conformity Report. **SECR** to inform SEAC about the outcome of the Conformity check.

	SECR to inform the applicants about the outcome of the conformity check.
b) Agreement on Draft Opinions	
1. Chromium trioxide_SNECMA (1 use) (CT_Snecma) RAC agreed on the draft opinion with modifications related to the consistency of the RMMs and OCs across the sites. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided to recommend additional conditions and monitoring arrangements for review reports. RAC agreed to give 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.
2. Chromium trioxide_MTU (2 uses) (CT_MTU) *Uses 1 and 2:* RAC agreed on the draft opinions as proposed by the Rapporteur. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided to recommend additional conditions and monitoring arrangements for review reports. RAC agreed to give 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 Applicant for commenting.
3. Chromium trioxide_ABLOY (1 use) (CT_Abloy) RAC agreed on the draft opinion with modifications related to the conditions. Air monitoring is to be required for tasks undertaken by outsourced workers and biomonitoring will not be set as a condition for outsourced workers. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided to recommend additional conditions and monitoring arrangements for review reports taking into consideration the modification above.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

RAC agreed to give no advice to SEAC on the length of the review period.	
4. Chromium trioxide_HOOGOVENS Court Roll Surface Technologies (1 use) (CT_Hoogovens) RAC agreed on the draft opinion with modifications related to the consistency of the RMMs and OCs across the sites. Biomonitoring will not be set as a condition. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided to recommend additional conditions and monitoring arrangements for review reports. RAC agreed to give 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. Chromium trioxide_TOPOCROM GmbH (1 use) (CT_Topocrom) 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 risk. RAC decided to recommend additional conditions and monitoring arrangements for review reports. RAC agreed to give 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.
6. Chromium trioxide_FN HERSTAL S.A. (2 uses) (CT_Herstal) *Use 1:* RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC acknowledged the differences in OCs and RMMs between the two applicants' sites where the substance is used, i.e. that these are not appropriate and effective in limiting the risks at the Erith site. RAC agreed to offer no advice to SEAC on the length of the review period. *Use 2:* RAC agreed on the draft opinion as proposed by the Rapporteurs. 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. Chromium trioxide_GERARDHI KUNSTOFFTECHNIK GmbH (1 use) (CT_Gerardhi) 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 risk. RAC decided to recommend additional monitoring arrangements for the application. RAC proposed to address specifically RMMs related to hierarchy of control, segregation, maintenance and efficiency of the local and general ventilation systems and respiratory protection equipment for some worker contributing scenarios. RAC recommended in addition that the Applicant consider containment of the plating lines across all sites through, i.e. the use of covers where feasible and /or the use of mist suppressants. RAC agreed to give 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.
8. Chromium trioxide; Potassium dichromate; Sodium dichromate_SOURIAU SAS (3 uses, 3 opinions) (CT_PD_SD_Souriau) RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC agreed to also reflect in the opinions the original MvE assessment carried out by the Applicant in addition to that using EUSES. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided to recommend additional monitoring arrangements for review reports. RAC proposed to better describe the need for monitoring arrangements for review reports based on the wording of similar recent applications. RAC agreed to give 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 Applicant for commenting.
9. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC) RAC took for the information update of the Rapporteurs on the progress of the opinion development.	
10. Ammonium dichromate_VECO BV (1 use) (AD_Veco) RAC agreed on the draft opinion as proposed by the Rapporteur. RAC is of the opinion that RMMs and OCs are not appropriate in limiting the risk. RAC decided to recommend additional monitoring arrangements based on relevant standard methodologies or protocols to be performed as soon	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

as the authorisation is granted. Biomonitoring should be continued. The information gathered shall be used to review and improve the appropriateness and effectiveness of the RMMs and OCs to limit workers' exposure. The hierarchy of control principles shall be followed in the selection of appropriate RMMs. In case the authorisation is granted, the use of full enclosure (such as glove box) with air extraction around the area where the tasks resulting in exposure are performed should be considered, especially for WCS 3. Furthermore, all releases of Cr(VI) to wastewater related to the use of ammonium dichromate described in this application shall be measured. RAC agreed to give no advice to SEAC on the length of the review period.	
11. Sodium dichromate_TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH (1 use) (SD_Total) RAC agreed on the draft opinion as proposed by the Rapporteur. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided not to recommend any monitoring arrangements for the authorisation nor for the 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.
12. Sodium dichromate_JACOBS DOUWEE EGBERTS DE GmbH (1 use) (SD_Jacobs) RAC agreed on the draft opinion as proposed by the Rapporteur. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. RAC decided not to recommend any monitoring arrangements for the authorisation nor for the 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.
13. EDC_BASF SE (2 uses) (EDC_BASF_2) RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC proposed additional conditions and monitoring arrangements for the review report. RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. 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 Applicant for commenting.

14. EDC_ELI LILLY S.A. (1 use) (EDC_Eli_Lilly) RAC agreed on the draft opinion as proposed by the Rapporteur. RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC did not propose any additional conditions and monitoring arrangements for the authorisation nor the review report. 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.
15. EDC_DOW ITALIA S.R.L. (1 use) (EDC_Dow) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC did not propose any additional conditions and monitoring arrangements for the authorisation. In case of a review report, the applicants should include all sources of release to the air (including fugitive emissions) in the exposure assessment. 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.
16. EDC_LANXESS Deutschland GmbH (2 uses) (EDC_Lanxess) RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC did not propose any additional conditions and monitoring arrangements for the authorisation. In case of a review report, the applicants should include regular occupational exposure measurements including all sources of release to the air (also fugitive emissions) in the exposure assessment. 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 Applicant for commenting.
17. EDC_H&R OLWERKE SCHINDLER GmbH (1 use) (EDC_Olwerke) RAC agreed on the draft opinion as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC did not propose any additional conditions and monitoring arrangements for the authorisation. In case of a review report, the Rapporteurs proposed additional conditions as listed in the opinion. RAC agreed to offer no advice to SEAC on the length of the review period.	
18. EDC_GRUPPA LOTOS S.A. (1 use) (EDC_Lotos) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC agreed that the risk management measures and operational conditions described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC did not propose any additional conditions and monitoring arrangements for the authorisation. In case of a review report, the Rapporteurs proposed additional conditions as listed in the opinion. 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.
19. EDC_GE HEALTHCARE Bio-Sciences (1 use) (EDC_Bio-Sciences) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC agreed that while the implemented risk management measures and operational conditions are appropriate and effective in limiting the risk to workers, they are <u>not</u> appropriate and effective in limiting the risk to the general population. RAC recommended additional conditions and monitoring arrangements for the authorisation and the review report as listed in the opinion. 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. Technical MDA_POLYNT COMPOSITES France (2 uses) (MDA_Polynt) RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk. Overall reduction of risks might be expected by new hardener. No final conclusion possible due to deficient documentation RAC agreed to recommend monitoring arrangements for the authorisation and for the review reports.	**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. **Rapporteurs** to revise the opinion in accordance with comments received during the RAC consultations as necessary and to provide it to the SECR.

RAC decided to give no advice to SEAC on the length of the review period.	**SECR** to table the dossier for discussion and agreement at RAC 39 or by **written procedure**.
21. EDC_EURENCO (1 use) (EDC_Eurenko) RAC is of the opinion that RMMs and OCs are not appropriate in limiting the risk both for workers and for general population (MvE). RAC decided to give no advice to SEAC on the length of the review period.	**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. **Rapporteurs** to revise the opinion in accordance with comments received during the RAC consultations as necessary and to provide it to the SECR. **SECR** to table the dossier for discussion and agreement at RAC 39 or by written procedure.
22. Sodium dichromate-Brenntag (3 uses) (SD_Brenntag) **23. Potassium dichromate-Brenntag (2 uses) (PD_Brenntag)** **24. Dichromium tris(chromate)-Henkel (2 uses) (DtC_Henkel)** **25. Strontium chromate-Akzo Nobel (2 uses) (SC_Akzo)** **26.Potassium hydroxyoctaoxodizincatedichromate -PPG (2 uses) (PH_PPG)** RAC agreed on the draft opinions by consensus. **Common to all uses:** RAC considered that the applicant's assessment of the exposure, risk and impacts for humans via the environment is based on a series of default assumptions that are likely to result in a significant overestimate of impacts. This introduces considerable uncertainty to the applicant's assessment, which should be addressed in any review report. The re-use of the estimated additional statistical fatal cancer cases outside of the socioeconomic analysis is advised against. **Common to Formulation, Paints and coatings & Surface treatment** RAC considered that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements are expected to improve the situation. RAC proposes conditions and monitoring arrangements (e.g., improved exposure scenarios without delay and their validation; air monitoring for	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicants for commenting.

workers; monitoring of emissions to the environment) and conditions related to the review report as listed in the opinions. **Formulation**: RAC proposes to include a specific condition on waste management to this use. RAC gave no advice to SEAC on the length of the review period. **Paints and coatings**: RAC proposes to include specific conditions to this use (i.e., regarding biomonitoring, access control, physical segregation and appropriate RPE). RAC recommended to SEAC a review period of no longer than 7 years. **Surface treatment**: In addition to the conditions and monitoring arrangements above, RAC proposes to include specific conditions to this use (i.e., regarding waste management and control of exposure during decanting and weighing of solids). RAC recommended to SEAC a review period no longer than 7 years. **Passivation of tin-plated steel**: RAC confirmed that the operational conditions and risk management measures described in the application limit the risk, provided that the risk management measures and operational conditions as described in the application and the suggested conditions and monitoring arrangements are adhered to. RAC proposed conditions and monitoring arrangements (e.g., improved OCs & RMMs; air monitoring for workers) and conditions related to the review report (e.g. monitoring of emissions to the environment) as listed in the opinions. RAC gave no advice to SEAC on the length of the review period. The Secretariat will ensure that all changes agreed regarding the uncertainties and estimates of exposure of humans via the environment will be included also for the opinion on this use.	
27. Potassium dichromate GENTROCHEMA BV (2 uses) (PD_Gentrochema)	

RAC took for the information update of the Rapporteurs on the progress of the opinion development.	
28. Sodium dichromate GENTROCHEMA BV (3 uses) (SD_Gentrochema) RAC took for the information update of the Rapporteurs on the progress of the opinion development.	
c) Adoption of final opinion	
1. Chromium trioxide-Kromatek (1 use) (CT_Kromatek) RAC adopted the final opinion with no changes following the Applicants' comments on the draft opinion.	**SECR** to send the final opinion to the EC, MSs and the Applicants.
2. Chromium trioxide 1 (6 uses) (CT_Lanxess) <u>Uses 1, 2, 3, 4, 5 and 6</u> RAC adopted the final opinions with changes in the text addressing the comments by the Applicant, as proposed by the Rapporteurs.	**Rapporteurs** together with **SECR** to do the final editing of the final opinions on the Uses 1, 2, 3, 4, 5 and 6. **SECR** to send the final opinions to the EC, MSs and the Applicants.
9.3 Appointment of RAC (co-)Rapporteurs for authorisation applications	
RAC/38/2016/10 RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to CIRCABC restricted.
10. AOB	
11. Action points and main conclusions of RAC-38	
SECR to upload the adopted action points to CIRCA BC.	

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

RAC-38

1. Mesosulfuron-methyl
2. 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone
3. Spirodiclofen (ISO)
4. Acetaldehyde
5. Tetramethrin (ISO)
6. D-trans-tetramethrin (ISO)
7. Pyrocatechol
8. Pinoxaden
9. Succinic anhydride
10. Maleic anhydride

Table 1: Classification & labelling tables for substances for which RAC adopted an opinion

Acetaldehyde; ethanal

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

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

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

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	607-RST-00-Y	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	607-RST-00-Y	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	Repr. 2 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1A STOT SE 3 Aquatic Acute 1 Aquatic Chronic 3	H361d H332 H302 H319 H317 H335 H400 H412	GHS08 GHS07 GHS09 Wng	H361d H332 H302 H319 H317 H335 H410		M=1	
Resulting Annex VI entry if agreed by COM	607-RST-00-Y	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	Repr. 2 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1A STOT SE 3 Aquatic Acute 1 Aquatic Chronic 3	H361d H332 H302 H319 H317 H335 H400 H412	GHS08 GHS07 GHS09 Wng	H361d H332 H302 H319 H317 H335 H410		M=1	

Pyrocatechol; 1,2-dihydroxybenzene

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	604-016-00-4	1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	Acute Tox. 4* Acute Tox. 4* Skin Irrit. 2 Eye Irrit. 2	H302 H312 H315 H319	GHS07 Wng	H302 H312 H315 H319			
Dossier submitter's proposal	604-016-00-4	1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	**Retain** Skin Irrit. 2 Eye Irrit. 2 **Add** Carc. 2 Muta. 2 **Modify** Acute Tox. 3 Acute Tox. 3	**Retain** H315 H319 **Add** H351 H341 **Modify** H301 H311	**Add** GHS08 GHS06 **Modify** Dgr **Remove** GHS07	**Retain** H315 H319 **Add** H351 H341 **Modify** H301 H311			
RAC opinion	604-016-00-4	1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	**Retain** Skin Irrit. 2 Eye Irrit. 2 **Modify** Acute Tox. 3 Acute Tox. 3 **Add** Muta. 2 Carc. 1B	**Retain** H315 H319 **Modify** H301 H311 **Add** H341 H350	**Add** GHS08 GHS06 **Modify** Dgr **Remove** GHS07	**Retain** H315 H319 **Modify** H301 H311 **Add** H341 H350			
Resulting Annex VI entry if agreed by COM	604-016-00-4	1,2-dihydroxybenzene; pyrocatechol	204-427-5	120-80-9	Carc. 1B Muta. 2 Acute Tox. 3 Acute Tox. 3 Skin Irrit. 2 Eye Irrit. 2	H350 H341 H301 H311 H315 H319	GHS08 GHS06 Dgr	H350 H341 H301 H311 H315 H319			

Tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2*H*-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	607-RST-00-Y	tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2*H*-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	231-711-6	7696-12-0	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H332 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H332 H371 (nervous system) (inhalation) H410		M=100 M=100	
RAC opinion	607-RST-00-Y	tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2*H*-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	231-711-6	7696-12-0	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H371 (nervous system) (inhalation) H410		M=100 M=100	
Resulting Annex VI entry if agreed by COM	607-RST-00-Y	tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2*H*-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	231-711-6	7696-12-0	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H371 (nervous system) (inhalation) H410		M=100 M=100	

D-trans-tetramethrin; (1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	607-RST-00-Y	(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	214-619-0	1166-46-7	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H332 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H332 H371 (nervous system) (inhalation) H410		M=100 M=100	
RAC opinion	607-RST-00-Y	(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	214-619-0	1166-46-7	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H371 (nervous system) (inhalation) H410		M=100 M=100	
Resulting Annex VI entry if agreed by COM	607-RST-00-Y	(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl)cyclopropanecarboxylate	214-619-0	1166-46-7	Carc. 2 Acute Tox. 4 STOT SE 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H371 (nervous system) (inhalation) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H371 (nervous system) (inhalation) H410		M=100 M=100	

Succinic anhydride

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-103-00-5	Succinic anhydride	203-570-0	108-30-5	Acute Tox. 4* Eye Irrit. 2 STOT SE 3	H302 H319 H335	GHS07 Wng	H302 H319 H335		* Eye Irrit. 2; H319: C ≥ 1% STOT SE 3; H335: C ≥ 1%	
Dossier submitter's proposal	607-103-00-5	Succinic anhydride	203-570-0	108-30-5	**Retain** STOT SE 3 **Add** Skin Corr. 1 Resp. Sens. 1 Skin Sens. 1 **Modify** Acute Tox. 4 Eye Dam. 1	**Retain** H335 **Add** H314 H334 H317 **Modify** H302 H318	**Retain** GHS07 **Add** GHS05 GHS08 Dgr **Remove** Wng	**Retain** H335 **Add** H314 H334 H317 **Modify** H302 H318		**Retain** STOT SE 3; H335: C ≥ 1 % **Remove** * Eye Irrit. 2; H319: C ≥ 1%	
RAC opinion	607-103-00-5	Succinic anhydride	203-570-0	108-30-5	**Add** Skin Corr. 1 Resp. Sens. 1 Skin Sens. 1 **Modify** Acute Tox. 4 Eye Dam. 1 **Remove** STOT SE 3	**Add** H314 H334 H317 **Modify** H302 H318 **Remove** H335	**Add** GHS05 GHS08 Dgr **Retain** GHS07 **Remove** Wng	**Add** H314 H334 H317 **Modify** H302 **Remove** H335	EUH071	**Remove** * Eye Irrit. 2; H319: C ≥ 1% STOT SE 3; H335: C ≥ 1 %	
Resulting Annex VI entry if agreed by COM	607-103-00-5	Succinic anhydride	203-570-0	108-30-5	Acute Tox. 4 Skin Corr. 1 Eye Dam. 1 Resp. Sens. 1 Skin Sens. 1	H302 H314 H318 H334 H317	GHS07 GHS05 GHS08 Dgr	H302 H314 H334 H317	EUH071		

Maleic anhydride

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-096-00-9	Maleic anhydride	205-571-6	108-31-6	Acute Tox. 4* Skin Corr. 1B Skin Sens. 1 Resp. Sens. 1	H302 H314 H317 H334	GHS07 GHS05 GHS08 Dgr	H302 H314 H317 H334			
Dossier submitter's proposal	607-096-00-9	Maleic anhydride	205-571-6	108-31-6	**Retain** Skin Corr. 1B Resp. Sens. 1 **Add** Eye Dam. 1 STOT RE 1 STOT RE 2 **Modify** Acute Tox. 4 Skin Sens. 1A	**Retain** H302 H314 H334 **Add** H318 H372 (respiratory system) H373 (kidney) **Modify** H317	**Retain** GHS07 GHS05 GHS08 Dgr	**Retain** H302 H314 H317 H334 **Add** H372(respiratory system) H373 (kidney)	**Add** EUH071		
RAC opinion	607-096-00-9	Maleic anhydride	205-571-6	108-31-6	**Retain** Skin Corr. 1B Resp. Sens. 1 **Add** Eye Dam. 1 STOT RE 1 **Modify** Acute Tox. 4 Skin Sens. 1A	**Retain** H302 H314 H334 **Add** H318 H372 (respiratory system) (inhalation) **Modify** H317	**Retain** GHS07 GHS05 GHS08 Dgr	**Retain** H302 H314 H317 H334 **Add** H372 (respiratory system) (inhalation)	**Add** EUH071	**Add** Skin Sens. 1A; H334 C≥ 0.001%	
Resulting Annex VI entry if agreed by COM	607-096-00-9	Maleic anhydride	205-571-6	108-31-6	Acute Tox. 4 Skin Corr. 1B Eye Dam. 1 Resp. Sens. 1 Skin Sens. 1A STOT RE 1	H302 H314 H318 H334 H317 H372 (respiratory system) (inhalation)	GHS07 GHS05 GHS08 Dgr	H302 H314 H334 H317 H372 (respiratory system) (inhalation)	EUH071	Skin Sens. 1A; H334 C≥ 0.001%	

2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitter's proposal	606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	**Add** Repr. 2	**Add** H361d	**Add** GHS08	**Add** H361d			
RAC opinion	606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	**Add** Repr. 1B	**Add** H360D	**Add** GHS08 **Modify** Dgr	**Add** H360D			
Resulting Annex VI entry if agreed by COM	606-047-00-9	2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone	404-360-3	119313-12-1	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	GHS08 GHS09 Dgr	H360D H410			

Table 2: Classification & labelling tables for substances for which RAC agreed on specified hazard classes, but did not yet adopt an opinion

Mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-{[(methylsulfonyl) amino]methyl}benzoate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate	-	208465-21-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=100 M=100	
RAC opinion	TBD	mesosulfuron-methyl; methyl 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-{[(methylsulfonyl)amino]methyl}benzoate	-	208465-21-8	Aquatic Acute 1 Aquatic Chronic 1 Human health hazard classes for RAC-39	H400 H410	GHS09 Wng	H410		M=100 M=100	
Resulting Annex VI entry if agreed by COM	TBD										

Spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statementCode(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	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	-	148477-71-8	Carc. 1B Repr. 2 Skin Sens. 1B STOT RE 2 Aquatic Chronic 1	H350 H361f H317 H373 H410	GHS07 GHS08 GHS09 Dgr	H350 H361f H317 H373 H410		M=10	
RAC opinion	TBD	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	-	148477-71-8	Carc. 1B Repr. 2 **Skin Sens. 1B** **STOT RE 2** **Aquatic Chronic 1**	H350 H361f **H317** **H373** **H410**	GHS07 GHS08 GHS09 Dgr	H350 H361f **H317** **H373** **H410**		**M=10**	
Resulting Annex VI entry if agreed by COM	TBD	spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	-	148477-71-8							

Remaining Hazard classes for RAC-39

Part III. List of Attendees of the RAC-38 meeting

6-9 September 2016 and 13-16 September 2016

RAC Members
ANDREOU Kostas
BARAŃSKI Bogusław
BIRO Anna
BJØRGE Christine
BRANISTEANU Radu
CARVALHO João
CHANKOVA-PETROVA Stephka
CHIURTU Elena (co-opted Member)
CZERCZAK Sławomir
DE LA FLOR TEJERO Ignacio
DI PROSPERO FANGHELLA Paola
DUNAUSKIENĖ Lina
DUNGEY Stephen
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HUSA Stine
HÖLZL Christine
ILIE Mihaela
JANKOWSKA Elżbieta (co-opted Member)
KADIĶIS Normunds
KAPELARI Sonja
LECLOUX Hèléne
LEINONEN Riitta
LUND Bert-Ove
MARTINEK Michal
MENARD Anja

MOELLER Ruth
MULLOOLY Yvonne
MURRAY Brendan
NEUMANN Michael
PARIS Pietro
PASQUIER Elodie
POLAKOVICOVA Helena
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHLÜTER Urs
SCHULTE Agnes
SMITH Andrew
SOGORB Miguel
SØRENSEN Peter Hammer
SPETSERIS Nikolaos
STAHLMANN Ralf
STAŠKO Jolanta
TOBIASSEN Lea Stine
TSITSIMPIKOU Christina
UŽOMECKAS Žilvinas
VAN DER HAAR Rudolf (co-opted Member)
VARNAI Veda Marija
VIEGAS Susana (co-opted Member)
Apologies
COPIN Stephanie (maternity leave)

Invited experts
DEWHURST Ian (Health&Safety Executive UK) DNEL
Commission observers
GARCIA-JOHN Enrique DG GROW
MORRIS Alick DG EMPL
RAC advisors
ESPOSITO Dania (Pietro Paris)
DUSSART Aurélie (Hélène Lecloux)
LOIKKANEN Jarkko (Riitta Leinonen)
PAPPONEN Hinni (Riitta Leinonen)
SONNENBURG Anna (Ralf Stahlmann) (CLH Acetaldehyde)
SCHUUR Gerlienke (Marja Pronk)
STOCKMANN-JUVALA Helene (Tiina Santonen)
SUUTARI Tiina (Riitta Leinonen)
UUKSULAINEN Sanni (Tiina Santonen)
WOUTERSEN Marjolij (Marja Pronk) (CLH 2-benzyl-2-dimethylamino-4-morpholinobutyrophenone

Stakeholders observers
ANNYS Erwin, Cefic
BARRY Frank, ETUC
BERNARD Alice (occasional stakeholder observer)
DEN HAAN Klaas, Concawe
MUNARI Tomaso (EuCheMs)
VEROUGSTRAETE Violaine, Eurometaux
ROMANO Dolores
ROWE Rocky, ECPA
Dossier submitters
HOLMBERG Rikke (restriction DEHP,DBP, BBP,DIBP)
WINTHER Toke (TDSAs)
WOUTERSEN Marjolijn (CLH Acetaldehyde)
Industry experts
BERENDS Albert (CLH pyrocatechol)
GARTLAND Kevan (Ecpa, Sumitomo Corp.; CLH tetramethrin, D-trans tetramethrin)
KROESCHE Christoph (Cefic, EVONIK Industries; TDFAs)
LLOYD Sara (Ecpa, Syngenta, CLH pinoxaden)
MERVART Jan (Cefic, DEZA, a.s; phthalates)

REMOTE PARTICIPANTS		
RAC Members:		**EFSA**
BRANISTEANU Radu		KARDASSI Dimitra
DUNGEY Steven		
HAKKERT Betty		**ECHA staff**
SCHLÜTER Urs		BERGES Markus
Advisors		BLAINEY Mark
BALL Elanor (Andrew Smith)		BOWMER Tim, Chairman
LOSERT Annemarie (Christine Hölzl)		BROECKAERT Fabrice
McCabe Laura (Andrew Smith)		CHLEBUŠ Marek
		DVORAKOVA Dana
Dossier submitters:		ERICSSON Gunilla
Denmark		GIGIOLI Roberto
DOBEL Shima (phthalates DEHP,DBP,BBP,DIBP)		HENRICSSON Sanna
		HOPLAND Eivind
Germany		JONES Stella
KNEUER Carsten (CLH tetramethrin)		KANELLOPOULOU Athanasia
		KARJALAINEN Ari
France		KIVELÄ Kalle
CHARLES Sandrine (CLH pyrocatechol)		KLAUK Anja
		KOKKOLA Leila
Italy		KOSK-BIENKO Joanna
ATTIAS Leonello (restriction DMF)		KOULOUMPOS Vasileios
Di PROSPERO Paola (restriction DMF)		LIOPA Elīna
		LOGTMEIJER Christiaan
Netherlands		LUDBORŽS Arnis
GERAETS Liesbeth (CLH spirodiclofen)		LUSCHÜTZKY Evita
GOMEZ Contreras Jeannette (CLH spirodiclofen)		MAJOROS Laszlo
MÜLLER Andre (CLH acetaldehyde, CLH sprirodiclofen)		MARQUEZ-CAMACHO Mercedes
Commission observers:		MAZZOLINI Anna
BERTATO Valentina		MERKOURAKIS Spyridon
FERNANDES de BARROS Mariana		MOTTET Denis
GARCIA JOHN Enrique		MULLER Gesine
JAMERS An		NICOT Thierry
LUVARA Giuseppina		NYGREN Jonas
ROZWADOWSKI Jacek		ORISPÄÄ Katja

O´ROURKE Regina		
PELTOLA Jukka		
PENNESE Daniele		
PERAZZOLA Chiara		
PILLET Monique		
PREVEDOUROS Konstantinos		
REGIL Pablo		
RHEINBERGER Christoph		
RODRIGUEZ-IGLESIAS Pilar		
ROGGEMAN Maarten		
ROSSI Laura		
SADAM Diana		
SIHVONEN Kirsi		
SIMOES Ricardo		
SIMPSON Pete		
SMILOVICI Simona		
SOSNOWSKI Piotr		
SOTIRIOS Kiokias		
SPJUTH Linda		
STOYANOVA Evgenia		
TSIFOUTIS Vasileios		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-38 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-38 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-38 meeting

ANNEX IV Administrative issues and information items

Annex I (RAC-38)

6 September 2016
RAC/A/38/2016

Final Agenda

38th meeting of the Committee for Risk Assessment

6-16 September 2016

ECHA Conference Centre (Annankatu 18, Helsinki)

6 September starts at 09.00
9 September breaks at 13.30
13 September resumes at 09.00
16 September ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/38/2016
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-37 action points, written procedures and update on other ECHA bodies

RAC/38/2016/01

RAC/38/2016/02
Room document

For information

b) RAC workplan for all processes

For information

c) Annual update of RAC accredited stakeholders' list.

RAC/38/2016/03
(restricted document)
For agreement

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

No requests.

Item 6 – Requests under Article 95 (3)

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

RAC/38/2016/04
(no document)
For discussion/or agreement

b) OEL-DNEL methodology request

RAC/38/2016/05
For discussion

Item 7 – Harmonised classification and labelling (CLH)

7.1 General CLH issues

7.2 CLH dossiers

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

k) spirodiclofen (ISO)

physical hazards, acute toxicity (all routes), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, germ cell mutagenicity, aspiration hazard

l) Maleic anhydride

acute toxicity (oral), skin sensitisation

m) Succinic anhydride

acute toxicity (oral), skin sensitisation

n) D-trans-tetramethrin

physical hazards, acute toxicity (dermal), skin corrosion / irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, aspiration hazard, environmental hazards

o) Tetramethrin (ISO)

physical hazards, acute toxicity (dermal), skin corrosion irritation, serious eye damage / eye irritation, respiratory or skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, aspiration hazard, environmental hazards

p) Mesosulfuron-methyl

environmental hazards

q) 1,2 dihydroxybenzene, pyrocatechol

acute toxicity (dermal)

B. Hazard classes for agreement with plenary debate

r) Acetaldehyde, ethanal
s) Pinoxaden (ISO)
t) 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone
u) Spirodiclofen
v) Pyrocatechol
w) Mesosulfuron-methyl (Please note that no discussion is foreseen for this substance at RAC-38 – HH is going to be discussed at RAC-39)
x) Tetramethrin (ISO)
y) D-trans-tetramethrin
z) Maleic anhydride
aa) Succinic anhydride

For discussion and adoption

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

RAC/38/2016/06
(Restricted room document)
For agreement

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a) Conformity check
   1. N,N-dimethylformamide; dimethyl formamide (DMF)

For agreement

b) Opinion development
   1. (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives (TDFAs)
   2. Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP)

For discussion

8.2 Appointment of (co-)Rapporteurs for restriction dossiers

RAC/38/2016/07
(Restricted room document)
For agreement

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)

RAC/38/2016/08
RAC/38/2016/09
For discussion and/or agreement

c) Communication with the Commission (two COM letters)

RAC/38/2016/11
RAC/38/2016/12
Room documents
For discussion

9.2 Authorisation applications

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

1. Diglyme_Merck

b) Agreement on Draft Opinions

1. Chromium trioxide_SNECMA (1 use) (CT_Snecma)
2. Chromium trioxide_MTU (2 uses) (CT_MTU)
3. Chromium trioxide_ABLOY (1 use) (CT_Abloy)
4. Chromium trioxide_HOOGOVENS Court Roll Surface Technologies (1 use) (CT_Hoogovens)
5. Chromium trioxide_TOPOCROM GmbH (1 use) (CT_Topocrom)
6. Chromium trioxide_FN HERSTAL S.A. (2 uses) (CT_Herstal)
7. Chromium trioxide_GERARDHI KUNSTOFFTECHNIK GmbH (1 use) (CT_Gerardhi)
8. Chromium trioxide; Potassium dichromate; Sodium dichromate_SOURIAU SAS (7 opinions) (CT_PD_SD_Souriau)
9. Chromium trioxide_HAPOC (4 uses) (CT_HAPOC)
10. Ammonium dichromate_VECO BV (1 use) (AD_Veco)

11. Sodium dichromate_TOTAL RAFFINERIE MITTELDEUTSCHLAND GmbH (1 use) (SD_Total)
12. Sodium dichromate_JACOBS DOUWEE EGBERTS DE GmbH (1 use) (SD_Jacobs)
13. EDC_BASF SE (2 uses) (EDC_BASF_2)
14. EDC_ELI LILLY S.A. (1 use) (EDC_Eli_Lilly)
15. EDC_DOW ITALIA S.R.L. (1 use) (EDC_Dow)
16. EDC_LANXESS Deutschland GmbH (2 uses) (EDC_Lanxess)
17. EDC_H&R OLWERKE SCHINDLER GmbH (1 use) (EDC_Olwerke)
18. EDC_GRUPPA LOTOS S.A. (1 use) (EDC_Lotos)
19. EDC_GE HEALTHCARE Bio-Sciences (1 use) (EDC_Bio-Sciences)
20. Technical MDA_POLYNT COMPOSITES France (2 uses) (MDA_Polynt)
21. EDC_EURENCO (1 use) (EDC_Eurenko)
22. Sodium dichromate-Brenntag (3 uses) (SD_Brenntag)
23. Potassium dichromate-Brenntag (2 uses) (PD_Brenntag)
24. Dichromium tris(chromate)-Henkel (2 uses) (DtC_Henkel)
25. Strontium chromate-Akzo Nobel (2 uses) (SC_Akzo)
26. Potassium hydroxyoctaoxodizincatedichromate-PPG (2 uses) (PH_PPG)
27. Potassium dichromate GENTROCHEMA BV (2 uses) (PD_Gentrochema)
28. Sodium dichromate GENTROCHEMA BV (3 uses) (SD_Gentrochema)

For discussion and agreement

c) Adoption of Final Opinion

1. Chromium trioxide-Kromatek (1 use) (CT_Kromatek)

b. Chromium trioxide 1 (6 uses) (CT_Lanxess)

For discussion and adoption

9.3 Appointment of (co-)Rapporteurs for authorisation applications

RAC/38/2016/10
(Restricted room document)
For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-38

Table with Conclusions and Action points from RAC-38

For adoption

Annex II (RAC-38)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-38 meeting.

Document number	Title
RAC/A/38/2016	Final Draft Agenda
RAC/A/38/2016 Restricted	Draft outline agenda
RAC/38/2016/01	Report from other ECHA bodies
RAC/38/2016/02 Room document	Administrative issues
RAC/38/2016/03 Restricted	Annual update of RAC accredited stakeholders´ list
RAC/38/2016/05	OEL-DNEL methodology request
RAC/38/2016/06 Room document Restricted	Appointment of Rapporteurs for CLH dossiers
RAC/38/2016/07 Room document Restricted	Appointment of Rapporteurs restriction
RAC/38/2016/08	DNEL setting for the reprotoxic properties of 1-bromopropane
RAC/38/2016/09	DNEL setting for the reprotoxic properties of diisopentylphthalate (DIPP)
RAC/38/2016/09 Restricted	Appointment of Rapporteurs authorisation

ANNEX III (RAC-38)

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
Harmonised classification & labelling		
Pinoxaden (ISO) **(UK)**	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the dossier; directly involved in the preparation of the dossier, asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Acetaldehyde **(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.
Restrictions		
4-phthalates **(DK)**	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Peter Hammer SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
TDFAs **(DK)**	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Peter Hammer SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Article 95(3) requests		
1-methyl-2-pyrrolidone (NMP)	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.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW declarations at RAC 38		
Restrictions		
DMF **(IT)**	Paola DI PROSPERO FANGHELLA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Pietro PARIS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Applications for Authorisation		
Harmonised classification & labelling		
Spirodiclofen (ISO) **(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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.
Pyrocatechol Mesosulfuron-methyl (FR)	Elodie PASQUIER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Maleic anhydride Succinic anhydride (AT)	Christine HÖLZL	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Annemarie LOSERT[3]	Working for the CA submitting the dossier.
Tetramethrin (ISO) D-*trans*-tetramethrin (DE) **2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone (IND)**	Agnes SCHULTE	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.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

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[3] Adviser to Christine Hölzl

Helsinki, 30 August 2016

RAC/38/2016/02

ROOM DOCUMENT

38TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

6-16 September 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-37 Action Points

The RAC-37 action points due for RAC-38 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-37	22 August 2016	closed

2.2 RAC consultations (status by 26 August 2016)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	8 June 2016 (extended by 16 June 2016)	closed
Spirodiclofen (ISO)	8 August 2016	closed
Maleic anhydride	1 August 2016	closed
Succinic anhydride	1 August 2016	closed
D-trans-tetramethrin	8 August 2016	closed
Tetramethrin (ISO)	8 August 2016	closed
Mesosulfuron-methyl	12 July 2016	closed
Pyrocatechol	29 July 2016	closed
Acetaldehyde	18 August 2016	closed
Pinoxaden (ISO)	25 July 2016	closed
Application for Authorisation		
RAC consultation on draft AfA Review Report	15 August 2016	closed
Diglyme_Merck Consultation on conformity	17 August 2016	closed
Diglyme_Merck Consultation on application	28 September 2016	closed
EDC_BASF2 Consultation on draft opinion	5 August 2016	closed
EDC_Eli Lilly Consultation on draft opinion	12 August 2016	closed

Subject / document	Deadline	Status / follow-up
EDC_DOW Consultation on draft opinion	19 August 2016	closed
EDC_Lotos Consultation on draft opinion	19 August 2016	closed
EDC_Lanxess Consultation on draft opinion	19 August 2016	closed
EDC_Oelwerke Consultation on draft opinion	19 August 2016	closed
EDC_Healthcare Biosciences Consultation on draft opinion	19 August 2016	closed
CCST_SD Brenntag Consultation on draft opinion	27 July, extended to 1 August	closed
CCST_PD Brenntag Consultation on draft opinion	27 July, extended to 1 August	closed
CCST_DtC Henkel Consultation on draft opinion	27 July, extended to 1 August	closed
CCST_SC Akzo Consultation on draft opinion	27 July, extended to 1 August	closed
CCST_PH PPG Consultation on draft opinion	27 July, extended to 1 August	closed
SD Total Consultation on draft opinion	23 August 2016	closed
SD Jacobs Consultation on draft opinion	23 August 2016	closed
CT_Snecma Consultation on draft opinion	24 August 2016	closed
CT_MTU Consultation on draft opinions	25 August 2016	closed
CT_Herstal Consultation on draft opinions	25 August 2016	closed
CT_Abloy Consultation on draft opinion	24 August 2016	closed
CT_Hoogovens Consultation on draft opinion	24 August 2016	closed
CT_Topocrom Consultation on draft opinion	24 August 2016	closed
CT_Gerhardi Consultation on draft opinions	19 August 2016	closed
CT_PD_SD_Souriou Consultation on draft opinions	24 August 2016	closed
AD_Veco Consultation on draft opinion	23 August 2016	closed
EDC_Eurenco	24 August 2016	closed

Subject / document	Deadline	Status / follow-up
Consultation on draft opinion		
MDA_Polynt Consultation on draft opinions	24 August 2016	closed
CT_Kromatek Consultation on final opinion	19 August 2016	closed
CT_Lanxess Consultation on final opinions	22 August 2016	closed
Restrictions		
Consultations on the Annex XV dossier on TDFAs on 4phthalates	7 August 2016 7 July 2016	closed closed
Consultations on the first draft versions of TDFAs And 4phthalates	25 August 2016 25 August 2016	closed closed
Consultations on the conformity check outcome of DMF	29 August 2016	closed

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

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-37	25 July 2016	closed
Approach proposed to be taken when a review report is submitted to ECHA according to Art 61(1) of REACH	15 August 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	15 July – 12 August 2016	18 CLH dossiers
Applications for Authorisation – no calls		
-	-	-
Restrictions		
Call for expression of interest for rapporteurship 4 July - 22 August 2016 2 Restriction proposals	4 July – 22 August 2016	Five volunteers came forward

- Diisocyanates - Lead and its compounds			

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)	▪ Dimethyl disulphide ▪ Octamethylcyclotetrasiloxane ▪ Carboxin (5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide) ▪ Hypobromous acid ▪ α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; cyfluthrin (ISO) ▪ α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; beta-cyfluthrin ▪ esfenvalerate (ISO); (αS)-α-cyano-3-phenoxybenzyl (2S)-2-(4-chlorophenyl)-3-methylbutyrate ▪ mecetronium etilsulfate; N-ethyl-N,N-dimethylhexadecan-1-aminium ethyl sulfate; Mecetronium ethyl sulphate [MES] ▪ barium diboron tetraoxide ▪ bis(α,α-dimethylbenzyl) peroxide ▪ 2-butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime ▪ methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)-β-alaninate; valifenalate ▪ mesotrione (ISO); 2-[4-(methylsulfonyl)-2-nitrobenzoyl]-1,3-cyclohexanedione	22 August 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– no written procedures			
-	-	-	-
Restrictions – no written procedures			
-	-	-	-