RAC/M/40/2017
Final
10 May 2017

Minutes of the 40th Meeting of the Committee for Risk Assessment (RAC 40)

6 March starts at 14.00
10 March breaks at 13.30
14 March resumes at 9.00
15 March ends at 13.30

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 40th meeting of the Committee for Risk Assessment (RAC-40). On the occasion of the 40th plenary meeting, the ECHA Executive Director, Geert Dancet, gave a welcome address, highlighting the peak performance of the Committee on applications for authorisation and the overall high volume of harmonised classification and labelling as well as restriction dossiers successfully processed since the address at the 30th RAC-meeting. He mentioned the strong role of the Committee and interlink between ECHA's Committees and at European and international level. He thanked the RAC Members, the co-opted Members, and the observers from the Commission and the regular stakeholders for all their efforts and the participation in the meetings.

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 from the 39th 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. Apologies were received from four Members.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/40/2017). The Committee agreed that the following items proposed by the Secretariat could be added to the agenda:

a) A short report from the authorisation Rapporteurs' workshop held on the morning of 6 March 2017;
b) Commission note to ECHA with request to evaluate chemical compounds arsenic acid and its inorganic salts and MOCA.

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

4. Report from other ECHA bodies and activities

a) Report on RAC-39 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-39 had been completed. 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/40/2017/01). The summary of all consultations, calls for expression of interest in rapporteurships and written procedures (room document RAC/40/2017/02) is also available in the usual meeting document on S-CIRCABC (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-39 had been adopted via written procedure and were uploaded to S-CIRCABC and will be published 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 Q1-Q4/2017, 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 to be considered for each Harmonised Classification and Labelling (CLH) dossier are given in the relevant section.

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

There are no items under this agenda point currently.

6. Requests under Article 95(3)

a) OEL-DNEL methodology request

The Chairman informed that the final report (RAC/40/2017/03) of the Joint ECHA/RAC-SCOEL TF on DNEL-OEL methodology for threshold endpoints contains a critical assessment of REACH DNEL and SCOEL OEL methodologies a) for the inhalation route and b) for the dermal route, the latter including 'skin notation' and dermal DNEL. An interim report of the joint Task Force was presented at RAC-39. In order to achieve the results by the Commissions 28 February 2017 deadline, additional meetings were organised on 14 December 2016 (Luxembourg) and 18 January 2017 (Brussels). At the January meeting the draft text of the joint RAC-SCOEL report on the above two tasks was agreed by Members of the Task Force. The final report, representing the views of the Members of the ECHA/RAC – SCOEL Joint Task Force, as defined in the mandate by the Executive Director and requested by the Commission, was sent to the Commission on 28 February 2017 and will be published on ECHA's website. The report is tabled at RAC-40 for endorsement.

A RAC Member, Member of the Joint ECHA-RAC/SCOEL Task Force, presented the content of the joint ECHA/RAC-SCOEL Task Force report on scientific aspects and methodologies related to exposure of chemicals at the workplace (RAC/40/2017/03). RAC Members endorsed the report.

The Chairman thanked the Members of the Joint RAC-SCOEL Task Force for their work on the two tasks of the mandate and informed that in parallel, within this mandate, a third discussion

of the joint RAC-SCOEL Task Force on carcinogens and their treatment as threshold, practical-threshold or non-threshold was initiated and is intended for completion by September 2017.

7. Harmonised classification and labelling (CLH)

7.1 General CLH issues

None tabled for discussion.

7.2 CLH dossiers

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

RAC reviewed an 'A-listing' of hazard classes for a range of substances and being informed by the Secretariat of the appropriate scrutiny by Rapporteurs and commenting RAC Members in each case, agreed these without plenary debate. The details for each substance are given below in section B.

Thiabendazole (ISO)

Thiabendazole is a systemic benzimidazole fungicide used as an active substance in plant protection products. It has an existing Annex VI entry as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

The DS (ES) proposed to retain the existing classification and to add an M-factor of 1 for both hazards. The proposal was supported and the Committee adopted the opinion by consensus.

B. Substances with hazard classes for agreement in plenary session

a) Glyphosate (ISO)

The Chairman informed that the RAC-40 plenary discussions on glyphosate (ISO) would take place on 8 March and on 15 March 2017. On 8 March 2017, he then welcomed all parties attending in person or following the debate remotely (see footnote[2]).

The Chairman explained that Glyphosate (ISO) is a herbicide that has been authorised for use in plant protection products, and that the outcome of the opinion development on harmonised classification in RAC could play a role in the pending renewal of its authorisation. The substance already has an entry in Annex VI to CLP where it is classified as Eye Dam. 1 (H318) and Aquatic

[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.

[2] On 8 March 2017 the Chairman welcomed the representatives and experts of ECPA, Cefic, the Health and Environment Alliance (HEAL) and ClientEarth stakeholder observers as well as two representatives from the German Dossier Submitter one of which was following the discussions remotely. He also welcomed observers from the Commission and from the European Food Safety Authority (EFSA) as well as experts from the International Agency for Research on Cancer of WHO (IARC). Finally he welcomed an internal expert on epidemiology, an external expert on statistical methods as well as the adviser to the Rapporteur present at the invitation of the Secretariat.
On 15 March 2017, the Chairman welcomed the representatives and experts of the ECPA and HEAL stakeholder observers as well as two representatives from the German Dossier Submitter who followed the discussions remotely. He also welcomed an expert from IARC as well as observers from the Commission and from EFSA, the latter following the discussions remotely. He finally welcomed an internal expert on epidemiology and the advisers to the Rapporteur who were following the discussions remotely.

Chronic 2 (H411). The Dossier Submitter (Germany), having evaluated all health and environmental hazards in accordance with CLP, proposed to retain the existing harmonised hazard classifications and to add STOT RE 2 (H373) to the entry.

The Chairman informed that Glyphosate (ISO) was tabled for the second time at a RAC plenary meeting; the legal deadline for the adoption of an opinion is 1 December 2017. He reminded the committee that at the previous RAC meeting, key issues pertaining to the hazard assessment of glyphosate were presented by EU and International bodies as well as Industry. There were presentations from IARC, EFSA, the DS (Germany), the Glyphosate Task Force, HEAL representing civil society and a representative of the FAO/WHO JMPR.

The Chairman clarified that all hazard classes presented in the opinion would be open for discussion and agreement at this plenary. He gave the floor to the Rapporteurs and their advisor who presented the hazards in the following sequence: germ cell mutagenicity, carcinogenicity, STOT RE, reproductive toxicity (effects on fertility and development), acute toxicity (all routes), STOT SE, skin corrosion/irritation, eye damage/eye irritation, respiratory and skin sensitisation and finally the aquatic hazards. He noted that RAC Members had provided extensive written comments during the RAC consultation, particularly on the CMR endpoints.

In relation to **germ cell mutagenicity**, the Rapporteur reported that two germ cell mutagenicity assays were negative; however, the usefulness of these tests was questioned during the discussion. Bacterial tests and mammalian cell gene mutation tests showed that glyphosate does not induce gene mutations, but there were indications of clastogenicity in few of the studies conducted *in vitro*, including a non-standard test using buccal cells. In the many *in vivo* mutagenicity studies, all the findings from oral studies were negative, but some positive findings were seen in some studies with intraperitoneal (i.p.) administration. There were also indications of induction of DNA strand breaks both *in vitro* and *in vivo*, but the biological significance of these was considered unclear.

There were some human biomonitoring studies and the results from these were considered equivocal and conclusions could not readily be drawn based on experimental design and/or potential confounding factors such as lack of clear information about exposures, and the extent to which other substances or lifestyle factors could have contributed to the findings. Some suggestion of induction of oxidative stress was seen *in vivo* (via the intraperitoneal but not the oral route) but the biological significance of this was questionable.

RAC was informed that in one of the biomonitoring studies, the measurements were conducted a long time after exposure and their relevance was therefore questioned. In reference to another study IND noted that the authors of the relevant paper themselves stated that there was not sufficient information to draw firm conclusions on the ability of glyphosate (ISO) to cause DNA damage.

It was noted that IARC had also considered data from non-mammalian species, but RAC considered that the relevance of data from non-mammalian species for human hazard assessment is uncertain and noted that this is reflected in the fact that test guidelines using non-mammalian species have been removed from the OECD [human health] test guidelines. IARC noted that this was merely part of their weight of evidence determination, in which the greatest weight was given to the data from humans.

The issue of whether glyphosate reached the bone marrow was raised, considering that it was known to be poorly absorbed. It was noted that bone marrow is a highly perfused tissue and that according to the CLH report, glyphosate (ISO) does reach the bone marrow. There was also evidence of toxicity to bone marrow at very high doses. ECPA referred to a tissue distribution study which showed that the concentration of glyphosate-derived radioactivity in the bone

marrow 30 min after a dose of over 1,000 mg/kg bw in rats was 267 µg/g in males and 413 µg/g in females.

The *in vitro* findings suggested that glyphosate could damage DNA *in vitro* under some circumstances. It was noted that in the *in vivo* micronucleus studies, cells from the bone marrow and not peripheral blood were measured. The *in vivo* micronucleus studies, with the exception of a few i.p. studies were negative. *In vivo* mutagenicity assays are given more weight than *in vitro* assays and indicator tests in the evaluation of mutagenicity. The available studies were considered suitable for identifying a hazard. Taking all data into account, and based on the overall negative responses in the existing gene mutation and chromosomal aberration tests, RAC concluded that there is insufficient evidence to warrant classification of glyphosate for germ cell mutagenicity.

In relation to **carcinogenicity**, the Rapporteurs reported that the CLH report summarised the results from a number of epidemiology studies, 7 long term carcinogenicity studies in rats (6 conducted according to OECD 453) and 5 studies in mice (all conducted according to OECD 451). It was also noted that in the CLH report a re-analysis of the data from animal studies was presented using two standard statistical tests: the pairwise Fisher's exact test and the Cochran-Armitage trend test.

The epidemiology studies comprised a single, on-going prospective cohort study and multiple retrospective case-control studies. Indications of a statistical association with non-Hodgkin lymphoma (NHL) were seen in some of the case control studies. The cohort study however did not show any increased risk of NHL.

In the discussion it was noted that the risk estimates reported in the individual case control studies had wide confidence intervals and were not statistically significant when full adjustment for confounding was applied. IARC noted that they agreed that there was 'limited evidence' of carcinogenicity in humans (meaning that glyphosate according to the IARC criteria should normally be classified as at least 2B), adding a number of points suggestive of carcinogenicity: that the low statistical power of some studies could not explain the positive associations seen, and concerning recall bias, that at the time when the case control studies were done, there was no reason for cases to believe that glyphosate could be carcinogenic thereby prompting biased reporting of exposure. Following discussion RAC agreed that the epidemiology data were not sufficient for classification as a known human carcinogen. It was also agreed that the epidemiology data could be further considered together with the animal data for the purposes of classification.

In the rats, indications of increased incidences of tumours were seen in pancreatic islet cells, liver and thyroid and these were considered in detail. Following discussion it was noted that no tumours were seen in the majority of the studies and overall the rat studies were not considered to constitute evidence for carcinogenicity.

Concerning the findings in mice, the fact that very high doses were provided in two of the five studies (up to 4,800 mg/kg bw/d for the duration of the study) was discussed. It was noted that the relevant OECD guideline recommends that doses not greater than 1,000 mg/kg bw/d be used, although one Member commented that this would assume high absorption. It was also noted that the highest doses approached but did not exceed the recommended limit of 5% in feed. The representative of the Dossier Submitter noted that it was difficult to establish a maximum tolerated dose (MTD) for a substance of such low toxicity, but there was evidence that at the highest doses the MTD had been exceeded (lower terminal bodyweight in one study and lower bodyweight gain in the other).

It was noted that historical control data (HCD) were not available for all the studies and in some studies the HCD that was available was not from the same test facility and/or from a relevant

time period from the study, as advised in ECHA's guidance. Some reservations were expressed about the use of such data, but the absence of a complete set of HCD was not seen as a crucial factor for deciding on the classification. IND provided details of a "blank" study which had been conducted under the same conditions as the Wood (2009) study in which a control incidence of 12% for malignant lymphomas was seen. The data indicated that background incidences of tumours may indeed be high in the conditions of the Wood (2009) study, but as this was only one study the value of the study as a HCD is limited. Concerning the use of the HCD from the papers by Giknis and Clifford, HEAL noted that the housing conditions changed (from single housing to group housing, in both cases in wire bottom cages) and the tumour incidences decreased by half between 2005 and 2010 while in the studies the mice were group housed in solid bottom cages. A RAC Member responded that the data from 2010 were from fewer studies and therefore the data from 2005 were given greater weight. The incidences were also described as being uniformly spread across the range.

Concerning the statistical analyses, it was noted that none of the findings were statistically significant when a pairwise comparison using a significance level of 5% was used. HEAL noted that in some studies the findings at the highest dose became statistically significant under pairwise testing because the significance level would be cut in half when used. It was also noted that there was a positive trend test for some findings in some studies.

Overall, it was noted that an unusually large number of studies addressing the carcinogenicity of glyphosate were available in two species (rats and mice). Some evidence for increased incidences of tumours was seen in different organs/tissues in both species. However, it was also noted that the increases were small, mostly without a clear dose-response relationship, in some cases at exposure levels (>1,000 mg/kg bw/d) not normally seen in carcinogenicity studies and with evidence that the MTD may have been exceeded. In addition, the tumour findings were not consistently observed over the studies (within and between species) and only in males (without any mechanistic explanation for the apparent sex-specificity), there was no evidence of pre-neoplastic lesions, or no progression to malignancy (for the benign tumours). Also, there were no clear indications of a genotoxic mechanism. Taken together with the uncertainties in the epidemiology studies, RAC concluded that the available information provided insufficient evidence to meet the criteria for classification for carcinogenicity.

In relation to **specific target organ toxicity after prolonged/repeated exposure** (STOT RE), the Rapporteur informed that summaries of short-term studies, non-cancer effects in long-term studies and data on maternal toxicity from developmental toxicity studies in rabbits have been assessed for classification for STOT RE. Data from humans had not been available. The Rapporteur reported that mortality among pregnant rabbits had been used by the Dossier Submitter to justify the proposal for classification of glyphosate (ISO) for STOT RE 2. The Rapporteurs noted that although unscheduled deaths occurred in 5 of 7 developmental studies in rabbits, a pronounced increase in deaths at doses below the guidance values (adjusted using Haber's rule) were only seen in 2 studies. Whereas some of the deaths were not substance-related, some were unexplained or there was too little detail provided to establish a clear link with glyphosate-treatment. The Rapporteur concluded that considering the uncertainties relating to the deaths having arisen from a direct effect of glyphosate (ISO), taking a weight of evidence approach, a STOT RE classification did not appear justified for glyphosate (ISO). The Committee agreed to this conclusion.

In relation to **effects on fertility**, the Rapporteur informed that six 2-generation toxicity studies in rats and one 3-generation study in rats were assessed by the Dossier Submitter, the latter showing no treatment-related effects at doses up to 502 mg/kg bw/d. In addition, a study (Dai et al. 2016) investigating effects on reproductive organs in male rats was submitted during public consultation. Overall, there was no evidence of effects of glyphosate (ISO) on fertility or

on male and female reproductive organs; any effects seen were at high dose levels (> 1,000 mg/kg bw/d) in the presence of maternal toxicity. Apart from the studies in rats, also several epidemiological studies were assessed for fertility; however, there was a lack of statistically significant positive associations for a range of findings in any of the studies. As there was overall no evidence from humans and or from experimental animals of fertility effects caused by glyphosate (ISO), the Committee agreed that classification for fertility effects was not justified.

In relation to **developmental effects**, the Rapporteur informed that a range of studies performed on rats and rabbits as well as human information had been available and were assessed. The findings from each of the studies were considered in detail. In two of six rat studies no effects were seen in either dams or foetuses. In the remaining rat studies, doses up to 3,500 mg/kg bw/d showed insufficient evidence of developmental toxicity for classification following *in utero* exposure to glyphosate (ISO). Reduced ossification and skeletal malformations, which were not statistically significant and without a clear dose-response relationship, at maternally toxic doses were observed, with LOAEL for developmental effects ≥ 1,000 mg/kg bw/d.

In five of seven developmental toxicity studies in rabbits, cardiovascular malformations, skeletal malformations, post-implantation losses and embryo-foetal deaths were reported following *in utero* exposure. The effects were reported in the presence of severe maternal toxicity including death of the does and/or abortions and were often accompanied by evidence of GI tract intolerance to glyphosate (ISO) exposure. Some of the deaths were likely to be related to mis-gavage but in other cases the cause of death was not clear. The findings in foetuses were at low incidences and in some of the studies without a clear dose-response and were also seen in the control groups. These effects were not consistently reported in the 7 studies, and for cardiac malformations more than one were seen in the same foetus. In some of the studies serious deficiencies in the reporting of the results were evident as well as insufficient number of foetuses available for assessment. A statistically significant increase in cranial bone malformations was reported in a single study in a different strain of rabbits than the one used in the other studies, but no similar finding was reported in the other studies. Industry noted that when all skeletal malformations are considered separately there is no dose-effect relationship. Epidemiological studies showed no convincing evidence of developmental effects following *in utero* exposure to glyphosate (ISO). Overall, the Rapporteur concluded that considering the inconsistencies in the results between studies, the evidence for maternal toxicity in some studies, and serious deficiencies in others, no classification of glyphosate (ISO) for developmental effects was justified. The Committee agreed to this conclusion.

In relation to **acute oral toxicity**, the Rapporteur informed that 24 studies in rats and 4 in mice had been assessed. Following oral exposure to glyphosate (ISO), LD_{50} values in rats and mice were consistently above 2,000 mg/kg bw which, according to the CLP Regulation, is the classification threshold for category 4 after oral exposure. Consequently, glyphosate (ISO) should not be classified for acute oral toxicity. The Committee agreed to this conclusion.

In relation to **acute dermal toxicity**, the Rapporteur informed that 20 studies in rats and one in mice had been assessed. Following dermal exposure to glyphosate (ISO), LD_{50} values in rats and mice were consistently found to be above 2,000 mg/kg bw which, according to the CLP Regulation, is the classification threshold for category 4 after dermal exposure. Consequently, glyphosate (ISO) should not be classified for acute dermal toxicity. The Committee agreed to this conclusion.

In relation to **acute inhalation toxicity**, the Rapporteur informed that 13 studies in rats had been assessed. Following inhalation exposure to glyphosate (ISO), no LC_{50} values in rats were reported to be below 5.0 mg/L which, according to the CLP Regulation, is the classification

threshold for acute inhalation toxicity (dusts and mists). Consequently, glyphosate (ISO) should not be classified for acute inhalation toxicity. The Committee agreed to this conclusion.

In relation to **specific target organ toxicity after single exposure** (STOT SE 1 or 2), the Rapporteur noted that in acute toxicity studies in rats and mice, non-lethal unspecific effects were only reported at very high doses. This was consistent with an acute neurotoxicity study in rats in which no neurotoxicity was seen at up to 2,000 mg/kg bw. Otherwise no clinical signs were reported after the first exposure in the repeated dose toxicity studies where lower doses were applied. For these reasons, glyphosate (ISO) should not be classified for STOT SE 1 or 2. The Committee agreed to this conclusion. Further to this, RAC agreed not to classify for STOT SE 3, because neither narcotic effects were reported in any of the toxicity studies nor did the available evidence conclusively point to respiratory tract irritation.

In relation to **skin corrosion/skin irritation**, the Rapporteur informed that 11 guideline-compliant studies on rabbits had been assessed, out of which 9 proved to be negative. Two studies showed reversible effects which do not justify classification even for skin irritation according to the CLP criteria. The Committee agreed with the conclusion that no classification for this hazard class was warranted.

In relation to **eye damage/ eye irritation**, the Rapporteur informed that glyphosate (ISO) had already a harmonised classification as Eye Dam. 1 (H318) (TC C&L 1999). She reported on 13 studies which had not been evaluated by TC C&L. Out of these 13 studies, two studies demonstrated that the CLP criteria for classification in category 1 were fulfilled, a third study suggested appropriateness of this classification, four studies suggested rather category 2, four studies were negative and two studies were inconclusive. The Rapporteur concluded that the weight of evidence was clearly pointing to Eye Dam. 1 (H318). During discussion the variability in the data was noted, but taking into account that there was an existing classification (and the data on which this was based were not available) and that there was clear data indicating that it could produce serious eye damage, the Committee agreed that classification as Eye Dam. 1 was justified.

In relation to **respiratory sensitisation**, the Committee recognised that no data was provided and therefore no classification proposal could be evaluated by RAC.

Regarding **skin sensitisation**, the Rapporteur informed that two LLNA studies and 12 Magnusson and Kligman maximisation tests (GPMT) were assessed. All studies were negative, therefore no classification for this hazard class was proposed. The Committee agreed with this conclusion.

In relation to the **aquatic hazards**, a Member of the ad hoc working group who had prepared the evaluation at the request of the Rapporteurs noted that only Aquatic Chronic 2 (H411) was proposed by the Dossier Submitter. All tests, including two OECD guideline tests, showed that glyphosate (ISO) was not rapidly degradable and that the bioconcentration factors measured in different bioaccumulation studies demonstrated a low potential of glyphosate (ISO) to bioaccumulate. On the other hand, based on the acute toxicity data available for all three trophic levels, glyphosate (ISO) does not fulfil the criteria for classification as Aquatic Acute 1, nor do the data for the aquatic metabolites (aminomethylphosphonic acid and hydroxymethyl-phosphonic acid), as they are less toxic than glyphosate (ISO) itself. By contrast, chronic toxicity data available for all three trophic levels showed that classification as Aquatic Chronic 2 (H411) was justified, fish being the most sensitive trophic species. This conclusion was confirmed by RAC and it was concluded to retain the current classification of glyphosate (ISO) as Aquatic Chronic 2 (H411). Beyond this conclusion RAC also noted that in view of the relatively slow mode of action on plants, the classification might need to be reviewed should relevant aquatic plant data become available in future.

The Committee adopted the opinion **by consensus**. The Chairman thanked the Rapporteurs for the presentation of the arguments, the Committee Members for their comments and the Stakeholders for their active particpation.

b) 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone

The Chairman welcomed an expert accompanying the Cefic stakeholder observer. He reported that BDMBP was an industrial chemical which is used as a photosensitive agent in printing inks, pigmented coatings and photopolymers for imaging applications. 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone (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. In the year 2016, RAC already adopted an opinion for BDMBP, which concluded to add a harmonised classification as a presumed human reproductive toxicant in relation to developmental effects (Repr. 1B (H360D)) to Annex VI.

For the current dossier the Dossier Submitter (Germany) proposed to remove the aquatic classifications from Annex VI. The legal deadline for the adoption of an opinion is 20 November 2017.

The Rapporteur clarified that the Dossier Submitter's proposal was based on acute toxicity information on fish and algae and chronic information on Daphnia. However, the Rapporteur noted that according to the OECD Guidance Document 23, an absence of acute toxic effects at the saturation concentration could not be used as the basis for predicting no chronic toxicity at saturation or at lower concentrations. Consequently, the use of the surrogate system was not possible and there was no reliable test data on chronic toxicity for algae and fish. Consequently, removal of the aquatic classifications was not justified. In view of the uncertainties linked to the weight of evidence approach applied, it was on the other hand not possible to assign M-factors to the existing classifications.

RAC agreed to the Rapporteur's assessment and decided to retain the entry in Annex VI in the form as it is currently.

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.

c) Mandestrobin (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that mandestrobin (ISO) is a fungicide used as an active substance in plant protection products. It has no current Annex VI entry and the DS (AT) proposed to classify the substance as Aquatic Acute 1 (H400, M=1) and Aquatic Chronic 1 (H410, M=10).

As mandestrobin (ISO) is an active substance with no existing harmonised classification all hazard classes had to be assessed.

The Committee supported no classification for physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, STOT RE and germ cell mutagenicity.

RAC supported the conclusion that mandestrobin (ISO) was considered not readily biodegradable and with low potential for bioaccumulation. The substance fulfils the criteria for category 1 for acute and chronic aquatic toxicity (Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410)) with an acute M-factor of 1 and a chronic M-factor of 10.

As to carcinogenicity, the CLH report presented two studies conducted in two species (rat and mouse). There was a dose-related increased frequency of ovarian tumours (benign sex-cord stromal tumours) in female rats. The incidence of tumours exceeded the upper limit of the historical controls (HCD) in two highest doses (7,000 ppm and 15,000 ppm). However, the findings were not statistically significant when compared to the concurrent control that was also above HCD. In the discussion, the industry expert accompanying the ECPA stakeholder observer noted that there were other seven background HCD studies with only one showing this type of tumour, no tumours were observed in other studies.

There were no adverse effects observed in the mice study. Mandestrobin (ISO) was not found to be genotoxic and there was no evidence of hormone imbalance from *in vitro* tests.

Whereas RAC Members agreed that the overall evidence was not sufficient for classification, they asked for a well-balanced argumentation keeping the focus on the existing study results and avoiding references/suggestions to carcinogenic mechanisms not substantiated by the available data.

The Committee briefly discussed toxicity to reproduction and supported the DS proposal for no classification based on no evidence of adverse effects in a number of studies in two species (rat and rabbit).

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

d) Methylmercuric chloride

The Chairman welcomed a representative of the Dossier Submitter from France who was following the discussion via remote connection. He reported that methylmercuric chloride was a laboratory chemical.

Methylmercuric chloride, being part of an Annex VI group entry to the CLP Regulation for organic mercury compounds, is classified as Acute Tox. 1 (H310), Acute Tox. 2* (H330, minimum classification), Acute Tox. 2* (H300, minimum classification), STOT RE 2* (H373**) with SCL ≥ 0.1%, Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), with no M-factors set.

The Chairman stated that the substance was discussed for the first time at a RAC plenary meeting; legal deadline for the adoption of an opinion is 22 September 2017. The Dossier Submitter from France proposed to create an own entry for methylmercuric chloride in Annex VI where to retain Acute Tox. 1 (H310), to modify to Acute Tox. 2 (H330 and H300), to upgrade to STOT RE 1 (H372 (nervous system, vision and kidneys)) and also to assign Muta 2. (H341), Carc. 2 (H351), Repr. 1A (H360Df) and Lact. (H362) to the substance. The Dossier Submitter proposed to retain the classification for environmental hazards from the group entry.

The Chairman recalled that the Committee had already agreed to Acute Tox. 2 (H330) and to STOT RE 1 (H372 (nervous system, kidneys)) through the fast-track procedure at an earlier point in time at this meeting. He stated that the CMR hazards, acute oral and dermal toxicity as well as STOT SE were left for plenary discussion.

In relation to fertility effects, the Rapporteur informed that the data available did not show an effect of methylmercuric chloride on the fertility of humans while some findings have been reported in rat experiments. However, considering the inconsistency of effects on fertility between animals and humans occurring at high dose levels which produce general toxicity, a classification for Repr. 1B did not appear appropriate, but rather a classification as Repr. 2 for effects on fertility. The Committee agreed to this conclusion.

In relation to developmental effects, the Rapporteur informed that data on mice, rats, monkeys and humans had been evaluated in the dossier. He reported that effects on motor and mnemonic function in adult C57/B6 mice, embryotoxicity and operant behavioural changes in rats after prenatal exposure as well as effects on the vibration sensitivity in monkeys could be observed after exposure to the substance. As to humans, data on pre- and or postnatal development were not available while epidemiological data suggested the occurrence of effects in connection with significant exposures (Japan and Iraq) to methylmercuric compounds or a fish-based diet. RAC was of the opinion that for classification purposes both animal and human data were relevant and that studies with other methylmercuric compounds had to be regarded as supporting evidence of the toxicity of methylmercuric chloride. Therefore, the Committee agreed on Rep. 1A for developmental effects, the overall reproductive toxicity classification thus being Rep. 1A (H360Df).

In relation to effects on or via lactation, the Rapporteur informed that around 20% of the methylmercury amount measured in mothers' plasma was found in their milk, with mean concentrations of 0.21 to 0.45 µg/kg. In the absence of specific studies addressing possible effects via lactation, but based on pharmacokinetic data, he proposed to classify methylmercuric chloride as Lact. (H362). The Committee agreed to this conclusion.

In relation to acute oral toxicity, the Rapporteur informed that the mouse appeared to be the most sensitive species when tested for this endpoint. He noted that the LD_{50} in male mice was < 20 mg/kg and > 50 mg/kg in female mice, therefore justifying a classification as Acute Tox. 2 (H300). The Committee agreed to this conclusion.

In relation to acute dermal toxicity, the Rapporteur informed that no information for methylmercuric chloride was available and that the basis for the current category 1 (H310) classification is unknown. By referring to an old study one RAC Member noted that absorption after dermal exposure seems low (around 5%) compared with 100% for the oral route. Thus, there was no reason to assume that the substance was more toxic via the dermal route than via the oral route, justifying a classification as Acute Tox. 2 (H310). The Committee agreed to this conclusion.

In relation to specific target organ toxicity after single exposure (STOT SE), the Rapporteur informed that there was only limited evidence of neurotoxicity after single exposure to non-lethal concentrations of methylmercury. Overall, this appeared to be insufficient to support classification for this endpoint. The Committee agreed to this conclusion.

In relation to germ cell mutagenicity, the Rapporteur informed that data showed that the substance had the potential to damage the genetic material of mammalian cells *in vitro*. However, definitive reliable evidence to show that these effects occurred *in vivo* by a relevant physiological route was not available. Others indicated the IP data can be used because of the high oral absorption (100%) of methylmercuric chloride. In addition, the human studies were poorly reported, therefore not allowing firm conclusions to be drawn. On the whole, the Rapporteur was of the view that there was insufficient evidence of the mutagenic potential of methylmercuric chloride, to justify classification. Some RAC Members confirmed that the data base for assessing this hazard class was poor, while others noted that the IP study with a substance that is almost completely absorbed via the oral route, while not being standard, was well-conducted and showed positive results suitable for use in the overall weight of evidence, together with the epidemiological data available. It was finally agreed not to classify for germ cell mutagenicity, with one RAC Member taking a minority position in favour of classifying the substance, being of the opinion that the statement in the CLP Guidance 3.5.2.4 states that: "If there are positive results from at least one valid *in vivo* mutagenicity test using intraperitoneal application, or from at least one valid genotoxicity test using intraperitoneal application plus supportive *in vitro* data, classification is warranted.", is fulfilled for methylmercuric chloride.

In relation to carcinogenicity, studies in mice and rats where available in addition to very limited human data. The data in animals supported induction of tumours. However, since this was in one sex and one species it was proposed by the DS, and agreed by RAC that category 2 was more appropriate than category 1B. The human data available were not considered sufficient to justify a more severe classification, given the uncertain nature of the results and the potential for confounding.

RAC adopted the opinion by majority, with one RAC Member reserving a minority position related to germ cell mutagenicity, pending the final wording in the opinion.

The Chairman finally clarified that in the event that methylmercuric chloride, which is currently part of a group entry of organic mercury compounds, received a separate entry in Annex VI, the existing classification and labelling for the aquatic hazards would be transferred across to the new entry without further review as these hazards were not part of the current assessment.

The Chairman thanked the Rapporteurs for their commitment and the Committee for the critical reflection of the arguments during the discussions. The opinion was adopted by majority with one reservation for a minority position. The Chairman noted that if the Secretariat received no written minority position from the RAC Member within a reasonable time after the RAC opinion was completed by the Rapporteurs, it would be assumed that the reservation had been withdrawn and the adoption would then revert to 'by consensus'.

e) Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)

f) N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5)

g) Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)

The Chairman welcomed the representative of the Dossier Submitters and reported that the three substances are chelating agents (the acid and two salts) used in a wide number of industries including pulp and paper, laundry detergents, cleaning agents, soaps, and textiles. None of the substances has an existing entry in Annex VI to the CLP Regulation.

The Dossier Submitters from industry (Akzo Nobel Functional Chemicals BV for DTPA-H5 and DTPA-K5 and Dow Chemical Company Ltd for DTPA-Na5) proposed to classify the substances as follows: DTPA-H5 and DTPA-K5 for developmental toxicity (Repr. 2 (H361d; oral), acute toxicity via inhalation (Acute Tox. 4 (H332)), for specific target organ toxicity after repeated exposure (STOT RE 2 (H372; respiratory system, inhalation)) and for eye irritation (Eye Irrit. 2 (H319)). As regards DTPA-Na5, the DS proposed to classify as Repr. 2 (H361d), Acute Tox. 4 (H332) and STOT RE 2 (H372). Additionally, the DS proposed no classification for fertility for all three substances.

Based on similar molecular structures, a common mechanism of action altering the homeostasis of metal ions and similar physico-chemical properties, read-across to other chelates (DTPA's and EDTA's) was used for the evaluation of the three substances.

The Committee supported the DS proposal to classify the three DTPAs into category 4 for acute toxicity via inhalation (Acute Tox. 4 (H332)) based on the effects observed in a 5-day repeated dose toxicity study in the rat performed with EDTA-Na2H2.

Using the weight of available evidence, RAC supported the classification of DTPA-H5 and DTPA-K5 as proposed by the DS – into category 2 (Eye Irrit. 2 (H319)). Despite the availability of data on this endpoint for DTPA-Na5, RAC for procedural reasons could not address this hazard class for DTPA-Na5 as the DS had not included it in the CLH dossier.

The Committee discussed the DS proposal for classification of the three DTPAs into category 2 for repeated exposure via inhalation route. Some Members were more in favour of no classification based on the overall weight of evidence taking into account the findings in the oral and inhalation repeated toxicity studies presented by the DS in the CLH report. In the discussion, other Members pointed out that the effects in the 5-day inhalation study in rats (namely epithelial necrosis in epiglottis) could not be considered as reversible and would therefore be more in favour of classification. Those Members also asked for further clarification of the inconsistency between the effects observed in the 5-day inhalation study and no or only reversible effects observed in the 13-week study in the rat. Two Members suggested that rather STOT SE classification (irritation to respiratory tract) could be considered due to quite severe local effects after relatively short time of exposure. No conclusion was reached at this meeting.

The Committee was presented with the proposal on toxicity to reproduction and held an initial discussion. The Members asked for a more thorough assessment of the proposed read-across to other chelates including the justification for the comparison with another substance (silver zinc zeolite) proposed by the DS, clarification of values used as historical controls and more details about the toxicity to reproduction studies used by the DS.

The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments. The Rapporteur will revise the proposals (STOT RE and toxicity to reproduction) in accordance with the discussion and the dossiers will be tabled for the next plenary meeting in June.

C. Presentation of key issues

h) Titanium dioxide

The Chairman welcomed the experts of the Cefic and Eurometaux stakeholder observers as well as the representatives of the Dossier Submitter from France, the latter following the discussion via remote connection. He reported that titanium dioxide (TiO_2) was an HPV chemical manufactured and imported in the European Economic Area at 1,000,000 – 10,000,000 tonnes per year. Products/articles in which titanium dioxide is incorporated are numerous and include paints, coatings, plastics, rubbers, papers, plasters, adhesives, coated fabrics and textiles, glassware, ceramics, electro-ceramics, electronic components, catalysts, welding, floor coverings, roofing, but also food additives (E171), pharmaceuticals, and cosmetics. Titanium dioxide was classified by IARC (2010) as Carc. 2B (possibly carcinogenic to humans).

Titanium dioxide does not currently have an entry in Annex VI to CLP. The Dossier Submitter from France proposed to classify the substance as Carc. 1B via the inhalation route (H350i). During public consultation around 500 comments were received, referring to a range of particle sizes, forms and modifications of titanium dioxide. The substance was discussed for the first time at a RAC plenary meeting; legal deadline for the adoption of an opinion is 27 November 2017.

The Chairman clarified that at this plenary meeting, key issues relating to the properties of poorly soluble low-toxicity particles and the implications of lung overload would be presented, followed by discussion. The intention of this session was to familiarise RAC Members with the complexity of the issues involved, and to support the Rapporteurs in finalising drafting the opinion so that it could proceed to RAC consultation. The Chairman emphasised that the plenary debate on the draft opinion was foreseen at the RAC-41 meeting in June.

The Rapporteur pointed out that the aim of the presentation was to discuss the scope of Annex VI entry for TiO_2, considering the toxicity associated with the shape, structure, size and surface chemistry of respirable and poorly soluble particles of low toxicity (PSLT). He raised that particle

toxicity of respirable PSLT aerosols, including TiO_2, was a consequence of alveolar macrophages being loaded with a significant volume of (inert) particles which results in stress on the macrophages, reduces the alveolar clearance rates of the particles and triggers a cascade of physiological consequences in rats which reflected the intrinsic properties of these particles. Referring to two key inhalation studies[3] on granular/non-fibrous TiO_2 particles with differences in crystal structure (rutile/anatase and rutile) and size of primary particles (nano and micro), he reported that these studies showed two types of malignant and two types of benign lung tumours in rats, namely adenocarcinoma (malignant), squamous cell carcinoma (malignant), cystic keratinizing epitheliomas (benign) (Heinrich et al. 1995), and bronchio-alveolar adenomas (benign) (Lee et al. 1985) with apparently minor potency differences between the tested substances. The Rapporteur concluded by stating that lung tumours were found in rats under TiO_2 overload conditions, irrespective of differences in crystal structures and sizes of the primary particles involved.

The advisor to the Rapporteur reported that the major mode of action of inert particles and rigid fibres (WHO fibres) leading to lung cancer was as a result of 'frustrated phagocytosis' at conditions below lung overload. This was different from the mode of action of PSLT nano- and micromaterials (i.e. stressed macrophages under overload conditions) although he pointed out that both MoAs can lead to cancer via chronic lung inflammation.

It was subsequently discussed that dose metrics play a role in the determination of potency. Following some comments by the RAC Members and observers, the Rapporteur reminded that the topic at this meeting was limited to the context of the CLH proposal, and that the mode of action and relevance to humans would be discussed in the next meeting. The Commission observer queried whether the intrinsic properties cover both physical and chemical properties of the substance. The expert accompanying the Eurometaux stakeholder observer informed the Committee that none of the Member companies of the TiO_2 Industry consortium had an interest in fibres as these were not currently marketed in the EU. IND observers noted that they did not consider fibres as part of the SID in the CLH proposal as TiO_2 fibres were considered to be different from granular TiO_2. Some of the issues raised for potential discussion in the context of the TiO_2 classification included relevance of the findings to humans, epidemiological data, effects in other species (including differences in macrophage clearance), mode of action, potency, differences in toxicity induced by different types of particles and application of weight of evidence.

The Chairman noted that the scientific issues discussed at this meeting should be duly reflected in the draft opinion. He thanked the Rapporteur and the advisor for their presentations and the stakeholder experts and Committee Members for their comments during the discussion.

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

[3] Lee et al. 1985, Heinrich et al. 1995

1) Diisocyanates

The Chairman welcomed the Dossier Submitter's representatives from Germany, the SEAC Rapporteurs (following via WebEx) as well as an industry expert accompanying a regular stakeholder observer. He informed the participants that the restriction dossier had been submitted by Germany in October 2016 and had been considered not in conformity by RAC in its December 2016 plenary. The Dossier Submitter resubmitted their dossier on 6 February 2017. The proposal limits the use of diisocyanates in industrial and professional applications to those scenarios where a minimum standardised training package have been implemented. Information on how to gain access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of diisocyanates in the substance or mixture placed on the market or used is less than 0.1% by weight, as well as for substances or mixtures containing diisocyanates at higher levels than 0.1% by weight but which fulfil criteria that show that the potential risks of using such products are very low.

The Dossier Submitter provided an introductory presentation on the dossier, focussing on the changes made in the revised report.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter and proposed to the Committee that the dossier is considered in conformity. The Dossier Submitter has provided additional information in the revised report, especially with regard to substance identity, risk reduction capacity, format of training, practicability aspects and monitorability. The Committee agreed that the dossier does conform to the Annex XV requirements. In addition, the Rapporteurs presented the key issues identified by them in the dossier. One RAC Member mentioned that there is a similar national legislation in place in Sweden and apparently it has been considered successful, as the number of asthma cases has decreased in recent years. It was suggested that such information should be submitted in the public consultation. Additionally, two RAC Members expressed some concerns on whether the limit of 0.1% by weight proposed in the restriction should be considered protective enough or if sensitisation cases still occur at diisocyanates concentration levels below this limit. It was also suggested to request further information on this topic in the public consultation.

The Chairman informed the Committee that the public consultation on this restriction proposal will be launched in March 2017 (provided that also SEAC considers the dossier conforming).

2) Lead in PVC

The Chairman welcomed the RAC Rapporteurs and the Dossier Submitters representative from ECHA, as well as the industry expert accompanying the regular stakeholder observer. The restriction proposal was submitted by ECHA in December 2016.

The Dossier Submitter’s representative (ECHA) presented the restriction proposal. The dossier proposes a restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15 year derogation for certain building and construction articles produces from recycled PVC (with a higher restriction limit of 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter and proposed to the Committee that they consider the dossier to be in conformity. The Committee agreed that the dossier does conform to the Annex XV requirements. In addition the Rapporteurs presented their key issues of the restriction proposal. The discussion started whether the emission could be used as a proxy for the risk. Furthermore, one RAC Member noted that because the majority of emissions were associated with the waste stage there could be overlaps with the waste legislation. The RAC Member also posed questions

regarding PVC drinking water pipes and the relevant legislation on food contact materials and drinking water quality. One industry expert mentioned that the wording of the restriction should target articles, not placing on the market of lead compounds used in articles. One stakeholder representative raised the issue of circular economy and the need to confirm the assumptions on tonnages of lead in PVC recyclate. The commission representative asked RAC to give an opinion on whether a concentration threshold of 1% for recycled material is appropriate in terms of remaining risk. It was also suggested to require further information on this topic in the public consultation.

The Chairman informed the Committee that the public consultation on this restriction proposal will be launched in March 2017 (provided that also SEAC considers the dossier conforming).

b) Opinion development

1) TDFAs – third draft opinion

The Chairman welcomed the RAC Rapporteurs and the dossier submitter's representatives from Denmark, as well the industry expert accompanying the regular stakeholder representative. A restriction is proposed on the use of TDFA ((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). It 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 solvents at certain concentration levels. The Rapporteurs developed the third draft opinion, taking into account the discussion held at RAC-39 as well as the outcome of the public consultation which ended on 15 December 2016 (13 comments received). The Chairman reminded the Committee that RAC is invited to adopt its opinion at this meeting.

The Rapporteurs noted that revisions were made in the identified hazards, the exposures and risks. RAC supported the Rapporteurs' view that while professionals are expected to be the main group of users of these mixtures, consumers are also expected to be the main users of spray products in general. It was furthermore agreed that a restriction is an appropriate EU wide measure to prevent the hazard and associated risks to consumers with the use of sprays containing TDFAs & organic solvents. While there is evidence confirming the previous presence of TDFA's & organic solvents in spray products on the market for consumer use, there is currently (since 2014) no evidence confirming the presence of such spray products on the EU market for consumers. However, as professional products still exist on the market, without the proposed restriction in place, there is a potential that these could also be placed on the market for consumer use. RAC also agreed to recommend standardised test methods to quantify TDFAs to be established based on available methods and limits of detection proposed by the Dossier Submitter. RAC could not confirm from the reported poisoning incidents whether the proposal warrants an EU wide measure as the presence of TDFA and organic solvents in the reported accidents involving impregnation, proofing sprays could not be confirmed. However, RAC considered an EU wide restriction would be an effective measure to address the risks (identified in animal studies) associated with the use of mixtures of TDFA and organic solvents in spray products. In addition, RAC noted that there is a need to ensure mixtures of TDFAs and organic solvents are correctly labelled as "fatal if inhaled" to ensure that professional and industrial users are properly informed about the hazards.

In relation to a question by an industry observer why Rapporteurs had not used the study data that they had provided, the Rapporteurs explained that they had used more suitable studies to establish the DNELs and following the requirements of Annex I of REACH.

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

2) Diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP) – third draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA and Denmark (the latter following the discussion via WebEx), an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer (with an accompanying expert). 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 Chairman reminded that the public consultation on this restriction proposal ended on 15 December 2016 with 29 comments received. The third draft opinion was made available to RAC on 6 February 2017 and comments were received from one Member in the subsequent commenting round.

The Rapporteurs presented their third draft opinion focussing on the input received in the public consultation and its impact on the RAC opinion, as well as additional derogations requested during the public consultation.

In relation to criticism by industry regarding extrapolation of DEMOCOPHES results to the EU-28, one RAC Member noted that recent data from Finland is now available (for the general working age population) that is very similar to the measurements from the DEMOCOPHES study which confirms that the extrapolation is reasonable. An industry expert expressed concerns that comments submitted by industry in writing within the public consultation seem largely to have been rejected by RAC and the Dossier Submitter. In his view, there should be more informal dialogue between RAC and industry experts and they suggested to consider this for future dossiers. The Committee agreed with the view of the RAC Rapporteurs that issues raised by industry with regard to hazard, exposure and risk have been given due consideration (also at previous RAC discussions on this dossier), have been further elaborated and explained in the opinion, the Background Document as well as in the responses to comments document, and do not affect the conclusions drawn earlier and agreed upon.

The Secretariat informed the Committee that prior to the meeting, the Commission had stressed the need to provide solid justifications and clear scope for any derogations to the restriction, for example on articles used in agricultural workplaces and for measuring devices. In response to this the Rapporteurs and Dossier Submitter had made some adjustments to the Background Document. Following an intervention by the Commission, it was furthermore agreed to specifically clarify in the justification to the opinion that phthalates in components of agricultural machinery and equipment are an example of a source of potential food contamination and as such contribute to the uncertainties in the assessment of the proposal.

Following an inquiry by one RAC Member with regard to the derogation request for aerospace articles in the interior of aircraft, the Secretariat explained that this request did not contain sufficient information to justify this derogation. The Secretariat clarified that the aerospace industry would be given the opportunity to provide stronger justifications for their request in the public consultation on the SEAC draft opinion.

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

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

RAC agreed in the closed session on the pool of (co-)rapporteurs for the restriction dossier on Lead and its compounds used in shots (as stated in the restricted room document RAC/40/2017/05).

9. Authorisation

9.1 General authorisations issues

a) Updated working procedure for authorisation process

The RAC Chairman informed the Committee about the two meeting documents on the agenda of the meeting (RAC/40/2017/07, a note explaining a new approach for the conformity check, and RAC/40/2017/06, the updated Committees' working procedure for the opinion development on the applications for authorisation).

He noted that the Application for Authorisation (AfA) process was implemented in 2012, including how conformity of the applications would be checked. At that time, the procedure stated that after the submission of the application the ECHA secretariat would verify that all the information mentioned in Article 62(4) had been provided by Applicants. This was done at the same time as the invoice was prepared for the Applicant. Should any information appear to be missing, then the ECHA secretariat informed the Rapporteurs so that they could take this into account. Upon payment of the invoice, the application was considered "received" and the public consultation was started. At the same time, the Rapporteurs formally checked that the application conformed with the requirements of Article 62(4) taking into account the information provided by the ECHA Secretariat. If an application was found not to be in conformity, then the Committees would require the Applicants to bring it into conformity within the 10-month deadline. At that time only the presence of formally required documents such as the CSR AoA and SEA (for non-threshold substances) were checked but not their content or meaningfulness and in practise, all dossiers were considered technically to be in conformity.

From the experience gained in evaluating many applications by RAC and SEAC, from the input from stakeholders and especially on the advice of the Commission, ECHA saw the need to make adjustments to the conformity check procedure. The procedural steps to implement this change were described in the note RAC/40/2017/07 and were implemented by updating the Committees' working procedure for opinion development on applications for authorisation. The updated working procedure is available for the Committee in the document RAC/40/2017/06. The updated working procedure was applicable with immediate effect. More specifically, the changes in the Committees procedure stipulate that the RAC and SEAC rapporteurs will check, if the application conforms with the requirements of Article 62(4) with the help of ECHA secretariat. However, RAC and SEAC will not conclude on conformity at this stage. When the RAC and SEAC rapporteurs will ask questions/clarifications of the applicants, they will indicate when these relate to conformity. However, in all cases, irrespective of such conformity indications, applications may not conform with the requirements of Article 62(4) if the applicants fail to provide the information requested by the Committees. RAC and SEAC will conclude on the conformity at the

same time when they agree on the draft opinions, or earlier, if it is considered that the information provided is sufficient and no conformity issues have been raised by the rapporteurs.

The RAC Chairman pointed out that as this is a policy driven change in administrative practise related to REACH implementation, the updated Committees' working procedure has not been consulted with the Committees, or tabled for agreement.

During the discussions one representative of the stakeholder observer organisation and one RAC Member expressed their appreciation for the updated working procedure. Two RAC Members made suggestions regarding practical routines of the RAC Rapporteurs on the Chemical Safety Reports submitted by the Applicants.

Since the conformity check has now been integrated into the opinion development procedure, the Committees working procedure for the conformity check of applications for authorisation has become obsolete.

b) New applications received during the February 2017 submission window

The ECHA Secretariat informed the Committee that one application for authorisation was received during the February 2017 submission window. It was a downstream user application by a single Applicant on the use of sodium chromate and potassium chromate in fabrication of alkali metal dispensers for production of photocathodes. The substances are used by the Applicant in very low quantities. Less than 10 workers are directly exposed during the use of the substances. The Applicant requested a seven years review period.

c) Report from the AfA Task Force

The ECHA Secretariat informed the Committee that the new guide on how to apply for authorisation was published in December 2016[4]; the project took approximately 8 months. The Secretariat thanked the RAC Members who took part in the work of the AfA Task Force. RAC noted the new document and thanked the secretariat for their efforts in assisting the Applicants (especially small and medium-sized enterprises) to submit better quality, fit-for-purpose applications for evaluation.

d) Feedback from seminar 'Man via the Environment'

The Eurometaux representative provided a brief report to the Committee about the seminar on "man via the environment", which was organised by Eurometaux with support from RIVM and ECHA. The seminar took place 26 January 2017 in Brussels[5].

e) Capacity building

1. Dose response setting for coal tar pitch

2. Dose response setting for anthracene oil

The ECHA Consultant presented their methodology to be used in drafting of the two following notes: (1) The assessment of remaining cancer risks related to the use of Anthracene oil and

[4] "How to apply for authorisation", European Chemicals Agency, December 2016; https://echa.europa.eu/documents/10162/13637/apply_for_authorisation_en.pdf/bd1c2842-4c90-7a1a-3e48-f5eaf3954676

[5] http://www.reach-metals.eu/index.php?option=com_content&task=view&id=220&Itemid=331

Pitch coal tar, high temperature (CTPHT) in Applications for Authorisation, and (2) the DNEL setting for CTPHT related to its toxicity for reproduction.

RAC noted the presentation by the ECHA Consultant which considered the information contained in the registration dossiers, the uncertainties, a proposal for addressing variability in the composition, the selection of critical studies, the quantification of the risks and levels of exposure, and finally, the quantification of the cancer risk.

RAC discussed the proposed approach and Members acknowledged the difficulties of the task, considering that both substances are UVCBs (i.e. substances of unknown or variable composition, complex reaction products or biological materials).

The Committee suggested to the ECHA Contractor to employ the top-down approach in the development of the draft report/notes, i.e to work with the existing international or national studies on the marker substances (e.g. carcinogenicity dose-response relationship of benzo[a]pyrene, its genotoxic mode of action etc.). It was suggested to seek for existing evaluation studies done by the Scientific Committee on Occupational Exposure Limits (SCOEL) and the Dutch Expert Committee on Occupational Standards (DECOS). Some RAC Members advised to consider carefully the scope of the project, routes of exposure evaluated in the Contractor's report (e.g. oral route of exposure was considered relevant to the general public in the evaluation report by the European Food Safety Agency (EFSA), environmental exposure in case constituents meet the aquatic toxicity criterion), information to be demonstrated by the potential Applicants in their applications for authorisation (e.g. variation in concentration of the marker substance benzo[a]pyrene), how exposure assessment could be done, as well as units in the exposure assessment. Several RAC Members noted that there are many very old studies (ca. 70 years old) available, which were used in the preparation of the original benzopyrene restriction. One RAC Member noted that the specific concentration limit values in Annex VI of the CLP Regulation have to be taken as a criterion in choosing the marker substance.

The Chairman advised the consultant to provide RAC with some options at the next meeting rather than just one way forward and to work closely with the Rapporteur in making such selections. He also noted that it was important that Applicants could receive this advice as to how RAC would assess the cancer risks of the two substances as early as possible in preparing their applications for authorisation.

The ECHA Secretariat informed the Committee that the first draft of the notes will be discussed at RAC-41 in June 2017 and the second draft will be considered for adoption in September 2017.

9.2 Authorisation applications

a) Discussion on key issues

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the three new applications for authorisation listed below. In the presentation of the cases, the Secretariat outlined the key issues identified by the Rapporteurs, which would need further clarification by the Applicants and asked the Committee for comments and further suggestions. The Committee discussed these key issues. Where needed, RAC will request further clarifications from the Applicants on the issues identified and discussed by the Committee.

1. SD_Colle (1 use)

It is a single use downstream application on the use of sodium dichromate as mordant in wool dyeing. The scope of the application is narrow.

The number of sites relevant for the application is not clear. However, it is indicated that there are 59 dyeing reactors at the Applicant's site and 15 at another site. The number of operators involved is not provided.

The tonnage used and requested review period are respectively <50 tonnes per annum and 10 years.

The Committee discussed the key issues in the application for authorisation. One RAC Member noted some deficiencies in the supplied data with likely relevance to the conformity of the application.

2. CT_Hansgrohe(2 uses)

It is a downstream application on the two following uses of chromium trioxide:

> Use 1: The use of chromium trioxide for electroplating of different types of substrates with the purpose to create a long-lasting high durability surface with bright (shiny) or matte look (Functional plating with decorative character),
> Use 2: The use of chromium trioxide for a pre-treatment step (etching) in the electroplating process.

The scope of the application is narrow.

The downstream application covering the two uses of chromium trioxide at the two sites. Chrome plating is carried out in two modular automated lines or in one manual plating unit. The chrome plating process is integrated into a complex electroplating process, which in the manual process involves 10 steps and in the automated lines combines up to 30 successive treatments plus rinsing baths. The number of workers exposed is 69.

The etching is integrated with the plating steps that avoids handling and prevents any contamination of the etched surface. The number of workers exposed is 26 and the Applicant requested a 12 year review period for both uses.

3. SD_Hapoc (1 use)

This is a single use downstream application on the use of sodium dichromate in molten bath form to modify surfaces, especially by blackening of delicate medical products, specifically microsurgical instruments. The maximum risk of 8:10,000. The scope of the application is narrow.

Most notably, the use is not yet performed in Europe, i.e. it is an application on paper for a future use.

The number of sites is given as 1 to 10 and the authorisation is requested for companies with no more than 5 regularly exposed workers. The application is for 0.25 tonnes per annum and the review period requested is 25 years.

The Committee discussed the key issues in the application for authorisation. RAC Members noted considerable deficiencies in the data supplied with possible relevance to the conformity of the application. A RAC Member initiated a discussion on how to label questions to the applicant as conformity questions. A stakeholder observer expressed their concern regarding the lack of guidance for RAC Members to identify which information is required for an application to be considered in conformity.

b) Agreement on Draft Opinions

1. CT_Reachlaw (4 uses)

The Rapporteurs presented the draft opinions on the application for authorisation submitted by REACHLaw Ltd (acting as Only Representative on behalf of the Joint Stock Company "Novotroitsk Plant of Chromium Compounds" (Russia)) on the following uses of chromium trioxide:

Use 1: Formulation of mixtures of chromium trioxide for functional chrome plating, functional chrome plating with decorative character and surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering,
Use 2: Functional chrome plating,
Use 3: Functional chrome plating with decorative character,
Use 4: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering.

The information submitted by the Applicant (including the assessment reports CSR, AoA and SEA) is equivalent in all significant aspects to the one submitted in the LANXESS Deutschland GmbH application for the Uses 1, 2, 3 and 5 (April 2015). The only relevant differences identified in the application are the smaller tonnages used and the number of sites covered. The Applicant reported a total tonnage covering the four uses of less than 1,000 tonnes per year. No actual detail on the tonnage split between the uses was provided but the Applicant estimates that the proportionate breakdown is the same as in the LANXESS Deutschland GmbH application.

RAC discussed how the Applicant is related to the CTAC and CTAC Sub consortia, and that the imposed conditions and monitoring arrangements should be equivalent as in the case of the LANXESS Deutschland GmbH application. Three RAC Members recognised the possibility of linking the end date of the review period with the end date of the review period of LANXESS Deutschland GmbH. RAC noted that the assessment reports are similar in all significant aspects to those submitted by LANXESS Deutschland GmbH for the same uses of chromium trioxide. RAC agreed on an approach that refers to the opinion justification on the application for authorisation LANXESS Deutschland GmbH and discussed specific information reported by REACHLaw Ltd (e.g. on the tonnage expected and the number of sites covered) in addition to the information included in the assessment reports. RAC agreed on the four draft opinions by consensus. RAC agreed to propose the same conditions and monitoring arrangements and to suggest the same advice on the length of the review period to the SEAC, as were agreed by the Committee at RAC-37 on the respective uses in the application for authorisation LANXESS Deutschland GmbH.

Some Members noted that the relevance of the original CTAC (and CCST) information as supplied to RAC in the original applications and respective written responses to RAC questions had some limitations in time for their reuse without adjustment in such subsequent applications. It was acknowledged that this might need to be looked into in the future but that for now, the subsequent applications were for smaller tonnages and the original information provided was fully relevant.

Another Member questioned the ability of the Applicants of such subsequent applications to actually apply the conditions if granted. While acknowledging the concern, the Chairman pointed to the 'subsequent Applicant' provisions under Art. 63(2) of the Regulation and that the ability of the subsequent Applicant to deliver on any conditions would always be a matter for the National enforcement authorities.

2. CT_Clariant (1 use)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream user for the use of chromium trioxide in a catalyst for the dehydrogenation of propane gas to propene. The scope of the application was well defined.

The substance is imported by the Applicant and used on the site of a downstream user. The downstream user's operations with chromium trioxide take place at one site; 146 workers are potentially exposed and the annual tonnage in use is less than 10 tonnes. The Applicant requested a 12 years review period.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. In particular, RAC was of the opinion that the RMMs and OCs are appropriate in limiting the risks to workers and the general population. RAC did not recommend additional conditions or monitoring arrangements and gave no advice to SEAC on the length of the review period.

3. CT_Cryospace (1 use)

The Rapporteurs presented the draft opinion on a downstream user application submitted by Euro Cryospace, France covering one use of chromium trioxide for the surface preparation (pickling) cryogenic tanks constructed of aluminium alloy and used in the Ariane 5 rocket launcher. Chromium trioxide allows the formation of adhesive metallic oxide layers on the aluminium alloys used to construct the cryogenic tanks and prepares the surface for adhesive bonding in the processing steps that follow. The annual tonnage used is < 1 tonne/year. The review period requested is seven years. Less than 10 workers are potentially exposed.

The RAC discussion focused on one of the conditions requesting the Applicant to continue regular programmes of occupational exposure measurements. The Members recommended to change the wording of the condition by specifying that the measurements should be appropriate to the duration of the tasks.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs with the one above mentioned editorial change. In particular, RAC is of the opinion that the RMMs are appropriate and effective in limiting the risks to workers and general public. RAC decided to recommend conditions and monitoring arrangements for the authorisation and the review period with the minor modifications discussed at the plenary. RAC agreed to give no advice to SEAC on the length of the review period.

4. SD_Borealis (1 use)

The Rapporteur presented the draft opinion on the application for authorisation submitted by a downstream user for the use of sodium dichromate as in-situ corrosion inhibitor in a closed water/ammonia absorption cooling system. The scope of the application was well defined.

The operations with sodium dichromate take place in one site and 8 workers are potentially exposed. The annual tonnage is 90 kg. The Applicant requested an 18-years long review period.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteur. In particular, RAC was of the opinion that RMMs and OCs are appropriate in limiting the risks to workers and the general population. RAC did not recommend additional conditions or monitoring arrangements and gave no advice to SEAC on the length of the review period.

5. SD_Ormezzano (2 uses)

The Rapporteurs presented the draft opinions on the application for authorisation submitted by a downstream user on the following two uses of sodium dichromate:

Use 1: Repackaging of sodium dichromate to be supplied as a mordant in the dyeing of wool as silver and/or yarn with dark colours in industrial settings,
Use 2: Use of sodium dichromate as a mordant in the dyeing of wool as silver and/or yarn with dark colours in industrial settings.

The scope of the application was well defined.

Regarding the Use 1, operations take place at the Applicant's site and 16 workers are potentially exposed. The annual tonnage is 130 tonnes/year of 61% sodium dichromate solution. The Applicant requested a review period of 7 years.

RAC discussed the type of respiratory protection equipment used by the workers and concluded that the filter in use (ABEK 1) was not adequate to protect workers from exposure to chromium (VI). RAC Members noted minor uncertainties with regard to the biomonitoring dataset as it was not clear how closely the biomonitoring campaigns are related to tasks with potential exposure to chromium (VI). Finally, RAC Members noted the small number of air measurements available to support the exposure assessment of workers. RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. RAC noted in its evaluation the fully automated process, closed reactors, fixed pipework, and the reduction of Cr(VI) to Cr(III) before the reactors are opened. In particular, RAC was of the opinion that the RMMs and OCs are not appropriate in limiting the risk to workers due to uncertainties about the RPE currently being used. However, RAC was of the opinion that RMMs and OCs are appropriate in limiting the risk for the general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and review reports. For the authorisation, following a review of the selection of the most appropriate RMMs, in accordance with the hierarchy of control, where it is concluded that RPE is also needed, the Applicant must evaluate which tasks require the use of RPE and ensure that appropriate RPE is selected to provide adequate protection for all of the different possible exposure situations. For review reports, the Applicant is required to continue to implement regular campaigns of occupational exposure assessment. They are also required to provide an analysis of the biomonitoring data with sufficient contextual information. It is also required that the emissions of Cr(VI) to air and wastewater shall be subject to regular measurements. RAC agreed to give no advice to SEAC on the length of the review period.

Regarding the Use 2, the Applicant submitted an upstream application for 11 downstream users in the same geographical region. Three of the downstream users are textile manufacturers and the other eight are exclusively dyers. The total number of potentially exposed workers is 125. The substance volume used is 80 tonnes/year of 61% sodium dichromate solution. The Applicant requested a review period of 7 years.

RAC discussed the air monitoring, biomonitoring and modelled exposure data submitted by the Applicant and Members noted substantial differences between the measured and modelled data. RAC Members noted minor uncertainties with regard to the biomonitoring dataset as it was not clear how closely the biomonitoring campaigns are related to tasks with potential exposure to chromium (VI). They considered moderate uncertainties related to the fact that the biomonitoring data originated from only four sites out of 11. Additionally, they noted some uncertainties due to the small number of biomonitoring results dedicated to maintenance and cleaning tasks. RAC Members considered the uncertainties identified in the exposure assessment being low for indirect exposure of humans via the environment and moderate for the workers.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. Also for this use, RAC noted in its evaluation the fully automated process, closed reactors, fixed pipework, and the reduction of Cr(VI) to Cr(III) before the reactors are opened. In particular, RAC was again of the opinion that RMMs and OCs are not appropriate in limiting the risk to workers mainly due to the RPE currently being used and current frequency of trainings on the use of RPE. RAC

was of the opinion that RMMs and OCs are appropriate in limiting the risk for general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and review reports. For the authorisation, following a review of the selection of the most appropriate RMMs, in accordance with the hierarchy of control, where it is concluded that RPE is also needed, the Applicant must evaluate which tasks require the use of RPE and ensure that appropriate RPE is selected to provide adequate protection for all of the different possible exposure situations. The Applicant also must implement yearly trainings on the adequate use of RPE. For the review reports, the Applicant was requested to continue to implement regular campaigns of occupational exposure assessment, to provide an analysis of the biomonitoring data with sufficient contextual information, and that emissions of Cr(VI) to air and wastewater shall be subject to regular measurements. RAC agreed to give no advice to SEAC on the length of the review period.

6. AD_BAE (2 uses)

The Rapporteur presented the draft opinions on the applications for authorisation submitted by downstream users for the use of ammonium dichromate in the process of manufacturing holographic combiners for diffractive head-up displays intended to be used in military aircrafts (use 1) and in the process of manufacturing Cathode Ray Tubes for head up displays intended to be used in military and civilian aircrafts (use 2).

> Use 1: Industrial use of Ammonium Dichromate in the process of manufacturing holographic combiners for diffractive head-up displays intended to be used in military aircrafts.

The number of sites covered is 2, the number of workers is 6; the volume used per year is 6kg and the review period requested is 12 years.

For the Rochester site RAC agreed that the RMM are appropriate and effective in limiting the risk of workers.

However, for the St. Asaph site, RAC concluded that the RMMs are not appropriate and effective in limiting the risk of workers and agreed with the proposal of the Rapporteur that the Applicants shall select and implement risk management measures following the hierarchy of control principles and review the need for implementation of organisational measures. RAC also agreed that the Applicant shall review the use of PPE (gloves) as there is a significant reliance on PPE (gloves) to demonstrate adequate control of dermal exposure.

Furthermore the proposed monitoring arrangements for occupational exposure were agreed.

> Use 2: Industrial use of Ammonium Dichromate in the process of manufacturing Cathode Ray Tubes for head up displays intended to be used in military and civilian aircrafts.

The number of sites covered is 1 the number of workers is 2, the volume used per year is 0.6 kg and the review period requested is 4 years.

There are few technical measures to control emissions to the workplace atmosphere. There is a lack of overall training of workers, and significant reliance on PPE (gloves) to demonstrate adequate control of dermal exposure. RAC agreed with the proposal of the Rapporteur that the Applicants shall select and implement risk management measures following the hierarchy of control principles, and review the need for implementation of organisational measures and, with a view to prevent dermal exposure, review the use of PPE. RAC agreed that the RMMs are not appropriate and effective in limiting the risks to workers.

Finally, monitoring arrangements for occupational exposure are proposed and RAC agreed not to give advice to SEAC on the length of the review period.

7. EDC_Biotech (1 use)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream User for the use of EDC as a solvent in manufacture of polymeric particles for pharmaceutical and research purification processes.

The number of exposed workers is <10 at one site covered by this application. The annual tonnage used is 1.25 tonnes and the Applicant requested a 12-year review period.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. In particular, RAC concluded that the RMMs and OCs are appropriate in limiting the risk to workers. However, RAC considers that the absence of RMMs for preventing releases of EDC to air from tasks not performed under closed systems and captured by LEVs makes the environmental controls not appropriate. Therefore, RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and for review reports, as described in the draft opinion. RAC also agreed to give no advice to SEAC on the length of the review period.

8. EDC_ORGAPHARM (2 uses)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream User with a well-defined scope for two uses of EDC:

Use 1: as process solvent in the manufacture of an Active Pharmaceutical Ingredient: Flecainide acetate

Use 2: as process solvent in the manufacture of an Active Pharmaceutical Ingredient: Nefopam

The number of exposed workers is < 50 at the single site covered by this application. The annual tonnage used is between 10-100 tonnes/year for each of the uses. The Applicant requested a 7-year review period.

RAC agreed by consensus on the draft opinions as proposed by the Rapporteurs. In particular, RAC concluded that the RMMs and OCs are appropriate in limiting the risk to the general population. However, regarding worker exposure, RAC is of the opinion that considering the type of RMMs used and also the workers affected by background EDC levels, the RMMs in place should be reviewed with a view to reduce exposure. Therefore, RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and for review reports, as described in the draft opinions. RAC agreed to give no advice to SEAC on the length of the review period.

9. EDC_Akzo (1 use)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream User with a well-defined scope for the use of EDC as a recyclable solvent in the production of a polyacrylate surfactant.

The number of exposed workers is < 50 at the single site covered by this application. The annual tonnage used is 2 tonnes and the Applicant requested a 9-year review period.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. In particular, RAC concluded that the RMMs and OCs are appropriate in limiting the risk to the general population. However, RAC considers that the RMMs and OCs are appropriate and effective in limiting the risk to workers and the general population, only provided that the improvement plan described by the applicant is implemented. RAC decided to recommend additional monitoring arrangements for the authorisation, as described in the draft opinion.

RAC agreed to give no advice to SEAC on the length of the review period.

10. Diglyme_Roche (1 use)

This is an application for authorisation submitted by the downstream user Roche Diagnostics GmbH for a future industrial use of Diglyme as a process chemical in the manufacture of one specific type of bead used in immunodiagnostic assays. The annual volume of the substance is expected to be 8 tonnes and to rise to 11 tonnes/year. The number of workers that will be potentially exposed to diglyme is two (possibly growing to seven workers). The Applicant requested a 12-year review period.

The Rapporteurs presented changes in the RAC-part of the Draft opinion document made after discussion during RAC-39.

The draft opinion as proposed by the Rapporteurs was agreed by consensus. In particular, taking into account that the application refers to a future use of Diglyme, RAC concluded that with the presented information the Applicant demonstrates that adequate control is achievable as long as the facility meets the same conditions as described in the exposure scenarios. RAC decided to recommend additional monitoring arrangements for the authorisation and the review report, as described in the draft opinion. RAC agreed to give no advice to SEAC on the length of the review period.

11. Diglyme_LifeTech (1 use)

This is an application for authorisation submitted by the downstream user Life Technologies AS for the industrial use of Diglyme as a process chemical in the manufacture of beads, which are mono-sized particles used in biomolecular research and in the in-vitro immunodiagnostic assays market. The annual volume of the substance used is ca. 10 tonnes, which is expected to rise to ca. 34 tonnes; two sites are covered by the application and less than 10 workers are potentially exposed at each site. The Applicant requested a 12-year review period.

The Rapporteurs presented changes in the RAC-part of the opinion document made after discussion during RAC-39.

The draft opinion was agreed by consensus as proposed by the Rapporteur. In particular, RAC concluded that adequate control has been demonstrated for worker exposure and general population. Nevertheless, RAC noted that the exposure and risk assessment presents a number of significant uncertainties, especially regarding the effectiveness of PPE. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and for the review reports. RAC agreed to give no advice to SEAC on the length of the review period.

12. Diglyme_Acton (2 uses)

The Rapporteurs presented the draft opinion for the use 1 of the application for authorisation submitted by the Acton Technologies Limited: bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes). The annual volume of the substance used is 20 tonnes and the Applicant requested a 12-year review period. This is a downstream user application for two uses. Discussion on Use 2 was postponed until the next RAC plenary in June 2017 due to operational reasons.

The discussion during the plenary focused mainly on the question of whether the combined route (inhalation and dermal) RCR of 7.85 should result in a negative opinion of RAC or that the Committee should recommend very strict conditions and the shortest review period.

Some of the Members expressed their concerns on the effectiveness of gloves which is the main dermal RMM. They pointed out that in case of improper use gloves can become a secondary source of the exposure. Then they questioned if the Applicant will be able to implement the strict conditions of the application. On the other hand RAC noted that the models used to assess dermal exposure tend to overestimate the dermal exposure mainly because of the number of manual tasks involved. Some of the Members expressed the opinion that strict conditions addressing all concerns and a short review period of no more than 4 years should be sufficient in this case.

The Chairmen concluded the discussion that there was no general support to reject this case and RAC endorsed the strict conditions proposed and to recommend a short review period to SEAC (see below).

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. In particular, RAC is of the opinion that for the use applied for, adequate control has NOT been demonstrated for workers. Adequate control has however been demonstrated for the general population exposed via the environment. The currently employed RMMs are not sufficient and that appropriate engineering controls are currently missing at the Applicant's site, especially in relation to minimising the potential for dermal exposure. RAC decided to recommend extensive additional conditions and monitoring arrangements for the authorisation and the review period. RAC agreed to recommend to SEAC that in the event that COM decided to grant the application, then a review period of no longer than 4 years should apply.

c) Discussion on draft opinions

1. MOCA_Reachlaw (1 use)

The Rapporteur presented status of the opinion development process on the application for authorisation submitted by REACHLaw Ltd (acting as Only Representative of Suzhou Xiangyuan Special Fine Chemical Co., Ltd (China)) on the industrial use of 2,2'-dichloro-4,4'-methylenedianiline (MOCA) as a curing agent/chain extender in cast polyurethane elastomer production. The scope of the application is broad.

The annual tonnage of the used MOCA is 516 tonnes. It is reported to be used at 89 sites, of which an estimated 89% are automatic and the remaining 11% are manually operated. According to the Applicant 219 workers are potentially exposed to the substance. The requested review period is 12 years.

The Rapporteur informed the Committee that in many cases, MOCA has been replaced already many years ago. However, according to the Applicant substitution is not possible yet for all products, especially for those demanding specific properties, e.g. high dynamic strength.

RAC took note and discussed the key elements presented by the Rapporteur. During their interventions five RAC Members expressed concerns about the worker exposure levels during the use of MOCA as a curing agent/chain extender in manual polyurethane casting processes. One RAC Member noted higher potential susceptibility, hence higher negative impact on, female workers of reproductive age. One RAC Member pointed to the wide range in the biological measurements provided by the Applicant.

RAC discussed the setting of strict conditions related to OCs and RMMs as well as monitoring arrangements (biomonitoring), considering the broad working practices covered by the application (manual and automatic processes).

The Committee also recommended to the RAC Rapporteur to reflect in the draft opinion the level of uncertainty associated with the biomonitoring data presented in the application.

2. **CT_Haas (1 use)**
3. **SD_Haas (1 use)**
4. **PD_Haas (1 use)**
5. **SC_Aviall (2 uses)**

The RAC Rapporteurs presented the key elements and the state of play regarding the opinion development on the four upstream (importer) applications for authorisation prepared with the support of the Global Chromates Consortium for Aerospace (GCCA). Three of the applications have been submitted by Haas Group International SCM Ltd with one use each:

> Chromium trioxide for chemical conversion treatment and slurry coating by aerospace companies and their suppliers. The estimated number of sites covered by the application is 275. The number of involved workers is 7,456 according to the Applicant. The annual tonnage used is 2 tonnes.
>
> One application for use of sodium dichromate and one application for use of potassium dichromate for sealing after anodizing by aerospace companies and their suppliers. In each of the two applications, the estimated number of sites covered is 126; the number of involved workers is 4,203; and the annual tonnage used is <5 tonnes.

The fourth application has been submitted by Aviall Services Inc. as the lead Applicant and Haas Group International as co-Applicant for two uses of sodium chromate:

> Use 1: Formulation of mixtures of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace companies and their suppliers. The number of sites covered by the application is 2. The number of involved workers is 86 according to the Applicant. The annual tonnage used is <1 tonne.
>
> Use 2: Use of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace companies and their suppliers. The estimated number of sites covered by the application is 103. The number of involved workers is 3,044 according to the Applicant. The annual tonnage used is <1 tonne.

A review period of 12 years or more is requested for all five uses covered in these applications for authorisation.

RAC noted that thousands of workers are involved, and that the applications cover small scale use at many individual sites. The RAC Rapporteurs informed the Committee that while many aspects of the applications are closely related to similar previous applications by the CCST application (by Brenntag UK Ltd) and the CTAC consortia (by LANXESS Deutschland GmbH), there are some differences that need to be considered. Amongst others, the applications submitted by the GGCA consortium cover in comparison to applications submitted by the CCST and the CTAC consortia less processes (e.g., no electroplating), based the exposure assessment almost exclusively on modelling, and used lower volumes and maximum bath concentrations. RAC discussed how the GCCA applications relate to those of CCST and CTAC, and suggested issues to be clarified further with the Applicants at the trialogue.

The Committee requested the RAC Rapporteurs to draft opinions on these applications for authorisation for discussion and agreement at RAC-41 in June 2017.

6. **CT_Hapoc (4 uses)**

The RAC Rapporteurs presented the two draft opinions on the application for authorisation submitted by HAPOC GmbH & Co KG on the following uses of chromium trioxide:

Use 1: Use of chromium trioxide in dissolved and solid form to produce aqueous solutions of any composition for industrial application (at a maximum risk level of 4:10,000),
Use 2: Use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow, in category III (at a maximum risk level of 2:100),
Use 3: Use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow, in category II (at a maximum risk level of 4:1,000),
Use 4: Use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow, in category I (at a maximum risk level of 4:10,000).

The original application was submitted in the German language and the language of communication with the Applicant is also German. The opinion development process therefore heavily relies on the Commission translation services. Uses 2 to 4 are intended to cover all kinds of plating and surface treatment activities with chromium trioxide at different risk levels across the uses.

The first draft opinion presented by the Rapporteurs was on the Use 1, and the second was on the Use 2, as representative of Uses 2 to 4 which are practically identical with the exception of the stated differences in risk levels.

On Use 1, the RAC Rapporteurs noted that the information provided is insufficient for assessing the worker and environment exposures with any accuracy. On Uses 2 to 4, the RAC Rapporteurs noted that the information provided is insufficient for assessing the worker and environmental exposure to Cr(VI) with any accuracy due to the stated information gaps and uncertainties. It was summarised as follows:

- lack of contextual information regarding the air measurements provided,
- lack of clarity about the evidence that will be requested by the Applicant from its downstream users about the RMM implementation and effectiveness,
- lack of clarity about the evidence that will be requested by the Applicant to its downstream users about the monitoring campaigns for demonstrating that workers are indeed not exposed to more than 0.1, 1 or 5 µg Cr(VI)/m^3 for up to 8 hours,
- lack of representativeness of the measurements of Cr(VI) released to the atmosphere,
- absence of any evidence showing that the RMMs implemented will effectively reduce to less than 0.1, 1 or 5 µg Cr(VI)/m^3 the occupational exposure,
- absence of evidence showing that the RMMs implemented will effectively reduce the release of Cr(VI) to waste water to less than 0.1 mg/L,
- absence of a valid indirect exposure assessment of humans via the environment.

The RAC Rapporteurs considered that the application in its current form does not contain sufficient information for a meaningful evaluation of whether the RMMs and OCs described in the exposure scenario are (or are not) appropriate and effective in limiting the risk to workers and the general population. They further considered the exposure scenario described by the Applicant to be too broad to be meaningful.

The maximum exposure requested in this application (5 µg Cr(VI)/m^3) is greater than the 90^{th} percentile of the measurement dataset provided. However, due to a lack of any contextual data no relationships could be established between the measurements provided and any specific OCs and RMMs.

RAC discussed the approach to take on the development of the draft opinions , including the approach in the risk assessment taken by the Applicant, the available modelling data and its

input parameters , the (lack of) information provided on existing OCs and RMMs at the workplaces relevant to and representative of the users of the substance. In addition the Applicant has provided an alternative approach to evaluating the cancer risk in their application for authorisation. The Committee discussed deficiencies in the Statistical First Cancer Level (SFCL) approach elaborated by the Applicant. The Committee noted that it is not possible to correlate each WCSs with specific tasks, specific RMMs, or specific exposures. Regarding Use 1, only one single measurement datum was provided in the application. Regarding Uses 2, 3 and 4, the Applicant has not provided a plausible combined exposure scenario. For all of the uses the Committee acknowledged that the application currently contains insufficient information for a meaningful evaluation of whether the RMMs and OCs described in the exposure scenario are or are not appropriate and effective in limiting the risk to workers and the general population. RAC recognised the following limitations in the estimation of both environmental releases and indirect exposure to humans via the environment:

- The unknown representativeness of the reported real exhaust gas measurements,
- The absence of measurements of discharges on waste water,
- The lack of an assessment of the indirect man via environment exposure beyond the assumption that compliance with exposure permits would result in a negligible risk (see below).

Regarding release of the substance to the environment the Committee noted that the adherence to the release limits does not warrant the absence of impact or its minimisation in the case of non-threshold substance.

The Rapporteurs proposed on the one hand, that should the aforementioned information gaps not be adequately filled, then the Committee could consider recommending a negative opinion. On the other, depending on the level to which the Applicant's responses to the Committee's written questions (and the outcome of the trialogue planned for 27-28 March, 2017) provide additional information, then RAC could consider a recommendation with strict conditions. RAC agreed in principle to this approach.

The RAC Members, representatives of the European Commission and of the stakeholder organisations who took part in the debate, called for consistency between the Committee's opinions on upstream applications submitted on similar uses of chromium trioxide, i.e. that the recommendation to grant or the conditions applied to this application and its uses should be carefully aligned with those of previous upstream applications.

The Committee requested the RAC Rapporteurs to draft their opinions on these uses of chromium trioxide for discussion and agreement at RAC-41 in June 2017.

7. CT_Hapoc_2 (1 use)

The RAC Rapporteurs presented the status of the opinion development process on the upstream application for authorisation submitted by HAPOC GmbH & Co KG on the use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of plastic, with or without current flow. The scope of the application is broad and covers three to four downstream users (based on oral communication by the Applicant; it is not apparent from the application itself). The total number of sites covered by the application is not known. According to the Applicant the number of workers involved is about 15 per site. The tonnage and the requested review period are respectively 100 tonnes of Cr(VI) per annum over a requested review period of 25 years.

The RAC Rapporteurs informed the Committee that considering similarities in the approach taken by the same Applicant as of CT_Hapoc, the Rapporteurs will continue their work on the opinion development on CT_Hapoc_2 applying the same approach as discussed by the Committee on CT_Hapoc application for authorisation.

8. CT_Hapoc_3 (1 use)

The RAC Rapporteurs presented the status of the opinion development process on the upstream application for authorisation submitted by HAPOC GmbH & Co KG on the use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of brass, bronze, copper and other copper alloys for medical engineering, aviation and automation products. The scope of the application is broad and covers one downstream user (based on oral communication by the Applicant; it is not apparent from the application itself). The total number of sites covered by the application is not known. According to the Applicant the number of workers involved is about five per site. The tonnage and the requested review period are 250 kilograms of Cr(VI) per annum over a requested review period of 30 years.

The RAC Rapporteurs informed the Committee that considering similarities in the approach taken by the same Applicant as of CT_Hapoc, the Rapporteurs will continue their work on the opinion development on CT_Hapoc_3 applying the same approach as discussed by the Committee on CT_Hapoc application for authorisation.

d) Adoption of final opinions

1. AsA_Circuit (1 use)

The Applicant provided comments on the SEAC part of the draft opinion. There was then no need to change the RAC draft opinion or discuss it at the plenary and the Rapporteurs recommended to RAC to adopt the Final opinion without further changes.

RAC adopted by consensus the Final opinion.

2. CT Circuit (1 use)

The Applicant provided comments on the Draft opinion. The Rapporteurs informed RAC that out of the three comments provided on the RAC part of the draft opinion they implemented one editorial change proposed by the Applicant. They did not agree with the 2 other comments concerning statements in the opinion on lack of hazards and risk characterisation of alternatives which are not technically suitable.

RAC adopted by consensus the Final opinion with one editorial change.

3. EDC_Eli Lilly (1 use)

The Chairman informed Members that, as the Applicant had no comments on the draft opinion, the RAC and SEAC Chairmen have declared the opinion as final. The document has been sent to the Applicant, European Commission and Member States.

4. CT_Gerhardi (1 use)

The Rapporteur informed the Committee that the Applicant had provided comments on the draft opinion. All comments related to the SEAC part of the draft opinion (following the SEAC recommendation for a shorter review period (RP) compare to the RP requested by the Applicant) and no changes were proposed for the RAC draft opinion.

9.3 Appointment of Rapporteurs for authorisation applications (closed session)

The Committee made no changes to the restricted room document RAC/40/2017/08.

10. AOB

A Stakeholder observer expressed a concern that during the discussions on authorisation, there seemed to be a general misunderstanding regarding the legal implications of the expiry of review periods, which could unduly influence the outcome of the opinions.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 40 6–10 March 2017
14-15 March 2017

(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/40/2017**) was adopted.	**SECR** to upload the adopted Agenda to the RAC S-CIRCABC and to the ECHA website as part of the RAC-40 minutes.
4. Report from other ECHA bodies and activities	
a) Report on RAC 39 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/40/2017/01** and document **RAC/40/2017/02.**	**SECR** to upload the document to the S-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-40 meeting on S-CIRCABC.
7. Harmonised classification and labelling (CLH)	
A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate • Mandestrobin (ISO): no classification for the following hazards: physical hazards, acute toxicity (all routes of exposure), STOT SE, skin corrosion / irritation, serious eye damage / irritation, skin sensitisation, STOT RE, germ cell mutagenicity. • Methylmercuric chloride: Acute Tox. 2 (H330), STOT RE 1 (H372) (nervous system, kidneys) • pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5): Acute Tox. 4 (H332) • Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5): Acute Tox. 4 (H332) • N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5): Acute Tox. 4 (H332) • Thiabendazole (ISO): Aquatic Acute 1 (H400, M=1), Aquatic Chronic 1 (H410, M=1)	

The opinion was adopted by consensus with the harmonised classification and labelling as indicated in Table 1 below.	
B. Substances with hazard classes for agreement in plenary session a) Glyphosate (ISO) b) 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone c) Mandestrobin (ISO) d) Methylmercuric chloride e) Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5) f) N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5) g) Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)	
a) Glyphosate (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Eye Dam. 1 (H318), Aquatic Chronic 2 (H411) Other hazards: No classification for germ cell mutagenicity, carcinogenicity, reproductive toxicity (effects on fertility and development), acute toxicity (all routes of exposure), STOT SE, STOT RE, skin corrosion / irritation, skin sensitisation.	**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.
b) 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. No declassification for the aquatic hazards, but retain Aquatic Acute 1 (400) and Aquatic Chronic 1 (H410) (no M-factors could be set)	**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.
c) Mandestrobin (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Aquatic Acute 1 (H400, M=1), Aquatic Chronic 1 (H410, M=10)	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
d) Methylmercuric chloride	
RAC adopted by majority the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

New entry split out of the group entry of organic mercury compounds: Acute Tox. 2 (H300, H310 and H330), Carc. 2 (H351), Repr. 1A (H360Df), Lact. (H362), STOT RE 1 (H372 (nervous system, kidneys)); aquatic classifications to be transferred from the previous entry	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
e) Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)	
RAC agreed the harmonised classification and labelling as indicated in Table 2 below. Acute Tox. 4 (H332), Eye Irrit. 2 (H319)	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **Rapporteur** to provide the revised draft opinion (STOT RE and toxicity to reproduction) to the SECR. **SECR** to launch a RAC consultation on these endpoints prior to RAC-41.
f) N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5)	
RAC agreed the harmonised classification and labelling as indicated in Table 2 below. Acute Tox. 4 (H332), Eye Irrit. 2 (H319)	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **Rapporteur** to provide the revised draft opinion (STOT RE and toxicity to reproduction) to the SECR. **SECR** to launch a RAC consultation on these endpoints prior to RAC-41.
g) Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)	
RAC agreed the harmonised classification and labelling as indicated in Table 2 below. Acute Tox. 4 (H332)	**Rapporteur** to revise the opinion in accordance with the discussion in RAC. **Rapporteur** to provide the revised draft opinion (STOT RE and toxicity to reproduction) to the SECR. **SECR** to launch a RAC consultation on these endpoints prior to RAC-41.
C. Dossiers for key issues debate i) Titanium dioxide No particular conclusions and action points agreed. Discussion about the draft opinion is only foreseen for RAC-41	
h) Titanium dioxide	
	n/a
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 S-CIRCA BC confidential.

8. Restrictions	
8.1 Restriction Annex XV dossiers	
a) Conformity check	
1) Diisocyanates RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter.	**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.
2) Lead in PVC RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter.	**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.
b) Opinion development	
1) TDFAs Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on TDFAs restriction proposal by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
2) Diisobutyl phthalate (DIBP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), bis(2-ethylhexyl) phthalate (DEHP) Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on this restriction proposal (with modifications agreed at RAC-40) by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with SECR, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.

	SECR to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
9. Authorisation	
9.1 General authorisation issues	
a) Updated working procedure for authorisation process	
	n/a
b) New applications received during the February 2017 submission window	
	n/a
c) Report from the AfA Task Force	
	n/a
d) Feedback from seminar 'Man via the Environment' New applications received during the February 2017 submission window	
	n/a
e) Capacity building	
1. Carcinogenicity dose-response relationship and DNEL setting for the reprotoxic properties of coal-tar pitch, high temperature (CTPHT) **2. Carcinogenicity dose-response relationship of anthracene oil** RAC noted the presentation by the ECHA Consultant on methodology for - reviewing information in the registration dossiers, - uncertainties, - proposal in addressing variability in composition, - selection of critical studies, - quantification of the risks and levels of exposure, - quantification of the cancer risk. RAC discussed the proposed approach and provided advice regarding the way forward.	**ECHA Consultant** to consider the plenary discussion in drafting of the notes.
9.2 Authorisation applications	
a) Discussion on key issues	

1. SD_Colle (1 use) **2. CT_Hansgrohe (2 uses)** **3. SD_Hapoc (1 use)** RAC discussed the key issues in the three applications for authorisation and provided advice as needed to the Rapporteurs, also in relation to the conformity.	**SECR** to inform SEAC about the outcome of the discussion.
b) Agreement on Draft Opinions	
1. CT_Reachlaw (4 uses) RAC noted that the assessment reports are similar in all significant aspects to those submitted by LANXESS Deutschland GmbH (CTAC consortium) for the same uses of chromium trioxide. RAC agreed on an approach that refers to the opinion justification on the application for authorisation CT_Lanxess (CTAC) and discussed specific information reported by REACHLaw Ltd (e.g. on the tonnage expected and the number of sites covered) in addition to the information included in the assessment reports. The conclusions agreed by the Committee were similar in all respects to those agreed at RAC-37 on the application for authorisation CT_Lanxess. RAC agreed on the draft opinions by consensus. <u>Use 1 (Formulation) – corresponds to the Use 1 of the CT Lanxess application for authorisation</u> RAC recommended additional conditions and monitoring arrangements for the application and the review report as described in the opinion. The Committee agreed to give no advice to SEAC regarding the length of the review period. <u>Use 2 (Functional chrome plating) – corresponds to the Use 2 of the CT Lanxess application for authorisation</u> • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • Reflecting uncertainty concerns with the very wide scope of the application for this use, RAC agreed to recommend to SEAC that the length	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.

of the review period should "*not be longer than seven years*". <u>Use 3 (Functional chrome plating with decorative character) – corresponds to the Use 3 of the CT Lanxess application for authorisation</u> • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • RAC gave no advice to SEAC regarding the length of the review period. <u>Use 4 (Surface treatment (except ETP)) – corresponds to the Use 5 of the CT Lanxess application for authorisation</u> • RAC concluded that the operational conditions and risk management measures described in the application **do not** limit the risk, however the suggested conditions and monitoring arrangements will improve the situation. • RAC gave no advice to SEAC on the length of the review period.	
2. CT_Clariant (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risks to workers and the general population. RAC did not recommend additional conditions or monitoring arrangements. 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.
3. CT_Cryospace (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion for the use applied for the RMMs are appropriate and effective in limiting the risks to workers and general public. RAC decided to recommend conditions and monitoring arrangements for the authorisation and the review period with the minor modifications discussed at the plenary.	**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. SD_Borealis (1 use) 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 risks to workers and the general population. RAC did not recommend additional conditions or monitoring arrangements. RAC agreed to give 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.
5. SD_Ormezzano (2 uses) **Use 1:** RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that RMMs and OCs are **not** appropriate in limiting the risk to workers mainly due to uncertainties about the RPE currently being used. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk for general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and review reports. For Authorisation: - Following a review of the selection of the most appropriate RMMs, in accordance with the hierarchy of control, where it is concluded that RPE is also needed, the Applicant must evaluate which tasks require the use of RPE and ensure that appropriate RPE is selected to provide adequate protection for all of the different possible exposure situations. For review reports: - Continue to implement regular campaigns of occupational exposure assessment. - Provide an analysis of the biomonitoring data with sufficient contextual information. - Emissions of Cr(VI) to air and wastewater shall be subject to regular measurements. 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.

Use 2: RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that RMMs and OCs are **not** appropriate in limiting the risk to workers mainly due to the RPE currently being used and current frequency of trainings on the use of RPE. RAC is of the opinion that RMMs and OCs are appropriate in limiting the risk for general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and review reports. For Authorisation: - Following a review of the selection of the most appropriate RMMs, in accordance with the hierarchy of control, where it is concluded that RPE is also needed, the Applicant must evaluate which tasks require the use of RPE and ensure that appropriate RPE is selected to provide adequate protection for all of the different possible exposure situations. - The Applicant must implement yearly trainings on the adequate use of RPE. For review reports: - Continue to implement regular campaigns of occupational exposure assessment. - Provide an analysis of the biomonitoring data with sufficient contextual information. - Emissions of Cr(VI) to air and wastewater shall be subject to regular measurements. RAC agreed to give no advice to SEAC on the length of the review period.	
6. AD_BAE (2 uses) **Use 1:** RAC agreed on the draft opinion as proposed by the Rapporteur. For the Rochester site, RAC agreed that the RMMs and OCs are appropriate in limiting the risk for workers. For the St. Asaph site, RAC agreed that the RMMs and OCs are <u>not</u> appropriate and effective in limiting the risk for workers.	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.

RAC recommended additional conditions and monitoring arrangements for the authorisation, as described in the draft opinion. 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 Rapporteur. RAC agreed that the RMMs and OCs are <u>not</u> appropriate and effective in limiting the risk for workers. RAC recommended additional conditions and monitoring arrangements for the authorisation, as described in the draft opinion. RAC agreed to offer no advice to SEAC on the length of the review period.	
7. EDC_Biotech (1 use) 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 to workers. However, the absence of RMMs for preventing releases of EDC to air from tasks not performed under closed systems and captured by LEVs makes the ENV controls <u>not</u> appropriate. RAC decided to recommend additional monitoring arrangements for the authorisation and for review reports, as described in the draft opinion. 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. EDC_ORGAPHARM (2 uses) **Uses 1 and 2:** RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs are appropriate and effective in limiting the risk to the general population. However, the heavy reliance on PPE to reduce worker exposure should be addressed by the Applicant by investigating how the OCs and RMMs could be adjusted for specific WCS, with a view to reducing exposure.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.

RAC decided to recommend additional monitoring arrangements for the authorisation and for review reports, as described in the draft opinions. RAC agreed to give no advice to SEAC on the length of the review period.	
9. EDC_Akzo (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs are appropriate and effective in limiting the risk to workers and the general population, provided that the improvement plan described by the Applicant is implemented. RAC decided to recommend additional monitoring arrangements for the authorisation, as described in the draft opinion. 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.
10. Diglyme_Roche (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that with the presented information the Applicant demonstrates that adequate control is achievable as long as the facility meets the same conditions as described in the exposure scenarios. RAC decided to recommend additional monitoring arrangements for the authorisation and the review report, as described in the draft opinion. 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.
11. Diglyme_LifeTech (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs are appropriate and effective in limiting the risk to workers and the general population, provided that the improvement plan described by the Applicant is implemented. RAC decided to recommend additional monitoring arrangements for the authorisation, as described in the draft opinion.	**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.	
12. Diglyme_Acton (use 1) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that for the use applied for, adequate control has NOT been demonstrated for workers. Adequate control has been demonstrated for the general population exposed via the environment. RAC is of the opinion that, the currently employed RMMs are not sufficient and that not all possible engineering controls are currently implemented at the Applicant's site, especially in relation to minimising the potential for dermal exposure. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and the review period. RAC agreed to recommend to SEAC the review period no longer than 4 years.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the Applicant for commenting.
d) Discussion on draft opinions	
1. MOCA_Reachlaw (1 use) RAC took note and discussed the key elements presented by the Rapporteur. RAC discussed setting of strict conditions related to OCs and RMMs as well as monitoring arrangements (biomonitoring), considering the broad working practices covered by the application (manual and automatic processes). The Committee also recommended to the RAC rapporteur to reflect in the draft opinion the level of uncertainty associated with the biomonitoring data presented in the application.	**Rapporteur** to consider plenary discussion and prepare the draft opinion for the applied use for a consultation with RAC Members. The draft opinion will be tabled for discussion for agreement at RAC-41.

2. CT_Haas (1 use) **3. SD_Haas (1 use)** **4. PD_Haas (1 use)** **5. SC_Aviall (2 uses)** RAC took note and discussed the key elements presented by the Rapporteurs. RAC noted that while many aspects of the applications are closely related to those of CCST and the CTAC, less processes are covered. RAC recommended that CCST conditions could be used as the starting point, while looking for more specific conditions, where possible.	Rapporteurs to consider plenary discussions and prepare the draft opinions for the applied uses for a consultation with RAC Members. The draft opinions will be tabled for discussion for agreement at RAC-41.
6. CT_Hapoc (4 uses) RAC discussed approach to take on the draft opinions development on the application for authorisation. RAC noted that it is not possible to correlate each WCSs with specific tasks, specific RMMs, or specific exposures. **Use 1:** The only single measurement data provided in the application might not be representative of the real situation. **Uses 2, 3 and 4:** Applicant has not provided a plausible combined exposure scenario. **All uses:** RAC acknowledged that the application currently contain insufficient information for a meaningful evaluation of whether the RMMs and OCs described in the exposure scenario are or are not appropriate and effective in limiting the risk to workers and the general population. RAC recognised the following limitations in the estimation of both environmental releases and indirect exposure to humans via the environment: - The unknown representativeness of the reported real exhaust gas measurements,	**Rapporteurs** to consider discussion at the RAC plenary meeting and to draft the opinions for discussion and agreement at the next RAC plenary meeting in June 2017.

- The absence of measurements of discharges on waste water, - The lack of an assessment of the indirect man via environment exposure beyond the assumption that compliance with exposure permits would result in a negligible risk (see below). **Regarding release of the substance to the environment:** The adherence to the release limits does not warrant the absence of impact or its minimisation in the case of non-threshold substance.	
7. CT_Hapoc_2 (1 use) **8. CT_Hapoc_3 (1 use)** RAC noted oral updates by the Rapporteurs on the draft opinion development.	
d) Adoption of final opinions	
1. AsA Circuit (1 use) 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. CT_Circuit (1 use) RAC adopted the final opinion with one editorial change in the text addressing comments by the Applicant, as proposed by the Rapporteurs.	**SECR** to send the final opinion to the EC, MSs and the Applicants.
3. CT_Gerhardi (1 use) 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.
9.3 Appointment of RAC (co-)rapporteurs for authorisation applications	
RAC/40/2017/08 RAC agreed on the updated pool of Rapporteurs for the applications for authorisation.	**SECR** to upload the pool of Rapporteurs to S-CIRCABC restricted.
10. AOB	
11. Action points and main conclusions of RAC-40	
SECR to upload the adopted action points to S-CIRCABC.	

Table 1: CLH opinions which were adopted at RAC-40

Glyphosate (ISO); N-(phosphonomethyl)glycine

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-315-00-8	glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411	-	-	-
Dossier submitter's proposal	607-315-00-8	glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	**Retain** Eye Dam. 1 Aquatic Chronic 2 **Add** STOT RE 2	**Retain** H318 H411 **Add** H373	**Retain** GHS05 GHS09 Dgr **Add** GHS08	**Retain** H318 H411 **Add** H373	-	-	-
RAC opinion	607-315-00-8	glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	**Retain** Eye Dam. 1 Aquatic Chronic 2	**Retain** H318 H411	**Retain** GHS05 GHS09 Dgr	**Retain** H318 H411	-	-	-
Resulting Annex VI entry if agreed by COM	607-315-00-8	glyphosate (ISO); N-(phosphonomethyl)glycine	213-997-4	1071-83-6	Eye Dam. 1 Aquatic Chronic 2	H318 H411	GHS05 GHS09 Dgr	H318 H411	-	-	-

Methylmercuric chloride

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	080-004-00-7	organic compounds of mercury with the exception of those specified elsewhere in this Annex			Acute Tox. 2 * Acute Tox. 1 Acute Tox. 2 * STOT RE 2 * Aquatic Acute 1 Aquatic Chronic 1	H330 H310 H300 H373 ** H400 H410	GHS06 GHS08 GHS09 Dgr	H330 H310 H300 H373 ** H410		* STOT RE 2; H373: ≥ 0,1%	A1
Dossier submitter's proposal	TBD	methylmercuric chloride	204-064-2	115-09-3	**Retain** Acute Tox. 1 **Add** Muta. 2 Carc. 2 Repr. 1A Lact. **Modify** Acute Tox. 2 Acute Tox. 2 STOT RE 1	**Retain** H310 **Add** H341 H351 H360Df H362 **Modify** H300 H330 H372 (nervous system, vision, kidneys)	**Retain** GHS06 GHS08 Dgr	**Retain** H310 **Add** H341 H351 H360Df H362 **Modify** H300 H330 H372 (nervous system, vision, kidneys)		**Remove** * STOT RE 2; H373: ≥ 0,1%	**Retain** Note 1 **Remove** Note A
RAC opinion	TBD	methylmercuric chloride	204-064-2	115-09-3	**Add** Carc. 2 Repr. 1A Lact. **Modify** Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1	**Add** H351 H360Df H362 **Modify** H330 H310 H300 H372 (nervous system, kidneys)	**Retain** GHS06 GHS08 Dgr	**Add** H351 H360Df H362 **Modify** H330 H310 H300 H372 (nervous system, kidneys)		**Remove** * STOT RE 2; H373: ≥ 0,1%	**Retain** Note 1 **Remove** Note A
Resulting Annex VI entry if agreed by COM	TBD	methylmercuric chloride	204-064-2	115-09-3	Carc. 2 Repr. 1A Lact. Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H360Df H362 H330 H310 H300 H372 (nervous system, kidneys) H400 H410	GHS06 GHS08 GHS09 Dgr	H351 H360Df H362 H330 H310 H300 H372 (nervous system, kidneys) H410			1

Note: Hazard classes highlighted in grey in the row denoting the current Annex VI entry are not subject to assessment by RAC.

Mandestrobin (ISO); (*RS*)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-*o*-tolyl]acetamide

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	616-RST-VW-Y	mandestrobin (ISO); (*RS*)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-*o*-tolyl]acetamide;	-	173662-97-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=10	
RAC opinion	616-RST-VW-Y	mandestrobin (ISO); (*RS*)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-*o*-tolyl]acetamide;	-	173662-97-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=10	
Resulting Annex VI entry if agreed by COM	616-RST-VW-Y	mandestrobin (ISO); (*RS*)-2-methoxy-N-methyl-2-[α-(2,5-xylyloxy)-*o*-tolyl]acetamide;	-	173662-97-0	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=10	

Thiabendazole (ISO); 2-(1,3-thiazol-4-yl)-1*H*-benzimidazole

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-054-00-0	thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole	205-725-8	148-79-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitter's proposal	613-054-00-0	thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole	205-725-8	148-79-8	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410		**Add** M=1 M=1	
RAC opinion	613-054-00-0	thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole	205-725-8	148-79-8	**Retain** Aquatic Acute 1 Aquatic Chronic 1	**Retain** H400 H410	**Retain** GHS09 Wng	**Retain** H410		**Add** M=1 M=1	
Resulting Annex VI entry if agreed by COM	613-054-00-0	thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole	205-725-8	148-79-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	

2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone ("BDMBP")*

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

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

* RAC adopted an opinion for BDMBP in the year 2016, which concluded to add a harmonised classification as a presumed human reproductive toxicant in relation to developmental effects (Repr. 1B; H360D) to Annex VI.

Table 2: CLH opinions not (yet) adopted at RAC-40, but with agreed hazard classes

Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate ("DTPA-K5")

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 2 STOT RE 2 Acute Tox. 4 Eye Irrit. 2	H361d (oral) H373 (respiratory system; inhalation) H332 H319	GHS08 GHS07 Wng	H361d H332 H373 H319			
RAC opinion	TBD	pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7	Repr. 1B STOT RE 2 Acute Tox. 4 Eye Irrit. 2	H360D H373 H332 H319	GHS08 GHS07 Dgr	H360D H373 H332 H319			
Resulting Annex VI entry if agreed by COM	TBD	pentapotassium 2,2′,2″,2‴,2⁗-(ethane-1,2-diylnitrilo)pentaacetate	404-290-3	7216-95-7							

Note: Hazard classes highlighted in yellow in the row denoting the hazard classes agreed by RAC have not yet been agreed, but will be tabled for discussion at the next RAC plenary meeting.

N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (”DTPA-H5”)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter’s proposal	TBD	*N*-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Repr. 2 STOT RE 2 Acute Tox. 4 Eye Irrit. 2	H361d (oral) H373 (respiratory system; inhalation) H332 H319	GHS08 GHS07 Wng	H361d H373 H332 H319			
RAC opinion	TBD	*N*-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6	Repr. 1B STOT RE 2 Acute Tox. 4 Eye Irrit. 2	H360D H373 H332 H319	GHS08 GHS07 Dgr	H360D H373 H332 H319			
Resulting Annex VI entry if agreed by COM	TBD	*N*-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid)	200-652-8	67-43-6							

Note: Hazard classes highlighted in yellow in the row denoting the hazard classes agreed by RAC have not yet been agreed, but will be tabled for discussion at the next RAC plenary meeting.

Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate ("DTPA-Na5")

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	TBD	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Repr. 2 STOT RE 2 Acute Tox. 4	H361d (oral) H373 (respiratory system; inhalation) H332	GHS08 GHS07 Wng	H361d H373 H332			
RAC opinion	TBD	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2	Repr. 1B STOT RE 2 Acute Tox. 4	H360D H373 H332	GHS08 GHS07 Dgr	H360D H373 H332			
Resulting Annex VI entry if agreed by COM	TBD	pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate	205-391-3	140-01-2							

Note: Hazard classes highlighted in yellow in the row denoting the hazard classes agreed by RAC have not yet been agreed, but will be tabled for discussion at the next RAC plenary meeting.

Part III. List of Attendees of the RAC-40 meeting

6-10 March and 14-15 March 2017

RAC Members
ANDREOU Kostas
BARAŃSKI Bogusław
BIRO Anna
BJØRGE Christine
CARVALHO João
CHANKOVA-PETROVA Stephka
CHIURTU Elena (co-opted Member)
CZERCZAK Slawomir
DE LA FLOR TEJERO Ignacio
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 Helene
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
TOBIASSEN Lea Stine
TSITSIMPIKOU Christina
UŽOMECKAS Žilvinas
VAN DER HAAR Rudolf (co-opted Member)
VARNAI Veda Marija
VIEGAS Susana (co-opted Member)
Apologies, Members
BRANISTEANU Radu
DI PROSPERO FANGHELLA Paola
STAHLMANN Ralf
Apologies, stakeholders
MUNARI Tomaso, EuCheMs
VAIOPOULOU Eleni, Concawe

Commission observers
BINTEIN Sylvain, DG ENV
JAMERS An, DG GROW
MORRIS Alick, DG EMPL
ROZWADOWSKI Jacek, DG GROW
WILLIAMS Mark, DG SANTE
RAC advisors
BISCEGLIE Sara (Pietro Paris)
ESPOSITO Dania (Pietro Paris) CLH glyphosate
GEBEL Thomas (Norbert Rupprich)_CLH titanium dioxide
LINDEMAN Birgitte (Christine Bjoerge)_CLH glyphosate
LOIKKANEN Jarkko (Riitta Leinonen)
McCabe Laura (Andrew Smith)_CLH mandestrobin, methyl mercuric chloride
PAPPONEN Hinni (Riitta Leinonen)
STOCKMANN-JUVALA Helene (Tiina Santonen)
SUUTARI Tiina (Riitta Leinonen)
TALASNIEMI Petteri (Riitta Leinonen)
UUKSULAINEN Sanni (Tiina Santonen)
WITASP HENRIKSSON Erika (Anne-Lee Gustafson)

Stakeholders observers
ANNYS Erwin, Cefic
BARRY Frank, ETUC
BERNARD Alice (ClientEarth); occasional stakeholder observer, AfA, restriction)
CLAUSING Peter (HEAL; occasional stakeholder observer, CLH glyphosate)
LOOMIS Dana, IARC (glyphosate)
ROMANO Dolores (EEB)
ROWE Rocky (ECPA)
TILLIEUX Geoffroy (EUPC;occasional stakeholder observer, restrictions)
VEROUGSTRAETE Violaine, (Eurometaux)
Dossier submitters
NEUMANN Lars (DE, glyphosate)
HINDLE Stuart (DE, DTPAs)
ROUW Aarnout (DE, diisocyanates)
WALENDZIK Gudrun (DE, diisocyanates)

Industry experts
BATTERSBY Rodger (Eurometaux, EBRC Consulting GmbH, titanium dioxide)
BUTTERWORTH Graham (Cefic, IGM Resins Ltd, 2-benzyl-2-dimethylamino-4-morpholinobutyrophenone)
CAVALLERO Alain (Cefic, European Stabiliser Producer Association ESPA, Lead in PVC)
KROESCHE Christoph (Cefic, EVONIK Industries, TDFAs)
LEVINE Steve (ECPA, GTF, glyphosate)
LÜCKE-BRUNK Gudrun (Cefic, Covestro Deutschland AG, diisocyanates)
MARTENS Mark (ECPA, GTF, glyphosate)
SALTMIRAS David (Monsanto, glyphosate)
SARGINSON Nigel (EuPC, ExxonMobil, phthalates)
WARHEIT David (Cefic, Chemours, titanium dioxide)
YAMADA Tomoya (ECPA, Sumitomo, mandestrobin)
Invited experts
McELVENNY Damien (statistician, glyphosate)
NOVOTNY Tomas (EcoMole Ltd, dose-response)
PRICHYSTALOVA Radka (Technical University of Ostrava, dose-response)

REMOTE PARTICIPANTS
RAC Members:
CHIURTU Elena Ruxandra
DUNGEY Steve
JANKOWSKA Elzbieta
STAHLMANN Ralf
VIEGAS Susana
Advisors
ESPOSITO Dania (Pietro Paris)
LINDEMAN Birgitte (Christine Bjoerge)
LOSERT Annemarie (Christine Hölzl)
VAN DER HAGEN Marianne (Christine Bjoerge)
Dossier submitters:
Germany
HERMANN Georgia (glyphosate)
NIEMANN Lars (glyphosate)

France
CHARLES Sandrine (titanium dioxide)
JOMINI Stéphanie (titanium dioxide)
ROUSSELLE Christophe (titanium dioxide)
Commission
GARCIA JOHN Ennrique
JAMERS An
PRINZ Maurits-Jan
ROZWADOWSKI Jacek
EFSA
ISTACE Frederique
ECHA staff
BERGES Markus
BLAINEY Mark
BOWMER Tim, Chairman
BROECKAERT Fabrice
DVOŘÁKOVÁ Dana
ERICSSON Gunilla
GILIOLI Roberto
HENRICHSON Sanna
HOPLAND Eivind
KANELLOPOULOU Athanasia
KARJALAINEN Antti
KARJALAINEN Ari
KIOKIAS Sotirios
KIVELÄ Kalle
KOKKOLA Leila
KOSK-BIENKO Joanna
LAPENNA Silvia
LINNA Risto
LIOPA Elīna
LOGTMEIJER Christiaan
LUDBORŽS Arnis

MAJOROS Laszlo
MARQUEZ-CAMACHO Mercedes
MERKOURAKIS Spyridon
MOTTET Denis
MUSHTAQ Fesil
MÜLLER Gesine
NICOT Thierry
NYGREN Jonas
ORISPÄÄ Katja
O´ROURKE Regina
PELTOLA Jukka
PENNESE Daniele
PILLET Monique
PREVEDOUROS Konstantinos
REGIL Pablo
RHEINBERGER Christoph
RODRIGUEZ-IGLESIAS Pilar
ROGGEMAN Maarten
SADAM Diana
SIMOES Ricardo
SIMPSON Peter
SMILOVICI Simona
SOSNOWSKI Piotr
STOYANOVA Evgenia
UPHILL Simon
UPHOFF Andreas

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-40 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-40 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-40 meeting

ANNEX IV Administrative issues and information items

ANNEX V Short summary: Rapporteur's preparatory workshop on the Authorisation Applications from the February Authorisation window

6 March 2017
RAC/A/40/2017

Final Agenda

40th meeting of the Committee for Risk Assessment

6– 10 March 2017
and
14 – 15 March 2017

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 6 March starts at 14.00
Friday 10 March breaks at 13.30
Tuesday 14 March resumes at 9.00
Wednesday 15 March ends at 13.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/40/2017
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

For information

Item 4 – Report from other ECHA bodies and activities

a) Report on RAC-39 action points, written procedures and update on other ECHA bodies

RAC/40/2017/01

RAC/40/2017/02
Room document
For information

b) RAC workplan for all processes

For information

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

No requests.

Item 6 – Requests under Article 95 (3)

a) OEL-DNEL methodology

RAC/40/2017/03

For agreement

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)

Mandestrobin (ISO): no classification for the following hazards: physical hazards, acute toxicity (all routes of exposure), STOT SE, skin /eye irritation, skin sensitisation, STOT RE, germ cell mutagenicity

Methylmercuric chloride: Acute Tox. 2 (H330), Acute Tox. 2 (H300), STOT RE 1 (H372) (central nervous system, kidneys)

Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5): Acute Tox. 4 (H332)

Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5): Acute Tox. 4 (H332)

N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5): Acute Tox. 4 (H332)

Thiabendazole (ISO) : Aquatic Acute 1 (H400), M=1. Aquatic Chronic 1 (H410), M=1

For agreement/adoption

B. Hazard classes for agreement with plenary debate

h) Glyphosate (ISO)

i) 2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone

j) Mandestrobin (ISO)

k) Methylmercuric chloride

l) Pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)

m) N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5)

n) Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)

For discussion and adoption

C. Dossiers for key issues debate

o) Titanium dioxide

For discussion only

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

RAC/40/2017/04

Restricted room document

For agreement

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a) Conformity

1. Diisocyanates – conformity and key issues discussion
2. Lead in PVC – conformity and key issues discussion

For agreement

b) Opinion development

1. TDFAs – third draft opinion
2. 4 phthalates- third draft opinion

For adoption

8.2 Appointment of (co-)rapporteurs for restriction dossiers

RAC/40/2017/05
Restricted document
For agreement

Item 9 – Authorisation

9.2 General authorisation issues

a) Updated working procedure for the authorisation process

RAC/40/2017/06
RAC/40/2017/07

b) New applications received during the February 2017 submission window

c) Report from the AfA Task Force

d) Feedback from seminar 'Man via the Environment'

For information

e) RAC Reference values

1. Carcinogenicity dose-response relationship development and DNEL setting for the reprotoxic properties for coal tar pitch high temperature (CTPHT)
2. Carcinogenicity dose-response relationship development for anthracene oil

For discussion

9.3 Authorisation applications

a) Discussion on key issues

1. SD_Colle (1 use)
2. CT_Hansgrohe (2 uses)
3. SD_Hapoc (1 use)

For discussion

b) Agreement on draft opinions
   1. CT_Reachlaw (4 uses)
   2. CT_Clariant (1 use)
   3. CT_Cryospace (1 use)
   4. SD_Borealis (1 use)
   5. SD_Ormezzano (2 uses)
   6. AD_BAE (2 uses)
   7. EDC_Biotech (1 use)
   8. EDC_ORGAPHARM (2 uses)
   9. EDC_Akzo (1 use)
   10. Diglyme_Roche (1 use)
   11. Diglyme_LifeTech (1 use)
   12. Diglyme_Acton (2 uses)

For discussion and agreement

c) Discussion on draft opinions
   1. MOCA_Reachlaw (1 use)
   2. CT_Haas (1 use)
   3. SD_Haas (1 use)
   4. PD_Haas (1 use)
   5. SC_Aviall (2 uses)
   6. CT_Hapoc (4 uses)
   7. CT_Hapoc_2 (1 use)
   8. CT_Hapoc_3 (1 use)

For discussion

d) Adoption of final opinions
   1. AsA_Circuit (1 use)
   2. CT Circuit (1 use)
   3. EDC_Eli Lilly (1 use)
   4. CT_Gerhardi (1 use)

For discussion and adoption

9.4 Appointment of (co-)rapporteurs for authorisation applications

RAC/40/2017/08
Restricted room document
For agreement

Item 10 – AOB

Item 11 – Action points and main conclusions of RAC-40

Table with Conclusions and Action points from RAC-40

Annex II (RAC 40)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 40 meeting.

Document number	Title
RAC/A/40/2017	Final Draft Agenda
RAC/A/40/2017 Restricted	Draft outline agenda
RAC/40/2017/01	Report from other ECHA bodies
RAC/40/2017/02 Room document	Administrative issues
RAC/40/2017/03	Joint Task Force ECHA Committee for Risk Assessment (RAC) and Scientific Committee on Occupational Exposure Limits (SCOEL) on scientific aspects and methodologies related to the exposure on chemicals at the workplace
RAC/40/2017/04 Room document Restricted	Appointment of Rapporteurs for CLH dossiers
RAC/40/2017/06	Updated working procedure for authorisation process
RAC/40/2017/07	Updated working procedure for authorisation process
RAC/40/2017/08 Room document Restricted	Appointment of Rapporteurs for authorisation applications

ANNEX III (RAC-40)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLÜTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
Glyphosate (ISO) **(DE)**	Agnes SCHULTE	Working for the CA submitting the dossier; and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Norbert RUPPRICH	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on these substances - 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 these substances - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Restrictions		
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.
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.
Diisocyanates **(DE)**	Agnes SCHULTE	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Norbert RUPPRICH	Working for the CA submitting the dossier; and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Urs SCHLÜTER	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

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

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
Restrictions		
Applications for Authorisation		
Harmonised classification & labelling		
Methylmercuric chloride **Titanium dioxide** **(FR)**	Nathalie PRINTEMPS	Working for the CA submitting the dossier and acting as the Dossier Submitter's representative (transitional arrangement as new RAC member) - involved in its preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
Thiabendazole (ISO) **(ES)**	Ignacio de la FLOR TEJERO	ES was the reporting MS for this dossier (under renewal process), but no personal involvement – no other mitigation measures applied.
2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone (BDMP) **(DE)**	Agnes SCHULTE	Working for the CA submitting the dossier but not personally 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.
	Norbert RUPPRICH	Working for the CA submitting the dossier but not personally 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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Urs SCHLÜTER	Working for the CA submitting the dossier but not personally 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.
	Michael NEUMANN	Working for the CA submitting the dossier but not personally 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.
Mandestrobin (ISO) **(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.

Helsinki, 2 March 2017

RAC/40/2017/02

ROOM DOCUMENT

40TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

6– 10 March 2017
and
14 – 15 March 2017

Helsinki, Finland

Concerns: **Administrative issues and information items**

Agenda Point: **4b**

Action requested: **For information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-39 Action Points

The RAC-39 action points due for RAC-40 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-39	20 February 2017	closed

2.2 RAC consultations (status by 27 February 2017)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
Methylmercuric chloride	23 January 2017	Closed
Glyphosate (ISO)	31 January 2017	Closed
Mandestrobin (ISO)	9 February 2017	Closed
pentapotassium 2,2',2'',2''',2''''-(ethane-1,2-diylnitrilo)pentaacetate (DTPA-K5)	19 January 2017	Closed
N-carboxymethyliminobis(ethylenenitrilo)tetra(acetic acid) (DTPA-H5)		Closed
Pentasodium (carboxylatomethyl)iminobis(ethylenenitrilo)tetraacetate (DTPA-Na5)		Closed
Thiabendazole (ISO)	30 January 2017	Closed
2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	20 December 2016	Closed
Application for Authorisation		
CT_Hapoc_2 Consultation on application	4 January 2017	Closed
CT_Hapoc_3 Consultation on application	4 January 2017	Closed
CT_Haas Consultation on application	4 January 2017	Closed
SD_Haas Consultation on application	4 January 2017	Closed
PD_Haas	4 January 2017	Closed

Subject / document	Deadline	Status / follow-up
Consultation on application		
CT_Reachlaw Consultation on application	4 January 2017	Closed
CT_Clariant Consultation on application	4 January 2017	Closed
CT_ZFL Consultation on application	4 January 2017	Closed
SD_ZFL Consultation on application	4 January 2017	Closed
CT_Cryospace Consultation on application	4 January 2017	Closed
SC_Aviall Consultation on application	4 January 2017	Closed
SD_Borealis Consultation on application	4 January 2017	Closed
SD_Ormezzano Consultation on application	4 January 2017	Closed
AD_BAE Consultation on application	4 January 2017	Closed
EDC_Biotech Consultation on application	4 January 2017	Closed
EDC_ORGAPHARM Consultation on application	4 January 2017	Closed
EDC_Akzo Consultation on application	4 January 2017	Closed
EDC_Bayer Consultation on application	4 January 2017	Closed
EDC_Olon Consultation on application	4 January 2017	Closed
MOCA_Reachlaw Consultation on application	4 January 2017	Closed
SD_Colle Consultation on conformity	15 February 2017	Closed
SD_Colle Consultation on application	29 March 2017	Ongoing
CT_Hansgrohe Consultation on conformity	15 February 2017	Closed
CT_Hansgrohe Consultation on application	29 March 2017	Ongoing
SD_Hapoc Consultation on conformity	15 February 2017	Closed
SD_Hapoc Consultation on application	29 March 2017	Ongoing

Subject / document	Deadline	Status / follow-up
Diglyme_LifeTech Consultation on draft opinion	15 February 2017	Closed
CT_Reachlaw Consultation on draft opinions	16 February 2017	Closed
SD_Borealis Consultation on draft opinion	20 February 2017	Closed
CT_Clariant Consultation on draft opinion	20 February 2017	Closed
Diglyme_Acton Consultation on draft opinion	20 February 2017	Closed
CT_Cryospace Consultation on draft opinion	21 February 2017	Closed
AD_BAE Consultation on draft opinions	22 February 2017	Closed
EDC_Akzo Consultation on draft opinion	22 February 2017	Closed
EDC_ORGAPHARM Consultation on draft opinions	22 February 2017	Closed
EDC_Biotech Consultation on draft opinion	22 February 2017	Closed
Diglyme_Roche Consultation on draft opinion	24 February 2017	Closed
SD_Ormezzano Consultation on draft opinions	27 February 2017	Closed
CT_Hapoc Consultation on draft opinions	27 February 2017	Closed
Restrictions		
Consultations on the third draft versions of TDFAs And 4phthalates	24 February 2017 24 February 2017	Closed Closed
Consultations on the conformity check outcome of diisocyanates and lead and its compounds	27 February 2017	Closed

2.3 Other written consultations of RAC (status by 17 February 2017)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-39	6 February 2017	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	11 – 20 January 2017	11 dossiers / intentions
Applications for Authorisation – no calls		
Restrictions Call for expression of interest for rapporteurship 1 restriction dossier (appointment to be done at RAC 40 plenary)	17 January – 16 February 2017	

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-)rapporteurs	▪ cyflumetofen (ISO) ▪ formic acid ▪ mefentrifluconazole ▪ d-Allethrin ▪ fluxapyroxad ▪ azoxystrobin ▪ tribenuron-methyl ▪ 1,2-epoxy-4-epoxyethylcyclohexane	30 January 2017	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			

2.6 Follow-up on the opinions on applications for authorisation agreed by RAC and SEAC

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and Applicants	
PD_Brenntag (2 opinions), SD_Brenntag (3 opinions), DtC_Henkel (2 opinions), ST_Akzo (2 opinions), PH_PPG (2 opinions)	13 December 2016
SD_Arkema (1 opinion), SD_Akzo (2 opinions), SD_Total (1 opinion),	14 December 2016

Opinion(s)	Sent on
SD_Jacobs (1 opinion)	
CT_Cromomed (1 opinion), CT_Hoogovens (1 opinion), CT_PD_SD_Souriau (3 opinions), EDC_BASF_2 (2 opinions)	15 December 2016
CT_Topocrom (1 opinion) CT_Herstal (2 opinions)	16 December 2016
CT_Friedberg (1 opinion) CT_Valvetrain (1 opinion) CT_Burscheid (1 opinion) CA_Bosch (1 opinion)	22 December 2016
EDC_Dow (1 opinion)	24 January 2017
EDC_Olwerke (1 opinion)	26 January 2017
EDC_Lotos (1 opinion)	30 January 2017
EDC_Lanxess (2 opinions)	1 February 2017
CT_Snecma (1 opinion)	21 February 2017
EDC_Eli_Lilly (1 opinion)	27 February 2017
CT_MTU (2 opinions)	28 February 2017
Diglyme_Merck (1 opinion)	3 March 2017