RAC/M/45/2018
Final
21 August 2018

Minutes of the 45th Meeting of the Committee for Risk Assessment (RAC 45)

4 June started at 09.00
8 June ended at 13.30

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 45th meeting of the Committee for Risk Assessment (RAC 45). Apologies were received from four Members.

In his opening address, he then provided an overview of the recent REACH review by the Commission as it applies to RAC. Some parts of the following text are taken from the REACH Review, mainly Annex 6 of the Staff Working Document.

Workload

In light of the increasing workload of RAC which has tripled from 34 opinions in 2012 to 102 opinions in 2016 (and 98 in 2017), the review recognised that a number of initiatives have been taken to increase the working capacity of the Committee but also to streamline procedures and working methods.

- Membership of RAC increased from 39 members in 2012 to 51 members in 2017.
- In addition, to cope with the high number of authorisation dossiers, RAC and also SEAC co-opted four members each.
- RAC plenary meetings now usually take two weeks, four times per year. One week is mainly dedicated to the assessment of classification and labelling dossiers under CLP. The other week is dedicated to the evaluation of applications for authorisation and proposals for restrictions, as well as specific requests for opinions under Article 77(3)(c) of REACH, (including OELs). For ECHA, this recognition of the dedication of the different weeks to specific processes with different expertise needs is significant. In this light, we are exploring a small lowering of the quorum to allow members more freedom to choose which week (process) they are best suited to attend.
- RAC and SEAC may face increased workloads in the future; therefore the members should really commit to dedicate 50% of their time to this work.

Expertise of RAC

- When nominating members to the Committees, there are often difficulties to find appropriate experts within and outside national competent authorities and Member States for all relevant areas of expertise which includes human toxicology, ecotoxicology, epidemiology.
- While the expertise in RAC for the evaluation of classification and labelling dossier has been solid, the expertise in the other area (REACH) needed some reinforcement. In particular as the workload is still increasing (projections for 2019 and 2020 fully bear this out) mainly due to the increased number of applications for authorisation and other new tasks. These tasks are quite different and having a big pool of experts in each area is complex.
- In order to have more flexibility, ECHA could create a list of experts to be continuously updated and use these experts for 'ad hoc' attendance at the meetings of RAC.
- The Committee could also benefit from allocating more support ECHA staff in specific areas where this expertise is requested.

Deriving OELs

- The REACH review also noted that: "*Stakeholders have repeatedly expressed concerns about a lack of coherence in the implementation of REACH and OSH. A large number of respondents from industry in the replies to the online public consultation confirmed the need for further clarity for the interface between REACH and OSH legislation. NGO and*

Trade Unions stressed the need for a better coherence and harmonisation between OELs developed under the OSH legislation and the DNELs developed under REACH with a preference to have one single numerical value " (Annex 6, paragraph 6.3.2.2).

- RAC and SCOEL also worked together (ECHA/RAC – SCOEL Joint Task Force) to discuss their methodology in deriving occupational exposure limits (OEL) and Derived No-Effect Level (DNEL) for the inhalation route.
- Following this discussion, the Commission questioned the need to have at EU level two different committees dealing with the evaluation of the same chemicals.
- Therefore, it was considered necessary to build within RAC the necessary expertise to cover the areas covered by SCOEL in a very short-time period and over a longer time period to replace SCOEL with RAC.
- **Action 12:** *Interface REACH and OSH legislation*

  (3) Align methodologies to establish safe levels of exposure to chemicals at the workplace by first quarter 2019.

  (4) Enhance the role of ECHA's risk assessment committee (RAC), involving also social partners, to provide scientific opinions under the OSH legislation while respecting the role of the Advisory Committee on Health and Safety at Work.

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The participants at RAC 45 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 44th meeting had already been destroyed. The Chairman noted that the minutes are adopted and they have been uploaded to S-CIRCABC and published on the ECHA website. The minutes include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/45/2018). It was noted that a short discussion of the RAC note on the dose response of coal-tar-pitch (high temperature) will be added to the agenda. No other points were raised under any other business.

The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes in Part IV (Annexes I and II) and Part II, respectively.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. 14 Members and the Chairman 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 Part IV, Annex III.

4. Appointment of (co-) rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) (c) requests (closed session).

The Secretariat collected the names of volunteers for rapporteurships as stated in the restricted room document.

The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted CLH, as well as the forthcoming applications for Authorisation and restrictions.

5. Report from other ECHA bodies and activities

a) Report on RAC-44 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-44 had been completed. The summary of all consultations, calls for expression of interest in rapporteurships and written procedures (room document RAC/45/2018/01) is also available in the usual meeting document on S-CIRCABC (see Part IV, Annex II).

The Chairman also informed the Committee that the final minutes of RAC-44 had been adopted via written procedure and were uploaded to S-CIRCABC and are published on the ECHA website, and thanked those Members who had provided comments on the draft.

b) RAC workplan for all processes

The Chairman informed the meeting participants about the updated RAC work plan for 2018 and Q1/Q2 2019, 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, 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.

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

1) CT_Wesco (formerly Haas): chemical conversion and slurry coating application, re-consideration of a proposed authorisation condition.

The Chairman informed the Committee that the Executive Director had exceptionally requested RAC[1], to consider the clarifications provided by the applicant for authorisation and to conclude if the condition "The scope of the authorisation for the use of chromium trioxide is limited to slurry coating (sacrificial coating and diffusion coating) and chemical conversion coating operations by aerospace companies and their suppliers. Chemical conversion coating by spraying and slurry coating by dipping, brushing, swabbing or roller shall not be covered by the authorisation, if granted." is still necessary.

The Chairman informed that RAC adopted its opinion on this case on 30 Nov 2017. At the end of 2017 the applicant contacted ECHA stating that the second sentence in the abovementioned condition has serious consequences for them. RAC had introduced this condition because it considered there were no Worker Contributing Scenarios (WCS) adequately covering these tasks. The applicant submitted a revised Chemical Safety Report (CSR) in February 2018 that

[1] Mandate of 18 April 2018 https://echa.europa.eu/documents/10162/13641/rac_mandate_wesco_en.pdf/dc3bd58e-f32b-cafe-313b-859f525bf4b8

provided the missing information and the clarifications necessary to support the applicant's view that the CSR as originally submitted intended to cover these processes. Exceptionally, RAC was requested to consider removing the aforementioned condition from its opinion. Furthermore, the Chairman informed the participants that the deadline for forwarding the RAC-opinion to the Commission is 30 June 2018.

The RAC Rapporteurs then presented the draft opinion that responds to the mandate. They proposed that based on the revised CSR the entire aforementioned condition is no longer necessary because the scope of the use is unambiguous in the revised CSR and the removal of the condition has no impact on the conclusions of the risk assessment. The amended opinion on the application and its amended justification, will replace the opinion of 30 November 2017.

The RAC Members supported the Rapporteurs proposals. However, RAC highlighted that it is important that applicants unambiguously define the scope of the use applied for, describe in detail the processes covered, and present exposure scenario(s) with a clearly defined set of Operational Conditions and Risk Management Measures for all the corresponding tasks and processes covered by the scope of the use applied for. Lack of such clear information greatly hinders the evaluation of applications for authorisation.

The Committee adopted its opinion on this Article 77(3)(c) request by consensus. The Rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted RAC opinion. The Chairman thanked the Rapporteurs for their efficient and thorough handling of this proposal and the Committee Members for their contributions.

2) Request to review a derogation request for the PFOA restriction (entry 68 of Annex XVII to REACH)

The Chairman informed the Committee that the Commission had received a request for re-examination of the existing restriction of PFOA and related substances (entry 68 of Annex XVII to REACH) in view of including a derogation for the use of PFOB for the manufacturing of certain pharmaceutical products using pressurised, metered-dose inhalers for the treatment of pulmonary diseases. RAC and SEAC were requested to prepare an opinion in view of a possible derogation from the existing Annex XVII restriction of PFOA, its salts and the related substances, by 1 December 2018. The Secretariat had prepared an analysis of the information provided by the companies concerned and the ECHA report had been made available to RAC prior to RAC-45. The Secretariat considers that this derogation request is justified.

The Rapporteur then presented to the Committee the Commission request, the ECHA analysis, the timelines proposed for the opinion development and his initial findings. The Rapporteur noted that most probably he could agree to the derogation, but has concerns with regard to the plans for waste water treatment – which are unclear and thus minimisation of emissions in the future is also not clear. Furthermore, the description of waste handling in CSR could be improved.

The Chairman suggested that as the process for handling Article 77(3)(c) requests is relatively flexible, the Rapporteur could consider asking specific written questions to the company and this was supported by RAC.

The Chairman informed that the public consultation on this proposal will be launched on 20 June and will last until 20 August 2018. The Chairman thanked the Rapporteur and requested him to develop a draft opinion for discussion and agreement at RAC-46 plenary meeting.

7. Requests under Article 95(3)

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8. Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 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.

B. Substances with hazard classes for agreement in plenary session

1) paclobutrazol (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that paclobutrazol is used as a pesticidal active substance within the EU. The substance has no existing entry in Annex VI of the CLP Regulation thus in accordance with Article 36(2) of CLP all hazard classes need to be assessed. The legal deadline for the adoption of an opinion is 27 September 2018.

The DS (UK) proposed classification as Repr. 2; H361d, Acute Tox. 4; H332, Acute Tox. 4; H302, Eye Irrit. 2; H319, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=10).

RAC agreed not to classify for the following hazard classes via the fast-track procedure, with scrutiny but without plenary debate: physical hazards, acute toxicity (dermal route of exposure), skin corrosion / irritation, respiratory / skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE and aspiration hazard, as well as classifications for Acute Tox. 4; H332, ATE = 3.13 mg/L (dust and mist), Acute Tox. 4; H302, ATE = 490 mg/kg bw, Eye Irrit. 2; H319, Aquatic Acute 1; H400, M = 10 and Aquatic Chronic 1; H410, M = 10.

RAC then discussed specific target organ toxicity after repeated exposure (STOT RE) and toxicity to reproduction. RAC did not consider the hepatotoxicity (mainly steatosis) reported in the 90-day study in rats and the 2-year studies in mice and rats, respectively, to be relevant for STOT RE classification since the effects were mainly seen at doses above the CLP guidance values for Category 2.

RAC also considered the testicular effects noted in the 90-day study dogs as not relevant for classification purposes. RAC supported no classification of the substance for sexual function and fertility, given further the absence of effects in the 1- and 2 generation studies.

There were six developmental toxicity studies available for evaluation: four in rats and two in rabbits. In the CLH report by the DS, only two studies in rats (two OECD 414 studies with different dose levels) and two rabbit studies (OECD 414) were included. However, during the public consultation, two additional rat studies were submitted by Industry: one preliminary study and one publication (Vergieva, 1998).

The RAC noted that the following effects may be relevant for classification purposes:

i) malformation (cleft palate) in rats (in three out of four studies),

[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 the Committee.

ii) variations (alterations in ossification) in rats and rabbits, and
iii) variations (alterations in kidney) in one study in rats.

Cleft palates are seen in three out of four rat studies, but not in rabbits. During the discussion many RAC members pointed out that there are several issues that increase the uncertainty and that could justify classification in category 2 for developmental toxicity instead of category 1B. These are:

- the severe maternal toxicity (mortality) seen in two of the three positive studies,
- in one study cleft palates were seen in only one litter in the high dose, the low dose and also in the controls, but not at all in the mid dose,
- inconsistent results in the third positive study (Vergieva, 1998) together with limited reporting: e.g. no reporting of maternal toxicity, no dose-response, higher incidences after a single dose than after repeated exposure even though the sensitive window was covered in both dosing regimes, and no cleft palates seen at the highest dose at GD 13,
- not seen in rabbits, however, the doses were lower than the doses where it was seen in rats.

The RAC rapporteur considered classification of paclobutrazol in category 2 for development appropriate since the malformations (cleft palate) were reported only in one species and were seen together with high maternal mortality (20 %), while at non maternal toxicity doses only variations (mainly retardation in ossification) were reported. It should be noted that it is unclear if there was any maternal toxicity in the Vergieva, 1998, study due to the limited reporting. The RAC members supported the DS's and the Rapporteur's proposal for classification of paclobutrazol as Toxic to reproduction category 2 (H361d: Suspected of damaging the unborn child).

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

2) dimethyl disulphide

The Chairman welcomed the industry dossier submitter's representative (Arkema).

The Chairman reported that the dossier is tabled for a first discussion at the RAC plenary meeting. The legal deadline for the adoption of an opinion is 15 November 2018.

Dimethyl disulphide (DMDS) is an industrial chemical manufactured, imported and used in Europe in large quantities as an intermediate for chemical synthesis, processing aid in refineries and petrochemical sites. It is also proposed to be approved as an active substance in plant protection products in accordance with Regulation (EC) No 1107/2009. It has no existing entry in Annex VI to the CLP Regulation.

The dossier submitter (Arkema) proposed to classify DMDS as Flam. Liquid 2; H225, Acute Tox. 4; H302, Acute Tox. 3; H331, Eye Irrit. 2; H319, Skin Sens. 1B; H317, STOT SE 3; H335, Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=10).

The following hazard classes were agreed via the fast-track procedure, with scrutiny but without plenary debate: Flam. Liquid 2; H225, Acute Tox. 3; H331 (ATE 5 mg/L), Eye Irrit. 2; H319, Aquatic Acute 1; H400, Aquatic Chronic 1; H410, and no classification for acute toxicity (dermal route) and aspiration hazard.

RAC discussed acute oral toxicity, skin irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity and toxicity to reproduction at the plenary.

As regards acute oral toxicity, RAC discussed whether an acute oral study by Shapiro (1985a) was valid to be used for classification in Category 3 due to its LD_{50} value fitting within the guidance value range for Cat. 3, as the test substance (98% DMDS) in this study contained 1% of an impurity methyl mercaptan that was classified for acute inhalation toxicity in category 3.

IND also clarified that the acute oral LD_{50} of sodium salt of methyl mercaptan was 100 mg/kg bw. The LD_{50} values in five other available studies on DMDS without such concentration of the impurity were inconclusive and one fit within the guidance value range for category 4. RAC concluded that without the data showing that the impurity was responsible for the observed effect of DMDS, it could not be used as a justification to invalidate the study. A RAC member also pointed out that considering the LD_{50} of sodium salt of methyl mercaptan (100 mg/kg bw), it was very unlikely that 1 % of this substance would be the cause of the LD_{50} observed in Shapiro (1985a). RAC members did not support the DS proposal to dismiss the result observed in Shapiro (1985a), and supported the Rapporteurs proposal to classify Dimethyl disulphide for Acute oral toxicity Category 3, H301: Toxic if swallowed with an ATE = 190mg/kg bw.
Concerning the proposed classification for STOT SE 3; H335, the rapporteurs agreed with the DS proposal. During the discussion, several RAC members pointed out that degeneration of olfactory epithelium was an irreversible effect (leading to a loss of smell) and therefore a classification as transient respiratory tract irritation (Cat. 3) was not appropriate. One RAC member suggested to rather consider a supplementary labelling element EUH071 "Corrosive to the respiratory tract" (for substances in addition to classification for inhalation toxicity, if data are available that indicate that the mechanism of toxicity is corrosivity). As the degeneration of olfactory epithelium was observed at dose levels within the guidance value range for STOT SE 1, RAC agreed to classify DMDS for STOT SE 1; H370 (upper respiratory tract, inhalation). RAC agreed not to add the supplementary labelling EUH071.
RAC then discussed the dossier submitter´s proposal to classify DMDS for Skin Sens. 1B; H317, supported by the RAP. Several RAC members agreed that both available in vivo studies were positive and showed that the substance was a sensitizer. This was supported by some in vitro studies. RAC concluded, however, that the category 1A could not be excluded based on the in vivo data, and that the in vitro tests had not yet been validated for setting sensitisation potencies. RAC concluded to classify DMDS as Skin sensitisation Category 1 without a sub-category.
Concerning the observed skin effects in the 4-week dermal study (Prinsen, 1990) and acute skin corrosion/irritation study performed according to OECD TG 404 (Guillot, 1985a), the Rapporteurs asked RAC to discuss the following options: classification for STOT RE 2, Skin irrit. 2 or no classification. One RAC member pointed that in the Prinsen (1990) study erythema, oedema, ischemic necrosis (from the first week of exposure) and incrustation of skin were observed. The effects were observed at all doses and they were worsening with the length of time of exposure. On the other hand, the data on skin irritation was inconclusive as the observation period in the OECD TG 404 study was only 72 h (not 14 days) but the effects were not fully reversible within this time. Therefore she opted for classification for STOT RE or Skin irritation. Several members expressed their view that STOT RE was not applicable for skin irritation effects even if the substance was not classified as Skin irrit. 2. Some members opposed this view and considered that classification for STOT RE due to skin irritation as a consequence of repeated exposure was an option because the data was not sufficient or it was inconclusive for classification as Skin Irrit. 2 and because the worsening skin effects occurred after repeated exposure within the guidance value range for STOT RE 1. One member suggested EUH066 or Skin Irrit. 2. One member supported classification as Skin irrit. 2 based on weight of evidence from the Guillot (1985a) and Prinsen (1990) studies. RAC concluded not to classify for skin irritation or for STOT RE because the criteria were not fulfilled. Also EUH066 was not considered appropriate because there were no signs of skin dryness or cracking.
RAC agreed that there is no need in this case to classify either for Skin irritation or for STOT RE. RAC supported the proposal to additionally classify for STOT SE 3; H336 (May cause drowsiness or dizziness) due to the transient narcotic effects observed in repeated dermal toxicity study on rabbits, supported by behavioural effects seen in rats in acute studies on DMDS.

RAC supported without further discussion the conclusion proposed by the Rapporteurs to not classify dimethyl disulphide for mutagenicity nor for reproductive toxicity based on information provided in the dossier.
RAC adopted the opinion by consensus. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

3) 2,2-bis(bromomethyl)propane-1,3-diol

The Chairman reported that BMP is used in polymers and in the manufacture of plastic products. The substance has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 18 October 2018.

The DS (NO) proposed to classify the substance for mutagenicity 1B; H340 and carcinogenicity 1B; H350. The following hazard classes were agreed via fast-track procedure:

- Carcinogenicity 1B; H350

Regarding mutagenicity, no in vivo tests were available for germ cells, therefore classification was proposed based on in vitro studies and in vivo somatic cell tests in combination with evidence from other studies that the substance can reach the germ cells, such as those on carcinogenicity and reproductive toxicity

RAC discussed whether the supporting data were sufficiently robust and concluded that the reproductive effects observed in female mice, the formation of tumours at multiple sites in the carcinogenicity studies and, the evidence of presence of the substance in testis in a toxicokinetic/distribution study sufficiently robust enough to assume systemic distribution of BMP and that the substance reaches the germ cells. RAC agreed that classification of BMP as Muta. 1B is warranted on the basis of the available in vitro/in vivo genotoxicity data and evidence that BMP reaches germ cells.

In conclusion, RAC agreed to classify BMP as Muta. 1B; H340 and Carc. 1B; H350.

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

4) pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc

Mr Watze de Wolf, replacing the Chairman of RAC Tim Bowmer for this agenda item, welcomed the representative of the dossier submitter (SE), experts accompanying the Cefic, ECPA and Eurometaux stakeholder observers and the expert accompanying the occasional RAC stakeholder Cosmetics Europe. He reported that zinc pyrithione is an active substance in biocidal products with wide range of uses. The substance has no existing Annex VI entry. The legal deadline for the adoption of an opinion is 21 November 2018.

The DS (SE) proposed to classify zinc pyrithione for acute oral toxicity (Acute Tox 3; H301), acute toxicity via inhalation (Acute Tox 2; H330), for serious eye damage (Eye Dam. 1; H318), for developmental toxicity (Repr. 1B; H360D), repeated dose toxicity (STOT RE 1; H372) and for environmental hazards (Aquatic Acute 1; H400, M-factor=1000, Aquatic Chronic 1; H410, M-factor=10 (adjusted to 100 following comments during the public consultation)).

The following hazards were agreed via the fast-track procedure, with scrutiny but without plenary debate:

Acute Tox 3; H301, ATE oral = 221 mg/kg bw,

Acute Tox 2; H330, ATE inhalation = 0.14 mg/l,

Eye Dam. 1; H318, and

no classification for physical hazards, acute toxicity (dermal route), STOT SE, skin irritation/sensitisation and carcinogenicity.

RAC discussed STOT RE, mutagenicity, toxicity to reproduction and environmental hazards at the plenary.

The Committee briefly discussed the environmental hazards of ZnPT and noted that the study on the marine diatom *Skeletonema costatum*, used by the dossier submitter to derive the acute and chronic M-factors, may be of lower reliability due to reasons addressed in the draft opinion and discussed further in the RAC plenary. In addition, the unaudited draft versions of two new experimental studies (on the same marine diatom species) which were brought to the attention of RAC at a very late stage were briefly discussed. RAC considered they may impact on the M-factor and agreed that the the final study reports could be used to conclude on environmental hazards provided that they can be fitted into the Committee's schedule.

The representative of Eurometaux confirmed that the final study reports of the two ENV studies would be made available to ECHA in due time for a short targeted public consultation and following assessment by RAC before the final adoption of the opinion in September 2018 (RAC 46).

RAC concurred with the DS proposal to classify the substance into category 1 for repeated dose toxicity based on mortality observed in several oral and inhalation studies in rats and neurotoxic effects (hind limb paralysis) observed in the oral and inhalation studies in rats. Comments submitted in public consultation, some of which were further clarified at the meeting by the ECPA expert, were discussed and RAC considered they did not require a change in the suggested classification. RAC concluded that there was no MoA data available that could explain the differences in sensitivity to neurotoxicity.

The Committee further discussed whether or not to specify target organs (blood, nervous system and lethality) and concluded on no specification of target organs, nor the route of exposure.

RAC agreed that no classification is warranted for germ cell mutagenicity based on negative *in vivo* studies (two NM tests, a CA test in monkeys and a Comet assay in rats).

The data did not support classification for fertility or sexual function, thus RAC agreed that no classification was warranted for this endpoint.

The Committee then discussed developmental toxicity of zinc pyrithione based on six reproductive toxicity studies in two species (rat and rabbit) taking into account comments submitted in public consultation and further clarified by the expert from CEFIC. The specific developmental findings (increase in post-implantation loss, decrease in foetal viability and/or increase in resorption and increase in skeletal and soft tissue malformations were observed in three studies and two species (rat and rabbit). Multiple modes of action were considered. A single mechanism of action of ZnPT, aconitase inhibition, was proposed by industry. RAC noted that there was insufficient data to conclude on a single mechanism of action of ZnPT, as proposed by industry, while the role of other possible molecular target(s) and mechanism(s) could not be ruled out.

In the discussion the RAC members noted that although the effects were observed in the presence of maternal toxicity (at top doses) in several studies, the maternal toxicity was not demonstrated to be causative of the effects seen and there was no mechanistic data available to indicate specific maternally-mediated mechanisms that would imply that the developmental effects would not be relevant for humans.

In conclusion, in line with the proposal of the dossier submitter and the Rapporteur, RAC agreed to classify zinc pyrithione into category 1B for developmental toxicity.

Prior to the final adoption of the opinion, the Secretariat will launch a short targeted public consultation on the aforementioned two environmental studies, the Rapporteurs will reflect the outcome as appropriate. The dossier will be tabled for final adoption at RAC 46. The Chairman noted that endpoints agreed at RAC 45 will not be reopened.

The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

5) bis(α,α-dimethylbenzyl) peroxide

The Chairman reported that bis(α,α-dimethylbenzyl) peroxide is used for polymers in formulation of mixtures and/or re-packaging and for the manufacture of plastic products, rubber products and chemicals. The substance has an existing entry in Annex VI of the CLP Regulation where it is classified as Org. Perox. F; H242, Skin Irrit. 2; H315, Eye Irrit. 2; H319 and Aquatic Chronic 2; H411. The legal deadline for the adoption of an opinion is 28 October 2018.
The DS (NO) proposed to additionally classify bis(a,a-dimethylbenzyl)peroxide for Repr. 2; H361d and to remove the classification for Skin Irrit. 2; H315 and Eye Irrit. 2; H319.

RAC agreed that there are clear effects of reproductive toxicity, such as increased malformations that do not correlate with maternal toxicity, and that these effects are sufficient to classify the substance as Repr. 1B H360D.

The DS proposed to remove the classification for skin irritation based on a study with rabbits where the criteria for classification was not met. In addition, as the classification dates back to the Dangerous Substances Directive, it was suggested that the possible reason for classification at the time was that the substance contains a peroxide group and these are known as potential irritants (see Guidance on CLH, section 3.2.2.1.2.1. Consideration of physico-chemical properties). RAC discussed the quality of the existing study and found it not to be sufficient to remove the concern because the vehicle was not used as requested in the study guideline.
In addition, RAC notes that the substance is a peroxide; according to ECHA CLP guidance which refers to ECHA guideline R7, section R.7.2.6.2 testing and assessment strategy for skin corrosion/irritation, if the substance is an organic peroxide it is considered as a skin irritant Cat. 2.

RAC discussed the removal of the eye irritation classification and concluded that although in the rabbit study there is lack of information on purity it was conducted according to OECD guidelines. The study showed minor irritation but did not fulfil the criteria for classification. However, RAC considered that stronger irritation could have occurred had the substance been applied in a lipophilic vehicle and therefore decided to retain the current classification in the absence of conclusive evidence both from the current study and the evidence behind the existing classification.

In conclusion, RAC proposed to classify bis(α,α-dimethylbenzyl) peroxide as Repr. 1B; H360D and to retain the existing classification as Skin Irrit. 2; H325 and Eye Irrit. 2; H319
RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

6) N-(hydroxymethyl)acrylamide (NMA)

The Chairman reported that N-(hydroxymethyl)acrylamide is an industrial chemical manufactured and used (in polymer products) at industrial sites only. The substance has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 13 October 2018.

The DS (FR) proposed to classify NMA as Carc. 1B; H350, Muta. 1B; H340 and STOT RE 1; H372 (peripheral nervous system)).

Classification for repeated dose toxicity was discussed based on two GLP oral gavage studies with rats and mice and relevant data from four epidemiological studies in tunnel workers. RAC members considered the neurological findings (a statistically significant decrease in hindlimb grip strength at the lowest dose to be just above the cut-off value for cat. 1) in the animal studies to point to classification in category 1 since no NOAEL value was derived from the studies and thus possible effects below 10 mg/kg bw/day could not be excluded. Taking into consideration the epidemiological studies showing effects on the peripheral nervous system of tunnel workers co-exposed to NMA and AA (acrylamide) (with the known ratio of 1:20 between AA and NMA) with symptoms persisting up to 16-18 months after end of exposure (which was considered to be more than transient), along with evidence of exposure (formation of haemoglobin adducts) RAC agreed to the DS proposal to classify NMA in STOT-RE category 1 with the peripheral nervous system as the target organ.

RAC concurred with the DS proposal to classify NMA as1B for mutagenicity based on positive results in vivo (in two independent Dominant lethal assays, and a MN study in mice) and on in vitro evidence, i.e. a dose related increase in chromosome aberration in Chinese Hamster Ovary cells.

Following discussion on the carcinogenic potential of NMA, RAC agreed to classify the substance in category 1B based on the lung tumours reported in male and female mice, the ovary tumours in female mice and taking into consideration the mutagenicity profile of NMA. Although no tumours were reported in rats, it was considered that the doses used in the study were too low.

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

7) mecetronium ethyl sulphate [MES]

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that MES is a biocidal active substance to be used as a disinfectant in human hygiene products. The active substance has not been approved yet under BPR. It has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 4 November 2018.

The DS (PL) proposed to classify MES for Acute Tox 4; H302, Acute Tox 3; H311, Skin Corr. 1C; H314, Eye Dam 1; H318, Aquatic Acute 1; H400 (M=100) and Aquatic Chronic 1; H410 (M=10).

RAC agreed not to classify the following hazard classes via fast-track procedure with scrutiny but without plenary debate: Physical hazards, STOT SE, Skin sensitisation, Germ cell mutagenicity.

RAC discussed acute toxicity (oral, dermal, inhalation), skin corrosion, eye damage, STOT RE and reproductive toxicity at the plenary. The proposal for environmental classification is scheduled for discussion at RAC-46 in September 2018.

Carcinogenicity was not within the scope of the CLH dossier (no data available). RAC concluded not to classify for acute toxicity via the oral and dermal routes due to inconclusive data, as the highest tested doses were not sufficient to determine whether the LD_{50} values would be within the range of values warranting classification. One member suggested to consider EUH066

(repeated exposure may cause dryness and cracking), but the Rapporteur noted that the substance was corrosive and therefore EUH066 was not appropriate. There was no data on MES or detailed information available to support read-across which would enable assessment of acute inhalation toxicity. RAC concluded however that EUH071 was warranted because MES was a corrosive substance and could be inhaled in certain circumstances. The stakeholder observer expert stated that MES was not used in sprays, there was no generation of aerosol in production and the exposure was limited to the dermal route. RAC concluded that such risk considerations were not relevant to classification.

RAC agreed to classify MES as Skin Corr. 1; H314 based on irreversible effects in the OECD TG 404 study after a 4 hour exposure to 4 % MES supported by the effects observed in the acute dermal study. RAC concluded that the data was insufficient for sub-categorisation since the tested concentration was so low higher concentrations were likely to cause the effects after shorted exposure. RAC also classified MES for Eye Dam. 1; H318 without a hazard statement in the label because skin corrosive substances are automatically classified for Eye Dam. 1; H318.

Regarding STOT RE, the mortalities observed at the top dose in the 90-day study and 1-gen study just above the guidance value range, and their relevance for classification was discussed. RAC concluded that it was not appropriate to adjust the guidance values in this case because the mortalities were likely to be consequences of corrosion that was already an assigned classification and not due to the systemic toxicity.

RAC concluded no classification is warranted for fertility and sexual function as effects were present only at doses that caused severe maternal toxicity (17% mortality and clinical signs). RAC concluded also that no classification was warranted for developmental toxicity as the effects co-occurred with severe maternal toxicity. In addition, effects on foetal and placental weight remained within historical control data range and abortions were considered as a consequence of maternal gastrointestinal toxicity.

In conclusion, RAC agreed to classify MES as Skin Corr. 1; H314 and Eye Dam. 1; H318 and EUH071, reaching agreement on the classification of human health hazards. A discussion on the environmental hazards is scheduled for RAC-46, at which time the opinion will be adopted.

8) Glyoxylic acid … %

The substance has no harmonised classification and labelling entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 7 November 2018.

The DS (Germany) proposed to classify the substance as Eye Dam. 1; H318, Skin Sens. 1B; H317, to add Note B and no classification for skin irritation. The Committee concurred with the DS's proposal via fast-track and agreed to classify the substance accordingly, adopting the opinion by consensus.

9) 2-Methyl-1,2-benzisothiazol-3(2*H*)-one; [MBIT]

The Chairman welcomed the expert accompanying the Cefic stakeholder observer and reported that 2-methyl-1,2-benzisothiazol-3(2*H*)-one (MBIT) is a biocide used widely as a preservative in Product Types 6 (In-can preservatives) and 13 (Metal working fluid preservatives) according to Annex V of Regulation (EU) No 528/2012. The substance has no existing entry in Annex VI of the CLP Regulation. Therefore, in accordance with Article 36(2) of CLP, all hazard classes need to be assessed. The legal deadline for the adoption of an opinion is 7 November 2018.

The DS (PL) proposed classification as Acute Tox. 3; H301 (ATE = 175 mg/kg bw), Acute Tox. 3; H311 (ATE = 300 mg/kg bw), Acute Tox. 3; H331 (ATE = 0.5 mg/L (dusts or mists)), Skin

Corr. 1B; H314, Eye Dam. 1; H318, Skin Sens. 1A; H317 (with a GCL = 0.1 %), Aquatic Acute 1; H400 (M=1), and Aquatic Chronic 2; H411.

RAC agreed to no classification of MBIT for the following hazard classes via the fast-track procedure, with scrutiny but without plenary debate: physical hazards, respiratory sensitisation (no available data), germ cell mutagenicity, carcinogenicity (no available data), toxicity to reproduction, STOT RE and aspiration hazard (no available data).

RAC discussed acute toxicity (oral, dermal, inhalation), skin corrosion, respiratory irritation and STOT SE, eye damage, skin sensitisation, and aquatic toxicity hazard classes at the plenary.

RAC concurred with the views of the RAC rapporteur to classify the substance as Acute Tox. 3; H301 (ATE = 175 mg/kg bw) and Acute Tox. 4; H312 (ATE = 1 100 mg/kg bw) but not to classify the substance for acute toxicity via inhalation due to lack of reliable data. RAC also agreed to classify MBIT as Skin Corr. 1C; H314, Eye Dam. 1; H318, Aquatic Acute 1; H400 (M = 1) and Aquatic Chronic 2; H411.

During the discussion on a weight of evidence evaluation of the relevant *in vivo* studies for respiratory tract irritation after inhalation, the Rapporteurs proposed to classify the substance as STOT SE 3; H335 (may cause respiratory irritation) or to label it instead with the supplemental hazard information EUH071 (corrosive to the respiratory tract). The rapporteurs informed that in the CLH dossier, the DS noted that there were no clinical signs or findings in the gross necropsy indicating respiratory irritation. Five RAC members acknowledged that labelling with EUH071 in this case would be more appropriate as other substances of a similar chemical structure (MIT and CMIT/MIT (3:1)) are also classified with EUH071 in the CLP Regulation. One member noted that the *in vivo* observed effects are not typical for STOT SE (respiratory irritation) hazards. The Committee agreed to add the supplemental hazard information as EUH071.

RAC concurred with the DS that MBIT is a strong sensitiser based on the results of a mouse Local Lymph Node Assay (LLNA) and that it should be classified as Skin Sens. 1A. RAC however did not agree with the DS that a Generic Concentration Limit (GCL) of 1 000 ppm (0.1 % w/w) should be applied as this concentration would not be sufficiently low to prevent further induction of sensitisation in the human population. In line with the CLP Regulation, RAC agreed that an Specific Concentration Limit (SCL) for MBIT needed to be set on the basis of testing of the substance (CLP Annex I, 3.4.3.1.1). During the discussion, the rapporteur explained that a substantial number of workers and consumers have already been sensitised to similar substances e.g. MIT or BIT. From the data presented, RAC concurred with the views of the Rapporteur that MBIT is similarly potent as MIT, based on a comparison of EC3 values from LLNA studies (0.69 vs. 0.86 %, respectively). Therefore, an SCL of 15 ppm, which is in line with the SCL previously set for MIT, was proposed. One RAC member, although agreeing with the rapporteurs that a SCL needs to be set, questioned whether it should be set as low as 15 ppm. He argued that based on the available data it should be at least 50 ppm, i.e. one tenth of the concentration causing sensitisation in humans. The rapporteur emphasised the results of the Human Repeated Insult Patch Test (HRIPT) study (Davies *et al*. 1975) which provided evidence that MBIT is a potent sensitiser in humans. At 500 ppm (0.05 %), 9/45 (20 %) volunteers were sensitised, although several details describing how the study was performed are lacking. In addition, the rapporteur reported that the similar substance BIT which appeared to be a less potent sensitiser than MBIT with an SCL of 500 ppm (0.05%) in the CLP Regulation, has caused allergic contact dermatitis in workers at an average concentration of 0.002% (20 ppm) (Aalto-Korte *et al*., 2006; Aalto-Korte *et al*. 2007). The rapporteur also raised the issue of possible cross reactivity between isothiazolinones that has been recently reported (Schwensen *et al*. 2017). This means that already sensitised individuals to isothiazolinones may react to other isothiazolinones if exposed to sufficient concentrations. One RAC member also suggested that

in order to warn consumers already sensitised to isothiazolones, using the supplemental labelling element EUH208 may be considered by RAC. It was not considered necessary as for sensitising substances with specific concentration limit lower than 0.1 %, the concentration limit for elicitation should be set at one tenth of the specific concentration limit i.e. 1.5 ppm (CLP Annex I, 3.4.3.3.2, Note 1 to Table 3.4.6).

The expert accompanying the Cefic stakeholder observer questioned the approach taken by the RAC rapporteurs in setting the SCL value. She accepted that skin sensitisation is an intrinsic property of the substance and reference to the other substances is not appropriate since data on MBIT do exist. In her intervention, she favoured either to use the GCL as proposed by the DS, or to set SCL based on the available data on MBIT.

RAC concluded that it was appropriate on the basis of the available data to set an SCL value for MBIT at 15 ppm (0.0015 % w/w).

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

10) butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime

Butanone oxime by virtue of its anti-skinning properties is used in formulations of alkyd paints, primers, varnishes and coatings both for workers and consumers. The substance has an existing entry in Annex VI of the CLP Regulation where it is classified as Carc. 2; H351, Acute Tox. 4*; H312, Skin Sens. 1; H317, and Eye Dam. 1; H318. The legal deadline for the adoption of an opinion is 17 November 2018.

The DS (DE) proposed to retain classification Eye Dam. 1; H318, to add Acute Tox. 3; H301 (ATE = 100 mg/kg) and STOT SE 3; H336, to modify Carc. 1B; H350, Acute Tox. 4; H312 (ATE = 1 848 mg/kg), and Skin Sens. 1B; H317.

RAC agreed on the following hazard classes via the fast-track procedure, with scrutiny but without plenary debate: Acute Tox. 4; H312, ATE dermal = 1100 mg/kg bw, Eye Dam. 1; H318, Skin Irrit. 2; H315 and no classification for acute toxicity (inhalation route of exposure), mutagenicity, and toxicity to reproduction.

RAC discussed acute toxicity (oral), skin sensitisation, carcinogenicity, STOT SE and STOT RE.

RAC concurred with the views of the rapporteurs to classify the substance as Acute Tox. 3; H301 (ATE = 100 mg/kg bw), Skin Sens. 1; H317, Carc. 1B; H350 (with no SCL) and STOT SE 3; H336 (narcotic effects).

During the discussion on STOT SE for respiratory irritation the rapporteurs explained that as butanone oxime is irritating to the eyes, it may also be irritating to the respiratory tract. Three out of five available inhalation studies report degeneration of the olfactory epithelium lining (up to 10 % of epithelium) in the dorsal meatus (turbinate sections 2-4). Several RAC members spoke in favour of classification of the substance as STOT SE 1 H370 (upper respiratory tract) noting that the observed effects are not due to irritation but are systemic effects. RAC agreed to this proposal.

During the discussion on blood system effects the rapporteurs presented the following observations:

- Premature deaths in anaemic animals that are not limited to the first three days of treatment in the repeated dose study. (Mortality during days 0-3 may be relevant for acute toxicity.)
- Clinical signs of hypoxia, e.g. cyanosis, dyspnoea, pallor in anaemic animals that are not limited to the first three days of treatment in the repeated dose study.

- Reduction in functional Hb at ≥ 20 % due to a combination of Hb reduction and MetHb increase.
- Marked increase of haemosiderosis in the spleen, liver or kidney in combination with other changes indicating significant haemolytic anaemia (e.g. a reduction in Hb at ≥ 10 %) in a 28-day study.
- Significant increase in haemosiderosis in the spleen, liver or kidney in combination with microscopic effects like necrosis, fibrosis or cirrhosis.

RAC agreed that the totality of the observed effects (consistency across the studies and the dose response) on the haematopoietic system is sufficient to classify the substance in category 2. RAC agreed to classify the substance as STOT RE 2; H373 (blood system).

Since the STOT RE hazard class was not open for commenting during the public consultation, in order to complete the process transparently, ECHA will launch a short targeted public consultation on this endpoint after the meeting. Taking the outcome, the opinion will be adopted via written procedure or tabled for the adoption at RAC-46 in September 2018.

11) trimethoxyvinylsilane; trimethoxy(vinyl)silane

The Chairman welcomed the expert accompanying the Cefic stakeholder observer and reported that trimethoxyvinylsilane is an industrial chemical used in polymers, adhesives and sealants, coating products, non-metal-surface treatment products and laboratory chemicals. The substance has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 14 November 2018.

The DS (SE) proposed to classify trimethoxyvinylsilane for skin sensitisation (Skin. Sens. 1B; H317).

The skin sensitisation potential of trimethoxyvinylsilane has been assessed in five studies (2 Buehler assays and 3 Guinea Pig Maximisation Tests), performed with four different test materials available on the market and containing various amount of trimethoxyvinylsilane. The Committee supported the proposed classification based on the positive Buhler test and considered that the tests with negative results were not sufficient to outweigh the positive result due to the lower doses used in those tests and the potential for hydrolysis of the substance during the sample preparation that could further decrease the concentration of available trimethoxyvinylsilane. In the discussion, the expert accompanying the Cefic stakeholder observer pointed out that with each type of vehicle used a small part of the substance hydrolyses, thus none of the studies should be invalidated.

To the comment that there is an absence of sensitisation cases amongst industry workers, RAC considered that there are not enough details (e.g. number of workers, exposure levels, use of PPE, etc.) to allow for an appropriate comparison that could potentially outweigh the evidence from the animal data.

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

12) tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane

Tris(2-methoxyethoxy)vinylsilane is an industrial chemical used as a crosslinking, binding and coupling agent and as a surface modifier; it is also used as a monomer in the production of silicone polymers. The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 30 November 2018.

RAC agreed via fast-track to the proposal by Austria to classify the substance for toxicity to reproduction into category 1B; H360FD.

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

13) azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate

Azoxystrobin (ISO) is an active substance used in plant protection products and biocidal products as a fungicide and is manufactured in the EU. The legal deadline for the adoption of an opinion is 5 January 2019.

The substance has an existing entry in Annex VI to the CLP Regulation for Acute Tox 3*; H331 (minimum classification), Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

Via fast-tracking RAC agreed to the proposal by the United Kingdom to remove the asterisk from acute inhalation toxicity (Acute Tox. 3; H331), to add an inhalation acute toxicity estimate (ATE=0.7 mg/L) and an M-factor of 10 for both Aquatic Acute and Aquatic Chronic classifications.

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

14) bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme

The Chairman reported that tetraglyme is an aprotic colourless organic solvent with high chemical and thermal stability and is used in e.g. paints and coatings as well as in separation processes and high temperature reactions. It is a homologue of diglyme, which latter is currently listed on Annex XIV of REACH and subject to Authorisation. The substance has no existing entry in Annex VI to the CLP Regulation. The legal deadline for the adoption of an opinion is 25 January 2019.

The DS (Austria) proposed to classify the substance for toxicity to reproduction (Repr. 1B; H360, without sub-categorisation) based on read-across approach to other 'glymes', e.g. diglyme as well as their assumed common metabolites, and supported by adverse effects on fertility and development of tetraglyme in two dose range finding studies and one repeated dose toxicity study.

The Rapporteur concurred with the DS proposal for classification as Cat 1B, but in addition proposed to subcategorise for the effects on development, while for the effects on fertility, the rapporteur provided two options (Cat. 1B or Cat. 2 (F or f)).

RAC evaluated fertility effects based on data for tetraglyme itself (i.e. a dose-range finding study (OECD 421), a combined repeated dose toxicity study with reproductive/developmental toxicity screening (OECD 422, GLP), as well as a 28-day repeated dose study (OECD 407)), supported by read-across data from the other glymes (mono-, di-, triglyme) and their metabolites (2-ME, MAA).

The three studies show adverse effects of tetraglyme on fertility and sexual function in rats without any significant general toxicity. More specifically, tetraglyme showed significant effects on the male reproductive organs (decreased testis and epididymis weight, degradation of germinal epithelium, single cell necrosis, decreased sperm counts) at the limit dose (1 000 mg/kg bw/day) and effects at 300 and 500 mg/kg bw/day (degeneration of seminiferous tubular epithelium, slight or moderate hypospermia, decreased number of corpora lutea and implantations).

RAC concluded that based on the aforementioned effects, supported by likely metabolism of tetraglyme to MAA and similar toxicity by other glymes, the classification for effects on fertility in Cat. 1B (F) is warranted.

RAC evaluated the effects on development based on data for tetraglyme itself (i.e. dose-range finding study (OECD 421), combined repeated dose toxicity study with reproductive/ developmental toxicity screening (OECD 422, GLP), as well as a dose-range finding study (OECD 414)), supported by read-across data from the other glymes (mono-, di-, triglyme) and their metabolites (2-ME, MAA).

The three studies show adverse effects of tetraglyme on development in rats without any significant general toxicity (increase of post-implantation loss at 250, 500 and 1 000 mg/kg bw/day).

RAC concluded that based on the overall significant effects on foetal development, supported by likely metabolism of tetraglyme to MAA and similar toxicity by other glymes, the classification for effects on development in Cat. 1B (D) is warranted.

In conclusion, RAC agreed on the opinion to classify tetraglyme as Repr. 1B; H360FD.

RAC agreed to not set specific concentration limits, as most ED_{10} values remained within the range appropriate to the generic concentration limits. RAC adopted the opinion by consensus. The Chairman thanked the Rapporteur for the presentation of the arguments and the Committee Members for their comments.

15) nitric acid …%

This dossier was on the agenda of the RAC for the second time. The substance originally had a harmonised classification and labelling entry in Annex VI of the CLP Regulation (Ox. Liq. 3; H272 and Skin Corr. 1A; H314 [Ox. Liq. 3; H272 C ≥ 65%, Skin Corr. 1A; H314 C ≥ 20%, Skin Corr. 1B; H314 5% ≤ C < 20%]).

In 2012 the DS (DE) submitted a proposal to ECHA to supplement the current classification of nitric acid by adding a new classification as Acute Tox. 1; H330 (based on two studies using highly concentrated nitric acid) with the supplemental hazard information EUH071 (Corrosive to the respiratory tract) and a change of the current classification as Ox. Liq. 3 to Ox. Liq. 2; H272 for concentrated nitric acid (C ≥ 99%). RAC, at its 24th meeting agreed to this proposal, which was subsequently included in the 7th Adaptation To Progress (ATP) to the CLP Regulation [Ox. Liq. 2; H272, Skin Corr. 1A; H314, EUH071, Ox. Liq. 2; H272: C ≥ 99%, Ox. Liq. 3; H272: 65% ≤ C < 99%, Skin Corr. 1A; H314: C ≥ 20 %, Skin Corr. 1B; H314: 5 % ≤ C < 20 %, Note B], except for Acute Tox. 1. This classification was postponed, after Industry commented that there is a non-linear relationship between the nitric acid concentration and toxicity, with large consequences for the classification of nitric acid mixtures (containing < 70%) using the additivity formula.

In July 2015, the final report of an acute inhalation toxicity study in Wistar rats (4-hour vapour exposure, nose-only) with nitric acid 70% was submitted by Industry, which is the basis for the current CLH proposal by the DS.

Based on this data the dossier submitter proposed to split the existing entry on "nitric acid …%" into the two following entries:

(1) "nitric acid …% [C > 70%]" and

(2) "nitric acid …% [C ≤ 70%]".

While maintaining the Committee's previous agreement for > 70% nitric acid (Acute Tox. 1; H330), it was proposed to classify ≤ 70% nitric acid as Acute Tox. 3; H331, with an ATE of 2.1

mg/L/4h, and with the additional labelling EUH071. RAC agreed on the additional labelling EUH071 at its 44th meeting. The study report on the acute inhalation study was discussed at RAC-44 and it was questioned whether rats that "lost the nose tip" should have been humanely killed. If so, it would have consequences for the LC_{50} and the classification.

In April 2018, the owner of the study provided a letter further explaining the results and their interpretation of the study. According to this, exposure to the test substance caused superficial, small-area tissue damage at the very tip of the noses of the four animals, which is indicative of the known corrosivity of nitric acid. The consequence of this tissue damage was the formation of a scurf of 2 to 3 mm in diameter within one day after exposure, which fell off at the end of the observation period, disclosing young healthy skin underneath. The wording "*loss of the nose tip*" was chosen to describe this shedding of a piece of dead skin, i.e., the scurf, and this is considered a normal step in successful wound healing. The expert stated that the observed clinical signs and histopathological findings are in line with the conclusion that the 'lost nose tips' represented shedding of superficial necrotic tissue towards the end of the wound healing process. The study owner realised, however, that the wording 'loss of the nose tip' is misleading and will amend the study report to clarify the effect.

During the plenary debate an expert accompanying an observer from the industry stakeholder organisation stated that the industry takes the criticism of the study very seriously. The expert was of the opinion that the acute toxicity inhalation test was performed in full compliance with OECD guidance document No 19 "Guidance document on the recognition, assessment, and use of clinical signs as humane endpoints for experimental animals used in safety evaluation." The amended study report will be sent to DS and RAC.

RAC concluded that the corrosion of the nose tip ('loss of nose tip' now revised into 'shedding of scurf') is not reported in sufficient detail for an independent assessment of the severity (e.g. depth of corrosion). However, although the corrosion seems severe and painful, there is no evidence to contradict the new explanation by the study director. Hence, the original LC_{50} value was taken into account.

In conclusion, RAC confirmed classification of nitric acid … % as Acute Tox. 1; H330 (C > 70 %) and added the new classification (C ≤ 70%) as Acute Tox. 3; H331 (ATE = 2.65 mg/L/4h).

The Chairman thanked the Rapporteur for the presentation of the arguments, the DS for clarifying the study description and the Committee Members for their comments.

16) Granulated copper (ENV hazards only)

The Chairman welcomed a representative of the European Copper Institute as the expert accompanying the Eurometaux stakeholder observer, a representative of the Copper Compounds Consortium and Arch Timber Protection who was attending as the expert accompanying the CEFIC stakeholder observer and the dossier submitter's representative (FR) attending the meeting in person.

The Chairman reported that the part of the CLH dossier related to environmental hazards was tabled for a second RAC plenary discussion. He reminded the Committee that they had agreed on the classification of the health hazards at RAC 44. The legal deadline for the adoption of an opinion is 15 August 2018.

The Rapporteur introduced the case by re-summarising the proposal from the DS (FR) and presenting the explanatory information that had been submitted by the DS since the previous plenary (e.g. long-term *Ceriodaphnia* toxicity data, and a justification for the loading rate extrapolation in the transformation/dissolution protocol (T/Dp) study).

The Commission observer asked for clarification concerning the normalisation of the aquatic toxicity data for DOC, whether the test item represents the smallest particle size placed on the market and for the possibility to cover granulated copper under the already existing Annex VI entry for copper flakes.

The Chairman clarified that the proposal submitted by FR is for an active substance approved under the Biocidal Product Regulation (BPR) where the active substance is precisely defined and there is no overlap in size and surface area between granulated copper and another existing entry for copper flakes. The industry expert confirmed that the classification proposal covers granulated copper which is a form of copper metal defined by its particle size and specific surface area as specified in the CLH dossier. It was further clarified that only one source and one grade of granulated copper approved as an active substance for product type 8 (PT8) under the BPR and that all studies conducted on granulated copper used the same source and grade. The RAC Chairman asked for confirmation in writing which was received by ECHA on 8 June 2018 following the RAC 45 discussions.

With regards to the request for clarification on the DOC normalisation, the Rapporteur explained that a certain level of standardisation is considered appropriate when evaluating large datasets for harmonised classification purposes. As an example he referred to the lipid normalisation conducted for BCF tests and stressed that although it made no difference for granulated copper, it should be left open for future metal cases. The industry expert agreed with the Rapporteur that normalisation or bioavailability correction are scientifically justified.

Dissolved copper concentrations reached a maximum of 3.4 µg/L in the T/Dp study (7 days, pH 6 - 8 at a loading rate of 1 mg/L), which does not exceed the acute ecotoxicological reference values (ERVs) (≥ 11-12 µg/L). RAC therefore concluded that no classification for acute aquatic hazard was warranted, in agreement with the DS proposal. However, as dissolved copper concentrations in the T/Dp study exceeded the chronic ERVs of 4-13 µg/L at a loading rate of 1 mg/L (13 and 8.6 µg/L after 28 days at pH 6 and 7, respectively) but not 0.1 mg/L (maximum of 1.3 µg/L, extrapolated), RAC agreed with the DS that classification as Aquatic Chronic 2 was warranted. The Commission observer asked to add a note which clearly provides a definition of the Annex VI entry.

RAC adopted the opinion by consensus and included the note to the entry which defines the size of granules.

9. Restrictions

9.2 Restriction Annex XV dossiers

a) Opinion development

1) Substances used in tattoo inks and permanent make-up

The Chairman welcomed the representatives of the Dossier Submitter (from Denmark, Norway and ECHA). The restriction proposal was submitted by ECHA together with Denmark, Italy and Norway on 6 October 2017. The proposal aims to restrict the intentional use of certain substances in tattoo inks or to impose concentration limits for selected substances. These substances include those with harmonised classifications as carcinogenic, mutagenic, reprotoxic, skin sensitising/corrosive/irritant, eye damaging/irritant as well as other substances prohibited in cosmetic products (under the Cosmetic Products Regulation, (EC) 1223/2009) and selected impurities. A number of colourants, which do not currently have alternatives or where

information is insufficient to demonstrate risk, are exempted. Two restriction options (RO1 and RO2) with the same scope are proposed. They differ in terms of the proposed concentration limits and how the links with the Cosmetic Products Regulation annexes are managed.

The Rapporteurs then presented the second draft opinion. They outlined the hazard and risk evaluation for substances not discussed at RAC-44 and presented their proposals for concentration limits for most groups. Following the presentation, RAC members exchanged views regarding the different concentration limits. The discussion continued in an evening ad-hoc group, organised for the rapporteurs, interested RAC members and the Secretariat, with the aim to facilitate finalisation of this part of the draft opinion. During the second discussion in plenary, a presentation was provided by the Rapporteurs, reporting back on the issues discussed by the ad-hoc group and seeking agreement from RAC.

RAC agreed that substances with CMR, skin sensitising, irritant/corrosive properties and substances prohibited under Cosmetics Products Regulation (CPR) (Annex II and Annex IV, column g) should not be present in tattoo inks. For the purpose of ensuring the practicality and monitorability of the proposed restriction, sufficiently low concentration limits (CLs) should be derived for these substance groups.

Furthermore, RAC supported the proposed concentration limits for the following substances:

- a practical limit[2] of 0.001 % w/w for skin sensitisers;
- a risk based limit of 10.9 % w/w for methanol (MeOH, using 8 mg/kg bw/d (DNEL)/ 1.7 mg/kg bw);
- a risk based limit of 0.00003 % w/w for primary aromatic amines (PAAs), recognising that there may be practical reasons to set a higher limit;
- a practical limit of 0.1 % w/w for azo colourants listed in Supplementary Table B in the Background Document (BD) to discourage use and
- a limit of 0.00005 % w/w for individual Polyaromatic Hydrocarbons (PAH) with a harmonised classification as carcinogenic or mutagenic.
- to include two additional primary aromatic amines (PAAs) in the scope of the restriction (6-amino-2-ethoxynaphthaline and 2,4-xylidine from Table 1 of the Council of Europe ResAP(2008)1) and final;
- confirmed that risk of effects from skin irritants cannot be excluded.

In addition, RAC recommended that the rapporteurs consider setting a concentration limit for reproduction toxicity Cat 1A and 1B substances on the basis of the lowest derived DNEL for the substances found in tattoo inks (i.e., for DBP) using an additional factor of 10 to account for: mixture /cumulative effects and remaining uncertainties, including ED effects and the possibility that more potent repro substances may be in tattoo inks.

It was also discussed whether the limits derived for some of the specific groups of carcinogenic and mutagenic substances (e.g., PAHs, PAAs) could also be considered for use as a practical limit for the carcinogenic and mutagenic substances as a whole. This limit or the limit for skin sensitisers could also be considered for CPR Annex II and Annex IV column g, as C or M or SS are the largest substance groups included in Annex II.

As an additional action point, it was proposed that the Secretariat will arrange an ad hoc WebEx with interested RAC members to discuss the concentration limits for the remaining substances in the scope of the proposed restriction ahead of the next RAC meeting.

[2] A practical limit is one that takes into account a concentration limit based on risk (i.e. the CLP classification limit) but also takes into account other issues such as uncertainties, detection limits of identification limits, etc,

The Rapporteurs were requested to prepare the third draft opinion, taking into account RAC-45 discussions and the results of the public consultation, by the beginning of August 2018. Finally, the Chairman restated his observation from RAC-44, that due to the complexity of this restriction proposal, the Committee might need to take more time to address all aspects than normally allowed in the process timelines.

2) C9-C14 PFCAs, their salts and related substances

The Chairman welcomed the Dossier Submitter's representatives from Germany and Sweden and the SEAC Rapporteur (following via WebEx). He informed the participants that the restriction dossier proposes to restrict the use, placing on the market and import of C9-C14 PFCAs, on their own or in a mixture or in an article or parts therein in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. The Rapporteurs had developed the second draft opinion on this dossier, taking into account the discussion held at RAC-44, which was made available for written consultation prior to RAC-45 and two comments were received from RAC Members. The Chairman recalled that as agreed at the previous RAC-44 plenary, the Committee at this plenary meeting was invited to take note of the status update on the opinion development on this restriction dossier.

The Rapporteurs then presented the developments since RAC-44 plenary meeting. They explained that the entry text of the restriction proposal has been updated compared to the first draft opinion and will be discussed by RAC at the next RAC-46 plenary. Furthermore, the Rapporteurs presented the additional derogation requests received in the ongoing public consultation – these will also be discussed in detail at the next RAC plenary, after the public consultation finishes on 20 June.

The Rapporteurs were asked to prepare the third draft opinion, taking into account the results of the public consultation and comments by RAC Members on the second draft opinion, by the beginning of August 2018.

10. Authorisation

10.1 General authorisations issues

a) Update on incoming/future applications

The Secretariat informed the Committee that two new applications for authorisation were received during the May 2018 submission window. One of the received applications for authorisation concerns use of chromium trioxide in functional chrome plating of engine valves for automotive applications. The other application for authorisation concerns industrial formulation of a chromium trioxide solution below 0.1 % w/w concentration for the passivation of copper foil used in the manufacture of Lithium Ion Batteries (LiB) for motorised vehicles. Key issues in both new applications for authorisation will be discussed at RAC-46 plenary meeting in September 2018.

b) Updated AfA opinion templates

Following a presentation of the updated AfA opinion templates at the RAC-44 plenary meeting in February/March 2018 the RAC consultation had been held in April 2018. Six RAC members provided their comments on the new template, and the formats were updated accordingly. The draft opinion on the application for authorisation Diglyme_Omnichem (agenda point 10.2.b.3) was created in the new format.

10.2 Authorisation applications

a) Discussion on key issues

1. No discussion on key issues

b) Agreement on Draft Opinions

1. PCO_IP (2 uses)

This is a relatively broad scope application for the two uses of pentazinc chromate octahydroxide in formulation of mixtures (Use 1) and in stoved epoxy primer for corrosion protection of aircraft engine components in aerospace and aero-derivative applications (Use 2).

The annual volume used at < 100 kg/year for each of the 2 uses is very small. It is used in < 10 sites (Use 1) and < 100 sites (Use 2). The applicant requested a review period of 12 years for each use. The trialogue meeting took place in March 2018. The RAC Rapporteurs considered the applicant's responses in drafting the opinions.

Regarding Use 2 the rapporteurs noted that Cr(VI)-containing coating material is used for corrosion protection in engine components. The concentration of pentazinc chromate octahydroxide in coating material is less than 1 % (i.e. Cr(VI) < 0.1 %). Ca. 90 % of the substance in the application is used across the three sites belonging to the same downstream user in UK. The remaining 10 % are distributed to suppliers across the rest of Europe (mainly touch-up during maintenance and repair activities).

Exposure estimates are based on qualitative assessment and modelling, although some supportive measurement data were provided by the applicant. Pentazinc chromate octahydroxide is a non-volatile substance and its dominant health effect is lung cancer due to inhalation. In the exposure assessment the applicant assumed that all the inhalable particles were within the respirable size range.

Regarding paint coating, the rapporteurs explained that the applicant presented three most likely combined exposure estimates, ranging from 0.02 to 0.06 µg/m^3. They relate to the application of the Cr(VI)-containing mixture by paint spraying, by brushing/rolling and by touch-up application. A maximum individual exposure value of 1.0 µg Cr(VI)/m^3 was used by the applicant for risk characterisation. Weighing the evidence as a whole, RAC considered that the proposed exposure estimate presented by the applicants (1.0 µg Cr(VI)/m^3) is sufficient for risk characterisation and impact assessment.

For humans via the environment, the rapporteurs concluded that indirect exposure estimates made by the applicants are sufficient for risk characterisation and impact assessment.

For Use 2, the rapporteurs recommended to RAC that the risk management measures (RMMs) and operating conditions (OCs) described are appropriate and effective in limiting the risk to workers and the general population, although measured data for all worker contributing scenarios would provide more confidence in the effectiveness of such RMMs/OCs. They proposed additional monitoring arrangements and conditions for the authorisation and for any future review report. They also proposed to give no advice to SEAC regarding a length of the review period.

A representative of the European Commission noted that if RAC concludes that existing RMMs/OCs are appropriate in limiting the risks, the Commission cannot impose conditions in the

authorisation, but only the monitoring arrangements. The Chairman took note but requested further discussion with the Commission and ECHA.

Regarding Use 1 the RAC rapporteurs explained that it consists of typical worker contributing scenarios associated with formulation, e.g. delivery of the raw material, decanting and weighing, transfer to mixing vessels, mixing and grinding, transfer to small containers, maintenance, laboratory analysis (including test spraying) and waste management. Formulation of primer is performed in batches (about 8 batches per year, 0.8 tonnes per batch) over any year. The concentration of the substance in formulated primer is less than 1 % (hence concentration of Cr(VI) < 0.1 %). Exposure assessment is limited to inhalation of the dust and/or aerosols. They noted that the applicant described well the worker contributing scenarios with detailed information of process and RMMs/OCs. Exposure estimates are based on qualitative assessment and modelling. No (supportive) measurement data provided. Highest exposure estimates used for risk assessment is 0.022 µg/m^3. They concluded that exposure-related information provided is sufficient for use in risk assessment. RMMs/OCs described are appropriate and effective in limiting the risk to workers and the general population. They proposed additional monitoring arrangements and conditions for the authorisation and for review report. They also proposed to give no advice to SEAC regarding a length of the review period.

The Committee agreed by consensus on the two draft opinions. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

2. SD_Olwerke

This is the downstream application for authorisation on the single use of sodium dichromate as a corrosion inhibitor in ammonia absorption deep cooling systems, applied for the de-waxing and de-oiling process steps of petroleum raffinate. Up to 0.01 tonne annually of sodium dichromate is used at two sites. The applicant requested a 20-year long review period. A trialogue on the application for authorisation took place in April 2018.

The RAC rapporteurs noted that calculations in the application for authorisation are based exclusively on modelled data and/or default release estimates and that no measured data are available. The RAC rapporteurs considered that the applicant undertook appropriate modelling and that, due to the characteristics of the substance and the OCs and RMMs applied, the exposures estimated by the applicant are acceptable for risk characterisation and impact assessment, and the remaining uncertainties are low. RAC noted that taking meaningful exposure measurements at such low concentrations would be challenging. They also considered that the assessment of indirect exposure to man via the environment using the default assumptions in the ART model are likely to overestimate exposure. Therefore, they concluded that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. No additional conditions or monitoring arrangements were proposed neither for the authorisation nor for the review report. The RAC rapporteurs gave no advice to SEAC regarding a length of the review period. The Committee concurred with the conclusions by the RAC rapporteurs.
The RAC agreed by consensus on the draft opinion on the application for authorisation. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

3. Diglyme_Omnichem

This is the downstream application for authorisation on the single use of Bis(2-methoxyethyl) ether (diglyme) as a solvent for the synthesis of the anti-HIV active pharmaceutical ingredient (API) dapivirine. The application covers one site with a pilot installation and a commercial installation (the latter used only once so far, but is foreseen to be predominantly used if authorisation is granted). The tonnage concerned by the use applied for is 1-10 t/y and the requested review period is 7 years. 5 workers are exposed directly.

For inhalation exposure assessment, the applicant used a combination of air monitoring data and modelling data based on Advanced REACH Tool. Estimation of dermal exposure by the applicant was based on modelling using ECETOC TRA v3 and RISKofDERM. On the basis of the exposure values taken forward by RAC for risk characterisation, the highest calculated RCR for workers was 0.6 for shift-long exposure and combined exposure routes; the main contribution has been from dermal exposure. The Risk Characterisation Ratio calculated for the general population exposed via the environment on local and regional scale for combined routes (inhalation and oral) were 1.13×10^{-5} and 5.57×10^{-8} respectively. Therefore the rapporteur concluded that adequate control has been demonstrated both for workers and the general population exposed via the environment. The Rapporteur proposed monitoring arrangements for the authorisation and recommendations for the review report, in order to address the uncertainty in the exposure assessment for the commercial installation and ensure implementation of the applicant's plans for improvement of RMMs.
RAC discussed why in WCS6 (Discharge of centrifuge) there is need to use a full mask and whether hierarchy of control principles has been followed. The Rapporteur and the ECHA Secretariat clarified that the use of full mask in WCS6 is required in the pilot installation only. The applicant, having recognized that the highest inhalation exposure of workers is associated with WCS6, has automated the respective process in the commercial installation. RAC however agreed to remove from the opinion conclusion the statement that RMMs implemented follow the principles of hierarchy of controls.
RAC agreed by consensus on the draft opinion on the application for authorisation. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

4. DBP_AVX

This is a downstream application for authorisation on a single industrial use of dibutyl phthalate in the manufacture of ceramic sheets for the production of multi-layer ceramic capacitors. The application covers one site with a tonnage of 1-10 t/y and the applicant requested a review period of 7 years.Ca. 100 workers are potentially exposed.

The exposure assessment is mostly based on modelling. For inhalation and dermal exposure of workers the ECETOC TRA Worker v3 model is used and EUSES 2.1.2 (in Chesar) for indirect exposure of human via the environment. Modelling was supplemented by personal and static air monitoring data for workers. The highest calculated combined RCR for workers is 0.736. The RCR calculated for local and regional scale for combined routes (inhalation and oral) are 0.027 and < 0.01 respectively. Therefore, the rapporteurs proposed to conclude that adequate control has been demonstrated both for workers and the general population exposed via the environment with some uncertainties. The Rapporteurs proposed additional conditions and monitoring arrangements for the authorisation and conditions and monitoring arrangements for review reports.

RAC briefly discussed the impact of 12 h working shift with 1h break on the risk characterisation because this is a different situation than the basis on which the DNELs for workers are derived. RAC acknowledged that the applicant clarified that the working week is in average 42 hours and

provided calculations (combined exposure and RCRs) with the measured data (personal sampling) for which a recalculation to an 11 hours TWA was done. RAC agreed that the RCRs for the individual and combined scenarios stay anyway below 1.
RAC agreed by consensus on the draft opinion on the application for authorisation. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

c) Adoption of final opinions

No final opinions on the applications for authorisation had been discussed at this plenary meeting.

10.3 Review reports

a) Discussion on key issues

No key issues in the review reports had been discussed at this plenary meeting.

b) Agreement on draft opinions

1. **RR1_DEHP_VINYLOOP (2 uses)**
2. **RR1_DEHP_PP (2 uses)**

An authorisation is a time limited Commission decision; a short review period is 4 years, 7 years is normal and a long review period is 12 years. These are the first two review reports received by ECHA in the Authorisation process. They were submitted separately by two of the three authorisation holders. Both companies are Italian recycling companies that process waste into flexible PVC recyclate.

Use 1 of the review report covers formulation of recycled soft PVC containing DEHP in compounds and dry-blends. The broad scope of Use 2 in the initial application is in both review reports reduced to three article groups. The authorisation holders state that the three article groups are not in the scope of ECHA's restriction proposal on four phthalates and the RoHS restriction. Use 2 covers industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce the following PVC articles: (1) articles used outside of the interior space in applications in the field of construction, civil engineering, garden features such as ponds and roofing, agriculture (including horticulture) and industrials workplaces without potential for mouthing or prolonged contact with human skin or any contact with mucous membranes; (2) articles used in interior space in industrial and agricultural workplaces; or (3) footwear used in professional, industrial and/or agricultural workplaces.

The maximum concentration of DEHP in PVC recyclate decreased from < 20 % in the initial application for authorisation to < 5 %. The annual volume of 1 000-4 000 tonnes in the initial application is reduced to 50-500 tonnes (Vinyloop) and 10-100 tonnes (Plastic Planet). The review reports suggest that the use of the DEHP-containing recyclate may take place at ≤ 20 sites (1-10 sites per authorisation holder) and that about 200 workers are exposed. Vinyloop Ferrara SpA requested a 7-year review period, whereas Plastic Planet srl requested 12 years.

The rapporteurs concluded that adequate control was demonstrated by both authorisation holders and for both uses.

There are some uncertainties in the individual exposure estimates for workers, but when the estimates based on air measurements, post-shift biomonitoring and modelling are assessed together, confidence in the worker exposure estimates is strengthened. The most important uncertainty relates to the exposure estimate for calendering (WCS 5 of Use 2). Conditions and monitoring arrangements were proposed by the rapporteurs to address these uncertainties in the worker exposure assessment, including monitoring of worker exposure.

Regarding exposure of humans via the environment the rapporteurs were of the view that the methodology used is suitable and the information provided is sufficient for risk assessment. However, since limited measurement data for releases to air was presented, the authorisation holders resorted to default release factors to air. The overall default release factor to air that is used in the assessment for Use 2 could be argued to be 0.7 % for the whole process for mixing and calendering in small facilities, which is an order of magnitude higher than 0.05 % used by the authorisation holders. Due to the uncertainty to the release factor to air, conditions regarding release to the environment are recommended in the draft opinions on Use 2.

RAC members supported the conclusions by the rapporteurs. During the discussion, the Committee members examined in detail the conditions and monitoring arrangements proposed by the rapporteurs and agreed on their revised wording. RAC agreed to give no advice to SEAC on the length of the review period.

RAC agreed by consensus on the four draft opinions on the two review reports. The Chairman thanked the Rapporteurs for the presentation of the arguments and the Committee Members for their comments.

11. AOB

a) RAC consultations – efficiency in administration

The RAC chairman briefly summarised current practice when providing comments via the S-CIRCABC Newsgroups, its consequences to the efficiency of the opinion making part of all processes and he outlines some potential for improvement. When comments are submitted in track changed documents during RAC consultations, these have to be separated into substantial and editorial by ECHA and then the former are extracted manually one by one into an Opinion Response to Comment (ORCOM) Document.

ECHA's preference is therefore that members make all of their substantive comments in a separate file which can then be more easily and accurately combined into an ORCOM document. Editorial comments provided in track-changed documents are always welcomed but in future would be treated as purely editorial by the Secretariat.

He thanked the members for their co-operation and noted that the Secretariat would return to this topic as the INTERACT collaboration portal developed.

b) Adoption of the RAC note on reference dose-response relationship for the carcinogenicity of pitch, coal tar, high temperature (CTPHT) and on PBT and vPvB properties

Following the agreement at RAC-43 in November 2017, the Secretariat had revised the RAC note on reference dose-response relationships for the carcinogenicity of pitch, coal tar, high temperature (CTPHT) and on PBT and vPvB properties. This took account of the discussion at the plenary meeting and comments received during the following RAC consultation in March 2018. Since the final version of the RAC note was substantially different from the version agreed

in RAC-43 the Secretariat was seeking for the adoption of the final version of the RAC note on CTPHT via written procedure.

The written procedure for the adoption of the note was launched on 18 May 2018. Since the number of responses received from the RAC members during by the deadline was insufficient to adopt the RAC note, the Secretariat requested the RAC members to adopt the RAC note at this plenary meeting.

The Committee then adopted the RAC note by consensus.

8 June 2018

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 45 4 – 8 June 2018

(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/45/2018**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-45 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests **SECR** presented the document.	
5. Report from other ECHA bodies and activities	
a) Report on RAC 44 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/45/2018/01.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes	
6. Requests under Article 77 (3)(c)	
1) CT_Wesco (formerly Haas): chemical conversion and slurry coating application, re-consideration of a proposed authorisation condition. The rapporteurs presented the opinion of RAC that responds to the request under Art. 77(3)(c), including the annexed amended opinion on the application and its amended justification which aims to replace the opinion of RAC of 30 November 2017.	**Rapporteurs**, together with **SECR,** to make final editorial changes to the adopted RAC opinion. **SECR** to forward the adopted opinion to the Commission and the applicant. **SECR** to publish the adopted opinion on the ECHA website and S-CIRCABC IG.

RAC discussed the opinion. RAC adopted the opinion by consensus.	**SECR** to replace the opinion on the application of RAC of 30 November 2017 with the amended opinion on the application and its amended justification.
2) Proposal on a derogation to the PFOA restriction RAC took note of the new request and the proposed timelines.	**SECR** to launch a public consultation on the proposal in June 2018. **Rapporteur** to develop a draft opinion for the discussion and agreement at RAC-46 plenary meeting.
7. Requests under Article 95 (3)	
-	
8. Harmonised classification and labelling (CLH)	
8.1 General CLH issues	

8.2 CLH dossiers

A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate

- paclobutrazol (ISO): physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, respiratory / skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, aspiration hazard, environmental hazards
- dimethyl disulphide: physical hazards (flammable liquid), acute toxicity (dermal and inhalation routes of exposure), serious eye damage / eye irritation, environmental hazards, aspiration hazard
- 2,2-bis(bromomethyl)propane-1,3-diol: carcinogenicity
- pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc: physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, carcinogenicity, STOT SE
- mecetronium ethyl sulphate [MES]: physical hazards, skin sensitisation, germ cell mutagenicity, STOT SE
- glyoxylic acid … %: skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation
- 2-methyl-1,2-benzisothiazol3(2H)-one;[MBIT]: physical hazards, respiratory sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT RE, aspiration hazard
- butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime: acute toxicity (dermal and inhalation routes of exposure), skin irritation/corrosion, serious eye damage / eye irritation, mutagenicity, toxicity to reproduction
- tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane: germ cell mutagenicity, toxicity to reproduction
- azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate: acute toxicity (inhalation route of exposure), environmental hazards

B. Substances with hazard classes for agreement in plenary session

1. paclobutrazol (ISO)

2. dimethyl disulphide
3. 2,2-bis(bromomethyl)propane-1,3-diol
4. pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc
5. bis(α,α-dimethylbenzyl) peroxide
6. N-(hydroxymethyl)acrylamide (NMA)
7. mecetronium ethyl sulphate [MES]
8. Glyoxylic acid … %
9. 2-Methyl-1,2-benzisothiazol3(2H)-one;[MBIT]
10. butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime
11. trimethoxyvinylsilane; trimethoxy(vinyl)silane
12. tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane
13. azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
14. bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme
15. nitric acid …%
16. Granulated copper (ENV hazards only)

1. paclobutrazol (ISO)

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 2; H361d, Acute Tox. 4; H302 (oral ATE = 490 mg/kg bw), Acute Tox. 4; H332 (inhalation ATE = 3.13 mg/L (dust and mist)), Eye Irrit. 2; H319, Aquatic Acute 1; H400 (M = 10), Aquatic Chronic 1; H410 (M = 10)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

2. dimethyl disulphide

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Flam. Liquid 2; H225, Acute Tox. 3; H301 (oral ATE= =190mg/kg bw), Acute Tox. 3; H331 (inhalation ATE=5mg/L), Eye Irrit. 2; H319, Skin Sens. 1; H317, STOT SE 1; H370 upper respiratory tract (inhalation), STOT SE 3; H336, 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.

3. 2,2-bis(bromomethyl)propane-1,3-diol

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B; H350, Muta. 1B; H340]	**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.
4. pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc	
RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox 3; H301, ATE oral = 221 mg/kg bw, Acute Tox 2; H330, ATE inhalation = 0.14 mg/l, Eye Dam. 1; H318, STOT RE 1, H372, Repr. 1B; H360D] RAC agreed to take into account two new environmental studies on condition that final audited versions are submitted by mid-July 2018 (to be subjected to a short targeted public consultation).	**IND** to submit the final study reports of the two environmental studies that were provided as drafts close to RAC 45 plenary meeting (Hoover 2018, Goudie 2018) (including measured concentration values), fully audited and sanitised from any confidential information so that they can be subjected to a targeted public consultation, by 13 July 2018 at the latest. **SECR** to launch a short targeted PC on the two studies. **Rapporteurs** to reflect the outcome of the targeted PC and revise the draft opinion (environmental part) accordingly. **SECR** to put the revised draft opinion for RAC consultation. **Rapporteurs** to revise the opinion in accordance with the comments from the RAC consultation and to provide it to SECR. **SECR** to launch a written procedure for the adoption of the opinion / table the dossier for the adoption at RAC 46 (September 2018).
5. bis(α,α-dimethylbenzyl) peroxide	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Org. Perox. F; H242, Repr. 1B; H360D, Eye Irrit. 2; H319, Skin Irrit. 2; H315, Aquatic Chronic 2; H411]	**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.

6. N-(hydroxymethyl)acrylamide (NMA)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B; H350, Muta. 1B; H340 and STOT RE 1; H372 (peripheral nervous system)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
7. mecetronium ethyl sulphate [MES]	
RAC agreed to classify MES for human health hazards as indicated in Table 2 below. [Skin Corr. 1; H314, Eye Dam. 1; H318 and EUH071 (corrosive to the respiratory tract)]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **Rapporteur** to finalise the revision of the ENV part of the draft opinion and to provide it to the SECR. **SECR** will table the case for discussion on environmental hazards and adoption at RAC 46.
8. Glyoxylic acid … %	
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, Skin Sens. 1B; H317, note B]	**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.
9. 2-Methyl-1,2-benzisothiazol3(2H)-one; [MBIT]	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3; H301 (ATE = 175 mg/kg bw), Acute Tox. 4; H312 (ATE = 1 100 mg/kg bw), Skin Corr. 1C; H314, Eye Dam. 1; H318, Skin Sens. 1A; H317 (C ≥ 0.0015 %), a supplemental hazard information EUH071 (corrosive to respiratory tract), Aquatic Acute 1; H400 (M = 1), Aquatic Chronic 2; H411]	**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.
10.butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	

RAC agreed the opinion with a proposal for the harmonised classification and labelling as indicated in Table 2 below. [Carc. 1B; H350, Acute Tox. 3; H301 (ATE = 100 mg/kg), Acute Tox. 4; H312 (ATE = 1 100 mg/kg), STOT SE 1; H370 (upper respiratory tract), STOT SE 3; H336, STOT RE 2; H373 (blood system), Skin Sens. 1; H317, Skin Irrit. 2; H315, Eye Dam. 1; H318]	**SECR** to launch a short targeted PC on STOT RE. **Rapporteurs** to reflect the outcome of the targeted PC and revise the draft opinion accordingly. **SECR** to put the revised draft opinion for RAC consultation. **Rapporteurs** to revise the opinion in accordance with the comments from the RAC consultation and to provide it to SECR. **SECR** to launch a written procedure for the adoption of the opinion / table the dossier for the adoption at RAC 46 (September 2018).
11. trimethoxyvinylsilane; trimethoxy(vinyl)silane	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1B; H317]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
12. tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360FD]	**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.
13. azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3; H331, inhalation ATE=0.7 mg/L (dust or mist), Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
14. bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

[Repr. 1B; H360FD]	**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.
15. nitric acid … %	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [To confirm C > 70 % Acute Tox. 1; H330, to add C ≤ 70 % Acute Tox. 3; H331, ATE = 2.65 mg/L/4h ***Agreed at RAC-44:*** A supplemental hazard information EUH071 (corrosive to respiratory tract)]	**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.
16. Granulated copper (ENV hazards only)	
RAC adopted by consensus the part of the opinion on ENV hazards with a proposal for the harmonised classification and labelling as indicated in Table 1 below. Note to the entry: Granulated copper particles are cylindrical with a length greater than 1 mm (range: 0.9 – 6.0 mm; mean: 2.1 mm) and width below 1 mm (range: 0.494 – 0.949 mm; mean: 0.706 mm), and a surface area of 25.6 cm^2/g. [Aquatic Chronic 2; H411]	**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.
9. Restrictions	
9.1 Restriction Annex XV dossiers	
a) Opinion development	
1. Substances used in tattoo inks and permanent make-up The Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed that substances with CMR, skin sensitisers, irritant/corrosive properties and substances prohibited under Cosmetics Products Regulation (CPR) (Annex II and Annex IV, column g) should not be present in tattoo inks. For the purpose of ensuring the practicality and monitorability of the proposed restriction, sufficiently low concentration limits (CLs) are to be derived for these substance	**Secretariat** to arrange an ad hoc WebEx to conclude on the concentration limits for the remaining substances in the scope of the proposed restriction. **Rapporteurs** to prepare the third draft opinion, taking into account RAC-45 discussions and the results of the public consultation, by beginning of August 2018.

groups. RAC supported the proposed CLs for the following substances: - 0,001% w/w for skin sensitisers; - 10.9% w/w for methanol (MeOH), using 8 mg/kg bw/d (DNEL)/ 1.7 mg/kg bw - 0.00003% w/w risk based CL for primary aromatic amines (PAAs), recognising that there are practical reasons to set higher limit - 0.1% practical limit to discourage azo colourants listed in Supplementary Table B in the Background Document (BD) to discourage use - 0.00005% w/w for individual PAHs with harmonised classification as carcinogenic or mutagenic RAC also agreed to use CPR Annex II and Annex IV column g → as for "CLP group" with the lowest concentration limit of 0.001% (skin sensitisers). RAC agreed to include two additional PAAs in the scope of the restriction and confirmed that risk from skin irritants cannot be excluded. RAC recommended the rapporteurs consider setting a CL for repro Cat 1a/b substances on the basis of the lowest derived DNEL for the substances found in tattoo inks (i.e., for DBP) using an additional factor of 10 to account for: mixture /cumulative effects and uncertainties, including ED effects and the possibility that more potent repro substances may be in tattoo inks.	
2. C9-C14 PFCAs, their salts and related substances RAC took note of the presentation by the Rapporteurs on the opinion development progress update.	**Rapporteurs** to prepare the third draft opinion, taking into account RAC-45 discussions and the results of the public consultation, by beginning of August 2018.
10. Authorisation	
10.1 General authorisation issues	
a) Update on incoming/future applications	
RAC noted the information presented by the Secretariat.	

b) Updated AfA opinion templates	
RAC noted the information presented by the Secretariat.	
10.2 Authorisation applications	
a) Discussion on key issues	
-	
b) Agreement on Draft Opinions	
1. PCO_IP (2 uses) **Use 1 and Use 2** RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and the review report as explained in the draft opinions. 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.
2. SD_Olwerke (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided not to recommend additional conditions and/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. Diglyme_Omnichem (1 use) RAC agreed on the draft opinion as proposed by the Rapporteur. RAC concluded that adequate control has been demonstrated for workers' exposures, as well as for the general population exposed via the environment.	**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 decided to recommend monitoring arrangements for the authorisation and recommendation for the review report as explained in the draft opinion with one textual change. RAC agreed to give no advice to SEAC on the length of the review period.	
4. DBP_AVX (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC concluded that adequate control has been demonstrated for workers' exposures, as well as for the general population exposed via the environment. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and the review report as explained 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.
c) Adoption of final opinions	
-	
10.3 Review Reports	
a) Discussion on key issues	
-	
b) Agreement on draft opinions	
1. RR1_DEHP_VINYLOOP (2 uses) **2. RR1_DEHP_PP (2 uses)** **Use 1 and Use 2** RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC concluded that adequate control has been demonstrated for workers' exposures, as well as for the general population exposed via the environment. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and the review reports as explained in the draft opinions. 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 authorisation holders for commenting.
11. AOB	
a) Efficiency in RAC Consultations	
b) Adoption of the RAC note on reference dose-response relationship for the carcinogenicity of pitch, coal tar, high temperature	**SECR** to publish the adopted RAC note on the ECHA website.

(CTPHT) and on PBT and vPvB properties RAC adopted by consensus the RAC note on reference dose-response relationship for the carcinogenicity of pitch, coal tar, high temperature (CTPHT) and on PBT and vPvB properties.	
12. Action points and main conclusions of RAC-45	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: CLH opinions which were adopted at RAC-45

1. Nitric …%
2. Granulated copper
3. 2-Methyl-1,2-benzisothiazol3(2H)-one; [MBIT]
4. 2,2-bis(bromomethyl)propane-1,3-diol
5. bis(α,α-dimethylbenzyl) peroxide
6. N-(hydroxymethyl)acrylamide; [NMA]
7. trimethoxyvinylsilane; trimethoxy(vinyl)silane
8. dimethyl disulphide
9. tetraglyme
10. tris(2-methoxyethoxy)vinylsilane
11. glyoxylic acid …%
12. azoxystrobine
13. paclobutrazole

1. Nitric acid …%

Existing & new Annex VI entries (CLP, Table 3)

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 and ATE	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	007-004-001	nitric acid ... %	231-714-2	7697-37-2	Ox. Liq. 2 Skin Corr. 1A	H272 H314	GHS03 GHS05 Dgr	H272 H314	EUH071	Ox. Liq. 2; H272: C ≥ 99% Ox. Liq. 3; H272: 65% ≤ C < 99% Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 %	B
Dossier submitters proposal	007-004-001	nitric acid …% [C > 70 %]	231-714-2	7697-37-2	**Add** Acute Tox. 1	**Add** H330	**Add** GHS06	**Add** H330	**Retain** EUH071	**Retain** Ox. Liq. 2; H272: C ≥ 99% Ox Liq. 3: 70% ≤ C < 99%	**Retain** B
Dossier submitters proposal	TBD	nitric acid …% [C ≤ 70 %]	231-714-2	7697-37-2	**Add** Acute Tox. 3	**Add** H331	**Add** GHS06	**Add** H331	**Retain** EUH071	**Retain** Ox Liq. 3: ≥ 65% Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 % **Add** inhalation: ATE = 2.1 mg/L	**Retain** B
RAC opinion	007-004-00-1	nitric acid …% [C > 70 %]	231-714-2	7697-37-2	**Add** Acute Tox. 1	**Add** H330	**Add** GHS06	**Add** H330	**Retain** EUH071	**Retain** Ox. Liq. 2; H272: C ≥ 99% Ox Liq. 3: 70% ≤ C < 99%	**Retain** B
RAC opinion	TBD	nitric acid …% [C ≤ 70 %]	231-714-2	7697-37-2	**Add** Acute Tox. 3	**Add** H331	**Add** GHS06	**Add** H331	**Retain** EUH071	**Retain** Ox Liq. 3: ≥ 65%	**Retain** B

										Skin Corr. 1A; H314: C ≥ 20 % Skin Corr. 1B; H314: 5 % ≤ C < 20 % **Add** inhalation: ATE = 2.65 mg/L (vapour)	
Resulting Annex VI entry if agreed by COM	007-004-00-1	nitric acid …% [C > 70 %]	231-714-2	7697-37-2	Ox. Liq. 2 Acute Tox. 1 Skin Corr. 1A	H272 H330 H314	GHS03 GHS06 GHS05 Dgr	H272 H330 H314	EUH071	Ox. Liq. 2; H272: C ≥ 99% Ox. Liq. 3; H272: 70% ≤ C < 99%	B
Resulting Annex VI entry if agreed by COM	TBD	nitric acid …% [C ≤ 70 %]	231-714-2	7697-37-2	Ox. Liq. 3 Acute Tox. 3 Skin Corr. 1A	H272 H331 H314	GHS03 GHS06 GHS05 Dgr	H272 H331 H314	EUH071	Ox. Liq. 3; H272: C ≥ 65% inhalation: ATE = 2.65 mg/L (vapour) Skin Corr. 1A; H314: C ≥ 20% Skin Corr. 1B; H314: 5% ≤ C < 20%	B

2. Granulated copper

No current Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Granulated copper	231-159-6	7440-50-8	Eye Irrit. 2 Aquatic Chronic 2	H319 H411	GHS07 GHS09	H319 H411			
RAC opinion	TBD	Granulated copper	231-159-6	7440-50-8	Aquatic Chronic 2	H411	GHS09	H411			
Resulting Annex VI entry if agreed by COM	TBD	Granulated copper	231-159-6	7440-50-8	Aquatic Chronic 2	H411	GHS09	H411			

3. 2-Methyl-1,2-benzisothiazol3(2H)-one;[MBIT]

No current Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2-methyl-1,2-benzothiazol-3(2H)-one; [MBIT]	-	2527-66-4	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 2	H331 H311 H301 H314 H318 H317 H400 H411	GHS05 GHS06 GHS09 Dgr	H331 H311 H301 H314 H317 H410		**inhalation**: ATE = 0.5 mg/L (dusts or mists) **dermal**: ATE = 300 mg/kg bw **oral**: ATE = 175 mg/kg bw M=1	
RAC opinion	TBD	2-methyl-1,2-benzothiazol-3(2H)-one; [MBIT]	-	2527-66-4	Acute Tox. 4 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 2	H312 H301 H314 H318 H317 H400 H411	GHS05 GHS06 GHS09 Dgr	H312 H301 H314 H317 H410	EUH071	**dermal**: ATE = 1100 mg/kg bw **oral**: ATE = 175 mg/kg bw Skin Sens. 1A; H317: C ≥ 0.0015% M=1	
Resulting Annex VI entry if agreed by COM	TBD	2-methyl-1,2-benzothiazol-3(2H)-one; [MBIT]	-	2527-66-4	Acute Tox. 4 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 2	H312 H301 H314 H318 H317 H400 H411	GHS05 GHS06 GHS09 Dgr	H312 H301 H314 H317 H410	EUH071	**dermal**: ATE = 1100 mg/kg bw **oral**: ATE = 175 mg/kg bw Skin Sens. 1A; H317: C ≥ 0.0015%	

										M=1	

4. 2,2-bis(bromomethyl)propane-1,3-diol

No current Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2,2-bis(bromomethyl)propane-1,3-diol	221-967-7	3296-90-0	Muta. 1B Carc. 1B	H340 H350	GHS08 Dgr	H340 H350			
RAC opinion	TBD	2,2-bis(bromomethyl)propane-1,3-diol	221-967-7	3296-90-0	Muta. 1B Carc. 1B	H340 H350	GHS08 Dgr	H340 H350			
Resulting Annex VI entry if agreed by COM	TBD	2,2-bis(bromomethyl)propane-1,3-diol	221-967-7	3296-90-0	Muta. 1B Carc. 1B	H340 H350	GHS08 Dgr	H340 H350			

5. Bis(α,α-dimethylbenzyl) peroxide

Existing Annex VI entry (CLP, Table 3)

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 and ATE	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	617-006-00-X	bis(α,α-dimethylbenzyl) peroxide	201-279-3	80-43-3	Org. Perox. F Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 2	H242 H315 H319 H411	GHS02 GHS09 GHS07 Wng	H242 H315 H319 H411			
Dossier submitters proposal	617-006-00-X	bis(α,α-dimethylbenzyl) peroxide	201-279-3	80-43-3	**Add** Repr. 2 **Remove** Skin Irrit. 2 Eye Irrit. 2	**Add** H361d **Remove** H315 H319	**Add** GHS08 **Remove** GHS07	**Add** H361d **Remove** H315 H319			
RAC opinion	617-006-00-X	bis(α,α-dimethylbenzyl) peroxide	201-279-3	80-43-3	**Add** Repr. 1B **Retain** Skin Irrit. 2 Eye Irrit. 2	**Add** H360D **Retain** H315 H319	**Add** GHS08 Dgr **Retain** GHS07	**Add** H360D **Retain** H315 H319			
Resulting Annex VI entry if agreed by COM	617-006-00-X	bis(α,α-dimethylbenzyl) peroxide	201-279-3	80-43-3	Org. Perox. F Repr. 1B Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 2	H242 H360D H315 H319 H411	GHS02 GHS07 GHS08 GHS09 Dgr	H242 H360D H315 H319 H411			

6. N-(hydroxymethyl)acrylamide (NMA)

No current Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	N-(hydroxymethyl)acrylamide (NMA)	213-103-2	924-42-5	Muta. 1B Carc. 1B STOT RE 1	H340 H350 H372 (peripheral nervous system)	GHS08 Dgr	H340 H350 H372 (peripheral nervous system)			
RAC opinion	TBD	N-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]	213-103-2	924-42-5	Muta. 1B Carc. 1B STOT RE 1	H340 H350 H372 (peripheral nervous system)	GHS08 Dgr	H340 H350 H372 (peripheral nervous system)			
Resulting Annex VI entry if agreed by COM	TBD	N-(hydroxymethyl)acrylamide; methylolacrylamide; [NMA]	213-103-2	924-42-5	Muta. 1B Carc. 1B STOT RE 1	H340 H350 H372 (peripheral nervous system)	GHS08 Dgr	H340 H350 H372 (peripheral nervous system)			

7. Trimethoxyvinylsilane

No current Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	trimethoxyvinylsilane	220-449-8	2768-02-7	Skin Sens. 1B	H317	GHS07 Wng	H317			
RAC opinion	TBD	trimethoxyvinylsilane; trimethoxy(vinyl)silane	220-449-8	2768-02-7	Skin Sens. 1B	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	trimethoxyvinylsilane; trimethoxy(vinyl)silane	220-449-8	2768-02-7	Skin Sens. 1B	H317	GHS07 Wng	H317			

8. Dimethyl disulphide

No current Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	dimethyl disulphide	210-871-0	624-92-0	Flam. Liq. 2 Acute Tox. 4 Acute Tox. 3 Eye Irrit. 2 Skin Sens. 1B STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H225 H302 H331 H319 H317 H335 H400 H410	GHS02 GHS06 GHS09 Dgr	H225 H302 H331 H319 H317 H335 H410		M =1 M =10	
RAC opinion	TBD	dimethyl disulphide	210-871-0	624-92-0	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 3 STOT SE 1 Eye Irrit. 2 Skin Sens. 1 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H225 H301 H331 H370 (upper respiratory tract, inhalation) H319 H317 H336 H400 H410	GHS02 GHS06 GHS09 Dgr	H225 H301 H331 H370 (upper respiratory tract, inhalation) H319 H317 H336 H410		oral: ATE = 190mg/kg bw Inhalation: ATE = 5 mg/L M =1 M =10	
Resulting Annex VI entry if agreed by COM	TBD	dimethyl disulphide	210-871-0	624-92-0	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 3 STOT SE 3 STOT SE 1 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H225 H301 H331 H336 H370 (upper respiratory tract, inhalation) H319 H317 H400 H410	GHS02 GHS06 GHS09 Dgr	H225 H301 H331 H336 H370 (upper respiratory tract, inhalation) H319 H317 H410		oral: ATE = 190mg/kg bw Inhalation: ATE = 5 mg/L M =1 M =10	

9. Tetraglyme

No current Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	603-RST-VW-Y	bis(2-(2-methoxyethoxy)ethyl) ether; tetraglyme	205-594-7	143-24-8	Repr. 1B	H360	GHS08 Dgr	H360			
RAC opinion	603-RST-VW-Y	bis(2-(2-methoxyethoxy)ethyl) ether; tetraglyme	205-594-7	143-24-8	Repr. 1B	H360FD	GHS08 Dgr	H360 FD			
Resulting Annex VI entry if agreed by COM	603-RST-VW-Y	bis(2-(2-methoxyethoxy)ethyl) ether; tetraglyme	205-594-7	143-24-8	Repr. 1B	H360FD	GHS08 Dgr	H360 FD			

10. Tris(2-methoxyethoxy)vinylsilane

No current Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	tris(2-methoxyethoxy)vinylsilane	213-934-0	1067-53-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane	213-934-0	1067-53-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			
Resulting Annex VI entry if agreed by COM	TBD	tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane	213-934-0	1067-53-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

11. Glyoxylic acid …%

No current Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Glyoxylic acid …%	206-058-5	298-12-4	Eye Dam. 1 Skin Sens. 1B	H318 H317	GHS05 GHS07 Dgr	H318 H317			B
RAC opinion	TBD	Glyoxylic acid …%	206-058-5	298-12-4	Eye Dam. 1 Skin Sens. 1B	H318 H317	GHS05 GHS07 Dgr	H318 H317			B
Resulting Annex VI entry if agreed by COM	TBD	Glyoxylic acid …%	206-058-5	298-12-4	Eye Dam. 1 Skin Sens. 1B	H318 H317	GHS05 GHS07 Dgr	H318 H317			B

12. Azoxystrobin

Existing Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard Statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-256-00-8	azoxystrobin (ISO); methyl (2E)-2-(2-{[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl)-3-methoxyacrylate		131860-33-8	Acute Tox. 3* Aquatic Acute 1 Aquatic Chronic 1	H331 H400 H410	GHS06 GHS09 Dgr	H331 H410			
Dossier submitters proposal	607-256-00-8	azoxystrobin (ISO); methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate		131860-33-8	**Modify** Acute Tox. 3 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Modify** H331 **Retain** H400 H410	**Modify** GHS06 **Retain** GHS09 Dgr	**Modify** H331 **Retain** H410		**Add** inhalation: ATE=0,7 mg/L (dust or mist) M=10 M=10	
RAC opinion	607-256-00-8	azoxystrobin (ISO); methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate		131860-33-8	Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H331 H400 H410	GHS06 GHS09 Dgr	H331 H410		inhalation: ATE = 0,7 mg/L (dust or mist) M=10 M=10	
Resulting Annex VI entry if agreed by COM	607-256-00-8	azoxystrobin (ISO); methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate		131860-33-8	Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H331 H400 H410	GHS06 GHS09 Dgr	H331 H410		inhalation: ATE = 0,7 mg/L (dust or mist) M=10 M=10	

13. Paclobutrazol (ISO)

No current Annex VI entry (CLP, Table 3)

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 and ATE	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	603-RST-VW-Y	paclobutrazol (ISO); (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol	-	76738-62-0	Repr. 2 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H332 H302 H319 H400 H410	GHS08 GHS07 GHS09 Wng	H361d H332 H302 H319 H410		M=10 M=10	
RAC opinion	603-RST-VW-Y	paclobutrazol (ISO); (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol	-	76738-62-0	Repr. 2 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H332 H302 H319 H400 H410		H361d H332 H302 H319 H410		inhalation: ATE = 3.13 mg/L (dust and mist) oral: ATE = 490 mg/kg bw M=10 M=10	
Resulting Annex VI entry if agreed by COM	603-RST-VW-Y	paclobutrazol (ISO); (2RS,3RS)-1-(4-chlorophenyl)-4,4-dimethyl-2-(1H-1,2,4-triazol-1-yl)pentan-3-ol	-	76738-62-0	Repr. 2 Acute Tox. 4 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H361d H332 H302 H319 H400 H410		H361d H332 H302 H319 H410		inhalation: ATE = 3.13 mg/L (dust and mist) oral: ATE = 490 mg/kg bw M=10 M=10	

Table 2: CLH opinions which postponed to RAC-46

1. mecetronium etilsulfate; [MES]
2. butanone oxime
3. zinc pyrithione

1. Mecetronium etilsulfate

No current Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	mecetronium etilsulfate; N-ethyl-N,N-dimethylhexadecan-1-aminium ethyl sulfate; Mecetronium ethyl sulphate [MES]	221-106-5	3006-10-8	Acute Tox. 4 Acute Tox. 3 Skin Corr. 1C Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H311 H314 H318 H400 H410	GHS05 GHS06 GHS09 Dgr	H302 H311 H314 H410		M=100 (Acute) M=10 (Chronic)	
RAC opinion	TBD	mecetronium etilsulfate; N-ethyl-N,N-dimethylhexadecan-1-aminium ethyl sulfate; Mecetronium ethyl sulphate [MES]	221-106-5	3006-10-8	Skin Corr. 1 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1[3]	H314 H318 H400 H410	GHS05 GHS09 Dgr	H314 H410	EUH071	M=100 (Acute) Option 1: M=10 Option 2: M=100 (Chronic)	
Resulting Annex VI entry if agreed by COM	TBD	mecetronium etilsulfate; N-ethyl-N,N-dimethylhexadecan-1-aminium ethyl sulfate; Mecetronium ethyl sulphate [MES]	221-106-5	3006-10-8							

[3] Environmental hazards to be discussed at RAC 46

2. Butanone oxime[4]

Existing Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	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	616-014-00-0	butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	202-496-6	96-29-7	Acute Tox. 4* Eye Dam. 1 Skin Sens. 1 Carc. 2	H312 H318 H317 H351	GHS08 GHS05 GHS07 Dgr	H312 H318 H317 H351			
Dossier submitters proposal	616-014-00-0	butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	202-496-6	96-29-7	**Retain** Eye Dam. 1 **Add** Acute Tox. 3 STOT SE 3 **Modify** Acute Tox. 4 Skin Sens. 1B Carc. 1B	**Retain** H318 **Add** H301 H336 **Modify** H312 H317 H350	GHS06 GHS05 GHS08 Dgr	H318 H301 H312 H317 H350 H336		**Add** ATE oral, 100 mg/kg bw ATE dermal, 1848 mg/kg bw	
RAC opinion	616-014-00-0	butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	202-496-6	96-29-7	**Retain** Eye Dam. 1 Skin Sens. 1 **Add** Acute Tox. 3 Skin Irrit. 2 STOT SE 1 STOT SE 3 STOT RE 2 **Modify** Acute Tox. 4 Carc. 1B	**Retain** H318 H317 **Add** H301 H315 H370 (upper respiratory tract) H336 H373 (blood system) **Modify** H312 H350	GHS06 GHS05 GHS08 Dgr	H318 H317 H301 H315 H312 H350 H336		**Add** ATE oral, 100 mg/kg bw ATE dermal, 1100 mg/kg bw	
Resulting Annex VI entry if agreed by COM	616-014-00-0	butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	202-496-6	96-29-7	Carc. 1B Acute Tox. 4 Acute Tox. 3 STOT SE 1 STOT SE 3	H350 H312 H301 H370 (upper respiratory tract)	GHS06 GHS05 GHS08 Dgr	H350 H312 H301 H370 (upper respiratory tract)		oral: ATE = 100 mg/kg bw dermal: ATE = 1100 mg/kg bw	

[4] Targeted PC to be launched for STOT RE

					STOT RE 2 Skin Sens. 1 Skin Irrit. 2 Eye Dam. 1	H336 H373 (blood system) H317 H315 H318		H336 H373 (blood system) H317 H315 H318			

3. Zinc pyrithione

No current Annex VI entry (CLP, Table 3)

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 and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc	236-671-3	13463-41-7	Acute Tox. 3 Acute Tox. 2 Eye Dam. 1 Repr. 1B STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H330 H318 H360D H372 H400 H410	GHS05 GHS06 GHS08 GHS09 Dgr	H301 H330 H318 H360D H372 H410		M=1000 (acute) M=10 (chronic)	
RAC opinion	TBD	pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc	236-671-3	13463-41-7	Acute Tox. 3 Acute Tox. 2 Eye Dam. 1 Repr. 1B STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1[5]	H301 H330 H318 H360D H372 H400 H410	GHS05 GHS06 GHS08 GHS09 Dgr	H301 H330 H318 H360D H372 H410		ATE oral = 221 mg/kg bw ATE inhalation = 0.14 mg/l M=100 (acute) M=10 (chronic)	
Resulting Annex VI entry if agreed by COM	TBD	pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc	236-671-3	13463-41-7							

[5] Environmental hazards to be discussed at RAC-46

Part III. List of Attendees of the RAC-45 meeting

RAC Members
Agapiou Agapios
Andreou Kostas
Aquilina Gabriele
Baranski Boguslaw
Biró Anna
Bjørge Christine
Borg Daniel
Carvalho João
Chankova-Petrova Stephka
Czerczak Slawomir
de la Flor Tejero Ignacio
Dunauskiene Lina
Dungey Stephen
Geoffroy Laure
Gruiz Katalin
Hakkert Betty
Husa Stine
Kadikis Normunds
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martinek Michal
Menard Srpčič Anja
Moeller Ruth
Mullooly Yvonne
Murray Brendan
Neumann Michael
Paris Pietro
Polakovicova Helena
Printemps Nathalie
Rucki Marian
Santonen Tiina
Schlüter Urs
Schulte Agnes
Seba Julie
Smith Andrew
Soerensen Hammer Peter
Sogorb Miguel A.
Stahlmann Ralf
Tobiassen Lea Stine
Tsitsimpikou Christina
Užomeckas Žilvinas
Varnai Veda
RAC co-opted members
Chiurtu Elena-Ruxandra
Jankowska Elzbieta
van der Haar Rudolf
Viegas Susana
Apologies, Members
Ilie Mihaela
Pronk Marja
Rupprich Norbert
Spetseris Nikolaos

Members' advisers
Crowther Ally (Andrew Smith)_CLH butanoe oxime
Esposito Dania (Pietro Paris)
Kuittinen Marko (Riitta Leinonen)
Mahiout Selma (Tiina Santonen)
Mohammed Ali Ifthekhar (Bert-Ove Lund)
Peczkowska Beata (Boguslaw Baranski)
Talasniemi Petteri (Riitta Leinonen)
Commission
Rozwadowski Jacek (DG GROW)
Bintein Sylvain (DG ENV)
Regular stakeholder observers
Annys Erwin (CEFIC)
Barry Frank (ETUC)
Comini Andrea (EuCheMS)
Romano Mozo Dolores (EEB)
Rowe Rocky (ECPA)
Verougstraete Violaine (Eurometaux)
Waeterschoot Hugo (Eurometaux)
Apologies, stakeholders
Bernard Alice (ClientEarth)
Occasional stakeholder observers
Brzuska Karolina (Cosmetics Europe)

Dossier submitters
Chion Béatrice (FR)_CLH granulated copper
Mohammed Ali Ifthekhar (SE)_CLH pyrithione zinc
Regnier Jean- Francois (Arkema) CLH dimethyl disulphide
Stakeholder experts
Baken Stijn (Eurometaux, European Copper Institut), CLH granulated copper
Barnes Emma (Ecpa, Syngenta), CLH paclobutrazol
Daston George (Cefic, P&G, ZnPT consortium), CLH Pyrithione zinc
Dzik Ewa (Cefic, Dow Europe GmbH), CLH MBIT
Gerdes Herta (Ecpa, Bode Chemie), MES
Koch Wendy (Cefic, Epona Associates), CLH trimethoxyvinisilane
Mackie Carol (Cefic, EU Zinc Pyrithione Task Force, Biocides, Lonza and Janssen), CLH granulated copper
Moore Nigel (Ecpa, Lonza, ZnPT consortium), CLH pyrithione zinc
Nash Frank Jay (Cosmetics Europe, P&G), CLH Pyrithione zinc
Unterberger Elif (Cefic, BASF SE), CLH nitric acid

REMOTE PARTICIPANTS	**PL**
RAC Members	Dominiak Dorota
Pronk Marja	Godala Mariusz
Rupprich Norbert	Jusko Kararzyna
Members' advisers	**Commission**
Andersson Alicja (Bert-Ove Lund)	Blass Rico Ana Maria
Beestra Renske (Betty Hakkert)	Garcia-John Enrique
Groothuis Floris (Betty Hakkert)	Jamers An
Martin Theresa (Ralf Stahlmann)	
Partosch Falko (Ralf Stahlmann)	
Pearson Audrey (Steven Dungey)	
SEAC rapporteurs	
Brignon Jean-Marc_Rest: tattoo inks	
Dossier submitters	
DE	
Biegel-Engler Annegret	
DK	
Lerche Dorte	
FR	
Manière Isabelle	
No	
Blom Cécile	
Hofer Tim	
Larsen Ann Kristin	
Olsen Ann-Karin	
Øystein Fotland Tor	

ECHA staff
Blainey Mark
Bowmer Tim, Chairman
Broeckaert Fabrice
Dvorakova Dana
Georgiadis Nikolaos
Hellsten Kati
Hollins Steve
Jaagus Triin
Jones Stella
Karjalainen Ari
Kivelä Kalle
Kokkola Leila
Kosk-Bienko Joanna
Kouloumpos Vasileios
Lapenna Silvia
Liopa Elīna
Logtmeijer Christiaan
Ludborzs Arnis
Luschutzky Evita
Nicot Thierry
Nygren Jonas
Orispää Katja
O´Rourke Regina
Pennese Daniele
Perazzolo Chiara
Pillet Monique
Prevedouros Konstantinos
Regil Pablo

Roggeman Maarten
Sadam Diana
Simoes Ricardo
Smilovici Simona
Sosnowski Piotr
Spjuth Linda
Stoyanova Evgenia
Uphill Simon
Van Haelst Anniek

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-45 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-45 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-45 meeting

ANNEX IV Administrative issues and information items

Final Agenda
45th meeting of the Committee for Risk Assessment

4 – 8 June 2018

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 4 June starts at 09.00
Friday 8 June ends at 13.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/45/2018
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests

For agreement

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 44 action points, written procedures and update on other ECHA bodies

RAC/45/2018/01
Room document
For information

b) RAC workplan for all processes

For information

Item 6 – Requests under Article 77(3)(c)

1) CT_Wesco (formerly Haas): chemical conversion and slurry coating application, re-consideration of a proposed authorisation condition

2) Request to review a derogation request for the PFOA restriction (entry 68 of Annex XVII to REACH)

For discussion/adoption

Item 7 – Requests under Article 95(3)

None

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 CLH dossiers

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

- paclobutrazol (ISO): physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, respiratory / skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, aspiration hazard, environmental hazards
- dimethyl disulphide: physical hazards (flammable liquid), acute toxicity (dermal and inhalation routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT SE, environmental hazards
- 2,2-bis(bromomethyl)propane-1,3-diol: carcinogenicity
- pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc: physical hazards, acute toxicity (all routes of exposure), skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, carcinogenicity, STOT SE
- mecetronium ethyl sulphate [MES]: physical hazards, skin sensitisation, germ cell mutagenicity, STOT SE
- glyoxylic acid … %: skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation
- 2-methyl-1,2-benzisothiazol3(2H)-one;[MBIT]: physical hazards, respiratory sensitisation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, STOT RE, aspiration hazard
- butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime: acute toxicity (dermal and inhalation routes of exposure), serious eye damage / eye irritation, mutagenicity, toxicity to reproduction
- tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane: germ cell mutagenicity, toxicity to reproduction
- azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate: acute toxicity (inhalation route of exposure), environmental hazards

B. Hazard classes for agreement with plenary debate

1) paclobutrazol (ISO)
2) dimethyl disulphide
3) 2,2-bis(bromomethyl)propane-1,3-diol
4) pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc
5) bis(α,α-dimethylbenzyl) peroxide
6) N-(hydroxymethyl)acrylamide (NMA)
7) mecetronium ethyl sulphate [MES]
8) Glyoxylic acid … %
9) 2-Methyl-1,2-benzisothiazol3(2H)-one;[MBIT]
10) butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime
11) trimethoxyvinylsilane; trimethoxy(vinyl)silane
12) tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-

silaundecane
13) azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
14) bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme
15) nitric acid …%
16) Granulated copper (ENV hazards only)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a) Opinion development

1) Substances used in tattoo inks and permanent make-up – second draft opinion

For discussion

2) C9-C14 PFCAs, their salts and related substances– second draft opinion

For information

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications

b) Updated AfA opinion templates

RAC/45/2018/02

For information

10.2. Authorisation applications

a) Dossiers for discussion of key issues
   1. None

b) Agreement on draft opinions

   1. PCO_IP (2 uses)
   2. SD_Olwerke (1 use)
   3. Diglyme_Omnichem (1 use)
   4. DBP_AVX (1 use)

For discussion/agreement

c) Adoption of final opinions
   1. None

10.3. Authorisation review reports

a) Dossiers for discussion of key issues
   1. None

b) Agreement of draft opinions
   1. RR1_DEHP_VINYLOOP (2 uses)
   2. RR1_DEHP_PP (2 uses)

For discussion/ agreement

c) Adoption of final opinions
   1. None

Item 11 – AOB

a) Efficiency in RAC consultations

For discussion

Item 12 – Action points and main conclusions of RAC-45

Table with Conclusions and Action points from RAC-45

For adoption

Annex II (RAC 45)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 45 meeting.

Document number	Title
RAC/A/45/2018	Final Draft Agenda
RAC/A/45/2018 Restricted	Draft outline agenda
RAC/45/2018/01 Room document	Report on RAC-44 action points, written procedure and update on other ECHA bodies
RAC/45/2018/02	Authorisation applications: Updated AfA opinion templates

ANNEX III (RAC-45)

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		
Granulated copper FR	Nathalie PRINTEMPS	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. Personal involvement.
Nitric acid ...% DE	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in (2) nitric acid
Requests under Article 77(3) (c)		

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	-	-
Restrictions		
Tattoo inks	Peter Hammer SOERENSEN	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.
Tattoo inks	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.
Tattoo inks	Agnes SCHULTE	Working for the CA which has been 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.
Tattoo inks	Urs SCHLÜTER	Working for the CA which has been involved in the preparation the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Stine HUSA	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.
Tattoo inks	Christine BJORGE	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.
PFCAs	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
	Daniel BORG	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. Personal involvement.
PFCAs	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. No personal involvement
PFCAs	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
PFCAs	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
PFCAs	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
Article 77.3(c)		
-	-	-
Restrictions		
-	-	-
Applications for Authorisation		
-	-	-
Harmonised classification & labelling		
1) Glyoxylic acid ...% **2) Butanone oxime** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in (1) and (2).
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1) Paclobutrazol (ISO) **2) Azoxystrobin (ISO)** **UK**	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement in (1)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
1) N-(hydroxymethyl) acrylamide (NMA) **FR**	Nathalie PRINTEMPS	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. Personal involvement.
1) 2,2-bis (bromomethyl)propane-1,3-diol **2) bis(α,α-dimethylbenzyl) peroxide** **NO**	Christine BJORGE	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. Involvement in (2)
	Stine HUSA	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.
1) bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme **2) tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane** **AT**	Sonja KAPELARI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Annemarie LOSERT	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. Personal involvement in (1) and (2).
1) pyrithione zinc **2) trimethoxyvinyl silane; trimethoxy(vinyl)silane** **SE**	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Daniel BORG	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. No personal involvement
1) mecetronium ethyl sulphate [MES] **2) 2-Methyl-1,2-benzisothiazol3(2H)-one;[MBIT]** **PL**	Boguslaw BARANSKI	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. No personal involvement.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
pyrithione zinc	Tim BOWMER (RAC Chairman)	The Chairman declared an potential interest, noting that prior to joining ECHA in 2012, he had worked in support of the Biocidal Products registration of a related pyrithione salt. He declared that he had not dealt with the opinion development of this dossier with the exception of agenda management and would not chair this agenda point.

Helsinki, 29 May 2018

RAC/45/2018/01

ROOM DOCUMENT

45TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

4 – 8 June 2018

Helsinki, Finland

Concerns:	**Administrative issues and information items**
Agenda Point:	**5a**
Action requested:	**for information**

ADMINISTRATIVE ISSUES AND INFORMATION ITEMS

1 Status report on the RAC-44 Action Points

The RAC-44 action points due for RAC-45 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-44	25 May 2018	closed

2.2 RAC consultations (status by 29 May 2018)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
paclobutrazol (ISO)	9 May 2018	closed
dimethyl disulphide	11 May 2018	closed
2,2-bis(bromomethyl)propane-1,3-diol	7 May 2018	closed
pyrithione zinc; (T-4)-bis[1-(hydroxy-.kappa.O)pyridine-2(1H)-thionato-.kappa.S]zinc	11 May 2018 (HH) 10 May 2018 (ENV) → extended until 14 May 2018	closed
bis(α,α-dimethylbenzyl) peroxide	11 May 2018	closed
N-(hydroxymethyl)acrylamide (NMA)	11 April 2018	closed
mecetronium ethyl sulphate [MES]	11 May 2018	closed
glyoxylic acid … %	25 April 2018	closed
2-methyl-1,2-benzisothiazol3(2H)-one;[MBIT]	9 May 2018	closed
butanone oxime; ethyl methyl ketoxime; ethyl methyl ketone oxime	4 May 2018	closed
trimethoxyvinylsilane; trimethoxy(vinyl)silane	9 May 2018	closed
tris(2-methoxyethoxy)vinylsilane; 6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane	26 April 2018	closed
azoxystrobin (ISO); methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate	3 May 2018	closed
bis(2-(2-methoxyethoxy)ethyl)ether; tetraglyme	11 May 2018	closed
nitric acid…%	n.a.	n.a.

Subject / document	Deadline	Status / follow-up
granulated copper	2 May 2018	closed
Application for Authorisation / Review Report		
RR1_DEHP_VINYLOOP RR1_DEHP_PP Consultation on draft opinions	16 May 2018	closed
SD_Olwerke Consultation on draft opinion	16 May 2018	closed
DBP_AVX Consultation on draft opinion	18 May 2018	closed
Diglyme_Omnichem Consultation on draft opinion	18 May 2018	closed
PCO_IP Consultation on draft opinions	21 May 2018	closed
Consultation on updated application for authorisation opinion format	16 April 2018	closed
Restrictions		
Consultation on second draft opinion on PFCAs	25 May 2018	closed
Consultation on second draft opinion on tattoo inks	25 May 2018	closed
Art. 77. 3. c request on CT Wesco		
Consultation on draft final opinion on the mandate and the revised final opinion on CT_Wesco (formerly CT_Aviall)	28 May 2018	open
Art. 77. 3. c request on evaluations OELs		
no consultations		

2.3 Other written consultations of RAC (status by 29 May 2018)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-44	25 April 2018	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest in rapporteurship for CLH dossiers / new intentions	24 April – 2 May 2018	12 volunteers expressed their interest
Application for Authorisation		

Call for expression of interest in rapporteurship on applications for authorisation on SVHCs in 12 new entries in Annex XIV of the REACH Regulation. Full list of the new entries is published in Annex of the Commission Regulation (EU) 2017/999[6].		
Restriction Call for expression of interest in rapporteurship for DMF and Cobalt restriction dossiers	20 April – 21 May 2018	Three volunteers expressed their interest for Cobalt restriction dossier and one volunteer expressed her interest for DMF

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	▪ diammonium decaborate ▪ barium diboron tetraoxide ▪ pentaboron sodium octaoxide ▪ sodium metaborate, anhydrous ▪ margosa ext. [from the kernels of Azadirachta indica extracted with water and further processed with organic solvents] ▪ imidacloprid (ISO); 1-(6-chloropyridin-3-ylmethyl)-N-nitroimidazolidin-2-ylidenamine	2 April 2018	closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)Rapporteurs were appointed with tacit agreement.
Written procedure for the appointment of (co-)rapporteurs	▪ 1H-Benzotriazole ▪ pyridalyl; 2,6-dichloro-4-(3,3-dichloroallyloxy)phenyl ▪ 1,2-epoxy-4-epoxyethylcyclohexane ▪ chloropropham ▪ melamine ▪ 2-(2-methoxyethoxy)ethanol ▪ bentazone ▪ daminozide ▪ tetrafluoroethylene ▪ benfluralin ▪ trifloxystrobin (ISO) ▪ desmedipham ▪ dicamba (ISO); 2,5-dichloro-6-methoxybenzoic acid; 3,6-dichloro-2-methoxybenzoic acid ▪ d-Allethrin; (RS)-3-allyl-2-methyl-4-oxo-cyclopent-2-enyl-(1R,3RS)-2,2-dimethyl-3-(2-methylprop-1-enyl)- ▪ esbiothrin ▪ piperonyl Butoxide ▪ pyridazine-3,6-diol;maleic hydrazide ▪ clomazone ▪ chlorfenapyr (ISO); 4-bromo-2-(4-chlorophenyl)-1- ethoxymethyl-5-	3 April 2018	closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)Rapporteurs were appointed with tacit agreement.

[6] Commission Regulation (EU) 2017/999 of 13 June 2017 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
	trifluoromethylpyrrole-3-carbonitrile ▪ Multi-Walled Carbon Nanotubes (MWCNT) / Synthetic Graphite in Tubular Shape with Fibre Geometry		
Written procedure for the appointment of (co-)rapporteurs	▪ oxathiapiprolin ▪ PHMB - Polyhexamethylene biguanide hydrochloride with a mean numberaverage molecular weight (Mn) of 1415 and a mean polydispersity ▪ silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface-treated silicon dioxide ▪ tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate ▪ tolclofos-methyl (ISO); O-(2,6-dichloro-p-tolyl) O,O-dimethyl thiophosphate ▪ benzyl salicylate ▪ propyl [3-(dimethylamino)propyl]carbamate monohydrochloride ▪ diflufenican (ISO) ▪ trifloxystrobin (ISO) ▪ reaction mass of: tert-alkyl(C12-C14)ammonium bis[1-[(2-hydroxy-5-nitrophenyl)azo]-2-naphthalenolato(2-)]-chromate(1-)tert-alkyl(C12-C14)ammonium bis[1-[(2-hydroxy-4-nitrophenyl)azo]-2-naphthalenolato(2-)]-chromate(1-)tert-alkyl(C12-C14)ammonium bis[1-[[5-(1,1-dimethylpropyl)-2-hydroxy-3-nitrophenyl]azo]-2-naphthalenolato(2-)]-chromate(1-)tert-alkyl(C12-C14….. ▪ 1,4-dioxane ▪ thiophanate-methyl ▪ transfluthrin (ISO)	21 May 2018	closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)Rapporteurs were appointed with tacit agreement.

Article 77 (3)(c) CT Wesco

Written procedure for the appointment of (co-)rapporteurs 10 May 2018 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 adopted by RAC and SEAC

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and applicants	
CT_ZFF (1 opinion)	13 March 2018
SD_Hapoc (1 opinion)	28 March 2018