RAC/M/49/2019

Final

30 August 2019

Minutes of the 49th Meeting of the Committee for Risk Assessment (RAC 49)

Tuesday 4, 14.00 to Friday 7 June, 13.00 and Wednesday 12, 09.00 to Thursday 13 June 17.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 49th meeting of the Committee for Risk Assessment (RAC 49). Apologies were received from four Members.

The participants were informed that the meeting would not be recorded. The Chairman noted that the RAC-48 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/49/2019). The Committee adopted its agenda and agreed to include the following item proposed by the Secretariat:

- Feedback from the DG-EMPL Working party on chemicals regarding Occupational Exposure Limits for benzene, nickel compounds and acrylonitrile.

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

3. Declarations of conflicts of interests to the Agenda

The Chairman declared that he had no potential conflict of interest to any agenda points for the meeting.

The Chairman further requested all participants to declare any potential conflicts of interest to any of the agenda items. In all, 15 Members declared potential conflicts of interest, each to specific agenda items, the majority related to concurrent employment of Members at agencies submitting dossiers to RAC but who had not been involved in the preparation. In the event of a vote, these Members were requested to refrain from voting on the respective agenda items, as stated in Article 9.2 of the RAC Rules of Procedure. Where Members declared that they had contributed to the preparation of a substance dossier for consideration by RAC, or similar potential conflict, they were asked to refrain from voting and the Chairman noted that he would consider additional mitigation measures. The list of persons declaring potential conflicts is attached to these minutes as Annex III.

4. Appointment of (co-)rapporteurs

a) Appointment of (co-)rapporteurs for CLH dossiers and authorisation applications

The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers and authorisation for applications, 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.

5. Report from other ECHA bodies and activities

a) Report on RAC-48 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that the action points from the previous meeting RAC-48, pending publications of three CLH opinions, were nearing completion. The summary of all substance-related written procedures, calls for expression of interests in (co-)rapporteurship and written procedures for appointments of rapporteurs, and adopted opinions, is provided in the room document on administrative issues (RAC/49/2019/01) (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-48 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 work plan for all processes

The Chairman informed the meeting participants about the updated RAC work plan for 2019 and the first quarter of 2020, covering the four processes of Restriction, Authorisation, and Harmonised Classification and Labelling of substances and scientific evaluations of Occupational Exposure Limits. He informed Members that they could find the expected schedules for Restriction and Authorisation dossiers in the work plan. In addition, the schedules for each Harmonised Classification and Labelling (CLH) dossier are given in the relevant section.

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

None.

7. Health based exposure limits at the workplace

a) Working Procedure for RAC on the evaluation of occupational exposure limits and other values

The Secretariat presented working procedure RAC/49/2019/02 outlining the general procedure for RAC for the scientific evaluation of occupational exposure limits and other values in support of Carcinogens and Mutagens Directive and the Chemical Agents Directive. This working procedure is applicable to future requests under the Service Level Agreement between DG-EMPL and ECHA.

RAC agreed with the proposed working procedures. The Secretariat will publish the agreed Working Procedure on the ECHA website and S-CIRCABC IG.

8. Harmonised classification and labelling (CLH)

8.1 General CLH issues

a) Report from the workshop on the applicability of the Rapid Removal concept for environmental hazard classification

The Secretariat presented to the Committee the Report from the workshop on the applicability of the Rapid Removal concept for environmental hazard classification which took place at ECHA on 11 June 2019.

The Committee took note of the Report from the workshop on the applicability of the Rapid Removal concept for environmental hazard classification and proposed minor editorial changes.

b) CLP – suggested changes in the timing of the Appointment of rapporteurs

The Secretariat presented the Committee options to facilitate the planning of the work for the Rapporteurs through deferring the appointments to a later stage in the process, i.e. after a dossier is found to be in accordance, as compared to the current practice in which the Rapporteurs are recruited once a dossier is submitted for the first time or when the indicated date of the first submission is approaching.

Once a dossier is found in accordance, the public consultation is scheduled and the consequent steps in the opinion development are known. Appointing Rapporteurs at this time would allow better planning of the work for all concerned and give a better overview to the Secretariat about the actual RAC-related workload of the Members.

In the discussion, RAC Members welcome the proposed changes and appreciated that it would lead to better predictability of the workload. At the same time several RAC Members underlined the importance of their (voluntary) contributions to the accordance check as an efficient tool to improve the quality of the dossiers and asked for an alternative way of communicating their comments efficiently to the dossier submitters. Commenting through public consultations was not seen as efficient, due to the nature of comments and their timing.

The Secretariat will reflect on the feedback, revise the proposed approach accordingly and bring this point back to RAC at the next plenary

8.2 CLH dossiers

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

RAC reviewed an 'A-listing' of hazard classes for a range of substances and 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. 2-phenoxyethanol

The Chairman welcomed the experts accompanying the ECPA and Cefic stakeholder observers and reported that 2-phenoxyethanol is an existing biocidal active substance used as a biocide in a range of products and articles. It is also used in machine wash liquids and detergents, paints and in cooling liquids.

2-phenoxyethanol has an existing entry in Annex VI to the CLP Regulation for acute oral toxicity (Acute Tox. 4*; H302 – minimum classification) and for eye irritation (Eye Irrit. 2; H319).

The legal deadline for the adoption of an opinion is 6 February 2020.

The dossier submitter (UK) proposed to confirm the acute oral toxicity classification (Acute Tox. 4; H302) with an acute toxicity estimate (ATE, oral) of 1 394 mg/kg bw and to classify the substance as Eye Dam. 1; H318 and STOT SE 3; H335. For acute inhalation toxicity and STOT RE the dossier submitter proposed no classification.

[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.

RAC agreed the following via the fast-track procedure, i.e. with scrutiny but without plenary debate: Acute Tox. 4; H302, ATE(oral) of 1 394 mg/kg bw and no classification for acute inhalation toxicity.

The Committee agreed to classify 2-phenoxyethanol into category 1 for eye damage (Eye Dam. 1; H318) based on the not fully reversible effects (corneal opacity) in two eye irritation rabbit studies after 15 and 21 days of exposure, and no clear evidence on full reversibility of eye effects from other available studies. The Cefic expert contended that there was no clear data showing irreversibility. He further pointed out that one of the two key studies showed reversibility of the eye effects and that the reported data (including in the REACH registration dossier) should be corrected based on the raw data available in the study report. Furthermore, according to the Cefic expert, the effects observed in the other study were also expected to be reversible, although with a delayed time-course. Further studies showing reversibility are available. Hence, the Cefic expert suggested that in a weight of evidence approach a category 2 would be more appropriate. However, RAC did not share this view and supported the proposal to classify by the dossier submitter.

As regards respiratory tract effects, effects in a 14-days inhalation study are used by the dossier submitter to support their proposal for STOT SE rather than STOT RE classification. One RAC Member considered the effects in the 14-day study (degeneration, metaplasia, inflammatory cell infiltrates, hypertrophy and hyperplasia) pointing rather to STOT RE, but the STOT SE classification was finally decided by RAC as best addressing the effects in the respiratory tract in the 14-day inhalation study.

The Industry expert noted that no clinical signs were observed in the 14-day study even in the highest concentration and that repeated exposure was required to induce effects at the site of contact. Other Industry expert questioned the fact that no human data is available that would support the STOT SE classification and that the available animal data do not support the STOT SE classification, too, as after single exposure no obvious irritant effects were observed and as in the 14-day study a detailed analysis was performed after repeated exposure, only.

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

2. mecoprop-P (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that mecoprop-P (ISO) is an active substance used in plant protection products as an herbicide.

Mecoprop-P (ISO) has an existing entry in Annex VI to the CLP Regulation for Acute Tox. 4*; H302 (minimum classification), Eye Dam. 1; H318 and for hazards to aquatic environment as Aquatic Chronic 2; H411.

The legal deadline for the adoption of an opinion is 30 January 2020.

The dossier submitter (UK) proposed to confirm the acute oral toxicity classification Acute Tox. 4; H302, with an ATE(oral) of 431 mg/kg bw and to change the environmental classification to Aquatic Chronic 3; H412. For STOT RE and reproductive toxicity the dossier submitter proposed no classification.

RAC agreed the following via the fast-track procedure, i.e. with scrutiny but without plenary debate: Acute Tox. 4; H302 with an ATE (oral) of 431 mg/kg bw and no classification for STOT RE.

Toxicity to reproduction

Fertility:

RAC Members noted that a dose-dependent reduction in implantation sites in a 1-generation study. The concurrent control was outside the historical control data (HCD) range, thus they were of limited value for the weight of evidence analysis. Reduced body weight gain was not enough to explain the effect seen. The 2-generation study used lower doses, so could not be used to compare/dismiss such effects. RAC Members further mentioned that in the 1-generation study there were also effects at lower doses, where maternal toxicity was not seen. It was pointed out that one of the doses used is the same in both 1-generation study and the 2-generation study. At this dose in the 1-generation study, the number of pup pups born was decreased and no parental toxicity was seen, while in the 2-generation study, there was an increased number of dead pups on day 1.In conclusion there is a clear effect in the number of implantation sites in the 1-generation study (this effect was not assessed in the 2-generation study). The IND expert clarified that the 2-generation study was carried out before 1-generation study; and that the latter was conducted to further investigate toxicity to reproduction as the 2-generation study had used too low doses. In the view of the IND expert there are no effects in the low and mid doses (as the control value is unusually high), only at the high dose, when compared with the HCD. The normal litter size in this strain is 12. Industry also expressed the view that the number of dead pups was incorrectly shown in the presentation. It should be made on a litter basis (mean value).

RAC Members noted that according to the Draft Assessment Report (DAR), the HCD was not considered acceptable. It was also noted that the concurrent control is always the main source for comparison when interpreting effects. There is a dose-response relationship, even if it is not so clear, and effects were seen from 50 ppm. It was argued that the difference in BW (230 vs 250 g) is less than 10%, and does not represent excessive maternal toxicity. Other members stated that the reduction in the low and mid dose were not enough to classify, leaving effects at the high dose as key findings for classification.

Given the difficulty in interpreting the evidence for fertility effects, the Chairman proposed to ask Industry for the full study report.

Development:

Two options, No classification or category 2, were proposed by the Rapporteur for developmental toxicity.

It was mentioned that the substance is very toxic to rabbits making the data difficult to assess. The study in mice shows clear effects, while in the rat there were only effects in the high dose. According to the study guideline there should also be some toxicity at the mid dose, throwing some doubts on the adequacy of the dose selection in the rat study. In the mice study, the number of doses was larger, a larger number of animals were used; it was appeared to be well conducted. However, information on the purity of test substance, and details on the performance of the study, including details on maternal toxicity is missing.

There was some discussion on the mouse study (Roll and Matthiaschk, 1983), including whether the strain used was in-bred or out-bred. The study also contained data on another substance previously assessed by RAC, where no classification was concluded despite positive data. The Secretariat explained that each case has to be assessed separately on its own database and the Chairman noted that the Committee should be cautious in using a reference which had already been rejected with good reason in another case. Some differences between this case and the previous one were however pointed out by members.

The Committee requested Industry to provide the original study report for the one-generation study in rats to allow for more detailed assessment of the effects on fertility. The Rapporteur will revise the opinion based on the plenary discussion and the study report provided by Industry. The revised draft opinion will be scheduled for a second debate and adoption at the next plenary meeting (September 2019).

Environmental hazards

As regards hazards to the aquatic environment, the dossier submitter proposed to change the existing classification from Aquatic Chronic 2 to Aquatic Chronic 3, based on available information on the active substance mecoprop-P. However, RAC decided to base the environmental classification on aquatic toxicity information of the formulated product that led to the substance being classified as Aquatic Acute 1, M=10 (based on an E_rC_{50} value of 0.0269 mg/L in *Myriophyllum spicatum*) and as Aquatic Chronic 1, M = 10 (based on an E_rC_{10} value of 0.001 mg/L also in *Myriophyllum spicatum*). The reasons for this were (i) the specific mode of action of mecoprop-P as a herbicide; (ii) the similar toxicities of the active substance and the formulated product in other algae species as reported in the DAR document (iii) the low concentration of the co-formulants and (iv) the high purity of the technical product. Several RAC Members expressed their support to this approach.

It was agreed to complete the discussion on both fertility and development at next meeting.

3. 6,6'-di-*tert*-Butyl-2,2'-methylenedi-*p*-cresol

Methylenedi-*p*-cresol is an antioxidant and a stabilising additive that is used at industrial sites in manufacturing as well as by professional workers (rubber and non-rubber polymers, fuels, adhesives, etc.) and by consumers (fuels, lubricants and greases, paints and coatings, etc.).

The substance has no existing entry in Annex VI to the CLP Regulation.

The legal deadline for the adoption of an opinion is 30 January 2020.

RAC agreed via the fast-track procedure, i.e. with scrutiny but without plenary debate to the proposal by Denmark to classify metylenedi-*p*-cresol as a substance that may damage fertility (Repr. 1B; H360F). RAC adopted the opinion by consensus.

4. diflufenican (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that diflufenican (ISO) is used for the control of broadleaf weeds and a few annual grasses in winter cereals. The substance has an existing entry in Annex VI of the CLP Regulation: Aquatic Chronic 3; H412. The legal deadline for the adoption of an opinion was 7 February 2020.

The dossier submitter (UK) proposed to classify the substance Aquatic Acute 1; H400 with an M-factor of 1 000 and Aquatic Chronic 1; H410 with an M-factor of 100. For reproductive toxicity and hazards to the ozone layer the dossier submitter proposed no classification. After the public consultation, one study report containing additional information on the hazard to the aquatic environment was submitted to both ECHA and EFSA. The information was relevant to the assessment of the environmental hazards for the substance, increasing the proposed M-factors 10-fold. The new study report was the subject of a targeted public consultation.

RAC agreed the following via the fast-track procedure (i.e. with scrutiny but without plenary debate): no classification for hazards to the ozone layer.

During the discussion on the aquatic hazards, one RAC Member raised a question about the suitability of the freshwater green algae *Ankistrodesmus falcatus* used in the new 72-hour algal toxicity study under static exposure conditions according to OECD TG 201. The Rapporteur informed that the ECHA Secretariat had performed a screening of all the REACH Registration databases that reported this specific species and found that it had been used 39 times, covering 22 unique substances. RAC agreed that the results of this apparently reliable and protocol-compliant study should be taken into account for the aquatic classification and derivation of M factors, especially as the species belongs to the same freshwater algae species family (*Selenastraceae*) as other species that are mentioned in the test Guideline. The Committee agreed to classify the substance as Aquatic Acute 1; H400 with an acute M-factor of 10 000, and Aquatic Chronic 1; H410 with a chronic M-factor of 1 000.

During the discussion on reproductive toxicity (fertility) the rapporteur proposed that the Committee discuss the following two options based on the available two-generation study in rat: 1) no classification for diflufenican based on the dystocia having been mainly observed at a dose level exceeding the limit dose, and that the dystocia was observed together with some maternal toxicity; 2) Repr. 2 H361f based on the incidence of dystocia being considered to be related to exposure to diflufenican, the incidence being clearly above the historical control data in the high dose group, and no effect on corrected body weight gain having been observed despite reduced body weight gain and food consumption. RAC Members agreed that there is some evidence for a dose-response relationship, and that the dystocia is likely to be substance related. However, it is mainly seen at a dose slightly above the limit dose, the incidence is low, and some maternal and foetal toxicity was also seen. It was noted that one case was seen also at the mid-dose, i.e. below the limit dose, but this was the only case across the generations. The Committee agreed on no classification for effects on fertility.

Regarding developmental toxicity, three studies on Sprague Dawley rats, Wistar rats and New Zealand white rabbits were available. The Committee agreed on the proposal of the RAC rapporteur for no classification of the substance. The three studies did not show evidence of developmental effects in the absence of other toxic effects.

Regarding the effects on or via lactation the RAC rapporteur noted that a two-generation study in rats showed reduced pup weight gain and reduced litter weights in the mid and high dose group from birth up to day 21 consistent with the reduced maternal body weight. The Committee members agreed for no classification on this classification endpoint.

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

5. tetrakis(2,6-dimethylphenyl)-*m*-phenylene biphosphate

The Chairman reported that tetrakis (2,6-dimethylphenyl)-*m*-phenylene biphosphate is an industrial chemical used as a flame retardant in electronic products, such as circuit boards.

It has an existing entry in Annex VI to the CLP Regulation as Skin Sens. 1; H317.

The dossier submitter (UK) proposed to remove the existing classification as Skin Sens. 1; H317. For skin corrosion/irritation the dossier submitter proposed no classification.

The legal deadline for the adoption of an opinion is 29 February 2020.

RAC agreed via the fast-track procedure, i.e. with scrutiny but without plenary debate that the substance does not warrant classification for skin corrosion / irritation.

RAC discussed in detail the skin sensitisation potential of the substance. Members concurred that the available *in chemico* data did not suggest reactivity and the *in vitro* data were not suitable for the assessment of skin sensitisation potential of this substance due to its physico-chemical properties (poor water solubility). The available human data (an epicutaneous test with human volunteers) were also considered to have limitations, due to the physico-chemical properties (poor water solubility and large molecular weight) suggesting limited dermal penetration, the small size of the study group and a potential impact of the vehicles used.

RAC then focused on the assessment of the Guinea Pig Maximisation Test (GPMT) which was positive for skin sensitisation at challenge concentrations of 50% and 75% in arachis oil, and the BrdU-LLNA (Local Lymph Node Assay) which was negative at 50% concentration in acetone/olive oil 4:1 (presumably the maximum concentration achieved in this test with the solvent used). Some RAC Members considered the GPMT test as weakly positive, with no dose-response relationship due to the poor solubility. Another RAC Member noted that the severity of symptoms appeared to increase.

In conclusion, RAC agreed, based on a weight of evidence assessment of the available studies, which also took into account the physico-chemical properties – mainly the low water solubility, the high molecular size of the compound and the absence of any functional groups that would raise concern for skin sensitisation, that the substance does not warrant classification as skin sensitiser. The existing harmonized classification for skin sensitisation would therefore be removed from the Annex VI of CLP.

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

6. 3-aminomethyl-3,5,5-trimethylcyclohexylamine

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that 3-aminomethyl-3,5,5-trimethylcyclohexylamine is an industrial chemical used in articles, by professional workers (widespread uses), at industrial sites and in manufacturing as an intermediate and as raw material.

The substance has an existing entry in Annex VI to the CLP Regulation for acute oral and dermal toxicity (Acute Tox. 4*; H312, Acute Tox. 4*; H302 (minimum classifications)), for skin corrosion (Skin Corr. 1B; H314), for skin sensitisation (Skin Sens. 1; H317) and for hazards to the aquatic environment (Aquatic Chronic 3; H412).

The legal deadline for the adoption of an opinion is 29 February 2020.

The dossier submitter (DE) proposed to confirm the acute oral toxicity classification (Acute Tox. 4; H302), with an ATE (oral) of 1 030 mg/kg bw, to remove the acute dermal toxicity and the environmental classifications, to add classification as Eye Dam. 1; H318 and to modify the existing classification for skin sensitisation by adding a subcategory (Skin Sens. 1A).

RAC agreed the following via the fast-track procedure, i.e. with scrutiny but without plenary debate: no classification for acute dermal toxicity, and classification for Eye Dam. 1; H318 and Skin. Sens. 1A; H317.

The Committee concurred with the proposal to classify the substance as Acute Tox. 4; H302. In the discussion on the acute toxicity estimate (ATE) value, five RAC Members initially indicated that a generic ATE value of 500 mg/kg bw might be more appropriate due to the absence of details in the reporting of the acute toxicity study. Other Members supported the Dossier Submitter's and Rapporteur's proposal to use the experimental value of 1 030 mg/kg bw, which

was also used to confirm the classification. In conclusion, RAC agreed to assign an ATE value of 1 030 mg/kg bw as this corresponds to the LD_{50} value resulting from the acute toxicity study, and is further supported by the available repeated-dose studies.

RAC Members proposed to set a specific concentration limit (SCL) for skin sensitisation as the available animal studies (GPMTs) indicate that the substance is a strong-to-extreme sensitiser. The strong sensitising potential is also supported by the available human data. In the discussion, RAC Members concurred to assign an SCL of 0.001% based on extreme potency. They also noted that the human data do not allow for any quantitative analysis and have a limited value for SCL setting.

As regards to chronic hazards to the aquatic environment, the dossier submitter proposed to remove the existing classification based on new evaluation of the existing data. Based on further details provided by the dossier submitter on the acute toxicity fish study concerning the maintenance of test concentrations in that test, RAC agreed on the removal of the existing environmental classification based on the clear evidence in the full study report that test concentrations have adequately been maintained. As a general point, it was clarified that nominal values should not be used automatically and if available, measured data should be taken into account. In all cases, best available reliable data are being used.

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. azamethiphos (ISO)

The Chairman reported that azamethiphos (ISO) is used within the EU in insecticides, acaricides and to control other arthropods (PT 18). The substance has no existing entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 5 March 2020.

The dossier submitter (UK) proposed to classify the substance as Acute Tox. 3; H331 (ATE = 0.5 mg/L (dusts and mists)), Acute Tox. 4; H302 (ATE = 500 mg/kg bw), Skin Sens. 1; H317, Aquatic Acute 1; H400 with an M-factor of 1 000 and Aquatic Chronic 1; H410 with an M-factor of 1 000.

RAC agreed the following via the fast-track procedure (i.e. with scrutiny but without plenary debate): no classification for physical hazards, reproductive toxicity, acute toxicity via dermal route of exposure, skin corrosion/irritation, serious eye damage/irritation, aspiration hazard, and classification for Acute Tox. 3; H331 (ATE = 0.5 mg/L (dusts and mists)), Acute Tox. 4; H302 (ATE = 500 mg/kg bw), Aquatic Acute 1; H400 (M = 1 000) and Aquatic Chronic 1; H410 (M = 1 000).

During the discussion on skin sensitisation the Rapporteur noted that the results of the Local Lymph Node Assay (LLNA) indicated high potency: the calculated EC3 value of 2.1% was at the border of sub-categorisation. The Rapporteur suggested that it is likely that a plateau of response had been reached in the test. That could mean that the calculated EC3 value might underestimate the skin sensitising potential of azamethiphos. However, in the absence of a reliable EC3 no sub-categorisation is possible. RAC Members agreed with the Rapporteurs' conclusions to classify the substance as Skin Sens. 1; H317.

During the discussion on specific target organ toxicity the Rapporteur noted that neurotoxic effects due to acetylcholinesterase inhibition were seen in acute and repeated dose studies with azamethiphos. They mostly appeared acute-like, and occurred at doses clearly below the guidance value of 300 mg/kg bw for STOT SE 1 via the oral route (≥ 50 mg/kg bw) and just above the guidance value of 1 mg/L for STOT SE 1 via the inhalation route (at 1.1 mg/L).

Therefore the RAC rapporteurs proposed to classify the substance as STOT SE 1 with nervous system as a target organ, and not as STOT RE.

Neurotoxic symptoms were seen after acute oral and inhalation exposure, but not after acute dermal exposure. However, as a value of 20% for dermal absorption has been derived from an *in vitro* test using human skin (Confidential, 2009, CAR 3.1), effects after dermal exposure cannot be completely excluded. Regarding the inhalation route it was noted that the dose of 1.1 mg/L was associated with death (4 of 10 animals died at that dose) and it was assumed that classification as Acute Tox. 3, inhalation also covers the neurotoxic effects seen at that dose. In response to written comments received from RAC Members the RAC rapporteur proposed to specify the oral and dermal route for classification as STOT SE 1, nervous system. Several RAC Members advised not to mention routes of exposure, since that could possibly give a false impression about inhalation route of exposure as 'safe' in terms of target organ toxicity. Classification for STOT SE 3 was not warranted, as no signs of respiratory tract irritation were observed in the acute studies available, and the observed neurotoxicity, though transient in nature, did not fulfil the criteria for narcotic effects. The Committee agreed to classify the substance as STOT SE 1; H370 (nervous system).

Regarding germ cell mutagenicity, the Rapporteur noted that when comparing the results of the *in vitro* and *in vivo* tests with the classification criteria for germ cell mutagens, it is obvious that classification in category 1 is not justified. There are no human data and there are no animal studies demonstrating genotoxic or mutagenic potential neither in germ cells nor in somatic cells. As for category 2, CLP Regulation states that a substance is regarded as a category 2 mutagen, if it causes concern for humans owing to the possibility that it may induce heritable mutations in germ cells of humans. Classification is based on positive results in mammals and/or, in some cases, in *in vitro* experiments with supporting information from *in vivo* studies or chemical structure activity relationship to known germ cell mutagens. The RAC rapporteur concluded that also category 2 is not applicable for azamethiphos as none of the three *in vivo* studies gave positive results. However, based on the clear positive signal from a total of four *in vitro* tests giving positive results together with some limitations in the available *in vivo* studies, the RAC rapporteur concluded that an *in vivo* mutagenic potential cannot be completely ruled out. However, as the available data do not fulfil the criteria RAC agreed that azametiphos should not be classified as germ cell mutagen

Regarding carcinogenicity the rapporteur proposed two options for the Committee to consider: Carc. 2; H351 or no classification based on the tumours observed in rats: leiomyomas in the jejunum of female rats at doses of 0.05 mg/kg bw/day and higher, with a single leiomyosarcoma in male rat of the top dose of 5 mg/kg bw/day and an increase in endometrial adenocarcinoma in the top dose. No tumours were observed in mice. The increase in tumour incidence was only slight and tumours were only seen in one species, in one study and in one sex. However, there were two types of tumours, one clearly malignant. In both organs, which were affected by tumour increase, the small intestine and the endometrium, inflammation and hyperplastic lesions were described. Although these findings were in different studies and, for the effects on the gastrointestinal tract, in a different species (mouse), it demonstrated that endometrium and small intestine are targets of azamethiphos toxicity. All available *in vitro* genotoxicity/mutagenicity tests were positive and it was demonstrated that azamethiphos has strong alkylating properties and *in vivo* mutagenic potential could not be completely excluded on the basis of the available studies. Considering all the evidence, the Committee agreed to classify the substance as Carc. 2; H351.

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

8. imidacloprid (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder attending the meeting and reported that imidacloprid (ISO) is used as an active substance in biocides and plant protection products.

It has as existing entry in Annex VI to the CLP Regulation for Acute Tox. 4*; H302, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410.

The dossier submitter (DE) proposed to modify classification to Acute Tox. 3; H301 with ATE (oral) = 131 mg/kg bw and to retain classification as Aquatic Acute 1 and Aquatic Chronic 1, adding M- factors to aquatic hazards (Aquatic Acute M = 100 and Aquatic Chronic M = 1000).

The legal deadline for the adoption of an opinion is 4 March 2020.

RAC agreed to classify imidacloprid (ISO) for acute oral toxicity, category 3, based on the results of an acute oral toxicity study in mice which appear to be a more sensitive species compared to rats with an LD_{50} of 131 mg/kg bw, thus fulfilling the criteria for category 3.

In the discussion on hazards to the aquatic environment, RAC considered non-standard key studies with two non-standard species (mayflies) as relevant and reliable. RAC Members agreed to the approach taken by the dossier submitter that given the mode of action of neonicotinoid imidacloprid (disturbing synaptic signal transmissions of insects), insects are the representative group for the invertebrate trophic level. Both species show similar sensitivity to the substance.

The ECPA expert expressed concerns towards using non-standard species and non-standard test protocols. They also expressed concern towards the use of formulation data for deriving the classification. However, RAC considered the test relevant and reliable for classification. RAC also considered that the information provided by the dossier submitter regarding the use of formulations in the key studies as adequate to allow their use for classification.

RAC briefly discussed the details of the test used for the classification and the measured parameters but concurred that for the used species the 48-h and 21-day endpoints were justified. This was particularly the case for the chronic classification where choice of species used was questioned. RAC agreed to classify imidacloprid (ISO) as Aquatic Acute 1 with an M-factor of 100 and as Aquatic Chronic 1 with an M-factor of 1000.

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

9. *S*-abscisic acid

S-abscisic acid is and active substance in plant protection products.

The substance has no existing entry in Annex VI to the CLP Regulation.

The legal deadline for the adoption of an opinion is 28 March 2020.

RAC agreed via the fast-track procedure, i.e. with scrutiny but without plenary debate to the proposal by the Netherlands to classify *S*-abscisic acid as a substance that is very toxic to aquatic life with long lasting effects (Aquatic Acute 1; H400 (M = 1) and Aquatic Chronic 1; H410 (M = 1)). RAC adopted the opinion by consensus.

10. 2,2-dibromo-2-cyanoacetamide (DBNPA)

The Chairman welcomed the expert accompanying the ECPA stakeholder and reported that DBNPA is an active substance used in biocidal products for disinfection and preservation.

It has no existing entry in Annex VI to the CLP Regulation.

The legal deadline for the adoption of an opinion is 22 November 2019.

The dossier submitter (DK) proposed to classify DBNPA as Acute Tox. 3; H301 with an ATE (oral) of 167 mg/kg bw, Acute Tox. 2; H330 with an ATE (inhalation) of 0.275 mg/L, Skin Irrit. 2; H315, Eye Dam. 1; H318, Skin Sens. 1; H317 and for hazards to the aquatic environment as Aquatic Acute 1; H400, M = 1 and Aquatic Chronic 2; H411. Following comments in the public consultation the dossier submitter changed the latter classification to Aquatic Chronic 1; H410, M = 1, and additionally proposed STOT RE 1; H372 (respiratory tract, thyroid).

RAC agreed the following via the fast-track procedure, i.e. with scrutiny but without plenary debate: Skin. Irrit. 2; H315, Eye. Dam. 1; H318, Skin Sens. 1; H317, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with M-factors of 1 for both endpoints. RAC further agreed on no classification for the following hazards: selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, substance or mixture corrosive to metals), acute dermal toxicity, STOT SE, carcinogenicity, germ cell mutagenicity, toxicity to reproduction and hazardous to the ozone layer.

RAC concurred with the dossier submitter to classify DBNPA into category 3 for acute oral toxicity but contrary to the dossier submitter's proposal of using the rat LD_{50} value, assigned an ATE value of 118 mg/kg bw based on the LD_{50} value from the most sensitive species (rabbit and Guinea Pig).

RAC agreed to classify DBNPA into category 2 for acute inhalation toxicity, but assigned an ATE value of 0.24 mg/L based on LD_{50} for female rats in the guideline-compliant study supported by the results of another reliable 2-week study. RAC further agreed that an additional labelling with EUH071 is not warranted as the available data do not demonstrate that corrosivity is the leading mechanism behind the observed mortality.

The Committee briefly discussed the effects in the repeated dose toxicity studies. Contrary to the dossier submitter's proposal, RAC did not consider the effects in the 90-day dog study sufficient to warrant to include the thyroid as the target organ. Whilst the dossier submitter explained that in addition to the dog data they also considered effects in studies on other bromines as a supporting evidence for their conclusion on the thyroid as the target organ, the committee did not however agree that classification as STOT RE for thyroid effect was warranted.

RAC supported the Rapporteurs conclusion that the effects in the kidney, haematopoiesis and associated with mortality do not warrant classification for STOT RE.

The Committee supported the classification of DBNPA into category 1 for STOT RE for the respiratory tract through the inhalation route of exposure based on the effects in the larynx and the lungs observed in a 2-week inhalation study in rats. The absence of effects on respiratory tract in oral and dermal rat studies justified the specification of the exposure route.

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

11. 5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that pyriofenone is an active substance used in plant protection products as a fungicide.

Pyriofenone has no existing entry in Annex VI to the CLP Regulation.

The legal deadline for the adoption of an opinion is 24 August 2019.

The dossier submitter (UK) proposed to classify pyriofenone for carcinogenicity (Carc. 2; H351) and for hazards to aquatic environment as Aquatic Chronic 1; H410 with an M-factor of 1.

RAC agreed the following via the fast-track procedure, i.e. with scrutiny but without plenary debate: to classify pyriofenone as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1; H410) with an M-factor of 1. RAC further agreed on no classification for the following hazards: physical hazards, acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, germ cell mutagenicity, toxicity to reproduction, STOT SE, STOT RE and aquatic acute toxicity.

Discussion between Cat. 2 (proposed by the dossier submitter and supported by the Rapporteur) and no classification (all other commenting RAC Members considered pyriofenone as a weak carcinogen and the effects - slight increase in liver tumours in one species and one sex only - as insufficient for classification). Overall, RAC was of the opinion that pyriofenone is a borderline case for classification as a carcinogen. The increase of adenoma in rat liver in the treated animals (2, 4 and 12%, low, mid and high dose, respectively) was not statistically significant due to an 8 % incidence in the concurrent control. The unexpectedly high incidence of adenoma in the control may have masked a real effect, this hypothesis was supported by the HCD within 5 years: average 1.3%, range 0-4%, in which case the adenomas may not be considered as substance related. Despite this, RAC considered that the low increased incidence in the carcinomas (0, 2, 2 and 4% in the control, low, mid and high dose, respectively) was substance related and as these are rare tumours (HCD within 5 years: 0%), *de facto* an effect triggering the highest concern. Some members also considered that the tumours in mice, despite being considered by the Rapporteur and the majority of RAC Members as of no concern, should not be completely disregarded in the overall evaluation.

MoA studies showed conflicting results and had significant limitations, so no clear conclusion could be drawn of a potential MoA related to liver tumours according to RAC thus, the relevance to human could not be discarded.

Historical Control Data (HCD) were also notable due to an unexpectedly high incidence of adenomas in the concurrent male rat controls and a few, extremely rare, carcinomas in male rats. Industry claimed that both the adenoma and the carcinoma where within the HCD range provided and that the whole dataset (~ 33 years) should be considered not only a fraction of it, as it was more representative of the incidences observed in the study concurrent control. RAC argued that only the contemporary HCD (within 5 years) should be considered as indicated in the CLP guidance, and that there are several other reasons why to discard very old HCD, such as change in feeding, housing conditions etc.

Overall, RAC concluded that i) a relation with pyriofenone treatment cannot be excluded for the liver carcinoma observed in rats, and ii) the proposed MoA could not demonstrate a non-relevance to humans, and thus agreed to classify pyriofenone as Carc. 2; H351.

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

9. Restrictions

9.1 General restriction issues

a) Report from the recent Restrictions Task Force activities

The Secretariat presented to the Committee the report from the last Restrictions Task Force (RTF) meeting that took place on 22 May 2019 via WebEx, as well as the issues planned to be

tackled in the near future. The Committee welcomed the work of the RTF. It was agreed that the Secretariat will share the Action points of the last RTF meeting with RAC and SEAC via S-CIRCABC.

9.2 Restriction Annex XV dossiers

a) Conformity check

1) Perfluorohexane-1-sulphhonic acid, its salts and related substances

The Chairman welcomed the RAC rapporteurs and the dossier submitter representatives from Norway. The representative of the dossier submitter gave an introductory presentation on the dossier. They explained that the dossier outlines a proposal to restrict the manufacture, use and placing on the market of PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof. The restriction proposal aims at reducing emissions of PFHxS, its salts and their related substances to the environment and, as a result, minimise human exposure (the main potential exposure pathways are intake via food and drinking water and through exposure to house dust). PFHxS is found in human blood and in environmental samples from all around the world, including remote regions. Human elimination half-life of PFHxS in serum is more than seven years. It takes many years (>42) to reduce a certain amount of PFHxS in the environment by half, though no degradation has so far been demonstrated. Even though PFHxS including its salts and PFHxS-related substances are not registered under REACH, there is an ongoing exposure of humans and the environment to PFHxS from diffuse and point sources. The continuous emissions of PFHxS combined with the very persistent nature of the substance is expected to lead to increasing exposure if the emissions are not reduced. Human exposure to PFHxS occurs. Several human biomonitoring studies have demonstrated elevated levels of PFHxS in blood serum, related to exposure to PFHxS via drinking water. Furthermore, food and exposure via articles in the home environment can lead to elevated concentrations of PFHxS in human blood similar to or above those observed in occupational settings.

The (co-)rapporteurs then presented the outcome of the conformity check and the recommendations to the Dossier Submitter, and they consider the dossier to be in conformity. RAC Members asked some clarifying questions from the Rapporteurs and noted the similarities between the previous restriction proposals on PFOA and C9-C14 PFCAs.

The Committee agreed that the dossier conforms to the Annex XV requirements. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 19 June 2019 (provided that also SEAC considers it in conformity).

2) Skin sensitisers in textiles, leather, fur and hide articles

The Chairman welcomed the Dossier Submitter's representatives from France and Sweden and an occasional stakeholder observer. He informed the participants that the restriction dossier had been submitted in April 2019.

The Dossier Submitter's representative provided an introductory presentation on the dossier. She explained that the dossier proposes to restrict the skin sensitising substances in finished textile, leather, hide and fur articles, placed on the market for the first time. There is a growing concern at the EU level and worldwide about skin sensitisation of the general population from exposure to chemicals in textile and leather articles, such as clothes and footwear. The number of individuals sensitised to chemical substances in textile and leather in the EEA population is estimated by the Dossier Submitters to be between 4 and 5 million, which corresponds to 0.8-

1% of the EEA population. The number of new (incident) cases of sensitisation to chemicals in textile and leather are estimated by the Dossier Submitter to be between 45 000 and 180 000 per year, which corresponds to 0.01-0.04% of the EU28 general population annually.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitters. They noted that the restriction targets dermal exposure to sensitising chemicals from textiles and leathers and has thus a broad scope. The proposal covers CLH skin sensitisers category 1A/1B/1 and disperse dyes, and a clear parallel is made with the Restriction on CMRs in textiles, including potential overlaps. The Rapporteurs pointed out that they had made a few recommendations to the Dossier Submitter (on the proposed restriction and on information on hazards and risks), but none of the recommendations are of high priority. The Commission observer stressed the importance of the alignment of this proposal with the existing Restriction of CMRs in textiles. The dossier submitter's representative responded that hopefully this issue will be clarified in the opinion development.

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the Rapporteurs presented their key issues of the restriction proposal. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 19 June 2019 (provided that also SEAC considers that the proposal is in conformity).

b) Opinion development

1) D4/D5/D6

The Chairman welcomed the Dossier Submitter's representatives from ECHA, an industry expert accompanying the regular CEFIC stakeholder observer and an occasional stakeholder observer. He informed the participants that this restriction dossier had been submitted in January 2019 and had been considered in conformity in the previous RAC-48 meeting. The dossier proposes to restrict placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance. These substances are manufactured and used in a variety of sectors across the EEA. They are mainly used as intermediates for the production of silicone polymers (which is outside of the scope of the proposed restriction) but are also used as substances on their own or in the formulation of various mixtures that are subsequently used by consumers and professionals. D4, D5 and D6 were identified by ECHA`s MS Committee as SVHC substances with PBT/vPvB properties.

The Rapporteurs presented their first draft opinion and invited the Committee at this meeting to confirm the justification of the scope of the proposed restriction, to finalise the discussion on hazards and to start the discussion on releases and risks to be addressed. With regard to the scope, the Rapporteurs explained the justification and reasons for grouping and RAC agreed that these are indeed clear. Furthermore, the Rapporteurs highlighted that the scope is targeted on use of D4, D5 and D6 (as such or in mixtures) in 'leave-on cosmetic products' and 'other consumer or professional products' that are not included in the existing restriction on the placing on the market of D4 and D5 on 'wash-off' cosmetic products (Entry 70) , including use of D6 in 'wash-off' cosmetic products, and that the proposal does not cover uses at industrial sites and uses of silicone polymers. The Committee agreed with the Rapporteurs that the reasons for targeting consumer and professional uses are also clear. The Chairman noted that possible derogations will be discussed at the later stage of the opinion development process, after the public consultation has ended.

In relation to hazard, the Rapporteurs pointed out the (27 June 2018) ECHA MSC decision, where D4, D5 and D6 had been identified as SVHC substances with vPvB properties. D4 had also been identified as having PBT properties; D5 and D6 are considered to be PBT substances where the

concentration of D4 (as a constituent) exceeds a concentration limit of 0.1% w/w. RAC agreed to take note of the decision of the MSC.

With regard to the exposure and risk assessment of PBT/vPvB substances (where releases are taken as a proxy for risk), the Rapporteurs emphasised that the Dossier Submitter's use of an 'environmental stock pollution approach' provides additional and useful information for risk assessment compared to an assessment based on emissions alone. In the case of D4, D5 and D6 the multimedia modelling demonstrated that releases to air contribute to a steady state pollutant stock, as was the case with releases to water. The Rapporteurs indicated that the previous proposal on D4 and D5 in wash-off cosmetics had been targeted to address emissions to the aquatic environment. The Dossier Submitter of the current proposal, however, demonstrated qualitatively with the multi-media fate modelling that emissions to air also contribute to environmental stocks. The dossier submitter representative confirmed that the SIMPLEBOX tool used here had been developed by RIVM originally, but had been used as a standard tool for this type of risk assessment under REACH. The industry expert argued that SIMPLEBOX does not in their view appropriately address the unique physico-chemical properties and environmental behaviour of these substances and promised to provide more information within the public consultation. The Committee concluded that total releases of D4, D5 and D6 into the environment should be used as a proxy for risk.

In relation to whether the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk, RAC concluded provisionally that the risks are not adequately controlled and that releases of D4, D5 and D6 covered by the proposed restriction are not minimised throughout their life-cycle.

The Chairman informed the Committee that the Secretariat will launch a written consultation on the first draft opinion after RAC-49. The Rapporteurs were asked to prepare the second draft opinion, taking into account the RAC-49 discussion and the RAC consultation, by early August 2019.

2) Formaldehyde and formaldehyde releasers

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the expert accompanying the regular Cefic stakeholder observer, the occasional stakeholder observers from EuPC and ETRMA, as well as the expert accompanying the occasional stakeholder, and the RAC Rapporteurs. He informed the participants that the restriction dossier had been submitted by ECHA in January 2019. The proposal aims to restrict the placing on the market or the use of articles that would release formaldehyde above a certain threshold (concentration ≥ 0.124 mg/m^3 in the air of a test chamber under the conditions prescribed in EN 717-1). Formaldehyde released from an article may come from formaldehyde and/or other substances that release formaldehyde (formaldehyde releasers) used in the production process of the article. Articles subject to the CMRs in textiles restriction as well as the use of formaldehyde and formaldehyde releasers as biocide are exempted from the proposed restriction.

RAC discussed the first draft opinion and the approach taken by the Rapporteurs for the hazard evaluation. RAC Members asked the dossier submitter to clarify the scope of the restriction proposal. The dossier submitter representative noted that the proposed wording of the Annex XVII entry is relatively broad and the restriction applies to all articles. However, the dossier submitter clarified that the focus of the proposed restriction is on articles produced with the use of formaldehyde or formaldehyde-based substances. Articles used exclusively outdoors are considered out of the scope. Wood-based articles have been identified as the most relevant permanent emission source of formaldehyde, hence the focus of the assessment on these types of articles. The dossier submitter informed next update of the Background Document will provide

further clarification on the proposed restriction scope. Responding to the RAC Members' questions, the dossier submitter further clarified that untreated articles are intended to be outside of the scope of the restriction proposal, despite the fact that solid wood also releases a small amount of formaldehyde as a part of the natural breakdown of lignin. However, if solid wood was treated with formaldehyde or formaldehyde-based substances (e.g. painting, varnishing or impregnation), it will fall into the scope of the proposed restriction.

The RAC Members and the representative of the occasional stakeholder observer discussed the conditions and limitations of the available standard testing methods EN 717-1 (Wood-based Panels – Determination of Formaldehyde Release – Formaldehyde emission by the chamber method), which is referred to in the Annex XVII entry proposal by the dossier submitter, and EN 16516 (Construction products: Assessment of release of dangerous substances - Determination of emissions into indoor air). The EuPC expert noted that the smallest testing chamber size for EN 717-1 is 225 L with a loading rate of 1 m^2/m^3. EN 16516 is more flexible with regard to chamber size and loading rate and uses a more up-to-date analytical method. The biggest chamber for testing under EN 16516 used in Europe, according to the EuPC expert, is about 50 m^3. EN 16516 determines 29 VOCs and formaldehyde in one test, while the EN 717-1 testing method is specifically designed for the determination of formaldehyde. A representative of the European Commission expressed their concerns with regard to stating a specific testing method in the Annex XVII entry. They also noted that while the CMRs in textiles restriction sets a content limit for formaldehyde, the current restriction proposal would introduce an emission limit on textile articles not covered by the CMRs in textiles restriction. This would result in a situation where a content limit applies to some textile articles while an emission limit would apply to other textile articles. A representative of the occasional stakeholder observer from ETRMA expressed concerns on the suitability of the proposed test methods for all types of articles and on the current scope of the restriction proposal as it would also include articles with no or negligible formaldehyde releases. A list of articles for exemption will be submitted by the association in the public consultation.

During their further presentation the RAC rapporteurs discussed the use of the DNEL of 0.1 mg/m^3 (30-min average concentration) as proposed by the dossier submitter, based on an existing WHO guideline. This DNEL value is derived from human sensory irritation data and based on a NOAEC of 0.6 mg/m^3 for eye blinking frequency (EBF) and is adjusted by using an Assessment Factor (AF) of 5 derived from the standard deviation of nasal pungency thresholds. A limit based on this short-term test result would also prevent long-term health effects. According to the dossier submitter, ECHA's policy is to use assessments carried out under relevant Community legislation when available in accordance with Annex I of REACH. However, the RAC rapporteurs noted concerns that the high baseline variability of the EBF response could prevent the detection of statistically significant effects at low doses. They also proposed that an AF of 10, as given in the ECHA Guidance as a default value, would be a more appropriate AF. The ECHA Guidance also advises against the use of low AF, if a small sample is used (10-30) and the variability in population is not covered.

The Rapporteurs proposed to consider a DNEL of 0.05 mg/m^3 based on a weight of evidence approach taking into account available data for cell proliferation; hyper/metaplasia; irritation/inflammation/hyperplasia/early tumour responses in rats and monkeys. After discussion on the available evidence to be used in setting the DNEL, and pending a further consultation of the text, RAC agreed in principle on a weight of evidence approach considering human and animal data for the relevant precursor events, deriving a chronic DNEL of 0.05 mg/m^3 for the inhalation route based on a study with monkeys (Rusch et al., 1983).

The Committee also held a brief discussion on the exposure scenarios presented in the Background Dossier. The RAC rapporteurs presented information relating to 1) Formaldehyde

concentrations in buildings from permanent emission sources (measurement data on residential buildings and Monte Carlo simulations), 2) Mixtures (modelling consumer exposure from mixtures), and 3) Temporary emission sources (measurement data). The Rapporteurs noted that there is no exposure scenario for indoor environments other than buildings, such as road vehicles, railway coaches and aircraft due to absence of information. Both the dossier submitter and RAC rapporteurs expressed their hope that exposure information for these kinds of indoor environments will be submitted by the interested parties in the public consultation.

The Rapporteurs were requested to take the discussion of RAC-49 and the results of the RAC consultation after RAC-49 into account in the second draft RAC opinion. The Chairman concluded that the Committee will continue discussions on the exposure and risk parts of the draft RAC opinion at the next Committee meeting RAC-50 in September 2019. He also encouraged industry to contribute actively to the ongoing public consultation by submitting available data ahead of the next RAC plenary meeting in September.

3) Intentionally added microplastics

The Chairman welcomed the RAC rapporteurs, the Dossier Submitter representatives from ECHA, supported by experts from Sweden via WebEx. The Chairman also welcomed the occasional stakeholders and their accompanying experts (from A.I.S.E, MedTech Europe, IFRA, IVC, ETRMA, EuPC, Cosmetics Europe, Yara and from CIRFS) and the regular stakeholder observers and their accompanying experts (the industry expert (Corteva and AgChem manufacturers using MP) accompanying ECPA, the industry expert (MIT) accompanying Cefic, and a civil society expert (Fauna&Flora International) accompanying EEB). At the beginning of the discussions, the stakeholders were given the floor to briefly present their positions for the restriction proposal.

The Chairman informed the participants that the restriction dossier had been prepared by ECHA, with support from Sweden (KEMI) and submitted in January 2019. He explained that the proposal aims to restrict the use and placing on the market of intentionally added microplastics and is comprised of various measures including a ban on the placing on the market of uses of microplastics where they will inevitably be released to the environment, alongside requirements for better information in the supply chain and mandatory reporting for uses where better risk management could further reduce releases. The restriction includes derogations for uses in certain sectors (e.g. medicinal products) and for naturally occurring and (bio)degradable polymers. The term 'microplastic' is not consistently defined, but is typically considered to refer to small, solid particles made of a synthetic polymer. The Dossier Submitter has estimated that approximately 36 000 tonnes of intentionally added microplastics are currently released to the environment (2017 value). These are most likely to accumulate in terrestrial environments. Data on the toxicological and ecotoxicological effects of microplastics are limited, particularly for the terrestrial environment, which makes conventional risk assessment challenging. The first RAC plenary meeting was intended to discuss the proposed scope of the restriction as well as the hazard posed by microplastics. The Dossier Submitter has considered the risk assessment of microplastics using the threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH and considers that microplastics should be treated as a group of non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances. Overall, the Dossier Submitter concludes that the intentional use of microplastics in products that result in releases to the environment are not adequately controlled. The scope covers a wide range of uses in consumer and professional products, including cosmetic products, detergents and maintenance products, paints and coatings, construction materials and medical products, as well as various products used in agriculture and horticulture. The proposed restriction is estimated to result in a cumulative emission reduction of approximately 400 thousand tonnes of

microplastics over the 20 year period following its entry into force. It is also estimated that once all the transitional periods would have expired, the steady state emissions of microplastics would be reduced by 85-95% yearly compared to the baseline scenario (i.e. in the absence of a restriction).

A representative from the Commission underlined the complexity and unprecedented magnitude of the restriction dossier as well as the significant mobilisation of a wide range of stakeholders, including public entities and authorities. She drew the attention of RAC Members to certain issues requiring clarification and further elaboration in order to ensure that RAC's opinion provides a sound evidence basis for sub-sequent decision-making by the Commission. Namely, uses not analysed explicitly in the dossier, including infill material for artificial turfs; impacts of reporting and labelling requirements, including emission reduction estimated as well as dealing with uncertainties in the overall assessment. She also asked to what extent RAC is going to look into the interim biodegradability criteria proposed in the Annex XV dossier.

The Rapporteurs presented and RAC discussed the first draft opinion. Following the presentation, RAC Members requested the Rapporteurs to better elaborate the relationship between microplastic hazard, 'concern' and exposure. One civil society stakeholder observer expert pointed out that in their view, there is lack of clarity in the justification for a proposed derogation for (bio)degradable polymers. Several stakeholder observers also raised concerns regarding the proposed definition of microplastics. It was suggested that a summary table of effects observed and reliability of underlying data could be useful. The Chairman concluded that the Secretariat will arrange an ad hoc evening meeting on the proposed biodegradation criteria at RAC-50. Finally, due to the complexity of the dossier, the Chairman concluded that interested members should come forward to volunteer for an ad hoc support group to assist the RAC Rapporteurs in the opinion development.

The rapporteurs stated that this is a restriction on materials, to which ECHA clarified that it is a restriction on substances in mixtures.

In conclusion, RAC provisionally agreed that there is sufficient evidence to conclude that intentionally added microplastics constitutes a concern for the environment that needs to be addressed. RAC took note of the risk assessment and provisionally agreed that the non-threshold approach using the case-by-case assessment (Annex I, Preamble 0.10) is the most relevant to assess the risk. More specifically, RAC provisionally agreed with the grouping approach i.e. intentionally-added microplastics should be addressed as a group of polymer-based materials sharing similar physical properties and potential concern for the environment. In addition, RAC provisionally agreed with the proposed definition of microplastics that all substances with the properties of concern should be identified as 'microplastics', irrespective of the identity of the particular polymer, or the identity of any additives or other substances that could also be present.

Finally, the Rapporteurs were requested to prepare the second draft opinion, taking into account RAC-49 discussions and the RAC consultation after RAC-49, by early August 2019.

4) *N,N*-dimethylformamide

The Chairman welcomed the Dossier Submitter's representative from Italy (via WebEx), the occasional stakeholder observers from CIRFS and EUPC, as well as the expert accompanying the occasional stakeholder, and the RAC Rapporteurs. The restriction dossier had been submitted by Italy in October 2018. The proposal aims to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3%, unless exposure conditions described as DNEL values for inhalation (3.2 mg/m^3) and dermal (0.79 mg/kg bw/day) exposure of workers

are met. DMF is manufactured in the EU, and used in several industrial uses e.g. in the production of fine chemicals, pharmaceuticals, polymers, textiles, non-metallic products, and perfumes/fragrances. It is also used in the petrochemical industry and as a laboratory reagent (professional use). There is no consumer use of DMF.

The Rapporteurs presented the second draft opinion. They outlined the hazard, exposure and risk evaluation for DMF. At RAC-48, RAC preliminarily agreed on a dermal DNEL of 1.1 mg/kg/day, which was above the dermal DNEL value proposed by the dossier submitter (0.79 mg/kg/bw). RAC confirmed the approach taken by the Rapporteurs and agreed the dermal DNEL of 1.1 mg/kg/day. At RAC-48 the Committee also had made a preliminary agreement on the inhalation DNEL of 6 mg/m^3, which is higher than 3.2 mg/m^3 suggested by the dossier submitter. The systemic long term DNEL of 6 mg/m^3 for inhalation based on rabbit developmental toxicity data and human liver toxicity data was agreed by the Committee. Regarding the proposal for a biomarker DNEL value, one RAC Member explicitly supported setting of DNEL for NMF_{total}/L urine. However, the RAC rapporteurs explained that the restriction proposal does not contain such value, therefore it might be inappropriate to introduce it. The rapporteurs added that RAC may add in the draft opinion some recommendations on biomarker DNEL/recommendation limit value for workplace exposure.

During the following discussion on exposure the rapporteurs concluded that the information on the uses described and listed in the Annex XV restriction report is rather limited since only a sparse general description is provided. In addition, the air monitoring data on DMF concentrations presented provide only limited support to the modelled data since the measurements were not performed under the same conditions as described for the modelled data. Information on combined (aggregated, shift-long) exposure was presented for two uses only. All in all, the exposure assessment in the Annex XV restriction report was not considered by the Rapporteurs to be a robust basis for the risk assessment. They also point out that the use of a TIER 1 model for the exposure assessment always results in some uncertainties. However, the Rapporteurs were of the opinion that the exposure estimation presented in the Annex XV restriction dossier can be used as basis for the risk characterisation, because the modelling may sufficiently well represent the typical conditions and RMMs (including PPE) of different settings. In addition, the Rapporteurs were aware of the uncertainties regarding the use of PROCs and highlighted this issue in the section "Risk characterisation". The Rapporteurs also were aware of the fact that dermal exposure modelling could result in overestimation since local exhaust ventilation had not been taken into account. On the other hand they acknowledged that dermal exposure also could be underestimated because the modelled values do not consider the fact that DMF vapour is readily absorbed via the exposed skin. Following a brief discussion the Committee agreed on the rapporteurs' conclusions on the exposure assessment in the draft opinion.

During the Rapporteurs' presentation on risk assessment they concluded that they have doubts whether PROC 19 ("manual activities involving hand contact") occurs in the production of pharmaceuticals. During the public consultation the following statement had been received from the relevant industrial sector: "The OCs and RMMs applied in the pharmaceutical industry for manufacturing of active ingredients will allow the proposed exposure limits to be achieved." They also questioned if there is risk that is not adequately controlled for individual activities/tasks in this sector. The man-made fibres industry and the polyurethane coatings and membranes sectors pointed out that PROC 10 was not relevant for their uses, and that "The proposed DNEL for the inhalation route would be complied with when RPE is used". They also commented that wearing continuously RPE for a whole shift is prohibited in some countries. The Rapporteurs admitted that since it is not clear if these statements are valid for all companies in

this sector in Europe, they noted that there might be a risk for workers that is not adequately controlled.

RAC agrees with the Dossier Submitter's conclusion that risks might be adequately controlled in the following sectors, based on the modelled exposure/risk estimation: manufacture of substance, formulation of the substance, industrial use for the manufacture of perfumes/fragrances, industrial use in the petrochemical industry (including industrial gases industry), and professional use as laboratory agent. The Rapporteurs pointed out that the combined/aggregated exposure resulting from the different tasks workers have to perform within one working day, is not sufficiently well addressed in the Restriction dossier. Only two combinations (e.g. combination of PROC 2 and 8b in the "Industrial use for the production of fine chemicals" and PROC 9 and PROC 10 in the "Industrial use for the production of textiles, leather and fur") were considered. The limited consideration of potential combined exposure during a working day raises some uncertainties with regard to all other uses. The Rapporteurs also noted that the industrial gases industry confirmed their ability to comply with the exposure concentrations recommended in the Annex XV restriction report.

During the discussion a representative from IVC/CIRFS informed that in the public consultation they submitted information that dermal exposure model is underestimating exposure (If the temperature parameter is increased in the model used by the Dossier Submitter, inhalation exposure is also increased but dermal exposure remains the same). They also stated that the proposed restriction is an appropriate measure. Following a question by a representative of the European Commission about PROC 10 exposure scenario, the ECHA Secretariat responded that both PROC 10 and PROC 19 are uses advised against in the registration dossier. There were no downstream user notifications submitted for uses in which these two PROCs would occur. The ECHA Secretariat also reminded RAC that downstream user notifications are to be submitted by companies using DMF in quantities of 1 t/year or more and CSR – for any tonnage[2]. Following the discussion the Committee agreed that as several RCRs > 1, this indicate that exposure is not sufficiently controlled in all workplaces. RAC concluded that there is risk that needs to be addressed.

The Rapporteurs were requested to prepare the third draft opinion, taking into account RAC-49 discussions and the results of the public consultation, by the beginning of August 2019.

5) Cobalt salts

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the SEAC Rapporteurs (following the discussion remotely via WebEx), an industry expert accompanying the regular Eurometaux stakeholder observer, and an occasional stakeholder observer. He informed the participants that the restriction dossier had been submitted in October 2018 and proposes to restrict the placing on the market, manufacture and use of the cobalt salts as substances on their would own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications. The five cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)) are manufactured and used in a variety of sectors within the European Economic Area, including the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. The cobalt salts are classified as Carc. 1B (inhalation), Muta. 2, Repr. 1B and as skin and respiratory sensitisers. In 2016, RAC had agreed that the cobalt salts should be considered as genotoxic carcinogens with a non-threshold mode of action and had endorsed a dose-response relationship for these substances.

[2] https://echa.europa.eu/regulations/reach/downstream-users/more-on-downstream-user-responsibilities/downstream-user-chemical-safety-assessment

The Rapporteurs presented and RAC discussed the third draft opinion. They reminded the Committee that the dossier submitter had used the RAC (2016) dose-response derived on the respirable fraction (and also applied to the inhalable fraction) to calculate the risks in different exposure scenarios and to set the reference limit for occupational exposure. The risk level of $1*10^{-5}$ (which according to the REACH guidance could be seen as indicative tolerable risk levels when setting DMELs for workers) had been chosen and a corresponding exposure level had been set as a reference limit 0.01µg/m³. The Rapporteurs noted that since the last RAC meeting, industry had provided some new *in vitro* mechanistic data, in addition to two new epidemiological studies published since 2016 (Sauni et al., 2017, and Marsh et al., 2017), due to which they considered that there is a need to re-evaluate whether the current data is sufficient to apply MoA based threshold approach as agreed by RAC/SCOEL JTF and as written down in Draft appendix to R.8 guidance. The Rapporteurs compared this dossier with the nickel case and highlighted that the main difference between these two cases are that for nickel, there was some additional *in vivo* dose-response data on non-cancer effects that is not available for cobalt, and the question is then how critical this information is considered for MoA based threshold setting and how much weight is given to negative human data. The Rapporteurs reminded the Committee that while RAC (2016) had stated in its conclusions that 'the cobalt salts may be considered genotoxic carcinogens using a non-threshold approach for risk assessment' it also had acknowledged that 'the current scientific findings and mode of action considerations support the notion that water soluble cobalt substances may be threshold carcinogens although there are some uncertainties related to initiation by catalytic ROS generation and direct oxidative DNA damage'. Because of these threshold mechanisms, the use of a linear approach for dose-response is a very conservative approach, which is likely to result in the overestimation of risks especially at lower exposure levels (acknowledged also by RAC 2016). According to the Rapporteurs, based on the current analysis of available data, the level of 1 µg/m³ could possibly be considered to represent a MoA based threshold in the dose-response curve for cobalt carcinogenicity. This threshold is based on inflammation, and secondary genotoxicity driven by inflammatory effects. The Rapporteurs stressed that this is not necessarily a true health-based threshold below which any remaining risks can be excluded, but rather a more pragmatic threshold below which residual risk is likely to be low. One member, supported by several other RAC Members, reminded that in the previous RAC-48 plenary, it had been agreed that RAC would support the dossier submitter's approach, if no new data is provided by industry meanwhile in the public consultation that would give the reason for RAC to change their approach. As the new data received from industry does not give sufficient evidence to deviate from the non-threshold approach. It was questioned why RAC is deviating from its earlier agreement. Another member pointed out that it is clear that the exposures are high and that there is a risk that needs to be addressed at any level. For that purpose it may be more practical to set a fixed limit, rather than dose-response (also from the enforceability and monitorability point of view). Several other RAC Members expressed support for these views. It was finally agreed that due to the lack of quantitative in vivo dose-response data on local genotoxicity versus inflammation and the uncertainties in the available data prevent the MoA-based approach agreed by the joint task force between RAC and SCOEL from being applied. This would then leave the dossier submitters approach, but although RAC did not reject the REV, the Committee recognised the conservatism in the non-threshold approach, due to the likely impact of inflammation and indirect genotoxicity on the dose-response of cobalt carcinogenicity. RAC agreed to consider an alternative approach, assuming the dose-response curve to have a breakpoint based on inflammation, while describing clearly the uncertainties and the remaining cancer risk below this level. Several RAC Members expressed their concerns regarding a breakpoint value of 1 µg Co/m³. This value was estimated by applying an assessment factor of 30 (3x5x2) which was not considered protective enough due to the uncertainties related to the threshold for inflammation (the possibility of indirect genotoxicity occurring below the threshold

for inflammation cannot be excluded) and the severity of the effects. One RAC Member suggested that a higher assessment factor, in the order of 50 to 100, was probably needed to account for the significant level of uncertainty related to the threshold value, and this was finally agreed.

In relation to cancer risk of non-respirable particles, the Rapporteurs informed RAC that the dossier submitter had applied the dose-response relationship derived for lung cancer to characterize also local upper respiratory tract and systemic cancer risk since it was not possible to exclude systemic and local carcinogenicity caused by the particles deposited to upper respiratory tract and ingested. Therefore, the same lung cancer dose-response had been applied also for non-respirable cobalt dust. The Rapporteurs explained to the Committee that as there is no evidence on these cancers from studies with cobalt salts and as concluded by RAC (2017) on cobalt metal the mechanisms of systemic cancers may be related to the high doses used in animal studies and may exert a threshold, applying a lung cancer dose-response for non-respirable cobalt dust is not considered appropriate from the toxicological point of view in the view of the Rapporteurs. RAC agreed that applying the dose-response for lung cancer to systemic and upper respiratory tract carcinogenicity was not justified. There was not sufficient indication that the inhalable fraction would significantly increase the individual cancer risk.

With regard to exposure and emissions, the Rapporteurs noted that the levels of exposure as presented in the dossier are of an order of magnitude to be expected in their view and that the exposure values are for all of the evaluated uses significantly higher than the proposed reference exposure value of 0.01 µg/m³. The Rapporteurs reminded the Committee that the dossier submitter had made risk characterisation based on linear extrapolation and found excess cancer risks $>10^{-4}$ in almost all scenarios and that the dossier submitter had selected the level of 0.01 µg/m³, representing calculated cancer risk level of $1*10^{-5}$, as a reference value to be applied for cobalt salts (RO1d). The Rapporteurs had made risk characterisation using four different approaches: 1) Linear dose-response and 100% respirable particles (the approach by the dossier submitter); 2) Linear dose-response and 50% respirable particles; 3) Breakpoint at ~ 1µg/m³ resulting in 10-fold reduction in cancer risk (factor of 10 is a default factor coming from the German AGS approach), 50% respirable particles and 4) True threshold at 1µg/m³, 50% respirable particles. The Rapporteurs proposed that RAC should decide which of the options to choose, noting that all of them include some uncertainties or default assumptions. RAC agreed to use 50% respirable fraction in the exposure assessment.

The Rapporteurs were requested to update the third draft opinion by mid-June 2019 in line with RAC-49 discussions for a further RAC written consultation. The Rapporteurs were also requested to prepare a next draft opinion, taking into account RAC-49 discussions, the RAC written consultation and the results of the public consultation, by early August 2019.

6) Plastic and rubber granulates containing PAHs

The Chairman welcomed the Dossier Submitter representatives from the Netherlands (via WebEx) and the RAC Rapporteurs, two occasional stakeholders (from EuPC and from ETRMA). He informed the participants that the restriction dossier was submitted by the Netherlands in July 2018, in cooperation with ECHA. The proposed restriction focusses on granules and mulches used as infill material in synthetic turf pitches and in loose form on playgrounds and in sport applications. The basis for this dossier is a concern for human health resulting from the current concentration limits for polycyclic aromatic hydrocarbons (PAHs) in End-of-Life Tyre (ELT)-derived rubber infill granules used in synthetic turf pitches. The primary concern is to address risks to individuals playing and performing sports activities (e.g. football) on artificial turf pitches

with rubber granules made of recycled tyres. Recent evaluations by RIVM (2017) and ECHA (2017) concluded that PAH levels found in granules on synthetic turf pitches currently in use are assessed to have a relatively low excess cancer risk. However the reports highlighted that the current concentration limits permitted in entry 28 of Annex XVII of REACH are insufficient to adequately protect those who come into contact with the granules and mulches while playing at sports facilities and playgrounds. The public consultation on this dossier finished on 19 March 2019 with 31 comments received.

The Rapporteurs presented the third draft opinion, which was modified following the RAC written commenting round. RAC then discussed the Rapporteurs' proposal for the remaining issues in the draft opinion, mainly related to editorial changes of the restriction proposal.

RAC agreed that action is required on a Union wide basis and that the suggested restriction is the most appropriate EU wide measure.

Finally, RAC agreed that the proposed restriction is effective in reducing the identified risk noting, however, that the restriction may have limited effectiveness in Member States where the End of Waste status of rubber granules has not been agreed. RAC also agreed that the proposed restriction is implementable, enforceable, manageable and monitorable. The Commission observers pointed out that some further information would be appreciated on how the theoretical maximum concentration limit of 387 mg/kg was derived by the Dossier Submitter. The Secretariat confirmed that this will be added to the Background Document.

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

10. Authorisation

10.1 General authorisations issues

a) Update on incoming/future applications

The Secretariat informed the Committee that 38 new applications for authorisation were received during the May 2019 submission window. One of them is on use of chromium trioxide for Electrolytic Chromium Coating of Steel. Another seven are applications for authorisation for the uses of coal tar pitch, high temperature (CTPHT) formulation of mixtures (five AfAs) and manufacture of clay targets (two AfAs). Four of these AfAs involve also use of anthracene oil in formulation of mixtures. The remaining 30 applications for authorisation are for the uses of octylphenol ethoxylates and nonylphenol ethoxylates in the life sciences sector, including production of pharmaceutical active ingredient, formulation of reagents further incorporated in in vitro devices, their production and their use by professionals, such as laboratories, hospitals etc. Key issues in the new applications for authorisation will be discussed at RAC-50 plenary meeting in September 2019.

The Secretariat also informed about high numbers of applications for authorisation expected to be received during extraordinary submission window which is open until 4 July 2019 and during the regular August 2019 submission window.

b) Report from the AfA Working Group

The Secretariat presented to the Committee the Report of the 1st Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC-AFA WG) which took place in ECHA 16-17 April 2019.

The Committee took note of the Report. The Secretariat informed members about tentative dates of RAC-AFA WG meetings in 2019 and 2020.

10.2 Authorisation applications

a) Discussion on key issues

1) 11 applications for authorisation received during the February 2019 submission window (7 OPE/NPE, 3 Cr(VI), 1 CTPHT)

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the new applications for authorisation and specified the identified key issues in the applications listed below:

- CT_TES (single use, downstream)
- SC_Ariston (single use, downstream)
- SD_Bussi (single use, downstream)
- CTPht_Ariane (single use; downstream)
- OPE_Boehringer (single use, downstream)
- OPE_Ortho (two uses, downstream)
- OPE_Stago (two uses, downstream)
- OPE_BioMarin (two uses, downstream)
- OPE_Sebia (three uses, downstream)
- NPE_Sebia (single use, downstream)
- OPE_bioMerieux (three uses; downstream)

b) Agreement on draft opinions

1) CT_Aloys

This is a downstream user's application for authorisation on one use of chromium trioxide.

Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications. The applicant is using 1 to 10 tonnes of the substance annually. 38 workers are exposed directly on 1 site in Germany. Combined risk level for workers is 3.28×10^{-3}, combined risk for humans via the environment is 9.41×10^{-6}. The applicant requested a long (12-year) review period.

The RAC rapporteur concluded that RMMs already implemented, in relation to both workers and general population, can be considered to be appropriate and effective in limiting the risk. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. The RAC rapporteur proposed before the RAC consultation on the draft opinion to A-list the draft opinion at the RAC-49 plenary. A written RAC consultation had been held prior to RAC-49 on the draft opinion; 7 comments were submitted from members during the commenting round. The Committee agreed on the draft opinion via A-listing procedure.

2) CT_Ideal

This is a downstream user's application for authorisation on two uses of chromium trioxide.

Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications. The applicant is using 10 to 100 tonnes of the substance annually. 171 workers are exposed directly on 3 sites in Germany and Bulgaria. Combined risk level for workers is 3.05×10^{-3}, combined risk for humans via the environment is 2.29×10^{-6}. The applicant requested a long (12-year) review period.

The RAC rapporteur concludes that RMMs as proposed in the application are appropriate and effective in limiting the risk. As the application refers to the future increase in production, the applicant should prove the effectiveness of the RMMs (both for worker protection and reducing emissions to the environment) implemented and used in all applicants facilities by using relevant on site monitoring data. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. The RAC rapporteur proposed before the RAC consultation on the draft opinion to A-list the draft opinion at the RAC-49 plenary.

Use 2: Etching of plastics with chromium trioxide as pre-treatment step for electroplating processes. The applicant is using 1 to 10 tonnes of the substance annually. 10-50 workers are exposed directly on 1 site in Bulgaria. Combined risk level for workers is 1.74×10^{-3}, combined risk for humans via the environment is 1.23×10^{-6}. The applicant requested a long (12-year) review period.

The RAC rapporteur concludes that RMMs as proposed in the application are appropriate and effective in limiting the risk. As the application refers to the future increase in production, the applicant should prove the effectiveness of the RMMs (both for worker protection and reducing emissions to the environment) implemented and used in the applicant's facilities by using relevant on site monitoring data. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. The monitoring also comprises emission to air and waste water. The RAC rapporteur proposed before the RAC consultation on the draft opinion to A-list the draft opinion at the RAC-49 plenary.

A written RAC consultation had been held prior to RAC-49 on the draft opinions; 6 comments were submitted from members during the commenting round. The Committee agreed on the two draft opinions via A-listing procedure.

3) CT_Keuco

This is a downstream user's application for authorisation on two uses of chromium trioxide.

Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications. The applicant is using 1 to 10 tonnes of the substance annually. 36 workers are exposed directly on 1 site in Germany. Combined risk level for workers is 1.81×10^{-3}, combined risk for humans via the environment is 8.4×10^{-7}. The applicant requested a long (12-year) review period.

The RAC rapporteur concludes that RMMs already implemented, in relation to both workers and general population, can be considered to be appropriate and effective in limiting the risk. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. The RAC rapporteur proposed before the RAC consultation on the draft opinion to A-list the draft opinion at the RAC-49 plenary.

Use 2: Etching of plastics with chromium trioxide as pre-treatment step for electroplating processes. The applicant is using 1 to 10 tonnes of the substance annually. 14 workers are exposed directly on 1 site in Germany. Combined risk level for workers is 3.46×10^{-3}, combined risk for humans via the environment is 1.96×10^{-6}. The applicant requested a long (12-year) review period.

The RAC rapporteur concluded that RMMs as proposed in the application are appropriate and effective in limiting the risk. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. The RAC rapporteur proposed before the RAC consultation on the draft opinion to A-list the draft opinion at the RAC-49 plenary.

A written RAC consultation had been held prior to RAC-49 on the draft opinions; 7 comments were submitted from members during the commenting round. The Committee agreed on the two draft opinions via the A-listing procedure.

4) CT_Schell

This is a downstream user's application for authorisation on one use of chromium trioxide.

Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications. The applicant is using 1 to 10 tonnes of the substance annually. 46 workers are exposed directly on 1 site in Germany. Combined risk level for workers is 1.71×10^{-3}, combined risk for humans via the environment is 1.94×10^{-6}. The applicant requested a long (12-year) review period.

The RAC rapporteur concluded that RMMs already implemented, in relation to both workers and general population, can be considered to be appropriate and effective in limiting the risk. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. The RAC rapporteur proposed before the RAC consultation on the draft opinion to A-list the draft opinion at the RAC-49 plenary. A written RAC consultation had been held prior to RAC-49 on the draft opinion; 8 comments were submitted from members during the commenting round. The Committee agreed on the draft opinion via A-listing procedure.

5) CT_Thyssen

This is a downstream user's application for authorisation on two uses of chromium trioxide. Both uses are conducted on the same site in Germany.

Use 1: Use of Chromium (VI) Trioxide for Passivation of tinplated steel (ETP). The applicant is using 95 tonnes of chromic acid (50% CrO_3 dissolved in water) maximum per year. 377 workers are exposed directly. Combined risk level for workers are 0 to 2.41×10^{-4}, combined risk for humans via the environment is 1.17×10^{-5}. The applicant's requested review period is 7 years (starting from expected decision in 2020).

The RAC rapporteur concludes that RMMs implemented in relation to workers and human via the environment are appropriate and effective in limiting the risk. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. Before the RAC consultation on the draft opinion, the RAC rapporteur proposed to A-list the draft opinion at the RAC-49 plenary. However, during the RAC consultation on the draft opinion two RAC Members wished to discuss the proposed conditions and monitoring arrangements in the plenary.

Use 2: Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS). The applicant is using 200 tonnes of chromic acid (50% CrO_3 dissolved in water) maximum per year. 57 workers are exposed directly. Combined risk level for workers is 0 – 6.84 x 10^{-4}, combined risk for humans via the environment is 5.24 x 10^{-6}. The applicant's requested review period is until the end of 2028.

The RAC rapporteur concludes that RMMs implemented in relation to workers and human via the environment as well as the environment are appropriate and effective in limiting the risk. Additional monitoring arrangements related to exposure assessment are recommended for the authorisation, also recommendations to the applicant related to the content of the potential Review Report are made. Before the RAC consultation on the draft opinion, the RAC rapporteur proposed to A-list the draft opinion at the RAC-49 plenary. However, during the RAC consultation on the draft opinion two RAC Members wished to discuss the proposed conditions and monitoring arrangements in the plenary.

RAC agreed on the two draft opinions as proposed by the rapporteur. RAC concluded that there appear to be no alternatives that would further reduce the overall risks. RAC was of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the humans via the environment. RAC set the following additional monitoring arrangements for the authorisation and the Review Report. Regular monitoring of emissions to the air (in line with the requirements set in the environmental permit delivered by the national environmental authority) shall be conducted. In addition, if the applicant switches from chromic acid (liquid) to chromium trioxide (solid), monitoring of workers exposure during the dissolution step shall be conducted regularly. The information gathered via the measurements and related contextual information shall be used by the applicant to confirm the effectiveness of the OCs and the RMMs in place and, if needed, to introduce measures to further reduce workplace exposure respectively air emissions to chromium (VI). Besides, the information from the monitoring programmes and any further measures of exposure / emissions reduction shall be documented, maintained and made available by the authorisation holder, upon request, to the competent authority. RAC agreed to give no advice to SEAC on the length of the review period.

The Chairman thanked the rapporteur for the presentation of the arguments and the Committee members for their comments.

11. AOB

The Chairman reported on the work of the DG-Employment Working Party on Chemicals meeting in April 2019, informing the Committee of the outcome of the discussions on impact assessments provided by consultants in determining Occupational Exposure Limits for benzene, nickel compounds and acrylonitrile. He noted that the Secretariat would continue to follow the progress of OEL values proposed by RAC in the future.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 49 **4-7 June 2019**
12-13 June 2019
(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/49/2019**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-49 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications	
5. Report from other ECHA bodies and activities	
a) Report on RAC 48 action points, written procedures and update on other ECHA bodies **SECR** presented document **RAC/49/2019/01.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes	
7. Health based exposure limits at the workplace	
a) Working Procedure for RAC on the evaluation of occupational exposure limits and other values **SECR** presented document **RAC/49/2019/02** for agreement. RAC agreed with the Working Procedure for RAC on the evaluation of occupational exposure limits and other values	**SECR** to publish the agreed Working Procedure on the ECHA website and S-CIRCABC IG.
8. Harmonised classification and labelling (CLH)	
8.2 CLH dossiers	

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

Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC through fast-tracking.

- 2-phenoxyethanol: acute toxicity (oral and inhalation routes of exposure)
- mecoprop-P (ISO): acute toxicity (oral route of exposure), STOT RE
- 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol: toxicity to reproduction
- diflufenican (ISO):hazardous to the ozone layer
- tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate: skin corrosion / irritation
- 3-aminomethyl-3,5,5-trimethylcyclohexylamine: acute toxicity (dermal route of exposure), serious eye damage / eye irritation, skin sensitisation (except setting an SCL value)
- azamethiphos (ISO): selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid), acute toxicity, skin corrosion/irritation, serious eye damage/irritation, toxicity to reproduction, aspiration hazard, environmental hazards
- S-abscisic acid: selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid), acute toxicity, STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, toxicity to reproduction, STOT RE, environmental hazards
- 2,2-dibromo-2-cyanoacetamide (DBNPA): selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid, substance or mixture corrosive to metals), acute toxicity (dermal route of exposure), STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, carcinogenicity, germ cell mutagenicity, toxicity to reproduction, environmental hazards, hazardous to the ozone layer
- pyriofenone: physical hazards, acute toxicity, STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, environmental hazards

B. Substances with hazard classes for agreement in plenary session

Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC, including those agreed through fast-tracking.

- 2-phenoxyethanol
- mecoprop-P (ISO)
- 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol
- diflufenican (ISO)
- tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate
- 3-aminomethyl-3,5,5-trimethylcyclohexylamine
- azamethiphos (ISO)
- imidacloprid (ISO)

• S-abscisic acid • 2,2-dibromo-2-cyanoacetamide (DBNPA) • 5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone)	
1. 2-phenoxyethanol	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, ATE(oral)=1394 mg/kg bw Eye Dam. 1; H318, STOT SE 3; H335 (respiratory tract irritation)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
2. mecoprop-P (ISO)	
RAC agreed on the harmonised classification and labelling for acute oral toxicity and for hazards to aquatic environment as indicated in Table 2 below. RAC discussed toxicity to reproduction and agreed that further assessment was needed to conclude on this hazard (for both endpoints - fertility and development). RAC requested IND to provide original study report for the one-generation study in rats. [Acute Tox. 4; H302, ATE(oral)=431 mg/kg bw, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**IND** to provide the Rapporteur (though ECHA) with original study report on the one generation study in rats. **Rapporteurs** to assess the study reports and revise the opinion taking into account the discussion in RAC and to provide it to SECR. **SECR** to put the revised draft opinion / toxicity to reproduction for a RAC consultation prior to RAC 50 and schedule the dossier for the discussion at RAC 50 in September 2019.
3. 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F]	**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. diflufenican (ISO)	

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1; H400 (M = 10 000) and Aquatic Chronic 1; H410 (M = 1 000)]	**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.
5. tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [no classification]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
6. 3-aminomethyl-3,5,5-trimethylcyclohexylamine	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, ATE(oral) = 1030 mg/kg bw), Eye Dam. 1; H318, Skin Sens. 1A; H317, SCL of 0.001%]	**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. azamethiphos (ISO)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Acute Tox. 3; H331, ATE(inhalation) = 0.5 mg/L (dusts and mists), Acute Tox. 4; H302, ATE(oral)= 500 mg/kg bw, Skin Sens. 1; H317, STOT SE 1; H370 (nervous system), Aquatic Acute 1; H400, M=1 000), Aquatic Chronic 1; H410, M=1000]	**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.
8. imidacloprid (ISO)	
RAC adopted <u>by consensus</u> 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.

[Acute Tox. 3; H301, ATE(oral) = 131 mg/kg bw, Aquatic Acute 1; H400, M=100, Aquatic Chronic 1; H410, M=1000]	**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. S-abscisic acid	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Acute 1;H400, M=1, Aquatic Chronic 1; H410 M=1]	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
10. 2,2-dibromo-2-cyanoacetamide (DBNPA)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3 ; H301, ATE(oral)= 118 mg/kg bw, Acute Tox. 2; H330, ATE(inhalation)=0,24 mg/L, STOT RE 1 ; H372 (respiratory tract) (inhalation), Skin Irrit. 2 ; H315, Eye Dam. 1 ; H318, Skin Sens. 1; H317, 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.
11. 5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone)	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Aquatic Chronic 1; H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
9. Restrictions	
9.1 General restriction issues	
a) Report from the recent Restrictions Task Force activities RAC took note of the report from the Restrictions Task Force meeting.	**SECR** to share the Action points of the last RTF meeting with the Committee.
9.2 Restriction Annex XV dossiers	

a) Conformity check and key issues discussion	
1. Perfluorohexane-1-sulphhonic acid, its salts and related substances	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and inform the dossier submitter of the outcome.
2. Skin sensitisers in textile	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the dossier submitter.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and inform the dossier submitter of the outcome.
b) Opinion development	
1. D4/D5/D6	
Rapporteurs presented and RAC discussed the first draft opinion. RAC agreed that the justification and reasons for grouping for the purpose of this restriction are clear. RAC also agreed that the reasons for targeting the scope on consumer and professional uses are clear. RAC took note of the hazard assessment and decision of the ECHA MSC. RAC agreed that for the characterisation of risk of PBT/vPvB substances an 'environmental stock pollution approach' provides additional and useful information compared to emissions alone. Total releases of D4, D5 and D6 into the environment are used as a proxy for risk. RAC indicated provisionally that the risks may not be adequately controlled and that uses of D4, D5 and D6 are not minimised throughout their life-cycle.	**SECR** to launch written consultation on the first draft opinion. **Rapporteurs** to prepare the second draft opinion, taking into account RAC-49 discussions and RAC consultation, by early August 2019.
2. Formaldehyde	
RAC took note of the DNEL of 0.1 mg/m^3 as proposed by the dossier submitter, based on an existing WHO guideline, derived from human sensory irritation	**SECR** to launch written consultation on the first version of the draft opinion.

data. RAC highlighted several limitations of the underlying data. RAC agreed on a weight of evidence approach considering human and animal data for the relevant precursor events deriving a chronic DNEL of 0.05 mg/m^3 for the inhalation route based on a study with monkeys.	**Rapporteurs** to prepare the second draft opinion, taking into account RAC-49 discussions and RAC consultation, by early August 2019.
3. Microplastics	
Rapporteurs presented and RAC discussed the first draft opinion. RAC provisionally agreed that there is sufficient evidence to conclude that intentionally added microplastics constitutes a concern for the environment that needs to be addressed. RAC took note of the risk assessment and agreed that the non-threshold approach is the most relevant to assess the risk. RAC provisionally agreed with the grouping approach i.e. intentionally-added microplastics should be addressed as a group of polymer-based materials sharing similar physical properties and potential concern for the environment. RAC provisionally agreed with the proposed definition of microplastics that all substances with the properties of concern should be identified as 'microplastics' , irrespective of the identity of the particular polymer, or the identity of any additives or other substances that could also be present.	**SECR** to launch written consultation on the first version of the draft opinion. **Rapporteurs** to prepare the second draft opinion, taking into account RAC-49 discussions and RAC consultation, by early August 2019. **SECR** to arrange ad hoc evening group meeting on bio-degradation criteria at RAC-50. **Members** to volunteer for the ad hoc support group to assist the RAC Rapporteurs in the opinion development
4. N,N-dimethylformamide	
Rapporteurs presented and RAC discussed the second draft opinion. RAC agreed on dermal DNEL of 1.1 mg/kg/day based on a dermal study. RAC agreed on a systemic long-term DNEL of 6 mg/m^3 for the inhalation route based on rabbit developmental toxicity data and human liver toxicity.	**Rapporteurs** to prepare the third draft opinion, taking into account RAC-49 discussions and the results of the public consultation, by early August 2019.

RAC acknowledged that a biomarker DNEL should be recommended in the RAC opinion. RAC agreed on the rapporteurs' conclusions on the exposure assessment in the draft opinion. RAC agreed that the exposure estimation presented in the Restriction dossier can be used as basis for the risk characterisation, because the modelling may sufficiently well represent the typical conditions and RMMs (including PPE) of different settings. RAC agreed that as several RCRs > 1, this indicate that exposure is not sufficiently controlled in all workplaces. RAC concluded that there is risk that needs to be addressed.	
5. Cobalt salts	
The Rapporteurs presented and RAC discussed the second and third draft opinion. RAC agreed that due to the lack of quantitative *in vivo* dose-response data on local genotoxicity versus inflammation, it cannot derive a MoA-based threshold. The uncertainties in the available data prevent, the MoA-based approach agreed by the joint task force between RAC and SCOEL from being applied. RAC did not reject the dossier submitter exposure reference value but recognised the conservatism in the non-threshold approach, due to the likely impact of inflammation and indirect genotoxicity on the dose-response of cobalt carcinogenicity. RAC agreed to consider a higher limit value than suggested by dossier submitter based on inflammation, while describing clearly the uncertainties and the remaining cancer risk. RAC agreed to use 50% respirable fraction in the exposure assessment. Applying the dose-response for lung cancer to systemic and upper respiratory tract carcinogenicity was not considered justified. There was not sufficient indication that the inhalable fraction would significantly increase the individual cancer risk.	**Rapporteurs** to update the third draft opinion by mid-June 2019 in line with RAC-49 discussions for the RAC written consultation. **Rapporteurs** to prepare the fourth draft opinion, taking into account RAC-49 discussions, the RAC written consultation and the results of the public consultation, by early August 2019.
6. Plastic and rubber granulates containing PAHs	

Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on this restriction proposal by consensus.	**Rapporteurs** to make final editorial changes (as discussed during RAC-49) to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.
10. Authorisation	
10.1 General authorisation issues	
a) Report from the AfA Working Group	
RAC endorsed the Report from the 1st Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC-AFA WG).	Secretariat to attach the Report from the 1st Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation (RAC-AFA WG) to the minutes of RAC-49.
10.2 Authorisation applications	
a) Discussion on key issues	
1. 11 applications for authorisation received during the February 2019 submission window (7 OPE/NPE, 3 Cr(VI), 1 CTPHT) RAC discussed the key issues in the eleven applications for authorisation.	**SECR** to inform SEAC about the outcome of the discussion.
b) Agreement on draft opinions	
1. CT_Aloys (1 use) **2. CT_Ideal (2 uses)** **3. CT_Keuco (2 uses)** **4. CT_Schell (1 use)** RAC agreed on the six draft opinions as proposed by the rapporteur via A-listing. RAC concluded that there appear to be no alternatives that would further reduce the overall risks.	**Rapporteur** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting.

RAC is of the opinion that the RMMs and OCs described in the applications are appropriate and effective in limiting the risk to workers and the humans via the environment. For the authorisations and the review reports, RAC concluded that the applicants should implement regular monitoring programmes for chromium (VI) comprising static and/or personal inhalation sampling. The suggested monitoring arrangements are expected to address RAC's minor concerns. RAC agreed to give no advice to SEAC on the length of the review period.	
5. CT_Thyssen (2 uses) RAC agreed on the two draft opinions as proposed by the rapporteur. RAC concluded that there appear to be no alternatives that would further reduce the overall risks. 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 humans via the environment. For the authorisation and the review report, regular monitoring as covered by the discharge / emission licences shall be submitted. . RAC agreed to give no advice to SEAC on the length of the review period.	**Rapporteur** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicant for commenting.
12. Action points and main conclusions of RAC-49	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: CLH opinions which were adopted at RAC-49

1. 3-aminomethyl-3,5,5-trimethylcyclohexylamine
2. 2-phenoxyethanol
3. Imidacloprid (ISO)
4. Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate
5. 2,2-dibromo-2-cyanoacetamide (DBNPA)
6. Diflufenican (ISO)
7. Pyriofenone (ISO)
8. Azamethiphos (ISO)
9. S-abscisic acid
10. 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol

1. 3-aminomethyl-3,5,5-trimethylcyclohexylamine

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

	Index No	Chemical name	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	612-067-00-9	3-aminomethyl-3,5,5-trimethylcyclohexylamine	220-666-8	2855-13-2	Acute Tox. 4 * Acute Tox. 4 * Skin Corr. 1B Skin Sens. 1 Aquatic Chronic 3	H312 H302 H314 H317 H412	GHS05 GHS07 Dgr	H312 H302 H314 H317 H412			
Dossier submitters proposal	612-067-00-9	3-aminomethyl-3,5,5-trimethylcyclohexylamine	220-666-8	2855-13-2	**Retain** Skin Corr. 1B **Add** Eye Dam. 1 **Modify** Acute Tox. 4 Skin Sens. 1A **Remove** Acute Tox. 4 * Aquatic Chronic 3	**Retain** H314 H302 H317 **Add** H318 **Remove** H312 H412	**Retain** GHS05 GHS07 Dgr	**Retain** H314 H302 H317 **Remove** H312 H412		oral: ATE = 1030 mg/kg bw	
RAC opinion	612-067-00-9	3-aminomethyl-3,5,5-trimethylcyclohexylamine	220-666-8	2855-13-2	**Retain** Skin Corr. 1B **Add** Eye Dam. 1 **Modify** Acute Tox. 4 Skin Sens. 1A **Remove** Acute Tox. 4 * Aquatic Chronic 3	**Retain** H314 H302 H317 **Add** H318 **Remove** H312 H412	**Retain** GHS05 GHS07 Dgr	**Retain** H314 H302 H317 **Remove** H312 H412		oral: ATE = 1030 mg/kg bw Skin Sens. 1A; H317: C ≥ 0.001%	
Resulting Annex VI entry if agreed by COM	612-067-00-9	3-aminomethyl-3,5,5-trimethylcyclohexylamine	220-666-8	2855-13-2	Acute Tox. 4 Skin Corr. 1B Eye Dam. 1 Skin Sens. 1A	H302 H314 H318 H317	GHS05 GHS07 Dgr	H302 H314 H317		oral: ATE = 1030 mg/kg bw Skin Sens. 1A; H317: C ≥ 0.001%	

2. 2-phenoxyethanol

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	603-098-00-9	2-phenoxyethanol	204-589-7	122-99-6	Acute Tox. 4* Eye Irrit. 2	H302 H319	GHS07 Wng	H302 H319			
Dossier submitters proposal	603-098-00-9	2-phenoxyethanol	204-589-7	122-99-6	**Modify** Acute Tox. 4 Eye Dam. 1 **Add** STOT SE 3	**Retain** H302 **Modify** H318 **Add** H335	**Retain** GHS07 **Add** GHS05 **Modify** Dgr	**Retain** H302 **Modify** H318 **Add** H335		**Add** oral: ATE = 1394 mg/kg bw	
RAC opinion	603-098-00-9	2-phenoxyethanol	204-589-7	122-99-6	**Modify** Acute Tox. 4 Eye Dam. 1 **Add** STOT SE 3	**Retain** H302 **Modify** H318 **Add** H335	**Retain** GHS07 **Add** GHS05 **Modify** Dgr	**Retain** H302 **Modify** H318 **Add** H335		**Add** oral: ATE = 1394 mg/kg bw	
Resulting Annex VI entry if agreed by COM	603-098-00-9	2-phenoxyethanol	204-589-7	122-99-6	Acute Tox. 4 STOT SE 3 Eye Dam. 1	H302 H335 H318	GHS05 GHS07 Dgr	H302 H335 H318		oral: ATE = 1394 mg/kg bw	

3. Imidacloprid (ISO)

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

	Index No	Chemical name	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	612-252-00-4	imidacloprid (ISO); (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine	-	138261-41-3	Acute Tox. 4 * Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410			
Dossier submitters proposal	612-252-00-4	imidacloprid (ISO); (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine	-	138261-41-3	**Modify** Acute Tox. 3 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Modify** H301 **Retain** H400 H410	**Modify** GHS06 Dgr **Retain** GHS09	**Modify** H301 **Retain** H410		**Add** oral: ATE = 131 mg/kg bw M=100 M=1000	
RAC opinion	612-252-00-4	imidacloprid (ISO); (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine	-	138261-41-3	**Modify** Acute Tox. 3 **Retain** Aquatic Acute 1 Aquatic Chronic 1	**Modify** H301 **Retain** H400 H410	**Modify** GHS06 Dgr **Retain** GHS09	**Modify** H301 **Retain** H410		**Add** oral: ATE = 131 mg/kg bw M=100 M=1000	
Resulting Annex VI entry if agreed by COM	612-252-00-4	imidacloprid (ISO); (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine	-	138261-41-3	Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1	H301 H400 H410	GHS06 GHS09 Dgr	H301 H410		oral: ATE = 131 mg/kg bw M=100 M=1000	

4. Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate

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 ATEs	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	015-192-00-1	tetrakis(2,6-dimethylphenyl)-*m*-phenylene biphosphate	432-770-2	139189-30-3	Skin Sens. 1	H317	Wng	H317			
Dossier submitters proposal	015-192-00-1	tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate; tetrakis(2,6-dimethylphenyl) 1,3-phenylene bis(phosphate)	432-770-2	139189-30-3	**Remove** Skin Sens. 1	**Remove** H317	**Remove** Wng	**Remove** H317			
RAC opinion	015-192-00-1	tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate; tetrakis(2,6-dimethylphenyl) 1,3-phenylene bis(phosphate)	432-770-2	139189-30-3	**Remove** Skin Sens. 1	**Remove** H317	**Remove** Wng	**Remove** H317			
Resulting Annex VI entry if agreed by COM	No resulting entry in Annex VI of CLP										

5. 2,2-dibromo-2-cyanoacetamide (DBNPA)

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

	Index No	Chemical name	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-dibromo-2-cyanoacetamide	233-539-7	10222-01-2	Acute Tox. 2 Acute Tox. 3 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 2	H330 H301 H315 H318 H317 H400 H411	GHS06 GHS08 GHS05 GHS09 Dgr	H330 H301 H315 H318 H317 H410		inhalation: ATE = 0.275 mg/l (dusts or mists) oral: ATE = 167 mg/kg bw M=1	
RAC opinion	TBD	2,2-dibromo-2-cyanoacetamide	233-539-7	10222-01-2	Acute Tox. 2 Acute Tox. 3 STOT RE 1 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H301 H372 (respiratory tract) (inhalation) H315 H318 H317 H400 H410	GHS06 GHS08 GHS05 GHS09 Dgr	H330 H301 H372 (respiratory tract) (inhalation) H315 H318 H317 H410		inhalation: ATE = 0.24 mg/l (dusts or mists) oral: ATE = 118 mg/kg bw M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	2,2-dibromo-2-cyanoacetamide	233-539-7	10222-01-2	Acute Tox. 2 Acute Tox. 3 STOT RE 1 Skin Irrit. 2 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H330 H301 H372 (respiratory tract) (inhalation) H315 H318 H317 H400 H410	GHS06 GHS08 GHS05 GHS09 Dgr	H330 H301 H372 (respiratory tract) (inhalation) H315 H318 H317 H410		inhalation: ATE = 0.24 mg/l (dusts or mists) oral: ATE = 118 mg/kg bw M=1 M=1	

6. Diflufenican (ISO)

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

	Index No	Chemical name	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	616-032-00-9	diflufenican (ISO); *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide; 2′,4′-difluoro-2-(α,α,α-trifluoro-*m*-tolyloxy) nicotinanilide	-	83164-33-4	Aquatic Chronic 3	H412		H412			
Dossier submitters proposal	616-032-00-9	diflufenican (ISO); *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide; 2′,4′-difluoro-2-(α,α,α-trifluoro-*m*-tolyloxy) nicotinanilide	-	83164-33-4	**Modify** Aquatic Chronic 1 **Add** Aquatic Acute 1	**Modify** H410 **Add** H400	GHS09 Wng	H410		**Add** M=1000 M=100	
RAC opinion	616-032-00-9	diflufenican (ISO); *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide; 2′,4′-difluoro-2-(α,α,α-trifluoro-*m*-tolyloxy) nicotinanilide	-	83164-33-4	**Modify** Aquatic Chronic 1 **Add** Aquatic Acute 1	**Modify** H410 **Add** H400	GHS09 Wng	H410		**Add** M=10000 M=1000	

Resulting Annex VI entry if agreed by COM	616-032-00-9	diflufenican (ISO); *N*-(2,4-difluorophenyl)-2-[3-(trifluoromethyl)phenoxy]-3-pyridinecarboxamide; 2′,4′-difluoro-2-(α,α,α-trifluoro-*m*-tolyloxy) nicotinanilide	-	83164-33-4	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=10000 M=1000	

7. Pyriofenone (ISO)

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	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone; pyriofenone	692-456-8	688046-61-9	Carc. 2 Aquatic Chronic 1	H351 H410	GHS08 GHS09 Wng	H351 H410		M=1	
RAC opinion	TBD	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone; pyriofenone	692-456-8	688046-61-9	Carc. 2 Aquatic Chronic 1	H351 H410	GHS08 GHS09 Wng	H351 H410		M=1	
Resulting Annex VI entry if agreed by COM	TBD	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone; pyriofenone	692-456-8	688046-61-9	Carc. 2 Aquatic Chronic 1	H351 H410	GHS08 GHS09 Wng	H351 H410		M=1	

8. Azamethiphos (ISO)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	azamethiphos (ISO); S-[(6-chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate	252-626-0	35575-96-3	Acute Tox. 3 Acute Tox. 4 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H331 H302 H317 H400 H410	GHS06 GHS09 Dgr	H331 H302 H317 H410		inhalation: ATE = 0.5 mg/L (dusts or mists) oral: ATE = 500 mg/kg bw M=1000 M=1000	
RAC opinion	TBD	azamethiphos (ISO); S-[(6-chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate	252-626-0	35575-96-3	Carc. 2 Acute Tox. 3 Acute Tox. 4 STOT SE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H331 H302 H370 (nervous system) H317 H400 H410	GHS06 GHS08 GHS09 Dgr	H351 H331 H302 H370 (nervous system) H317 H410		inhalation: ATE = 0.5 mg/L (dusts or mists) oral: ATE = 500 mg/kg bw M=1000 M=1000	
Resulting Annex VI entry if agreed by COM	TBD	azamethiphos (ISO); S-[(6-chloro-2-oxooxazolo[4,5-b]pyridin-3(2H)-yl)methyl] O,O-dimethyl thiophosphate	252-626-0	35575-96-3	Carc. 2 Acute Tox. 3 Acute Tox. 4 STOT SE 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H331 H302 H370 (nervous system) H317 H400 H410	GHS06 GHS08 GHS09 Dgr	H351 H331 H302 H370 (nervous system) H317 H410		inhalation: ATE = 0.5 mg/L (dusts or mists) oral: ATE = 500 mg/kg bw M=1000 M=1000	

9. S-abscisic acid

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

	Index No	Chemical name	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	[*S*-(*Z*,*E*)]-5-(1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl)-3-methylpenta-2,4-dienoic acid ; *S*-abscisic acid	244-319-5	21293-29-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	
RAC opinion	TBD	[*S*-(*Z*,*E*)]-5-(1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl)-3-methylpenta-2,4-dienoic acid ; *S*-abscisic acid	244-319-5	21293-29-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	
Resulting Annex VI entry if agreed by COM	TBD	[*S*-(*Z*,*E*)]-5-(1-hydroxy-2,6,6-trimethyl-4-oxocyclohex-2-en-1-yl)-3-methylpenta-2,4-dienoic acid ; *S*-abscisic acid	244-319-5	21293-29-8	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M=1 M=1	

10. 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol

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

	Index No	Chemical name	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	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol; [DBMC]	204-327-1	119-47-1	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol; [DBMC]	204-327-1	119-47-1	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol; [DBMC]	204-327-1	119-47-1	Repr. 1B	H360F	GHS08 Dgr	H360F			

Table 2: CLH opinions carried over to RAC 50

1. Mecoprop-P (ISO)

1. Mecoprop-P (ISO)

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	607-434-00-5	mecoprop-P [1] and its salts (R)-2-(4-chloro-2-methylphenoxy)propionic acid	240-539-0	16484-77-8	Acute Tox. 4* Eye Dam. 1 Aquatic Chronic 2	H302 H318 H411	GHS07 GHS05 GHS09 Dgr	H302 H318 H411			
Dossier submitters proposal	607-434-00-5	mecoprop-P (ISO) [1] and its salts; (R)-2-(4-chloro-2-methylphenoxy)propionic acid [1] and its salts	240-539-0 [1]	16484-77-8 [1]	**Retain** Eye Dam. 1 **Modify** Acute Tox. 4 Aquatic Chronic 3	**Retain** H302 H318 **Modify** H412	**Retain** GHS07 GHS05 Dgr **Remove** GHS09	**Retain** H302 H318 **Modify** H412		**Add** oral: ATE = 431 mg/kg bw	
RAC opinion	607-434-00-5	mecoprop-P (ISO) [1] and its salts; (R)-2-(4-chloro-2-methylphenoxy)propionic acid [1] and its salts	240-539-0 [1]	16484-77-8 [1]	**Retain** Eye Dam. 1 **Modify** Acute Tox. 4 Aquatic Chronic 1 **Add** Aquatic Acute 1 Repr. 2	**Retain** H302 H318 **Modify** H410 **Add** H400 H361	**Retain** GHS07 GHS05 GHS09 Dgr **Add** GHS08	**Retain** H302 H318 **Modify** H410 **Add** H361		**Add** oral: ATE = 431 mg/kg bw M=10 M=10	
Resulting entry in Annex VI if adopted by Commission	607-434-00-5	mecoprop-P (ISO) [1] and its salts; (R)-2-(4-chloro-2-methylphenoxy)propionic acid [1] and its salts	240-539-0 [1]	16484-77-8 [1]	Acute Tox. 4 Eye Dam. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H318 H400 H410	GHS07 GHS05 GHS09 Dgr	H302 H318 H410		oral: ATE = 431 mg/kg bw M=10 M=10	

Part III. List of Attendees of the RAC-49 meeting

RAC Members
Aquilina Gabriele
Andreou Kostas
Barański Bogusław
Biró Anna
Bjørge Christine
Borg Daniel
Branisteanu Radu (co-opted member)
Brovkina Julija
Carvalho João
Chankova-Petrova Stephka
Chiurtu Elena (co-opted member)
Czerczak Sławomir
de la Flor Tejero Ignacio
Dobrev Ivan
Dunauskienė Lina
Dungey Stephen
Geoffroy Laure
Gruiz Katalin
Hakkert Betty
Husa Stine
Ilie Mihaela
Kadiķis Normunds
Kapelari Sonja
Karadjova Irina
Leinonen Riitta
Losert Annemarie
Lund Bert-Ove
Martínek Michal
Menard Srpčič Anja
Moeller Ruth
Moldov Raili
Mullooly Yvonne
Murray Brendan
Neumann Michael
Paris Pietro
Pribu Mihaela
Printemps Nathalie
Pronk Marja
Rucki Marian
Santonen Tiina
Schlüter Urs
Schulte Agnes
Séba Julie
Smith Andrew
Sørensen Hammer Peter
Sogorb Miguel A.
Spetseris Nikolaos
Stahlmann Ralf
Tobiassen Lea Stine
Tsitsimpikou Christina
Užomeckas Žilvinas
Van der Haar Rudolf (co-opted member)
Varnai Veda
Apologies, Members
Agapiou Agapios
Hartwig Andrea (co-opted member)
Heederik Dick (co-opted member)
Zeljezic Davor

Members' advisers
Esposito Dania (Pietro Paris)_CLH adviser for imidacloprid
Hoy Simon (Steven Dungey)
Hyytinen Eija-Riitta (Riitta Leinonen)
Kuittinen Marko (Riitta Leinonen)
Peczkowska Beata (Boguslaw Baranski)_CLH adviser for 2-phenoxyethanol
Sonnenburg Anna (Ralf Stahlmann)_CLH adviser for Tetrakis
Commission
Bertato Valentina (DG ENV)
Lekatos Stylianos (DG GROW)
Regular stakeholder observers
Barry Frank (ETUC)
Van de Broeck Steven (Cefic)
Comini Andrea (EuCheMS)
Fornabaio Lara (ClientEarth)
Romano Mozo Dolores (EEB)
Rowe Rocky (ECPA)
Serrano Ramon Blanca (Cefic)
Verougstraete Violaine (Eurometaux)
Waeterschoot Hugo (Eurometaux)

Dossier submitters
Correll Myhre Ingunn (NO)_PFHxS
Dorfh Helena (SE)_Skin sensitisers in textile
Heggelund Audun (NO)_PFHxS
Steward Alexandra (SE)_Skin sensitisers in textile
Occasional stakeholders
Akdag Ali (CIRFS)_microplastics, DMF
Almeida Filipe (Cosmetics Europe)_microplastics
Angiulli Francesca (A.I.S.E)_microplastics
Buijs Nathalie (MedTech Europe)_microplastics, D4/D57D6
Perfetti Marco (EuPC)_heath based exposure limits, skin sensitisers in textile, microplastics, DMF, formaldehyde, PAHs, general Authorisation issues
Perez Simbor Laia (ETRMA)_formaldehyde, microplastics, cobalt salts, PAHs
Vaini Nicole (IFRA)_microplastics
Stakeholder experts
Bade Steffen (Cefic/BASF)_2-phenoxyethanol
Ballach Jochen (Cefic/IVC)_DMF (CIRFS/IVC)_Microplastics
Begolly Sage (Cefic/Dow/duPont)_DBNPA
Begolly Sage (ECPA/Dow Biosciences)_2-phenoxyethanol
Bonifay Sebastien (ECPA/Corteva and AgChem)_microplastics
Foster John (ECPA/ISK)_pyrifenone
Gelbke Heinz-Peter (CIRFS/BASF)_DMF

Jenner Karen (IFRA/Givaudan)_microplastics

Leibold Edgar (Cefic/Formacare)_formaldehyde
Mihaylova Dilyana (EEB/Fauna&Flora)_microplastics
Moxon Mary (ECPA/Nufarm)_mecoprop-p
Mulato Riccardo (A.I.S.E/YARA)_microplastics
Plotzke Kathy (Cefic/CES-Silicone Europe)_D4/D5/D6
Salthammer Tunga (EuPC/Fraunhofer WKI)_formaldehyde
Shipp Elizabeth (ECPA/Bayer CropScience)_imidacloprid_diflufenicam
Viegas Vanessa (Eurometaux/Cobalt Institute and Cobalt REACH Consortium Ltd)_Cobalt salts
Invited expert
Susana Viegas
REMOTE PARTICIPANTS
RAC Members
Carvalho Joao
Dungey Steven
Printemps Nathalie
Smith Andrew
Sogorb Miguel A
Members' advisers
Ball Elanor (Andrew Smith)
Boel Els (Julie Seba)
Catone Tiziana (Gabriele Aquilina)
Esposito Dania (Pietro Paris)
Kinzl Maximilian (Annemarie Losert)
McGarry Helen (Andrew Smith)

Rother Dag (Ruth Moeller)
Russo Maria Teresa (Gabriele Aquilina)
Schalles Simone (Michael Neumann)
SEAC rapporteurs
Alexandre Joao (Cr)
Bergs Ivars (Cobalt salts)
Fankhauser Simone (Cobalt salts)
Fock Lars (DMF)
Krajnc Karmen (OPE NPE)
Leahy Eimear (IPE NPE)
Rouw Aarnout (OPE Boehringer and Sebia)
Dossier submitters
FR
Dubois Celine (Skin sensitizers in textile)
NL
Ter Burg Wouter (PAHs in rubber granulates)
Geraets Lisbeth (PAHs in rubber granules)
Luit Richard (PAHs in rubber granules)
SE
Carlsson Feng Mattias (Skin sensitizers in textile)
Johansson Olof (microplastics)
Mork Anna-Karin (Skin sensitizers in textile)

Moilanen Marianne (Riitta Leinonen)	

UK	
Caitens Andrea (2-phenoxyethanol, 5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone), Azamethiphos, tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate, diflufenican (ISO), Mecoprop-p	Lapenna Silvia
	Lefevre-Brevart Sandrine
Commission	Logtmeijer Christiaan
Blass Rico Ana	Ludborzs Arnis
Grow Miriam	Luschutzky Evita
Hualde-Grasa Eva Patricia	Marques-Camacho Mercedes
Krassnig Christian	Montiel Pablo
Roebben Gert	Mushtaq Fesil
Rozwadowski Jacek	Nicot Thierry
	Nygren Jonas
ECHA staff	Orispää Katja
Blainey Mark	O´Rourke Regina
Bowmer Tim, Chairman	Ottati Maria
Broeckaert Fabrice	Peltola Jukka
Broere William	Perazzolo Chiara
Di Bastiano Augusto	Pillet Monique
Dvorakova Dana	Prevedouros Konstantinos
Georgiadis Nikolaos	Regil Pablo
Gmeinder Michael	Roggeman Maarten
Hellsten Kati	Sadam Diana
Henrichson Sanna	Simoes Ricardo
Hollins Stephen	Simpson Peter
Jones Stella	Smilovici Simona
Karjalainen Ari	Sosnowski Piotr
Kivelä Kalle	Stoyanova Evgenia

Kokkola Leila	Uphill Simon
Kosk-Bienko Joanna	Van Haelst Anniek

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-49 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-49 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-49 meeting

ANNEX IV Administrative issues and information items

4 June 2019
RAC/A/49/2019

Final Agenda
49th meeting of the Committee for Risk Assessment

4 - 7 June 2019
and
12 – 13 June 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Tuesday 4 June starts at 14.00
Friday 7 June breaks at 13.00
Wednesday 12 June resumes at 09.00
Thursday 13 June ends at 17.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/49/2019
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

For agreement

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 48 action points, written procedures and update on other ECHA bodies

RAC/49/2019/01
(Room document)
For information

b) RAC workplan for all processes

For information

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

None

Item 7 – Health based exposure limits at the workplace

a) Working Procedure for RAC on the evaluation of occupational exposure limits and other values

RAC/49/2019/02

For agreement

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

a) Report from the workshop on the applicability of the Rapid Removal concept for environmental hazard classification

b) CLP– suggested changes in the timing of the Appointment of rapporteurs

For discussion/agreement

8.2 CLH dossiers

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

2-phenoxyethanol: acute toxicity (oral and inhalation routes of exposure)

mecoprop-P (ISO): acute toxicity (oral route of exposure), STOT RE

6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol: toxicity to reproduction

diflufenican (ISO):hazardous to the ozone layer

tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate: skin corrosion / irritation

3-aminomethyl-3,5,5-trimethylcyclohexylamine: acute toxicity, serious eye damage / eye irritation, skin sensitisation (except setting an SCL value)

azamethiphos (ISO): selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid), acute toxicity, skin corrosion/irritation, serious eye damage/irritation, STOT RE, toxicity to reproduction, aspiration hazard, environmental hazards

S-abscisic acid: selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable gas, oxidising solid), acute toxicity, STOT SE, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, toxicity to reproduction, STOT RE, environmental hazards

2,2-dibromo-2-cyanoacetamide (DBNPA): selected physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance or mixture which in contact with water emits flammable

gas, oxidising solid, substance or mixture corrosive to metals), acute toxicity (dermal route of exposure), STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, carcinogenicity, germ cell mutagenicity, toxicity to reproduction, environmental hazards, hazardous to the ozone layer

pyriofenone: physical hazards, acute toxicity, STOT SE, skin corrosion / irritation, serious eye damage / eye irritation, skin sensitisation, STOT RE, germ cell mutagenicity, toxicity to reproduction, environmental hazards

B. Hazard classes for agreement with plenary debate

1) 2-phenoxyethanol
2) mecoprop-P (ISO)
3) *6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol (Fully fast-tracked – no plenary discussion)*
4) diflufenican (ISO)
5) tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate
6) 3-aminomethyl-3,5,5-trimethylcyclohexylamine
7) azamethiphos (ISO)
8) imidacloprid (ISO)
9) *S-abscisic acid (Fully fast-tracked – no plenary discussion)*
10) 2,2-dibromo-2-cyanoacetamide (DBNPA)
11) 5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone)

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

a) Report from the recent Restrictions Task Force activities

For information

9.2 Restriction Annex XV dossiers

a) Conformity Check
   1) Perfluorohexane-1-sulphhonic acid, its salts and related substances
   2) Skin sensitisers in textile

For discussion and agreement

b) Opinion development
   1) D4/D5/D6 – first draft opinion
   2) Formaldehyde – first draft opinion
   3) Microplastics – first draft opinion
   4) *N,N*-dimethylformamide – second draft opinion
   5) Cobalt salts – second draft RAC opinion

For discussion

6) Plastic and rubber granulates containing PAHs – final draft opinion

For discussion and adoption

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications
b) Report from the AfA Working Group

For information

10.2. Authorisation applications

a) Discussion on key issues
   1. 11 applications for authorisation received during the February 2019 submission window (7 OPE/NPE, 3 Cr(VI), 1 CTPHT)

For discussion

b) Agreement on draft opinions

   1. CT_Aloys (1 use)
   2. CT_Ideal (2 uses)
   3. CT_Keuco (2 uses)
   4. CT_Schell (1 use)
   5. CT_Thyssen (2 uses)

For discussion and agreement

Item 11 – AOB

Item 12 – Action points and main conclusions of RAC-49

Table with Conclusions and Action points from RAC-49

For adoption

Annex II (RAC 49)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 49 meeting.

Document number	Title
RAC/A/49/2019	Final Draft Agenda
RAC/A/49/2019 Restricted	Draft outline agenda
RAC/49/2019/01 Room document	Administrative issues and information items
RAC/49/2019/02	Committee working procedure on the scientific evaluation of occupational exposure limits and other values in support of the Chemical Agents Directive and the Carcinogens and Mutagens Directive

ANNEX III (RAC-49)

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 / dossier submitter	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	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		
-	-	-
Requests under Article 77(3) (c)		
Restrictions		

New dossiers

AP/Dossier / dossier submitter	RAC Member	Reason for potential CoI / Working for
NEW		
Article 77.3(c)		
no dossiers	-	-
Restrictions		
Perfluorohexane-1-sulphhonic acid, its salts and related substances	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. No personal involvement.
	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. No personal involvement.
Skin sensitisers in textile	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.
	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. Partial personal involvement.
	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. No personal involvement.
Applications for Authorisation		
-	-	-
Harmonised classification & labelling		
1) 3-aminomethyl-3,5,5-trimethylcyclohexanamine	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

AP/Dossier / dossier submitter	RAC Member	Reason for potential CoI / Working for
2) imidacloprid (ISO) **DE**		measures applied. No personal involvement.
	Ivan DOBREV	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 SCHLUTER	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.
1) 2-phenoxyethanol **2) mecoprop-P (ISO)** **3) diflufenican (ISO)** **4) tetrakis** **5) azamethiphos (ISO)** **6) pyriofenone** **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. Personal involvement in all apart for (3).
	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 drafting / commenting on the environmental part of all dossiers.
1) 6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol **2) 2,2-dibromo-2-cyanoacetamide (DBNPA)** **DK**	Peter Hammer SORENSEN	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).
	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. Personal involvement in (1), but not in (2)
s-abscisic acid	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting

AP/Dossier / dossier submitter	RAC Member	Reason for potential CoI / Working for
NL		in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Marja PRONK	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement

Annex IV

Helsinki, 3 June 2019

RAC/49/2019/01

ROOM DOCUMENT

49TH MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

4 - 7 June 2019
and
12 – 13 June 2019

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-48 Action Points

The RAC-48 action points due for RAC-49 are completed with the exception of one CLH dossier (RAC consultation on the final opinion pending).

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-48	23 May 2019	closed

2.2 RAC consultations (status by 3 June 2019)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
2-phenoxyethanol	10 May 2019	closed
mecoprop-P (ISO)	9 May 2019	closed
6,6'-di-tert-Butyl-2,2'-methylenedi-p-cresol	7 May 2019	closed
diflufenican (ISO)	6 May 2019	closed
tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate	25 April 2019	closed
3-aminomethyl-3,5,5-trimethylcyclohexanamine	10 May 2019	closed
azamethiphos (ISO)	26 April 2019	closed
imidacloprid (ISO)	26 April 2019	closed
S-abscisic acid	6 May 2019	closed
2,2-dibromo-2-cyanoacetamide (DBNPA)	15 May 2019	closed
5-Chloro-2-methoxy-4-methyl-3-pyridyl)(4,5,6-trimethoxy-o-tolyl)methanone (Pyriofenone)	15 May 2019	closed
Application for Authorisation / Review Report		
CT_Aloys (one draft opinion) CT_Ideal (two draft opinions) CT_Keuco (two draft opinions) CT_Schell (one draft opinion) CT_Thyssen (two draft opinions) Consultations on draft opinions on	22 May 2019	closed

Subject / document	Deadline	Status / follow-up
applications for authorisation		
CT_TES SC_Ariston SD_Bussi OPE_Boehringer OPE_Ortho OPE_Stago OPE_Sebia NPE_Sebia OPE_bioMerieux CTPht_Ariane OPE_BioMarin Consultations on applications for authorisation	3 July 2019	ongoing
Restrictions		
Consultation on the second draft opinions on DMF and on Cobalt	24 May 2019	closed
Consultation on the conformity of Annex XV dossiers on PFHxS and on skin sensitisers in textile	27 May 2019	closed
Consultation on the third version of the draft opinion on Rubber granules	9 May 2019	closed
Art. 77. 3. c request		
no consultations		
Art. 77. 3. c request on evaluations OELs		
no consultations		

2.3 Other written consultations of RAC (status by 3 June 2019)

Subject / document	Deadline	Status / follow-up
Written procedure for adoption of the minutes of RAC-48	23 May 2019	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	26 April – 7 May 2019	4 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[3].		
Restriction n/a		

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

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling - no written procedures			
Written procedure for the appointment of (co-)rapporteurs	▪ carbendazim (ISO) ▪ benzophenone ▪ Perfluoroheptanoic acid (PFHpA)	22 May 2019	closed No comments were received from RAC Members on the recommendation of the Chairman; the RAC (co-)Rapporteurs were appointed with tacit agreement.
Restrictions Written procedure for the appointment of (co-)rapporteurs	▪ Appointment of RAC co-rapporteur for PFHxS restriction dossier	25 May 2019	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			

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	
No opinion had been sent since RAC-48.	

[3] 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)

RAC/M/49/2019

Appendix

Appendix to
Minutes of the 49th Meeting
of the Committee for Risk Assessment (RAC 49)

Stakeholder observers' written statements presented during the plenary discussions on Microplastics restriction proposal at RAC-49

Disclaimer: The invited stakeholder observers and their experts contributed to the written summary of statements in their capacity as individual organisations. The statements expressed in the document are their own and do not represent the views of the European Chemicals Agency or of the Committee for Risk Assessment.

International Association for Soaps, Detergents and Maintenance Products

RAC 49 A.I.S.E. OPENING STATEMENT

(Speakers' notes)

4 June 2019

Dear Members of the RAC Committee,
I address you today on behalf of A.I.S.E., the EU Association for Detergents and Maintenance Products.
A.I.S.E.'s members use different **polymers as functional ingredients** to formulate their products. Therefore, A.I.S.E. has been consulting its members to gather information on the **available scientific knowledge**, the assessment of **potential impacts** and the identification of **opportunities for innovation**.

This information has been shared with you via the on-going Public Consultation and I will now summarize the main conclusions on our scientific position where we call for further refinement of the current dossier.

Firstly, we support the need for a definition of microplastics - and of all the parameters needed to determine if a material qualifies as one - which covers plastic materials contributing to aquatic litter, e.g. by clearly indicating the role of materials' water-solubility. Also, although all plastics are polymers, not all polymers are plastics.

The current definition **goes well beyond the issue of aquatic litter and establishes a link between '*microplastics*' and '*solid polymers particles*'** without substantiating in the report the scientific ground for such link. **As a result, the proposed restriction could target hundreds of polymers that are not linked with 'plastic'.**

In addition, the Annex XV report is based on the REACH definition of polymer, while most of the dossier data refer to the term 'microplastics'. We believe this creates ambiguity on the scope of the dossier and does not provide clarity in the identification of the targeted substances.

To address these ambiguities, we suggest that:

- **Microplastics should be defined in terms of "plastic" and not of "polymer", possibly via an ISO definition, or otherwise more narrowly defined in terms of the properties which potentially cause the concern.**
- **A decision tree covering all the elements needed to conclude if a polymer is subject to the restriction should be prepared to help a practical, harmonized and clear interpretation of the definition**

To conclude, the second key aspect is the one related to the derogation 3(b) on biodegradability. A series of recommendations on the testing strategies are included in a white paper prepared with IFRA and submitted via the Public Consultation. I take the chance today to stress our support to this derogation as we believe is fit for purpose. However, the recommendations made, as well as their stability, are critical for a swift implementation of these criteria and to ensure they are applied to a relevant set of materials that can be identified without ambiguity. Thank you very much for your attention!

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International Association for Soaps,
Detergents and Maintenance Products

F. Angiulli on behalf of A.I.S.E., the EU Association for Detergents and Maintenance Products

A.I.S.E.'s members use different polymers as functional ingredients to formulate their products. Therefore, A.I.S.E. has been gathering the available scientific knowledge and has been assessing the potential impacts while looking for opportunities for innovation. The analysis of such information led to conclude that further refinement of the current dossier is needed.

Firstly, to ensure that the definition of microplastics - and of all the parameters needed to determine if a material qualifies as one - covers plastic materials contributing to aquatic litter, e.g. by clearly indicating the role of materials' water-solubility.

The current definition establishes a link between '*microplastics*' and '*solid polymers particles*' without substantiating in the report the scientific ground for such link. As a result, the proposed restriction could target hundreds of polymers that are not linked with 'plastic'.

In addition, the Annex XV report is based on the REACH definition of polymer, while most of the dossier data refer to the term 'microplastics'. This creates ambiguity on the scope of the dossier.

To address these ambiguities, A.I.S.E. suggests that:

- Microplastics should be defined in terms of "plastic" and not of "polymer", possibly via an ISO definition, or otherwise more narrowly defined in terms of the properties which potentially cause the concern.
- A decision tree covering all the elements needed to conclude if a polymer is subject to the restriction should be prepared to help a practical, harmonized and clear interpretation of the definition

The second key aspect is the implementation of derogation 3(b) on biodegradability. A series of recommendations on the testing strategies are included in a white paper prepared with IFRA. A.I.S.E. strongly supports this derogation. However, the recommendations made, as well as their stability, are critical for a swift implementation of these criteria and to ensure they are applied to a relevant set of materials that can be identified without ambiguity.

Summary of RAC SPEAKING POINTS BY CEFIC

General comments

Scope or restriction option analysis

Cefic believes the Annex XV proposal for a restriction on intentionally added microplastics does not follow the requirements of the REACH regulation, does not achieve the intended objective of protecting human health and the environment, and therefore cannot be supported by industry.

Key concerns:

- The assessment of a group of substances in a generic manner is not a suitable basis for the assessment of environmental effects, in particular hazard and risk according to the REACH provisions
- The broad and generic definition makes the restriction extremely difficult to understand, interpret, and enforce
- The restriction lacks the first defining element of risk: an identified hazard
- The extensive set of reporting requirements creates significant additional administrative burden without significant added value.

Many of these concerns arise from the fact that the proposed restriction dossier is based on a generic and extensive definition of microplastics that covers nearly all solid polymers and polymer containing particles, in spite of their very different chemical and physical properties. The above could be addressed with a targeted scope. The risk assessment carried out by ECHA concluding that such an approach would be equal in terms of effectiveness, practicality and monitorability is not adequate. [1]

[1] Annex XV Restriction Report Microplastics, Table 16, p. 74

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RAC 49 CIRFS and IVC. OPENING STATEMENT
Speakers' notes June 04th 2019, Helsinki

Dear Mr. Chairman and RAC Committee members,
Dear colleagues

First let me thank you to be able to speak to you for the European man-made fibres industry, represented by CIRFS and IVC within the German chemical association VCI.

Under the REACH Regulation, man-made fibres have been defined as 'articles' (see also ECHA: Guidance on requirements for substances in articles, Version 4.0; Juni 2017). They are made from either natural or synthetic polymers and are neither 'substances' nor 'mixtures'. As a matter of principle, articles cannot be subject to a restriction process under REACH. We therefore consider that man-made fibres are out of the scope of the current proposed restriction.

Nevertheless we are concerned about the actual restriction proposal in respect to the wide range of polymers covered and the lack of legal certainty of the restriction proposal which needs to be checked. This is already discussed in the public e.g. via Chemical watch article of May 15th 2019.

Starting with an insufficient description of substance identity this leads to several following topics:

- Lack of identification of hazard and risk
- Lack of detail in the risk assessment
- Disregard of the principles and standards for the application of the precautionary principle
- Lack of efficacy, effectiveness and proportionality
- Lack of legal basis for product labelling and reporting requirement

Therefore we first see the need of a clear definition of "intentionally added microplastic" on substances or narrowly defined substance group identity. This can then be the basis of a revised substance based risk assessment. Additionally we recommend following adjustments:

Water-soluble polymers should not fall under the restriction.

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Raise the permitted minimum concentration from 0.01 % to 0.1 %, analogously to PBT / vPvB substances.

Bring the requirements of the restriction in such a shape that suitable measuring methods are available to ensure implementation and enforcement

Labelling and reporting only for defined substances which are not biodegradable and released to the environment

More detailed proposals can be found in the uploaded public consultation comments provided by CIRFS/IVC, Cefic and VCI.

Thank you for your attention.

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European
Crop Protection

European Crop Protection Association opening statement for ECHA's Risk Assessment Committee meeting on the 4th of June 2019 – Microplastics session

Interest in Dossier

It is our belief that the current definition is far too broad and practically not workable.

As it stands, it is our belief there is not enough scientific information to justify the grouping approach as described in the ECHA Annex XV report. Furthermore, we strongly believe that the current definition would lead to disproportionate and very unfortunate impacts.

Scientific Position

- The proposed definition for microplastics has introduced a lower size limit of 1nm. Particles this small are not readily distinguishable between large macromolecules, colloidal dispersions, and aggregates. Simple calculations suggest that only a few dozen atoms are required before a molecule has the potential to become larger than 1nm in size. Including these macromolecules in scope would have the potential to massively expand the impact of the restriction. ECPA strongly recommends the lower limit should be 1 µm, on the basis that 1nm colloidal particles cannot be distinguished from macromolecules, and 1nm size particles cannot be reliably measured in commercial mixtures and hence enforced. It should be noted that at these small size scales both melting point and water solubility are potentially particle size dependent properties.

- Polymers <1µm are macromolecules best regulated as substances following a risk based approach. With the European Commission now signaling a REACH polymer registration concept on a similar timeline to the proposed microplastic restriction, this offers an established regulatory mechanism to control the risks from any potential hazards that may be established in future in a proportionate manner. A lower limit of 1µm would focus the microplastic restriction on unambiguous particles, and greatly improve the predictability, enforceability, and proportionality of the restriction.

- Repurposing the CLP definition of a solid to aid in the microplastic definition makes some regulatory sense. However, a melting point is a bulk property, which is contradictory when it should define the state of individual particles, which may be macromolecules. Furthermore, particles which are heterogeneous (e.g. composite or structured materials) may contain polymeric and non-polymeric components with multiple differing melting points. The CLP definition can only be unambiguously applied if the lower size limit is >1µm, and the melting point references the polymeric components.

ETRMA contribution to RAC 49 meeting - statement

End of life tyres have in place a successful recycling value chain in Europe. The individual components of Tyres: steel cords, textiles and rubber are treated separately. The rubber fractions is granulated in a wide range of particle sizes and quality levels.

The final use of the granules or powders is a determinant criteria to define the size required. A large majority of those granules are free particles in the size range of microplastics as defined in Annex XV dossier proposal. ***The step of granulation is an essential and unavoidable step in the material recovery of Tyres and any rubber article.***

Granules from End-of-Life Tyres derived rubber are used in several applications but 30% of the market for crumb rubber from End-of-Life Tyres in used as infill material in synthetic turf infill. The current Annex XV restriction proposal would ban the use of rubber granules in sizes 0.8mm-2.5 mm for the use as infill material in synthetic turf fields, or any other infill such as equestrian floors. In the current Annex XV proposal, no exception is foreseen for that use.

To date there are no material recycling alternatives to compensate for the market loss of approximately 30% of the market share of ELT derived rubber of infill materials. As a result, 527.000 tonnes of ELTs would need to be used in other applications or into energy recovery. ***The vast majority of the excess material will end up incinerated.***

The risk assessment included in Annex XV does not adequately quantifies or considers the potential dispersion of granules used as infill material. The releases are not quantified, neither likelihood of those potential releases to reach marine environments and pose a threat to the ecosystems.

We request to adequate consider the environmental benefits of the proposed ban against the benefits of using this material as infill material. We also request an adequate assessment of the potential dispersion to be done in order to justify the measures.

We also believe that essential information shall be considered when performing the environmental risk assessment, particularly the risk management measures and the operational conditions to be applied at synthetic turf infills. Those measures have proven to dramatically reduce the dispersion of granules.

ETRMA has submitted over the public consultation a description of the risk management measures in place. ***The risk management measures and operational conditions described minimize the dispersion of granules to the environment.*** We trust this information will help RAC to perform an accurate risk assessment of the use of granules as infill material in synthetic turf infill.

Short summary - EuPC Input to the public consultation on the restriction of intentionally added microplastics – RAC-49 meeting

According to the current definition of microplastics, any use of plastics pellets or powder used would be considered a use of microplastics at industrial sites. This use is still allowed at industrial sites but labelling and reporting requirements would apply. It is our view that this measure is not appropriate nor proportionate for these uses. Therefore, we call for these uses to be exempted from the restriction labelling and reporting requirements. It is EuPC view that the reporting requirement on pellet loss cannot bring meaningful results as long as a methodology for reporting is not defined. Without a standardized methodology, a defined order of magnitude of released quantity and a clear definition of "no release", the volumes reported by companies would not reflect actual release of microplastics to the environment.

RAC-49 Restriction discussion on Microplastics
Karen Jenner (Givaudan), Industry Expert for IFRA

IFRA welcome the ECHA proposal for enabling derogation based on biodegradability. We agree that it is manageable with recommended modifications.
We are asking for the derogation to allow a weight of evidence approach in the evaluation of microplastics biodegradation as it is an area of emerging science with significant research occurring.
Regarding screening tests we recommend that the testing time frame be extended in an enhanced ready test, because of the microplastic's physicochemical properties and that the log-phase requirement of < 3days in inherent tests be removed.
We request that the language in the section on "Bio(degradation) relative to a reference material" is changed from "and" to "or" to signify that only one method and pass result is needed.
Where higher tier tests are necessary, we ask that modifications to how biodegradation is measured be allowed as radiolabelling and cold analytical techniques to track parent compound and metabolites are limited.
The current dossier discusses the need to use test material that is comparable to the "*Microplastic on the market in terms of the composition, form, size and surface area*" but this is not practical in every case. We recommend the dossier be changed to "*the form that will exist in the receiving environment*". In the case of encapsulates, this would result in testing the form of a spent capsule, that is to say the capsule wall material with no fragrance core.
Currently there are no viable alternatives to fragrance encapsulation. It will take significant time to develop potential alternatives, and prove that the alternatives meet the biodegradation derogation – not least because the evaluation of microplastic and polymer biodegradation is an area of emerging science. Consequently, a longer transition period should be considered.

REACH Annex XV restriction report on Microplastics: SUMMARY of MedTech Europe statement presented at RAC-49 on 4 June 2019 (Submitted on 30 August 2019)

MedTech Europe is the European trade association for the medical technology industry, representing manufacturers and suppliers of medical devices and *in vitro* diagnostic (IVD) medical devices. We request the exclusion of these devices and similar products (e.g. Research Use Only) from the scope of the restriction, on the grounds that containment of microplastics and disposal as hazardous waste (to comply with derogation 5a) is not technically feasible for some applications (e.g. ion exchange resins for medical applications in open systems) and not practically and economically feasible for others.

Most notably, our sector uses very small amounts of microplastics in order to manufacture IVD reagents, which labs, hospitals and clinics across Europe operate in conjunction with automated high volume IVD instruments. Full containment of microplastics would require re-design of these IVD instruments, which could take up to 5-12 years. It would also pose serious logistical and financial challenges for hospitals and labs.

ECHA itself estimates that less than 0.27% of the microplastics used in the medical technology sector is potentially released to the environment. The inclusion of medical devices and IVDs in the scope of the restriction would therefore only marginally contribute to the overall effort to reduce microplastics in the environment, but holds a risk that critical healthcare products will not be available to patients in Europe.