RAC/M/43/2017
Final
20 February 2018

Minutes of the 43rd Meeting of the Committee for Risk Assessment (RAC 43)

27 November started at 14.00
1 December suspended at 13.00
4 December resumed at 09.00
5 December ended at 11.00

Part I Summary Record of the Proceedings

1. Welcome and apologies

The Chairman, Tim Bowmer, welcomed all the participants to the 43rd meeting of the Committee for Risk Assessment (RAC 43). Apologies were received from three Members.

In his opening address, the Chairman noted that the Secretariat had reviewed the workload of the Committee for 2018 and 2019. A significant increase in the numbers of CLH and Restriction dossiers is evident, and while a reduction in the number of Applications for Authorisations is clearly the case in 2018, this is followed by an expected increase again in 2019 and 2020. He informed Members that this would mean that two double meetings per year can be expected for the medium term, along with two or more single meetings.

He informed the Committee with regard to the derivation of Occupational Exposure Limits (OELs) in support of DG-EMPL under the Carcinogens and Mutagens Directive, that no further information had been received, beyond the five substances in the pilot project mandated under REACH Art. 77(3)c which was ongoing at this time.

He mentioned various initiatives to improve efficiency on an ongoing basis, including a redesign of the Authorisation opinion template next year and that a system of fast-tracking simpler dossiers may be investigated along the lines of that applied in CLP. Finally he noted that ECHA was considering the added value of a working group for worker protection issues, noting that the experience gained from the series of authorisation Rapporteurs' workshops had generally been very positive.

In his announcements, the Chairman also informed RAC of:

- two CLH-related meetings scheduled for early 2018;
- the new practise in submitting declarations;
- the updated RAC Rules of Procedure;
- new practices for meeting invitations and registrations (ELM tool) and
- the external Interact IT tool under development.

The participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed once no longer needed. He added that the recordings from the 42nd meeting had already been destroyed. The Chairman noted that the minutes are adopted by written procedure and they have been uploaded to S-CIRCABC and await publication on the ECHA website. The minutes would include a full list of participants as given in Part III of these minutes.

2. Adoption of the Agenda

The Chairman reviewed the agenda for the meeting (RAC/A/43/2017).

The agenda and the list of all meeting documents, including conclusions and action points are attached to these minutes as Annexes I and Part II, respectively. No points were raised under any other business.

3. Declarations of conflicts of interests to the Agenda

The Chairman requested all participants to declare any potential conflicts of interest to any of the agenda items. 17 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, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) (c) requests (closed session)

The Secretariat collected the names of volunteers for rapporteurships as stated in the restricted room document RAC/43/2017/01.

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

5. Report from other ECHA bodies and activities

a) Report on RAC-42 action points, written procedures and an update on other ECHA bodies

The Chairman informed the Committee that all action points from the previous meeting RAC-42 had been completed. He explained that the report covering the developments in the ECHA Management Board, the Socio-Economic Assessment Committee, Member State Committee, the Forum and the Biocidal Products Committee had been compiled and distributed to RAC as a meeting document (RAC/43/2017/02). The summary of all consultations, calls for expression of interest in rapporteurships and written procedures (room document RAC/43/2017/03) is also available in the usual meeting document on S-CIRCABC (see Annex IV).

The Chairman also informed the Committee that the final minutes of RAC-42 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.

The Chairman informed RAC that the two AFA Final Opinions on the two uses of Bis(2-methoxyethyl) ether (diglyme) submitted by Acton Technologies Limited have been adopted on 13 November 2017 via written procedure; 34 Members voted in favour and none against. The required quorum was 28 votes.

b) RAC workplan for all processes

The Chairman informed the meeting participants about the updated RAC work plan for Q1&2/2018, covering the four processes of Restriction, Authorisation, Harmonised Classification and Labelling of substances and evaluation of occupational exposure limits (Article 77(3)c requests. He informed Members that they could find the expected schedules for Restriction, Occupational Exposure Limit and Authorisation dossiers in the work plan. In addition, the scheduling to be considered for each Harmonised Classification and Labelling (CLH) dossier are given in the relevant section.

6 Requests under Article 77 (3)(c)

6.1 Dossiers occupational exposure- opinion development

The Chairman informed the Committee that following a request from the Commission, with the mandate of 12 May 2017, the Executive Director requested RAC, on the basis of proposals provided by ECHA, to draw up opinions on "the evaluation of the scientific relevance of occupational exposure limits (OELs)" for **nickel and its compounds, acrylonitrile and benzene**. The aim of the opinions is to provide scientific advice in support of the Commission action on the Proposal to amend Directive 2004/37/EC on the protection of workers from the risk related to exposure to carcinogens and mutagens at work (CMD) (4th amendment). This advice must include a recommendation to be given to the Advisory Committee on Safety and Health at Work (ACSH) in line with the relevant OSH legislative procedures and in the format used by SCOEL in drafting its opinion. The Chairman reminded the participants that the deadline for forwarding the RAC-opinions to the Commission is 26 March 2018.

An interim Committee working procedure on the evaluation of OELs in support of CMD Directive following the Article 77.3.c. requests was developed to make the roles and responsibilities of ECHA and RAC clear as well as the procedural steps to complete the task and was agreed at RAC-42 and published on ECHA's website.

a) Nickel and its compounds

The Chairman welcomed the industry expert accompanying a regular stakeholder observer, an occasional stakeholder from ETRMA and an occasional stakeholder from CONCAWE.

The Chairman informed the Committee that the first draft opinion and the draft ECHA proposal (restricted documents) on nickel and its compounds were first discussed at RAC-42. The public consultation on the ECHA proposal started on 10 October and ended 7 November.

The second draft opinion and the revised ECHA proposal, taking into account the comments of the public consultation, were made available to RAC Members on 15 November for comments.

The Chairman informed the Committee that the request from the European Commission is related to nickel and its compounds~~,~~ which refers to all nickel compounds, incl. organic and inorganic substances.

The Rapporteurs presented the main comments from the public consultation and the second draft opinion. The main revisions in the second draft RAC opinion concern the rounding up of the OEL value for the inhalable fraction to 0.03 mg/m^3 and the biomonitoring levels versus background levels. Based on newly received studies, the proposed BGV is revised to 4.5 µg nickel/l urine (instead of 3 µg nickel/l urine).

The Committee supported the Mode of Action- based Threshold approach and the setting of two OELs, one for the respirable and one for the inhalable fraction. Each of these would be common for the different nickel species. The respirable fraction OEL of 0.005 mg/m³ uses animal respiratory toxicity data on non cancer effects of different nickel compounds and includes nickel metal. These effects are also considered to be representative of the critical steps to protect from respiratory tumours in the case of Nickel compounds (to avoid oxidative DNA damage, regenerative processes etc.). The inhalable fraction OEL for nickel compounds (0.03 mg/m³) but not nickel metal addresses lung and nasal cancer and uses human data as a starting point. The discussion focussed on the interpretation of the key genotoxic data including the comparison of *in vitro* and *in vivo* findings and the significance of the different genotoxicity studies. Several Members mentioned that more justification on the selection of the MoA-based data was needed and whether there are reliable data to exclude direct genotoxic effects.

Furthermore the Committee supported the human equivalent calculations for deriving the respirable OEL but mentioned that more consideration concerning the LOAEC – NOAEC extrapolation factor applied to nickel subsulphide for cancer effects should be included.
The Committee supported the idea of organising a workshop on the concepts of the limit values for STEL, BGV and BLV in advance of RAC-44 and to have a further detailed discussion on these issues related to nickel and its compounds during the workshop in order to agree at RAC-44.

The Chairman requested the Rapporteurs to develop the final draft RAC opinion, taking into account the RAC-43 discussions and the results of the RAC written commenting round. In parallel, the Secretariat should revise and finalise the draft ECHA-proposal.

b) Benzene

The Chairman welcomed the industry expert accompanying a regular stakeholder observer (Cefic), an occasional stakeholder from ETRMA, and an occasional stakeholder from CONCAWE, accompanied by an expert.

The Chairman reminded the Committee that the first draft opinion and the draft ECHA proposal (restricted documents) on benzene were discussed at RAC-42. The public consultation on the ECHA proposal started on 10 October and ended 7 November.

The second draft opinion and the revised ECHA proposal (the background Document, e.g. as in the CLP and Restriction processes), taking into account the comments of the public consultation, were made available to RAC Members on 17 November for comments.

The focus of the discussion was on the weight of evidence approach to derive an OEL for benzene based on genotoxic (clastogenic and aneugenic) and haematotoxic effects observed in workers and a description of the remaining uncertainties below the OEL based on a cancer risk dose-response curve.

The Rapporteurs presented the main comments from the public consultation and the second draft opinion. The Rapporteurs presented their approach on linear cancer risk extrapolation. Based on comments received during public consultation, the linear cancer risk extrapolation as performed by AGS (2012) could be considered as a precautionary upper limit. Taking into account uncertainty due to the multiple mode of actions (MoAs) for benzene, a linear cancer risk extrapolation could still be considered the scientifically best justified and cautious approach at this point in time.

However, assuming that chromosomal aneuploidy is the trigger for leukemia, and that aneuploidy has a threshold mode of action, a sub-linear approach could pragmatically result in a 10-fold lower risk below the threshold, and it was also discussed if the evidence for a threshold is sufficiently robust to conclude that there is no appreciable risk below such threshold.

Based on the assumption that genotoxicity and haematotoxicity are threshold effects,the Rapporteurs also presented their revised approaches for genotoxic (clastogenic and aneugenic) and haematotoxic effects. Based on comments received during public consultation, some dose-response relationships had to be re-considered. In a weight of evidence assessments, LOAECs for haematotoxicity and clastogenic/aneugenic effects were found to be in the range of 0.5 ppm. Considering appropriate assessment factors, an 8-h TWA with respect to haematotoxic effects could be 0.2 ppm and for clastogenic and aneugenic effects ≤0.1 ppm.

RAC supported the general approach considering human and animal genotoxicity as well as human haematotoxicity in the elaboration of an OEL. Several Members requested further analysis of the data on human and animal genotoxicity, as well as further analysis of the human data on haematotoxicity.

In addition to setting an OEL, there is a need for setting biological limit values. The Committee supported to have a further more detailed discussion on the concepts of limit values for STEL,

BGV and BLV during the planned[1] Rapporteurs preparatory workshop (occupational exposure)i.e. in order to be able to agree at RAC-44.

The Chairman invited the RAC Members to submit further comments and noted that the deadline will be prolonged until 13 December 2017. The Rapporteurs should develop the draft final RAC-opinion, taking into account the RAC-43 discussions and the results of the RAC- written commenting round. In parallel, the Secretariat should develop the Background Document, to align with the revised RAC-opinion.

c) Acrylonitrile

The Chairman welcomed the industry expert accompanying a regular stakeholder observer (Cefic), an occasional stakeholder from ETRMA, an occasional stakeholder from CONCAWE and the ECHA contractors (via WebEx).

The Chairman reminded the Committee that the first draft opinion and the draft ECHA proposal (restricted documents) on acrylonitrile were discussed at RAC-42. The public consultation on the ECHA proposal started on 13 October and ended 10 November.

The second draft opinion and the revised ECHA proposal, taking into account the comments of the public consultation, were made available to RAC Members on 21 November.

The Rapporteurs presented the main comments from the public consultation and the second draft opinion. The Rapporteurs are of the view that although acrylonitrile is considered a genotoxic carcinogen, from the overall weight of evidence from both animal data and the human epidemiological data, a 'mode of action-based threshold' for the carcinogenic effects of acrylonitrile can be proposed. An OEL value was put forward that would also be protective against nasal irritation. The residual cancer risk at the OEL level as calculated based on the assumption of linearity was considered as an upper bound of the possible human cancer risk. A biological limit value, consistent with the OEL value, was considered relevant as well. The Rapporteurs did not propose to recommend a STEL.

The Committee discussed the overall weight of evidence for carcinogenicity including both animal and human data, including the modes of action. It was generally considered that the epidemiology data available for acrylonitrile is extensive and of good quality. The discussion focussed on how the negative data could be used in the setting of an OEL. Several Members considered that the epidemiological data in combination with the mechanistic data supports the derivation of an OEL based on a 'mode of action-based threshold'. Several Members considered that the epidemiology data may receive more weight in the OEL derivation with some proposing to consider whether the negative epidemiological data might support to reduce the assessment factor for severity.

RAC agreed to derive an OEL via the method proposed by the Rapporteurs. It was further agreed that the remaining issue is to address the assessment factor for the severity of cancer effects in the final draft opinion. RAC agreed to the limit value for nasal irritation proposed by the Rapporteurs. RAC also supported not to set a STEL. The Chairman noted that with the exception of the 'severity' assessment factor, these issues would not be reopened for discussion at RAC 44 and the Committee agreed.

The Committee supported to have a further detailed discussion on limit and guidance values for biomonitoring, respectively the BLV or BGV at RAC-44.

[1] See Section 11. Any Other Business

The Chairman invited the RAC Members to submit further comments on the second draft opinion and the ECHA proposal within the written consultation round by 13 December 2017. The Rapporteurs should develop the draft final RAC-opinion, taking into account the RAC-43 discussions and the results of the RAC's written commenting round. In parallel, the Secretariat should further develop the Background Document.

7. Requests under Article 95(3)

a) Methodology related to the exposure of chemicals at the workplace in relation to non-threshold substances

Note: this item preceded agenda item 6 at the meeting.

The Chairman welcomed an occasional stakeholder from ETRMA and an occasional stakeholder from CONCAWE.

The Chairman updated the meeting participants that the ECHA/RAC –SCOEL Joint Task Force (JTF) met on 18 January, 15 June, 23 August and 26 October 2017 to discuss Task 2 on threshold, 'mode of action-based threshold' and non-threshold approaches to defining Occupational Exposure Limits.

The report (RAC/43/12017/04) is the product of the Joint Task Force and was agreed by them on 24 November 2017. The report is therefore proposed for endorsement by RAC- and SCOEL at their plenary meetings (RAC-43 and SCOEL-103).

Following a presentation by a RAC JTF Member on the main outcomes, RAC endorsed the draft report, with one minor editorial change. The report will be forwarded to the Commission and published on ECHA's website, pending the endorsement of the draft final JTF report at the SCOEL plenary meeting in December 2017.

The Chairman noted that this JTF report, containing a review of mode of action-base threshold methodology for genotoxic carcinogens was of direct relevance to all three DG-EMPL requests under Art. 77(3)c of REACH for OEL recommendations from RAC.

8. Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 CLH dossiers

A. Hazard classes for agreement without plenary debate[2] (see section B below for hazard classes form the same substances debated in plenary)

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

B. Substances with hazard classes for agreement in plenary session

1) 2-phenylhexanenitrile

[2] 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.

2-Phenylhexanenitrile is included in Annex VI and classified as Acute Tox. 4*; H302 (minimum classification) and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410).

The Dossier Submitter (ES) proposed to modify the classification for Acute Tox. 4 (retain H302, with ATE 500 mg/kg bw) and Aquatic Chronic (modify to category 2; H411), as well as to remove the Aquatic Acute 1; H400 classification.

The Rapporteurs agreed with the DS's proposal and proposed for RAC to agree on this opinion via fast-track. This proposal was supported by Members during the RAC consultation, and the proposed classification was agreed via fast track.

2) carboxin (ISO)

The Chairman reported that Carboxin (ISO) is used within the EU as a fungicidal active substance, which is applied to the seeds of small grain cereals (wheat, barley, oats, rye and triticale) for control of seed and soil borne fungal diseases. The substance has no harmonised classification and labelling entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 19 April 2018.

The Dossier Submitter (UK) proposed to classify the substance Skin Sens. 1B; H317, STOT RE 2; H373 (kidneys), Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 2; H411.

The following hazard classes were agreed via fast-track procedure:

- physical hazards – no classification,
- acute toxicity via oral, dermal and inhalation route – no classification,
- specific target organ toxicity – single exposure (STOT SE) – no classification,
- skin corrosion/irritation – no classification,
- eye corrosion/irritation – no classification,
- respiratory sensitisation – no classification
- germ cell mutagenicity – no classification,
- effects on fertility, sexual function and developmental toxicity – no classification.

Thus skin sensitization, specific target organ toxicity – repeated exposure (STOT RE), carcinogenicity and environmental hazard classes were discussed at the plenary meeting.

Concerning skin sensitization, the DS proposed Skin Sens. 1B; H317, while Skin Sens. 1; H317 was proposed by the Rapporteurs. Some RAC Members who preferred to subcategorise the substance into category 1B argued that the sensitisation rate in the GPMT is less than 60% at the intradermal induction concentration of 10%. The topical challenge concentration was certainly sufficiently high (75%). The Rapporteurs agreed that the substance fulfil the criteria for sub-categorisation with 1B, i.e. response >30% at doses >1%, however no indication of sensitisation potential at lower induction doses is available. The Rapporteurs noted that classification into subcategories is only allowed, if data are sufficient. And indicated that this is particularly important if only data are available from certain tests showing a high response after exposure to a high concentration. Majority of the RAC Members who took part at the plenary debate assumed that this specific condition was not fulfilled, i.e. the intradermal challenge concentration was rather high (10%), but the sensitisation rate probably was not "high response" (because the sensitisation rate was less than 60%)." Hence the Committee acknowledged that based on the available data sub-category 1A although very unlikely, nevertheless cannot be excluded. The Committee agreed to classify the substance as Skin Sens. 1; H317.

The Committee Members also agreed to employ the same approach for future cases, i.e. if the available data would not meet the criteria to classify the substance as Skin Sens. 1A, but would also not allow sub-categories including 1A to be excluded, then the substance should by default be classified into category 1 without sub-categorisation. In this way, there would be less need to repeat such discussions with other substances.

Concerning STOT RE, the Rapporteurs proposed two options to consider. According to the first option, taking into account all available data, and giving the most weight to the effects observed in the 90-day oral studies, in the most sensitive species, where adverse effects in kidneys of male rats were observed at dose level of 10 and 10.5 mg/kg bw/day, Carboxin (ISO) might warrant classification as STOT RE 1; H372 (Causes damage to organs (kidneys) through prolonged or repeated exposure). On the second option, the same evidence was taken into account, however, it was also considered that the effects at doses within the guidance values for Cat. 1 were observed in male rats, where there is higher than in other species incidence of spontaneous chronic progressive nephropathy, which may aggravate nephrotoxicity of Carboxin (ISO). The other nephrotoxic effects were observed at higher doses, in both sexes in rats and in mice, hence classification as STOT RE 2; H373 (may cause damage to organs (kidney) through prolonged or repeated exposure) might be warranted. During the discussion five out of seven RAC Members acknowledged that chronic progressive nephropathy is (male) rat-specific effect, which is not of the relevance to humans, whereas the nephrotoxicity observed at exposure levels below the guidance value for category 2 is relevant. The Committee agreed to classify the substance as STOT RE 2; H373 (kidneys).

The Rapporteurs supported the proposal by the DS not to classify for carcinogenicity. However liver tumours in male rats and lung tumours (adenoma) in male mice were observed above the historical control values presented, but in male rats only and at doses above the MTD. The difference in incidence of lung adenoma in the 5,000 ppm group and concurrent control group was not statistically significant, and the incidence (34%) only slightly exceeded the laboratory historical control data range (31.1%). There was no treatment-related increase in alveolar-bronchiolar carcinomas in males and no treatment-related alveolar-bronchiolar adenomas or carcinomas in females. The combined incidence of adenoma and carcinoma in males at 5,000 ppm (34% vs 17% concurrent control) but was within the HCD upper limit for combined adenoma and carcinoma in males (37%). It is well established that CD-1 mice have a high spontaneous incidence of lung tumours, as shown by the concurrent and historical control data. Therefore, it was concluded that the slight increase (compared to controls) in lung adenomas observed in males at 5,000 ppm is unrelated to treatment with Carboxin (ISO). Hence RAC agreed on no classification for carcinogenicity.

Concerning environmental hazards the Committee agreed that Carboxin (ISO) is not rapidly degradable. The substance does not meet the criteria for bioaccumulation.

RAC supported the proposed Aquatic Acute 1 classification (M=1). For chronic toxicity, RAC concluded that for the purpose of classification the recalculated 96 h EC_{10} of 0.063 mg/L should be used. RAC concluded to classify Carboxin (ISO) as Aquatic Chronic 1; H410 (M-factor 1).

In conclusion, RAC agreed on the opinion to classify Carboxin (ISO) as Skin Sens. 1; H317, STOT RE 2; H373 (kidneys), Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1) by **consensus.**

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

3) metaflumizone (ISO);

4-{2-({[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that metaflumizone (ISO) is used as an insecticide indicated for the veterinary treatment of fleas and ticks. The substance has no existing entry in Annex VI of the CLP Regulation thus in accordance with Article 36(2) of CLP all hazard classes need to be assessed. The dossier was tabled for a first discussion at a RAC plenary meeting. The legal deadline for the adoption of an opinion is 6 May 2018.

The DS (UK) proposed to classify the substance for Repr. 2; H361d, Lact.; H362, STOT RE 2; H373 (oral, inhalation) and no classification for environmental hazards. Five MSCAs provided their comments during the public consultation. Six Members commented during the RAC consultation, also proposing that a STOT SE 3; H335 for respiratory tract irritation classification could be considered by RAC.

The following hazards were agreed by fast-track.

- Acute toxicity via oral, dermal and inhalation routes of exposure – no classification,
- Skin corrosion / irritation – no classification,
- Serious eye damage / eye irritation – no classification,
- Respiratory or skin sensitisation – no classification,
- Germ cell mutagenicity – no classification,
- Carcinogenicity – no classification.

The Rapporteurs agreed with the DS's proposal, including the 'no classification' for physical hazards, and in addition proposed to consider adding a classification for fertility (Repr. 2 (H361fd). They also assessed the potential need for respiratory tract irritation (STOT SE 3; H335).

The hazards regarding STOT SE, STOT RE, toxicity to reproduction, as well as the environmental hazards were discussed at the plenary.

With regard to STOT SE, RAC discussed the data from an acute and a 28-day inhalation studies in rats. RAC agreed that there is no clear evidence on respiratory tract irritation, thus no classification needed for this endpoint.

Regarding STOT RE, the Rapporteur presented the arguments for a category 2 versus category 1 classification, based on the body weight effects, as well as the mortality rates observed at doses relevant for these categories. Given lower severity of the effects at doses relevant for category 1 and some uncertainty as to the body weight effects being a direct effect or a result of reduced food consumption RAC agreed on a classification for STOT RE 2, without specified target organ.

Regarding toxicity to reproduction, RAC discussed first the effects on fertility and on maternal toxicity, based on a 2-generation (gavage) study. During the discussion, the Industry representative noted that the effects seen on two females were observed in high doses, and suggested to compare data from individual animals. The Rapporteur replied that no data on individual animals were available to RAC. RAC Members agreed that there is not enough evidence to discard a Repr. 2 classification for fertility (Repr. 2, H361f), which was the most appropriate based on the presented data.

The discussion continued with the effects on lactation and the observation based on a 2-generation (gavage) study in rats and developmental (gavage) study. Following a question from a Member, the Rapporteur clarified that metaflumizone (ISO), and not its metabolites, is found

in milk. Although it could be argued that the effects seen could be a result of maternal toxicity effects due to the dose used, RAC agreed that there is enough evidence, including studies on the metabolism of metaflumizone (ISO), to support a classification for Lact.; H362. At this point, the Chairman suggested to the Rapporteur to briefly clarify in the opinion document the effects and the comparison with the criteria for classification regarding lactation.

With regard to developmental toxicity, RAC discussed the available data based on a 2-generation (gavage) studies in rats and rabbits. Members discussed in details the observed malformations in relation to the historical control studies, and whether these effects could be a variation in the observations. RAC concluded that the observed effects are malformations and agreed on a classification for Repr. 2 H361d.

RAC agreed to not classify for environmental hazards.

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

4) pyridate (ISO)

The Chairman welcomed the expert accompanying the ECPA stakeholder observer and reported that pyridate (ISO) is a contact herbicide for use in agriculture and horticulture.

The substance has an existing entry in Annex VI of the CLP Regulation with the classifications as Skin Irrit. 2; H315, Skin Sens. 1; H317 and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). The legal deadline for the adoption of an opinion is 11 May 2018.

The DS (AT) proposed to retain the classification for skin irritation, to modify skin sensitisation (Skin Sens. 1B; H317), to add classification for STOT SE 1; H370, to have 'no classification' for acute toxicity, CMR and STOT RE and to retain the environmental classification with the addition of M-factors.

The following hazards were agreed by fast-track:

- Acute toxicity via oral, dermal and inhalation routes of exposure – no classification,
- Skin Irrit. 2; H315,
- Germ cell mutagenicity – no classification,
- Carcinogenicity – no classification,
- Toxicity to reproduction – no classification,
- M-factors for the environmental hazards (M=1 for aquatic acute toxicity and M=10 for aquatic chronic toxicity) were added.

The Committee discussed the DS proposal for subcategorization into category 1B for skin sensitisation, but did not find the data provided in the dossier sufficiently informative. Both studies (Magnusson and Kligman test from 1976 and a modified Buehler test from 1981) showed deficiencies that did not allow for a firm conclusion about skin sensitising potential of pyridate. The meeting agreed to retain the existing classification for skin sensitisation, without subcategorization.

Classification for toxicity after single exposure was originally proposed by the DS based on signs of impairment of neurological function in acute toxicity studies in rats and in 90-day repeated dose toxicity studies in dogs (observed already after single exposure).

During the public consultation a new acute neurotoxicity study in rats was submitted. The effects observed seem to be consistent rather with criteria for category 4 for acute oral toxicity - with

LD50 between 500 – 1,000 mg/kg bw and signs of neurological toxicity occurring only in high doses leading to mortality.

RAC discussed the available data in comparison with the criteria. The Members considered the clinical effects in dogs marked and severe (occurring already from 120 mg/kg bw) which would also signal rather acute toxicity. Although the exact time of deaths was not reported in the CLH report, the ECPA expert clarified that the animals did not die early in the study. RAC Members supported the proposal from the Rapporteur to classify pyridate in category 4 for acute oral toxicity (ATE 500 mg/kg bw) based on the observations from six guideline studies in rats and mice and on new neurotoxicity study in rats.

The Committee further discussed the need for classification for single or repeated dose toxicity, but concluded that the clinical signs observed in rats and dogs lead to high mortality and cannot thus be considered as specific systemic effects of pyridate. No classification for STOT SE and STOT RE was therefore agreed.

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

5) 2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol), Tinuvin UV-360

The Chairman reported that 2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol) is a mono-constituent substance with an existing entry in Annex VI to the CLP Regulation (Aquatic Chronic 4; H413).

Legal deadline for the adoption of an opinion is 30 March 2018.

The DS (DE) proposed to remove the existing classification as Aquatic Chronic 4 based on new experimental data.

The Committee did not agree to remove the existing classification because the weight of evidence (WoE) described by the DS for the bioaccumulation potential of the substance has not been sufficient. As a consequence, RAC considered the safety net classification (Aquatic Chronic 4; H413) warranted. In addition, it was noted that this approach was consistent with previous adopted opinions on two similar compounds.

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

6) dibutylbis(pentane-2,4-dionato-O,O')tin

The Chairman reported that dibutylbis(pentane-2,4-dionato-O,O')tin (DBTP) is used as a catalyst in several chemical product categories. The substance has no existing entry in Annex VI of the CLP Regulation. Legal deadline for the adoption of an opinion is 1 June 2018.

The DS (SE) proposed to classify the substance for repeated dose toxicity (STOT RE 1; H372, immune system) and for toxicity to reproduction (Repr. 1B; H360FD) using a category approach to allow read-across to other organotin compounds: dibutyltin dichloride (DBTC), dibutyltin maleate (DBTM), dibutyltin (di)acetate (DBTA), dibutyltin dilaurate (DBTL) and dibutyltin oxide (DBTO).

The Committee agreed on the category approach as justified by the DS based on hydrolysis in simulant gastric fluid for other organotin compounds and further supported by the available toxicological data that show similar toxicological profiles for the substances in this category. It

was noted that this approach was also consistent with the RAC opinion on dibutyltin dilaurate (DBTL) from 2015.

RAC supported the classification of DBTP in category 1 for repeated dose toxicity based on data from three key studies on DBTC which all showed effects on immune system (marked reduction in thymus size and cellularity and similar effects on the spleen and lymph nodes) after oral exposure. There was no available data on either dermal or inhalation routes.

The Committee supported the classification in category 1B for toxicity to reproduction–developmental effects and fertility – based on the foetal effects (external and skeletal malformations), increased number of early resorptions and increase in pre-implantation and post implantation loss.

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

7) 2-methylimidazole

The Chairman reported that 2-methylimidazole is used as a starting material, a chemical intermediate, and as a component in the manufacture of pharmaceuticals, photographic- and photo-thermographic chemicals, dyes and pigments, agricultural chemicals, and rubber. It has many other uses, see REACH registration, 2014. The substance has no harmonised classification and labelling entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 27 April 2018.

The Dossier Submitter (SE) proposed to classify the substance Repr. 1B; H360Df.

The Committee concurred with the DS proposal.

Regarding the effects of 2-methylimidazole on sexual function and fertility RAC noted that in a reproduction/developmental screening study, two top dose dams died during or shortly after parturition (postnatal days 2 and 3), both showing signs of complicated parturition preceding death. As a consequence their pups either died or had to be killed for humane reasons. There were no pathological findings that could explain these deaths. No other effects on fertility were seen. In the absence of evidence of overt general toxicity, RAC concurred with the conclusion of the DS, i.e. that the deaths of two dams during, or shortly after, parturition in the screening study appeared to have been a specific adverse effect on female fertility that is not secondary to general toxicity. Therefore RAC considered that classification for effects on sexual function and fertility is warranted. It was noted that the indication of an adverse effect was derived from a single screening study with only 10 rats/sex/dose and that ultimately, the evidence of an adverse effect on fertility was limited to that observed in two dams only. There were no mechanistic explanation for the findings. Effects on sperm parameters were seen in a 90-d study, but the effects were not considered to be severe enough to justify classification. Taking all the evidence together, Category 1B was not considered appropriate. Overall, RAC agreed that there was some evidence for an adverse effect of 2-methylimidazole on female fertility, and therefore supported classification of 2-methylimidazole in Category 2; H361f for effects on sexual function and fertility.

Regarding developmental toxicity, RAC acknowledged that in rats there was a dose-related increased incidence of aneurysms in pups exposed to 2-methylimidazole from doses as low as 2 mg/kg bw/d (slightly above HCD; clear effect from 10 mg/kg bw/d), in two separate studies. In addition, there was a decrease in viability index at 500 mg/kg bw/d in one of the studies. The observed developmental effects were not considered to be secondary to maternal toxicity because maternal toxicity was limited to bodyweight changes at 500 mg/kg bw/d. Therefore the

effects were considered to be clear and the criteria for classification in Category 1B; H360D for developmental toxicity were considered to be met.

RAC also acknowledged that there was not sufficient data available to classify the substance for effects on or via lactation.

RAC agreed to classify 2-methylimidazole as Repr. 1B; H360Df by consensus.

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

8) cyflumetofen (ISO)

The Chairman reported that Cyflumetofen (ISO) is a specific acaricide and is used in both indoor and outdoor spray application to ornamental crops, nursery trees, perennial ornamentals and to public greens for the control of *Tetranychyus urticae* (red spider mite). The substance has no harmonised classification and labelling entry in Annex VI of the CLP Regulation. The legal deadline for the adoption of an opinion is 27 June 2018.

The Dossier Submitter (NL) proposed to classify the substance Skin Sens. 1A; H317 and Carc. 2; H351.

The following hazard classes were agreed via fast-track procedure:

- Acute toxicity via oral route – no classification,
- Acute toxicity via dermal route – no classification,
- Acute toxicity via inhalation route – no classification,
- Specific target organ toxicity – single exposure (STOT SE) – no classification,
- Skin corrosion/irritation – no classification,
- Eye damage /Eye irritation – no classification,
- Skin sensitisation – Skin Sens. 1A; H317, no SCL,
- Germ cell mutagenicity – no classification,
- Aspiration hazard – no classification.
- Physical hazards – no classification

Thus Specific target organ toxicity – repeated exposure (STOT RE), toxicity to reproduction, carcinogenicity and environmental hazard classes were discussed at the plenary meeting.

Concerning STOT RE, 'no classification' was proposed by the DS, and this was supported by the Rapporteurs and six RAC Members who provided their comments during the RAC consultation. The Rapporteur noted that vacuolation of the adrenal cortical cells was the only effect observed and that the rat was the most sensitive species. One RAC Member expressed the opinion that as summarised in the ODD, adrenal vacuolation attributable to cyflumetofen exposure had been observed at doses below the guidance values for STOT RE 2 in various species (rat, dog) and at high doses in the mouse in multiple studies. However, the Rapporteur noted that the lowest observed effect level was similar in the 2 year rat study as in other (shorter term) studies.

Other RAC Members noted that although histologically the finding appeared to be adverse, there was no evidence of dysfunction. During the discussion these effects were not considered sufficiently severe for classification, hence RAC concluded 'no classification' of Cyflumetofen (ISO) for STOT RE.

Concerning toxicity to reproduction, 'no classification' was proposed by the DS, and this was supported by the Rapporteurs and six RAC Members who provided their comments during the RAC consultation. One RAC Member who provided comments was of the opinion that the absence of effects on pup viability, teratogenicity or pregnancy rates was not sufficient to justify no

classification for Reproductive toxicity and that in fact delayed puberty, sexual hormone imbalance, vacuolation of ovarian cells and/or the decreased body weight gain in F2 pups are sufficient to at least trigger a Repr. 2; H360f classification. During the discussion, some RAC Members noted that the observed effects might be considered significant although they were within the historical control data (HCD) range. It was also noted that although findings indicative of adverse effects on the steroid hormone system were found in the reproductive toxicity studies, these were not considered sufficient for classification. RAC noted that at the highest exposure dose of 140 mg/kg, no significant maternal toxicity had been reported and since there were indications that higher doses would have been tolerated, the test guideline conditions had not been met. The RAC Members considered that although the criteria for classification for effects on fertility and reproductive function were not met, based on the available data, the doses used in the laboratory tests were likely to be too low to enable possible effects of the substance on the tested animals to be observed. Although incidences of common variations were increased, there was no evidence of malformations, hence RAC concluded that the criteria for classification for developmental toxicity were considered not to be met.

Concerning carcinogenicity, Carc. 2 was proposed by the DS, and this was supported by the Rapporteurs and RAC Members who commented during the RAC consultation. Other commenting RAC Members acknowledged that it is a borderline case. The Leydig cell neoplasms were dismissed as not relevant for humans, because these are very common in the F344 rat. Three RAC Members were of the opinion that emphasising the non-statistically significant increase in C-cell adenoma, recognising a similar pathological profile (in the relationship between hyperplasia, adenoma and carcinoma in the controls and the high dose group), they were not sure whether the RAC has sufficient evidence for a treatment-related effect. On the other hand, incidences of carcinomas alone and carcinomas + adenomas were statistically significantly increased at the highest dose and the carcinoma incidences were well above the range of incidences reported in the (well distributed) historical control data (HCD). One RAC Member questioned why a wider range of increased tumour types were not seen at the high doses tested. It was also noted during the discussion that standard methodology in histology is to not report adenomas where carcinomas are seen. Some RAC Members raised concern about potential underreporting of the observed effects in the testing report due to the sectioning methodology (a single cut is normally used, which might not contain adenomas, which are usually smaller than the more clearly identifiable carcinomas). RAC concluded that based on the carcinomas observed in male rats showing a very specific tumour type, classification of Carc. 2; H351 is warranted.

Concerning environmental hazards the Committee agreed that Cyflumetofen (ISO) is not rapidly degradable. The bioaccumulation potential of the substance is low. Acute aquatic toxicity is available for all three trophic levels. Water solubility of Cyflumetofen (ISO) is 0.028 mg/L (at 20°C and pH 7). No acute effects on aquatic organisms were observed at test concentrations below or at the limit of solubility of Cyflumetofen (ISO). Therefore, the substance does not fulfil the criteria for acute aquatic hazard.

Chronic aquatic toxicity is available for all trophic levels and the available information shows no toxicity at levels in excess of the water solubility, therefore the NOEC for classification purposes was considered greater than the measured water solubility (0.028 mg/L at 20°C and pH 7). The DS considered that the category Aquatic Chronic 4 does not apply, because Cyflumetofen (ISO) is considered as not rapidly degradable, but the experimental BCF value does not exceed the criteria threshold of 500 L/kg. Therefore, RAC concluded not to classify Cyflumetofen (ISO) for chronic aquatic hazards.

In conclusion, RAC agreed on the opinion to classify Cyflumetofen (ISO) as Skin Sens. 1A; H317 and Carc. 2; H351 by consensus.

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

9) MCPA-thioethyl (ISO)

The Chairman reported that MCPA-thioethyl (ISO) is used as a herbicide and plant growth regulator. The substance has no existing entry in Annex VI of the CLP Regulation thus in accordance with Article 36(2) of CLP all hazard classes need to be assessed.

Legal deadline for the adoption of an opinion is 2 May 2018.

The DS (PL) proposed to classify the substance for acute oral toxicity (Acute Tox. 4; H302) and for environmental hazards (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 with an M-factor of 10 for both).

The following hazards were agreed via the fast-track procedure:

- Physical hazards – no classification,
- Acute toxicity via dermal and inhalation routes of exposure – no classification,
- Acute Tox. 4; H302 (ATE = 450 mg/kg bw),
- Skin corrosion / irritation – no classification,
- Serious eye damage / eye irritation – no classification,
- Germ cell mutagenicity – no classification,
- Carcinogenicity – no classification,
- Aspiration hazard – no classification,
- Aquatic Acute 1; H400, M=10
- Aquatic Chronic 1; H410, M=10.

RAC concurred with the DS as regards no classification for skin sensitisation based on no signs of allergic responses in the available dermal sensitisation studies with both MCPA and MCPA-thioethyl.

As regards specific organ toxicity after single exposure, one RAC Member asked for clarification about the effects observed in a sub-acute neurotoxicity study in rats which were not related to lethality and could not according to the Member be explained only by decreased/lower body weight. The Rapporteur clarified that there had been a general decrease in motoric activity, but covered by the acute toxicity classification.

Several studies were used by the DS in assessment of repeated dose toxicity (in rats, mice, dogs and rabbits). The Committee agreed to completely exclude 4 studies from a known unreliable source from the evaluation of the substance. For other studies details were missing and thus these studies were of limited use for the assessment of this hazard. However, Members were of the opinion that a classification may be warranted based on mortality observed in the dog study at the highest dose. This would be supported by effects observed in kidneys in the studies with rats and dogs. In conclusion, RAC appreciated that the data set was not robust enough to draw a conclusion and asked the ECPA stakeholder observer to check if further details (esp. availability of the dog study) may be provided.

RAC did not discuss toxicity to reproduction as a research study (in German) originally referred in the CLH dossier (but declared as being unavailable to the applicant) was made available to the Committee at a late stage of the process. The study will be subject to a targeted public consultation.

The Chairman confirmed that toxicity to reproduction and specific target organ toxicity repeated exposure for MCPA-thioethyl will be discussed and agreed at the next RAC plenary meeting.

9. Restrictions

9.2 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

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

The Chairman welcomed the RAC Rapporteurs, representatives of the Dossier Submitter (from Norway and ECHA) and Dossier Submitter experts from Germany. The restriction proposal was submitted by ECHA together with Denmark, Italy and Norway on 6 October 2017. In addition, Germany contributed significantly to the proposal.

The Dossier Submitter's representative (Norway) presented the restriction proposal. The proposal aims to restrict the intentional use of certain substances in tattoo inks or to impose concentration limits for selected substances. These substances include those with harmonised classifications as carcinogenic, mutagenic, reprotoxic, skin sensitising/corrosive/irritant, eye damaging/irritant as well as other substances prohibited in cosmetic products (under the Cosmetic Products Regulation, (EC) 1223/2009) and selected impurities. A number of colourants, which do not currently have alternatives or where information is insufficient to demonstrate risk, are exempted.

Two restriction options (RO1 and RO2) with the same scope are proposed. They differ in terms of the proposed concentration limits and how the links with the Cosmetic Products Regulation annexes are managed.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter, and proposed to the Committee that they consider the dossier to be in conformity. The Committee agreed that the dossier 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 in December 2017.

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

The Chairman welcomed the Dossier Submitters' representatives from Germany and Sweden and the SEAC Rapporteurs. He informed the participants that the restriction dossier had been submitted by Germany and Sweden in October 2017 and proposes to restrict the use, placing on the market and import of C9-C14 PFCAs, their salts and related substances as substances on their own or in a mixture or in an articles or parts therein in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. No current uses of C9-C14 PFCAs have been identified in the EU and only one importer for the semi-conductor industry. The restriction is intended to prohibit industry switching to using C9-C14 PFCAs instead of PFOA after restriction entry 68 for PFOA becomes effective in 2020. C9-C14 PFCAs, their salts and related substances are mainly unintended by-products occurring during the manufacturing of per- and polyfluorinated substances containing a carbon chain of less than nine carbon atoms, such as perfluorooctanoic acid (PFOA, C8-PFCA) based substances and perfluorohexanoic acid (C6-PFCA) based substances. Articles and mixtures manufactured in Europe are reported to comply with the proposed threshold.

The Commission observers highlighted that this is the second dossier with a grouping approach and this is to be welcomed. They questioned if it is necessary for this dossier to deal with the

human health hazard part, or only with environment. The Rapporteurs responded that the dossier is based on PBT and vPvB-properties of the substances, and that the human health hazards will only be addressed qualitatively.

The Rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter, and proposed to the Committee that they consider the dossier to be in conformity. **The Committee agreed that the dossier 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 in December 2017.

b) Opinion development

1) Diisocyanates

The Chairman welcomed the Dossier Submitter's representatives from Germany, the SEAC Rapporteurs, an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer from EuPC. He reminded the participants that this restriction proposal (submitted by Germany) limits the use of diisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures as well as a minimum standardised training package have been implemented. Information on how to get access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of diisocyanates in the substance or mixture placed on the market or used would be less than 0.1% by weight, as well as for mixtures in specific products containing diisocyanates at higher levels than 0.1% by weight but which fulfil criteria demonstrating that the potential risks using such products are very low. The Chairman reminded the Committee that the public consultation on this restriction proposal ended on 22 September 2017 with more than 50 comments received. The third draft opinion was made available to the Committee on 10 November and no comments were received from RAC in the subsequent commenting round. The aim of the meeting was for the Committee to adopt its opinion on this dossier taking into account the comments received in the public consultation.

The Rapporteurs presented the third draft opinion. They informed the Committee that the following aspects are proposed for discussion and final agreement by RAC – conditions of the proposed restriction; justification whether the restriction is the most appropriate measure (derogations of the proposal, effectiveness in reducing the identified risks and practicality/monitorability); uncertainties in the risk characterisation and risk reduction capacity of alternatives. The Rapporteurs also described the comments received within the public consultation, noting that these were generally supportive comments from industry. Some parties commented that the transition period should be longer (up to 6 years), that conditions of the proposal need to be improved/clarified, that qualification of trainers should be recognised between MSs and that there should be mechanisms to identify product-use combinations with very low potential for exposure resulting in exemptions from training. Furthermore, comments related to diisocyanate-related occupational asthma incidence and risk reduction capacity were received as well as a request for an exemption for diisocyanate-based medical device synthetic casting products.

The Secretariat then presented the revised conditions of the restriction, developed by the RAC and SEAC Rapporteurs, together with the ECHA Secretariat, in order to present them in a more structured and simplified way (that were made available to the Committee prior to RAC-43).

Furthermore, the Dossier Submitter representative provided a brief presentation of a real life draft example to define exempted products, developed by FEICA (Association of European Adhesive and Sealant Industry).

Several Members and the Commission observers expressed the view that the proposed restriction should not include reference to a specific dermal assessment tool, as the tool mentioned in the current restriction proposal has not yet been validated, but should rather refer to any recognised tool. Other Members, however, noted that there are actually advantages from all MSs using the same tool - this would ensure that comparable information is generated across different MSs, which would facilitate the future review of the restriction. Several Members suggested to leave the tool open, but to define the criteria in the RAC opinion (or annex to the opinion) – if the same set of criteria is applied throughout the EU, it does not matter what tool a company uses. The Committee supported this suggestion. It was also agreed that the Rapporteurs will clarify in the final opinion what is a recognised dermal assessment tool.

The Rapporteurs, together with the Secretariat, updated the revised conditions of the restriction during the plenary, in line with comments made by the Committee during the RAC-43 discussion. The updated conditions were then presented to the Committee during the second discussion on the dossier. Several Members were uncertain regarding the new paragraph in the conditions of the restriction, defining the role of the MSs. It was finally agreed to remove this reference from the conditions and include it in the justification of the opinion. One Member suggested that the Secretariat would consult the Forum again – on the final set of conditions. The Secretariat informed RAC that this would be done, while the public consultation on the SEAC draft opinion is ongoing, so that SEAC could take the advice into account in the final SEAC opinion.

The Committee adopted its opinion on the restriction proposal on diisocyanates (with the above modifications) by simple majority. One RAC Member reserved their position pending the final text. The Chairman informed that once the opinion was made available, the Member would be given a deadline by the Secretariat to provide a written minority position. Should the secretariat not receive this by the deadline, then the RAC decision would revert to Consensus.

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

2) Lead in PVC

The Chairman welcomed the Dossier Submitter's representatives from ECHA, an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer from EuPC. He reminded the participants that this restriction dossier (submitted by ECHA) proposes a restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15 year derogation for certain building and construction articles produced from recycled PVC (with a higher restriction limit of 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries. The Chairman reminded the Committee that the public consultation on this restriction proposal ended on 22 September 2017 with more than 20 comments received. The third draft opinion was made available to the Committee on 10 November and no comments were received from RAC in the subsequent commenting round. The aim of the meeting was for the Committee to adopt its opinion on this dossier taking into account the comments received in the public consultation.

The Rapporteurs presented the third draft opinion. They explained to RAC that they consider the suggested restriction the most appropriate EU wide measure, as keeping lead in articles is an effective risk management measure since it significantly delays entry into the life cycle stage where emissions are highest. The Rapporteurs added that the list of derogated rigid PVC articles has now been clarified and some soft PVC articles have been added on the basis of limited risk (when compared to risk from disposal). An observer from Client Earth expressed the view that by keeping lead in articles the problem is only delayed. Recycling is not a solution to reduce the risk, but only to delay it. The Rapporteurs responded that lead will no longer be added intentionally, so in the long run it will fade out. Lead shall not be added in an article containing recycled lead.

The Commission observers noted that there is major release of lead from soft PVC compared to rigid. However, it is not clear from the opinion how this release is considered in terms of risk, in particular over the 15-year review period. The Rapporteurs responded that there is more information on this in the Background Document and that they could include more details on this into the opinion justification as well. The Commission observers also asked, if articles covered by the ROHS directive have been taken into account in the risk assessment of this restriction proposal. The Secretariat responded that the only articles where there could be an overlap between this restriction proposal and ROHS, are a specific type of door with an electronic device inside; however, the risks of these are very low and therefore there is no major impact on the assessment. It was agreed that the Rapporteurs will add this explanation into the RAC opinion.

Several RAC Members, as well as the Commission observers, pointed out that the derogation for lead pigments should be more specific and should indicate that it applies only to the authorised uses. The Commission observers were also interested why 15 years review period is proposed. The Secretariat explained that after 15 years there is a substantial reduction in concentration of lead in the recyclate and therefore this time period was chosen. It was agreed that the Rapporteurs will explain it more clearly in the opinion.

The Committee adopted its opinion on the restriction proposal on lead in PVC (with modifications agreed at RAC-43) by consensus. The Rapporteurs were requested, together with the Secretariat, to make the agreed amendments 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.

3) Lead in shot

The Chairman welcomed the Dossier Submitter's representatives from ECHA, an industry expert accompanying a regular stakeholder observer and a representative from the UNEP-Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), accompanied by an expert. He reminded the participants that this restriction proposal had been submitted by ECHA in April 2017 and had been considered in conformity by RAC in its May/June plenary. The dossier proposes a restriction on the use of lead shot in wetlands. The harmonisation of the conditions of use of lead in shot with respect to wetlands is a priority at EU level as national legislation has already been enacted by some Member States (or regions in some Member States). The phasing out of lead gunshot in wetlands is also required under the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), under the auspices of the UN Environment Programme (UNEP), to which the EU and many Member States are Parties.

The Rapporteurs presented the second draft opinion. The Chairman invited the Committee to discuss the second draft opinion with the aim of reaching agreement on all the main components and enabling the Rapporteurs to develop a final version of the opinion or identify where remaining work is needed.

The Rapporteurs invited the RAC Members to address a comment submitted during the public consultation by industry stating that only population level effects should be of concern in environmental risk assessments and that the death of individual birds is not a concern. The Rapporteurs considered that the Dossier Submitter's central estimate of the lethal lead poisoning of 1 million waterbirds per year in wetlands (including several endangered and vulnerable waterbird species within the EU) is sufficient to conclude there is an unacceptable risk on an EU wide basis. In addition, several studies have indicated population-level impacts on waterbirds associated with the use of lead gunshot (Mateo *et al.,* 2009; Green and Pain, 2016). The RAC supported this approach and agreed that the widespread effects of lead on many waterbird species is sufficient to warrant the restriction. The RAC also noted that some waterbird species ingesting lead pellets are categorised as vulnerable/endangered and additional mortality caused by lead pellet ingestion can be of concern for the survival of those species.

RAC also considered that necessary action to address risks associated with the use of lead shot in wetlands should be implemented in all of the EU Member States, especially in the light of varying national regulations.

In considering the most appropriate EU-wide measure, the Rapporteurs suggested that a restriction covering all use of lead gunshot, i.e. a total ban, would be the most appropriate measure, considering practicality and enforcement of the restriction. However, the mandate given to ECHA by the Commission was acknowledged, and the evaluation of RAC was accordingly focused on the proposed scope that the suggested restriction is an appropriate EU-wide measure.

The Rapporteurs also informed the committee that the inclusion of certain types of peatland within the scope of the restriction had been questioned in the public consultation, specifically the inclusion of peatlands 'without visible open water'. However, RAC considered that the inclusion of all types of peatland within the scope of the proposed restriction (which is consistent with the Ramsar definition of a wetland) was justified when considering the available information on risks posed by the use of lead gunshot. The RAC Rapporteurs informed the Committee that, based on the submissions to the public consultation, hunters tend to prefer the 'well-known' definitions of wetlands currently used by their Member State to the Ramsar definition of a wetland.

RAC also agreed that obligatory specific labelling of lead-containing cartridges would enhance the enforceability of the proposed restriction. From a risk reduction point of view, RAC also considered that the time until entry into force of the restriction could be shortened from the 36 months period proposed by the Dossier Submitter.

In addition, RAC was of the view that the understanding of the restriction would be increased if "where spent gunshot would land within a wetland" is further explained in the restriction text. Several RAC Members supported the addition of an explicit (quantitative) buffer/exclusion zone around a wetland where lead gunshot shall not be used or be in the possession of the shooters. One RAC Member noted such a buffer zone may not always aid the implementation of the proposed restriction as hunters may need to legitimately move through wetland areas whilst possessing lead gunshot. RAC agreed that a defined buffer zone around wetlands could potentially facilitate the implementation of the proposed restriction and enhance risk reduction. Any increase to the scope of the restriction as proposed by the DS should however be avoided and this will be discussed further by the Rapporteurs.

The RAC Rapporteurs acknowledged that there was some uncertainty associated with quantitatively estimating the effectiveness of the restriction proposal. UNEP AEWA representative noted that 2/3 of the migratory waterbird species covered by AEWA feed exclusively in wetlands. With full compliance, the restriction would prevent an annual release of 1 452 to 7 767 tonnes of lead to wetlands and potentially avoid the lethal poisoning of approximately 1 million waterbirds per year.

Considering these uncertainties the RAC Rapporteurs considered that it would be reasonable to review the effectiveness of the proposed restriction a few years after its entry into force. After some discussion RAC agreed with the Rapporteurs on the conclusions about effectiveness in reducing the identified risks. The Committee agreed that the restriction is enforceable. RAC agreed that the proposed restriction is practical, as also indicated by already having similar restrictions in 24 of the EU Member States. Alternatives are already available on the market, and sufficient amounts available within a few years.

As for the monitorability of the restriction the Rapporteurs agreed with the Dossier Submitter that the most conclusive method of monitoring compliance with the restriction is to measure the prevalence of ingested or embedded shot in birds over time.

In conclusion, RAC reconfirmed their agreement on the characterisation of the risks. The Committee agreed that action is required on an EU-wide basis and that the restriction is an appropriate measure. RAC also agreed that a defined 'buffer/exclusion zone' around a wetland could facilitate the implementation of the proposed restriction and enhance risk reduction (to be further discussed at RAC-44). In addition, the RAC agreed that the restriction is practical, effective, enforceable and monitorable.

The Chairman informed the Committee that the third draft opinion should be developed by the Rapporteurs by beginning of February 2018.

10. Authorisation

10.1 General authorisations issues

a) Update on incoming/future applications

The Secretariat informed the Committee that three new applications for authorisation were submitted during the November 2017 submission window. One of the applications for authorisation concerns the downstream use of dibutyl phthalate (DBP) in the production of ceramic sheets for multi-layer ceramic capacitors. DBP is not present in the articles. The other application for authorisation concerns the downstream use of sodium dichromate as corrosion inhibitor in ammonia absorption deep cooling systems, applied for the dewaxing and deoiling process steps of petroleum raffinate. And the third new application for authorisation concerns the downstream use of bis(2-methoxyethyl) ether (diglyme) as a solvent for the synthesis of an anti-HIV active pharmaceutical ingredient.

b) Report from the AfA Stock-taking Conference

The Secretariat informed the Committee about the Authorisation Stock-taking Conference, which took place on 13-14 November 2017. About 120 participants from ECHA, the European Commission, applicants, alternative suppliers, consultants, NGOs, the Member States, the RAC and SEAC Members participated in the Conference.

The participants of the Conference concluded that the overall aim of the authorisation system has been achieved: substitution has and is taken place and risks have been reduced at every stage of the authorisation process, including a candidate list, an authorisation list and when applying for authorisation. Applicants have demonstrated improvement in the description of the risks of continued use. This might have been achieved, e.g. due to the publication of the RAC and SEAC checklists. However, the main challenge is still how upstream applicants describe the uses also from the point of view of alternatives.

ECHA, the Commission and the AfA Task Force will further work to improve the authorisation system specifically in the following areas: 1) matching use description and analysis of alternatives; more robust and earlier input from alternative providers, 2) improving the cost-effectiveness of applications, 3) enhancing supply-chain communication, and 4) further actions may possibly be identified from the Commission REACH Review.

c) Lines to take for new Annex XIV substances (longer review periods)

The Secretariat informed the Committee about the document endorsed by CARACAL regarding criteria for review periods longer than 12 years. The document is available on S-CIRCABC. In addition, the Secretariat also informed the Committee Members about improvements on the application for authorisation process. Among the other activities it includes an update of formats for both applications and the Committees' opinions, wording and length of the justification part of the Committees' opinions, revision of the opinion trees (how additional conditions are set by RAC and SEAC), public consultations, AfA Task Force collaboration, consultations with RAC and SEAC.

d) Question and Answer document for future applicants handling substances with endocrine disrupting properties.

The Secretariat reminded the Committee that on 13 July 2017 4-nonylphenol, branched and linear, ethoxylated (NPnEO) and 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (OPnEO) were added to Annex XIV of REACH on the basis of their endocrine disrupting properties (Article 57(f) - environment). Latest application date for both of the substances is 4 July 2019, and the Sunset date is 4 January 2021. ECHA began to receive enquiries from applicants in spring 2017. Workshop on hazard/risk topics had been held in August 2017, and its outcome and next steps had been discussed at RAC-42 in September 2017. At RAC-42 the Committee agreed that it will not develop reference values. It was agreed that the Secretariat with assistance of the Committee will develop a series of Questions and Answers (Q&A) to make them available on the ECHA website. The Q&A document RAC/43/2017/05 is aiming at (1) clarifying RAC position on reference values, (2) clarifying the appropriate focus of hazard/risk assessment for alkylphenol 'parent' substance (with ED properties) or ethoxylates and intermediate breakdown products, and relevant taxa / environmental compartments, (3) highlighting uncertainties in PNEC derivation, and (4) outlining a 'non-threshold' approach to authorisation, i.e. RAC would evaluate applicant's assessment of releases and the appropriateness and effectiveness of OCs and RMMs (in relation to 'minimisation').

During the discussion some RAC Members stressed that endocrine disrupting effects of the substances have been associated with the aquatic environment, and the Q&A should be clearer on this aspect. The RAC Members also agreed that it may not be possible for applicants to establish a threshold level below which use of the substance could be considered being safe. The Committee Members highlighted that should this be the case the risk minimisation concept could be used in applications for authorisation for NPnEO and OPnEO.

RAC agreed on the Q&A document as prepared by the Secretariat. The Secretariat have to modify the document according to the plenary discussion. After that the Secretariat has to publish the agreed document on the ECHA website.

e) AfA DNEL/DR: Carcinogenicity dose-response relationship - development of:

1. Coal tar pitch, high temperature (CTPHT)

2. Anthracene oil

RAC noted presentations by the ECHA Consultant.

Based on the RAC discussions from the previous plenary meetings the ECHA Consultant presented dose-response relationships for lung and bladder cancer developed for workers via inhalation route of exposure based on monitoring of airborne benzo[a]pyrene and urinary 1-hydroxypyrene levels. The ECHA Consultant also used available animal data as basis for skin exposure assessment for workers, and oral exposure assessment for general population. They reviewed for its relevance the available epidemiological data of other reported cancer types.

Review of available epidemiological data demonstrated that limited evidence exists that PAHs may induce tumours at other sites than at the site of application, i.e. respiratory tract cancers after inhalation exposure or skin cancers after dermal exposure. Longitudinal study of a cohort of aluminium workers focused on total and specific mortality and incidence of 25 type/site of cancers (Spinelli et al., 2006) did not confirm any statistically significant risk of PAH exposure for cancer except for stomach cancer and bladder cancer. A review of cohort studies focussing on relationship between PAH and 21 cancer sites (Gibbs G.W., Labrèche F., 2014) found some significant results: mostly for lung cancer, pleura and bladder cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (IARC, 2010) reviewed more than 40 case-control and case-cohort studies, but many were not statistically significant.

On anthracene oil the ECHA Consultant reported that there were five registration dossiers available; some of them were reporting multiple compositions of the substance. The substance itself is consisting of ca. 30 reported constituents. Containing four of the 15+1 EU priority PAHs. In all of the registration dossiers registrants reported concentration of benzo[a]pyrene contents < 50 ppm, which means that it is likely that the authorisation dossiers submitted in the future to ECHA will deal with solely PBT/vPvB properties of anthracene oil.

During the plenary discussion on the draft RAC note the Committee Members requested the ECHA Contractor to recheck and verify calculations used in the deriving of carcinogenicity dose-response parameters values for lung and bladder cancer. They also requested the ECHA Contractor to use standardised terminology evenly throughout the RAC note. In addition, the RAC Members requested to do a technical editing of the draft note. The Secretariat noted that CTPHT is included in Annex XIV of the REACH Regulation based solely on its carcinogenic, PBT and vPvB intrinsic properties, however the substance is also mutagenic and reprotoxic according to the updated classification and labelling in Annex VI of the CLP Regulation. Therefore it is not obligatory for Applicants to consider these two properties in the future applications for authorisation.

RAC agreed on the note and requested the Secretariat after the final editorial work (including a short RAC consultation round) is complete to publish the note on the ECHA website.

10.2 Authorisation applications

a) Discussion on key issues

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding the new application for authorisation received during the August 2017 submission window.

1. PCO_IP (2 uses)

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

The annual volume used is <100 kg/year for Use 1 and Use 2. It is used in <10 sites (Use 1) and <100 sites (Use 2). The applicant requested a review period of 12 years for each use.

The Secretariat in cooperation with the RAC Rapporteurs provided general information regarding this new application. In the presentation of the case, the Secretariat outlined the key issues identified by the Rapporteur and asked the Committee for comments and further suggestions.

The Committee noted those key issues. RAC will request further clarifications from the applicant on the issues identified and discussed by the Rapporteurs and the Secretariat.

b) Discussion and agreement on Draft Opinions

1. CT_Hapoc (4 uses)

This is an upstream application on four uses of chromium trioxide. Use 1 (Use of chromium trioxide in dissolved and solid form to produce aqueous solutions of any composition for industrial application) will be dealt with by RAC at the next plenary meeting in February/March 2018. At this plenary meeting the RAC Rapporteurs presented the draft opinions for the Uses 2, 3 and 4. All three uses concern the use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow in categories I, II and III (equivalent to 0.1, 1 and 5 µg/m^3).

The applicant asked for additional time to answer the Rapporteurs' questions following the trialogue. By 31 July 2017, as agreed with ECHA, the applicant had provided additional information, including ca. 400 personal and static measurements from about half of their ~100 Members. Over 80% of Hapoc's Members carry out functional (hard) chrome plating and this gives the application a clearer focus for RAC to consider; it also clarifies to some extent the description of Operational Conditions (OC) and Risk Management Measures (RMM) provided.

On the Use 2 (category II the Rapporteurs proposed to use the 90th percentile of the measured data provided by the applicant of 3.6 µg Cr(VI)/m^3, noting that the corresponding median value is about 1 µg/m^3; the data had been thoroughly checked by the Rapporteurs. The application contains a set of minimum RMMs which RAC considered in relation to manual functional chrome plating, i.e. these are generally the worst case in terms of worker exposure from 'bath plating' activities. The RAC Rapporteurs considered that the RMMs and OCs described in the application are not appropriate and effective in limiting the risk to workers as this was based on the lack of a specific description of OC and RMM related to specific exposure levels.

The reported exposure values are broadly in line with those reported in several other applications assessed by RAC so far. The comparison can best be made with Kromatek's multi-site downstream application for which the European Commission had already issued an authorisation and where the exposure levels and the OC and RMM for manual functional chrome plating were also comparable. The application also shared characteristics with the CTAC applications as

previously discussed, but the exposure data received from Hapoc was seen as more representative.

During the discussion on the draft opinion on Use 2 the RAC Members commented on the workers' exposure and biomonitoring data, exposure of man via the environment, and the additional conditions proposed by the Rapporteurs in the draft opinion.

The Committee agreed in principle on the draft opinion on Use 2 as proposed by the Rapporteurs with modifications as proposed during the meeting:

- the applicant should provide guidelines for the DUs on how to report measurement data,
- the applicant should clarify the conditions of supply, i.e. that in order to receive chromium trioxide, the DU would provide appropriate exposure data,
- the applicant should ensure that DUs implement effective cleaning practises in the bath area.

Considering the uncertainties relating to the risks, RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and review report, as described in the draft opinion. RAC also agreed to advice SEAC on the length of the review period and recommended a review period no longer than 4 years.

With regard to Uses 3 and 4 the Committee was unable to confirm that the RMMs and OCs described by the applicant would be sufficient to ensure that the claimed exposure levels could be achieved. Although RAC has evaluated applications for functional chrome plating, demonstrating that such exposure levels are possible, the information provided by Hapoc in these uses is not sufficient to demonstrate this. RAC could not propose additional specific conditions that would ensure that downstream users of this application would reach the exposure levels indicated, i.e. 1 and 0.1 µg/m^3 (Category II and I) respectively.

RAC agreed that the Secretariat will launch a further consultation on the updated draft opinions on the Uses 2, 3 and 4 after the RAC-43 plenary meeting, including a final text of the conditions and a way forward for dealing with uses 3 and 4.

2. CT_Hapoc_2 (1 use)

3. CT_Hapoc_3 (1 use)

The Secretariat informed the Committee that draft opinions on the applications for authorisation CT_Hapoc_2 and CT_Hapoc_3 will be discussed and agreed at the next RAC plenary meeting in February/March 2018.

4. SD_Hapoc (1 use)

This is a downstream application for the use of sodium dichromate in molten bath form to modify surfaces, especially by blackening, of delicate medical products, specifically micro-surgical instruments.

RAC Members were informed that the Applicant did not address the RAC and SEAC Rapporteurs' questions by the given deadline of 31 August 2017. Instead, the applicant asked for a second extension of the deadline, which ECHA did not grant. Since a number of the Rapporteurs' questions addressed conformity issues, and these gaps in the application had not been addressed by the applicant, the Rapporteurs proposed that the Committee is not in the position to evaluate the risk to human health arising from the use of the substance as required under Article 64(4)(a) of the REACH Regulation. The Committee concluded that the applicant did not provide any exposure measurements or results of modelling to substantiate the claimed exposure for workers below 0.2 µg Cr(VI)/m^3. RAC agreed that it is not in the position to evaluate the risk to human health arising from the use of the substance as required under Article 64(4)(a) of the REACH Regulation.

5. PC_SC_Saes (2 uses)

This is an application with a narrow scope on the following two uses of sodium and potassium chromates, as submitted by Saes Getters S.p.A.

Use 1: Use of Sodium and Potassium chromate in the fabrication of alkali metal dispensers for production of photocathodes (use at Applicant's site).

Use 2: Use of alkali metal dispensers containing sodium and potassium chromate for production of photocathodes (use at customers' sites).

The Chairman informed RAC about the scope of the discussion and the Rapporteurs presented the draft opinions. The annual tonnage used is <20 kg per annum and the Applicant requested a 7-year review period.

RAC agreed on the draft opinions as proposed by the Rapporteurs, with some changes for Use 1. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population.

For Use 1, RAC decided to recommend additional conditions and monitoring arrangements for the authorisation. These include the revision of the RMMs on the basis of the existing air monitoring results, in particular relating to the level of enclosure and application of hierarchy of control principles. The improvements to be confirmed by the results of the continued biomonitoring.

For Use 2, RAC decided to recommend no additional conditions and monitoring arrangements for the authorisation and for review reports.

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

6. EDC_Microbeads (1 use)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by Microbeads AS for the single industrial use of 1,2-dichloroethane (EDC) as a swelling agent during the sulfonation reaction of crosslinked polystyrene beads in the manufacture of ion exchange resins for purification of radioactive waste. This is a narrow scope downstream user application. 8 workers exposed to EDC. The annual volume used is <1 tonne/year. The requested review period is 12 years.

During the discussion the Commission observers asked Rapporteurs to add, if possible, the following information into section 9:

- specify the implementation date for the additional risk management measures to minimise atmospheric release of EDC,
- give more details on the type of risk management measures which shall be installed to eliminate the manual transfer of EDC and sulfuric acid.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. 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 to general population only if the RMMs are implemented before the next production campaign as planned. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation as explained in the draft opinion. RAC did not give any advice concerning the length of the review period.

7. CT_ZFF (1 use)

The Rapporteurs presented the draft opinion on the application for authorisation submitted by a downstream User for the single use of chromium trioxide in functional chrome plating of piston rods for automotive and rail applications.

The number of exposed workers is <100 at the two sites covered by this application. The annual tonnage used is <100 tonnes and the Applicant requested a 21-year review period.

RAC agreed by consensus on the draft opinion as proposed by the Rapporteurs. In particular, RAC concluded that the RMMs and OCs are appropriate in limiting the risk to workers. However, RAC considers that for WCS 7 (sub-scenario 2) the risk reduction relies on the use of RPE and no exposure measured data are available. This introduces some uncertainty when assessing the appropriateness of the RMMs. Therefore, RAC decided to recommend additional conditions and monitoring arrangements for the review report, as described in the draft opinion. RAC also agreed to give no advice to SEAC on the length of the review period.

8. SC_Wesco (1 use)

9. DtC_Wesco (1 use)

10. PCO_Aviall (2 uses)

SC_Wesco is an upstream single use application on the use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains. The scope of the application is relatively broad. The number of sites relevant for the application is > 100. Number of workers exposed >15,000. The applicants requested a review period of 12 years. The substance is the main component in primers. These are one layer out of several layers of coating applied (i.e. spraying and brushing) to the surface of an aeronautic vehicle or component. The level of containment for tasks and processes is generally low.

DtC_Wesco is an upstream application on the use of dichromium tris(chromate) for chemical conversion coating applications by aerospace and defence companies and their associated supply chains. The scope of the application is relatively broad. The number of sites relevant for the application is >100. Number of workers exposed >10,000. The applicant requested a review period of 12 years. The substance is the main component in chemical conversion coatings used to provide corrosion resistance to the surface of an aeronautic vehicle or component. The level of containment of the process/tasks is generally low.

PCO_Aviall is an upstream application on the following two uses of pentazinc chromate octahydroxide: Use 1: Formulation of mixtures, Use 2: Use of pentazinc chromate octahydroxide in wash primer, fuel tank primer and aluminized primer for the purpose of corrosion protection in aeronautic applications. The scope of the application is relatively broad. The number of sites relevant for the application is <5 for Use 1 and <100 for Use 2. Number of workers exposed <50 for Use 1 and <1,000 for Use 2. The applicants requested a review period of 12 years. The substance is the main component in primers. Primers constitute one layer out of several layers of coating applied (i.e. spraying and brushing) to the surface of an aeronautic vehicle or component. For both uses, the level of containment is low.

The RAC Rapporteurs updated the Committee Members about the opinion development progress in light of the recent trialogues, which took place in November 2017. During the discussion the Rapporteurs acknowledged that more exposure data on spraying operations in booths are available for these applications comparing to previous cases, when applications had been submitted by upstream larger consortia. Some RAC Members doubted the high containment factors applied by the applicants in the exposure calculations. In general RAC Members concluded that the uncertainties level in these three cases is similar to these in the other upstream applications for authorisation.

The RAC Rapporteurs will consider the applicants' responses received after the trialogues along with the RAC plenary discussion to draft the opinions on the three applications for authorisation, which will be tabled for discussion and agreement at next Committee plenary meeting in February/March 2018.

c) Adoption of final opinions

1. MOCA_Reachlaw (1 use)

This is an upstream application by the only representative of a company located in China and involves a single industrial use of MOCA as a curing agent/chain extender in cast polyurethane elastomer production. The annual tonnage: <1,000 tonnes. It is reported to be used at <100 sites, of which an estimated 89% are automatic and the remaining 11% are manually operated. The use thus has a broad scope. An estimated <500 workers are exposed. The requested review period is 12 years.

The draft opinion on this upstream application by the only representative has been agreed by RAC and SEAC at their plenary meetings in June 2017. It was sent to the applicant on 24 July 2017. The applicant informed on 26 July 2017 that they will comment on the draft opinion. The applicant's comments were received on 2 October 2017.

The RAC Rapporteur examined the submitted comments and advised the Committee that no substantive changes to the opinion were justified. However, some further justification of the minimum OC and RMM conditions would be provided. RAC agreed with the Rapporteur's advice and adopted its opinion on the application for authorisation.

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

The RAC Rapporteurs presented the final opinions on the four upstream (importer) applications for authorisation prepared with the support of the Global Chromates Consortium for Aerospace (GCCA).

The first application above has been submitted for two uses of sodium chromate:

> Use 1: Formulation of mixtures of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace companies and their suppliers.
>
> Use 2: Use of sodium chromate for sealing after anodizing, chemical conversion coating, pickling and etching applications by aerospace companies and their suppliers.

Three of the above applications have been submitted by Haas Group International SCM Ltd with one use each: one application of chromium trioxide for chemical conversion treatment and slurry coating by aerospace companies and their suppliers; One application for the use of sodium dichromate and one for the use of potassium dichromate for sealing after anodizing is by aerospace companies and their suppliers.

Although the stated volume is low in each case, (<1 to <5 tonnes per year), each use can occur at ca. 100 sites and with a potential to expose several thousand workers.

The Applicant provided comments on the Draft opinions. The Rapporteurs informed RAC that they implemented (editorial) changes based on the comments received and that one conclusion

had been changed. RAC adopted the final opinions with the changes and clarifications in justification and conditions of the draft opinions following the Applicant's comments.

10.3 Review reports

a) Discussion on key issues

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

These are the first two review reports received by ECHA. The review reports were submitted separately by two of the three authorisation holders. Both companies are Italian waste recycling companies that process waste into flexible PVC recyclate. The third authorisation holder did not submit a review report.

ECHA secretariat provided general information regarding these two review reports.

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

The concentration of DEHP in PVC recyclate decreased from 1-20% in the initial application for authorisation to <5%. The annual volume of 1,000 – 4,000 tonnes in the initial application is reduced to 50 – 500 tonnes (Vinyloop) and 10 – 100 tonnes (Plastic Planet). The use of the DEHP-containing recyclate is taking place ≥8 sites for both review reports. About 200 workers exposed for both of the review reports. Vinyloop Ferrara SpA requested a 7-year review period, whereas Plastic Planet srl requested 12 years.

In the presentation of the case, the ECHA Secretariat furthermore outlined the key issues identified by the Rapporteurs and asked the Committee for comments and further suggestions. The Committee noted those key issues. RAC will request further clarifications from the authorisation holders on the issues identified and discussed by the Rapporteurs and the Secretariat.

11. Any Other Business

a) Report from the Impact Assessment Scoping Group meeting

The Secretariat gave an oral update from the first meeting of the Impact Assessment Scoping Group, held on 17 October 2017.

b) Information item: The CLH classification of Coal Tar Pitch High Temperature (CTPHT) as aquatic acute and chronic toxicity 1 has been formally annulled by the Appeal Court of European Court of Justice

RAC was informed of the above ruling by the European Court of Justice, which is definitive. The court found that, in applying the 'summation method' in the environmental classification of CTPHT based on its classified components (namely the 16 US EPA PAHs, which are present in the substance up to 10% w/w), RAC did not take the water solubility of CTPHT as such sufficiently into account. While the opinion of RAC was adopted quite early on in the history of the Committee (in November 2011), the Secretariat reminded RAC of the need for good scientific justification, particularly in unusual cases, where standard testing is absent or weak and/or guidance not necessarily clear or directly applicable.

The Secretariat will consider the implications of the decision for both high temperature CTPHT as a substance and in general for the use of the summation method for determining aquatic toxicity in UVCBs and mixtures.

c) CMD: notations BLV, BGV, STEL, notations such as 'skin'

One RAC Member, reflecting the challenges for RAC in evaluating proposals for occupational exposure limits under the Carcinogens and Mutagens Directive (2004/37/EC) asked if the secretariat could provide support in dealing with the following values or notations: biological limit and guidance values (BLV and BGV), the Short term exposure limit (STEL) and its derivation, as well as SCOEL 'notations' such as 'skin', noting that it was a question of establishing work practices to ensure consistency.

The matter was discussed briefly in plenary and at the request of Members, the Secretariat offered to add these items to the agenda of the next Rapporteurs' workshop on worker protection (RAC 44 in march 2018).

5 December 2017

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS

RAC 43 27 November – 1 December 2017
4 - 5 December 2017
(Adopted at the meeting)

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/43/2017**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-43 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95(3) requests and Article 77(3)(c) requests	
5. Report from other ECHA bodies and activities	
a) Report on RAC 42 action points, written procedures and other ECHA bodies **SECR** presented document **RAC/43/2017/02** and document **RAC/43/2017/03.**	**SECR** to upload the document to the CIRCABC non-confidential website.
b) RAC work plan for all processes -	
6. Requests under Article 77 (3)(c)	
6.1 Dossiers occupational exposure- opinion development	
a) Nickel and its compounds The rapporteurs presented the revised RAC-opinion. RAC discussed the revised draft opinion. The Committee supported the Mode of Action Threshold Approach and the approach of having only one occupational exposure limit for the different nickel species. The proposal includes one respirable	**Rapporteurs** to prepare the final draft RAC-opinion, taking into account the RAC-43 discussions and the results of the RAC-written commenting round. **SECR** to prepare the final draft ECHA-proposal, to align with the revised RAC-

and one inhalable OEL to address lung cancer and nasal cancer. The Committee supported that further explanation should be included in the revised draft RAC-opinion on: - Elaboration of key genotoxic data including the comparison of vitro-in vivo findings; - Clarification of the significance of the different genotoxicity studies; - Further elaboration of the justifications for AFs applied to nickel subsulphide LOAEC for cancer effects.	opinion and taking into account RAC-43 discussions and results RAC-written commenting round.
b) Benzene The Rapporteurs presented the revised draft RAC-opinion. RAC discussed the revised draft opinion. RAC supported the approach considering human and animal genotoxicity as well as human haematotoxicity in the elaboration of an OEL and requested further analysis of the above data.	**RAC Members** are invited to send their comments during the prolonged RAC-consultation until 13 December 2017. **Rapporteurs** to prepare the final draft RAC-opinion, taking into account the RAC-43 discussions and the results of the RAC-written commenting round. **SECR** to prepare the final draft ECHA proposal, taking into account the RAC-43 discussions and the results of the RAC-written commenting round and to align with the rapporteurs on the final draft RAC-opinion.
c) Acrylonitrile The rapporteurs presented the revised draft RAC-opinion. RAC discussed the revised draft opinion. RAC supported the proposal to derive an OEL via the method proposed. The remaining issue to discuss is the assessment factor for the severity of the cancer effects. RAC also supported not to set a STEL.	**RAC Members** are invited to submit further comments within the written consultation round until 13 December 2017. **Rapporteurs** to prepare the final draft RAC-opinion, taking into account the RAC-43 discussions and the results of the RAC-written commenting round. **SECR** to prepare the final draft ECHA proposal, taking into account the RAC-43 discussions and the results of the RAC-written commenting round and to align with the rapporteurs on the revised RAC-opinion.
7. Requests under Article 95 (3)	
a) Methodology related to the exposure of chemicals at the workplace in relation to non-threshold substances.	**SECR** to make an editorial check of the draft final JTF report. **SECR** to forward the final JTF report and publish it on the ECHA website, pending the

RAC endorsed the draft final RAC-SCOEL Joint Task Force report, agreed by the Joint Task Force on 24 November 2017 (RAC/43/2017/04).	endorsement of the draft final JTF report at the SCOEL plenary meeting in December 2017.
8. Harmonised classification and labelling (CLH)	
8.1 General CLH issues	
8.2 CLH dossiers	
A. Substances with hazard classes for agreement by A-listing following the usual scrutiny but without plenary debate **Please mention any ATE values for acute toxicity, together with the applicable route of exposure, where these were agreed by RAC through fast-tracking.**	
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.** 1. 2-phenylhexanenitrile 2. carboxin (ISO) 3. metaflumizone (ISO); 4-{2-({[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile 4. pyridate (ISO) 5. Tinuvin UV-360 6. dibutylbis(pentane-2,4-dionato-O,O')tin 7. 2-methylimidazole 8. cyflumetofen (ISO) 9. MCPA-thioethyl (ISO)	
1. 2-phenylhexanenitrile	
RAC adopted <u>by consensus</u> via fast-track the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302, oral ATE = 500mg/kg, 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.
2. carboxin (ISO)	

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [STOT RE 2; H373 (kidneys), Skin Sens. 1; H317, Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=1]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
3. metaflumizone (ISO); 4-{2-({[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 2; H361fd, Lact.; H362, STOT RE 2; H373]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
4. pyridate (ISO)	
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, oral ATE = 500 mg/kg bw, Skin Irrit. 2; H315, Skin Sens. 1; H317, Aquatic Acute 1; H400, M=1, Aquatic Chronic 1; H410, M=10]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
5.Tinuvin UV-360	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Aquatic Chronic 4; H413]	**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.dibutylbis(pentane-2,4-dionato-O,O')tin	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.	**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur.

[STOT RE 1; H372 (immune system), Repr. 1B; H360FD]	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
7. 2-methylimidazole	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360Df]	**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. cyflumetofen (ISO)	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Skin Sens. 1A; H317, Carc. 2; H351]	**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. MCPA-thioethyl (ISO)	
RAC agreed on the harmonised classification and labelling as indicated in Table 2 below. [Acute Tox. 4, H302, oral ATE = 450 mg/kg, Aquatic Acute 1; H400, M=10, Aquatic Chronic 1; H410, M=10]	**SECR** to launch a targeted public consultation (toxicity to reproduction). **Rapporteur** to revise the opinion in accordance with the discussion in RAC (for the hazards agreed at RAC 43) and to provide it to SECR**.** **Rapporteur** to revise the opinion based on the discussion at the plenary and the outcome of the targeted PC and send it to the SECR. **SECR** to launch RAC consultation on the revised draft opinion. **Rapporteur** to revise the opinion in accordance with RAC comments and to send it to the SECR. **SECR** to schedule the dossier for the next plenary meeting (March 2018).
9. Restrictions	
9.1 Restriction Annex XV dossiers	
a) Conformity check and key issues discussion	
1) Substances used in tattoo inks and permanent make-up RAC agreed that the dossier conforms to the Annex XV requirements.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG.

RAC took note of the recommendations to the dossier submitter.	**SECR** to inform the dossier submitter on the outcome of the conformity check.
2) C9-C14 PFCAs, their 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 upload this to S-CIRCABC IG. **SECR** to inform the dossier submitter on the outcome of the conformity check.
b) Opinion development	
1) Diisocyanates Rapporteurs presented and RAC discussed the third draft opinion. RAC agreed with the conditions of the restriction as revised during RAC-43 and that the Rapporteurs and SECR would make the opinion consistent with the conditions, in particular: - Inclusion of the criteria for very low exposure and clarifying what is a recognised dermal assessment tool; - Addition of the recommendation for MSs to ensure that the training material is fit for purpose; - Clarifying co-operation, entry into force and other editorials. RAC noted that the Forum will be consulted on the revised conditions. RAC adopted the opinion on this restriction proposal (with modifications agreed at RAC-43) by a majority.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
2) Lead in PVC Rapporteurs presented and RAC discussed the third draft opinion. RAC adopted the opinion on this restriction proposal (with modifications agreed at RAC-43) by consensus.	**Rapporteurs** to make final editorial changes to the adopted RAC opinion. **Rapporteurs**, together with **SECR**, to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC. **SECR** to publish the adopted opinion and its supporting documentation on the ECHA website and S-CIRCABC IG.
3) Lead in shot	**Rapporteurs** to prepare the third draft opinion by the beginning of February

The Rapporteurs presented and RAC discussed the second draft opinion. RAC reconfirmed their agreement on the characterisation of the risks. RAC agreed that action is required on an EU wide basis and that the restriction is an appropriate measure. RAC agreed that a defined buffer zone around a wetland could facilitate the implementation of the proposed restriction and enhance risk reduction (distance to be further discussed). RAC agreed that the restriction is practical, effective, enforceable and monitorable.	2018, taking into account the RAC-43 discussions and the results of the public consultation.
10. Authorisation	
10.1 General authorisation issues	
a) Update on incoming/future applications	
RAC noted the information presented by the Secretariat.	
b) Report from the AfA Stock-taking Conference	
RAC noted the information presented by the Secretariat.	
c) Lines to take for new Annex XIV substances	
RAC noted the information presented by the RAC rapporteurs.	
d) Question and Answer document for future applicants handling the endocrine disrupting properties.	
SECR presented document RAC/43/2017/05 **RAC** agreed with the approach as presented in the document.	**SECR** to make final editorial changes in the document. **SECR** to publish the document (RAC/43/2017/05) on the ECHA website.
e) AfA DNEL/DR	
1. Carcinogenicity dose-response relationship development of coal-tar pitch, high temperature (CTPHT) ECHA Contractor presented the revised draft report and the draft note (RAC/43/2017/06) on the carcinogenicity dose-response relationship of coal-tar pitch, high temperature (CTP-HT). The Committee discussed the draft report by the ECHA Contractor. The Committee agreed on the note on carcinogenicity coal-tar pitch, high temperature, with editorial	**Rapporteurs** together with **SECR** to do the final editing on the agreed note in accordance with RAC-43. **SECR** to launch a short RAC consultations round on the revised final note. **SECR** to publish the agreed note on the ECHA website.

revisions to be included concerning calculations formulas, standardisation of terminology and further technical editing. **2. Carcinogenicity dose-response relationship of anthracene oil** -	
10.2 Authorisation applications	
a) Discussion on key issues	
1. PCO_IP (2 uses) RAC discussed the key issues in the application for authorisation and provided advice as needed to the Rapporteurs, also in relation to the conformity.	**SECR** to inform SEAC about the outcome of the discussion.
b) Agreement on Draft Opinions	
1. CT_Hapoc (Uses 2, 3 and 4) <u>Use 2</u> RAC agreed in principle on the draft opinions as proposed by the Rapporteurs with modifications as proposed during the meeting. RAC is of the opinion that the RMMs and OCs are <u>not</u> appropriate and effective in limiting the risk to workers. Considering the uncertainties relating to the risks, RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and review report, as described in the draft opinion. RAC agreed to advice SEAC on the length of the review period and recommended a review period no longer than 4 years. <u>Uses 3 and 4</u> RAC agreed in principle on the draft opinions as proposed by the Rapporteurs with modifications as proposed during the meeting. RAC was unable to confirm that the RMMs and OCs described by the applicant would ensure the exposure levels and thereby the associated risk estimates indicated in the use title. RAC cannot propose additional conditions that would ensure downstream users of this application could reach the exposure levels indicated in the use title.	**Rapporteurs** together with **SECR** to revise the draft opinions in line with the discussion at the plenary. **SECR** to launch written consultation on the revised draft opinions. **Rapporteurs** to consider RAC comments and revise the draft opinions if relevant. **Rapporteurs** to draft the RAC draft opinion on the Use 1 of the application for authorisation.
2. CT_Hapoc_2 (1 use) RAC took note of the presentation by the Secretariat on the opinion development progress update.	**Rapporteurs** to develop draft opinion for the discussion and agreement at RAC-44 plenary meeting.

3. CT_Hapoc_3 (1 use) RAC took note of the presentation by the Secretariat on the opinion development progress update.	**Rapporteurs** to develop draft opinion for the discussion and agreement at RAC-44 plenary meeting.
4. SD_Hapoc (1 use) RAC agreed on the draft opinion as proposed by the Rapporteurs. The Applicant did not provide any exposure measurements or results of modelling to substantiate a claimed exposure for workers below 0.2 µg Cr(VI)/m^3. RAC agreed that it is not in the position to evaluate the risk to human health arising from the use(s) of the substance as required under Article 64(4)(a) of the REACH Regulation.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinions to the Applicant for commenting.
5. PC_SC_Saes (2 uses) RAC agreed on the draft opinion as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. **Use 1:** RAC decided to recommend additional conditions and monitoring arrangements for the authorisation and for review reports as described in the draft opinion, including revision and implementation of the RMMs, on the basis of the existing air monitoring results, relating to the level of enclosure and application of hierarchy of control principles. The improvements to be confirmed by the results of the continued biomonitoring. **Use 2:** RAC decided to recommend no additional conditions and monitoring arrangements for the authorisation and for review reports.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.
6. EDC_Microbeads (1 use) RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and to general	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.

population only if the RMMs are implemented before the next production campaign as planned. RAC decided to recommend additional conditions and monitoring arrangements for the authorisation.	
7. CT_ZFF (1 use) RAC agreed on the draft opinions as proposed by the Rapporteurs. RAC is of the opinion that the RMMs and OCs described in the application are appropriate and effective in limiting the risk to workers and the general population. RAC decided to recommend additional conditions and monitoring arrangements for the review reports as explained in the draft opinion.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the Applicant for commenting.
8. SC_Wesco (1 use) **9. DtC_Wesco (1 use)** **10. PCO_Aviall (2 uses)** RAC took note of the presentation by the RAC Rapporteurs on the opinion development progress update.	**Rapporteurs** to consider comments from the plenary discussion and to develop draft opinions for the discussion and agreement at RAC-44 plenary meeting.
c) Adoption of final opinions	
1. MOCA_Reachlaw (1 use) RAC adopted the final opinion with no changes in conclusions of the draft opinion following the Applicant's comments.	**Rapporteur** together with **SECR** to do the final editing of the opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.
2. SC_Aviall (2 uses) RAC adopted the final opinions with changes and clarifications in justification and conditions of the draft opinions following the Applicant's comments.	**Rapporteurs** together with **SECR** to do the final editing of the opinions. **SECR** to send the final opinions to the EC, MSs and the Applicant.
3. CT_Haas (1 use) RAC adopted the final opinion with changes and clarifications in justification and conditions of the draft opinion following the Applicant's comments.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.

4. SD_Haas (1 use) RAC adopted the final opinion with changes and clarifications in justification and conditions of the draft opinion following the Applicant's comments.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.
5. PD_Haas (1 use) RAC adopted the final opinion with changes and clarifications in justification and conditions of the draft opinion following the Applicant's comments.	**Rapporteurs** together with **SECR** to do the final editing of the opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.
10.3 Review Reports	
1. RR1_DEHP_VINYLOOP (2 uses) RAC discussed the key issues in the two review reports and provided advice as needed to the Rapporteurs, also in relation to the conformity.	**SECR** to inform SEAC about the outcome of the discussion.
2. RR1_DEHP_PP (2 uses) RAC discussed the key issues in the two review reports and provided advice as needed to the Rapporteurs, also in relation to the conformity.	**SECR** to inform SEAC about the outcome of the discussion.
11. AOB	
a) Report from the Impact Assessment Scoping Group meeting	
12. Action points and main conclusions of RAC-43	
SECR to upload the adopted action points to CIRCA BC.	

Table 1: CLH opinions which were adopted at RAC-43

RAC-43

1. 2-phenylhexanenitrile
2. Carboxin (ISO)
3. metaflumizone (ISO)
4. pyridate (ISO)
5. Tinuvin
6. dibutylbis(pentane-2,4-dionato-O,O')tin
7. 2-methylimidazole
8. cyflumetofen (ISO)
9.

2-phenylhexanenitrile

Existing Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	608-039-00-0	2-phenylhexanenitrile	423-460-8	3508-98-3	Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410			
Dossier submitters proposal	608-039-00-0	2-phenylhexanenitrile	423-460-8	3508-98-3	**Modify** Acute Tox. 4 Aquatic Chronic 2 **Remove** Aquatic Acute 1	**Retain** H302 **Modify** H411 **Remove** H400	**Retain** GHS07 GHS09 Wng	**Retain** H302 **Modify** H411			
RAC opinion	608-039-00-0	2-phenylhexanenitrile	423-460-8	3508-98-3	**Modify** Acute Tox. 4 Aquatic Chronic 2 **Remove** Aquatic Acute 1	**Retain** H302 **Modify** H411 **Remove** H400	**Retain** GHS07 GHS09 Wng	**Retain** H302 **Modify** H411		**Add** oral: ATE[1] = 500 mg/kg	
Resulting Annex VI entry if agreed by COM	608-039-00-0	2-phenylhexanenitrile	423-460-8	3508-98-3	Acute Tox. 4 Aquatic Chronic 2	H302 H411	GHS07 GHS09 Wng	H302 H411		oral: ATE[1] = 500 mg/kg	

Note: [1] Converted acute toxicity point estimate according to Table 3.1.2 of Annex I.

Carboxin (ISO)

No current Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	616-RST-VW-Y	carboxin (ISO); 2-methyl-*N*-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide	226-031-1	5234-68-4	STOT RE 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 2	H373 (kidneys) H317 H400 H411	GHS07 GHS08 GHS09 Wng	H373 (kidneys) H317 H410		M=1 M=1	
RAC opinion	616-RST-VW-Y	carboxin (ISO); 2-methyl-*N*-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide	226-031-1	5234-68-4	STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H373 (kidneys) H317 H400 H410	GHS07 GHS08 GHS09 Wng	H373 (kidneys) H317 H410		M=1 M=1	
Resulting Annex VI entry if agreed by COM	616-RST-VW-Y	carboxin (ISO); 2-methyl-*N*-phenyl-5,6-dihydro-1,4-oxathiine-3-carboxamide; 5,6-dihydro-2-methyl-1,4-oxathiine-3-carboxanilide	226-031-1	5234-68-4	STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H373 (kidneys) H317 H400 H410	GHS07 GHS08 GHS09 Wng	H373 (kidneys) H317 H410		M=1 M=1	

metaflumizone (ISO)

No currentAnnex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	616-RST-VW-Y	metaflumizone (ISO); (*EZ*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [*E*-isomer ≥ 90%, *Z*-isomer ≤10% relative content]; [1] (*E*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2]	-	139968-49-3 [1] 852403-68-0 [2]	Repr. 2 Lact. STOT RE 2	H361d H362 H373 (oral, inhalation)	GHS08 Wng	H361d H362 H373 (oral, inhalation)			
RAC opinion	616-RST-VW-Y	metaflumizone (ISO); (*EZ*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [*E*-isomer ≥ 90%, *Z*-isomer ≤10% relative content] [1] (*E*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2]	-	139968-49-3 [1] 852403-68-0 [2]	Repr. 2 Lact. STOT RE 2	H361fd H362 H373	GHS08 Wng	H361fd H362 H373			
Resulting Annex VI entry if agreed by COM	616-RST-VW-Y	metaflumizone (ISO); (*EZ*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [*E*-isomer ≥ 90%, *Z*-isomer ≤10% relative content] [1] (*E*)-2'-[2-(4-cyanophenyl)-1-(α,α,α-trifluoro-m-tolyl)ethylidene]-[4-(trifluoromethoxy)phenyl]carbanilohydrazide [2]	-	139968-49-3 [1] 852403-68-0 [2]	Repr. 2 Lact. STOT RE 2	H361fd H362 H373	GHS08 Wng	H361fd H362 H373			

pyridate (ISO)

Existing Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-232-00-7	pyridate (ISO); O-(6-chloro-3-phenylpyridazin- 4-yl) S-octyl thiocarbonate	259-686-7	55512-33-9	Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H315 H317 H400 H410	GHS07 GHS09 Wng	H315 H317 H410			
Dossier submitters proposal	607-232-00-7	pyridate (ISO); O-(6-chloro-3-phenylpyridazin- 4-yl) S-octyl thiocarbonate	259-686-7	55512-33-9	**Retain:** Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 **Modify:** Skin Sens. 1B **Add:** STOT SE 1	**Retain:** H315 H400 H410 H317 **Add:** H370	**Retain:** GHS07 GHS09 **Add:** GHS08 **Modify:** Dgr	**Retain:** H315 H410 H317 **Add:** H370		**Add:** M=1 M=10	
RAC opinion	607-232-00-7	pyridate (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate	259-686-7	55512-33-9	**Retain:** Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1 **Add:** Acute Tox. 4	**Retain:** H315 H317 H400 H410 **Add:** H302	**Retain:** GHS07 GHS09 Wng **Add:** GHS08	**Retain:** H315 H317 H410 **Add:** H302		**Add:** M=1 M=10 oral: ATE = 500 mg/kg	
Resulting Annex VI entry if agreed by COM	607-232-00-7	pyridate (ISO); O-(6-chloro-3-phenylpyridazin-4-yl) S-octyl thiocarbonate	259-686-7	55512-33-9	Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H302 H315 H317 H400 H410	GSH07 GSH08 GHS09 Wng	H302 H315 H317 H410		oral: ATE = 500 mg/kg M=1 M=10	

Tinuvin

Existing Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	604-052-00-0	2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)	403-800-1	103597-45-1	Aquatic Chronic 4	H413		H413			
Dossier submitters proposal	604-052-00-0	2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)	403-800-1	103597-45-1	**Remove:** Aquatic Chronic 4	**Remove:** H413		**Remove:** H413			
RAC opinion	604-052-00-0	2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)	403-800-1	103597-45-1	**Retain:** Aquatic Chronic 4	**Retain:** H413		**Retain:** H413			
Resulting Annex VI entry if agreed by COM	604-052-00-0	2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)	403-800-1	103597-45-1	Aquatic Chronic 4	H413		H413			

dibutylbis(pentane-2,4-dionato-O,O')tin

No current Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	650-RST-VW-Y	dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4	Repr. 1B STOT RE 1	H360FD H372	GHS08 Dgr	H360FD H372			
RAC opinion	650-RST-VW-Y	dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4	Repr. 1B STOT RE 1	H360FD H372	GHS08 Dgr	H360FD H372			
Resulting Annex VI entry if agreed by COM	650-RST-VW-Y	dibutylbis(pentane-2,4-dionato-O,O')tin	245-152-0	22673-19-4	Repr. 1B STOT RE 1	H360FD H372 (immune system)	GHS08 Dgr	H360FD H372 (immune system)			

2-methylimidazole

No current Annex VI entry (CLP, Table 3.1)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitter's proposal	613-RST-VW-Y	2-methylimidazole	211-765-7	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df			
RAC opinion	613-RST-VW-Y	2-methylimidazole	211-765-7	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df			
Resulting Annex VI entry if agreed by COM	613-RST-VW-Y	2-methylimidazole	211-765-7	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df			

cyflumetofen (ISO)

No current Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	607-RST-VW-Y	cyflumetofen (ISO); 2-methoxyethyl (RS)-2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-o-tolyl)propionate	-	400882-07-7	Carc. 2 Skin Sens. 1A	H351 H317	GHS07 GHS08 Wng	H351 H317			
RAC opinion	607-RST-VW-Y	cyflumetofen (ISO); 2-methoxyethyl (RS)-2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-o-tolyl)propionate	-	400882-07-7	Carc. 2 Skin Sens. 1A	H351 H317	GHS07 GHS08 Wng	H351 H317			
Resulting Annex VI entry if agreed by COM	607-RST-VW-Y	cyflumetofen (ISO); 2-methoxyethyl (RS)-2-(4-tert-butylphenyl)-2-cyano-3-oxo-3-(α,α,α-trifluoro-o-tolyl)propionate	-	400882-07-7	Carc. 2 Skin Sens. 1A	H351 H317	GHS07 GHS08 Wng	H351 H317			

Table 2

MCPA-thioethyl (ISO)

No current Annex VI entry (CLP, Table 3)

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard state-ment Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethan ethioate; S-ethyl 4-chloro-o-tolyloxythioacetate	246-831-4	25319-90-8	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		oral: ATE = 450 mg/kg bw M=10 M=10	
RAC opinion	TBD	MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethan ethioate; S-ethyl 4-chloro-o-tolyloxythioacetate	246-831-4	25319-90-8	Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H373 H400 H410	GHS07 GHS08 GHS09 Wng	H302 H373 H410		oral: ATE = 450 mg/kg bw M=10 M=10	
Resulting Annex VI entry if agreed by COM	TBD	MCPA-thioethyl (ISO); S-ethyl (4-chloro-2-methylphenoxy)ethan ethioate; S-ethyl 4-chloro-o-tolyloxythioacetate	246-831-4	25319-90-8							

Part III. List of Attendees of the RAC-43 meeting

27 November – 1 December and 4-5 December 2017

RAC Members
AGAPIOU Agapios
ANDREOU Kostas
BARAŃSKI Bogusław
BIRO Anna
BJØRGE Christine
CARVALHO João
CHANKOVA-PETROVA Stephka
CHIURTU Elena (co-opted Member)
CZERCZAK Sławomir
DE LA FLOR TEJERO Ignacio
DUNAUSKIENĖ Lina
DUNGEY Stephen
GEOFFROY Laura
GRUIZ Katalin
GUSTAFSON Anne-Lee
HAKKERT Betty
HUSA Stine
HÖLZL Christine
ILIE Mihaela
JANKOWSKA Elżbieta (co-opted Member)
KADIĶIS Normunds
KAPELARI Sonja
KARADJOVA Irina
LEINONEN Riitta
LUND Bert-Ove
MARTÍNEK Michal
MENARD SRPČIČ Anja
MOELLER Ruth
MULLOOLY Yvonne
MURRAY Brendan
NEUMANN Michael
PARIS Pietro
POLAKOVICOVA Helena
PRINTEMPS Nathalie
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SANTONEN Tiina
SCHULTE Agnes
SÉBA Julie
SMITH Andrew
SØRENSEN Peter Hammer
SOGORB Miguel A.
SPETSERIS Nikolaos
STAHLMANN Ralf
TOBIASSEN Lea Stine
TSITSIMPIKOU Christina
UŽOMECKAS Žilvinas
VAN DER HAAR Rudolf (co-opted Member)
VARNAI Veda Marija
VIEGAS Susana (co-opted Member)
Apologies, Members
AGUILINA Gabriele
BRANISTEANU Radu
SCHLÜTER Urs

Commission observers
GARCIA-JOHN Enrique, DG GROW
LUVARA Giuseppina, DG ENV
MORRIS Alick, DG EMPL
RAC advisors
ESPOSITO Dania (Pietro Paris)
LOIKKANEN Jarkko (Riitta Leinonen)
PAPPONEN Hinni (Riitta Leinonen)
PECZKOWSKA Beata (Bogusław Barański)_CLH carboxin and -phenylhexanenitrite
ROMOLI Debora (Pietro Paris)_CLH cyflumetofen
STOCKMANN-JUVALA Helene (Tiina Santonen)
SUUTARI Tiina (Riitta Leinonen)
TALASNIEMI Petteri (Riitta Leinonen)
Dossier submitters
BIEGEL-ENGLER Annegret (DE, C9-C14 PFCAs)
FOTLAND Tor Oystei (NO, tattoo inks)
ROUW Aarnout (DE, diisocyanates)
WALENDZIK Gudrun (DE, diisocyanates)

Stakeholders observers
ANNYS Erwin, Cefic
BARRY Frank, ETUC
BERNARD Alice, ClientEarth
GENNART Jean-Philippe, CONCAWE (occasional stakeholder observer, Article 77(3)(c), Article 95(3))
MIKANDER Nina, UNEP/AEWA, restriction lead in PVC
MUNARI Tomaso, EuCheMS
PEREZ SIMBOR Laia, ETRMA (occasional stakeholder observer, Article 77(3)(c) and Article 95(3))
ROWE Rocky, ECPA
TILLIEUX Geoffroy, EUPC (occasional stakeholder observer, restriction lead in PVC and diisocyanates)
VEROUGSTRAETE Violaine, Eurometaux
Apologies, stakeholders
DOLORES Romano, EEB
Industry experts
BINKS Steve (Eurometaux, International Lead Association, lead in PVC)
BOENIGK Winfried (Cefic, Rütgers Group, AfA CTHPT´s)
BOMANN Werner (ECPA, Belchim, pyridate)
BOOGAARD Peter (Cefic, Shell International B,V., benzene)
CROMIE Ruth (UNEP/AEWA, UK Wildfowl & Wetlands Trust (WWT), lead in shot)
FOSTER John (ECPA, Arysta, carboxin)

KELLY Craig (Cefic, TSGE Consulting, acrylonitrile)	**Dossier submitters**
LÜCKE-BRUNK Gudrun (Cefic, Covestro Deutschland AG, diisocyanates)	**Germany**
MELCHING-KOLLMUSS Stephanie (ECPA, BASF, metaflumizone)	LERCHE Dorte (tattoo inks)
OLLER Adriana (Eurometaux, Nipera Inc, CMD/CAD nickel)	NIEDERSTRASSER Bernd (C9-C14 PFCAs, their salts and related substances)
ROSOL Tom (ECPA, OAT/BASF, cyflumetofen (HH))	STAUDE Claudia (C9-C14 PFCAs)
VAN DE GEVEL Iris (ECPA, OAT/BASF, cyflumetofen (ENV))	**Norway**
WILLIAMS Steve (CONCAWE, Steve Williams Consulting Ltd, benzene)	BLOM Cecile(tattoo inks)
	VAN DER HAGEN Marianne (restriction: conformity and key issues, tattoo inks
Invited experts	**Poland**
HYNES Jarlath (EcoMole Ltd, dose-response)	DOMIANIK Dorota (MCPA-thioethyl (ISO))
	JUSKO Katarzyna (MCPA-thioethyl (ISO)
REMOTE PARTICIPANTS	**Sweden**
RAC Members:	BORG Daniel (C9-C14 PFCAs)
DUNGEY Steve	CEDERBERG Inger (C9-C14 PFCAs)
HÖLZL Christine	HENRIKSSON Witasp Erika (2-methylimidazole)
SCHLÜTER Urs	LINDQVIST Martin (C9-C14 PFCAs)
STAHLMANN Ralf	
Advisers	**Commission**
BEETSTRA Renske (adviser to Betty Hakkert)	BLASS RICO Ana Maria
LOSERT Annemarie (adviser to Christine Hölzl)	
WOUTERSEN Marjolijn (adviser to Betty Hakkert)	

ECHA staff		SIMOES Ricardo
BERGES Markus		SOSNOWSKI Piotr
BLAINEY Mark		SPJUTH Linda
BOWMER Tim, Chairman		STOYANOVA Evgenia
BROECKAERT Fabrice		TANARRO Celia
DVOŘÁKOVÁ Dana		UPHILL Simon
ERICSSON Gunilla		UPHOFF Andreas
HOLLINS Steve		VÄÄNÄNEN Virpi
HOPLAND Eivind		
JONES Stella		
KANELLOPOULOU Athanasia		
KARJALAINEN Antti		
KIVELÄ Kalle		
KOKKOLA Leila		
LIOPA Elīna		
LOGTMEIJER Christiaan		
LUDBORŽS Arnis		
LUSCHUTZKY Evita		
MARQUEZ-CAMACHO Mercedes		
MAZZOLINI Anna		
MERKOURAKIS Spyridon		
MUSHTAQ Fesil		
MÜLLER Gesine		
NATHANAIL Alexis		
NYGREN Jonas		
ORISPÄÄ Katja		
O'ROURKE Regina		
PELTOLA Jukka		
PENNESE Daniele		
PERAZZOLO Chiara		
PILLET Monique		
PREVEDOUROS Konstantinos		
REGIL Pablo		
REUTER Ulrike		
RHEINBERGER Christoph		
RODRIGUEZ-IGLESIAS Pilar		
ROGGEMAN Maarten		
SADAM Diana		

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-43 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-43 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-43 meeting

ANNEX IV Administrative issues and information items

27 November 2017
RAC/A/43/2017

Final Agenda

43th meeting of the Committee for Risk Assessment

27 November – 1 December 2017
and
4 - 5 December 2017

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 27 November starts at 14.00
Friday 1 December breaks at 13.00
Monday 4 December resumes at 09.00
Tuesday 5 December ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/43/2017
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Appointment of (co-)rapporteurs

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

RAC/43/2017/01
(restricted)
Room document
For agreement

Item 5 – Report from other ECHA bodies and activities

a) Report on RAC 42 action points, written procedures and update on other ECHA bodies

RAC/43/2017/02

RAC/43/2017/03
Room document
For information

b) RAC workplan for all processes

c) Announcement of administrative changes

For information

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

6.1 Dossiers occupational exposure- opinion development

a) Nickel and its compounds

b) Benzene

For discussion/adoption

c) Acrylonitrile

For discussion

Item 7 – Requests under Article 95 (3)

a) Methodology related to the exposure of chemicals at the workplace in relation to non-threshold substances

RAC/43/2017/04
Room document
For discussion and agreement

Item 8 – Harmonised classification and labelling (CLH)

8.1 General CLH issues

8.2 CLH dossiers

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

- 2-phenylhexanitrile: acute toxicity, environmental hazards
- carboxin (ISO): physical hazards, acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, STOT SE, germ cell mutagenicity, toxicity to reproduction, environmental hazards

- pyridate (ISO): acute toxicity (dermal and inhalation), skin irritation, germ cell mutagenicity, carcinogenicity, toxicity to reproduction, environmental hazards
- cyflumetofen (ISO): physical hazards, acute toxicity, skin corrosion / irritation, serious eye damage / eye irritation, STOT SE, germ cell mutagenicity, aspiration hazard
- MCPA-thioethyl (ISO): physical hazards, acute toxicity, skin corrosion / irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, aspiration hazard, environmental hazards

B. Hazard classes for agreement with plenary debate

1) 2-phenylhexanenitrile
2) carboxin (ISO)
3) metaflumizone (ISO); 4-{2-({[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile
4) pyridate (ISO)
5) Tinuvin UV-360
6) dibutylbis(pentane-2,4-dionato-O,O')tin
7) 2-methylimidazole
8) cyflumetofen (ISO)
9) MCPA-thioethyl (ISO)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

b) Conformity check and key issues discussion
   1) Substances used in tattoo inks and permanent make-up
   2) C9-C14 PFCAs, their salts and related substances

For agreement

c) Opinion development

   1) Diisocyanates – final draft opinion
   2) Lead and lead compounds in PVC – final draft opinion

For adoption

   3) Lead and lead compounds in shot – second draft opinion

For discussion/adoption

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications
b) Report from the AfA Stock-taking Conference
c) Lines to take for new Annex XIV substances

For information

d) Question and Answer document for future applicants handling the endocrine disrupting properties.

RAC/43/2017/05
For agreement

e) AfA DNEL/DR: Carcinogenicity dose-response relationship development of:

1. Coal tar pitch, high temperature (CTPHT)
2. Anthracene oil

RAC/43/2017/06
Room document
For discussion/ agreement

10.2. Authorisation applications

a) Discussion on key issues
2. PCO_IP (2 uses)

For discussion

11. Agreement on draft opinions

1. CT_Hapoc (3 uses)
2. SD_Hapoc (1 use)
3. PC_SC_Saes (2 uses)
4. EDC_Microbeads (1 use)
5. CT_ZFF (1 use)

For discussion and agreement

6. SC_Wesco (1 use)
7. DtC_Wesco (1 use)
8. PCO_Aviall (2 uses)

For discussion

9. CT_Hapoc_2 (1 use)
10. CT_Hapoc_3 (1 use)

Status update

12. Adoption of final opinions

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

For discussion and adoption

10.3. Review reports

b) Discussion on key issues

3. RR1_DEHP_Vinyloop (2 uses)
4. RR1_DEHP_PP (2 uses)

For discussion

Item 11 – AOB

a) Report from the Impact Assessment Scoping Group meeting

Item 12 – Action points and main conclusions of RAC-43

Table with Conclusions and Action points from RAC-43

For adoption

Annex II (RAC 43)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 43 meeting.

Document number	Title
RAC/A/43/2017	Final Draft Agenda
RAC/A/43/2017 Restricted	Draft outline agenda
RAC/43/2017/01 Restricted room document	Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, DNEL/dose-response relationships, Article 95 (3) requests and Article 77 (3) requests
RAC/43/2017/02	Report from other ECHA bodies
RAC/43/2017/03 Room document	Administrative issues
RAC/42/2017/04	Methodology related to the exposure of chemicals at the workplace in relation to non-threshold substances
RAC/42/2017/05	Question and Answer document for future applicants handling the endocrine disrupting properties
RAC/42/2017/06	AfA DNEL/DR: Carcinogenicity dose-response relationship development of: Coal tar pitch, high temperature (CTPHT)

ANNEX III (RAC-43)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLÜTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
-	-	-
Requests under Article 77(3) (c)		
	-	-
Restrictions		
Diisocyanates **(DE)**	Agnes SCHULTE	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Norbert RUPPRICH	Working for the CA submitting the dossier; and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.
	Urs SCHLÜTER	Working for the CA submitting the dossier and involved in the preparation; asked to refrain from voting in the event of a vote on this substance - other mitigation measures may be applied by the Chairman.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	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.

New dossiers

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW		
Article 77.3(c)		
-	-	-
Restrictions		
Tattoo inks	Peter Hammer SØRENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Agnes SCHULTE	Working for the CA which has been involved in the preparation of the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Urs SCHLÜTER	Working for the CA which has been involved in the preparation the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Christine BJORGE	Working for the CA which has been involved in the preparation the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Tattoo inks	Stine HUSA	Working for the CA which has been involved in the preparation the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
PFCAs	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
PFCAs	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.
PFCAs	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
PFCAs	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Applications for Authorisation		
-	-	-
Harmonised classification & labelling		
2-phenylhexanenitrile **ES**	Miguel A. SOGORB	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.
	Ignacio De La Flor TEJERO	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
Pyridate (ISO) **AT**	Christine HÖLZL	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. not involved
	Sonja KAPELARI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
Cyflumetofen (ISO) **NL**	Betty HAKKERT	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.- not involved
	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.- not involved
2,2'-methylenbis(6-(2H-benzotriazol-2-YL)-4-(1,1,3,3-tetramethylbutyl)phenol) **Tinuvin UV-360** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Norbert RUPPRICH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Urs SCHLÜTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
1) **Carboxin (ISO)** 2) **Metaflumizone (ISO)** **UK**	Andrew SMITH	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Steve DUNGEY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
MCPA-thioethyl (ISO) **PL**	Bogusław BARAŃSKI	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
1) dibutylbis(pentane-2,4-dionato-O,O')tin **2) 2-methylimidazole** **SE**	Bert-Ove LUND	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied.
	Anne-Lee GUSTAFSON	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. involved

Helsinki, 21 November 2017

RAC/43/2017/03

ROOM DOCUMENT

43RD MEETING OF THE COMMITTEE FOR RISK ASSESSMENT

27 November – 1 December 2017
and
4 - 5 December 2017

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-42 Action Points

The RAC-42 action points due for RAC-43 are completed.

2 Outcome of written procedures & other consultations

2.1 Written procedures for adoption of RAC opinions / minutes of the meeting

Opinions / minutes adopted via written procedure	Deadline	Report on the outcome
Written procedure for adoption of the two final opinions on the application for authorisation Diglyme_Acton	13 November 2017	closed
Written procedure for adoption of the minutes of RAC-42	24 November 2017	closed

2.2 RAC consultations (status by 15 November 2017)

Subject / document	Deadline	Status / follow-up
Harmonised classification and labelling		
2-phenylhexanenitrile	1 November 2017	closed
carboxin (ISO)	25 October 2017 (HH) 9 November 2017 (ENV)	closed
metaflumizone (ISO); 4-{2-({[4-(trifluoromethoxy)phenyl]carbamoyl}hydrazono)-2-[3-(trifluoromethyl)phenyl]ethyl}benzonitrile	9 November 2017 (ENV) 10 November 2017 (HH)	closed
pyridate (ISO)	24 October 2017	closed
2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol); Tinuvin UV-360	10 November 2017 (*extended*)	closed
dibutylbis(pentane-2,4-dionato-O,O')tin	3 November 2017	closed
2-methylimidazole	24 October 2017	closed
cyflumetofen (ISO)	2 November 2017 (ENV) 9 November 2017 (HH)	closed
MCPA-thioethyl (ISO)	6 November 2017	closed
Application for Authorisation / Review Report		
Diglyme_Acton Consultation on final opinions	19 October 2017	closed
SC_Aviall Consultation on final opinions	8 November 2017	closed
CT_Haas Consultation on final opinion	8 November 2017	closed

Subject / document	Deadline	Status / follow-up
SD_Haas Consultation on final opinion	8 November 2017	closed
PD_Haas Consultation on final opinion	8 November 2017	closed
EDC_Microbeads Consultation on draft opinion	9 November 2017	closed
MOCA_Reachlaw Consultation on final opinion	9 November 2017	closed
SD_Hapoc Consultation on draft opinion	13 November 2017	closed
CT_Hapoc Consultation on draft opinions (Uses 2-4)	13 November 2017	closed
CT_ZFF Consultation on draft opinion	16 November 2017	closed
PC_SC_Saes Consultation on draft opinions	16 November 2017	closed
PCO_IP Consultation on application	3 January 2018	open
RR1_DEHP_VINYLOOP Consultation on review report	3 January 2018	open
RR1_DEHP_PP Consultation on review report	3 January 2018	open
Restrictions		
Consultation on the outcome of the conformity check on: Tattoo inks and permanent make-up PFCAs	13 November 2017	closed
Consultation on second draft opinion on lead in shot	24 November 2017	open
Consultation on third draft opinion on lead in PVC	17 November 2017	closed
Consultation on third draft opinion on Diisocyanates	17 November 2017	closed
Art. 77. 3. c request on evaluations OELs		
Nickel and its compounds	27 September 2017 23 November 2017	closed open
Benzene	27 September 2017 23 November 2017	closed open
Acrylonitrile	27 September 2017 13 December 2017	closed open

2.3 Other written consultations of RAC (status by 21 November 2017)

Subject / document	Deadline	Status / follow-up
Consultation the draft minutes of RAC-42	30 October 2017	closed

2.4 Calls for expression of interest

Calls for expression of interest	Date	Outcome
Harmonised classification and labelling		
Call for expression of interest in rapporteurship for thirteen CLH intentions / dossiers	26 October – 7 November 2017	Three volunteers expressed their interest
Application for Authorisation		
No calls		
Restriction		
No calls		

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

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Harmonised classification and labelling			
Written procedure for the appointment of (co-)rapporteurs	▪ Ethametsulfuron methyl (ISO) ▪ Mecoprop-methyl; (R)-2-(4-chloro-2-methylphenoxy)propionic acid ▪ 1,5-naphthylene diisocyanate ▪ 1,3-bis(isocyanatomethyl)benzene ▪ 1,3-bis(1-isocyanato-1-methylethyl)benzene ▪ 2,4,6-triisopropyl-m-phenylene diisocyanate ▪ (RS)-1-{1-ethyl-4-[4-mesyl-3-(2-methoxyethoxy)-o-toluoyl]pyrazol-5-yloxy}ethyl methyl carbonate; Tolpyralate ▪ 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate ▪ iprovalicarb (ISO); isopropyl [(2S)-3-methyl-1-{[1-(4-methylphenyl)ethyl]amino}-1-oxobutan-2-yl]carbamate	23 November 2017	closed No comments were received from RAC members on the recommendation of the Chairman; the RAC (co-)Rapporteur was appointed with tacit agreement.
Applications for Authorisation– no written procedures			

Appointment of (Co-)rapporteur(s)	Substance	Deadline	Outcome
Restrictions – no written procedures			

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

Opinion(s)	Sent on
Opinions sent to the European Commission, the Member States and applicants	
SD_Borealis (1 opinion)	4 October 2017
EDC_Olon (2 opinions)	7 November 2017