RAC/M/56/2021

Final

19 March 2021

Minutes of the 56th Meeting

of the Committee for Risk Assessment

(RAC-56)

Monday 8 March, 14.00 to Thursday 11, 13.15
and
Monday 15 March, 10.00 to Friday 19 March, 13.00

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair, Tim Bowmer, reflected on the following topics in his opening address:

- RAC is asked to discuss the proposed changes to the structure and operation of the Committee in 2021. The intention is that plenary meetings will become much shorter and the existing and newly created working groups will have the time to look at the details and provide adequate scrutiny to all the dossiers on their agendas. The proposal has the full backing of the agency and will also be presented at an upcoming Caracal meeting for information.

- ECHA staff continue full teleworking due to the Covid-19 situation in Finland and according to the latest decision, there will be no face-to-face external meetings at ECHA before September 2021. RAC meetings will remain virtual at least until then.

- At this meeting RAC members will discuss and approve the procedure for the selection of new co-opted members.

Finally, the Chair welcomed two new RAC Members, Manual Facchin, and Ifthektar Ali Mohammed.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/56/2021**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-56 minutes.
4. Appointment of (co-)rapporteurs	
a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers and restriction dossiers, as listed in the restricted documents in the Interact collaboration tool. The Committee agreed upon the proposed appointments of the Rapporteurs for the intentions and/or newly submitted CLH dossiers, as well as to the pool of volunteers for the restriction dossiers.	-
5. Report from other ECHA bodies and activities	
a) RAC work plan for all processes The Chair presented the RAC work plan for 2021.	
b) Procedure for admission of ASO observers RAC took note of and discussed the restricted meeting document on Approach on the admission of observers from accredited stakeholder organisations to the work of the ECHA committees (RAC/56/2021/01.) RAC agreed on the revised procedure for admission of Accredited Stakeholder Organisation observers.	**SECR** to publish the updated approach on the ECHA website and to update the list of RAC STOs on ECHA website (i.e. to only include regular STOs).
c) Revision of Rules of Procedure RAC agreed to the proposed revisions to the RAC RoPs (in line with the restricted meeting document RAC/56/2021/02).	**SECR** to forward the revised RAC Rules of Procedure to ECHA's Management Board for their adoption.

d) RAC co-opted members RAC took note of and discussed the restricted meeting document on co-opted members (RAC/56/2021/03.) RAC agreed on proposals for the required competences and selection procedure for co-opting additional members. Furthermore, RAC agreed on the members of the Selection and Appeal panels.	**SECR** to take note of discussions on the call for expression of interest on the appointment of co-opted members.
e) Proposal by the Secretariat to set up the standing Working Groups of RAC for Restrictions and CLH RAC discussed and agreed the set-up of the RAC Restriction and the CLH Working Groups. Members expressed their concerns regarding a sufficient number of RAC members to deal with the increasing workload. They proposed to consider increasing the number of members per MS, or the number of co-opted members and seeking a stronger commitment from MSs to assign 50% of working time of members to RAC. RAC adopted the Mandates of the RAC Restriction Working Group and the RAC CLH Working Group with two editorial corrections. Both mandates are valid for one year.	**SECR** to publish the mandates on the ECHA website and to schedule and organise the RAC Restriction Working Group and the RAC CLH Working Group meetings.
6. Request under Article 77(3)(c)	
1) Request to review Microplastics - infill material and 'inorganic polymers'	
The Chair welcomed the regular stakeholders from EEB, Cefic, ClientEarth, CropLife Europe and the occasional stakeholder observers from CIRFS, EDANA, ECETOC, Euroseeds, ETRA, EuPC, Chimic, ETRMA and their accompanying experts (from NTNU Norway, Corteva, FIDRA, ESTC, KWS, ETRA Secretary General, NVR/RecyBEM). In early February 2021, the Commission made a request on a supplementary opinion on the proposed restriction on intentionally-added microplastics, taking into account new elements which emerged after RAC had adopted its final opinion in June 2020.	
RAC rapporteurs presented and RAC discussed the draft opinion on this Article 77(3)(c) request. 1. <u>Effectiveness of risk management measures to contain microplastic infill material on artificial turf sports pitches, specifically the publication of CEN TR 17519 *'Guidance on*</u>	**Rapporteurs** to make final editorial changes in the adopted opinion. **SECR** to send the RAC opinion to the Commission and to publish it on the ECHA website.

how to minimize infill dispersion into the environment' RAC concluded that the *Magnusson & Mácsik (2020)* study is well reasoned and reported and that it is reasonable to assume that implementing the appropriate combination of RMMs proposed in CEN TR 17519 can, in principle, limit infill dispersion to levels below 7 g/m^2/year, provided that they are adhered to in newly constructed pitches and fully implemented retrospectively on pre-existing fields. RAC noted the many uncertainties but supported the supplementary opinion as prepared by the rapporteurs, and concluded there was no reason to change its recommendation for the full ban on infill material. 2. The applicability of Annex XIII of REACH to polymers without carbon atoms RAC supported the rapporteurs' conclusions, but noted that the absence of data on the ecotoxicity of polymers without carbon could not be used as evidence that they would not pose the same risks as microplastics. In conclusion, RAC adopted the opinion by consensus.	
Regular and occasional stakeholder observers (CIRFS, ESTC, ETRA, and FIDRA) and their accompanying experts (EEB, ETRMA) asked clarifying questions related to emissions or commented on the technical requirements for infill pitches/material. Regular stakeholder observer (Cefic and EEB) commented on the question on polymers without carbon atoms.	
2) Classification for environmental toxicity of lead	
The Chair welcomed the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers as well as an Occasional Stakeholder Observers from EuPC and from ECOPA. He reminded that on 30 November 2018, RAC had adopted an opinion on the harmonised classification and labelling of lead, which concluded that for both the massive and the powder forms, it should be classified as Aquatic Acute 1 (M=1) and Aquatic Chronic 1 (M=10). New information had been provided by Industry on the chronic toxicity of lead in the pond snail *Lymnea stagnalis* (OECD TG 243) and RAC was requested, based on Article 77(3)(c), to review its opinion of 30 November 2018 as regards to the environmental classification of lead. The *ad hoc* consultation was carried out prior to RAC-55. The Commission's deadline for the adoption of an opinion is 13 May 2021 (for which an extension will be sought).	

RAC discussed the revised draft opinion. RAC provisionally agreed that reasonable handling and use of the massive form generate particles < 1 mm. RAC Members were asked to provide details of verifiable examples of reasonable handling uses of massive lead that generate particles < 1 mm. ECHA offered to clarify whether lead sheets of 99 % purity (which exist in various thicknesses) are articles and whether alloys are relevant for classification of a pure metal (i.e. particles generated from alloys). COM was asked to clarify whether disposal or any other modes of handling and use in CLP guidance 1.2.2 should be disregarded for metals. RAC provisionally agreed that generated particles are relevant for classification of the massive form. The Chairman requested the Rapporteurs and the Members of the *ad hoc* working group to firm up on the evidence supporting this. Industry was kindly requested to provide more information regarding the generation of particles < 1 mm from massive lead, including: • Total tonnage of lead sheeting exposed to cutting processing from ILA doc K Feb 2021. As this results in 0.0018% of the overall material as particles < 1 mm this will allow a detailed estimate of the amount generated (by tonnage). • A particle distribution analysis of the swarf generated from the cutting of the lead sheets. • Details on the nature of the particles < 1 mm generated by this process (i.e. dimensions, shape, surface area). • Process diagram and decision tables for lead similar to those given for aluminium in the Guidance on requirements for substances in articles, Appendix 4, Example 16 (V 4.0, June 2017, page 79).	**SECR** to plan further discussion on the dossier in the RAC CLH WG meeting in April. **Rapporteur(s)**, with the support from the *ad hoc* group and the SECR, to revise the opinion in accordance with the discussion in RAC-56 and in RAC CLH WG and to provide it to SECR. **SECR** to table the revised draft opinion for final discussion and adoption at RAC-57 in June 2021.
The COM observer, the Eurometaux Regular Stakeholder Observer and the accompanying experts of the Cefic and Eurometaux Regular Stakeholder Observers commented on different aspects of the revised draft opinion.	
7. Health based exposure limits at the workplace	
a) Opinion development	
1. Asbestos – first draft opinion	

The Chairman welcomed the expert accompanying the regular ETUC stakeholder observer, two occasional stakeholders as well as the three observers from the DG-EMPL, Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC). The Commission made a request on 08/01/2020, with a deadline of 18 months, to evaluate the current OEL, which impose on employers the obligation to ensure that no worker is exposed to an airborne concentration of asbestos in excess of 0.1 fibres per cm3 as an 8-hour time-weighted average (TWA) in accordance with Article 8 Directive 2009/148/EC. "The scientific evaluation shall include, where appropriate, review of/or proposals for OEL(s), biological limit value(s) and/or appropriate notations. It shall include an evaluation of different types of asbestos fibres (as defined in Art 2, Dir 2009/148/EC) and take into account the nature of the health effects due to these differences. It shall include an assessment of whether a differentiated limit value may be appropriate for the different types of asbestos fibres.". A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 2 March 2020 to 2 June 2020. The ECHA scientific report is open for a two-month consultation from 1 February to 1 April 2021. During the opinion development process, the ECHA scientific report will be transferred to an Annex to the RAC opinion.	
RAC discussed the first draft opinion and the Scientific Report on the scientific evaluation of limit values for asbestos. The following points were discussed and/or agreed: • RAC supported the approach taken in the selection of the epidemiological studies as the basis for the assessment. • RAC supported the two different risk assessment approaches (general principle and methodology) for the risk response relation describing the combined excess risk of dying from mesothelioma and lung cancer in relation to exposure. • RAC agreed to further explain in the final draft opinion the uncertainties in the risk estimates included, resulting from exposure to asbestos and subsequent occurrence of other cancer types and asbestosis than lung cancer and mesothelioma. More justification and details on the other cancer types will be inserted in the final draft opinion. • RAC asked for further clarification on the analytical methods and to justify an appropriate conversion factor to translate PCM to TEM results. More justification for the use of the conversion factor will be inserted in the final draft opinion. • It was agreed to further explain in the draft final opinion the effect of using an approach	Rapporteurs to prepare the draft final opinion taking into account RAC-56 discussions.

in which exposure to mixed asbestos is assumed (as simulated by combining exposure response slopes for the different asbestos types) in view of the higher mesothelioma potency of amphiboles. • It was agreed to further explain in the final draft opinion why a STEL is not proposed.	

The expert accompanying the regular ETUC observer commented the derived Exposure risk relationship in the light of the estimated current asbestos disease burden.
The observer from the Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC), representing the Workers Interest Group and the expert accompanying the regular ETUC observer commented on the consideration of other cancers than lung cancer and mesothelioma.
The observer from the Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC), representing the Employers Interest Group, commented on the justification of the conversion factor to translate PCM to TEM factors.

b) Adoption of opinions

1. Cadmium and its inorganic compounds – final draft opinion

The Chairman welcomed the expert accompanying the regular Eurometaux stakeholder observers, three occasional stakeholders as well as the three observers from the DG-EMPL, Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC).

Directive (EU) 2019/37/EC, the third amendment of the Carcinogens and Mutagens Directive (Dir 2004/37/EC) was published on 5 June 2019, and included cadmium and its inorganic compounds in Annex III. However in Recital (17) it stated that " ….the Commission should, no later than three years after the date of entry into force of this Directive, assess the option of amending Directive 2004/37/EC by adding provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds". Therefore, the Commission made a request on 08/01/2020, with a deadline of 18 months, to ECHA to evaluate the following chemical agents: Cadmium and its inorganic compounds, in particular "to assess the option of an airborne occupational exposure limit (OEL) and/or a combination of an airborne occupational exposure limit and a biological monitoring value for cadmium and its inorganic compounds based on their possible equal effectiveness in protecting the health of workers".

A call for evidence in the preparatory phase inviting interested parties to submit comments and evidence on the subject took place from 2 March 2020 to 2 June 2020. The ECHA scientific report was open for a two-month consultation from 14 September to 12 November 2020.

During the opinion development process, the ECHA scientific report is to be transferred to an Annex to the RAC opinion.

The rapporteurs presented and RAC discussed the final draft opinion on the scientific evaluation of limit values for cadmium and its inorganic compounds at the workplace. RAC agreed that the combination of an OEL and biomonitoring value as proposed in the SCOEL	Rapporteurs to revise the opinion in accordance with the agreed modifications in RAC 56 and to provide it to SECR. SECR to make an editorial check of the opinion documents in consultation with

Opinion 336 (2017) when compared to the OEL adopted in Directive 2019/983 are not equally effective in protecting workers' health. RAC discussed the uncertainties concerning setting a BLV close to the background level in certain parts of Europe. It was agreed to elaborate further details in the final opinion on how close the values for the BLV and the background levels would be. RAC agreed to include in the final opinion, advice that may be relevant for the monitoring of the occupational health of employees such as taking into account background levels. RAC agreed with the biological and air limit values for cadmium and its inorganic compounds, as proposed in the final draft opinion. RAC agreed not to propose a 15 minutes short term exposure limit (STEL), notations or a BGV. RAC adopted its opinion (with modifications agreed at RAC-56) by consensus.	the Rapporteurs and to ensure that the Annex and the RCOM is in line with the adopted opinion. SECR to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

The expert accompanying the regular Eurometaux stakeholder observer commented on the evaluation of the data from HBM4EU in the final draft opinion and on the uncertainties associated with the data from the general population at very low exposure levels, if used to derive occupational exposure limit values for cadmium. The observer from the Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC), representing the Employers Interest Group, commented on the proposed 8 h TWA value for the inhalable fraction, and possible double counting as this is covered by BLV and the observer commented as well on the proposed BLV in relation to the background level in certain parts of Europe.

8. Harmonised classification and labelling (CLH)

8.1 CLH dossiers

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

- Ethyl acrylate: acute dermal toxicity
- Methyl acrylate: acute dermal toxicity, acute inhalation toxicity
- Allyl methacrylate: acute dermal toxicity, acute inhalation toxicity
- TODI: mutagenicity, respiratory sensitisation, skin sensitisation
- Foramsulfuron (ISO): physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, reproductive

toxicity, STOT SE, STOT RE, aspiration hazard, acute aquatic hazards, chronic aquatic hazards, hazardous to the ozone layer

- Mepiquat chloride (ISO): acute toxicity via all routes, skin sensitisation, carcinogenicity
- Transfluthrin (ISO): acute oral toxicity, skin irritation, acute aquatic hazards, chronic aquatic hazards
- Benfluralin (ISO): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE, germ cell mutagenicity

B. Substances with hazard classes for agreement in plenary session

1) Ethyl acrylate (EC: 205-438-8; CAS: 140-88-5)
2) Methyl acrylate (EC: 202-500-6; CAS: 96-33-3)
3) Allyl methacrylate (EC: 202-473-0; CAS: 96-05-9)
4) 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF (EC: 216-036-7; CAS: 1478-61-1)
5) Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro- 2-(4-hydroxyphenyl)propan-2-yl]phenolate (EC: 479-100-5; CAS: 577705-90-9)
6) Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (EC: 278-305-5; CAS: 75768-65-9)
7) Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1) (EC: -; CAS: -)
8) Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (EC: -; CAS: -)
9) TODI (EC: 202-112-7; CAS: 91-97-4)
10) Cinnamaldehyde (EC: 203-213-9 and 604-377-8; CAS: 104-55-2 and 14371-10 9)
11) Foramsulfuron (ISO) (EC: -; CAS: 173159-57-4)
12) Mepiquat chloride (ISO) (EC: 246-147-6; CAS: 24307-26-4)
13) Transfluthrin (ISO) (EC: 405-060-5; CAS: 118712-89-3)
14) Benfluralin (ISO) (EC: 217-465-2; CAS: 1861-40-1) (HH only; ENV done at RAC-55)
15) Methyl methacrylate (EC: 201-297-1; CAS: 80-62-6)

1. Ethyl acrylate (EC: 205-438-8; CAS: 140-88-5)

The Chair welcomed the Occasional Stakeholder Observers (from CIRFS, EDANA, EUPC and ECETOC) and an expert accompanying the CIRFS Occasional Stakeholder Observer. He explained that **ethyl acrylate** is used in articles, in formulation or re-packing, at industrial sites and in manufacturing.

The substance has current Annex VI entry as Flam. Liq. 2; H225, Acute Tox. 4*; H302, Acute Tox. 4*; H312, Acute Tox. 4*; H332, Skin Irrit. 2; H315 (C≥5 %), Eye Irrit. 2; H319 (C≥5 %), Skin Sens. 1; H317, STOT SE 3; H335 (C≥ 5%).

The DS (AT) proposes to modify Acute Tox. 4; H302 (ATE=1120 mg/kg bw), Acute Tox. 4; H312 (ATE=1800 mg/kg bw) and Acute Tox. 3; H331 (ATE=9 mg/L (vapours)).
Acute toxicity via all routes was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 19 June 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE=1120 mg/kg bw, Acute Tox. 4; H312 (ATE=1800 mg/kg bw, Acute Tox. 3; H331 (ATE=9 mg/L (vapours)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

2. Methyl acrylate (EC: 202-500-6; CAS: 96-33-3)

The Chair welcomed the Occasional Stakeholder Observers (from CIRFS, EDANA, EUPC and ECETOC) and an expert accompanying the CIRFS Occasional Stakeholder Observer. He explained that **methyl acrylate** is used in articles, at industrial sites and in manufacturing.
The substance has current Annex VI entry as Flam. Liq. 2; H225, Acute Tox. 4*; H302, Acute Tox. 4*; H312, Acute Tox. 4*; H332, Skin Irrit. 2; H315, Eye Irrit. 2; H319, Skin Sens. 1; H317, STOT SE 3; H335.
The DS (AT) proposes to modify Acute Tox. 4; H302 (ATE=500 mg/kg bw), Acute Tox. 4; H312 (ATE=1250 mg/kg bw) and Acute Tox. 3; H331 (ATE=3 mg/L (vapours)).
Acute toxicity via all routes was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 19 June 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE=500 mg/kg bw), Acute Tox. 4; H312 (ATE=1100 mg/kg bw), Acute Tox. 3; H331 (ATE=3 mg/L (vapours)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

3. Allyl methacrylate (EC: 202-473-0; CAS: 96-05-9)

The Chair welcomed the Occasional Stakeholder Observers (from CIRFS, EDANA, EUPC and ECETOC) and an expert accompanying the CIRFS Occasional Stakeholder Observer. He explained that **allyl methacrylate** is used by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

The substance has current Annex VI entry as Flam. Liq. 3; H226, Acute Tox. 4*; H302, Acute Tox. 4*; H312, Acute Tox. 3*; H331, Aquatic Acute 1; H400.
The DS (AT) proposes to modify Acute Tox. 4; H302 (ATE=401 mg/kg bw), Acute Tox. 3; H311 (ATE=467 mg/kg bw) and Acute Tox. 2; H330 (ATE=1.47 mg/L (vapours)).
Acute toxicity via all routes was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 19 June 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE=400 mg/kg bw), Acute Tox. 3; H311 (ATE=300 mg/kg bw), Acute Tox. 2; H330 (ATE=1.5mg/L (vapours)]	**Rapporteur** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteur. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

4. 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF (EC: 216-036-7; CAS: 1478-61-1)

The Chair welcomed the Dossier Submitter representative and explained that **bisphenol AF (BPAF)** is e.g. used as a reactive process regulator in polymer materials and in rubber production and processing. The substance has no current Annex VI entry.
The DS (SE) proposes to classify the substance as Repr. 1B; H360F.
Reproductive toxicity was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 16 June 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F] RAC agreed on no classification for developmental toxicity and for effects on or via lactation due to inconclusive data.	**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. Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro- 2-(4-hydroxyphenyl)propan-2-yl]phenolate (EC: 479-100-5; CAS: 577705-90-9)

The Chair welcomed the Dossier Submitter representative and explained that **BDDP-BPAF** is used e.g. in fluoropolymers manufacturing. The substance has no current Annex VI entry.
The DS (SE) proposes to classify the substance as Repr. 1B; H360F.
Reproductive toxicity was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 16 June 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F] RAC agreed on no classification for developmental toxicity and for effects on or via lactation due to inconclusive data.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
6. Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (EC: 278-305-5; CAS: 75768-65-9)	
The Chair welcomed the Dossier Submitter representative and explained that **BTP-BPAF** is used e.g. in fluoropolymers manufacturing. The substance has no current Annex VI entry. The DS (SE) proposes to classify the substance as Repr. 1B; H360F. Reproductive toxicity was the only hazard class open for comments during the Consultation. Legal deadline for the adoption of an opinion is 16 June 2021.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F] RAC agreed on no classification for developmental toxicity and for effects on or via lactation due to inconclusive data.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
7. Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1) (EC: -; CAS: -)	
The Chair welcomed the Dossier Submitter representative and explained that **reaction mass of BDDP-BPAF** is used in vulcanization system of fluoroelastomers and in the manufacture of fine chemicals and rubber products. The substance has no current Annex VI entry. The DS (SE) proposes to classify the substance as Repr. 1B; H360F. Reproductive toxicity was the only hazard class open for comments during the Consultation. Legal deadline for the adoption of an opinion is 16 June 2021.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F]	**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.

RAC agreed on no classification for developmental toxicity and for effects on or via lactation due to inconclusive data.	**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

8. Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (EC: -; CAS: -)

The Chair welcomed the Dossier Submitter representative and explained that **reaction mass of BTP-BPAF** is used in manufacturing of rubber articles and as a fluoroelastomer. The substance has no current Annex VI entry.
The DS (SE) proposes to classify the substance as Repr. 1B; H360F.
Reproductive toxicity was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 16 June 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Repr. 1B; H360F] RAC agreed on no classification for developmental toxicity and for effects on or via lactation due to inconclusive data.	**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. 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate, TODI (EC: 202-112-7; CAS: 91-97-4)

The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **TODI** is used in articles and at industrial sites. The substance has no current Annex VI entry.
The DS (FR and DE) propose to classify TODI as Resp. Sens. 1; H334, Skin Sens. 1A; H317 (SCL≥0.001 %) and Carc. 1B; H350.
Respiratory sensitisation, skin sensitisation, germ cell mutagenicity and carcinogenicity were open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 12 August 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Resp. Sens. 1; H334, Skin Sens. 1A; H317 (SCL≥0.001 %)] RAC agreed on no classification for germ cell mutagenicity.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

10. Cinnamaldehyde (EC: 203-213-9 and 604-377-8; CAS: 104-55-2 and 14371-10-9)

The Chair welcomed the Dossier Submitter representative, one Occasional Stakeholder Observer (IFRA) and the expert accompanying the IFRA Occasional Stakeholder Observer. He explained that **cinnamaldehyde** is used in cosmetics, cleaning agents, polishes and wax blends, air care products, biocidal products and pharmaceuticals. The substance has no current Annex VI entry.
The DS (DK) proposes to classify cinnamaldehyde as Skin Sens. 1A; H317 (SCL≥0.02%).
Skin sensitisation was the only hazard class open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 13 August 2021.

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 (SCL≥0.01%)]	**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.

The expert accompanying the IFRA Occasional Stakeholder Observer commented on skin sensitisation.

11. Foramsulfuron (ISO) (EC: -; CAS: 173159-57-4)

The Chair welcomed the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **foramsulfuron (ISO)** is a sulfonyl-urea herbicide mainly used in corn and sugarbeet. The substance has no current Annex VI entry.
The DS (FI) proposes to classify the substance as Carc 2; H351, Aquatic Acute 1; H400 (M=1000) and Aquatic Chronic 1; H410 (M=100).
Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, aspiration hazard, hazardous to the aquatic environment and hazardous to the ozone layer were open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 15 May 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=100)] RAC agreed on no classification for the other hazard classes considered.	**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.

The expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity.	
12. Mepiquat chloride (ISO) (EC: 246-147-6; CAS: 24307-26-4)	
The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **mepiquat chloride (ISO)** is a plat growth regulator which is mainly used in cereals. The substance has current Annex VI entry as Acute Tox. 4*; H302 and Aquatic Chronic 3; H412. The DS (FI) proposes to modify the existing classification to Acute Tox. 3; H301 (ATE=115 mg/kg bw), to add Acute Tox. 4; H332 (ATE=2.8 mg/L (dusts or mists), STOT SE 2; H371 (nervous system), Repr. 2; H361d and to retain Aquatic Chronic 3; H412. Acute toxicity, skin sensitisation, carcinogenicity, reproductive toxicity, STOT SE and hazardous to the aquatic environment were open for comments during the Consultation. Legal deadline for the adoption of an opinion is 28 August 2021.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 3; H301 (ATE=270 mg/kg bw), Acute Tox. 4; H332 (ATE=2.8 mg/L (dusts or mists)), Aquatic Chronic 3; H412] RAC agreed on no classification for the other hazard classes considered.	**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.
13. Transfluthrin (ISO) (EC: 405-060-5; CAS: 118712-89-3)	
The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **transfluthrin** is a fast-acting pyrethroid insecticide intended for use by non-professional users, and is approved for product-type 18 (insecticides, acaricides and products to control other arthropods). The substance has current Annex VI entry as Skin Irrit. 2; H315, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The DS (NL) proposes to retain Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 and add M-factors of 1000 to both, to add Acute Tox. 4; H302; Carc. 2; H351, STOT SE 1; H370 (nervous system), STOT RE 2; H373 (kidney) and to remove Skin Irrit. 2; H315. Acute oral toxicity, skin corrosion/irritation, carcinogenicity, STOT SE, STOT RE and hazardous to the aquatic environment were open for comments during the Consultation. Legal deadline for the adoption of an opinion is 15 May 2021.	
RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H302 (ATE=580 mg/kg bw), Carc. 2; H351, STOT SE 1; H370 (nervous system), Aquatic	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=1000)] RAC agreed on no classification for the other hazard classes considered.	**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.
The expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity.	

14. Benfluralin (ISO) (EC: 217-465-2; CAS: 1861-40-1)

The Chair welcomed the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **benfluralin** is an active substance in the scope of the Regulation (EC) 1107/2009. The substance has no current Annex VI entry.
The DS (NO) proposes to classify the substance as Carc. 2; H351, Repr. 2; H361d, Lact.; H362, STOT SE 2; H371, Skin Irrit. 2; H315, Eye Irrit. 2; H319, Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1, H410 (M=10).
Selected physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment, hazardous to the ozone layer were open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 19 May 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 2; H351, Repr. 2; H361d; Skin Irrit. 2; H315, Eye Irrit. 2; H319, Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=10)] RAC agreed on no classification for the other hazard classes considered.	**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.
The expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity, reproductive toxicity and lactation.	

15. Methyl methacrylate (EC: 201-297-1; CAS: 80-62-6)

The Chair welcomed the Dossier Submitter representative, four Occasional Stakeholder Observers (CIRFS, EDANA, ECETOC, EuPC), the expert accompanying the Cefic Regular Stakeholder Observer and the expert accompanying the CIRFS Occasional Stakeholder Observer. He reminded that RAC had adopted its opinion on the **methyl methacrylate** dossier at RAC-52B in October 2020. However, after the meeting, ECHA was approached by Industry with their concerns regarding some of the conclusions made by the Committee. Therefore, exceptionally and in the interests of accuracy and transparency, the Chair decided to take the opinion back to RAC to give Members another opportunity to discuss these specific points before it is finalised and sent to the Commission.

RAC took note of the new information related to respiratory sensitisation but did not change its earlier classification conclusion (Resp. Sens. 1; H334) as a result of the new information.	**Rapporteurs** to make the final amendments to the RAC opinion and to provide it to SECR. **SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
The expert accompanying the Cefic Regular Stakeholder Observer commented on respiratory sensitisation.	

9. Restrictions

9.1 Restriction Annex XV dossiers

a) Conformity check

1. Lead in ammunition

The Chair welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA, as well as the occasional stakeholder observers from CONCAWE and EURAMETAUX and their accompanying expert from International Lead Association (ILA). He informed the participants that the restriction dossier had been submitted in January 2021 and concerns lead in outdoor shooting and fishing.	
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 to S-CIRCABC.
The RAC members, invited experts and stakeholder observers asked clarifying questions from the dossier submitter on various aspects mentioned in the dossier.	

b) Opinion development

1. Substances in single-use diapers

The Chair welcomed the Dossier Submitter's representatives from France, the occasional stakeholder observers from EDANA and their accompanying expert from Essity Hygiene and Health, CIRFS and their accompanying expert from Kelheim Fibres as well as CONCAWE. He informed the participants that the restriction dossier had been submitted in October 2020 and concerns substances in single-use baby diapers.	
The rapporteurs presented and RAC discussed the first draft opinion. The following points were discussed and/or agreed: • RAC provisionally agreed on the list of substances included in the scope. Furthermore, RAC does not support voluntary use of fragrances in single-use baby diapers.	**RAC members** to provide any remaining comments via the written consultation on the first draft opinion (by 26 March 2021). **Rapporteurs** to prepare the second draft opinion, taking into account RAC-56 discussions and the RAC written consultation, by late April 2021.

• RAC agreed on the proposed scope in terms of the population affected. • RAC provisionally agreed to exclude DL-PCBs from the PCDDs and PCDFs group and include them only under total PCBs to prevent double-counting of DL-PCBs. • For formaldehyde, the plausibility of systemic effects was discussed; skin sensitisation may be the most sensitive critical effect. RAC asked the Rapporteurs to further elaborate on uncertainties related to systemic toxicity of formaldehyde. • RAC recognised the uncertainties (at least one order of magnitude underestimation) in the Dossier Submitter's approach to the DMEL derivation for PAHs. The Committee also agreed that there was no need to apply ADAF in addition to high to low dose extrapolation. • RAC supported the Rapporteurs' approach to evaluate the DNEL derivation of dioxins and furans (including DL-PCBs) but noted that it is likely to be conservative. RAC recognised that an oral absorption factor higher than 87% could have been applied (e.g. 97%, or 100%). • RAC provisionally agreed with the Rapporteurs' conclusions with respect to a separate DNEL for total PCBs. The discussion on oral absorption factor for dioxins and furans also applies to total PCBs. • RAC provisionally supported the use of 50% dermal absorption for all substances but notes that a sensitivity analysis would be useful.	**RAC-S** to request additional data from the Dossier Submitter on the analysis of PAHs, and a justification on why solvent extraction is not a relevant method to include additional substances in the scope of the restriction proposal.
The occasional stakeholder observer from EDANA commented on the scope of the proposal and draft opinion, dermal absorption as well as the two regulatory options and their accompanying expert commented on the presence of PAHs in diapers. The Dossier Submitter commented on the use of age adjustment factors for setting the DMEL of PAHs, the oral absorption factor for NDL-PCBs and the HRV value chosen for total PCBs. The occasional stakeholder observer from CIRFS commented on the derivation of the DMEL for PAHs.	
10. Authorisation	
10.1 General authorisation issues	

a) Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2021/2022 and timelines. The ECHA Secretariat presented the information on horizontal issues related to the AFA process: - when to place conditions in sections 7, 8 or 9, - frequency of measurements. RAC discussed and took note of the information.	**SECR** to summarise criteria in a 'lines-to-take' document. **SECR** to consider discussing AFA horizontal issues at all RAC AFA WG meetings.
b) Report from RAC WG on AfAs during February 2021 meeting	
The 7th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 15-16 February 2021. Participants: 18 RAC members, 5 Members' advisers, 3 Regular stakeholder observers, 1 Invited expert, 2 Commission observers, ECHA. The working group recommended that the following draft opinions were suitable for consideration via the A-listing procedure. • 214_CT_Salzgitter (2 uses) • 217_Diglyme_Acton_2 (2 uses) The working group recommended that the following draft opinions required full discussion or discussion on specific points at the RAC plenary: • 212_CT_Lars (2 uses) • 213_CT_SteelColor (1 use) • 215_CT_Oras (2 uses) • 216_CT_Viega (2 uses)	
The Secretariat presented the Report of the 7th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation. RAC took note of the Report.	
~~**c) Update of the opinion format**~~	
d) Evaluation of review reports	
RAC discussed the questions proposed by the ECHA secretariat and the Commission concerning the approach to evaluation of review reports. The ECHA Secretariat was requested to adjust opinion format to the RR requirements.	**SECR** to summarise the discussion and prepare a "Approach for review reports" document schedule it for discussion at 8 RAC AFA WG and for agreement at RAC-57 and update accordingly the opinion template.
10.2 Authorisation applications	

1. Discussion on key issues	
1) 4 applications for authorisation/review reports (chromium trioxide, trichloroethylene, DEHP) from November 2020 submission window	
RAC discussed the key issues in 2 AfAs and 2 RRs / 4 uses	
10.3 Agreement on draft opinions	
A. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate 1. 214_CT_Salzgitter (2 uses) 2. 217_Diglyme_Acton_2 (2 uses) The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 7th meeting the RAC AFA WG on the 4 draft opinions have been proposed for agreement via the A-listing procedure. ECHA Secretariat presented the summary of the draft opinions. RAC agreed by consensus the 4 draft opinions on the following AFA cases.	
1. 214_CT_Salzgitter (2 uses) **Use1:** *Functional chrome plating using chromium trioxide in closed reactor systems for the establishment of a 'conventional' hard chrome coating on working rolls applied in the steel industry for the pre-manufacturing of cold-rolled, high-quality textured sheet metal.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers was estimated to be 0.258 µg Cr(VI)/m^3 (maximum combined exposure over a shift of 8 hours). For reference the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m³ (with a transitional value of 10 µg Cr(VI)/m³ until 17 January 2025). The exposure to the general population was estimated to be 1.98 x 10^{-4} µg Cr(VI)/m³ via inhalation and 6.80 x 10^{-7} µg Cr(VI)/kg bw/day via the oral route. The excess lifetime cancer risk for workers is estimated to be 1.03 x 10^{-3} (lung cancer) over 40	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

years, and 5.74 x 10^{-6} (combined lung and intestinal cancer) over 70 years for the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation a) The applicant shall implement an annual workplace exposure monitoring programme for Cr(VI). This programme shall be based on relevant standard methodologies or protocols, comprise both static and/or personal inhalation exposure sampling and be representative of: (i) the range of tasks undertaken where exposure to Cr(VI) is possible, including tasks involving maintenance workers; (ii) the OCs and RMMs typical for each of these tasks; (iii) the number of workers potentially exposed. (b) The applicant shall continue conducting monitoring programmes for Cr(VI) emissions to air at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicant´s site. (c) The information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicant to evaluate the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to a level as low as technically and practically feasible. (d) The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles) and refine worker and human via environment assessment if necessary. (e) The information from the monitoring programmes referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicant, upon request, to the national competent authority of the Member State where the authorised use will take place;	

(f) The applicant may reduce the frequency of measurements, once the applicant can clearly demonstrate to the national competent authority of the Member State where the use takes place, that exposure to humans and releases to the environment have been reduced to a level as low as technically and practically possible and that the RMMs and OCs function appropriately. 3. recommendations for the review report The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report.	
Use2: *Pretex® functional chrome plating using chromium trioxide in closed reactor systems for the establishment of adjustable hemispherical surface structures on working rolls applied in the steel industry for the manufacture of cold-rolled, high quality textured sheet metal.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in in exposure and emissions over the authorisation period. This information should also be included in the review report. The exposure to workers was estimated to be 0.258 µg Cr(VI)/m^3 (maximum combined exposure over a shift of 8 hours). For reference the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m³ (with a transitional value of 10 µg Cr(VI)/m³ until 17 January 2025). The exposure to the general population was estimated to be 1.347 x 10^{-3} µg Cr(VI)/m³ via inhalation and 4.62 x 10^{-6} µg Cr(VI)/kg bw/day via the oral route. The excess lifetime cancer risk for workers is estimated to be 1.03 x 10^{-3} (lung cancer) over 40 years, and 3.91 x 10^{-5} (combined lung and intestinal cancer) over 70 years for the general population. RAC agreed: 1. no additional conditions for the authorisation	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

2. monitoring arrangements for the authorisation (a) The applicant shall implement an annual workplace exposure monitoring programme for Cr(VI). These programmes shall be based on relevant standard methodologies or protocols, comprise both static and/or personal inhalation exposure sampling and be representative of: (i) the range of tasks undertaken where exposure to Cr(VI) is possible, including tasks involving maintenance workers; (ii) the OCs and RMMs typical for each of these tasks; (iii) the number of workers potentially exposed. (b) The applicant shall continue conducting monitoring programmes for Cr(VI) emissions to air at least annually. Those programmes shall be based on relevant standard methodologies or protocols and be representative of the OCs and RMMs used at the applicant´s site. (c) The information gathered via the measurements referred to in points (a) and (b) and related contextual information shall be used by the applicant to evaluate the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to a level as low as technically and practically feasible. (d) The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles) and refine worker and human via environment assessment if necessary. (e) The information from the monitoring programmes referred to in points (a) and (b), including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with point (c), shall be documented, maintained and be made available by the applicant, upon request, to the national competent authority of the Member State where the authorised use will take place; (f) The applicant may reduce the frequency of measurements, once the applicant can clearly demonstrate to the national competent authority of the Member State where the use takes place, that exposure to humans and releases to the	

environment have been reduced to a level as low as technically and practically possible and that the RMMs and OCs function appropriately. 3. recommendations for the review report. The information gathered via the measurements referred to in section 8 points (a) and (b) as well as the outcome and conclusions of the review and any action taken in accordance with point (c) shall be included in any subsequent authorisation review report.	
2. 217_Diglyme_Acton_2 (2 uses) **Use1:** *Use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the formulation and subsequent application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (in-house processes).* RAC concluded that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the OCs and RMMs as described in the application are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation The applicant shall continue its air and dermal monitoring activities, given that for dermal monitoring an appropriate monitoring method is available. The applicant shall additionally investigate the possibility of biomonitoring and implement a biomonitoring campaign to verify and support the results from air and dermal monitoring. These measurements must be based on relevant standard methodologies or protocols and the use of a method with detection limit and limit of quantification allowing meaningful exposure evaluation. The results of the monitoring must be included in any subsequent authorisation review report submitted. The applicant may choose to replace the air and dermal monitoring activities with biomonitoring if a method is found and validated that is equally suitable in the detection of diglyme and can be	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

used to ensure that the exposure is below the DNEL. The applicant shall continue its environmental monitoring campaigns, environmental emissions of diglyme from applicant's site shall be subject to measurements with the results of monitoring made available to enforcement bodies on request. Measurement programs shall be performed according to standard sampling and analytical methods, where available. Emissions data shall be presented in any subsequent review report. 3. recommendations for the review report Results of the monitoring activities in 8.1 must be included in any subsequent authorisation review report submitted.	
Use2: *Use of bis(2-methoxyethyl) ether (diglyme) as a carrier solvent in the application of sodium naphthalide etchant for fluoropolymer surface modification whilst preserving article structural integrity (downstream user processes).* RAC concluded that the risk assessment presented in this second application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures as described in the application are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. RAC agreed: 1. additional conditions for the authorisation The applicant (Du1) shall implement further RMM, already planned, for further containment of the process for tip etching. 2. monitoring arrangements for the authorisation The applicant shall continue its air and dermal monitoring activities, given that for dermal monitoring an appropriate monitoring method is available. The applicant shall additionally investigate the possibility of biomonitoring and if an appropriate method exists, implement a biomonitoring campaign to verify and support the results from air and dermal monitoring. These measurements must be based on relevant standard methodologies or protocols and the use	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

of a method with detection limit and limit of quantification allowing meaningful exposure evaluation. The results of the monitoring must be included in any subsequent authorisation review report submitted. The applicant may choose to replace the air and dermal monitoring activities with biomonitoring if a method is found and validated that is equally suitable in the detection of diglyme and can be used to ensure that the exposure is below the DNEL. The applicant shall continue its environmental monitoring campaigns, Environmental emissions of diglyme from applicant's site shall be subject to measurements with the results of monitoring made available to enforcement bodies on request. Measurement programs shall be performed according to standard sampling and analytical methods, where available. Emissions data shall be presented in any subsequent review report The applicant shall furthermore make the minutes and documents relevant of the annual meeting of the substitution steering group available to the relevant authorities on demand. 3. recommendations for the review report. Results of the monitoring activities in 8.1 must be included in any subsequent authorisation review report submitted.	
B. Draft opinions for agreement with plenary debate	
1. 212_CT_Lars (2 uses)	
Use 1: *Industrial use of chromium trioxide for the etching, pre-treatment step in the electroplating process of functional chrome plating with decorative character.* RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The highest combined exposure (8h adjusted TWA) to workers for Companies 1 to 4 was estimated to be (inhalation): 0.55, 0.55, 0.34 and 0.31 µg Cr(VI)/m^3,	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

respectively. For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure (24h adjusted TWA) to the general population for Companies 1 to 4 was estimated to be (inhalation, local) 1.5 *10^{-3}, 4.1 *10^{-3}, 2.2 *10^{-3} and 1.6 *10^{-3} µg Cr(VI)/m^3, respectively. The exposure to the general population for Companies 1 to 4 was estimated to be (oral, local) 6.3 *10^{-5}, 1.0 *10^{-3}, 1.1 *10^{-4} and 1.4 *10^{-4} µg/kg bw/day, respectively. The excess lifetime lung cancer risk (inhalation; 8h TWA exposure for 40 years, highest combined exposure) for workers for Companies 1 to 4 is estimated to be 2.2 *10^{-3}, 2.2 *10^{-3}, 1.4 *10^{-3} and 1.2 *10^{-3}, respectively. The excess lifetime lung cancer risk (inhalation, local 24h exposure for 70 years,) for the general population for Companies 1 to 4 is estimated to be 4.3 *10^{-5}, 1.2 *10^{-4}, 6.3 *10^{-5} and 4.5 *10^{-5}, respectively. The excess lifetime lung cancer risk (inhalation, local 8h exposure for 40 years) for the workers indirect exposed (nearby companies) for Companies 1 to 4 is estimated to be 6.0 *10^{-6}, 1.6 *10^{-5}, 8.7 *10^{-6} and 6.2 *10^{-6}, respectively. RAC agreed: 1. additional conditions for the authorisation The applicants shall ensure that workers perform the sealing test of their RPE before taking on relevant tasks and workers will be trained to do this test adequately. 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually for the exposed workers to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of:	

a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the operational conditions and risk management measures typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling; (vii) Validate the exposures for the loading operators of the jigs of Company 2 and loading/unloading operators of the jigs of Company 4; (b) The applicants shall continue to conduct their biomonitoring programme for workers (c) Environmental releases: (i) the applicants shall continue conducting their monitoring programme for Cr(VI) emission of wastewater; (ii) the applicants shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the operational conditions and risk management measures used at the applicants' site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicants to confirm the effectiveness of the operational conditions and risk management measures in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicants shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.	

4. The information from the studies and monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report RAC recommends that the applicants should: 1. Perform a study on: a) the feasibility to implement a closed and automated transfer system for the refilling of the line tanks with CrO_3 for Company 1 and Company 2. b) the feasibility to bring the implementation of operational conditions and risk management measures for controlling the workers' exposure more in line between the companies by applying the best available techniques and practice c) the improvement of the air abatement efficiency and the on-site wastewater treatment system efficiency of Company 2. 2. The results of the studies referred in section 8.1 paragraph 1 and of the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
Use 2: *Industrial use of chromium trioxide for the functional chrome plating with decorative character for automotive and sanitary industry.* RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The highest combined exposure (8h adjusted TWA) to workers for Companies 1 to 4 was estimated to be (inhalation): 0.55, 0.55, 0.34 and 0.31 µg Cr(VI)/m^3, respectively. For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure (24h adjusted TWA) to the general population for Companies 1 to 4 was estimated to be (inhalation, local) 1.5 *10^{-3}, 4.1 *10^{-3}, 2.2 *10^{-3} and 1.6 *10^{-3} µg Cr(VI)/m^3, respectively. The exposure to the general population for Companies 1 to 4 was estimated to be (oral, local) 6.3 *10^{-5}, 1.0 *10^{-3}, 1.1 *10^{-4} and 1.4 *10^{-4} µg/kg bw/day, respectively. The excess lifetime lung cancer risk (inhalation; 8h TWA exposure for 40 years, highest combined exposure) for workers for Companies 1 to 4 is estimated to be 2.2 *10^{-3}, 2.2 *10^{-3}, 1.4 *10^{-3} and 1.2 *10^{-3}, respectively. The excess lifetime lung cancer risk (inhalation, local 24h exposure for 70 years,) for the general population for Companies 1 to 4 is estimated to be 4.3 *10^{-5}, 1.2 *10^{-4}, 6.3 *10^{-5} and 4.5 *10^{-5}, respectively. The excess lifetime lung cancer risk (inhalation, local 8h exposure for 40 years) for the workers indirect exposed (nearby companies) for Companies 1 to 4 is estimated to be 6.0 *10^{-6}, 1.6 *10^{-5}, 8.7 *10^{-6} and 6.2 *10^{-6}, respectively. RAC agreed: 1. additional conditions for the authorisation The applicants shall ensure that workers perform the sealing test of their RPE before taking on relevant tasks and workers will be trained to do this test adequately. 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually for the exposed workers to Cr(VI). Should circumstances change, the frequency of the measurements should be	

increased to capture any potential increase in exposure; (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to Cr(IV) is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling; (vii) Validate the exposures for the loading operators of the jigs of Company 2 and loading/unloading operators of the jigs of Company 4; (b) The applicants shall continue to conduct their biomonitoring programme for workers (c) Environmental releases: (i) the applicants shall continue conducting their monitoring programme for Cr(VI) emission of wastewater; (ii) the applicants shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicants' site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicants to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.	

3. The applicants shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the studies and monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report RAC recommends that the applicants shall: 1. Perform a study on: a) the feasibility to implement a closed and automated transfer system for the refilling of the line tanks with CrO_3 for Company 1 and Company 2. b) the feasibility to bring more in line the implementation of operational conditions and risk management measures for controlling the workers' exposure between the companies by applying the best available techniques and practice. c) the improvement of the air abatement efficiency and the on-site wastewater treatment system efficiency of Company 2. 2. The results of the studies referred in section 8.1 paragraph 1 and of the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
2. 213_CT_SteelColor (1 use)	
Use 1: *Use of Chromium Trioxide as colouring and hardening agent for stainless steel plates.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to.	**Rapporteur** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period. This information should also be included in the review report. The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated to be 1.4 µg/m^3. For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to the general population was estimated to be (inhalation, local) $5.2*10^{-5}$ µg Cr(VI)/m^3 per 24h and (oral, local) $8.0*10^{-5}$ µg Cr(VI)/kg bw/d. The excess lifetime cancer risk for workers is estimated to be (inhalation) $5.7*10^{-3}$ (8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and (inhalation, local, without the effect of the conditions) $1.5*10^{-6}$ for 24h exposure for 70 years, or the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall implement the following monitoring programmes for chromium (VI): (a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) be representative of: a. the range of tasks undertaken where exposure to chromium is possible; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed; (v) include contextual information about the tasks performed during sampling.	

(vi) give specific attention to WCS 1 and WCS 8 as well as to maintenance technicians. (b) The applicant shall continue to conduct their biomonitoring programme for workers. (c) Environmental releases: (i) the applicant shall continue conducting their yearly monitoring programme for Cr(VI) emission to air or more frequently following any possible changes in the process; (ii) the monitoring programmes for air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant´s site. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the measurements referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report 1. RAC recommends that the applicant should perform a feasibility study on: (a) the implementation of a closed and automated transfer system for the refilling of the line tanks with CrO_3 (WCS 1)	

(b) the implementation of an automated rinsing system for the rinsing of the coloured plates with a watering can (WCS 8). 2. The results of the feasibility study of automatization of WCS 1 and WCS 8 referred to in paragraph 1 and of the measurements referred to in section 8.1 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
3. 215_CT_Oras (2 uses)	
Use 1: *Electroplating of metal and plastic substrates using chromium trioxide to achieve functional surfaces for sanitary applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The exposure to workers was estimated to be (inhalation) 0.04 µg Cr(VI)/m^3 per 8h adjusted TWA. This value corresponds to exposure of 1-10 workers expressed here as public range. For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The excess lifetime lung cancer risk for workers is estimated to be 1.6E-04 (8h TWA exposure for 40 years). The exposure to humans via the environment at the Olesno site (local) was estimated to be 1.63E-06 µg Cr(VI)/m^3 per 24h (inhalation) and 5.6E-06 µg/kg bw/day (oral). The associated risk estimates are 4.7E-05 for inhalation and 4.48E-09 for oral exposure. The exposure of humans via the environment at the Rauma site (local) was estimated to be 8.35E-07 µg Cr(VI)/m^3 per 24h TWA (inhalation) and 2.8E-06 µg/kg bw/day (oral). The associated risk estimates are 2.4E-05 (inhalation) and 2.3E-09 (oral).	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation RAC proposes that the existing occupational exposure monitoring programme should be revised in order to ensure reliable results for all the workplaces. Moreover, both Cr(VI) and Cr(III) are expected to be used in parallel and the exposure to hexavalent chromium has to be distinguished from the exposure to trivalent chromium. 1. The applicant shall continue to monitor for Cr(VI) by implementing the following monitoring programmes: (a) Occupational inhalation exposure monitoring programmes, which shall: (vii) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI) (viii) be based on relevant standard methodologies or protocols (ix) comprise personal and / or static inhalation exposure sampling (x) comprise personal sampling for maintenance workers (WCSs 6 and 7) (xi) be representative of: d. the range of tasks undertaken where exposure to Cr(VI) is possible e. the OCs and RMMs typical for each of these tasks f. the number of workers potentially exposed (xii) include contextual information about the tasks performed during sampling. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of risk management measures and operational conditions as well as to review annually the effectiveness of the risk management measures and operational conditions in place and, if needed, to introduce measures to further reduce workplace exposure to chromium (VI) to as low a level as technically and practically feasible. 3. The authorisation holder shall ensure that the application of risk management measures is in	

accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority of the Member State where the authorised use takes place. 3. recommendations for the review report RAC recommends that a biomonitoring programme should be implemented in Olesno. The results of the studies referred in section 8.1 paragraph 1 and of the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
Use 2: *Pre-treatment ("etching") of plastic substrates using chromium trioxide for electroplating processes in sanitary applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The exposure to workers was estimated to be (inhalation) 0.04 µg Cr(VI)/m^3 per 8h adjusted TWA. This value corresponds to exposure of 1-5 workers expressed here as public range. For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m3 until 17 January 2025). The excess lifetime lung cancer risk for workers is estimated to be 1.6E-04 (8h TWA exposure for 40 years). The exposure to humans via the environment was estimated to be (inhalation, local): 8.35E-07 mg/Cr(VI) m^3 per 24h TWA and (oral, local) 2.8E-06	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

µg/kg bw/day. The associated risk estimates are 2.4E-05 (inhalation) and 2.3E-09 (oral). RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation RAC proposes that the existing occupational exposure monitoring programme should be revised in order to ensure reliable results for all the workplaces. Moreover, both Cr(VI) and Cr(III) are expected to be used in parallel and the exposure to hexavalent chromium has to be distinguished from the exposure to trivalent chromium. 1. The applicant shall continue to monitor for Cr(VI) by implementing the following monitoring programmes: (b) Occupational inhalation exposure monitoring programmes, which shall: (xiii) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI) (xiv) be based on relevant standard methodologies or protocols (xv) comprise personal and / or static inhalation exposure sampling (xvi) comprise personal sampling for maintenance workers (WCSs 6 and 7) (xvii) be representative of: g. the range of tasks undertaken where exposure to Cr(VI) is possible h. the OCs and RMMs typical for each of these tasks i. the number of workers potentially exposed (xviii) include contextual information about the tasks performed during sampling. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of risk management measures and operational conditions as well as to review annually the effectiveness of the risk management measures and operational conditions in place and, if needed, to introduce measures to further reduce	

workplace exposure to chromium (VI) to as low a level as technically and practically feasible. 3. The authorisation holder shall ensure that the application of risk management measures is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority of the Member State where the authorised use takes place. 3. recommendations for the review report RAC recommends that a biomonitoring programme should be implemented in Olesno. The results of the studies referred in section 8.1 paragraph 1 and of the measurements referred to in section 8.1 paragraph 2, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 3, shall be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
4. 216_CT_Viega (2 uses)	
Use 1: *Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright silvery appearance for sanitary applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

The combined exposure to workers was estimated to be (inhalation) 0.97 µg Cr(VI)/m^3 per 8h adjusted TWA (highest value across all (combinations of) WCSs). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to humans via the environment was estimated to be (inhalation, local): 2.68E-04 µg/Cr(VI) m^3 per 24h TWA and (oral, local) 6.59E-05 µg/kg bw/day. The excess lifetime lung cancer risk for workers is estimated to be 3.88E-03 (8h TWA exposure for 40 years), and 7.77E-06 for 70 years (lung cancer) and 5.28E-08 for 70 years (intestinal cancer), for the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall continue to monitor for Cr(VI) by implementing the following monitoring programmes for Cr(VI): (d) Occupational inhalation exposure monitoring programmes, which shall: (xix) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (xx) be based on relevant standard methodologies or protocols; (xxi) comprise personal and / or static inhalation exposure sampling; (xxii) comprise personal sampling for maintenance workers (WCSs 6 and 7); (xxiii) be representative of: j. the range of tasks undertaken where exposure to Cr(VI) is possible; k. the OCs and RMMs typical for each of these tasks; l. the number of workers potentially exposed; (xxiv) include contextual information about the tasks performed during sampling. (e) Biomonitoring programme for workers (f) Environmental releases: (i) the applicant shall continue conducting their monitoring	

programme for Cr(VI) emission to wastewater; (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; (iii) the monitoring programmes for wastewater and air emissions shall: c. be based on relevant standard methodologies or protocols; and d. be representative of the OCs and RMMs used at the applicant´s site. 2.The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3.The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report The results of the measurements referred to in section 8 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8 paragraph 2, should be documented and included in any subsequent review report. RAC agreed on the draft opinion by consensus.	
Use 2: *Etching of plastics with chromium trioxide as pre-treatment step for electroplating processes.* RAC concluded that the operational conditions and risk management measures described in the	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

application are appropriate and effective in limiting the risk, provided that they are adhered to. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in exposure and emissions over the authorisation period The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The combined exposure to workers was estimated to be (inhalation) 0.33 µg Cr(VI)/m^3 per 8h adjusted TWA (highest value across all (combinations of) WCSs). For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m^3 (with a transitional value of 10 µg Cr(VI)/m^3 until 17 January 2025). The exposure to humans via the environment was estimated to be (inhalation, local): 1.34E-04 µg/Cr(VI) m^3 per 24h TWA and (oral, local) 3.30E-05 µg/kg bw/day. The excess lifetime lung cancer risk for workers is estimated to be 1.32E-03 (8h TWA exposure for 40 years), and 3.89E-06 for 70 years (lung cancer) and 2.64E-08 for 70 years (intestional cancer), for the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall continue to monitor for Cr(VI) by implementing the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure monitoring programmes, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI); (ii) be based on relevant standard methodologies or protocols; (iii) comprise personal and / or static inhalation exposure sampling; (iv) comprise personal sampling for maintenance workers (WCSs 6 and 7); (v) be representative of: a. the range of tasks undertaken where exposure to Cr(VI) is possible; b. the OCs and RMMs typical for	

each of these tasks; c. the number of workers potentially exposed; (vi) include contextual information about the tasks performed during sampling. (b) Biomonitoring programme for workers (c) Environmental releases: ○ the applicant shall continue conducting their monitoring programme for Cr(VI) emission to wastewater; ○ the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process; ○ the monitoring programmes for wastewater and air emissions shall: a. be based on relevant standard methodologies or protocols; and b. be representative of the OCs and RMMs used at the applicant´s site. 2.The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. 3.The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 3. recommendations for the review report	

The applicant should assess the feasibility of upgrading the actual dosing system to allow the use of liquid CrO_3 (instead of solid CrO_3 flakes), for the concentration adjustment in etching baths. This should be done in accordance with the hierarchy of control principles. The results of the feasibility study of upgrading the dosing system for liquid CrO_3 referred to in paragraph 1 and of the measurements referred to in section 8.1 paragraph 1, as well as the outcome and conclusions of the review and any action taken in accordance with section 8 paragraph 2 should be documented and included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	

10.4 Adoption of final opinions
The Applicants submitted comments on the following draft opinions agreed at RAC 54. 1. 200_OPE_RSI 2. 205_OPE_Pfizer (use 1)

1. 200_OPE_RSI (1 use)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as surfactant in in-vitro diagnostic device developer solution.* The RAC consultations on the draft Final Opinion has been held 12-19 February 2021. RAC concluded that the operational conditions (OCs) and risk management measures (RMMs) described in the application - are not appropriate and effective in limiting the risk for Exposure Scenario ESC1 (consumer use): The OCs and RMMs as described in the ESC 1 do not prevent or minimise release to the environment as far as technically and practically possible; - are appropriate and effective in limiting the risk for ESC 2 (professional use). The use applied for may result in emissions of 4-tert-OPnEO to the environment via the water compartment of 0.91 kg/year. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. no recommendations for the review report.	**Rapporteurs** together with **SECR** to do the final editing of the final opinion to justify why the OCs and RMMs are not appropriate and RAC do not propose the authorisation conditions. **SECR** to send the final opinion to the EC, MSs and the Applicant.

RAC adopted the final opinion by consensus with changes made to the draft final opinion.	
2. 205_OPE_Pfizer (use 1)	
Use 1: *The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) (Triton X-100) as a surfactant in the manufacture of biopharmaceuticals - Viral Inactivation and Associated Processes.* The RAC consultations on the draft Final Opinion has been held 18-23 February 2021. RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk. The proposed monitoring arrangements for the authorisation are expected to provide information on the trends in emission to waste water over the authorisation period. This information should also be included in the review report. The use applied for may result in max. 0.152 kg/year emissions of 4-tert-OPnEO to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation The applicant should establish and implement a monitoring programme of 4-tert-OPnEO and its principal degradation products in the relevant waste stream from the production prior to release to the municipal STP using an analytical method capable of adequately characterising the substance and its principal degradation products in water at an appropriately low level of quantification (the monitoring should be performed at least once per year during the time of operation). The results should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. The information from the monitoring programmes including contextual information associated with each set of measurements as well as the outcome and conclusion of the review and any action taken - if needed to further reduce emissions of 4-tert-OPnEO - shall be documented, maintained and be	**Rapporteurs** together with **SECR** to do the final editing of the final opinion. **SECR** to send the final opinion to the EC, MSs and the Applicant.

made available by the authorisation holder, upon request, to the competent authority. 3. recommendations for the review report RAC recommends that the results of the monitoring programme according to point 8 should be included in any review report, including details of sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. RAC adopted the final opinion by consensus with the change made to the draft final opinion.	
11. AOB	
12. Minutes of RAC-56	
RAC adopted the final minutes by consensus at the plenary meeting.	**SECR** to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-56 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-56B

1. Ethyl acrylate
2. Methyl acrylate
3. Allyl methacrylate
4. 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol bisphenol AF
5. Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro- 2-(4-hydroxyphenyl)propan-2-yl]phenolate
6. Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)
7. Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1)
8. Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)
9. 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate; [TODI]
10. Cinnamaldehyde
11. Foramsulfuron (ISO)
12. Mepiquat chloride (ISO)
13. Transfluthrin (ISO)
14. Benfluralin (ISO)
15. Methyl methacrylate

1. Ethyl acrylate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-032-00-X	Ethyl acrylate	205-438-8	140-88-5	Flam. Liq. 2 Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H225 H332 H312 H302 H335 H315 H319 H317	GHS02 GHS07 Dgr	H225 H332 H312 H302 H335 H315 H319 H317		STOT SE 3; H335: C ≥ 5 % Skin Irrit. 2; H315: C ≥ 5 % Eye Irrit. 2; H319: C ≥ 5 %	Note D
Dossier submitters proposal	607-032-00-X	Ethyl acrylate	205-438-8	140-88-5	**Modify** Acute Tox. 3 Acute Tox. 4 Acute Tox. 4	**Modify** H331 H312 H302	**Modify** GHS06	**Modify** H331 H312 H302		**Add** inhalation: ATE = 9 mg/L (vapours) dermal: ATE = 1800 mg/kg bw oral: ATE = 1120 mg/kg bw	Note D
RAC opinion	607-032-00-X	Ethyl acrylate	205-438-8	140-88-5	**Modify** Acute Tox. 3 Acute Tox. 4 Acute Tox. 4	**Modify** H331 H312 H302	**Modify** GHS06	**Modify** H331 H312 H302		**Add** inhalation: ATE = 9 mg/L (vapours) dermal: ATE = 1800 mg/kg bw oral: ATE = 1120 mg/kg bw	
Resulting Annex VI entry if agreed by COM	607-032-00-X	Ethyl acrylate	205-438-8	140-88-5	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 4 Acute Tox. 4 STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H225 H331 H312 H302 H335 H315 H319 H317	GHS06 GHS02 Dgr	H225 H331 H312 H302 H335 H315 H319 H317		inhalation: ATE = 9 mg/L (vapours) dermal: ATE = 1800 mg/kg bw oral: ATE = 1120 mg/kg bw STOT SE 3; H335: C ≥ 5 % Skin Irrit. 2; H315: C ≥ 5 % Eye Irrit. 2; H319: C ≥ 5 %	Note D

2. Methyl acrylate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-034-00-0	methyl acrylate; methyl propenoate	202-500-6	96-33-3	Flam. Liq. 2 Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H225 H332 H312 H302 H335 H315 H319 H317	GHS02 GHS07 Dgr	H225 H332 H312 H302 H335 H315 H319 H317			Note D
Dossier submitters proposal	607-034-00-0	methyl acrylate; methyl propenoate	202-500-6	96-33-3	**Modify** Acute Tox. 3 Acute Tox. 4 Acute Tox. 4	**Modify** H331 H312 H302	**Modify** GHS06	**Modify** H331 H312 H302		**Add** inhalation: ATE = 3 mg/L (vapours) dermal: ATE = 1250 mg/kg bw oral: ATE = 500 mg/kg bw	
RAC opinion	607-034-00-0	methyl acrylate; methyl propenoate	202-500-6	96-33-3	**Modify** Acute Tox. 3 Acute Tox. 4 Acute Tox. 4	**Modify** H331 H312 H302	**Modify** GHS06	**Modify** H331 H312 H302		**Add** inhalation: ATE = 3 mg/L (vapours) dermal: ATE = 1100 mg/kg bw oral: ATE = 500 mg/kg bw	
Resulting Annex VI entry if agreed by COM	607-034-00-0	methyl acrylate; methyl propenoate	202-500-6	96-33-3	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 4 Acute Tox. 4 STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1	H225 H331 H312 H302 H335 H315 H319 H317	GHS02 GHS06 Dgr	H225 H331 H312 H302 H335 H315 H319 H317		inhalation: ATE = 3 mg/L (vapours) dermal: ATE = 1100 mg/kg bw oral: ATE = 500 mg/kg bw	Note D

3. Allyl methacrylate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-246-00-3	allyl methacrylate 2-methyl-2-propenoic acid 2-propenyl ester	202-473-0	96-05-9	Flam. Liq. 3 Acute Tox. 3 * Acute Tox. 4 * Acute Tox. 4 * Aquatic Acute 1	H226 H331 H312 H302 H400	GHS02 GHS06 GHS09 Dgr	H226 H331 H312 H302 H400			
Dossier submitters proposal	607-246-00-3	allyl methacrylate 2-methyl-2-propenoic acid 2-propenyl ester	202-473-0	96-05-9	**Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 4	**Modify** H330 H311 H302		**Modify** H330 H311 H302		**Add** inhalation: ATE = 1,47 mg/L (vapours) dermal: ATE = 467 mg/kg bw oral: ATE = 401 mg/kg bw	
RAC opinion	607-246-00-3	allyl methacrylate 2-methyl-2-propenoic acid 2-propenyl ester	202-473-0	96-05-9	**Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 4	**Modify** H330 H311 H302		**Modify** H330 H311 H302		**Add** inhalation: ATE = 1,5 mg/L (vapours) dermal: ATE = 300 mg/kg bw oral: ATE = 400 mg/kg bw	
Resulting Annex VI entry if agreed by RAC and COM	607-246-00-3	allyl methacrylate 2-methyl-2-propenoic acid 2-propenyl ester	202-473-0	96-05-9	Flam. Liq. 3 Acute Tox. 2 Acute Tox. 3 Acute Tox. 4 Aquatic Acute 1	H226 H330 H311 H302 H400	GHS02 GHS06 GHS09 Dgr	H226 H330 H311 H302 H400		inhalation: ATE = 1,5 mg/L (vapours) dermal: ATE = 300 mg/kg bw oral: ATE = 400 mg/kg bw	

4. ,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol bisphenol AF

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF	216-036-7	1478-61-1	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF	216-036-7	1478-61-1	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF	216-036-7	1478-61-1	Repr. 1B	H360F	GHS08 Dgr	H360F			

5. Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro- 2-(4-hydroxyphenyl)propan-2-yl]phenolate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate	479-100-5	577705-90-9	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate	479-100-5	577705-90-9	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate	479-100-5	577705-90-9	Repr. 1B	H360F	GHS08 Dgr	H360F			

6. Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	278-305-5	75768-65-9	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	278-305-5	75768-65-9	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	278-305-5	75768-65-9	Repr 1B	H360F	GHS08 Dgr	H360F			

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1)	-	-	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1)	-	-	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1)	-	-	Repr. 1B	H360F	GHS08 Dgr	H360F			

8. Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	-	-	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	-	-	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	-	-	Repr. 1B	H360F	GHS08 Dgr	H360F			

9. 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate; [TODI]

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7	91-97-4	Carc. 1B Resp. Sens. 1 Skin Sens. 1A	H350 H334 H317	GHS08 Dgr	H350 H334 H317		Skin Sens. 1A; H317: C ≥ 0,001 %	
RAC opinion	TBD	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7	91-97-4	Carc. 2 Resp. Sens. 1 Skin Sens. 1A	H351 H334 H317	GHS08 Dgr	H351 H334 H317		Skin Sens. 1A; H317: C ≥ 0,001 %	
Resulting Annex VI entry if agreed by COM	TBD	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7	91-97-4	Carc. 2 Resp. Sens. 1 Skin Sens. 1A	H351 H334 H317	GHS08 Dgr	H351 H334 H317		Skin Sens. 1A; H317: C ≥ 0,001 %	

10. Error! Reference source not found.

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	cinnamaldehyde; 3-phenylprop-2-enal; cinnamic aldehyde; cinnamal, (2E)-3-phenylprop-2-enal	203-213-9, 604-377-8	104-55-2, 14371-10-9	Skin Sens. 1A	H317	GHS07 Wng	H317	EUH208	Skin Sens. 1; H317: C ≥ 0,02 %	
RAC opinion	TBD	cinnamaldehyde; 3-phenylprop-2-enal; cinnamic aldehyde; cinnamal, (2E)-3-phenylprop-2-enal	203-213-9, 604-377-8	104-55-2, 14371-10-9	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1; H317: C ≥ 0,01 %	
Resulting Annex VI entry if agreed by COM	TBD	cinnamaldehyde; 3-phenylprop-2-enal; cinnamic aldehyde; cinnamal, (2E)-3-phenylprop-2-enal	203-213-9, 604-377-8	104-55-2, 14371-10-9	Skin Sens. 1A	H317	GHS07 Wng	H317		Skin Sens. 1; H317: C ≥ 0,01 %	

11. Foramsulfuron (ISO)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	tbd	foramsulfuron (ISO); 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-formamido-N,N-dimethylbenzamide; 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl) urea	-	173159-57-4	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=1000 M=100	
RAC opinion	tbd	foramsulfuron (ISO); 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-formamido-N,N-dimethylbenzamide; 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl) urea	-	173159-57-4	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=1000 M=100	
Resulting Annex VI entry if agreed by COM	tbd	foramsulfuron (ISO); 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-formamido-N,N-dimethylbenzamide; 1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-formamidophenylsulfonyl) urea	-	173159-57-4	Carc. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H400 H410	GHS08 GHS09 Wng	H351 H410		M=1000 M=100	

12. Mepiquat chloride (ISO)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-127-00-7	mepiquat chloride (ISO); 1,1-dimethylpiperidinium chloride	246-147-6	24307-26-4	Acute Tox. 4* Aquatic Chronic 3	H302 H412	GHS07 Wng	H302 H412			
Dossier submitters proposal	613-127-00-7	mepiquat chloride (ISO); 1,1-dimethylpiperidinium chloride	246-147-6	24307-26-4	**Modify** Acute Tox. 3 **Add** Repr. 2 Acute Tox. 4 STOT SE 2 **Retain** Aquatic Chronic 3	**Modify** H301 **Add** H361d H332 H371 (nervous system) **Retain** H412	**Modify** GHS06 Dgr **Add** GHS08	**Modify** H301 **Add** H361d H332 H371 (nervous system) **Retain** H412		**Add** inhalation: ATE = 2,8 mg/L (dusts or mists) oral: ATE = 115 mg/kg bw	
RAC opinion	613-127-00-7	mepiquat chloride (ISO); 1,1-dimethylpiperidinium chloride	246-147-6	24307-26-4	**Modify** Acute Tox. 3 **Add** Acute Tox. 4 **Retain** Aquatic Chronic 3	**Modify** H301 **Add** H332 **Retain** H412	**Modify** GHS06 Dgr	**Modify** H301 **Add** H332 **Retain** H412		**Add** inhalation: ATE = 2,8 mg/L (dusts or mists) oral: ATE = 270 mg/kg bw	
Resulting Annex VI entry if agreed by COM	613-127-00-7	mepiquat chloride (ISO); 1,1-dimethylpiperidinium chloride	246-147-6	24307-26-4	Acute Tox. 4 Acute Tox. 3 Aquatic Chronic 3	H332 H301 H412	GHS06 Dgr	H332 H301 H412		inhalation: ATE = 2,8 mg/L (dusts or mists) oral: ATE = 270 mg/kg bw	

13. Transfluthrin (ISO)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-223-00-8	transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	405-060-5	118712-89-3	Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H315 H400 H410	GHS07 GHS09 Wng	H315 H400			
Dossier submitters proposal	607-223-00-8	transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	405-060-5	118712-89-3	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 Acute Tox. 4 STOT SE 1 STOT RE 2 **Remove** Skin Irrit. 2	**Retain** H400 H410 **Add** H351 H302 H370 (nervous system) H373 (kidneys) **Remove** H315	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H351 H302 H370 (nervous system) H373 (kidneys) **Remove** H315	**Add** EUH066	**Add** oral: ATE = 583 mg/kg bw M=1000 M=1000	
RAC opinion	607-223-00-8	transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	405-060-5	118712-89-3	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** Carc. 2 Acute Tox. 4 STOT SE 1 **Remove** Skin Irrit. 2	**Retain** H400 H410 **Add** H351 H302 H370 (nervous system) **Remove** H315	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H410 **Add** H351 H302 H370 (nervous system) **Remove** H315	**Add** EUH066	**Add** oral: ATE = 580 mg/kg bw M=1000 M=1000	
Resulting Annex VI entry if agreed by COM	607-223-00-8	transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	405-060-5	118712-89-3	Carc. 2 Acute Tox. 4 STOT SE 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H370 (nervous system) H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H370 (nervous system) H410	EUH066	oral: ATE = 580 mg/kg bw M=1000 M=1000	

14. Benfluralin (ISO)

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	benfluralin (ISO); *N*-butyl-*N*-ethyl-*a,a,a*-trifluoro-2,6-dinitro-*p*-toluidine	217-465-2	1861-40-1	Carc. 2 Repr. 2 Lact. STOT SE 2 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H361d H362 H371 H315 H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H361d H362 H371 H315 H319 H317 H410		M=10 M=10	
RAC opinion	TBD	benfluralin (ISO); *N*-butyl-*N*-ethyl-*a,a,a*-trifluoro-2,6-dinitro-*p*-toluidine	217-465-2	1861-40-1	Carc. 2 Repr. 2 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H361d H315 H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H361d H315 H319 H317 H410		M=10 M=10	
Resulting Annex VI entry if agreed by COM	TBD	benfluralin (ISO); *N*-butyl-*N*-ethyl-*a,a,a*-trifluoro-2,6-dinitro-*p*-toluidine	217-465-2	1861-40-1	Carc. 2 Repr. 2 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H351 H361d H315 H319 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H361d H315 H319 H317 H410		M=10 M=10	

15. Methyl methacrylate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	607-035-00-6	methyl methacrylate methyl 2-methylprop-2-enoate methyl 2-methylpropenoate	201-297-1	80-62-6	Flam. Liq. 2 STOT SE 3 Skin Irrit. 2 Skin Sens. 1	H225 H335 H315 H317	GHS02 GHS07 Dgr	H225 H335 H315 H317			D
Dossier submitters proposal	607-035-00-6	methyl methacrylate methyl 2-methylprop-2-enoate methyl 2-methylpropenoate	201-297-1	80-62-6	**Add** Resp. Sens. 1	**Add** H334	**Add** GHS08 **Remove** GHS07	**Add** H334			
RAC opinion	607-035-00-6	methyl methacrylate methyl 2-methylprop-2-enoate methyl 2-methylpropenoate	201-297-1	80-62-6	**Add** Resp. Sens. 1	**Add** H334	**Add** GHS08 **Remove** GHS07	**Add** H334			
Resulting Annex VI entry if agreed by COM	607-035-00-6	methyl methacrylate methyl 2-methylprop-2-enoate methyl 2-methylpropenoate	201-297-1	80-62-6	Flam. Liq. 2 STOT SE 3 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1	H225 H335 H315 H334 H317	GHS02 GHS08 Dgr	H225 H335 H315 H334 H317			D

Part II. List of Attendees of the RAC-56 meeting

RAC members	
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Bjørge	Christine
Branisteanu	Radu (co-opted member)
Brovkina	Julija
Chiurtu	Elena (co-opted member)
de la Flor	Ignacio
Doak	Malcolm
Dobrev	Ivan
Docea	Anca
Facchin	Manuel
Geoffroy	Laure
Hakkert	Betty
Hartwig	Andrea (co-opted member)
Heederik	Dick (co-opted member)
Husa	Stine
Kadikis	Normunds
Kapelari	Sonja
Karadjova	Irina
Leinonen	Riitta
Lund	Bert-Ove
Martinek	Michal
Menard Srpčič	Anja
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Paris	Pietro
Peczkowska	Beata
Pribu	Mihaela
Printemps	Nathalie
Rodriguez	Wendy
Rucki	Marian
Santonen	Tiina
Schlueter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel
Sørensen	Peter Hammer
Spetseris	Nikolaos
Stahlmann	Ralf
Tobiassen	Lea Stine
Tsitsimpikou	Christina
Uzomeckas	Zilvinas
van der Haar	Rudolf (co-opted member)

Varnai	Veda

Apologies members	
Xanthos	Theodore
Zeljezic	Davor

Members' advisers	
Boel	Els (Julie Seba)
Catone	Tiziana (Pietro Paris)
Clausen	Ian Henning (Peter Hammer Sörensen)
Durand	Emmanuelle (Nathalie Printemps)
Esposito	Dania (Pietro Paris)
Hadrup	Niels (Lea Stine Tobiassen)
Hoffmann	Frauke (Agnes Schulte)
Losert	Annemarie (Manuel Facchin)
Mahiout	Selma (Tiina Santonen)
Marinkovic	Marino (Betty Hakkert)
Martin	Theresa (Ralf Stahlmann)
Munch	Pernille (Lea Stine Tobiassen)
Partosch	Falko (Ralf Stahlmann)
Romoli	Debora (Pietro Paris)
Russo	Maria Teresa (Pietro Paris)
Saksa	Jana (Raili Moldov)
Seba	Julie (Wendy Rodriguez)
Sedláčková	Viktorie (Michal Martinek)
Sonnenburg	Anna (Ralf Stahlmann)
Suutari	Tiina (Riitta Leinonen)

Invited experts		**Substance**
Cromie	Ruth	Restriction: Lead
Dereliev	Sergey	Restriction: Lead
Levy	Patrick	OEL: Asbestos, Cadmium
Musu	Tony	OEL: Asbestos, Cadmium
Saarikoski	Sirkku	OEL: Asbestos, Cadmium
Viegas	Susana	AfAs
Wieske	Martin	OEL: Cadmium

Dossier submitters		**Substance**
Aurélie	Mathieu (FR)	Restrictions: Single use diapers
Charles	Sandrine (FR)	CLH: Methyl methacrylate
Dubois	Céline (FR)	Restrictions: Single use diapers
Fiore	Karine (FR)	Restrictions: Single use diapers
Guillou	Pauline (FR)	CLH: TODI
Kärkkäinen	Pauli (FI)	CLH: Mepiquat chloride (ISO)
Paludan	Ditte (DK)	CLH: Cinnamaldehyde
Pouzaud	Francois (FR)	CLH: TODI
Silins	Ilona (SE)	CLH: Bisphenol AF and 4 related substances
Woutersen	Marjolijn (NL)	CLH: Transfluthrin

Regular stakeholder observers	**Substance**

Barry	Frank (ETUC)	
Byrne	Dominic (A.I.S.E.)	
Comini	Andrea (EuCheMS)	
De Backer	Liisi (CEFIC)	
Duguy	Hélène (ClientEarth)	
Robinson	Jan (A.I.S.E.)	
Romano	Dolores (EEB)	
Ruelens	Paul (CropLife Europe)	
Van de Broeck	Steven (CEFIC)	
Verougstraete	Violaine (Eurometaux)	
Waeterschoot	Hugo (Eurometaux)	Art 77(3) Lead

Occassional stakeholders		**Substance**
Ballach	Jochen (CIRFS)	Art 77 (3): Microplastics; CLH: Ethyl acrylate, methyl acrylate, methyl methacrylate and Restrictions: Single-use diapers
Barbu	Luminita (EDANA)	Workplan; Art 77 (3): Microplastics; CLH: Ethyl acrylate, Methyl methacrylate
de Matos	Olivier (ECETOC)	Art 77 (3): Microplastics; CLH: Methyl acrylate and Methyl methacrylate
Kafka	Amalia (Euroseeds)	Art 77 (3): Microplastics
Lagemaat	Marines (EDANA)	Restrictions: single-use diapers
Musacchi	Ettore (ETRA)	Art 77(3): Microplastics
Niemela	Helena (CONCAWE)	OEL: Cadmium, asbestos; Restrictions: lead restriction, single-use diapers
Perez	Laia (ETRMA)	Art 77 (3): Microplastics
Perfetti	Marco (EuPC)	Art 77 (3): Microplastics; Art 77: Lead; OEL: cadmium; CLH: ethyl acrylate, methyl acrylate, allyl methacrylate, methyl methacrylate
Rovida	Costanza (ECOPA)	Art 77 (3): Microplastics; Art 77: Lead; OEL: asbestos, cadmium and minutes
Vey	Matthias (IFRA)	CLH: Cinnamaldehyde

Stakeholder experts		**Substance**
Aas	Bjørn (EEB/NTNU Norway)	Art 77 (3): Microplastics
Berg	Madeleine (ClientEarth/FIDRA)	Art 77 (3): Microplastics
Binks	Steve (CEFIC/Pb REACH consortium)	Art 77 (3): Lead
Binks	Steve (Eurometaux/International Lead Association)	Restrictions: Lead in ammunition
Bomann	Werner (CropLife Europe/Bayer)	CLH: Foramsulfuron
Bonifay	Sebastien (CropLife Europe/Corteva)	Art 77 (3): Microplastics
Chowdhury	Jasim (Eurometaux/	Art 77 (3): Lead

	International Lead Association)	
Cox	Alastair (CIRFS/ESTC)	Art 77 (3): Microplastics
Griem	Peter (IFRA/IFRA)	CHL: Cinnamaldehyde
Jukka	Takala (ETUC/International Commission of Occupational Health)	OEL: Asbestos
Lombaert	Noömi (Eurometaux/International Cadmium Association)	OEL: Cadmium
Ott	Wolfgang (CIRFS/Kelheim Fibres)	Restrictions: single-use diapers; CLH: ethyl acrylate, methyl acrylate and methyl methacrylate
Parsons	Paul (CropLife Europe/BASF)	CLH: Mepiquat-chloride
Pemberton	Mark (Cefic/MSG)	CLH: Methyl methacrylate
Renault-Billault	Dominique (CropLife Europe/Bayer)	CLH: Transfluthrin
Roth	Thomas (CropLife Europe/Nippon Soda company)	CLH: TODI
Schlünder	Klaus (Euroseeds/KWS)	Art 77 (3): Microplastics
Serrano	Blanca (Cefic/Cefic)	Art 77 (3): Microplastics
Strupp	Christian (CropLife Europe/Gowan company)	CLH: Benfluralin
Thelin	Anders (EDANA/Essity Hygiene and Health)	Restrictions: Single-use diapers
van Gelderen	Alex (ETRMA/NVR/RecyBEM)	Art 77 (3): Microplastics

European Commission		**DG**
Bertato	Valentina	DG ENV
Bintein	Sylvain	DG ENV
Blass	Ana	DG GROW
Kilian	Karin	DG ENV
Morris	Alick	DG EMPL
Pinte	Jérémy	DG GROW
Pirselova	Katarina	DG ENV
Podniece	Zinta	DG EMPL
Roebben	Gert	DG GROW
Schutte	Katrin	DG ENV
Tailler	William	DG EMPL
Teixeira	Carla	DG EMPL
Tosetti	Patrizia	DG GROW

ECHA staff	
Blainey	Mark
Bowmer	Tim (Chair)
Doyle	Simone
Figuiere	Romain
Gmeinder	Michael
Hellsten	Kati
Henrichson	Sanna
Karjalainen	Antti
Karjalainen	Ari
Kokkola	Leila
Koskinen	Marjo
Kvatchadze	Giorgi
Lapenna	Silvia
Lazic	Nina
Lefevre-Brevart	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Mannervesi	Maija
Marquez-Camacho	Mercedes
Mazzolini	Anna
Multasuo	Tiina
Mushtaq	Fesil
Orispää	Katja
O'Rourke	Regina
Pennese	Daniele
Perazzolo	Chiara
Pillet	Monique
Prevedouros	Kostas
Rasikari	Heidi
Regil	Pablo
Reuter	Ulrike
Rheinberger	Christoph
Rossi	Ludovica
Sadam	Diana
Simoes	Ricardo
Simpson	Peter
Smilovici	Simona
Sosnowski	Piotr
Spjuth	Linda
Stockmann-Juvala	Helene
Tanarro	Celia
Uphill	Simon
Uphoff	Andreas
Väänänen	Virpi
Vainio	Matti
Van Haelst	Anniek
Yagzan	Seyhan
Zeiger	Bastian

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-56 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-56 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-56 meeting

8 March 2021
RAC/A/56/2021

Final Agenda

56th meeting of the Committee for Risk Assessment

8-11 March
and
15-19 March 2021

Virtual meeting

Monday 8 March starts at 14.00
Thursday 11 March breaks at 19.00
Monday 15 March resumes at 10.00
Friday 19 March ends at 13.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/56/2021
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, evaluation of occupational exposure limits

For agreement
Closed session

Item 5 – Report from other ECHA bodies and activities

a) RAC Work Plan for all processes

For information

b) Procedure for admission of ASO observers

For adoption
RAC/56/2021/01
Restricted
Closed session

c) Revision of Rules of Procedure

For agreement
RAC/56/2021/02
Restricted
Closed session

d) RAC co-opted members

For information and agreement
RAC/56/2021/03
Restricted
Closed session

e) Proposal by the Secretariat to set up two standing Working Groups of RAC for Restrictions and CLH

For information and agreement
RAC/56/2021/04
RAC/56/2021/05

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

1) Request to review Microplastics - infill material and 'inorganic polymers'

For adoption

2) Classification for environmental toxicity of lead

For discussion

Item 7 –Health based exposure limits at the workplace

a) Opinion development

1) Asbestos – first draft opinion

For discussion

b) Adoption of opinions

1) Cadmium and its inorganic compounds – final draft opinion

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

8.1 CLH dossiers

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

- Ethyl acrylate: acute dermal toxicity
- Methyl acrylate: acute dermal toxicity, acute inhalation toxicity
- Allyl methacrylate: acute dermal toxicity, acute inhalation toxicity
- TODI: mutagenicity, respiratory sensitisation, skin sensitisation
- Foramsulfuron (ISO): physical hazards (explosives, flammable solids, self-reactive substances, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, reproductive toxicity,

STOT SE, STOT RE, aspiration hazard, acute aquatic hazards, chronic aquatic hazards, hazardous to the ozone layer

- Mepiquat chloride (ISO): acute dermal and inhalation toxicity, skin sensitisation, carcinogenicity
- Transfluthrin (ISO): acute oral toxicity, skin irritation, acute aquatic hazards, chronic aquatic hazards
- Benfluralin (ISO): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, STOT RE, germ cell mutagenicity

B. **Hazard classes for agreement with plenary debate**

16) Ethyl acrylate (EC: 205-438-8; CAS: 140-88-5)
17) Methyl acrylate (EC: 202-500-6; CAS: 96-33-3)
18) Allyl methacrylate (EC: 202-473-0; CAS: 96-05-9)
19) 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF (EC: 216-036-7; CAS: 1478-61-1)
20) Benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (EC: 479-100-5; CAS: 577705-90-9)
21) Benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (EC: 278-305-5; CAS: 75768-65-9)
22) Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1) (EC: -; CAS: -)
23) Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1) (EC: -; CAS: -)
24) TODI (EC: 202-112-7; CAS: 91-97-4)
25) Cinnamaldehyde (EC: 203-213-9 and 604-377-8; CAS: 104-55-2 and 14371-10-9)
26) Foramsulfuron (ISO) (EC: -; CAS: 173159-57-4)
27) Mepiquat chloride (ISO) (EC: 246-147-6; CAS: 24307-26-4)
28) Transfluthrin (ISO) (EC: 405-060-5; CAS: 118712-89-3)
29) Benfluralin (ISO) (EC: 217-465-2; CAS: 1861-40-1) (HH only; ENV done at RAC-55)
30) Methyl methacrylate (EC: 201-297-1; CAS: 80-62-6)

For discussion and adoption

Item 9 – Restrictions

9.1 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Lead in ammunition

For discussion and agreement

b) Opinion development

1) Substances in single-use diapers

For discussion

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications
b) Report from RAC WG on AfAs during February 2021 meeting
c) Evaluation of review reports

For information/discussion

RAC/56/2021/06

10.2 Authorisation applications

1. Discussion on key issues
   1) 4 applications for authorisation/review reports (chromium trioxide, trichloroethylene, 4-nonylphenol, branched and linear, ethoxylated) from November 2020 submission window

For discussion

10.3 Agreement on draft opinions

A. Draft opinions for agreement without plenary debate (A-list)

1) 214_CT_Salzgitter (2 uses)
2) 217_Diglyme_Acton_2 (2 uses)

B. Draft opinions for agreement with plenary debate

1. 212_CT_Lars (2 uses)
2. 213_CT_SteelColor (1 use)
3. 215_CT_Oras (2 uses)
4. 216_CT_Viega (2 uses)

For discussion and agreement

10.4 Adoption on opinions

1. 200_OPE_RSI (1 use)
2. 205_OPE_Pfizer (2 uses)

For discussion and adoption

Item 11 – AOB

A) Commission request_Borates Note

Item 12 – Minutes of RAC-56

a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-56

For adoption

Annex II (RAC 56)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 56 meeting.

Document number	Title
RAC/A/56/2021	Final Draft Agenda
RAC/56/2021/01 *Restricted document*	Procedure for admission of ASO observers
RAC/56/2021/02 *Restricted document*	Revision of Rules of Procedure
RAC/56/2021/03 *Restricted document*	RAC co-opted members
RAC/56/2021/04	Proposal by the Secretariat to set up two standing Working Groups of RAC for Restrictions and CLH
RAC/56/2021/05	Report from RAC WG on AfAs during February 2021 meeting

ANNEX III (RAC-56)

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 SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Restrictions		
Diapers (FR)	Nathalie PRINTEMPS	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
	Laure GEOFFROY	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Perfluorohexanoic acid – PFHxA (DE)	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. ~~No~~ Personal involvement.
	Ivan DOBREV	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Harmonised classification & labelling		
Benfluralin (ISO) (NO)	Christine BJORGE	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Stine HUSA	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Health based exposure limits at the workplace		
Cadmium and its inorganic compounds **ECHA**		
Article 77.3(c)		
Request to review Microplastics - infill material and 'inorganic polymers' **COM**	-	-

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Restrictions		
Lead in ammunition **ECHA**		
Harmonised classification & labelling		
Allyl methacrylate **Ethyl acrylate** **Methyl acrylate** **AT**	Manuel FACCHIN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF plus two salts and two reaction masses **SE**	Bert-Ove LUND	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
1. **Allyl methacrylate** 2. **Methyl acrylate** 3. **Ethyl acrylate** 4. **TODI** **DE**	Agnes SCHULTE	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on these substances - no other mitigation measures applied. No personal involvement in dossiers 1, 2 and 3. Personal involvement in dossier 4.
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
		substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ivan DOBREV	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
TODI **Methyl methacrylate** **FR**	Nathalie PRINTEMPS	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Laure GEOFFROY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Cinnamaldehyde **DK**	Peter Hammer SOERENSEN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Lea Stine TOBIASSEN	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
Foramsulfuron (ISO) **Mepiquat chloride (ISO)** **FI**	Riitta LEINONEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Tiina SANTONEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
		measures applied. No personal involvement.
Transfluthrin (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. No personal involvement.
	Gerlienke SCHUUR	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Health based exposure limits at the workplace		
Asbestos **ECHA**		
Article 77.3(c)		
Classification for environmental toxicity of lead		
No CA involvement – the request comes from COM		