RAC/M/57/2021

Final

29 June 2021

Minutes of the 57th Meeting

of the Committee for Risk Assessment

(RAC-57)

Monday 31 May, 14.00 to Thursday 3 June, 16.15
and
Tuesday 8 June, 10.00 to Thursday 10 June, 17.30

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

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

ECHA continues to follow the Finnish Government advice on return to work. Non-essential workers are still working from home in Finland. As a result, there will be no prospect of face-to-face meetings at ECHA before the end of September at the earliest. Regardless of when face-to-face meetings can restart, we expect to continue with a proportion of remote plenary meetings in the future in any case.

The July AfA working group meeting will be cancelled due to a short agenda and the four applications scheduled will be discussed at the September plenary. In line with Authorisation dossiers, from October 2021 onwards, all agenda items are expected to be processed through the CLH, and Restriction working groups before RAC-59 in December. Therefore, the timelines for dossier processing by Rapporteurs might be shorter and an earlier start is advised.

Finally, the Chair informed Members that Sonja Kapelari has resigned on 20 May and thanked her for her dedication and valuable contribution to the work of the Committee over the years.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/57/2021**) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-57 minutes.
4. Appointment of (co-)rapporteurs	

4.1. 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, restriction dossiers, applications for authorisation and OEL 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 dossiers for the above-mentioned processes.	-
5. Report from other ECHA bodies and activities	
5.1. RAC work plan for all processes The Chair presented the RAC work plan for 2021.	
5.2. CLH: Procedure for agreement seeking (A-listing) The Chair presented and RAC agreed on the revised procedure for agreement seeking in the CLH process (RAC/57/2021/01).	**SECR** to publish the updated procedure on the ECHA website.
6. Request under Article 77(3)(c)	
6.1. Classification for environmental toxicity of lead	
The Chair welcomed the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers. 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 was originally 13 May 2021, but an extension was sought until 30 July 2021.	
The Rapporteurs presented and RAC discussed the final draft opinion on environmental toxicity of lead. RAC concluded that the concentration of the dissolved lead ions in solution at a pH of 5.5 must be used for the chronic classification of lead. RAC concluded that it is not scientifically justified to normalise (modify) all the measured ERV values for lead to estimated ERV values that would occur under	**Rapporteur**, with the support of the *ad hoc* group and the SECR, to revise the opinion in accordance with the discussion in RAC and to provide it to the SECR. **SECR** to table the revised draft opinion for final discussion in RAC.

water quality conditions used in the T/Dp testing. The water quality conditions under which the original studies were carried out are diverse and the impact of the water quality parameters DOC, pH and hardness on comparable sets of results are not clear enough to warrant normalisation, including with the BLM tool. RAC agreed that chronic ERV for lead of 0.48 ug/L using *L. stagnalis* is relevant and reliable and should be used for the classification and labelling of lead. RAC took note of the ECHA's position on the topic of articles and waste. RAC noted that the lead sheet/swarf example provided a good basis for the discussion on the forms of lead. RAC also noted that other clear quantitative examples of produced particles < 1 mm were so far lacking, or anecdotal. Some RAC Members felt that the fact that particles < 1 mm were produced in the one example was sufficient reason to classify based on powder. RAC discussed and provisionally agreed that generated particles < 1 mm are relevant for the classification of the massive form of lead. Other Members considered that even if the particles < 1 mm were considered relevant, they were better represented by the 1 mm D/Tp data, other Members considered particles < 1 mm not to be relevant.	**SECR** to approach the COM for further extension of the deadline.

The Eurometaux Regular Stakeholder Observer and the expert accompanying the Cefic Regular Stakeholder Observer commented on different aspects of the final draft opinion.

7. Health based exposure limits at the workplace

7.1. Adoption of opinions

Asbestos – final 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.". The scientific report was made publicly available on 1 February 2021 and interested parties were invited to submit comments by 1 April 2021. The first draft opinion was discussed at RAC-56. The revised RAC draft opinion was made available for RAC consultation 8-17 May.	
The Rapporteurs presented and RAC discussed the final draft opinion on the scientific evaluation of limit values for asbestos at the workplace. RAC agreed with the exposure response for asbestos, as proposed in the final draft opinion. RAC discussed the possibility to propose a specific conversion factor to compare phase contrast microscopy results to those from electron microscopy but it was acknowledged that it is not possible to set a single factor since this is dependent on the occupational context. Instead, RAC agreed to describe a range of the conversion factors based on comparative studies described in the Annex of the draft opinion and to indicate the related uncertainties. RAC agreed not to propose a 15 minutes short term exposure limit (STEL), BLV, BVG or notations. RAC adopted its opinion (with modifications agreed at RAC-57) by consensus.	**Rapporteurs** to revise the opinion in accordance with the agreed modifications at RAC-57 and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM are 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 ETUC stakeholder observer commented on uncertainties in the risk characterisation. The stakeholder observers from the Advisory Committee for Safety and Health at Work (ACSH) - "Working Party on Chemicals (WPC)", representing the Employers and the Workers Interest Groups commented on the RAC conclusion not to propose a specific conversion factor for the transfer of PCM results to EM results.	
8. Harmonised classification and labelling (CLH)	
8.1 Report from the 27/28 April 2021 RAC CLH WG	
The Secretariat presented the Report of the 1st Meeting of the Committee for Risk Assessment Working Group on CLH held on 27-28 April 2021. The 2nd Meeting of the RAC Working Group on CLH will be held on 5-6 July 2021.	

8.2 CLH dossiers

8.2.1 Hazard classes for agreement without plenary debate

- Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -): germ cell mutagenicity, reproductive toxicity (discussed in the CLH WG)

- Sodium chlorate (EC: 231-887-4; CAS: 7775-09-9): acute oral toxicity, hazardous to the aquatic environment (discussed in the CLH WG)

- Potassium chlorate (EC: 223-289-7; CAS: 3811-04-9): acute oral and inhalation toxicity, hazardous to the aquatic environment (discussed in the CLH WG)

- Triethylamine (EC: 204-469-4; CAS: 121-44-8): acute inhalation and dermal toxicity, serious eye damage/eye irritation (discussed in the CLH WG)

- Di-n-butylamine (EC: 203-921-8; CAS: 111-92-2): acute oral, dermal and inhalation toxicity, skin corrosion/irritation, serious eye damage/eye irritation, STOT SE (discussed in the CLH WG)

- Difenoconazole (ISO): physical hazards, acute dermal and inhalation toxicity, skin sensitisation, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity, STOT SE, hazardous to the aquatic environment

- 4-Nitrosomorpholine: carcinogenicity

- N,N-dimethyl-p-toluidine: acute toxicity via all routes, germ cell mutagenicity

- Metribuzin (ISO): acute toxicity via all routes, skin irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE

- Lithium carbonate; lithium chloride; lithium hydroxide: germ cell mutagenicity, carcinogenicity

8.2.2 Substances with hazard classes for agreement in plenary session

8.2.2.1 Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -) – developmental toxicity

8.2.2.2 Triethylamine (EC: 204-469-4; CAS: 121-44-8) – acute oral toxicity

8.2.2.3 Difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (CAS: 119446-68-3)

8.2.2.4 4-Nitrosomorpholine (EC: 627-564-6; CAS: 59-89-2)

8.2.2.5 N,N-dimethyl-p-toluidine (EC: 202-805-4; CAS: 99-97-8)

8.2.2.6	Metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one (EC: 244-209-7; CAS: 21087-64-9)
8.2.2.7	[1] Lithium carbonate; [2] lithium chloride; [3] lithium hydroxide (EC: [1] 209-062-5; [2] 231-212-3; [3] 215-183-4; CAS: [1] 554-13-2; [2] 7447-41-8; [3] 1310-65-)
8.2.2.8	Nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: 500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; and others; CAS: 127087-87-0; 9016-45-9; 26027-38-3; 68412-54-4; 27986-36-3; 20427-84-3; 27176-93-8; 1119449-38-5 and others)
8.2.2.9	Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: 230-770-5; 248-743-1; 247-555-7; 248-293-6 and others; CAS: 127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others)
8.2.2.10	Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: -; CAS: 127087-87-0; 9016-45-9 and others)

8.2.2.1 Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -)

The Chair welcomed the Dossier Submitter representatives and explained that the **reaction mass** is used in inks and toners, in printing and recorded media reproduction as well as in adhesives and sealants. It has no current Annex VI entry.
The DS (NO) proposes to classify the substance as Muta. 2; H341 and Repr. 1B; H360F.
Germ cell mutagenicity and reproductive toxicity were the hazard classes open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 19 September 2021.

RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Muta. 2; H341, Repr. 1B; H360F] RAC agreed on no classification for developmental toxicity due to inconclusive data.	**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.

8.2.2.2. Triethylamine (EC: 204-469-4; CAS: 121-44-8)

The Chair explained that **triethylamine** is used in articles, 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. 2; H225, Acute Tox. 4 *; H332, Acute Tox. 4 *; H312, Acute Tox. 4 *; H302, Skin Corr. 1A; H314 and STOT SE 3; H335 (SCL ≥ 1%).

The DS (AT) proposes to modify the entry to Acute Tox. 4; H302 (ATE=500 mg/kg bw), Acute Tox. 3; H311 (ATE=420 mg/kg bw), Acute Tox. 3; H331 (ATE=7.2 mg/L (vapours)), Eye Dam. 1; H318 and to retain Flam. Liq. 2; H225, Skin Corr. 1A; H314 and STOT SE 3; H335 (SCL ≥ 1%).
Acute toxicity via all routes and serious eye damage/eye irritation were the hazard classes 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. 3; H301 (ATE=100 mg/kg bw), Acute Tox. 3; H311 (ATE=300 mg/kg bw), Acute Tox. 3; H331 (ATE=7.2 mg/L (vapours)), Eye Dam. 1; H318]	**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.

8.2.2.3. Difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (CAS: 119446-68-3)

The Chair welcomed the Dossier Submitter representative and an expert accompanying the CropLife Regular Stakeholder Observer. He explained that **difenoconazole** is an active substance of a plant protection product (PPP) and it is used as a fungicide. The substance has no current Annex VI entry.
The DS (ES) proposes to classify the substance as Acute Tox. 4; H302 (ATE=1453 mg/kg bw), Eye Irrit. 2; H319, 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 and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 18 September 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, Acute Tox. 4; H302 (ATE=1450 mg/kg bw), Eye Irrit. 2; H319, 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.	
8.2.2.4. 4-Nitrosomorpholine (EC: 627-564-6; CAS: 59-89-2)	
The Chair welcomed the Dossier Submitter representative and explained that **4-nitrosomorpholine** has been detected as impurity in higher amounts in consumer products (e.g. snow sprays). The substance has no current Annex VI entry. The DS (DE) proposes to classify the substance as Carc. 1B; H350 (SCL ≥ 0.001%) and STOT RE 1; H372 (liver). Germ cell mutagenicity, carcinogenicity and STOT RE were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 18 November 2021.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Carc. 1B; H350 (SCL ≥ 0.001%), STOT RE 1; H372 (liver), Muta 2; H341]	**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.
8.2.2.5. *N,N*-dimethyl-p-toluidine (EC: 202-805-4; CAS: 99-97-8)	
The Chair welcomed the Dossier Submitter representative and explained that ***N,N*-dimethyl-*p*-toluidine** is used as formulation in polyacrylic bone cements, as intermediate in the manufacture of other substance(s), in textile dyes, finishing and impregnating products; including bleaches and other processing aids, pH-regulators and manufacture of textiles, leather, fur. The substance is part of an existing Annex VI group entry (Index No. 612-056-00-9) as Acute Tox. 3 *; H331, Acute Tox. Tox. 3 *; H311, Acute Tox. 3 *; H301, STOT RE 2*; H373** and Aquatic Chronic 3; H412. The DS (DE) proposes <u>to add</u> Carc. 2; H351, <u>to modify</u> Acute Tox. 4; H301 (ATE=139 mg/kg bw), Acute Tox. 3; H332 (ATE=1.4 mg/L (mists) and STOT RE 2; H373 (blood system; nasal cavity), <u>to retain</u> Aquatic Chronic 3; H412 and <u>to remove</u> Acute Tox. 3; H311. Acute toxicity via all routes, germ cell mutagenicity, carcinogenicity and STOT RE were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 25 November 2021.	
RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below. [Acute Tox. 4; H332 (ATE=1.4 mg/L (mists)), Acute Tox. 3; H301 (ATE=140 mg/kg bw), STOT RE 2; H373 (blood, respiratory tract), Carc. 1B; H350] RAC agreed on no classification for acute dermal toxicity and 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.

8.2.2.6. Metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one (EC: 244-209-7; CAS: 21087-64-9)

The vice-Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. She explained that **metribuzin** is an active substance with herbicidal activity used for weed control in different agricultural crops, such as potatoes, soybean etc. Metribuzin is a selective triazinone herbicide acting as an inhibitor of photosynthesis, specifically the inhibition of the photosynthetic electron transfer in the stage of the second light reaction. The substance has current Annex VI entry as Acute Tox. 4 *; H302, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410.
The DS (EE) proposes to add STOT RE 2; H373 (blood, thyroid), to modify Acute Tox. 4; H302 (ATE=322 mg/kg bw) and Aquatic Chronic 1; H410 (M=100) and to retain Aquatic Acute 1; H400 (M=10).
Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.
Legal deadline for the adoption of an opinion is 1 January 2022.

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=320 mg/kg bw), STOT RE 2; H373 (blood), 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 STOT RE.

8.2.2.7. [1] Lithium carbonate; [2] lithium chloride; [3] lithium hydroxide (EC: [1] 209-062-5; [2] 231-212-3; [3] 215-183-4; CAS: [1] 554-13-2; [2] 7447-41-8; [3] 1310-65-)

The vice-Chair welcomed the Dossier Submitter representatives and the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers. She explained that **lithium carbonate** is the starting material for the production of lithium salts. It is used in the manufacture of aluminium and as a flux in the glass, enamel and ceramic industries, and in the construction industry. Further, it is applied in the prophylaxis and treatment of affective disorders. **Lithium chloride** is used to absorb moisture in air conditioning systems and in batteries and in welding and brazing fluxes in the production of lightweight alloys. **Lithium hydroxide** (monohydrate) is used in alkaline storage batteries and for manufacturing of lithium soaps. Lithium hydroxide (anhydrous) is used as an additive to potassium hydroxide in big industrial batteries and in the production of lithium stearate. Lithium is also used as a pharmaceutical in psychiatric medication. The substances have no current Annex VI entry.

The DS (FR) proposes to classify the substances as Repr. 1A; H360FD. Germ cell mutagenicity, carcinogenicity and reproductive toxicity were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 22 December 2021.	
RAC agreed to classify the substances as Repr. 1B; H360F and to discuss further developmental toxicity and lactation at the next RAC meeting. RAC agreed on no classification for germ cell mutagenicity and carcinogenicity.	**SECR** to table the dossier for further discussion in RAC (with regard to read-across of Lithium hydroxide and developmental and lactation endpoints).
The expert accompanying the Cefic Regular Stakeholder Observer commented on read-across and on reproductive toxicity. The Eurometaux Regular Stakeholder Observer and the expert accompanying the Eurometaux Regular Stakeholder Observer also commented on reproductive toxicity.	
9. Restrictions	
9.1 General restriction issues	
9.1.1 Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals	
The ECHA Secretariat presented and RAC discussed the revisions made in the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals. RAC was informed about the upcoming training of newcomers and other interested experts to be held on 23 June 2021.	**SECR** to publish the revised document on ECHA website. **RAC members** to propose topics to be covered in the training by 4 June.
9.1.2 Update on the Restrictions Task Force meeting (29/4)	
The ECHA Secretariat provided a report on the key points and recommendations from the recent Restrictions Task Force meeting held in April 2021.	**SECR** to consider the proposals to discuss Guidance paper in RAC.
9.1.3 Report from the 11/12 May 2021 RAC REST WG	
The ECHA Secretariat presented the report Report of the 1st Meeting of the Committee for Risk Assessment Working Group on Restrictions held on 11-12 May 2021. The 2nd Meeting of the RAC Working Group on Restrictions will be held on 19-20 August 2021.	

9.2 Restriction Annex XV dossiers	
9.2.1 Conformity check	
9.2.1.1 "Dechlorane Plus"™	
The Chair welcomed the Dossier Submitter's representatives from Norway. She informed the participants that the restriction dossier had been submitted in April 2021 and it aims at addressing the risks for human health and the environment from emissions of Dechlorane Plus™.	
RAC agreed that the dossier conforms to the Annex XV requirements. RAC took note of the recommendations to the Dossier Submitter (with additions to the recommendations to the Dossier Submitter to check the default release factors in Table 9 and to look into the decaBDE Background Document, particularly in relation to standards in the aviation industry).	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
The Commission observer provided a status update on the timelines with the POP Regulation.	
9.2.2 Opinion development	
9.2.2.1 Undecafluorohexanoic acid (PFHxA), its salts and related substances – revised fourth draft opinion	
The Chair welcomed the Dossier Submitter's representatives from Germany, regular stakeholder observers with their accompanying experts (to CEFIC and EEB), the occasional stakeholder observers from CONCAWE, EDANA, ETRMA, EURATEX, EUROFEU, and PlasticsEurope together with their accompanying experts. He informed the participants that the restriction dossier had been submitted in December 2019 and concerns the manufacture, use and placing on the market of perfluorohexanoic acid (PFHxA), its salts and the related substances.	
The rapporteurs presented and RAC discussed the revised fourth draft opinion. RAC agreed with the Substance identification-related scope proposed by the Dossier Submitter, covering PFHxA, its salts and related substances (with minor modifications by RAC). RAC supported the rapporteurs' conclusions on the emission assessment from the various sectors (with minor amendment in the chrome plating sector). RAC agreed on the qualitative approach to emissions proposed and the assessment of effectiveness. PFHxA, its salts and related substance are used in a wide variety of sectors and sub-sectors. Many of which, including the most substantial, are characterised by wide-dispersive releases where it is	**The rapporteurs,** together with **SECR**, to do the final editing of the adopted RAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted RAC opinion. **SECR** to forward the adopted opinion and its supporting documentation to SEAC.

not possible to implement specific RMMs to minimise emission to the environment. RAC agreed that normally a broad EU-wide restriction with targeted and carefully selected derogations and transitional periods is the most appropriate measure to reduce the risks of PFHxA, its salts and related substances. However, RAC did not agree from a risk/ emissions minimisation perspective with the majority of derogations proposed by the Dossier Submitter or requested in the consultation. RAC concluded based on the qualitative assessment that the proposed restriction would be effective in reducing emissions and the risks of PFHxA, its salts and related substances. By restricting the use of the substances in the three major use/emissions sources - Paper and cardboard (food contact materials), textiles, and firefighting foams, the emissions to the environment and increase in the already existing pollution stock are anticipated to be significantly reduced. Furthermore, RAC concluded that there are uncertainties associated with the restriction proposal, but that the uncertainties do not change the conclusion that there is a risk from PFHxA, its salts and related substances that is not adequately controlled. RAC concluded that the restriction, as modified by the Committee, is effective, practical, enforceable and monitorable. The available analytical methods do not justify revisions to the proposed concentration limits. RAC also concluded that the proposed restriction, as modified by RAC, is the most appropriate EU-wide measure. Finally, RAC agreed with the overall restriction proposal (as modified by RAC).	
The regular EEB stakeholder observer commented on the arrowhead approach, thresholds and on emissions and derogations (i.e. end of life textiles and semi-conductors). The accompanying expert to the regular stakeholder CEFIC commented on emissions, risks and wide-dispersive uses. The occasional stakeholders from ETRMA commented on enforceability and emissions, and from EUROFEU and its accompanying expert on firefighting foams, derogations and emissions from these uses, from EDANA on emissions. The expert accompanying occasional stakeholder observer from PlasticsEurope restated their comment on the terminology used for fluorinated polymers and commented on derogations and uncertainties.	
9.2.2.2 Substances in single-use diapers – second draft opinion	
The Chair welcomed the Dossier Submitter's representatives from France, the occasional stakeholder observers from EDANA and their accompanying expert from Protecter&Gamble,	

CIRFS and their accompanying expert from Lenzing and PlasticsEurope and their accompanying expert from LyondellBasell Corporate HSE 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 second draft opinion. The following points were agreed based on the RAC working group conclusions: • RAC confirmed its provisional agreement on the list of substances included in the scope. • RAC agreed that for formaldehyde, the local effect (i.e. skin sensitisation) is more relevant than systemic effects. • RAC further agreed with the DS's approach for setting DMELs for PAHs based on dermal studies (studies assessed by BAuA and Knafla et al.). RAC agreed with the DS's approach in that the DMEL for PAH mixtures is appropriate for risk assessment and noted that the DS's use of a 10^{-6} risk level for DMEL derivation is in line with typical practice and ECHA guidance. However, the Committee pointed out that a PAH-8-approach would have been more in line with previous PAHs´ assessments. • RAC agreed that, contrary to the provisional agreement and in line with the DS's proposal, DL-PCBs and PCDD/Fs should be considered together (for the estimation of TEQ). • RAC supported the input parameters selected by the DS for the exposure assessment. Further discussions were held at RAC-57 on the following: • RAC concluded that the Dossier Submitter's assessment of exposure leads to significant overestimation (by as much as 2 orders of magnitude), particularly due to the disparity in the "rewet" factor (baby´s urine refluxed from a diaper) between the DS and published studies, as well as comments by industry. RAC concluded that there are also major uncertainties relating to the quality and representativeness of the available measured data, including both the analytical method and, non-standard, simulated urine extraction method (on whole diapers). RAC also noted that direct skin exposure (to lipophilic	**Rapporteurs** to prepare the third draft opinion, taking into account RAC-57 discussions and the results of the third-party consultation, by early August 2021.

substances) was not adequately assessed in the exposure scenario. • Acknowledging the identified uncertainties and taking note of the results of sensitivity analysis of the risk characterisation presented by the Rapporteurs, RAC concluded that it was not possible to reconstruct the risk characterisation. An EU wide restriction on substances in diapers as proposed by the Dossier Submitter is not supported based on the available data. • RAC will consider how to most appropriately express its conclusions.	
The occasional stakeholder observer EDANA and their accompanying expert from EDANA commented on analytical methods, migration tests and on direct exposure of diapers. The occasional stakeholder observer CIRFS commented on analysis of uncertainties and on realistic exposure scenario. The Commission observer reminded about the remits of RAC to focus on clear technical conclusions, leaving policy decisions to be addressed by the Commission further along in the process.	
9.2.2.3 Lead and its compounds in ammunition and fishing tackles – first draft opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA, invited experts from UNEP/AEWA, the regular stakeholder observers, and their accompanying experts (from Arche Consulting, International Lead Association (ILA) and Cambridge University) as well as the occasional stakeholder observers from FACE. He informed the participants that the restriction dossier had been submitted in January 2021 and concerns lead in outdoor shooting and fishing.	
The rapporteurs presented and RAC discussed the first draft opinion. The following points were agreed based on the RAC working group conclusions: • RAC provisionally agreed with the rapporteurs' conclusions on the scope and conditions of the restriction. The training of non-civilian forces such as police forces using lead ammunition at shooting ranges should be further considered if additional information is made available in the consultation. • RAC agreed on the hazards to environment and human health. • RAC concluded that exposure from shooting is plausible but is very much case-specific and contribution from bullets and primers (out of scope) cannot be separated. Therefore, no quantitative assessment is currently possible.	**RAC members** to provide any remaining comments via the written consultation on the first draft opinion (by 18 June 2021). **Rapporteurs** to prepare the second draft opinion, taking into account RAC-57 discussions and the RAC written consultation, by late July 2021. **Secretariat** to table the second draft opinion for discussion at the second RAC working group on restrictions in August 2021.

• RAC concluded that exposure from home-casting is plausible, but the quantitative contribution is probably highly case-specific and no quantitative assessment is currently possible. The Dossier Submitter will provide additional information based on modelling that may contribute to a quantitative risk assessment. • RAC furthermore agreed on environmental risk from shooting ranges, including risk to surface water. Further analysis on the risks to ground water and ground drinking water sources is expected from the Dossier Submitter Further discussions were held at RAC-57 on the following: • RAC provisionally agreed with the Dossier Submitter that many species, particularly birds are at risk. However, the evaluation of the Dossier Submitter's assessment of the numbers of birds (primary and secondary poisoning) at risk is on-going and will be presented at the next RAC working group meeting. • Furthermore, RAC supported that there is robust evidence that the use of lead ammunition and fishing tackle remains widespread in Europe and the exposure of different bird species can induce adverse effects as well as mortality. • RAC discussed the Dossier Submitter's quantitative risk assessment of human health risk from eating game containing lead. RAC concluded that a sensitivity analysis considering different possible scenarios should be considered as part of the evaluation.	
The regular stakeholder observer from EUROMETAUX commented on risk estimates. The occasional stakeholder observer from FACE commented on the scope of the proposal and the numbers of birds at risk as well as on exposure estimates (meat consumption). The Dossier Submitter representative informed that they are currently working further on the analysis of risks to groundwater and on the modelling of exposure resulting from home casting and will make that available by the next working group meeting. The invited expert from AEWA commented on the size of ingested particles and on exposure estimates (lead concentration).	
10. Authorisation	
10.1 General authorisation issues	
10.1.1. Update on incoming/future applications	
The ECHA Secretariat presented the information on incoming/future applications, expected workload in	

2021/2022 and timelines, length of review period vs fixed date. RAC discussed and took note of the information.	
10.1.2. Report from RAC WG on AfAs during May 2021 meeting	
The 8th Meeting of the Committee for Risk Assessment Working Group on Applications for Authorisation took place on 4-5 May 2021. Participants: 18 RAC members, 3 Members' advisers, 2 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. • 218_CT_DOURECA (2 uses) • 219_CT_HusqvarnaAB (1 use) • 220_CT_SRG Global (2 uses) • 225_MOCA_LUC (2 uses) • 226_OPE_LETI (1 use) The working group recommended that the following draft opinions required full discussion or discussion on specific points at the RAC plenary: • 221_CT_SD_USSK (1 use) • 222_RR1_SD_Colle (1 use) • 223_RR1_EDC_Lanxess (1 use) • 224_RR1_EDC_Eurenco (1 use)	
The Secretariat presented the Report of the 8th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group. RAC took note of the Report.	
10.1.3. Update of the opinion format	
The ECHA Secretariat presented the new format of the RAC opinion on AFA. RAC supported the proposal for the new opinion format.	**SECR** to publish the new format for the RAC opinion on AFA and make it available for RAC Rapporteurs.
10.1.4. Evaluation of review reports	
The ECHA Secretariat presented the document on the Approach for the review reports. RAC discussed and supported the approach for the review reports.	**SECR** to publish the Approach for the review reports.
10.2 Authorisation applications	
10.2.1 Discussion on key issues	
10.2.1.1 5 applications for authorisation (chromium trioxide, chromic acid, dichromium tris(chromate))) from February 2021 submission window	
RAC discussed the key issues in 5 AfAs / 6 uses.	
10.3 Agreement on draft opinions	

10.3.1 Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate

10.3.1.1 218_CT_DOURECA (2 uses)
10.3.1.2 219_CT_HusqvarnaAB (1 use)
10.3.1.3 220_CT_SRG Global (2 uses)
10.3.1.4 225_MOCA_Luc (2 uses)
10.3.1.5 226_OPE_LETI (1 use)

The Chair informed the Committee that following the Rapporteurs' proposal, the RAC consultation and the recommendation of the 8th meeting the RAC AFA WG on the eight 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 eight draft opinions on the following AFA cases.

10.3.1.1 218_CT_DOURECA (2 uses) **Use1:** *Industrial use of chromium trioxide for a pre-treatment step (etching) in the electroplating process for automotive 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. This information should also be included in the review report. The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated to be 0.078 µg Cr(VI)/m^3 (exposure estimate for Use 1 and Use 2 combined). 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) $3.2*10^{-3}$ µg Cr(VI)/m^3 per 24h and (oral, local) $5.2*10^{-3}$ µg Cr(VI)/kg bw/d (Use 1 and Use 2 combined). The excess lifetime cancer risk for workers is estimated to be $3.1*10^{-4}$ (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and $9.2*10^{-5}$ (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. RAC agreed:	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes for Cr(VI): (a) Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed 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; (vi) include the determination of the background concentrations at the plating line and onsite WWTP working area; (b) Environmental releases: (i) the applicant shall continue their monitoring programme for Cr(VI) emission of wastewater by conducting their biannual measurements; (ii) the applicant shall conduct air emission measurements at least annually or more frequently in the periods 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 paragraphs 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. 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 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 made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant should act upon the outcomes of the measurements of the background exposure levels in such a way that the use of RPE by the workers involved in WCS 3 and WCS 9 will be minimised. 3. recommendations for the review report The information gathered via 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 and 5, should be documented and included in any subsequent authorisation review report.	
Use2: *Industrial use of chromium trioxide for the electrolytic step to create a long-lasting and high durability chromium decorative surface on plastic substrates in the electroplating process for automotive 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.	**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 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 0.078 µg Cr(VI)/m^3 (exposure estimate for Use 1 and Use 2 combined). 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) $3.2*10^{-3}$ µg Cr(VI)/m^3 per 24h and (oral, local) $5.2*10^{-3}$ µg Cr(VI)/kg bw/d (Use 1 and Use 2 combined). The excess lifetime cancer risk for workers is estimated to be $3.1*10^{-4}$ (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and $9.2*10^{-5}$ (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes for Cr(VI): (b) Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed 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; (vi) include the determination of the background concentrations at the plating line and onsite WWTP working area; (b) Environmental releases: (i) the applicants shall continue their monitoring programme for Cr(VI) emission of wastewater by conducting their biannual measurements ; (ii) the applicants shall conduct air emission measurements at least annually or more frequently in the periods 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 paragraphs 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 monitoring programmes referred to in paragraphs 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 made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place.	

5. The applicant should act upon the outcomes of the measurements of the background exposure levels in such a way that the use of RPE by the workers involved in WCS 3 and WCS 9 will be minimised. 3. recommendations for the review report RAC recommends, and in line with the applicant's commitment, that the applicant should continue to investigate the possibility to use liquid CrO_3 solution instead of solid CrO_3 (WCS 6). The results of this investigation and 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 and 5, should be documented and included in any subsequent authorisation review report.	
10.3.1.2 219_CT_HusqvarnaAB (1 use) **Use1:** *Industrial use of a mixture containing Chromium Trioxide in functional chrome plating of the saw chain cutter links in order to meet stay sharp and durability requirements for use with chainsaws.* 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. This information should also be included in the review report. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The highest combined exposure to workers was estimated to be 0.0089 µg Cr(VI)/m^3 (average exposure value for one worker corrected for RPE, duration and frequency, 8h-TWA value). For reference, the current 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 via inhalation was estimated to be 1.98×10^{-4} µg Cr(VI)/m^3 while via the oral route it was estimated to be 8.87×10^{-5} mg Cr(VI)/kg bw/day.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

Based on the above exposures, the highest excess lifetime cancer risk for workers (inhalation route) is estimated to be 3.58×10^{-5} over 40 years per worker, and for general population (inhalation and oral route combined, individual) 5.81×10^{-6}. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicant shall continue to conduct the following monitoring programmes for Cr(VI): a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall: • be conducted at least annually for the exposed workers to Cr(VI); • be based on relevant standard methodologies or protocols; • comprise personal and / or static inhalation exposure sampling; • be representative of: ✓the range of tasks undertaken where exposure to Cr(IV) is possible; ✓the OCs and RMMs typical for each of these tasks; ✓the number of workers potentially exposed. b) Environmental releases: • the applicant shall continue to conduct air emission measurements at least annually or more frequently following any possible changes in the process; • the monitoring programme for air emissions shall: ✓be based on relevant standard methodologies or protocols and ✓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 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 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 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 section 8 paragraph 2 shall be included in any subsequent authorisation review report.	
10.3.1.3 220_CT_SRG Global (2 uses) **Use1:** *Chromium trioxide-based etching as pre-treatment step for electroplating of plastics for transportation 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. This information should also be included in the review report. The highest combined inhalation exposure (8h adjusted TWA) to workers was estimated by RAC to be 0.32 µg Cr(VI)/m^3 (exposure estimate for Use 1). 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) $1.0*10^{-3}$ µg Cr(VI)/m^3 per 24h and (oral, local) $4.9*10^{-3}$ µg Cr(VI)/kg bw/d (exposure estimate for Use 1). The excess lifetime lung cancer risk for workers for Use 1 is estimated to be 1.3 $*10^{-3}$ (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and $3.0*10^{-5}$ (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. The excess lifetime intestinal cancer risk is estimated to be $3.9*10^{-6}$ (oral, local indirectly exposed over 70	**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, without the effect of the conditions) for 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 Cr(VI): (c) Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed 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; (vi) include the determination of the background concentrations at the plating line, loading /unloading working areas and the onsite WWTP working area. (b) Environmental releases: (i) the applicant shall continue their quarterly monitoring programme for Cr(VI) emission of wastewater; (ii) the applicant shall conduct air emission measurements at least annually at both emission points or more frequently in the periods 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 applicant's site. 2. The information gathered via the measurements referred to in paragraphs 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. 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 monitoring programmes referred to in paragraphs 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 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 monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report.	
Use2: *Functional chrome plating with decorative character for transportation 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. This information should also be included in the review report.	**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 highest combined inhalation exposure (8h adjusted TWA) to workers was estimated by RAC to be 0.32 µg Cr(VI)/m^3 (exposure estimate for Use 2). 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) $5.5*10^{-4}$ µg Cr(VI)/m3 per 24h and (oral, local) $2.6*10^{-3}$ µg Cr(VI)/kg bw/d (exposure estimate for Use 2). The excess lifetime cancer risk for workers for Use 2 is estimated to be 1.3 $*10^{-3}$ (inhalation, 8h TWA exposure for 40 years, combined highest value, without the effect of the conditions) and $1.6*10^{-5}$ (inhalation, local, for 24h exposure for 70 years, without the effect of the conditions) for the general population. The excess lifetime intestinal cancer risk is estimated to be $2.1*10^{-6}$ (oral, local indirectly exposed over 70 years, without the effect of the conditions) for the general population RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation The applicant shall implement the following monitoring programmes for Cr(VI): (d) Occupational inhalation exposure The applicant shall implement their monitoring programmes for Cr(VI) exposure, which shall : (i) be conducted at least annually for the workers exposed 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; (vi) include the determination of the background concentrations at the plating line, loading /unloading working areas and the onsite WWTP working area. (b) Environmental releases: (i) the applicant shall continue their quarterly monitoring programme for Cr(VI) emission of wastewater; (ii) the applicant shall conduct air emission measurements at least annually at both emission points or more frequently in the periods 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 applicant's site. 2. The information gathered via the measurements referred to in paragraphs 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. 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 monitoring programmes referred to in paragraphs 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 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 RAC recommends that the applicant should perform a study on the feasibility to implement a closed and automated transfer system for the refilling of the electroplating baths (Use 2). The results of the monitoring programmes referred to in section 8.1 paragraph 1(a) and in section 8.1 paragraph 1(b), as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, shall be documented and included in any subsequent authorisation review report.	
10.3.1.4 225_MOCA_Luc (2 uses) **Use1:** *Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors.* 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 over the authorisation period 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 3.66 µmol MOCA/mol creatinine (Use 1 and Use 2 combined) when measured from urinary samples collected on the Friday afternoon after the work week. This corresponds the daily intake of 12.22 µg/d (Use 1 and Use 2 combined). The excess lifetime cancer risk for workers is estimated to be **1.18×10^{-5}**, **2.7×10^{-7}** for the local population and **4.06×10^{-11}** for the regional population (Use 1 and Use 2 combined). RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The applicants shall implement the following monitoring programmes for Cr(VI): (e) Occupational inhalation exposure: The applicant shall continue their monitoring programmes for MOCA exposure, which shall:	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

(i) be conducted at least annually for the workers exposed to MOCA. 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 MOCA 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. b) Biomonitoring: (i) Exposure of all workers working within the premises in which MOCA is used shall be followed by twice yearly biomonitoring programmes, in which urinary total MOCA levels are measured from urinary samples collected on the Friday afternoon after the work week. If urinary levels are repeatedly low (below LoD using sensitive biomonitoring methods), frequency of monitoring may be reduced to once per year. c) Surface Measurement: (i) Surface measurements of surface contamination shall continue to be conducted at least twice per year in order to identify exposure sources and prevent exposure via the contaminated surfaces. This is especially important when biomonitoring shows measurable (above LoD) urinary MOCA levels. Surface monitoring shall be targeted to places with highest potential dust formation. If urinary levels consistently show urinary levels below LOD, surface monitoring may not be needed.	

2. The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the risk management measures (RMMs) and operational conditions (OCs) to further reduce workers' exposure to MOCA. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented. The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities, and included in any subsequent authorisation review report submitted. 3. recommendations for the review report RAC recommends the applicant to perform a study on the feasibility to implement machine casting in all casting lines and include the result in any subsequent authorisation review report.	
Use2: *Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors.* 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 over the authorisation period. 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 3.66 µmol MOCA/mol creatinine (Use 1 and Use 2 combined) when measured from urinary samples collected on the Friday afternoon after the work week. This corresponds the daily intake of 12.22 µg/d (use 1 and use 2 combined). The excess lifetime cancer risk for workers is estimated to be **1.18×10^{-5}**, **2.7×10^{-7}** for the local population and **4.06×10^{-11}** for the regional population (Use 1 and Use 2 combined). 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 The applicants shall implement the following monitoring programmes for Cr(VI): (f) Occupational inhalation exposure: The applicant shall continue their monitoring programmes for MOCA exposure, which shall: (i) be conducted at least annually for the workers exposed to MOCA. 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 MOCA 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. b) Biomonitoring: (i) Exposure of all workers working within the premises in which MOCA is used shall be followed by twice yearly biomonitoring programmes, in which urinary total MOCA levels are measured from urinary samples collected on the Friday afternoon after the work week. If urinary levels are repeatedly low (below LoD using sensitive biomonitoring methods), frequency of monitoring may be reduced to once per year. c) Surface Measurement: (i) Surface measurements of surface contamination shall continue to be conducted at least twice per year in order to identify exposure sources and prevent exposure via the contaminated surfaces. This is especially important when biomonitoring shows measurable (above LoD) urinary MOCA levels. Surface monitoring shall be targeted to places with highest potential dust	

formation. If urinary levels consistently show urinary levels below LOD, surface monitoring may not be needed. 2. The information gathered in the monitoring campaigns shall be used by the applicant to review and improve the risk management measures (RMMs) and operational conditions (OCs) to further reduce workers' exposure to MOCA. The outcomes and conclusions of this review, including those related to the implementation of any additional RMMs, must be documented. The results of the monitoring and of the review of the OCs and RMMs shall be maintained, be available to national enforcement authorities, and included in any subsequent authorisation review report submitted. 3. recommendations for the review report RAC recommends the applicant to perform a study on the feasibility to implement machine casting in all casting lines and include the result in any subsequent authorisation review report.	
10.3.1.5 226_OPE_LETI (1 use) **Use1:** *Use of 4-tert-OPnEO in aqueous buffers during the manufacturing process of the active pharmaceutical ingredient (Protein Q) of the veterinary vaccine LetiFend®.* 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 use applied for may result in 0 g per year emissions of the substance to the environment. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation The applicant shall carry out a mass balance analysis to confirm the appropriateness and effectiveness of the operational conditions and risk management measures in place. The mass balance shall be based on measurements for the relevant waste streams potentially containing 4-tert-OPnEO. The results shall be included in any subsequent review report, including details of the sampling points, the analytical method, the concentrations	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

detected and the corresponding environmental release values. 3. recommendations for the review report The information from the mass balance analysis, as well as the outcome and conclusions of any action taken regarding RMMs, should be documented and included in any subsequent authorisation review report.	
10.3.2 Draft opinions for agreement with plenary debate	
10.3.2.1. 221_CT_SD_USSK (1 use)	
Use 1: *Use of Chromium Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).* RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. 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 exposure to workers was estimated to be at maximum: - inhalation (µg Cr(VI)/m^3): 0.244 (highest exposure estimate) - dermal (µg Cr(VI)/kg bw/d): 25.4 (highest exposure estimates) For reference, as of January 2020, the binding occupational exposure limit (BOEL) for inhalation for Cr(VI) is 10 µg Cr(VI)/m^3 (transitional value until 17 January 2025, after which 5 µg Cr(VI)/m^3 applies). The exposure to the general population was estimated to be: - inhalation, local (µg Cr(VI)/m^3): 0.011 - oral: local (µg Cr(VI)/kg bw/d): 0.148 The excess lifetime cancer risk for workers (40 years of exposure) - directly exposed is estimated to be at maximum: o inhalation: 8.8 x 10^{-4} o RCR dermal (reproductive toxicity): 0.59	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

- indirectly exposed is estimated to be at maximum: o inhalation: 4.40 x 10^{-5} o oral: 2.96 x 10^{-5} RAC agreed: 1. additional conditions for the authorisation RAC proposes that the current investigation performed by the applicant in order to clarify if the higher exposure in WCS 9 compared to other tasks is due to unsuitable measurements or ineffective ventilation to be concluded within six months. The result shall be detailed in an updated CSR. If ventilation is found to be the cause of higher exposure values, the system shall be re-evaluated starting with the original design and completed with additional ventilation measurements. In addition, the effectiveness of the ventilation shall be periodically evaluated by means of annual campaigns of measurements. 2. monitoring arrangements for the authorisation a) The applicant shall continue and implement at least annual occupational/workers' exposure monitoring programmes for Cr(VI). First of these shall be completed in six months. Those programmes shall be based on relevant standard methodologies or protocols, comprise static and/or personal inhalation exposure sampling and be representative of: i. the range of tasks undertaken where exposure to chromium 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 and implement monitoring of Cr(VI) emissions to wastewater and air from local exhaust ventilation 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 review	

and confirm the effectiveness of proposed RMM and OCs 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. d) The applicant shall ensure that the application of RMMs at his site is in accordance with the hierarchy of control principles, and refine the worker and HvE assessments if necessary. e) The information from the measurements 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 competent national authority of the Member State where the authorised use will take place. 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. RAC agreed on the draft opinion by consensus.	
10.3.2.2. 222_RR1_SD_Colle (1 use)	
Use 1: *Use of Sodium dichromate as mordant in wool dyeing with dark colours.* 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 over the authorisation period. This information should also be included in the review report. 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 0.4 µg Cr(VI)/m^3 per 8h adjusted TWA via inhalation. For	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

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 local general population was estimated to be 6.54 x 10^{-7} µg Cr(VI)/m^3 via inhalation and 2.60 x 10^{-4} µg Cr(VI)/kg bw/day for the oral route. The excess lifetime lung cancer risk for workers is estimated to be 1.6 x 10^{-3} (inhalation; 8h TWA exposure for 40 years, highest combined exposure) and 1.89 x 10^{-8} (inhalation, local 24h exposure for 70 years) for the general population. The excess lifetime intestine cancer risk for the general population (oral, local 24h exposure for 70 years) is estimated to be 2.08 x 10^{-7}. The exposure to workers was estimated to be 0.69 µg Cr(VI)/kg bw/day via the dermal route. The RCR was estimated to be 1.6 x 10^{-2} for workers for the reprotoxic effect. RAC agreed: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation 1. The authorisation holder shall continue to conduct annual occupational exposure monitoring programmes for Cr(VI), using an sufficiently sensitive analytical method. Those programmes shall be based on relevant standard methodologies or protocols, comprise both static and personal inhalation exposure sampling, include detailed contextual information on the tasks performed, the duration of monitoring, the OCs and RMMs in place and be representative of: a. the range of tasks undertaken where exposure to chromium is possible, including tasks involving maintenance/cleaning tasks; b. the OCs and RMMs typical for each of these tasks; c. the number of workers potentially exposed, including workers not directly using the substance. 2. The authorisation holder shall continue to conduct at least annual Cr(VI) measurements in wastewater, using a sufficiently sensitive analytical method. 3. The information gathered via the measurements referred to in paragraph 1	

and 2 related contextual information shall be used by the authorisation holder to confirm the effectiveness of OCs and RMMs as well as to review regularly the effectiveness of OCs and RMMs in place and to introduce measures to further reduce workplace exposure respectively air emissions to Cr(VI) to as low a level as technically and practically feasible. 4. The information from the monitoring programmes referred to in paragraph 1 and 2, 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 3 shall be documented, maintained and be made available by the authorisation holder, upon request, to the competent authority, and included in any subsequent authorisation review report 3. recommendations for the review report The information gathered via the measurements referred to in section 8 points 1 and 2 as well as the outcome and conclusions of the review and any action taken in accordance with point 3 shall be included in any subsequent authorisation review report. Clear information that cleaning and maintenance do not result in potential exposure to Cr(VI) shall be included in any subsequent authorisation review report. RAC agreed on the draft opinion by consensus.	
10.3.2.3. 223_RR1_EDC_Lanxess (1 use)	
Use 1: *Industrial use as a swelling agent during the sulphonation reaction of polystyrene-divinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins.* RAC concluded that the alternative presented by the applicant, if implemented, would reduce the overall risks. 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. However, the proposed additional conditions for the authorisation are expected to further limit the risk.	**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 maximum inhalation exposure to workers was estimated to be 72 µg/m^3 (TWA-8-h; combined task exposure of WCS 1 and WCS 2) and the dermal exposure not more than 0.00039 µg/kg bw/day (TWA-8-h; task exposure WCS 5). For reference, the current binding Occupational Exposure Limit (BOEL) for this substance is: 8.2 mg/m³ [2 ppm]. The excess lifetime cancer risk for workers is estimated to be 4.3 x 10^{-5} (from combined dermal and inhalation exposure and tasks of WCS 1 and WCS 2), and 4.50 x 10^{-8} for the general population at the local scale and 7.68 x 10^{-11} at the regional scale. RAC agreed: 1. additional conditions for the authorisation The authorisation holder should implement the improvements of the recovery of EDC from the exhaust gas before it reaches the TAR, as the authorisation holder has planned. In addition, the authorisation holder should investigate the reasons for the TAR failures and put in place measures to reduce the number of instances and duration of such failures. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report The authorisation holder should continue to conduct an annual occupational monitoring programme (including measurements for WCS 4 and WCS 5 with a sufficiently sensitive analytical method) and an annual monitoring programme for emissions to air for EDC. The results of the occupational measurements (including maintenance and sampling tasks) and air emission measurements, as well as the outcome and conclusions of the review and any action taken in accordance should be included in any subsequent authorisation review report. Since TAR failure is the main driver for releases to air, RAC recommends that information on the duration of the TAR failure as well as the flow rate of the vent gases and the EDC concentration in these vent gases should be provided in any review report. RAC agreed on the draft opinion by consensus.	
10.3.2.4. 224_RR1_EDC_Eurenco (1 use)	

Use 1: *Industrial use of 1,2-dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives.* RAC concluded that the operational conditions and risk management measures described in the review report are **not** appropriate and effective in limiting the risk to workers. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. 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 inhalation exposure to workers was estimated to be up to 0.413 mg/m³ (8h TWA combined tasks corrected for PPE and frequency), and the dermal exposure to workers up to 0.094 mg/kg bw/day (8h TWA combined tasks corrected for PPE and frequency). For reference, the current binding Occupational Exposure Limit (BOEL) for this substance is: 8.2 mg/m³ [2 ppm]. The exposure to the general population was estimated to be 3.4 x 10^{-5} mg/m³ on a local scale and 1.01 x 10^{-8} mg/m³ on a regional scale. The excess lifetime risk for workers is estimated to be up to 4.44 x 10^{-4} for 8h TWA combined exposures corrected for PPE and frequencies for 40 years, and 3.07 x 10^{-7} for 24h exposure for 70 years for the general population on a local scale and 7.10 x 10^{-11} on the regional scale for the general population. RAC agreed: 1. additional conditions for the authorisation The authorisation holder shall use the information gathered via the measurements referred to in section **Error! Reference source not found.** to regularly review the effectiveness of the risk management measures and operational conditions, including the effectiveness and positioning of extraction ventilation, and to take action as appropriate, to further reduce workers' exposure and environmental exposure to 1,2-dichloroethane.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion. **SECR** to send the draft opinion to the applicant for commenting.

In addition, the authorisation holder shall further assess, and document, the feasibility to implement additional OCs and RMMs in line with the hierarchy of controls concept in order to reduce the need of personal protective equipment and act on the outcome of the feasibility study. Such action may encompass the implementation of an automatic transfer of 1,2-dichloroethane from a delivery truck to a reservoir. 2. monitoring arrangements for the authorisation The authorisation holder shall conduct regular occupational exposure measurements of 1,2-dichloroethane. Those measurements shall: (i) take place at least annually or, if the use of 1,2-dichloroethane does not occur annually, each time during the operation/production of PECH (i.e. when the use of 1,2-dichloroethane occurs); (ii) be representative of the range of tasks undertaken where exposure to 1,2-dichloroethane is possible and of the total number of workers that are potentially exposed – especially those involved in the collection of samples and their analysis; (iii) be based on relevant standard methodologies or protocols and use analytical methods with the lowest detection limit; (iv) include contextual information about the tasks with possible exposure to 1,2-dichloroethane and of the total number of workers that are potentially exposed. The authorisation holder shall continue to regularly measure emissions of 1,2-dichloroethane to the atmospheric compartment. They shall take place at least annually or, if the use of 1,2-dichloroethane does not occur annually, each time during the operation/production of PECH (i.e. when the use of 1,2-dichloroethane occurs). Those measurements shall be based on relevant standard methodologies or protocols and use analytical methods with the lowest detection limit. 3. recommendations for the review report The results of the measurements referred to in section 8.1, as well as the outcomes and conclusions of the review and any actions taken in accordance with section 7, shall be	

documented and included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place. 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. 196_OPE_Becton (1 use) 2. 198_OPE_Zoetis (4 uses; comments on Use 4 only) 3. 199_OPE_Biokit (2 uses; comments on Use 2 only) 4. 203_OPE_NPE_Qiagen (4 uses)	
10.4.1 196_OPE_Becton (1 use)	
Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) as a processing aid in imported diagnostics* The RAC consultations on the draft Final Opinion has been held 05-12 May 2021. RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk. The recommendations for the review report are designed to allow RAC to evaluate any potential review report efficiently. The use applied for may result in up to **18-30 kg per year** (approximately 0.03 kg per year per downstream user site) emissions of the substance to the environment. RAC agreed for: 1. additional conditions for the authorisation All solid and liquid waste shall be collected for an adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not considered by RAC to be an adequate treatment. Downstream users should be instructed to collect all solid and liquid waste for an adequate	**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.

treatment and should not discharge liquid waste containing residues of 4-tert-OPnEO down the drain. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant needs to conduct and report on a representative survey of their EEA downstream users (in terms of number of users and volume of diagnostics used) about the treatment methods that are applied at that point in time (e.g. incineration) following from the requirement to collect all solid and liquid waste containing 4-tert-OPnEO for an adequate treatment. If a review report is submitted, the applicant needs to carefully describe the substitution work done and that to be undertaken, the existing diagnostics to be substituted and exact milestones and timelines for the substitution. RAC adopted the final opinion by consensus with changes made to the draft final opinion.	
10.4.2 198_OPE_Zoetis (4 uses; comments on Use 4 only)	
Use 4: *Industrial use as a viral inactivating agent in the manufacture of two veterinary biologic drugs for treatment of osteoarthritis in cats and dogs.* The RAC consultations on the draft Final Opinion has been held 07-14 May 2021. 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 emissions over the authorisation period. This information should also be included in the review report. The use applied for may result in approximately 0.072 kg/year as 4-tert-OPnEO (measured, commercial scale assessment in 2020) emissions of the substance to the environment. RAC agreed for: 1. no additional conditions for the authorisation 2. monitoring arrangements for the authorisation	**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.

The applicant shall continue to undertake a monitoring programme to measure the concentration of 4-tert-OPnEO in individual waste streams prior to release to the municipal STP. The initial sampling frequency shall be sufficient to take account of daily fluctuations and to demonstrate the effectiveness of the new RMMs that will be implemented. Once the appropriate frequency has been established, the applicant shall monitor at least quarterly or at least 4 times per year 4-tert-OPnEO and its principal degradation products in the wastewater prior to release to the municipal STP, using an analytical method capable of adequately characterising the substance and its principal degradation products at an appropriately low level of quantification. As soon as the first measurements obtained through monitoring are available, the applicant shall carry out a mass balance analysis that takes those measurements into account. Based on the results, the applicant shall assess how the operational conditions and risk management measures can be optimized in such a way that the releases of 4-tert-OPnEO to the environment can be further minimised taking into account the outcomes of the monitoring programme and act on the outcome of the assessment. The results should be included in any subsequent review report, including details of the sampling point, the analytical method, the concentrations detected and the corresponding environmental release values. 3. recommendations for the review report The results of the monitoring program, as well as the mass balance and the outcome and conclusions of the actions taken with regards to minimising emissions, should be documented and included in any subsequent authorisation review report. RAC adopted the final opinion by consensus with the change made to the draft final opinion.	
10.4.3 199_OPE_Biokit (2 uses; comments on Use 2 only)	
Use2: *Professional use of 4-tert-OPnEO as a detergent during the final use of latex-based, ELISA and CLIA In-Vitro-Diagnostic kits.*	**Rapporteurs** together with **SECR** to do the final editing of the final opinion.

The RAC consultations on the draft Final Opinion has been held 03-10 May 2021. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to the environment. The proposed additional conditions for the authorisation are expected to result in operational conditions and risk management measures that are appropriate and effective in limiting the risk to the environment. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 22 kg/year of the substance to the environment for a total of 500-3 000 downstream users' sites (i.e. an average per site up to 7-44 g/year). RAC agreed for: 1. additional conditions for the authorisation All solid and liquid waste containing 4-tert-OPnEO shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Disposal of solid waste as common waste is not considered as adequate treatment, nor is the release of liquid waste into the sewer system or to surface waters. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicant shall report on a new representative Downstream User Survey about their efforts to collect all solid and liquid waste for adequate treatment, and which treatment methods are applied (e.g., incineration). RAC adopted the final opinion by consensus with the change made to the draft final opinion.	**SECR** to send the final opinion to the EC, MSs and the Applicant.
10.4.4 203_OPE_NPE_Qiagen (4 uses)	
Use1: *Formulation and filling of buffer solutions containing 4-tert-OPnEO/4-NPnEO for the manufacturing of and use in in-vitro Diagnostic and Life Sciences kits of the product groups sample preparation, PCR and sequencing.*	**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.

The RAC consultations on the draft Final Opinion has been held 03-10 May 2021. 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 use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 56.92 g per year and in emissions of 4-NPnEO to the environment of up to 52.95 g per year. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicants should monitor at the Hilden site at least quarterly/four times per year (when the processes are operating and the substances are used at maximum daily amounts) 4-tert-OPnEO and 4-NPnEO and their principal degradation products in the wastewater prior to release to the public sewage system using an analytical method capable of adequately characterising the substances and their degradation products in water and at an appropriately low level of quantification. The results should be included in any subsequent review report, including details of the 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.	
Use2: *Industrial use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for the use in in-vitro Diagnostic and Life Sciences kits of the product groups sample preparation, PCR and sequencing.* The RAC consultations on the draft Final Opinion has been held 03-10 May 2021. RAC concluded that the operational conditions and risk management measures described in the	**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.

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 use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 1.09 g per year and in emissions of 4-NPnEO to the environment of up to 78 g per year. RAC agreed for: 1. no additional conditions for the authorisation 2. no monitoring arrangements for the authorisation 3. recommendations for the review report RAC recommends that the applicant should monitor at least quarterly/four times per year (when the processes are operating and the substances are used at maximum daily amounts) 4-tert-OPnEO and 4-NPnEO and their principal degradation products in the wastewater prior to release to the public sewage system using an analytical method capable of adequately characterising the substances and their degradation products in water and at an appropriately low level of quantification. The results should be included in any subsequent review report, including details of the 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.	
Use3: *Professional downstream use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for the use in in-vitro Diagnostic and Life Sciences kits with regulatory impact of the product groups sample preparation, PCR, sequencing (and immunoassay for 4-tert-OPnEO only).* The RAC consultations on the draft Final Opinion has been held 03-10 May 2021. RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in	**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.

operational conditions and risk management measures that are appropriate and effective in limiting the risk. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 390 kg per year (average per site: up to 1.95-7.8 g) and in emissions of 4-NPnEO to the environment of 0 kg per year RAC agreed for: 1. additional conditions for the authorisation In addition to the solid waste containing 4-tert-OPnEO, all liquid waste containing 4-tert-OPnEO generated from the use applied for shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicants shall report on a representative survey of their downstream users about the treatment methods that are applied (e.g. incineration) following from the requirement to collect all liquid waste containing 4-tert-OPnEO for adequate treatment. RAC adopted the final opinion by consensus with the change made to the draft final opinion.	
Use4: *Professional downstream use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for Life Sciences kits without regulatory impact of the product groups sample preparation, PCR and sequencing.* The RAC consultations on the draft Final Opinion has been held 03-10 May 2021 RAC concluded that the operational conditions and risk management measures described in the application are **not** appropriate and effective in limiting the risk. The proposed additional conditions for the authorisation are expected to result in	**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.

operational conditions and risk management measures that are appropriate and effective in limiting the risk. The recommendations for the review report are expected to allow RAC to evaluate the review report efficiently. The use applied for may result in emissions of 4-tert-OPnEO to the environment of up to 22.4 kg per year (average per site: up to 0.112-0.448 g) and in emissions of 4-NPnEO to the environment of 0 kg per year. RAC agreed for: 1. additional conditions for the authorisation In addition to the solid waste containing 4-tert-OPnEO, all liquid waste containing 4-tert-OPnEO generated from the use applied for shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters is not adequate treatment. 2. no monitoring arrangements for the authorisation 3. recommendations for the review report In case a review report is submitted, the applicants shall report on a representative survey of their downstream users about the treatment methods that are applied (e.g. incineration) following from the requirement to collect all liquid waste containing 4-tert-OPnEO for adequate treatment. RAC adopted the final opinion by consensus with the change made to the draft final opinion.	
11. AOB	
11.1. Update form the ECHA legal services on the current legal cases Th ECHA legal services updated the Committee on recent court cases involving substances addressed in published RAC opinions.	
12. Minutes of RAC-57	
12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-57	
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-57 to CIRCA BC.

Table 1: CLH opinions which were adopted at RAC-57

Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane

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 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane	-	-	Muta. 2 Repr. 1B	H341 H360F	GHS08 Dgr	H341 H360F			
RAC opinion	TBD	Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane	-	-	Muta. 2 Repr. 1B	H341 H360F	GHS08 Dgr	H341 H360F			
Resulting Annex VI entry if agreed by COM	TBD	Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane	-	-	Muta. 2 Repr. 1B	H341 H360F	GHS08 Dgr	H341 H360F			

Triethylamine

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	612-004-00-5	triethylamine	204-469-4	121-44-8	Flam. Liq. 2 Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* Skin Corr. 1A	H225 H332 H312 H302 H314	GHS02 GHS07 GHS05 Dgr	H225 H332 H312 H302 H314		STOT SE 3; H335: C ≥ 1%	
Dossier submitters proposal	612-004-00-5	triethylamine	204-469-4	121-44-8	**Modify** Acute Tox. 3 Acute Tox. 3 Acute Tox. 4 **Add** Eye Dam. 1 **Retain** Flam. Liq. 2 Skin Corr. 1A	**Modify** H331 H311 H302 **Add** H318 **Retain** H225 H314	**Modify** GHS06 **Retain** GHS02 GHS05 Dgr	**Modify** H331 H311 **Retain** H225 H302 H314		**Add** inhalation: ATE = 7,2 mg/L (vapours) dermal: ATE = 420 mg/kg bw oral: ATE = 500 mg/kg bw **Retain** STOT SE 3; H335: C ≥ 1%	
RAC opinion	612-004-00-5	triethylamine	204-469-4	121-44-8	**Modify** Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 **Add** Eye Dam. 1	**Modify** H331 H311 H301 **Add** H318	**Modify** GHS06 **Retain** GHS05 Dgr	**Modify** H331 H311 H301 **Retain** H225 H314		**Add** inhalation: ATE = 7,2 mg/L (vapours) dermal: ATE = 300 mg/kg bw oral: ATE = 100 mg/kg bw	
Resulting Annex VI entry if agreed by COM	612-004-00-5	triethylamine	204-469-4	121-44-8	Flam. Liq. 2 Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1A Eye Dam. 1	H225 H331 H311 H301 H314 H318	GHS02 GHS06 GHS05 Dgr	H225 H331 H311 H301 H314		inhalation: ATE = 7,2 mg/L (vapours) dermal: ATE = 300 mg/kg bw oral: ATE = 100 mg/kg bw STOT SE 3; H335: C ≥ 1%	

di-n-butylamine

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	612-049-00-0	di-*n*-butylamine	203-921-8	111-92-2	Flam. Liq. 3 Acute Tox. 4* Acute Tox. 4* Acute Tox. 4*	H226 H332 H312 H302	GHS02 GHS07 Wng	H226 H332 H312 H302			
Dossier submitters proposal	612-049-00-0	di-*n*-butylamine	203-921-8	111-92-2	**Add** STOT SE 3 Skin Corr. 1B Eye Dam. 1 **Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 **Retain** Flam. Liq. 3	**Add** H335 H314 H318 **Modify** H330 H311 H301 **Retain** H226	**Add** GHS05 **Modify** GHS06 Dgr **Retain** GHS02	**Add** H335 H314 **Modify** H330 H311 H301 **Retain** H226		**Add** inhalation: ATE = 1,15 mg/L dermal: ATE = 768 mg/kg bw oral: ATE = 220 mg/kg bw	
RAC opinion	612-049-00-0	di-*n*-butylamine	203-921-8	111-92-2	**Add** Skin Corr. 1B Eye Dam. 1 **Modify** Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 **Retain** Flam. Liq. 3	**Add** H314 H318 **Modify** H330 H311 H301 **Retain** H226	**Add** GHS05 **Modify** GHS06 Dgr **Retain** GHS02	**Add** H314 **Modify** H330 H311 H301 **Retain** H226	**Add** EUH071	**Add** inhalation: ATE = 1,2 mg/L (vapours) dermal: ATE = 300 mg/kg bw oral: ATE = 220 mg/kg bw	
Resulting Annex VI entry if agreed by RAC and COM	612-049-00-0	di-*n*-butylamine	203-921-8	111-92-2	Flam. Liq. 3 Acute Tox. 2 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1	H226 H330 H311 H301 H314 H318	GHS02 GHS06 GHS05 Dgr	H226 H330 H311 H301 H314	EUH071	inhalation: ATE = 1,2 mg/L (vapours) dermal: ATE = 300 mg/kg bw oral: ATE = 220 mg/kg bw	

Sodium chlorate

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	017-005-00-9	Sodium chlorate	231-887-4	7775-09-9	Ox. Sol. 1 Acute Tox. 4* Aquatic Chronic 2	H271 H302 H411	GHS03 GHS07 GHS09 Dgr	H271 H302 H411			
Dossier submitters proposal	017-005-00-9	Sodium chlorate	231-887-4	7775-09-9	**Remove** Aquatic Chronic 2 **Modify** Acute Tox. 3	**Remove** H411 **Modify** H301	**Remove** GHS09 **Modify** GHS06	**Remove** H411 **Modify** H301		**Add** oral: ATE = 100 mg/kg bw	
RAC opinion	017-005-00-9	Sodium chlorate	231-887-4	7775-09-9	**Remove** Aquatic Chronic 2 **Modify** Acute Tox. 3	**Remove** H411 **Modify** H301	**Remove** GHS09 **Modify** GHS06	**Remove** H411 **Modify** H301		**Add** oral: ATE = 100 mg/kg bw	
Resulting Annex VI entry if agreed by COM	017-005-00-9	Sodium chlorate	231-887-4	7775-09-9	Ox. Sol. 1 Acute Tox. 3	H271 H301	GHS03 GHS06 Dgr	H271 H301		oral: ATE = 100 mg/kg bw	

Potassium chlorate

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	017-004-00-3	Potassium chlorate	223-289-7	3811-04-9	Ox. Sol. 1 Acute Tox. 4* Acute Tox. 4* Aquatic Chronic 2	H271 H332 H302 H411	GHS03 GHS07 GHS09 Dgr	H271 H332 H302 H411			
Dossier submitters proposal	017-004-00-3	Potassium chlorate	223-289-7	3811-04-9	**Remove** Acute Tox. 4* Aquatic Chronic 2 **Modify** Acute Tox. 3	**Remove** H332 H411 **Modify** H301	**Remove** Dgr GHS09 **Modify** GHS06	**Remove** H332 H411 **Modify** H301		**Add** oral: ATE = 100 mg/kg bw	
RAC opinion	017-004-00-3	Potassium chlorate	223-289-7	3811-04-9	**Remove** Acute Tox. 4* Aquatic Chronic 2 **Modify** Acute Tox. 3	**Remove** H332 H411 **Modify** H301	**Remove** GHS09 **Modify** GHS06	**Remove** H332 H411 **Modify** H301		**Add** oral: ATE = 100 mg/kg bw	
Resulting Annex VI entry if agreed by COM	017-004-00-3	Potassium chlorate	223-289-7	3811-04-9	Ox. Sol. 1 Acute Tox. 3	H271 H301	GHS03 GHS06 Dgr	H271 H301		oral: ATE = 100 mg/kg bw	

4-nitrosomorpholine

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	613-RST-VW-Y	4-nitrosomorpholine	-	59-89-2	Carc. 1B STOT RE 1	H350 H372 (liver)	GHS08 Dgr	H350 H372 (liver)		Carc. 1B; H350: C ≥ 0,001%	
RAC opinion	613-RST-VW-Y	4-nitrosomorpholine	-	59-89-2	Carc. 1B Muta. 2 STOT RE 1	H350 H341 H372 (liver)	GHS08 Dgr	H350 H341 H372 (liver)		Carc. 1B; H350: C ≥ 0,001%	
Resulting Annex VI entry if agreed by COM	613-RST-VW-Y	4-nitrosomorpholine	-	59-89-2	Carc. 1B Muta. 2 STOT RE 1	H350 H341 H372 (liver)	GHS08 Dgr	H350 H341 H372 (liver)		Carc. 1B; H350: C 0,001%	

Difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether

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	difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether		119446-68-3	Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H319 H400 H410	GHS07 GHS09 Wng	H302 H319 H410		oral: ATE = 1453 mg/kg bw M = 10 M = 10	
RAC opinion	TBD	difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether		119446-68-3	Carc. 2 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H319 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H319 H410		oral: ATE = 1450 mg/kg bw M = 10 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1H-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether		119446-68-3	Carc. 2 Acute Tox. 4 Eye Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H351 H302 H319 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H319 H410		oral: ATE = 1450 mg/kg bw M = 10 M = 10	

N,*N*-dimethyl-*p*-toluidine

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	612-056-00-9	*N,N-d*imethyl-*p*-toluidine [1] *N,N*-dimethyl-*m*-toluidine [2] *N,N*-dimethyl-*o*-toluidine [3]	202-805-4 [1] 204-495-6 [2] 210-199-8 [3]	99-97-8 [1] 121-72-2 [2] 609-72-3 [3]	Acute Tox. 3* Acute Tox. 3* Acute Tox. 3* STOT RE 2* Aquatic Chronic 3	H331 H311 H301 H373** H412	GHS06 GHS08 Dgr	H331 H311 H301 H373** H412		*	C
Dossier submitters proposal	612-RST-VW-Y	*N*,*N*-dimethyl-*p*-toluidine	202-805-4	99-97-8	**Add** Carc. 2 **Modify** Acute Tox. 4 Acute Tox. 3 STOT RE 2 **Remove** Acute Tox. 3	**Add** H351 **Modify** H332 H301 H373 (blood system; nasal cavity) **Remove** H311	**Retain** GHS06 GHS08 Dgr	**Add** H351 **Modify** H332 H301 H373 (blood system; nasal cavity) **Remove** H311		**Add** inhalation: ATE = 1,4 mg/L (mists) oral: ATE = 139 mg/kg bw **Remove** *	**Remove** C
RAC opinion	612-RST-VW-Y	*N*,*N*-dimethyl-*p*-toluidine	202-805-4	99-97-8	**Add** Carc. 1B **Modify** Acute Tox. 4 Acute Tox. 3 STOT RE 2 **Remove** Acute Tox. 3	**Add** H350 **Modify** H332 H301 H373 (blood; respiratory tract) **Remove** H311	**Retain** GHS06 GHS08 Dgr	**Add** H350 **Modify** H332 H301 H373 (blood; respiratory tract) **Remove** H311		**Add** inhalation: ATE = 1,4 mg/L (mists) oral: ATE = 140 mg/kg bw **Remove** *	**Remove** C
Resulting Annex VI entry if agreed by COM	612-RST-VW-Y	*N*,*N*-dimethyl-*p*-toluidine	202-805-4	99-97-8	Acute Tox. 4 Acute Tox. 3 STOT RE 2 Carc. 1B Aquatic Chronic 3	H332 H301 H373 (blood; respiratory tract) H350 H412	GHS06 GHS08 Dgr	H350 H332 H301 H373 (blood; respiratory tract) H412		inhalation: ATE = 1,4 mg/L (mists) oral: ATE = 140 mg/kg bw	

Metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one

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	606-034-00-8	metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4H)-one	244-209-7	21087-64-9	Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M = 10	
Dossier submitters proposal	606-034-00-8	metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one	244-209-7	21087-64-9	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2 **Modify** Acute Tox. 4	**Retain** H302 H400 H410 **Add** H373 (blood, thyroid)	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H302 H410 **Add** H373 (blood, thyroid)		**Retain** M = 10 **Add** oral: ATE = 322 mg/kg bw M = 100	
RAC opinion	606-034-00-8	metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one	244-209-7	21087-64-9	**Retain** Aquatic Acute 1 Aquatic Chronic 1 **Add** STOT RE 2 **Modify** Acute Tox. 4	**Retain** H302 H400 H410 **Add** H373 (blood)	**Retain** GHS07 GHS09 Wng **Add** GHS08	**Retain** H302 H410 **Add** H373 (blood)		**Retain** M = 10 **Add** oral: ATE = 320 mg/kg bw M = 10	
Resulting Annex VI entry if agreed by COM	606-034-00-8	metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one	244-209-7	21087-64-9	Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H302 H373 (blood) H400 H410	GHS07 GHS08 GHS09 Wng	H302 H373 (blood) H410		oral: ATE = 320 mg/kg bw M = 10 M = 10	

Part III. List of Attendees of the RAC-57 meeting

RAC members	
Aquilina	Gabriele
Barański	Bogusław
Biró	Anna
Bjørge	Christine
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
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
Pęczkowska	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	Žilvinas
van der Haar	Rudolf (co-opted member)
Varnai	Veda

Apologies members	
Branisteanu	Radu (co-opted member)
Xanthos	Theodore
Zeljezic	Davor

Members' advisers		
Boel	Els	(Julie Seba)
Catone	Tiziana	(Pietro Paris)
Clausen	Ian Henning	(Peter Hammer Sørensen)_Article 77(3)c Lead
Durand	Emmanuelle	(Nathalie Printemps)_OEL Asbestos
Esposito	Dania	(Pietro Paris)
Falck	Jonas	(Bert-Ove Lund)_Article 77(3)c Lead
Hadrup	Niels	(Lea Stine Tobiassen)_OEL Asbestos
Hoffmann	Frauke	(Agnes Schulte)
Janssen	Martien	(Betty Hakkert)
Losert	Annemarie	(Manuel Facchin)
Lottrup Lotus	Grete	(Tobiassen Lea Stine)
Luit	Richard	(Betty Hakkert)
Marinkovic	Marino	(Gerlienke Schuur)_Article 77(3)c Lead
Martin	Theresa	(Stahlmann Ralf)
Munch	Pernille Steenkæ	(Lea Stine Tobiassen)_Article 77(3)c Lead
Romoli	Debora	(Pietro Paris)
Russo	Maria Teresa	(Pietro Paris)
Saksa	Jana	(Raili Moldov)
Seba	Julie	(Wendy Rodriguez)
Sonnenburg	Anna	(Stahlmann Ralf)

SEAC Rapporteurs		
Cogen	Simon	Restrictions: Single-use diapers
Fankhauser	Simone	Restrictions: PFHxA Perfluorohexanoic acid
Kiiski	Johanna	Restrictions: PFHxA Perfluorohexanoic acid
Måge	Marit	Restrictions: Single-use diapers
Muncrief	Sandi	AfA: Key issues
Urban	Klaus	Restrictions: Lead in ammunition

Invited experts		**Substance**
Borg	Daniel (rapporteur)	Restrictions: PFHxA Perfluorohexanoic acid
Cromie	Ruth (AEWA Technical Committee)	Restrictions: Lead in ammunition
Dereliev	Sergey (UNEP/AEWA)	Restrictions: Lead in ammunition
Kapelari	Sonja (rapporteur)	Restrictions: Single-use diapers, AfA SD Colle_AfA EDC Lanxess
Levy	Patrick (Employer's Interest Group)	OEL: Asbestos
Musu	Tony (Workers' Interest Group)	OEL: Asbestos
Saarikoski	Sirkku (Government Interest Group)	OEL: Asbestos
Wieske	Martin (Employer's Interest Group)	OEL: Asbestos

Dossier submitters		**Substance**
Blom	Cecile (NO)	CLH: 8.1. Report from the CLH WG
Charles	Sandrine (FR)	CLH: 7) Lithium
Dahlberg Persson	Marie (NO)	Restrictions: Dodecachloropentacyclo & octadeca-7,15-diene ("Dechlorane Plus"™)
Dubois	Céline (FR)	Restrictions: Single use diapers
Erdmann	Christian (DE)	Restrictions: PFHxA Perfluorohexanoic acid
Filtvedt	Anne Line (NO)	Restrictions: Dodecachloropentacyclo & octadeca-7,15-diene ("Dechlorane Plus"™)
Fotland	Tor Øystein (NO)	Restrictions: Dodecachloropentacyclo & octadeca-7,15-diene ("Dechlorane Plus"™)
Guillou	Pauline (FR)	CLH: 7) Lithium
Gündel	Ulrike (DE)	CLH: 4-Nitrosomorpholine
Heesche-Wagner	Kerstin (DE)	Restrictions: PFHxA Perfluorohexanoic acid
Helmedach	Achim (DE)	Restrictions: PFHxA Perfluorohexanoic acid
Kacan	Stefan (DE)	Restrictions: PFHxA Perfluorohexanoic acid
Kopangen	Marit (NO)	Restrictions: Dodecachloropentacyclo & octadeca-7,15-diene ("Dechlorane Plus"™)
Langtvet	Espen (NO)	Restrictions: Dodecachloropentacyclo & octadeca-7,15-diene ("Dechlorane Plus"™)
Larsen	Ann Kristin (NO)	CLH: Report from the CLH WG
Mathieu	Aurelie (FR)	Restrictions: Single use diapers

Regular stakeholder observers	
De Backer	Liisi (CEFIC)
Duguy	Hélène (ClientEarth)
Robinson	Jan (A.I.S.E.)
Romano	Dolores (EEB)
Ruelens	Paul (CropLife Europe)
Santos	Tatiana (EEB)
Van de Broeck	Steven (CEFIC)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux)
De Backer	Liisi (CEFIC)
Duguy	Hélène (ClientEarth)

Apologies Regular stakeholder observers	
Barry	Frank (ETUC)
Comini	Andrea (EuCheMS)
Miliou	Emilia (MedTech)

Occassional stakeholders		Substance
Ballach	Jochen (CIRFS)	Restrictions: Single use diapers
Barbu	Luminita (EDANA)	CLH: 8) Nonylphenol, branched and linear, ethoxylated and others
Cassart	Michel (PlasticsEurope)	Restrictions: Single use diapers
Di Pietra	Marco (Euratex)	Restrictions: PFHxA Perfluorohexanoic acid
Lagemaat	Marines (EDANA)	Restrictions: Single use diapers
Leonhardt	Thomas (EUROFEU)	Restrictions: PFHxA Perfluorohexanoic acid
Niemela	Helena (CONCAWE)	Agenda items 1-5.1; Restrictions: PFHxA Perfluorohexanoic acid & Single use diapers & agenda items 11-12
Perez Simbor	Laia (ETRMA)	Restrictions: General restrictions & PFHxA Perfluorohexanoic acid
Puustinen	Seppo (FACE)	Restrictions: Lead in ammunition
Robin	Nicolas (PlasticsEurope)	Restrictions: PFHxA Perfluorohexanoic acid

Stakeholder experts		Substance
Binks	Steve (CEFIC/Pb REACH consortium)	Article 77(3)c
Bock	Ronald (PlasticsEurope/AGC Chemicals Europe, Ltd)	Restrictions: PFHxA Perfluorohexanoic acid
Bomann	Werner (Bayer)	CLH: Metribuzin
Chowdhury	Jasim (Eurometaux/ILA)	Article 77(3)c
de Graaff	Rene (PlasticsEurope/ LyondellBasell Corporate HSE)	Restrictions: Single use diapers
Hannebaum	Peter (EUROFEU/Tyco Fire Protection Products)	Restrictions: PFHxA Perfluorohexanoic acid
Jacobi	Sylvia (Cefic/Albemarle)	CLH: 7) Lithium
Kirsch	Taryn (EDANA/ Procter&Gamble)	Restrictions: Single use diapers
Köhl	Werner (Eurometaux/Li Consortium)	CLH: 7) Lithium

Lloyd	Sara (CropLife/Syngenta)	CLH: 3) Difenoconazole (ISO)
Pain	Debbie (EEB/Department of Zoology, Cambridge University)	Restrictions: Lead in ammunition
Rahbaran	Shayda (CIRFS/Lenzing atktiengesellschaft, Austria)	Restrictions: Single use diapers
Takala	Jukka (ETUC/President of the International Commission of Occupational Health)	OEL: Asbestos
Verdonck	Frederik (Eurometaux/Arche Consulting)	Restrictions: Lead in ammunition
Williams	Cris (CEFIC/ILA)	Restrictions: Lead in ammunition
Yada	Makiko (CEFIC/Daikin)	Restrictions: PFHxA Perfluorohexanoic acid

European Commission		**DG**
Bertato	Valentina	DG ENV
Bintein	Sylvain	DG ENV
Blass	Ana	DG GROW
Kilian	Karin	DG ENV
Lekatos	Stylianos	DG GROW
Morris	Alick	DG EMPL_OEL Asbestos
Podniece	Zinta	DG EMPL_OEL Asbestos
Roebben	Gert	JRC
Schutte	Katrin	DG ENV
Teixeira	Carla	DG EMPL_OEL Asbestos
Tosetti	Patrizia	DG SANTE

EU Agency Observers		
Borroto	Jorge Gonzalez	EFSA
Castoldi	Anna Federica	EFSA
Panzarea	Martina	EFSA

ECHA staff	
Blainey	Mark
Bowmer	Tim (Chair)
Broere	William
Doyle	Simone
Gmeinder	Michael
Hautamäki	Anne
Henrichson	Sanna
Jones	Stella

Karjalainen	Antti
Kokkola	Leila
Lapenna	Silvia
Lazic	Nina
Lefevre	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Mattiuzzo	Marco
Mottet	Denis
Myöhänen	Kirsi
Nicot	Thierry
Nurmi	Väinö
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Peltola-Thies	Johanna
Perazzolo	Chiara
Prevedouros	Kostas
Regil	Pablo
Reuter	Ulrike
Rheinberger	Christoph
Roggeman	Maarten
Rossi	Ludovica
Sadam	Diana
Sihvonen	Kirsi
Simoes	Ricardo
Simpson	Peter
Smilovici	Simona
Sosnowski	Piotr
Stockmann-Juvala	Helene
Tanarro	Celia
Uphill	Simon
Uphoff	Andreas
Väänänen	Virpi
van Haelst	Anniek
Zeiger	Bastian
Yagzan	Seyhan

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-57 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-57 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-57 meeting

31 May 2021
RAC/A/57/2021

Final Agenda
57th meeting of the Committee for Risk Assessment

31 May-3 June
and
8-10 June 2021

Virtual meeting

31 May starts at 14.00
10 June ends at 17:30

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/57/2021
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) CLH: Procedure for agreement seeking

For agreement
RAC/57/2021/01

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

1) Classification for environmental toxicity of lead

For discussion and adoption

Item 7 – Health based exposure limits at the workplace

7.1 Adoption of opinions: Asbestos – final draft opinion

For discussion and adoption

Item 8 – Harmonised classification and labelling (CLH)

A. Report from the 27/28 April 2021 RAC CLH WG

For information/discussion

RAC/57/2021/02

(RAC WG/CLH/R/1/2021)

B. CLH dossiers

8.2.1 Hazard classes for agreement without plenary debate

- Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -): germ cell mutagenicity, reproductive toxicity *(discussed in the CLH WG)*
- Sodium chlorate (EC: 231-887-4; CAS: 7775-09-9): acute oral toxicity, hazardous to the aquatic environment *(discussed in the CLH WG)*
- Potassium chlorate (EC: 223-289-7; CAS: 3811-04-9): acute oral and inhalation toxicity, hazardous to the aquatic environment *(discussed in the CLH WG)*
- Triethylamine (EC: 204-469-4; CAS: 121-44-8): acute inhalation and dermal toxicity, serious eye damage/eye irritation *(discussed in the CLH WG)*
- Di-n-butylamine (EC: 203-921-8; CAS: 111-92-2): acute oral, dermal and inhalation toxicity, skin corrosion/irritation, serious eye damage/eye irritation, STOT SE *(discussed in the CLH WG)*

- Difenoconazole (ISO): physical hazards, acute dermal and inhalation toxicity, skin sensitisation, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity, STOT SE, hazardous to the aquatic environment
- 4-Nitrosomorpholine: carcinogenicity
- N,N-dimethyl-p-toluidine: acute toxicity via all routes, germ cell mutagenicity

- Metribuzin (ISO): acute toxicity via all routes, skin irritation, serious eye damage/eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, STOT SE
- Lithium carbonate; lithium chloride; lithium hydroxide: germ cell mutagenicity, carcinogenicity

8.2.2 Hazard classes for agreement with plenary debate

8.2.2.1 Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane (EC: -; CAS: -) – *developmental toxicity*

8.2.2.2 Triethylamine (EC: 204-469-4; CAS: 121-44-8) – *acute oral toxicity*

8.2.2.3. Difenoconazole (ISO); 1-({2-[2-chloro-4-(4-chlorophenoxy)phenyl]-4-methyl-1,3-dioxolan-2-yl}methyl)-1*H*-1,2,4-triazole; 3-chloro-4-[(2RS,4RS;2RS,4SR)-4-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)-1,3-dioxolan-2-yl]phenyl 4-chlorophenyl ether (EC 601-613-1; CAS 119446-68-3)

8.2.2.4. 4-Nitrosomorpholine (EC: 627-564-6; CAS: 59-89-2)

8.2.2.5. N,N-dimethyl-*p*-toluidine (EC: 202-805-4; CAS: 99-97-8)

8.2.2.6. Metribuzin (ISO); 4-amino-6-tert-butyl-3-methylthio-1,2,4-triazin-5(4*H*)-one; 4-amino-4,5-dihydro-6-(1,1-dimethylethyl)-3-methylthio-1,2,4-triazin-5-one (EC: 244-209-7; CAS: 21087-64-9)

8.2.2.7. [1] Lithium carbonate; [2] lithium chloride; [3] lithium hydroxide (EC: [1] 209-062-5; [2] 231-212-3; [3] 215-183-4; CAS: [1] 554-13-2; [2] 7447-41-8; [3] 1310-65-)

8.2.2.8. Nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: 500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; and others; CAS: 127087-87-0; 9016-45-9; 26027-38-3; 68412-54-4; 27986-36-3; 20427-84-3; 27176-93-8; 1119449-38-5 and others)

8.2.2.9. Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: 230-770-5; 248-743-1; 247-555-7; 248-293-6 and others; CAS: 127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others)

8.2.2.10. Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: -; CAS: 127087-87-0; 9016-45-9 and others)

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

9.1.1. Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

For information/discussion

9.1.2. Update on the Restrictions Task Force meeting (29/4)

For information/discussion

9.1.3. Report from the 11/12 May 2021 RAC REST WG

RAC/57/2021/03

(RAC WG/REST/R/1/2021)

For information/discussion

9.2 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

9.2.1.1 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.1^{6,9}.0^{2,13}.0^{5,10}]octadeca-7,15-diene ("Dechlorane Plus"™)

For discussion and agreement

b) Opinion development

1) Undecafluorohexanoic acid (PFHxA), its salts and related substances – fourth draft opinion

For discussion and adoption

2) Substances in single-use baby diapers – second draft opinion

For discussion/agreement

3) Lead and its compounds in ammunition and fishing tackles – first draft opinion

For discussion/agreement

Item 10 – Authorisation

10.1 General authorisation issues

a) Update on incoming/future applications

For information/discussion

b) Report from RAC WG on AfAs during May 2021 meeting

For information/discussion

RAC/57/2021/04

c) Update of the opinion format

For information/discussion

d) Evaluation of review reports

For information/discussion
RAC/57/2021/05

10.2 Authorisation applications

1. Discussion on key issues
   10.2.1.1. 5 applications for authorisation (chromium trioxide, chromic acid, dichromium tris(chromate))) from February 2021 submission window

For discussion

10.3 Agreement on draft opinions

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

1) 218_CT_DOURECA (2 uses)
2) 219_CT_HusqvarnaAB (1 use)
3) 220_CT_SRG Global (2 uses)
4) 225_MOCA_Luc (2 uses)
5) 226_OPE_LETI (1 use)

B. Draft opinions for agreement with plenary debate

1. 221_CT_SD_USSK (1 use)
2. 222_RR1_SD_Colle (1 use)
3. 223_RR1_EDC_Lanxess (1 use)
4. 224_RR1_EDC_Eurenco (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 196_OPE_Becton (1 use)
2. 198_OPE_Zoetis (4 uses; comments on Use 4 only)
3. 199_OPE_Biokit (2 uses; comments on Use 2 only)
4. 203_OPE_NPE_Qiagen (4 uses)

For discussion and adoption

Item 11 – AOB

11.1. Update form the ECHA legal services on the current legal cases

For information

Item 12 – Minutes of RAC-57

a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-57

For adoption

Annex II (RAC 57)

Documents submitted to the Members of the Committee for Risk Assessment for the RAC 57 meeting.

Document number	Title
RAC/A/57/2021	Final Draft Agenda
RAC/57/2021/01	CLH: Procedure for agreement seeking (fast-track)
RAC/57/2021/02	Report from the 27/28 April 2021 RAC CLH WG
RAC/57/2021/03	Report from the 11/12 May 2021 RAC REST WG
RAC/57/2021/04	Report from RAC WG on AfAs during May 2021 meeting
RAC/57/2021/05	Evaluation of review reports

ANNEX III (RAC-57)

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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		substance - no other mitigation measures applied. No personal involvement
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement
Harmonised classification & labelling		
Triethylamine **Di-*n*-butylamine** **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.
Sodium chlorate **Potassium chlorate** **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. No personal involvement.
Reaction mass of 1-(2,3-epoxypropoxy)-2,2-bis ((2,3-epoxypropoxy)methyl) butane and 1-(2,3-epoxypropoxy)-2-((2,3-epoxypropoxy)methyl)-2-hydroxymethyl butane **NO**	Christine BJÖRGE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Stine HUSA	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

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

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
Restrictions		
Dechlorane Plus (NO)	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.
	Christine BJÖRGE	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.
Harmonised classification & labelling		
1. **4-Nitrosomorpholine** 2. **N,N-dimethyl-*p*-toluidine** **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. Personal involvement.
	Urs SCHLUTER	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	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.
Lithium carbonate; lithium chloride; lithium hydroxide **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

Dossier / DS	RAC Member	Reason for potential CoI / Working for
NEW DOSSIERS		
		substance - no other mitigation measures applied. No personal involvement.
Metribuzin (ISO) **EE**	Raili MOLDOV	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.
Difeconazole (ISO) **ES**	Ignacio de la FLOR TEJERO	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
1. **Nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol)** 2. **Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol)** 3. **Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol)** **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.