

**RAC/M/58/2021**

**Final**

**11 October 2021**

**Minutes of the 58<sup>th</sup> Meeting  
of the Committee for Risk Assessment  
(RAC-58)**

**Tuesday 7 September, 14.00 to Friday 10 September, 13.15  
and  
Monday 13 September, 14.00 to Thursday 16 September, 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 general topics in his opening address:

From October 2021, in principle, all agenda items for RAC-59 and subsequent plenary meetings will be processed through the Committee's CLH and Restriction working groups, thus the respective dossier processing timelines will be earlier.

ECHA is orientating slowly towards a return to the office, with a strong element of teleworking still in place. There will be no external meetings at the ECHA premises before 31<sup>st</sup> December 2021. Regardless of when face-to-face meetings can restart, we expect the Committees to continue with a proportion of remote plenary meetings in the future in any case.

Finally, due to technical problems with the upload function on ECHA's website, the publication of plenary documents (opinions, minutes etc) may be delayed and some lists such as Committee membership may not be properly updated in the interim.

<b>Agenda point</b>	
<b>Conclusions / agreements / adoptions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>2. Adoption of the Agenda</b>	
The Agenda ( <b>RAC/A/58/2021</b> ) was adopted.	<b>SECR</b> to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-58 minutes.
<b>4. Appointment of (co-)rapporteurs</b>	
<b>4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits</b>  The Secretariat collected the names of volunteers for rapporteurships for CLH dossiers, restriction dossiers and applications for authorisation, as listed in the restricted document 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.	-
<b>5. Report from other ECHA bodies and activities</b>	

<p><b>5.1 RAC work plan for all processes</b></p> <p>The Chair presented the RAC work plan for 2021.</p>	
<p><b>5.3 RAC co-opted members</b></p> <p>The Chair presented the outcome of the open call for candidates for co-option to the Committee under Art. 85(4). He introduced all candidates. RAC agreed to nominate 5 co-opted members for a 3 year term and to place one candidate on the reserve list.</p>	<p><b>SECR</b> to complete all administrative tasks to co-opt the new members.</p>
<p><b>5.4 Annual update of RAC accredited stakeholders' list</b></p> <p>The Secretariat presented the annual update of RAC accredited stakeholders' list. One new regular stakeholder observer PlasticsEurope was proposed to be nominated as a regular stakeholder. The Secretariat proposed to send a reminder to one regular stakeholder observer, MedTech Europe, concerning their absence at recent RAC plenary meetings. RAC agreed on the annual update of RAC accredited stakeholders' list.</p>	<p><b>SECR</b> to editorially finalise and publish the list on ECHA's webpage.</p>
<p><b>6. Request under Article 77(3)(c)</b></p>	
<p><b>6.1 Classification for environmental toxicity of lead</b></p>	
<p>The Chair welcomed the experts accompanying the CEFIC and the Eurometaux Regular Stakeholder Observers and the occasional stakeholder observers from EAA and U. 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 <i>Lymnea stagnalis</i> (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 <i>ad hoc</i> 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 originally until 30 July 2021 and later until 15 October 2021.</p>	
<p>The SECR presented the outcome of the member's survey conducted prior to RAC-58 on the opinion justification, noting that this followed directly on from the discussions at RAC-57. The Committee then discussed the outcome of the questionnaire as well as the options for conclusions on the forms of lead with their associated classification outcomes.</p> <p>RAC recalled its earlier analysis of the Technical Guidance on the classification of metals, in particular</p>	<p><b>Rapporteur</b>, with the support from SECR and the <i>ad-hoc</i> WG, to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.</p> <p><b>SECR</b> to make an editorial check of the opinion documents in consultation with the Rapporteur.</p>

the decision tree it had produced for this purpose and noted that this formed the main basis for its recommendations on the environmental classification of lead.

RAC noted the example of lead particles produced through normal use that had been provided by IND, i.e. from the cutting of lead sheets, which IND considered to be articles and as such outside the scope of CLP. However, RAC was of the view that as the lead sheets consist of pure, massive lead, they demonstrate in principle the production of particles from massive lead in general and not just from articles.

**RAC concluded that particles < 1mm are relevant and that lead powder is suitable for the classification of the massive form of lead.**

**RAC concluded that lead warrants classification as Aquatic Acute 1; H400, M=10 and Aquatic Chronic 1; H410, M=1000.**

In order to provide the European Commission with appropriate information on the classification options considered by RAC, the Committee agreed to include a full justification for the views of some Members who considered that two entries on Annex VI for the environmental classification of lead would be more appropriate.

RAC noted a discrepancy in the guidance *visa vi* the example given there, in relation to the appropriate loading rate for assessing dissolution in the context of chronic aquatic toxicity. It was agreed to follow the guidance but to point out the alternative value, should the guidance example prove to be correct.

RAC adopted its opinion on the environmental classification of lead **by consensus**.

**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The Eurometaux Regular Stakeholder Observer and the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers commented on different aspects of the presentation.

## **7. Health based exposure limits at the workplace**

No items tabled

## **8. Harmonised classification and labelling (CLH)**

## 8.1 Report from the July 2021 RAC CLH WG

The Secretariat presented the Report of the 2<sup>nd</sup> Meeting of the Committee for Risk Assessment Working Group on CLH held on 5-6 July 2021.

The 3<sup>rd</sup> Meeting of the RAC Working Group on CLH will be held on 25-28 October 2021.

### "Blood system" vs "Blood" for STOT classifications

The Secretariat introduced and RAC took note of the presentation on specifying "Blood system" vs "Blood" as the target organ for relevant STOT classifications.

RAC agreed to continue using "**blood system**" as the default and to retain the option of using "haematopoietic system" where specifically justified.

**SECR** to raise with COM whether action is needed on relevant past cases where designations other than "blood system" have been used.

## 8.2 CLH dossiers

### 8.2.1 Hazard classes for agreement without plenary debate

- Clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (EC: 433-460-1; CAS: 210880-92-5): acute oral toxicity, STOT SE, hazardous to the aquatic environment
- Hydrogen sulphide, hydrogen sulfide (EC: 231-977-3; CAS: 7783-06-4): physical hazards, acute inhalation toxicity
- Resorcinol; 1,3-benzenediol (EC: 203-585-2; CAS: 108-46-3): acute toxicity via all routes, skin sensitisation, STOT SE, hazardous to the aquatic environment
- 1-phenylethan-1-one (1-phenylethylidene)hydrazone (EC: 211-979-0; CAS: 729-43-1): skin sensitisation
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC: 278-355-8; CAS: 75980-60-8): skin sensitisation, reproductive toxicity
- Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5): physical hazards, acute inhalation toxicity
- Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC: 206-354-4; CAS: 330-54-1): acute toxicity via all routes, germ cell mutagenicity
- 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride; Basic Red 1 (EC: 213-584-9; CAS: 989-38-8): acute oral toxicity, serious eye damage/eye irritation
- Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide (EC: -; CAS: 137641-05-5): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, carcinogenicity, reproductive toxicity, STOT SE
- tetrabromobisphenol-A (TBBPA); 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; (EC: 201-236-9; CAS: 79-94-7): STOT RE, germ cell mutagenicity

- Dibutyltin maleate (EC: 201-077-5; CAS: 78-04-6): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity
- Dibutyltin oxide (EC: 212-449-1; CAS: 818-08-6): acute dermal toxicity, serious eye damage/eye irritation
- Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6): serious eye damage/eye irritation

### 8.2.2 Substances with hazard classes for agreement in plenary session

- 8.2.2.1 Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide (EC: 261-043-0; CAS: 57966-95-7)
- 8.2.2.2 Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5)
- 8.2.2.3 Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC: 206-354-4; CAS: 330-54-1)
- 8.2.2.4 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1 (EC: 213-584-9; CAS: 989-38-8)
- 8.2.2.5 Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide (EC: -; CAS: 137641-05-5)
- 8.2.2.6 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA) (EC: 201-236-9; CAS: 79-94-7)
- 8.2.2.7 Dibutyltin maleate (EC: 201-077-5; CAS: 78-04-6)
- 8.2.2.8 Dibutyltin oxide (EC: 212-449-1; CAS: 818-08-6)
- 8.2.2.9 Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6)
- 8.2.2.10 Dimethylpropylphosphonate (EC: 242-555-3; CAS: 18755-43-6)
- 8.2.2.11 Clothianidin(ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (EC: 433-460-1; CAS: 210880-92-5)
- 8.2.2.12 [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-)
- 8.2.2.13 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)
- 8.2.2.14 Nonylphenol, branched and linear, ethoxylated (with 352 g/mol  $\leq$  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)
- 8.2.2.15 Nonylphenol, branched and linear, ethoxylated (with 704 g/mol  $\leq$  average molecular weight  $\leq$  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 Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide** (EC: 261-043-0; CAS: 57966-95-7)

The Chair welcomed the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **cymoxanil** is used as an agricultural, viticultural and horticultural fungicide. The substance has current Annex VI entry as Repr. 2; H361fd, Acute Tox. 4; H302, STOT RE 2; H373 (blood, thymus), Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1).

The DS (LT and FI) proposes to modify STOT RE 2; H373 (blood, thymus, eye), Skin Sens. 1A; H317 and to add an oral ATE=356 mg/kg bw.

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, respiratory sensitisation, skin sensitisation, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazardous to the aquatic environment were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 11 December 2021.

**NOTE by the Secretariat:** RAC previously assessed this substance in 2012.

RAC adopted by simple majority\* the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Acute Tox. 4; H302 (ATE=360 mg/kg bw), Skin Sens. 1; H317, Repr. 2; H361fd, STOT RE 2; H373 (blood system, thymus, eyes), Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=1)]

RAC agreed on no classification for the other hazard classes considered.

\*pending a minority opinion by one RAC Member on developmental toxicity classification; should no written position be received, the outcome will revert to consensus..

**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 physical hazards, skin sensitisation, STOT RE and reproductive toxicity.

**8.2.2.2 Sulphur dioxide** (EC: 231-195-2; CAS: 7446-09-5)

The Chair welcomed the Dossier Submitter representative, the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers, the Occasional Stakeholder Observer from CIRFS with an accompanying expert, as well the Occasional Stakeholder Observer from the Only Representative Organisation.

He explained that **sulphur dioxide** is used as a fungicide in the context of BPR. Additionally, it has a broad spectrum of uses within industrial settings including winemaking, water treatment and metal purification. The substance has current Annex VI entry as Press. Gas; H280 (Notes U and 5), Skin Corr. 1B; H314, Acute Tox. 3\*; H331.

The DS (DE) proposes to add Skin Sens. 1; H317, Muta. 2; H341 and STOT SE 3; H335, to modify Acute Tox. 3; H331 (ATE=1041 ppmV (gases)) and to retain Press. Gas, Notes U and 5 and Skin Corr. 1B; H314.

Selected physical hazards (flammable gases (including chemically unstable gases), oxidising gases, gases under pressure), acute inhalation toxicity, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity and STOT SE were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 10 February 2022.

RAC agreed to classify the substance as Press. Gas, Notes U and 5, Acute Tox. 3; H331 (ATE=1000 ppmV (gases)) and on no classification for respiratory sensitisation.

RAC agreed to discuss skin sensitisation (including the read across argument for local effects), STOT SE (applicability of the data to the criteria for either Category 1 or 2), germ cell mutagenicity and carcinogenicity further at the next RAC CLH Working Group meeting (October 2021).

**SECR** to table the draft opinion for further discussion at the next CLH Working Group meeting (October 2021).

The expert accompanying the Cefic Regular Stakeholder Observer commented on read across, STOT SE and skin sensitisation. The CIFRS Occasional Stakeholder observer as well as his accompanying expert commented on STOT SE.

**8.2.2.3 Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea**  
(EC: 206-354-4; CAS: 330-54-1)

The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer. He explained that **diuron** is an existing pesticide active substance approved in accordance Directive 91/414/EEC. The substance has current Annex VI entry as Acute Tox. 4\*; H302, Carc. 2; H351, STOT RE 2\*; H373\*\*, Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 (M=10).

The DS (DE) proposes to modify Carc. 1B; H350, STOT RE 2; H373 (blood, bladder), to retain Aquatic Acute 1; H400 and Aquatic Chronic 1; H410 (but to modify M=100 for both) and to delete Acute Tox. 4\*; H302.

Acute toxicity via all routes, germ cell mutagenicity, carcinogenicity, 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 14 November 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Carc. 1B; H350, STOT RE 2; H373 (blood system), Aquatic Acute 1; H400 (M=100), Aquatic Chronic 1, H410 (M=100)]

RAC agreed on no classification for the other hazard classes considered.

**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs.

**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the CropLife Regular Stakeholder Observer commented on carcinogenicity.



**8.2.2.4 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylium chloride; Basic Red 1** (EC: 213-584-9; CAS: 989-38-8)

The Chair welcomed the Dossier Submitter representative and explained that **Basic Red 1** is used in the laboratory settings, as well as industrially and professionally. It might be found in products like inks and toners but also as binding agent in paints and coatings or adhesives. The substance has no current Annex VI entry.

The DS (DE) proposes to classify the substance as Acute Tox. 3; H301 (ATE=250 mg/kg w), Eye Dam. 1; H318, Skin Sens. 1B; H317, Aquatic Acute 1; H400 (M=10) and Aquatic Chronic 1; H410 (M=1).

Acute oral toxicity, serious eye damage/eye irritation, skin sensitisation 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 6 March 2022.

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=280 mg/kg bw), Eye Dam. 1; H318, Skin Sens. 1; H317, Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=1)]

**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs.

**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

**8.2.2.5 Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide** (EC: -; CAS: 137641-05-5)

The Deputy Chair welcomed the expert accompanying the CropLife Regular Stakeholder Observer and explained that **picolinafen** is an active substance in plant protection products with uses as a herbicide. The substance has no current Annex VI entry.

The DS (DE) proposes to classify the substance as STOT RE 2; H373 (blood, thyroid), Aquatic Acute 1; H400 (M=1000) and Aquatic Chronic 1; H410 (M=1000).

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 6 March 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[STOT RE 2; H373 (blood system, thyroid), Aquatic Acute 1; H400 (M=1000), Aquatic Chronic 1; H410 (M=1000)]

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.

	<p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>The expert accompanying the CropLife Regular Stakeholder Observer commented on STOT RE.</p>	
<p><b>8.2.2.6 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA)</b> (EC: 201-236-9; CAS: 79-94-7)</p>	
<p>The Chair welcomed the Dossier Submitter representatives and the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers. He explained that <b>tetrabromobisphenol A (TBBPA)</b> is a brominated flame retardant (BFR) commonly used in electronics to meet fire safety standards and has the largest worldwide production of any BFR. It is also used in printed circuit boards, paper, and textiles. The substance has current Annex VI entry as Aquatic Acute 1; H400 and Aquatic Chronic 1; H410. The DS (NO and DK) proposes <u>to add</u> Carc. 1B; H350 to the existing classification. Germ cell mutagenicity, carcinogenicity, reproductive toxicity and STOT RE were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 20 March 2022.</p>	
<p>RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.</p> <p>[Carc. 1B; H350]</p> <p>RAC agreed on no classification for the other hazard classes considered.</p>	<p><b>Rapporteurs</b> to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.</p> <p><b>SECR</b> to make an editorial check of the opinion documents in consultation with the Rapporteurs.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>The experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers commented on carcinogenicity. The expert accompanying the Cefic Regular Stakeholder Observer commented on reproductive toxicity.</p>	
<p><b>8.2.2.7 Dibutyltin maleate</b> (EC: 201-077-5; CAS: 78-04-6)</p>	
<p>The Deputy Chair welcomed the Dossier Submitter representative and the Occasional Stakeholder Observer from ORO. She explained that <b>dibutyltin maleate</b> is used in the manufacture and professional use of plastic products. The substance has no current Annex VI entry. The DS (AT) proposes to classify the substance as Muta. 2; H341, Repr. 1B; H360FD, Acute Tox. 2; H330 (ATE=0.317 mg/L (dusts or mists)), Acute Tox. 4; H302 (ATE=510 mg/kg bw), STOT RE 1; H372 (immune system), Skin Corr. 1; H314 and Eye Dam. 1; H318. Acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity, reproductive toxicity, STOT SE and STOT RE were the hazard classes open for comments during the Consultation. Legal deadline for the adoption of an opinion is 4 March 2022.</p>	

<p>RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.</p> <p>[Acute Tox. 2; H330 (ATE=0.317 mg/L (dusts or mists)), Acute Tox. 4; H302 (ATE=510 mg/kg bw), Skin Corr. 1; H314, Eye Dam. 1; H318, Muta. 2; H341, Repr. 1B; H360FD, STOT RE 1; H372 (immune system)]</p> <p>RAC agreed on no classification for the other hazard classes considered.</p>	<p><b>Rapporteur</b> to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.</p> <p><b>SECR</b> to make an editorial check of the opinion documents in consultation with the Rapporteur.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>The Occasional Stakeholder Observer from ORO commented on read across and on mutagenicity.</p>	
<p><b>8.2.2.8 Dibutyltin oxide</b> (EC: 212-449-1; CAS: 818-08-6)</p>	
<p>The Deputy Chair welcomed the Dossier Submitter representative and the Occasional Stakeholder Observer from ORO. She explained that <b>dibutyltin oxide</b> has many uses, e.g. in adhesives and sealants, coatings and paints, thinners and paint removes, in laboratory chemicals, leather treatment products, paper and board treatment products, polymer preparations and compounds, textile dyes, and impregnating products, etc.</p> <p>The substance has no current Annex VI entry.</p> <p>The DS (AT) proposes to classify the substance as Muta. 2; H341, Repr. 1B; H360FD, Acute Tox. 3; H301 (ATE=172 mg/kg bw), STOT RE 1; H372 (immune system), Skin Corr. 1; H314 and Eye Dam. 1; H318.</p> <p>Acute oral and dermal toxicity, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity, reproductive toxicity, STOT SE and STOT RE were the hazard classes open for comments during the Consultation.</p> <p>Legal deadline for the adoption of an opinion is 4 March 2022.</p>	
<p>RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.</p> <p>[Acute Tox. 3; H301 (ATE=170 mg/kg bw), Skin Irrit. 2; H315, Eye Dam. 1; H318, Muta. 2; H341, Repr. 1B; H360FD, STOT RE 1; H372 (immune system)]</p> <p>RAC agreed on no classification for the other hazard classes considered.</p>	<p><b>Rapporteur</b> to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.</p> <p><b>SECR</b> to make an editorial check of the opinion documents in consultation with the Rapporteur.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>The Occasional Stakeholder Observer from ORO commented on read across and on mutagenicity.</p>	

### 8.2.2.9 Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6)

The Chair welcomed the expert accompanying the Cefic Regular Stakeholder Observer and explained that **benzyl alcohol** is a colourless liquid with a faint, nondescript odour, which is used as a solvent, preservative, and fragrance ingredient. The substance has current Annex VI entry as Acute Tox. 4\*; H302 and Acute Tox. 4\*; H332.

The DS (DE) proposes to modify Acute Tox. 4; H302 (ATE=1570 mg/kg bw), to add Eye Irrit. 2; H319 and Skin Sens. 1B; H317 and to remove Acute Tox. 4\*; H332.

Acute toxicity via all routes, serious eye damage/eye irritation and skin sensitisation were the hazard classes open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 31 March 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Eye Irrit. 2; H319, Skin Sens. 1B; H317, Acute Tox. 4; H302 (ATE=1200 mg/kg bw)]

RAC agreed on no classification for the other hazard classes considered.

**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.

The expert accompanying the Cefic Regular Stakeholder Observer commented on skin sensitisation.

### 8.2.2.10 Dimethylpropylphosphonate (EC: 242-555-3; CAS: 18755-43-6)

The Chair welcomed the Dossier Submitter representatives and informed that **dimethyl propylphosphonate** is used in rigid foam, foam granules, rebounded PUR and CASE (coatings, adhesives, sealants and elastomers) applications by industrial and professional workers. It is also incorporated into articles which may be used by consumers. The substance has no current Annex VI entry.

The DS (IE) proposes to classify the substance as Muta. 1B; H340 and Repr. 1B; H360FD.

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 5 February 2022.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Muta. 1B; H340, Repr. 1B; H360Df]

**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.

**8.2.2.11 Clothianidin(ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine** (EC: 433-460-1; CAS: 210880-92-5)

The Chair welcomed the Dossier Submitter representative and the expert accompanying the CropLife Regular Stakeholder Observer and informed that **clothianidin (ISO)** is an active substance in the meaning of Directive 98/8/EC (repealed by Regulation (EU) No. 528/2012) and in the meaning of Regulation (EC) No. 1107/2009 (replaces Directive 91/414/EEC). 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 (DE) proposes to modify the classification to Acute Tox. 4; H302 (ATE=389 mg/kg bw), Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=100) and to add Repr. 2; H361fd and STOT SE 1; H370 (nervous system).

Acute oral toxicity, reproductive toxicity, STOT SE 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 21 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=390 mg/kg bw), Repr. 2; H361f, STOT SE 1; H370 (nervous system), Aquatic Acute 1; H400 (M=10), Aquatic Chronic 1; H410 (M=100)]

RAC agreed on no classification for the other hazard classes considered.

**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.

**SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs.

**SECR** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.

The expert accompanying the CropLife Regular Stakeholder Observer commented on reproductive toxicity.

**8.2.2.12 [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 Chair welcomed the Dossier Submitter representatives and the experts accompanying the Cefic and the Eurometaux Regular Stakeholder Observers. He 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.

<p>RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.</p> <p>[Repr. 1A; H360FD, Lact.; H362]</p> <p>RAC agreed on no classification for the other hazard classes considered.</p>	<p><b>Rapporteurs</b> to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.</p> <p><b>SECR</b> to make an editorial check of the opinion documents in consultation with the Rapporteurs.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>The expert accompanying the Cefic Regular Stakeholder Observer and the expert accompanying the Eurometaux Regular Stakeholder Observer commented on read-across and on reproductive toxicity. The expert accompanying the Cefic Regular Stakeholder Observer commented also on lactation.</p>	
<p><b>8.2.2.13 Nonylphenol, branched and linear, ethoxylated (with average molecular weight &lt; 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]</b> (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)</p>	
<p>The Chair welcomed the Dossier Submitter representatives and the Occasional Stakeholder Observer from EDANA and explained that <b>nonylphenol ethoxylates (NPEs)</b> fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The substance has no current Annex VI entry.</p> <p>The DS (NL) proposes to classify nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight &lt; 704 g/mol)) as Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=10).</p> <p>Hazardous to the aquatic environment was the only hazard class open for comments during the Consultation.</p> <p>Legal deadline for the adoption of an opinion is 26 December 2021.</p>	
<p>RAC adopted <u>by consensus</u> the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.</p> <p>[Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=10)]</p>	<p><b>Rapporteur</b> to revise the opinion in accordance with the discussion in RAC and to provide it to SECR.</p> <p><b>SECR</b> to make an editorial check of the opinion documents in consultation with the Rapporteur.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>

**8.2.2.14 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)

The Chair welcomed the Dossier Submitter representatives and the Occasional Stakeholder Observer from EDANA and explained that **nonylphenol ethoxylates (NPEs)** fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The substance has no current Annex VI entry.

The DS (NL) proposes to classify nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) as Aquatic Chronic 2; H411.

Hazardous to the aquatic environment was the only hazard class open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 26 December 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=10)]

**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.

**8.2.2.15 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)

The Chair welcomed the Dossier Submitter representatives and the Occasional Stakeholder Observer from EDANA and explained that **nonylphenol ethoxylates (NPEs)** fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The substance has no current Annex VI entry.

The DS (NL) proposes no environmental classification for nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol).

Hazardous to the aquatic environment was the only hazard class open for comments during the Consultation.

Legal deadline for the adoption of an opinion is 26 December 2021.

RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1 below.

[Aquatic Acute 1; H400 (M=1), Aquatic Chronic 1; H410 (M=10)]

**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.

	<b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
<b>9. Restrictions</b>	
<b>9.1 General Restriction issues</b>	
<b>9.1.2. Report from the August 2021 RAC REST WG</b>	
<p>RAC took note of the report Report of the 2nd Meeting of the Committee for Risk Assessment Working Group on Restrictions held on 19-20 August 2021.</p> <p>The 3rd Meeting of the RAC Working Group on Restrictions will be held on 3-4 November 2021.</p>	
<b>9.1 Restriction Annex XV dossiers</b>	
<b>9.1.1 Conformity check</b>	
<b>9.1.1.1 2,4-dinitrotoluene</b>	
<p>The Chair welcomed the Dossier Submitter's representatives from ECHA. He informed the participants that the restriction dossier had been submitted in July 2021 and concerns the placing on the market or use of 2,4 dinitrotoluene in articles for supply to the general public or to professional workers in concentrations greater than 0.1 % weight by weight. In accordance with Article 69(2) of REACH, ECHA considers that there are uses of the substance which may lead to a non-adequately controlled risk from 2,4-DNT presence in articles.</p>	
<p>RAC agreed that the dossier conforms to the Annex XV requirements.</p> <p>RAC took note of the recommendations to the Dossier Submitter.</p>	<b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload to S-CIRCABC.
<b>9.1.2 Opinion development</b>	
<b>9.1.2.1 Substances in single-use diapers – third draft opinion</b>	
<p>The Chair welcomed the Dossier Submitter's representatives from France, the occasional stakeholder observers from EDANA and their accompanying expert from Procter&amp;Gamble, CIRFS and their accompanying expert from Kelheim Fibres GmbH 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.</p>	



The rapporteurs presented the third draft opinion and summarised the discussion at the RAC-58 Restriction Working Group on 19 August 2021.

RAC adopted its opinion on this dossier (with modifications agreed at RAC-58) by consensus.

RAC agreed to remove apparent references to an ongoing process from the opinion.

Regarding the appropriateness of existing and recommended RMMs and OCs to control the risk, RAC agreed that substances in scope do not appear to be added intentionally but that a risk has not been sufficiently demonstrated for formaldehyde, PCDD/Fs/DL-PCBs by the Dossier Submitter and cannot be characterised for PAHs and NDL-PCBs.

RAC agreed to add "and preferably not be present at all" after "RAC is of the opinion that each of these substances should be kept to a level as low as possible/feasible".

Regarding the sufficiency of existing risk management instruments, RAC agreed that there is currently no binding EU legislation that deals with the substances in scope in diapers but that allergic effects would likely be addressed by the proposed restriction on skin sensitisers in textiles, leather, fur and hide articles. In RAC's view, no further action on formaldehyde is likely to be needed in this context.

Regarding the justification that action is required on a Union wide basis, RAC agreed that in case of any action being required, it would have to be on a Union wide basis. RAC further agreed to remove references to hazards, uncertainties and possible remaining health effects from this section of the opinion. Regarding the effectiveness in reducing risk, practicality and monitorability, RAC agreed that effectiveness cannot be assessed due to the uncertainties mentioned. In terms of practicality and monitorability, RAC requested that the Rapporteurs expand on the urine simulant extraction methodology based on the forum advice.

Regarding uncertainties, RAC proposed to remove from the table entry related to LoDs for PAHs any clarifying statement regarding the analytical method. RAC further asked the rapporteurs to consider whether mixture/cumulative effects need to be highlighted further.

**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.

The occasional stakeholder observer from EEB commented on the justification for action on a Union wide basis, on practicality and the Forum advice as well as on any remaining risk of the

substances in scope in diapers including from mixtures. The occasional stakeholder observer from EDANA commented on the consistency of units of migration limits in the restriction proposal and RAC opinion.

### **9.1.2.2 Lead and its compounds in outdoor shooting and fishing – second 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 European Anglers Alliance (EAA), European Plastics Converters (EuPC) and European Federation for Hunting and Conservation (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 second draft opinion.

The following points were agreed based on the RAC working group conclusions:

- RAC agreed on the human health risk from home-casting. Exposure from home-casting is plausible, but the quantitative contribution is probably highly case-specific and no quantitative assessment is currently possible.
- RAC concluded on the environmental risk to groundwater. The risk of groundwater contamination may vary from very low to high depending on the soil characteristics.
- RAC concluded that the exposure to lead ammunition and fishing tackle can induce mortality and also sublethal effects to different species of birds. Sublethal effects may affect behaviour and reproductive potential and affect the survival of endangered species.
- RAC concluded that the frequent consumption of game meat by children (less than seven years old) may result in a high risk for neurodevelopmental effects. In adults, although some slight effects on chronic kidney disease and some cardiovascular effects are possible even at low exposure levels, the level of adversity is not clear. Therefore, low risk is concluded for adults. However, RAC considered that the risks of game meat consumption for females at fertile age, and especially pregnant females, are relevant taking into

**Rapporteurs** to prepare the third draft opinion, taking into account RAC-58 discussions and the outcome of the third-party consultation (to the extent possible), by mid October 2021.

**Secretariat** to table the third draft opinion for discussion at the third RAC working group on restrictions in early November 2021.

<p>account that there is no threshold for the developmental neurotoxicity of lead.</p> <p>Further discussions were held at RAC-58 on the following:</p> <ul style="list-style-type: none"> <li>• RAC supported the conceptual model proposed by the rapporteurs for the qualitative risk assessment. The rapporteurs will include additional explanations on the model and information regarding the frequency of each event as far as known for discussion in the third RAC working group on restrictions. Considerations should also be given to sensitive sub-populations (specifically pregnant females).</li> <li>• RAC discussed the uncertainties. The uncertainties related to the number and location of sites with potential risk for groundwater contamination will be added to the opinion. The size of affected population is also not known and should be included as uncertainties in the opinion.</li> </ul>	
<p>The expert accompanying the regular stakeholder observer from EUROMETAUX commented on the uncertainties regarding the number and location of sites where lead contamination of groundwater may occur, the requirement of 90% lead recovery effectiveness in shooting ranges and informed about additional information to be submitted via the third-party consultation on game meat consumption and on the number of birds at risk. The expert accompanying the regular stakeholder observer from EEB commented on the lead exposure resulting from game meat consumption and on adding frequency aspects in the conceptual risk approach for qualitative risk assessment. The regular stakeholder observer from EUROMETAUX supported the frequency aspect in the conceptual risk approach. The occasional stakeholder observer from FACE commented on the lead background levels reported for children and adults in various Member States. The invited experts from UNEP/AEWA commented on lead exposure of birds from fishing tackle (to include divers) and on several adjustments in the characterisation of risk levels.</p>	
<p><b>10. Authorisation</b></p>	
<p><b>10.1 General authorisation issues</b></p>	
<p><b>10.1.1. Update on incoming/future applications</b></p>	
<p>The ECHA Secretariat presented the information on incoming/future applications, expected workload in 2021/2022 and timelines. The ECHA Secretariat presented general consideration for recommending applicants to perform biomonitoring. RAC discussed and took note of the information.</p>	

<b>10.1.2. Renewal of the Mandate for RAC Working Group on AfA</b>	
<p>The ECHA Secretariat presented the Mandate for RAC Working Group on AfA and requested RAC to extend the mandate until September 2022.</p> <p>Members expressed their concerns on the current additional workload due to WGs meetings. The possibility to involve advisors and other support to the members is limited especially in the small MS. The chair concluded that after the CLH and RESTR WG are on full speed there should be a discussion (in RAC-60) on whether the situation has improved.</p> <p>RAC agreed the Mandate for RAC Working Group on AfA by consensus.</p>	<p><b>SECR</b> to publish the Mandate on the ECHA website.</p> <p><b>SECR</b> to prepare discussion on the role and timing of the WGs at RAC-60.</p>
<b>10.1.3. Assessing representativeness of downstream users information (this item will be discussed in a joint session with SEAC)</b>	
<b>10.2 Authorisation applications</b>	
<b>10.2.1. Discussion on key issues</b>	
<b>10.2.1.1 6 applications for authorisation (chromium trioxide, sodium dichromate, 4-tert-OPnEO, 4-NPnEO) from May 2021 submission window</b>	
Presentation was made available at S-CIRCABC.	
<b>10.3 Agreement on draft opinions</b>	
<b>10.3.1. Agreement on draft opinions on AFA by A-listing following the usual scrutiny but without plenary debate</b>	
(no A-list opinions in this meeting)	
<b>10.3.2. Draft opinions for agreement with plenary debate</b>	
<b>10.3.2.1. 227_RR1_TCE_ROQUETTE (1 use)</b>	
<p><b>Use 1:</b> <i>Use as a processing aid in the biotransformation of starch to obtain betacyclodextrin.</i></p> <p>RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are adhered to.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion including information on actual releases to the environment and refined values for the workers exposure in the future situation.</p>

The monitoring arrangements for the authorisation are expected to provide information on the trends in exposure over the authorisation period. Given the foreseen increase in the use of TCE (from 3 t/y to 8 t/y) as well as the frequency of the production campaigns (from 6 months per year to 12 months per year), the monitoring arrangements for the authorisation shall remain unchanged in order to further reduce uncertainty and increase the representativeness of the exposure scenarios. This information should also be included in the review report.

The exposure to workers was estimated to be 1.3 mg/m<sup>3</sup> for production workers and 0.002 mg/m<sup>3</sup> for maintenance workers for inhalation, and 2.9 x 10<sup>-3</sup> and 2.3 x 10<sup>-5</sup> mg/kg bw dermal, respectively, per 8h adjusted TWA without the effect of the conditions. For reference, the current Binding Occupational Exposure Limit (BOEL) for this substance is: 54.7 mg/m<sup>3</sup>. The exposure to the general population was estimated to be 3.67 x 10<sup>-3</sup> mg/m<sup>3</sup> for inhalation and 3.07 x 10<sup>-4</sup> mg/kg/day for dermal exposure per 8h adjusted TWA without the effect of the conditions. Bearing in mind that the route of exposure for the general population may be different from the one relevant for workers

The excess lifetime kidney cancer risk for production workers is estimated to be 1.6 x 10<sup>-5</sup> for (inhalation and dermal), and 3.9 x 10<sup>-8</sup> for maintenance workers per mg/m<sup>3</sup> for 8h TWA exposure for 40 years, per year, for the review period without the effect of the conditions, and 8.2x10<sup>-7</sup> per mg/m<sup>3</sup> for 24h exposure for 70 years, per year, for the review period 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
  - (a) The authorisation holder shall continue to conduct regular occupational exposure measurements relating to the use of TCE described in this review report. These measurements shall:
    - (i) take place at least annually;
    - (ii) be based on relevant standard methodologies or protocols;
    - (iii) comprise
      - personal inhalation exposure sampling
      - and static inhalation exposure sampling

**SECR** to send the draft opinion to the applicant for commenting.

and biomonitoring (consisting of measurement of the trichloroethylene metabolite trichloroacetic acid in urine).

All these exposure assessment methods should be representative of the range of tasks undertaken and of the total number of workers that are potentially exposed (production and maintenance workers).

(b) The authorisation holder shall continue to conduct emission to air and wastewater monitoring before input to industrial on-site STP and in releases to natural water after treatment in the STP. The monitoring programmes for wastewater and 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

(c) the authorisation holder shall use the information gathered via the measurements referred to in points (a) and (b) including the contextual information to regularly review the effectiveness of the risk management measures and operational conditions and to introduce measures to reduce worker's exposure to trichloroethylene as well as emissions to the environment to as low a level as technically and practically feasible.

(d) the results of the measurements referred to in points (a) and (b), as well as the outcome and conclusions of the review and any actions taken in accordance with point (c), shall be documented and, upon request, be submitted to the competent authority of the Member State where the authorised use takes place;

### 3. recommendations for the review report

The review report shall document the results of the monitoring programs and the optimisation of RMMs and OCs carried out by the applicant in order to minimise exposure and fugitive emissions.

The authorisation holder should carry exposure assessment for the review report based on realistic exposure data and review the applied methodology for the exposure assessment.

RAC agreed on the draft opinion by consensus.

### 10.3.2.2. 228\_CT\_Eaton (1 use)

**Use 1:** *The use of Chromium Trioxide (EC 215-607-8) by Eaton Vehicle Group (Eaton) across two legal entities in the functional chrome plating of engine valves and valve actuation ("lash adjusters").*

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 additional conditions for the authorisation are expected to strengthen this conclusion.

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 exposure (8-h adjusted TWA) to workers was estimated to be (inhalation):

- 0.1 µg Cr(VI)/m<sup>3</sup> at the Bosconero site (Italy),
- 0.5 µg Cr(VI)/m<sup>3</sup> at the Bielsko-Biała site (Poland) and
- $3.3 \times 10^{-6}$  µg Cr(VI)/m<sup>3</sup> at the Turin site (Italy)

For reference, the binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is 5 µg Cr(VI)/m<sup>3</sup> (with a transitional value of 10 µg Cr(VI)/m<sup>3</sup> until 17 January 2025).

The exposure (24h adjusted TWA,) to the general population was estimated to be (inhalation, local)

- $3.6 \times 10^{-5}$  µg Cr(VI)/m<sup>3</sup> at the Bosconero site (Italy),
- $1.3 \times 10^{-4}$  µg Cr(VI)/m<sup>3</sup> at the Bielsko-Biała site (Poland) and
- $9.1 \times 10^{-7}$  µg Cr(VI)/m<sup>3</sup> at the Turin site (Italy)

The excess lifetime lung cancer risk (inhalation; 8-h TWA exposure for 40 years, highest combined exposure, without the effect of the conditions) for workers is estimated to be

- $4.0 \times 10^{-4}$  for the Bosconero site (Italy),
- $2.0 \times 10^{-4}$  for the Bielsko-Biała site (Poland) and
- $1.3 \times 10^{-8}$  for the Turin site (Italy)

The excess lifetime lung cancer risk (inhalation, local 24h exposure for 70 years, without the effect of the conditions) for the general population is estimated to be

- $1.1 \times 10^{-6}$  for the Bosconero site (Italy),

**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

**SECR** to send the draft opinion to the applicant for commenting.

- $3.7 \times 10^{-6}$  at the Bielsko-Biała site (Poland) and
- $2.6 \times 10^{-8}$  for the Turin site (Italy)

RAC agreed:

1. additional conditions for the authorisation

The applicants shall

- ensure that workers perform the sealing test of their respiratory protective equipment (RPE) before taking on relevant tasks and workers will be trained to do this test adequately.
- investigate the feasibility
  - not to use solid  $\text{CrO}_3$  for refilling the solution tank of the hard chrome plating line at the Bosconero site (Italy),
  - to replace the plastic curtains that gives access to the hard chrome plating lines by doors with electric lock like the rapid chrome plating lines, and
  - to install devices that measure continuously the functioning of the LEV systems.

2. monitoring arrangements for the authorisation

1. The applicants shall continue their monitoring programmes that shall include:

(a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall:

- 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 change in the exposure;
- 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 operational conditions and risk management measures typical for each of these tasks;
  - the number of workers potentially exposed;
- include the cleaning and maintenance activities covering all related tasks and



- comprising the onsite WWTP relevant activities;
- (vi) include contextual information about the tasks performed and its frequency during measurements;
- (c) Environmental releases:
- (i) the applicants shall conduct an annual monitoring programme for Cr(VI) emission of wastewater and air and increase its frequency in the periods following any possible changes in the process;
  - (ii) 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' sites.
2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the applicants to confirm the effectiveness of the operational conditions and risk management measures in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicants 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 paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the applicants, upon request, to the competent national authority of the Member State where the authorised use will take place.
3. recommendations for the review report
- The results of the feasibility studies as mentioned in section 7 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, should be documented and included in any subsequent authorisation review report. In addition, any subsequent authorisation review report should contain clear information that supports the air and wastewater abatement efficiencies.

The applicants should conduct annual biomonitoring programme for workers at both chrome plating sites and should review regularly the biomonitoring data and take action if the levels show chromium urine concentrations higher than levels expected from the background concentrations. The biomonitoring should be representative for Cr(VI) exposure.

RAC agreed on the draft opinion by consensus.

### 10.3.2.3. 229\_RR1\_CT\_Volta (1 use)

**Use 1:** *Industrial formulation of a chromium trioxide solution below 0.1% w/w concentration for the passivation of copper foil used in the manufacture of Lithium Ion Batteries (LiB) for motorised vehicles.*

RAC concluded that the operational conditions and risk management measures described in the review report are appropriate and effective in limiting the risk, provided that they are implemented and adhered to.

The highest inhalation exposure (8h adjusted TWA) to workers was estimated to be  $1.0 \times 10^{-3} \mu\text{g Cr(VI)/m}^3$ . For reference, the Binding Occupational Exposure Limit (BOEL) as of 17 January 2020 for this substance is  $5 \mu\text{g Cr(VI)/m}^3$  (with a transitional value of  $10 \mu\text{g Cr(VI)/m}^3$  until 17 January 2025).

The exposure to the general population was estimated to be (inhalation, local)  $2.3 \times 10^{-4} \mu\text{g Cr(VI)/m}^3$  per 24h and (oral, local)  $6.4 \times 10^{-4} \mu\text{g Cr(VI)/kg bw/day}$ .

The excess lifetime cancer risk for workers is estimated to be  $4.0 \times 10^{-6}$  (inhalation, 8h TWA exposure for 40 years, highest value) and  $6.6 \times 10^{-6}$  (inhalation, local, for 24h exposure for 70 years) for the general population.

RAC agreed:

1. no additional conditions for the authorisation

**Rapporteurs** together with **SECR** to do the final editing of the draft opinion.

**SECR** to send the draft opinion to the applicant for commenting.

2. monitoring arrangements for the authorisation

The authorisation holder shall implement the following monitoring programmes:

a) Occupational inhalation exposure monitoring programmes for Cr(VI), which shall:

- (i) be conducted at least annually for the workers exposed to Cr(VI). Should circumstances change, the frequency of the measurements should be increased to capture any potential change 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(VI) 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 exposure measurements for the workers involved in the on-site WWTP activities until it can be demonstrated that workers exposure to Cr(VI) has been appropriately minimised.

b) Environmental releases:

- (i) the authorisation holder shall continue conducting measurements of Cr(VI) in their wastewater and air emission at least annually or more frequently in the periods following any possible changes in the process
- (ii) 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 authorisation holder's site.

2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used by the authorisation holder 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 authorisation holder shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.

3. The authorisation holder shall ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
  4. The information from the studies and monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained, and be made available by the authorisation holder, upon request, to the competent national authority of the Member State where the authorised use will take place.
  5. The authorisation holder shall conduct the monitoring programmes mentioned in 1a i and 1b i at least until the plant functions at full capacity to ensure the impacts of the expansion are closely monitored. Afterwards, the authorisation holder may reduce the frequency of measurements, once they can clearly demonstrate to the national Competent Authority of the Member State where the use takes place that exposure to humans and releases to the environment have been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions function appropriately.
3. recommendations for the review report
- The results of the measurements referred to in section 8.1 paragraph 1, as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 paragraph 2, should be documented and included in any subsequent authorisation review report. In addition, any subsequent authorisation review report should contain clear information that supports the air and wastewater abatement efficiencies.

RAC agreed on the draft opinion by consensus.	
<b>10.4 Adoption of final opinions</b>	
No opinions to adopt.	
<b>11. AOB</b>	
<p><b>Information on Request to ECHA’s Executive Director to request RAC to deliver, in accordance with Art. 77(3)(c) of REACH, an opinion on reference DNEL/PNEC values or dose-response curves considering updated properties of DEHP, BBP, DIBP and DBP.</b></p> <p>The Chair informed the Committee on the request and its timeframes.</p>	
<b>12. Minutes of RAC-58</b>	
<b>12.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-58</b>	
RAC adopted the final minutes by consensus at the plenary meeting.	<b>SECR</b> to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-58 to CIRCA BC.

### **Table 1: CLH opinions which were adopted at RAC-58**

1. [Cymoxanil \(ISO\); 2-cyano-N-\[\(ethylamino\)carbonyl\]-2-\(methoxyimino\)acetamide Classification and labelling in accordance with the CLP Regulation \(Regulation \(EC\) 1272/2008\)](#)
2. [Diuron \(ISO\); 3-\(3,4-dichlorophenyl\)-1,1-dimethylurea](#)
3. [9-\[2-\(ethoxycarbonyl\)phenyl\]-3,6-bis\(ethylamino\)-2,7-dimethylxanthylum chloride; Basic Red 1](#)
4. [Picolinafen \(ISO\); N-\(4-fluorophenyl\)-6-\[3-\(trifluoromethyl\)phenoxy\]pyridine-2-carboxamide; 4'-fluoro-6-\[\( \$\alpha,\alpha,\alpha\$ -trifluoro-m-tolyl\)oxy\]picolinanilide](#)
5. [2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A \(TBBPA\)](#)
6. [Dibutyltin maleate](#)
7. [Dibutyltin oxide](#)
8. [Benzyl alcohol](#)
9. [Dimethylpropylphosphonate](#)
10. [Clothianidin\(ISO\); \(E\)-1-\(2-chloro-1,3-thiazol-5-ylmethyl\)-3-methyl-2-nitroguanidine](#)
11. [\[1\] Lithium carbonate; \[2\] lithium chloride; \[3\] lithium hydroxide](#)
12. [Nonylphenol, branched and linear, ethoxylated \(with average molecular weight < 352 g/mol\) \[includes ortho-, meta-, para- isomers or any combination thereof\]](#)
13. [Nonylphenol, branched and linear, ethoxylated \(with 352 g/mol  \$\leq\$  average molecular weight < 704 g/mol\) \[includes ortho-, meta-, para- isomers or any combination thereof\]](#)
14. [Nonylphenol, branched and linear, ethoxylated \(with 704 g/mol  \$\leq\$  average molecular weight  \$\leq\$  1540 g/mol\) \[includes ortho-, meta-, para- isomers or any combination thereof\]](#)
15. [Hydrogen sulphide, hydrogen sulfide](#)
16. [Resorcinol; 1,3-benzenediol](#)
17. [1-phenylethan-1-one \(1-phenylethylidene\)hydrazone](#)
18. [Diphenyl\(2,4,6-trimethylbenzoyl\)phosphine oxide](#)

# 1. Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	616-035-00-5	cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [1]  (2E)-2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [2]	261-043-0; [1]	57966-95-7; [1]  166900-80-7; [2]	Repr. 2 Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361fd H302 H373 (blood, thymus) H317 H400 H410	GHS08 GHS07 GHS09 Wng	H361fd H302 H373 (blood, thymus) H317 H410		M = 1 M = 1	
Dossier submitters proposal	616-035-00-5	cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [1]  (2E)-2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [2]	261-043-0; [1]	57966-95-7; [1]  166900-80-7; [2]	<b>Retain</b> Repr. 2 Acute Tox. 4 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1  <b>Modify</b> Skin Sens. 1A	<b>Retain</b> H361fd H302 H317 H400 H410  <b>Modify</b> H373 (blood, thymus, eyes)	<b>Retain</b> GHS08 GHS07 GHS09 Wng	<b>Retain</b> H361fd H302 H317 H410  <b>Modify</b> H373 (blood, thymus, eyes)		<b>Retain</b> M = 1 M = 1  <b>Add</b> oral: ATE = 356 mg/kg bw	
RAC opinion	616-035-00-5	cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [1]  (2E)-2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [2]	261-043-0; [1]	57966-95-7; [1]  166900-80-7; [2]	<b>Retain</b> Repr. 2 Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	<b>Retain</b> H361fd H302 H317 H400 H410  <b>Modify</b> H373 (blood system, thymus, eyes)	<b>Retain</b> GHS08 GHS07 GHS09 Wng	<b>Retain</b> H361fd H302 H317 H410  <b>Modify</b> H373 (blood system, thymus, eyes)		<b>Retain</b> M = 1 M = 1  <b>Add</b> oral: ATE = 360 mg/kg bw	
Resulting Annex VI entry if agreed by COM	616-035-00-5	cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide; [1]  (2E)-2-cyano-N-[(ethylamino)carbonyl]-2-	261-043-0; [1]	57966-95-7; [1]  166900-80-7; [2]	Repr. 2 Acute Tox. 4 STOT RE 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H361fd H302 H373 (blood system, thymus, eyes) H317 H400 H410	GHS08 GHS07 GHS09 Wng	H361fd H302 H373 (blood system, thymus, eyes) H317 H410		oral: ATE = 360 mg/kg bw  M = 1 M = 1	

(methoxyimino)acetamide;  
[2]

## 2. Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea

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	006-015-00-9	diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea	206-354-4	330-54-1	Carc. 2 Acute Tox. 4* STOT RE 2* Aquatic Acute 1 Aquatic chronic 1	H351 H302 H373 ** H400 H410	GHS08 GHS07 GHS09 Wng	H351 H302 H373 ** H410		M = 10	
Dossier submitters proposal	006-015-00-9	diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea	242-555-3	18755-43-6	<b>Retain</b> Aquatic Acute 1 Aquatic Chronic 1  <b>Modify</b> Carc. 1B STOT RE 2  <b>Remove</b> Acute Tox. 4	<b>Retain</b> H400 H410  <b>Modify</b> H350 H373 (blood, bladder)  <b>Remove</b> H302	<b>Retain</b> GHS08 GHS09 Dgr  <b>Remove</b> GHS07	<b>Retain</b> H410  <b>Modify</b> H350 H373 (blood, bladder)  <b>Remove</b> H302		<b>Add</b> M = 100  <b>Modify</b> M = 100	
RAC opinion	006-015-00-9	diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea	242-555-3	18755-43-6	<b>Retain</b> Aquatic Acute 1 Aquatic Chronic 1  <b>Modify</b> Carc. 1B STOT RE 2  <b>Remove</b> Acute Tox. 4	<b>Retain</b> H400 H410  <b>Modify</b> H350 H373 (blood system)  <b>Remove</b> H302	<b>Retain</b> GHS08 GHS09 Dgr  <b>Remove</b> GHS07	<b>Retain</b> H410  <b>Modify</b> H350 H373 (blood system)  <b>Remove</b> H302		<b>Add</b> M = 100  <b>Modify</b> M = 100	
Resulting Annex VI entry if agreed by COM	006-015-00-9	diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea	242-555-3	18755-43-6	Carc. 1B STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H350 H373 (blood system) H400 H410	GHS08 GHS09 Dgr	H350 H373 (blood system) H410		M = 100 M = 100	



### 3. 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1

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

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	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	9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1	213-584-9	989-38-8	Acute Tox. 3 Eye Dam. 1 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H301 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H301 H318 H317 H410		oral: ATE = 250 mg/kg bw M = 10 M = 1	
RAC opinion	TBD	9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1	213-584-9	989-38-8	Acute Tox. 3 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H301 H318 H317 H410		oral: ATE = 280 mg/kg bw M = 10 M = 1	
Resulting Annex VI entry if agreed by RAC and COM	TBD	9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1	213-584-9	989-38-8	Acute Tox. 3 Eye Dam. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H301 H318 H317 H400 H410	GHS06 GHS05 GHS09 Dgr	H301 H318 H317 H410		oral: ATE = 280 mg/kg bw M = 10 M = 1	

## 4. Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[(a,a,a-trifluoro-m-tolyl)oxy]picolinanilide

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	picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[(a,a,a-trifluoro-m-tolyl)oxy]picolinanilide	none	137641-05-5	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H373 (blood, thyroid) H400 H410	GHS08 GHS09 Wng	H373 (blood, thyroid) H410		M = 1000 M = 1000	
RAC opinion	TBD	picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[(a,a,a-trifluoro-m-tolyl)oxy]picolinanilide	none	137641-05-5	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H373 (blood system, thyroid) H400 H410	GHS08 GHS09 Wng	H373 (blood system, thyroid) H410		M = 1000 M = 1000	
Resulting Annex VI entry if agreed by COM	TBD	picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[(a,a,a-trifluoro-m-tolyl)oxy]picolinanilide	none	137641-05-5	STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1	H373 (blood system, thyroid) H400 H410	GHS08 GHS09 Wng	H373 (blood system, thyroid) H410		M = 1000 M = 1000	

## 5. 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA)

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 ATEs	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	604-074-00-0	tetrabromobisphenol-A; 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9	79-94-7	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410			
Dossier submitters proposal	604-074-00-0	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A	201-236-9	79-94-7	<b>Add</b> Carc. 1B	<b>Add</b> H350	<b>Add</b> GHS08  <b>Modify</b> Dgr	<b>Add</b> H350			
RAC opinion	604-074-00-0	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A	201-236-9	79-94-7	<b>Add</b> Carc. 1B	<b>Add</b> H350	<b>Add</b> GHS08  <b>Modify</b> Dgr	<b>Add</b> H350			
Resulting entry in Annex VI if adopted by RAC and agreed by Commission	604-074-00-0	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A	201-236-9	79-94-7	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H400 H410	GHS08 GHS09 Dgr	H350 H410			

## 6. Dibutyltin maleate Error! Reference source not found.

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	dibutyltin maleate	201-077-5	78-04-6	Muta. 2 Repr. 1B Acute Tox. 2 Acute Tox. 4 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H341 H360FD H330 H302 H372 (immune system) H314 H318	GHS08 GHS06 GHS05 Dgr	H341 H360FD H330 H302 H372 (immune system) H314		inhalation: ATE = 0,317 mg/L (dusts or mists) oral: ATE = 510 mg/kg bw	
RAC opinion	TBD	dibutyltin maleate	201-077-5	78-04-6	Muta. 2 Repr. 1B Acute Tox. 2 Acute Tox. 4 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H341 H360FD H330 H302 H372 (immune system) H314 H318	GHS08 GHS06 GHS05 Dgr	H341 H360FD H330 H302 H372 (immune system) H314		inhalation: ATE = 0,317 mg/L (dusts or mists) oral: ATE = 510 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	dibutyltin maleate	201-077-5	78-04-6	Muta. 2 Repr. 1B Acute Tox. 2 Acute Tox. 4 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H341 H360FD H330 H302 H372 (immune system) H314 H318	GHS08 GHS06 GHS05 Dgr	H341 H360FD H330 H302 H372 (immune system) H314		inhalation: ATE = 0,317 mg/L (dusts or mists) oral: ATE = 510 mg/kg bw	

## 7. Dibutyltin oxide

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	dibutyltin oxide	212-449-1	818-08-6	Muta. 2 Repr. 1B Acute Tox. 3 STOT RE 1 Skin Corr. 1 Eye Dam. 1	H341 H360FD H301 H372 (immune system) H314 H318	GHS08 GHS06 GHS05 Dgr	H341 H360FD H301 H372 (immune system) H314		oral: ATE = 172 mg/kg bw	
RAC opinion	TBD	dibutyltin oxide	212-449-1	818-08-6	Muta. 2 Repr. 1B Acute Tox. 3 STOT RE 1 Skin Irrit. 2 Eye Dam. 1	H341 H360FD H301 H372 (immune system) H315 H318	GHS08 GHS06 GHS05 Dgr	H341 H360FD H301 H372 (immune system) H315 H318		oral: ATE = 170 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	dibutyltin oxide	212-449-1	818-08-6	Muta. 2 Repr. 1B Acute Tox. 3 STOT RE 1 Skin Irrit. 2 Eye Dam. 1	H341 H360FD H301 H372 (immune system) H315 H318	GHS08 GHS06 GHS05 Dgr	H341 H360FD H301 H372 (immune system) H315 H318		oral: ATE = 170 mg/kg bw	

## 8. Benzyl alcohol

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	603-057-00-5	benzyl alcohol	202-859-9	100-51-6	Acute Tox. 4* Acute Tox. 4*	H332 H302	GHS07 Wng	H332 H302			
Dossier submitters proposal	603-057-00-5	benzyl alcohol	202-859-9	100-51-6	<b>Add</b> Eye Irrit. 2 Skin Sens. 1B  <b>Modify</b> Acute Tox. 4  <b>Remove</b> Acute Tox. 4*	<b>Retain</b> H302  <b>Add</b> H319 H317  <b>Remove</b> H332	<b>Retain</b> GHS07 Wng	<b>Retain</b> H302  <b>Add</b> H319 H317  <b>Remove</b> H332		<b>Add</b> oral: ATE = 1570 mg/kg bw	
RAC opinion	603-057-00-5	benzyl alcohol	202-859-9	100-51-6	<b>Add</b> Eye Irrit. 2 Skin Sens. 1B  <b>Modify</b> Acute Tox. 4  <b>Remove</b> Acute Tox. 4*	<b>Retain</b> H302  <b>Add</b> H319 H317  <b>Remove</b> H332	<b>Retain</b> GHS07 Wng	<b>Retain</b> H302  <b>Add</b> H319 H317  <b>Remove</b> H332		<b>Add</b> oral: ATE = 1200 mg/kg bw	
Resulting Annex VI entry if agreed by COM	603-057-00-5	benzyl alcohol	202-859-9	100-51-6	Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1B	H302 H319 H317	GHS07 Wng	H302 H319 H317		oral: ATE = 1200 mg/kg bw	

## 9. Dimethylpropylphosphonate

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	dimethyl propylphosphonate	242-555-3	18755-43-6	Muta. 1B Repr. 1B	H340 H360FD	GHS08 Dgr	H340 H360FD			
RAC opinion	TBD	dimethyl propylphosphonate	242-555-3	18755-43-6	Muta. 1B Repr. 1B	H340 H360Df	GHS08 Dgr	H340 H360Df			
Resulting Annex VI entry if agreed by COM	TBD	dimethyl propylphosphonate	242-555-3	18755-43-6	Muta. 1B Repr. 1B	H340 H360Df	GHS08 Dgr	H340 H360Df			

## 10. Clothianidin(ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	613-307-00-5	clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	433-460-1	210880-92-5	Acute Tox. 4* Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M = 10	
Dossier submitters proposal	613-307-00-5	clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	433-460-1	210880-92-5	<b>Retain</b> Aquatic Acute 1 Aquatic Chronic 1  <b>Add</b> Repr. 2 STOT SE 1  <b>Modify</b> Acute Tox. 4	<b>Retain</b> H302 H400 H410  <b>Add</b> H361d H370 (nervous system)	<b>Retain</b> GHS07 GHS09  <b>Add</b> GHS08  <b>Modify</b> Dgr	<b>Retain</b> H302 H410  <b>Add</b> H361d H370 (nervous system)		<b>Retain</b> M = 10  <b>Add</b> oral: ATE = 389 mg/kg bw  M = 100	
RAC opinion	613-307-00-5	clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	433-460-1	210880-92-5	<b>Retain</b> Aquatic Acute 1 Aquatic Chronic 1  <b>Add</b> Repr. 2 STOT SE 1  <b>Modify</b> Acute Tox. 4	<b>Retain</b> H302 H400 H410  <b>Add</b> H361f H370 (nervous system)	<b>Retain</b> GHS07 GHS09  <b>Add</b> GHS08  <b>Modify</b> Dgr	<b>Retain</b> H302 H410  <b>Add</b> H361f H370 (nervous system)		<b>Retain</b> M = 10  <b>Add</b> oral: ATE = 390 mg/kg bw  M = 100	
Resulting Annex VI entry if agreed by COM	613-307-00-5	clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	433-460-1	210880-92-5	Repr. 2 Acute Tox. 4 STOT SE 1 Aquatic Acute 1 Aquatic Chronic 1	H361f H302 H370 (nervous system) H400 H410	GHS08 GHS07 GHS09 Dgr	H361f H302 H370 (nervous system) H410		oral: ATE = 390 mg/kg bw M = 10 M = 100	



# 11. [1] Lithium carbonate; [2] lithium chloride; [3] lithium hydroxide

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	lithium carbonate [1] lithium chloride [2] lithium hydroxide [3]	209-062-5 [1] 231-212-3 [2] 215-183-4 [3]	554-13-2 [1] 7447-41-8 [2] 1310-65-2 [3]	Repr. 1A	H360FD	GHS08 Dgr	H360FD			
RAC opinion	TBD	lithium carbonate [1] lithium chloride [2] lithium hydroxide [3]	209-062-5 [1] 231-212-3 [2] 215-183-4 [3]	554-13-2 [1] 7447-41-8 [2] 1310-65-2 [3]	Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362			
Resulting Annex VI entry if agreed by COM	TBD	lithium carbonate [1] lithium chloride [2] lithium hydroxide [3]	209-062-5 [1] 231-212-3 [2] 215-183-4 [3]	554-13-2 [1] 7447-41-8 [2] 1310-65-2 [3]	Repr. 1A Lact.	H360FD H362	GHS08 Dgr	H360FD H362			

## 12. Nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]

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	nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; 687-833-9 and others	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	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	
RAC opinion	TBD	nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; 687-833-9 and others	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	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	nonylphenol, branched and linear, ethoxylated (with average molecular weight < 352 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	500-315-8; 500-024-6; 500-045-0; 500-209-1; 248-762-5; 243-816-4; 248-291-5; 687-833-9 and others	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	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	

### 13. Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]

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	nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	230-770-5; 248-743-1; 247-555-7; 248-293-6 and others	127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others	Aquatic Chronic 2	H411	GHS09	H411			
RAC opinion	TBD	nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	230-770-5; 248-743-1; 247-555-7; 248-293-6 and others	127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight < 704 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	230-770-5; 248-743-1; 247-555-7; 248-293-6 and others	127087-87-0; 9016-45-9; 7311-27-5; 27942-27-4; 26264-02-8; 27177-05-5; 14409-72-4 and others	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	

## 14. Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]

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	nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	-	127087-87-0 9016-45-9 and others	no classification						
RAC opinion	TBD	nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	-	127087-87-0 9016-45-9 and others	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para-isomers or any combination thereof]	-	127087-87-0 9016-45-9 and others	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	

## 15. Hydrogen sulphide, hydrogen sulfide

	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	016-001-00-4	hydrogen sulphide, hydrogen sulfide	231-977-3	7783-06-4	Flam. Gas 1 Press. Gas Acute Tox. 2* Aquatic Acute 1	H220 H330 H400	GHS02 GHS04 GHS06 GHS09 Dgr	H220 H330 H400			Note U
Dossier submitters proposal	016-001-00-4	hydrogen sulphide, hydrogen sulfide	231-977-3	7783-06-4	<b>Retain</b> Press. Gas Aquatic Acute 1  <b>Modify</b> Flam. Gas 1A Acute Tox. 2	<b>Retain</b> H220 H330 H400	<b>Retain</b> GHS02 GHS06 GHS09 Dgr  <b>Remove</b> GHS04	<b>Retain</b> H220 H330 H400		<b>Add</b> inhalation: ATE = 100 ppmV (gases)	<b>Retain</b> Note U
RAC opinion	016-001-00-4	hydrogen sulphide, hydrogen sulfide	231-977-3	7783-06-4	<b>Retain</b> Press. Gas Aquatic Acute 1  <b>Modify</b> Flam. Gas 1A Acute Tox. 2	<b>Retain</b> H220 H330 H400	<b>Retain</b> GHS02 GHS06 GHS09 Dgr  <b>Remove</b> GHS04	<b>Retain</b> H220 H330 H400		<b>Add</b> inhalation: ATE = 440 ppmV (gases)	<b>Retain</b> Note U
Resulting Annex VI entry if agreed by COM	016-001-00-4	hydrogen sulphide, hydrogen sulfide	231-977-3	7783-06-4	Flam. Gas 1A Press. Gas Acute Tox. 2 Aquatic Acute 1	H220 H330 H400	GHS02 GHS06 GHS09 Dgr	H220 H330 H400		inhalation: ATE = 440 ppmV (gases)	Note U

## 16. Resorcinol; 1,3-benzenediol

	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	604-010-00-1	resorcinol; 1,3-benzenediol	203-585-2	108-46-3	Acute Tox. 4* Skin Irrit. 2 Eye Irrit. 2 Aquatic Acute 1	H302 H315 H319 H400	GHS07 GHS09 Wng	H302 H315 H319 H400		*	
Dossier submitters proposal	604-010-00-1	resorcinol; 1,3-benzenediol	203-585-2	108-46-3	<b>Retain</b> Aquatic Acute 1  <b>Add</b> Skin Sens. 1A STOT SE 1  <b>Modify</b> Acute Tox. 4	<b>Retain</b> H400  <b>Add</b> H317 H370 (nervous system)  <b>Modify</b> H302	<b>Retain</b> GHS07 GHS09  <b>Add</b> GHS08  <b>Modify</b> Dgr	<b>Retain</b> H400  <b>Add</b> H317 H370 (nervous system)  <b>Modify</b> H302		<b>Add</b> oral: ATE = 500 mg/kg bw  M = 1  <b>Remove</b> *	
RAC opinion	604-010-00-1	resorcinol; 1,3-benzenediol	203-585-2	108-46-3	<b>Retain</b> Aquatic Acute 1  <b>Add</b> Skin Sens. 1B STOT SE 1  <b>Modify</b> Acute Tox. 4	<b>Retain</b> H302 H400  <b>Add</b> H317 H370 (nervous system)	<b>Retain</b> GHS07 GHS09  <b>Add</b> GHS08  <b>Modify</b> Dgr	<b>Retain</b> H302 H400  <b>Add</b> H317 H370 (nervous system)		<b>Add</b> oral: ATE = 500 mg/kg bw  M = 1  <b>Remove</b> *	
Resulting Annex VI entry if agreed by COM	604-010-00-1	resorcinol; 1,3-benzenediol	203-585-2	108-46-3	Acute Tox. 4 STOT SE 1 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1B Aquatic Acute 1	H302 H370 (nervous system) H315 H319 H317 H400	GHS07 GHS08 GHS09 Dgr	H302 H370 (nervous system) H315 H319 H317 H400		oral: ATE = 500 mg/kg bw  M = 1	

## 17. 1-phenylethan-1-one (1-phenylethylidene)hydrazone

	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	1-phenylethan-1-one (1-phenylethylidene)hydrazone	211-979-0	729-43-1	Skin Sens. 1	H317	GHS07 Wng	H317			
RAC opinion	TBD	1-phenylethan-1-one (1-phenylethylidene)hydrazone	211-979-0	729-43-1	Skin Sens. 1	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by COM	TBD	1-phenylethan-1-one (1-phenylethylidene)hydrazone	211-979-0	729-43-1	Skin Sens. 1	H317	GHS07 Wng	H317			

## 18. Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

	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	015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	Repr. 2	H361f	GHS08 Wng	H361f			
Dossier submitters proposal	015-203-00-X	Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	<b>Add</b> Skin Sens. 1B  <b>Modify</b> Repr. 1B	<b>Add</b> H317  <b>Modify</b> H360Fd	<b>Retain</b> GHS08  <b>Add</b> GHS07  <b>Modify</b> Dgr	<b>Add</b> H317  <b>Modify</b> H360Fd			
RAC opinion	015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	<b>Add</b> Skin Sens. 1B  <b>Modify</b> Repr. 1B	<b>Add</b> H317  <b>Modify</b> H360Fd	<b>Retain</b> GHS08  <b>Add</b> GHS07  <b>Modify</b> Dgr	<b>Add</b> H317  <b>Modify</b> H360Fd			
Resulting Annex VI entry if agreed by COM	015-203-00-X	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	278-355-8	75980-60-8	Repr. 1B Skin Sens. 1B	H360Fd H317	GHS08 GHS07 Dgr	H360Fd H317			



### **Part III. List of Attendees of the RAC-58 meeting**

<b>RAC members</b>	
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
Husa	Stine
Kadikis	Normunds
Karadjova	Irina
Leinonen	Riitta
Lund	Bert-Ove
Martinek	Michal
Mendas	Gordana
Menard Srpčič	Anja
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Paris	Pietro
Pęczkowska	Beata
Pribu	Mihaela
Printemps	Nathalie
Rodriguez	Wendy
Santonen	Tiina
Schlueter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sogorb	Miguel
Sørensen	Peter Hammer
Spetseris	Nikolaos
Stahlmann	Ralf
Tobiassen	Lea Stine
Tsakovska	Ivanka
Tsitsimpikou	Christina
Uzomeckas	Žilvinas
van der Haar	Rudolf (co-opted member)
Varnai	Veda
Viegas	Susana

<b>Apologies members</b>	
Hartwig	Andrea (co-opted member)
Heederik	Dick (co-opted member)
Xanthos	Theodore

<b>Members' advisers</b>		
Algharably	Engi	(Stahlmann Ralf)
Beetstra	Renske	(Schoor Gerlienke)
Catone	Tiziana	(Paris Pietro)
Clausen	Ian Henning	(Soerensen Peter Hammer)_Article 77(3)c Lead
Esposito	Dania	(Paris Pietro)_Resorcinol
Granato	Giuseppe	(Paris Pietro)
Hoffmann	Frauke	(Schulte Agnes)
Larsen	Janni	(Tobiassen Lea Stine)
Lecloux	Helene	(Rodriguez Wendy)
Losert	Annemarie	(Manuel Facchin)
Marinkovic	Marino	(Schoor Gerlienke)
Munch	Pernille Steenkæ	(Lea Stine Tobiassen)
Paludan	Ditte	(Soerensen Peter Hammer)_TBBPA
Panieri	Emiliano	(Paris Pietro)
Partosch	Falko	(Stahlmann Ralf)
Romoli	Debora	(Paris Pietro)
Russo	Maria Teresa	(Paris Pietro)
Sachno	Dmitrij	(Stahlmann Ralf)
Saksa	Jana	(Moldov Raili)
Seba	Julie	(Rodriguez Wendy)
Sonnenburg	Anna	(Stahlmann Ralf)
Stalter	Daniel	(Schulte Agnes)
Suutari	Tiina	(Leinonen Riitta)
Tarvainen	Emma	(Leinonen Riitta)
van Herwijnen	Rene	(Schoor Gerlienke)

<b>SEAC Rapporteurs</b>		
Cogen	Simon	Restrictions: Single-use diapers
Thiele	Karen	Restrictions: Lead in outdoor shooting and fishing

<b>Invited experts</b>		<b>Substance</b>
Cromie	Ruth (AEWA Technical Committee)	Restrictions: Lead in ammunition
Dereliev	Sergey (UNEP/AEWA)	Restrictions: Lead in ammunition
Kapelari	Sonja	Restrictions: Single-use diapers
Rucki	Marian	Article 77(3)c: Environmental properties of lead

<b>Dossier submitters</b>		<b>Substance</b>
Conway	Louise (IE)	CLH: Dimethylpropylphosphonate
Dang	Zhichao (NL)	CLH: Nonylphenol, branched and linear, ethoxylated

Dubois	Céline (FR)	Restrictions: Single use diapers
Drissi	Sammy (FR)	Restrictions: Single use diapers
Fiore	Karine (FR)	Restrictions: Single use diapers
Guillou	Pauline (FR)	CLH: Lithium
Hackmann	Anja (DE)	CLH: Sulphur dioxide (SO <sub>2</sub> ); Sulphur dioxide (SO <sub>2</sub> )
Heise	Tanja (DE)	CLH: Clothianidin
Hölzl	Christine (AT)	CLH: Dibutyltin maleate; Dibutyltin oxide
Kneuer	Carsten (DE)	CLH: Sulphur dioxide (SO <sub>2</sub> ); Diuron (ISO)
Kühnert	Agnes (DE)	CLH: 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1
Mathieu-Huart	Aurelie (FR)	Restrictions: Single use diapers
van der Hagen	Marianne (NO)	CLH: TBBPA

### Regular stakeholder observers

De Backer	Liisi (CEFIC)
Barry	Frank (ETUC)
Duguy	Hélène (ClientEarth)
Dunauskiene	Lina (A.I.S.E.)
Robinson	Jan (A.I.S.E.)
Romano	Dolores (EEB)
Ruelens	Paul (CropLife Europe)
Van de Broeck	Steven (CEFIC)
Verougstraete	Violaine (Eurometaux)
Waeterschoot	Hugo (Eurometaux)

Occasional stakeholders		Substance
Ballach	Jochen (CIRFS)	CLH: General CLH; Sulphur dioxide (SO <sub>2</sub> ); Hydrogen sulphide; Resorcinol; Restrictions: Single use diapers
Barbu	Luminita (EDANA)	Workplan; CLH: General CLH; Nonylphenol, branched and linear, ethoxylated; Restrictions: General restrictions
Barry	Edyta (PlasticsEurope)	Restrictions: Single use diapers
Drohmann	Dieter (ORO)	CLH: Sulphur dioxide (SO <sub>2</sub> ); Diuron (ISO); TBBPA
Kappel	Jan (EAA)	Article 77(3)c: Environmental properties of lead
Lagemaat	Marines (EDANA)	Restrictions: Single use diapers
Niemela	Helena (CONCAWE)	Agenda items 1-6.1; CLH: Hazard classes without plenary; Hydrogen sulphide; Restrictions: General restrictions; Single-use diapers
Puustinen	Seppo (FACE)	Restrictions: Lead in ammunition
Tillieux	Geoffroy (EuPC)	Restrictions: Lead in ammunition

<b>Stakeholder experts</b>		<b>Substance</b>
Battersby	Rodger V. (CEFIC/Grillo-Werke AG (SDIOC) - (EBRC Consulting GmbH)	CLH: Sulphur dioxide (SO <sub>2</sub> )
Binks	Steve (CEFIC/Pb REACH consortium)	Article 77(3)c: Environmental properties of lead
Beyer	Dieter (CropLife Europe/ORO)	CLH: Diuron (ISO)
Borghof	Susan (CEFIC/ BSEF, The International Bromin Council USA)	CLH: TBBPA
Burzlauff	Arne (Eurometaux/EBRC Consulting)	CLH: Sulphur dioxide (SO <sub>2</sub> )
Chowdhury	Jasim (Eurometaux/ILA)	Article 77(3)c: Environmental properties of lead
de Graaff	Rene (PlasticsEurope/LyondellBasell Corporate HSE)	Restrictions: Single use diapers
Geier	Johannes	Article 77(3)c: Environmental properties of lead; CLH: Benzyl alcohol
Hoberman	Alan (CropLife Europe/Sumitomo)	CLH: Clothianidin
Jacobi	Sylvia (Cefic/Albemarle)	CLH: Lithium
Jacobi	Sylvia (Eurometaux/Albemarle)	CLH: TBBPA
Kirsch	Taryn (EDANA/Procter&Gamble)	Restrictions: Single use diapers
Köhl	Werner (Eurometaux/Li Consortium)	CLH: Lithium
Ott	Wolfgang (CIRFS/Kelheim Fibres GmbH)	CLH: Sulphur dioxide (SO <sub>2</sub> ); Restrictions: Single use diapers
Pain	Debbie (EEB/Department of Zoology, Cambridge University)	Restrictions: Lead in ammunition
Richards-Doran	Ryan (CropLife Europe/Cymoxanil Task Force)	CLH: 1. Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide
Richmond	Emily (CropLife Europe/BASF)	CLH: Picolinafen (ISO)
Verdonck	Frederik (Eurometaux/Arche Consulting)	Restrictions: Lead in ammunition
Williams	Cris (CEFIC/ILA)	Restrictions: Lead in ammunition

<b>European Commission</b>		<b>DG</b>
Bertato	Valentina	DG ENV
Bintein	Sylvain	DG ENV
Blass	Ana	DG GROW
Fabbri	Marco	DG GROW
Kilian	Karin	DG ENV

Lekatos	Stylianos	DG GROW
Pinte	Jérémy	DG GROW
Pirselova	Katarina	DG ENV
Roebben	Gert	JRC
Tosetti	Patrizia	DG SANTE

<b>EU Agency Observers</b>		
Rincon	Anna	EFSA

<b>ECHA staff</b>	
Blainey	Mark
Bowmer	Tim (Chair)
Franke	Greta
Gmeinder	Michael
Henrichson	Sanna
Karjalainen	Antti
Karjalainen	Ari
Kokkola	Leila
Korjus	Pia
Lapenna	Silvia
Lefevre	Sandrine
Logtmeijer	Christiaan
Ludborzs	Arnis
Mattiuzzo	Marco
Mazzolini	Anna
Myöhänen	Kirsi
Nygren	Jonas
Orispää	Katja
O'Rourke	Regina
Peltola-Thies	Johanna (Chair)
Perazzolo	Chiara
Pillet	Monique
Prevedouros	Kostas
Rahkonen	Olli
Regil	Pablo
Reuter	Ulrike
Rheinberger	Christoph
Sadam	Diana
Simoes	Ricardo
Simpson	Peter
Smilovici	Simona
Sosnowski	Piotr
Spjuth	Linda
Uphill	Simon
Vainio	Matti
Zeiger	Bastian

### **Part III. LIST OF ANNEXES**

**ANNEX I** Final Agenda of the RAC-58 meeting

**ANNEX II** List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-58 meeting

**ANNEX III** Declarations of conflicts of interest to the Agenda of the RAC-58 meeting

**Final Agenda**  
**58<sup>th</sup> meeting of the Committee for Risk Assessment**

**7-9 September**  
**and**  
**13-16 September 2021**

**Virtual meeting**

**7 September starts at 14.00**  
**16 September ends at 17.30**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***RAC/A/58/2021***  
***For adoption***

**Item 3 – Declarations of conflicts of interest to the Agenda**

**Item 4 – Appointment of (co-)rapporteurs**

- 4.1 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**

- 5.1 RAC Work Plan for all processes

***For information***

- 5.2 RAC 59 and RAC 60 WG calendar and timings

***For information***

- 5.3 RAC co-opted members

The Secretariat will update you on the candidates recommended by the RAC co-opted members selection panel; you will then be asked to co-opt them to the Committee.

***RAC/58/2021/01***  
***(Restricted)***  
***For agreement***  
***Closed session***

#### 5.4 Annual update of RAC accredited stakeholders' list

The Secretariat will update you on the requests from stakeholder observers to attend RAC meetings since the last review of the RAC stakeholders. You will be invited to agree on the updated list of the accredited stakeholder organisations to RAC this year.

**RAC/58/2021/02**

**(Restricted)**

**For agreement**

**Closed session**

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

#### 6.1 Classification for environmental toxicity of lead

**For discussion and adoption**

### **Item 7 – Health based exposure limits at the workplace**

No agenda items.

### **Item 8 – Harmonised classification and labelling (CLH)**

#### **8.1 General CHL issues**

##### **1. Report from the July CLH WG**

**RAC/58/2021/03**

**(RAC WG/CLH/R/2/2021)**

**For information**

#### **8.2 CLH dossiers**

##### **1. Hazard classes for agreement without plenary debate (A-list)**

- Clothianidin (ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (EC: 433-460-1; CAS: 210880-92-5): acute oral toxicity, STOT SE, hazardous to the aquatic environment
- Hydrogen sulphide, hydrogen sulfide (EC: 231-977-3; CAS: 7783-06-4): physical hazards, acute inhalation toxicity
- Resorcinol; 1,3-benzenediol (EC: 203-585-2; CAS: 108-46-3): acute toxicity via all routes, skin sensitisation, STOT SE, hazardous to the aquatic environment
- 1-phenylethan-1-one (1-phenylethylidene)hydrazone (EC: 211-979-0; CAS: 729-43-1): skin sensitisation
- Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide (EC: 278-355-8; CAS: 75980-60-8): skin sensitisation, reproductive toxicity
- Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5): physical hazards, acute inhalation toxicity
- Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC: 206-354-4; CAS: 330-54-1): acute toxicity via all routes, germ cell mutagenicity
- 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1 (EC: 213-584-9; CAS: 989-38-8): acute oral toxicity, serious eye damage/eye irritation



- Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide (EC: -; CAS: 137641-05-5): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, carcinogenicity, reproductive toxicity, STOT SE
- tetrabromobisphenol-A (TBBPA); 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; (EC: 201-236-9; CAS: 79-94-7): STOT RE, germ cell mutagenicity
- Dibutyltin maleate (EC: 201-077-5; CAS: 78-04-6): acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, germ cell mutagenicity
- Dibutyltin oxide (EC: 212-449-1; CAS: 818-08-6): acute dermal toxicity, serious eye damage/eye irritation
- Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6): serious eye damage/eye irritation

## 2. Hazard classes for agreement [with plenary debate]

1. Cymoxanil (ISO); 2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide (EC: 261-043-0; CAS: 57966-95-7)
2. Sulphur dioxide (EC: 231-195-2; CAS: 7446-09-5)
3. Diuron (ISO); 3-(3,4-dichlorophenyl)-1,1-dimethylurea (EC: 206-354-4; CAS: 330-54-1)
4. 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethylxanthylum chloride; Basic Red 1 (EC: 213-584-9; CAS: 989-38-8)
5. Picolinafen (ISO); N-(4-fluorophenyl)-6-[3-(trifluoromethyl)phenoxy]pyridine-2-carboxamide; 4'-fluoro-6-[( $\alpha,\alpha,\alpha$ -trifluoro-m-tolyl)oxy]picolinanilide (EC: -; CAS: 137641-05-5)
6. 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA) (EC: 201-236-9; CAS: 79-94-7)
7. Dibutyltin maleate (EC: 201-077-5; CAS: 78-04-6)
8. Dibutyltin oxide (EC: 212-449-1; CAS: 818-08-6)
9. Benzyl alcohol (EC: 202-859-9; CAS: 100-51-6)
10. Dimethylpropylphosphonate (EC: 242-555-3; CAS: 18755-43-6): germ cell mutagenicity, reproductive toxicity (*discussed in the CLH WG*)
11. Clothianidin(ISO); (E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine (EC: 433-460-1; CAS: 210880-92-5): reproductive toxicity (*discussed in the CLH WG*)
12. [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-) (*discussed in the CLH WG*)
13. 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) (*discussed in the CLH WG*)
14. Nonylphenol, branched and linear, ethoxylated (with 352 g/mol  $\leq$  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) (*discussed in the CLH WG*)

15. Nonylphenol, branched and linear, ethoxylated (with 704 g/mol  $\leq$  average molecular weight  $\leq$  1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] (EC: -; CAS: 127087-87-0; 9016-45-9 and others) (*discussed in the CLH WG*)

***For discussion and adoption***

## **Item 9 – Restrictions**

### **9.1 General restriction issues**

1. ~~The role of the opinion for the decision-making phase~~

***For discussion***

2. Report from the August restriction WG

***RAC/58/2021/04***

***(RAC WG/REST/R/2/2021)***

***For information***

### **9.2 Restriction Annex XV dossiers**

1. Conformity check and key issues discussion

1. 2,4-dinitrotoluene [to be confirmed]

***For discussion and agreement***

2. Opinion development

1. Substances in single-use baby diapers – third draft opinion

***For discussion and adoption***

2. Lead in outdoor shooting and fishing – second draft opinion

***For discussion***

## **Item 10 – Authorisation**

### **10.1 General authorisation issues**

- a) Update on incoming/future applications

- b) Renewal of the Mandate for RAC Working Group on AfA

***RAC/58/2021/05***

***For information/discussion***

- c) Assessing representativeness of downstream users information (this item will be discussed in a joint session with SEAC)

***For discussion***

## **10.2 Authorisation applications**

### **1. Discussion on key issues**

1. 6 applications for authorisation (chromium trioxide, sodium dichromate, 4-tert-OPnEO, 4-NPnEO) from May 2021 submission window

***For discussion***

## **10.3 Agreement on draft opinions**

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

(no A-list opinions in this meeting)

### **B. Draft opinions for agreement with plenary debate**

1. 227\_RR1\_TCE\_ROQUETTE (1 use)
2. 228\_CT\_Eaton (1 use)
3. 229\_RR1\_CT\_Volta (1 use)

***For discussion and agreement***

## **10.4 Adoption on opinions**

No opinions to adopt.

***For discussion and adoption***

### **Item 11 – AOB**

### **Item 12 – Minutes of RAC-58**

- 12.1 Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-58

***For adoption***

## Annex II (RAC 58)

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

Document number	Title
RAC/A/58/2021	Final Draft Agenda
RAC/58/2021/01 <i>Restricted</i>	Appointment of co-opted members to RAC
RAC/58/2021/02 <i>Restricted</i>	Annual update of RAC accredited stakeholders' list
RAC/58/2021/03	Report from the RAC-58 CLH WG
RAC/58/2021/04	Report from the RAC-58 REST WG
RAC/58/2021/05	Working group on application for authorisation (renewal mandate)

## ANNEX III (RAC-58)

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
<b>ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)</b>		
<b>Applications for Authorisation</b>		
<b>All chromates</b>	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.
<b>Restrictions</b>		
<b>Diapers</b> (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
<b>Harmonised classification &amp; labelling</b>		
<b>Lithium carbonate; lithium chloride; lithium hydroxide</b>  <b>FR</b>	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.

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
	Laure GEOFFROY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<p><b>1. Nonylphenol, branched and linear, ethoxylated (with average molecular weight &lt; 352 g/mol)</b></p> <p><b>2. Nonylphenol, branched and linear, ethoxylated (with 352 g/mol ≤ average molecular weight &lt; 704 g/mol)</b></p> <p><b>3. Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol)</b></p> <p><b>NL</b></p>	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.
<p><b>Resorcinol</b></p> <p><b>FI</b></p>	Tiina SANTONEN	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.
	Riitta LEINONEN	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.
<p><b>Dimethyl propylphosphonate</b></p>	Brendan MURRAY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
<b>IE</b>		measures applied. No personal involvement.
	Malcolm DOAK	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.
<b>Health based exposure limits at the workplace</b>		
<b>None</b>		
<b>Article 77.3(c)</b>		
<b>Classification for environmental toxicity of lead</b> <b>No CA involvement – the request comes from COM</b>		

Dossier / DS	RAC Member	Reason for potential CoI / Working for
<b>NEW DOSSIERS</b>		
<b>Harmonised classification &amp; labelling</b>		
<b>1. Clothianidin (ISO)</b> <b>2. Hydrogen sulphide</b> <b>3. Sulphur dioxide</b> <b>4. Diuron (ISO)</b> <b>5. Basic Red 1</b> <b>6. Picolinafen (ISO)</b> <b>7. Benzyl alcohol</b>  <b>DE</b>	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 in nr. 5 and 7.
	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.
<b>1-phenylethan-1-one (1-phenylethylidene)hydrazide</b>  <b>FR</b>	Nathalie PRINTEMPS	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Laure GEOFFROY	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
<b>Cymoxanil (ISO)</b>  <b>LT</b>	Zilvinas Uzomeckas	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.



Dossier / DS	RAC Member	Reason for potential CoI / Working for
<b>NEW DOSSIERS</b>		
<b>Cymoxanil (ISO)</b>  <b>FI</b>	Tiina SANTONEN	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.
	Riitta LEINONEN	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.
<b>Dibutyltin maleate</b> <b>Dibutyltin oxide</b> <b>AT</b>	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.
<b>Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide</b>  <b>SE</b>	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.
	Iftekhar 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.
<b>2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA)</b>	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.

Dossier / DS	RAC Member	Reason for potential CoI / Working for
<b>NEW DOSSIERS</b>		
<b>NO</b>	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.
<b>2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A (TBBPA)</b> <b>DK</b>	Peter Hammer SORENSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Lea Stine TOBIASSEN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.