

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

**30 November – 3 December**  
**and**  
**7-10 December 2020**

**Virtual meeting**

**Monday 30 November starts at 14.00**  
**Thursday 3 December breaks at 18.00**  
**Monday 7 December resumes at 14.00**  
**Thursday 10 December ends at 15.00**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***RAC/A/55/2020***  
***For adoption***

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

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

- a) Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits

***For agreement***

**Item 5 – Report from other ECHA bodies and activities**

- a) RAC Work Plan for all processes

***For information***

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

- 1) DNEL development for trixylyl phosphate  
*For discussion and adoption*
- 2) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances  
*For discussion and adoption*
- 3) Classification for acute inhalation toxicity of EGBE  
*For discussion and adoption*
- 4) Classification for environmental toxicity of lead  
*For discussion*

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

- a) Opinion development
  - 1) Cadmium and its inorganic compounds – first draft opinion  
*For discussion and agreement*

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

### **8.1 CLH dossiers**

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

- C. I. Disperse Blue 124: skin sensitisation
- Bentazone (ISO): acute oral toxicity, skin sensitisation, acute aquatic hazards, chronic aquatic hazards
- Margosa ext.: physical hazards (explosives, flammable gases, flammable aerosols, oxidising gases, gases under pressure, flammable liquids, flammable solids, self-reactive substances and mixtures, pyrophoric liquids, pyrophoric solids, substances and mixtures which in contact with water emit flammable gases, oxidising liquids, oxidising solids, organic peroxides, substances and mixtures corrosive to metals), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, carcinogenicity, STOT SE, STOT RE, acute aquatic hazards, chronic aquatic hazards
- Benfluralin (ISO): physical hazards, acute aquatic hazards, chronic aquatic hazards
- Melamine: germ cell mutagenicity
- Valifenalate: physical hazards (explosives, flammable solids, self-heating substances, oxidising solids), acute toxicity via all routes, skin corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT SE, STOT RE, chronic aquatic hazards, hazardous to the ozone layer
- Isopyrazam: physical hazards (explosive, flammable solid, self-reactive substance or mixture, pyrophoric solid, self-heating substance or mixture, substance which in contact with water emit flammable gases, oxidising solid, corrosive to metals), acute dermal and inhalation toxicity, skin

corrosion/irritation, serious eye damage/eye irritation, skin sensitisation, germ cell mutagenicity, STOT RE, acute aquatic hazards, chronic aquatic hazards

- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta-PSCA Na-TEA): STOT RE

- 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA): STOT RE

- 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA): STOT RE

***For agreement***

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

- 1) Bentazone (ISO) (EC: 246-585-8; CAS: 25057-89-0)
- 2) Margosa ext. (EC: 283-644-7; CAS: 84696-25-3)
- 3) Perfluroheptanoic acid (PFHpA) (EC: 206-798-9; CAS: 375-85-9)
- 4) Bisphenol S (EC: 201-250-5; CAS: 80-09-1)
- 5) Melamine (EC: 203-615-4; CAS: 108-78-1)
- 6) Valifenalate (EC: -; CAS: 283159-90-0)
- 7) Isopyrazam (EC: -; CAS: 881685-58-1)
- 10) 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid, sodium and tris(2-hydroxyethyl)ammonium salts (Penta\_PSCA Na TEA) (EC: -; CAS: -)
- 11) 6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Tetra-PSCA) (EC: -; CAS: 2156592-54-8)
- 12) 6-[C12-18-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid (Penta-PSCA) (EC: -; CAS: -)
- 13) Divanadium pentaoxide

***For discussion and agreement***

## **Item 9 – Restrictions**

### **9.1 General restriction issues**

- a) Updated Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals

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

- a) Conformity check and key issues discussion
  - 1) Substances in single-use nappies

***For discussion and agreement***

b) Opinion development

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

***For discussion and provisional agreement***

**Item 10 – Authorisation**

**10.1 General authorisation issues**

- a) Update on incoming/future applications
- b) Substitution Plans
- c) Report from RAC WG on AfAs during October 2020 meeting

***RAC/55/2020/01***

***For information/discussion***

**10.2 Authorisation applications**

1. Discussion on key issues
  - 1) 9 applications for authorisation (EDC, Cr(VI), MOCA, 4-tert-OPnEO) from August 2020 submission window

***For discussion***

**10.3 Agreement on draft opinions**

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

1. 197\_OPE\_NPE\_Phadia (2 uses)
2. 198\_OPE\_Zoetis (uses 1 and 2)
3. 199\_OPE\_Biokit (use 2)
4. 202\_OPE\_Merckle (1 use)

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

1. 193\_OPE\_PPG (2 uses)
2. 196\_OPE\_Becton (1 use)
3. 198\_OPE\_Zoetis (uses 3 and 4)
4. 199\_OPE\_Biokit (use 1)
5. 203\_OPE\_NPE\_Qiagen (4 uses)
6. 207\_NPE\_Chemetall (2 uses)
7. 208\_RR1\_TCE\_BlueCube (1 use)
8. 209\_CT\_Safran (1 use)
9. 210\_CT\_SD\_TataSteel (1 use)
10. 211\_CT\_Hubner (3 uses)

***For discussion and agreement***

#### **10.4 Adoption on opinions**

1. 143\_OPE\_bioMerieux (use 1)
2. 147\_CTPht\_Bilbaina (1 use)
3. 148\_CTPht\_DEZA (1 use)
4. 149\_CTPht\_Nalon (1 use)
5. 150\_CTPht\_AO\_Koppers (1 use)
6. 153\_CTPht\_AO\_Bilbaina (1 use)
7. 162\_OPE\_LFB (1 use)
8. 176\_OPE\_Abbott\_1 (uses 1 and 2)
9. 184\_OPE\_Lilly (1 use)
10. 186\_OPE\_NPE\_Beckman (uses 1 and 3)
11. 187\_OPE\_AGC (2 uses)
12. 188\_OPE\_Wallac\_2 (2 uses)

***For discussion and adoption***

#### **Item 11 – AOB**

- a) ECHA administrative improvement proposals

#### **Item 12 – Minutes of RAC-55**

- a) Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-55

***For adoption***

## **PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-55 – WEEK 1**

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

### **Monday 30 November 2020: Afternoon session**

- Item 1 – Welcome and Apologies
- Item 2 – Adoption of the Agenda
- Item 3 – Declarations of conflicts of interest to the Agenda
- Item 5 – RAC Work Plan for Restriction, Authorisation and C&L processes
- Item 7 – OEL
- Item 6 – Requests under Article 77(3)(c)

### **Tuesday 1 December 2020: Morning session**

- Item 9 – Restrictions

### **Tuesday 1 December 2020: Afternoon session**

- Item 9 – Restrictions
- Item 6 – Requests under Article 77(3)(c)
- Item 10 – Authorisation applications

### **Wednesday 2 December 2020: Morning session**

- Item 10 – Authorisation applications

### **Wednesday 2 December 2020: Afternoon session**

- Item 10 – Authorisation applications

### **Thursday 3 December 2020: Morning session**

- Item 10 – Authorisation applications

### **Thursday 3 December 2020: Afternoon session**

- Item 10 – Authorisation applications
- Item 12 – Minutes of RAC-55

## **PROVISIONAL TIMELINE FOR THE DISCUSSIONS AT RAC-55 – WEEK 2**

Please note that this timeline is provisional. Changes can be made before and during the meeting in order to accommodate the discussions.

### **Monday 7 December 2020: Afternoon session**

- Item 1 – Welcome and Apologies
- Item 3 – Declarations of conflicts of interest to the Agenda
- Item 8 – CLH dossiers

### **Tuesday 8 December 2020: Morning session**

- Item 8 – CLH dossiers

### **Tuesday 8 December 2020: Afternoon session**

- Item 8 – CLH dossiers

### **Wednesday 9 December 2020: Morning session**

- Item 8 – CLH dossiers
- Item 6 – Requests under Article 77(3)(c)

### **Wednesday 9 December: Afternoon session**

- Item 6 – Requests under Article 77(3)(c)
- Item 8 – CLH dossiers

### **Thursday 10 December 2020: Morning session**

- Item 8 – CLH dossiers
- Item 6 – Requests under Article 77(3)(c)

### **Thursday 10 December: Afternoon session**

- Item 12 – Minutes of RAC-55
- Item 4 – Appointment of rapporteurs