

**Provisional Draft 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 15.30**

***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 agreement***

- 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 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***

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

##### **8.1 CLH dossiers**

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

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

- 1) C. I. Disperse Blue 124 (EC: 239-203-6; CAS: 15141-18-1)
- 2) Bentazone (ISO) (EC: 246-585-8; CAS: 25057-89-0)
- 3) Margosa ext. (EC: 283-644-7; CAS: 84696-25-3)
- 4) Perfluroheptanoic acid (PFHpA) (EC: 206-798-9; CAS: 375-85-9)
- 5) Benfluralin (ISO) (EC: 217-465-2; CAS: 1861-40-1)
- 6) Bisphenol S (EC: 201-250-5; CAS: 80-09-1)
- 7) Melamine (EC: 203-615-4; CAS: 108-78-1)
- 8) Valifanalate (EC: -; CAS: 283159-90-0)
- 9) 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 adoption***

## **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***

### **9.2 Appointment of (co-)rapporteurs for restriction dossiers**

***Doc to be distributed***

***For 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

***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**

5. 193\_OPE\_PPG (2 uses)
6. 196\_OPE\_Becton (1 use)
7. 198\_OPE\_Zoetis (uses 3 and 4)
8. 199\_OPE\_Biokit (use 1)
9. 203\_OPE\_NPE\_Qiagen (4 uses)
10. 207\_NPE\_Chemetall (2 uses)
11. 208\_RR1\_TCE\_BlueCube (1 use)
12. 209\_CT\_Safran (1 use)
13. 210\_CT\_SD\_TataSteel (1 use)
14. 211\_CT\_Hubner (3 uses)

***For discussion and agreement***

### **10.4 Adoption on opinions**

1. 143\_OPE\_bioMerieux (3 uses)
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 (5 uses)
9. 184\_OPE\_Lilly (1 use)
10. 186\_OPE\_NPE\_Beckman (5 uses)
11. 187\_OPE\_AGC (2 uses)
12. 188\_OPE\_Wallac\_2 (2 uses)

***For discussion and adoption***

### **Item 11 – AOB**

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

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

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

### **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