RAC/M/65/2023

21 June 2023

Minutes of the 65th Meeting

of the Committee for Risk Assessment

(RAC-65)

Monday, 5 June at 14.00
Thursday, 8 June ends at 18.10

Summary Record of the Proceedings, and Conclusions and action points

Chair's opening address

The Chair of RAC, Tim Bowmer opened the meeting and invited Sharon McGuinness the Executive Director of ECHA, to say some words of welcome.

The Executive Director welcomed the members and stakeholders to the 65th meeting of the Committee and thanked the Chair for his stewardship of RAC over 11 years, wishing him well on his upcoming retirement. She also welcomed the incoming Chair of RAC Roberto Scazzola, attending the meeting as an invited expert prior to joining ECHA on 16 June.

Agenda point	
Conclusions / agreements / adoptions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (**RAC/A/65/2023**) was adopted without amendment.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-65 minutes.
4. Appointment of (co-)rapporteurs	
4.1 Appointment of (co-)rapporteurs for CLH dossiers, restriction dossiers, authorisation applications, evaluation of occupational exposure limits The Secretariat collected the names of volunteers for rapporteurships for harmonised classification and labelling (CLH) dossiers, applications for authorisation and occupational exposure limit (OEL) requests, 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.	
5. Report from other ECHA bodies and activities	
5.1 RAC work plan for all processes The Chair presented the RAC work plan for 2023.	
12. RAC-SCCS joint symposium on risk assessment	
On behalf of ECHA, the Chair of RAC welcomed the Chair vice-Chairs and members of the Scientific Committee on Consumer Safety (SCCS) to the joint symposium on risk assessment, noting that they were holding their plenary meeting at ECHA. As this was quite a unique opportunity, he looked forward to an interesting discussion with the two Committees on the tree topics on the agenda.	
1. Substance grouping Fleur van Broekhuizen reviewed ECHAs work on grouping in the context of ECHAs Integrated Regulatory Strategy (IRS), including the Assessment of Regulatory Needs (ARN), including in the context of CLH. Sandrine Lefevre outlined ECHAs experience with the grouping of substances in restriction proposals, noting e.g. that with the perfluorinated substances, experience had	

been built up from restricting a single substance PFOA through smaller groups to fully grouped proposals such as PFAS in firefighting foams. 2. Use of non-animal methods Ofelia Bercaru, Director of Prioritisation and Integration presented an overview of ECHAs efforts to promote the use of non-animal methods and reported on the outcome of a workshop held at ECHA on this topic the previous week. In a presentation entitled, "The importance of non-animal methods (NAMs) for safety assessment of cosmetic ingredients – the current status and gaps, and the outlook for use in new generation risk assessment", the Chair Qasim Chaudhry and Vice Chairs Vera Rogiers and Pieter-Jan Coenraads of the Scientific Committee on Consumer Safety (SCCS) presented their Committee and how NAMs are essential in the context of their work. 3. Acceptability of cancer risk Tim Bowmer presented the final topic on "The (un-)acceptability of cancer risk at the workplace". He highlighted various examples of annualised risks, including cancer experienced by citizens. He noted that the opinion of the DG-EMPL Advisory Committee on Safety and Health (ACSH) at the workplace is an agreement between Employers, Trade Unions and MSs reached at EU level which, although not binding, could be a significant step forward for ECHA in developing restrictions and in evaluating authorisation for non-threshold carcinogens. He interpreted the recommended upper and lower levels in the context of cobalt (restriction and OEL) as well as chrome VI (authorisations).	

6. Request under Article 77(3)(c)

6.1 Article 77(3)(c) request on Silanamine (SAS-HMDS): review of the acute toxicit classification of Silanamine as adopted by RAC in its opinion of 5 December 201

The Chair welcomed an expert accompanying the CEFIC Regular Stakeholder Observer. He informed the Committee that based on the request from the Commission, RAC received an Executive Director mandate to review the RAC opinion in relation to the acute toxicity classification of **silanamine**, as adopted by RAC in its opinion of 5 December 2019.

In its opinion of 5 December 2019, RAC had concluded to classify the substance for acute toxicity by inhalation Cat. 2, with an ATE of 0.45 mg/L. Following adoption and publication of the RAC opinion, manufacturers of the substance provided an additional study which examines the mechanism for the observed acute toxicity of HMDZ-treated SAS via the inhalation route. RAC was therefore requested to review the available information on acute toxicity by inhalation, and, if appropriate, to amend the opinion of 5 December 2019 in relation to the classification for acute toxicity by the inhalation route and/or the setting of an ATE for the classification of mixtures.
A targeted consultation of the study report was organised on the ECHA website.

The deadline for the adoption of an opinion is 26 June 2023.

RAC noted that the Anonymous (2022) study indicates a mode of action (MoA) via suffocation. Still, some Members expressed doubts whether this was also the main MoA in the Anonymous (1994a) study, which was used as the basis for the Acute Tox. 2 classification in the previous RAC opinion. Further, RAC noted that Anonymous (2022) did not provide any dose-response information as only a single concentration was tested. Anonymous (2000) is another relevant study with regard to the MoA. It indicates an LC_{50} in the range for Acute Tox. 3 (0.5 mg/l < ATE ≤ 1.0 mg/l). Both a non-relevant MoA (obstruction of nose and larynx) and relevant MoAs (obstruction of bronchi and bronchioles, some inflammation) were probably involved in this study. However, Acute Tox. 3 would imply that the mortality was only due to lung effects and that Anon. (2000) is more reliable than Anon. (2022). Suffocation was considered the main cause of death in the Anonymous (2022) study. Considering also the findings of the older studies at higher concentrations and different MMAD in a weight of evidence assessment, RAC agreed on no classification **due to inconclusive data**. RAC adopted by consensus its opinion (with the modifications agreed at RAC-65).	**Rapporteurs** to revise the opinion in accordance with the agreed modifications in RAC-65 and to provide it to SECR. **SECR** to make an editorial check of the opinion documents in consultation with the Rapporteurs and to ensure that the Annex and the RCOM are in line with the adopted opinion. **SECR** to forward the adopted opinion and its annex to COM and publish it on the ECHA website.

The expert accompanying the CEFIC Regular Stakeholder commented on the study.

7. Health based exposure limits at the workplace

7.1.1 2,3-epoxypropyl methacrylate (glycidyl methacrylate) (EC: 203-441-9; CAS: 106-91-2)

The Chair welcomed the representatives from the Government and Workers Interest Groups and of DG Employment Working Party on Chemicals. He informed that the Commission had

requested ECHA to evaluate **2,3-epoxypropyl methacrylate (glycidyl methacrylate),** in accordance with the Directive 2004/37/EC. The ECHA scientific report was open for comments from 26 January until 28 March 2023 and the deadline for this request is 22 February 2024.

The Rapporteurs presented and RAC discussed the first draft opinion on the scientific evaluation of limit values for glycidyl methacrylate (GMA).

RAC agreed with the assessment of glycidyl methacrylate (GMA), as proposed in the draft opinion:

OEL as 8-hour TWA:	None

RAC agreed to propose no BGV and BLV.

RAC agreed to propose a "Skin" notation and a "Skin Sensitisation" notation.

RAC agreed on the cancer exposure-risk relationship (ERR), as presented in the opinion, so based on a T25 approach on the peritoneal mesotheliomas in rats found in the inhalation study with GMA.

RAC agreed on the proposed/derived limit values based on the non-cancer endpoints; local nasal effects and reproductive (fertility) effects. There was agreement to add in text "The Binding OEL based on cancer risk would also protect from non-cancer effects, provided that the chosen value will not exceed 0.095 mg/m3 (0.16 ppm)".

The Rapporteurs were asked to finalise the discussion on the STEL in the opinion after RAC-65 (on which a final consultation will be organised by the Secretariat).

RAC adopted by consensus its opinion (with the modifications agreed at RAC-65).

Rapporteurs to revise the opinion in accordance with the agreed modifications in RAC-65 and to provide it to SECR.

SECR to organise a RAC consultation on the draft final RAC opinion after RAC-65.

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

The representative from the Government Interest Group and the COM representative commented on the ERR on the non-cancer effects. The representative from the Workers Interest Group commented on recommending STEL.

8. Harmonised classification and labelling (CLH)

8.1 General CHL issues

8.1.1 Report from the April CLH Working Group

The Secretariat presented the Report of the 9th Meeting of the Committee for Risk Assessment Applications for Classification and Labelling Working Group which took place on 24-28 April 2023. RAC took note of the Report.	

8.2 CLH dossiers

8.2.1 Hazard classes for agreement without plenary debate (A-list)

- **9-Octadecenoic acid (*Z*)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt:** *mutagenicity, carcinogenicity, reproductive toxicity*
- **2,3-epoxypropyl isopropyl ether:** *reproductive toxicity*
- **Tetrahydrofurfuryl methacrylate:** *skin sensitisation, reproductive toxicity, STOT RE*
- **Bixlozone (ISO):** *physical hazards, acute toxicity via all routes, skin irritation, eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, hazards to the aquatic environment*
- **Trimethyl phosphate:** *acute toxicity via oral and dermal routes, mutagenicity, carcinogenicity, reproductive toxicity, STOT RE*
- **Barium chromate:** *mutagenicity, carcinogenicity, reproductive toxicity*
- **3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate:** *acute toxicity, STOT SE, EUH071, skin irritation, eye irritation, skin sensitisation*
- **Folpet (ISO); N-(trichloromethylthio)phthalimide:** *acute toxicity, skin irritation, eye irritation, skin sensitisation, carcinogenicity, mutagenicity, reproductive toxicity, STOT SE, STOT RE, hazards to the aquatic environment*
- **2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]:** *physical hazards, acute toxicity, skin irritation, eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazard to the aquatic environment, hazards to the ozone layer*
- **1,1-dichloroethylene; vinylidene chloride:** *acute toxicity, eye irritation, carcinogenicity, STOT RE, hazards to the aquatic environment*
- **Fluoroethylene:** *mutagenicity, note D*
- **Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1:** *carcinogenicity*
- **Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide (HH) (EC: 289-699-3; CAS: 89997-63-7)/ Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents:** *STOT SE, STOT RE*

8.2.2. Hazard classes for agreement with plenary debate

8.2.2.1. Fluoroethylene (EC 200-832-6; CAS 75-02-5): *carcinogenicity*

The Chair welcomed the Dossier Submitter representative and informed that **fluoroethylene** has mainly been used in the production of polyvinylfluoride (PVF) and other fluoropolymers. The substance has no current Annex VI entry. The DS (FR) proposes to classify the substance as Muta 2; H341 and Carc. 1A; H350. Mutagenicity and carcinogenicity were the hazard classes open for comments in the consultation. The deadline for the adoption of an opinion is 31 January 2024.	
The Rapporteurs presented further relevant data to substantiate the read across from bromoethylene (as was agreed at RAC-65 CLH WG). RAC also took note of the legal advice on the use of read across data for classification of carcinogens. In a weight of evidence approach, RAC decided that read-across from chloroethylene as well as bromoethylene was appropriate and, in combination with the data on fluoroethylene itself, RAC concluded that classification of fluoroethylene as Carc. 1A; H350, is justified. RAC discussed the uncertainties on the applicability of the T25 concept to gases and using route to route extrapolation. It was agreed that the case may need scrutiny once the SCL Expert Group have come up with a revised proposal on GCL/SCL setting for carcinogens via the inhalation route. It was agreed to organize a final written consultation with RAC on the updated opinion after RAC-65 (and the Secretariat will organize a legal consultation on the updated opinion). RAC provisionally adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Muta. 2; H341, Carc. 1A; H350, Note D] In the absence of any legal obstacles, the opinion will be finally adopted by the Chair.	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **SECR** to organise a RAC consultation on the draft final RAC opinion after RAC-65. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
8.2.2.2. 1,1-dichloroethylene; vinylidene chloride (EC 200-864-0; CAS 75-35-4): *mutagenicity*	
The Chair welcomed the Dossier Submitter representative and informed that **vinylidene chloride (VDC)** is an industrial chemical, used as an intermediate in organic synthesis reactions	

and as a monomer in the production of a variety of polyvinylidene chloride copolymers. Theses copolymers of vinylidene chloride have a broad spectrum of applications in the plastic industry and the major application is the production of films for food packaging. They are also used in many types of packing materials, as flame retardant coatings for fiber and carpet backing, in piping, as coating for steel pipes and in adhesive applications. The substance has current Annex VI classification as Flam. Liq. 1; H224, Carc. 2; H351, Acute Tox. 4*; H332 and Note D. The DS (FR) proposes to retain Flam. Liq. 1; H224 and Note D, to modify Carc. 1B; H350 and Acute Tox. 1; H330 (ATE=0.5 mg/L (vapours)) and to add Muta. 2; H341, Acute Tox. 3; H301 (ATE=200 mg/kg bw), STOT RE 1; H372 (liver, kidney, respiratory tract) and Aquatic Chronic 3; H412. Acute oral and inhalation toxicity, serious eye damage/eye irritation, mutagenicity, carcinogenicity, STOT RE and hazardous to the aquatic environment were the hazard classes open for comments in the consultation. The deadline for the adoption of an opinion is 12 October 2023.	
Mutagenicity RAC took note of the presentation of additional study details requested from the Rapporteurs at RAC-65 CLH WG and confirmed Muta. 2; H341 classification. RAC adopted by consensus the opinion with a proposal for the harmonised classification and labelling as indicated in Table 1. [Flam. Liq. 1; H224, Acute Tox. 1; H330 (ATE=0.5 mg/L (vapours)), Acute Tox. 3; H301 (ATE=300 mg/kg bw), Carc. 1B; H350, Muta. 2; H341, STOT RE 1; H372 (respiratory tract, kidney, liver), Aquatic Chronic 3; H412]	**Rapporteurs** to revise the opinion in accordance with the discussion in RAC and to provide it to Secretariat. **Secretariat** to make an editorial check of the opinion documents in consultation with the Rapporteurs. **Secretariat** to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
9. Restrictions	
9.1 General restriction issues	
9.1.1. Report from the May Restriction Working Group	
RAC took note of the timings for the upcoming meetings of the Committee for Risk Assessment Working Group on restrictions to be held in August and November 2023. The RAC-65 Working Group on restrictions (10-11 May 2023) was cancelled.	
9.1.2. Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers and changes in the opinion template	

The Secretariat presented and RAC agreed on the revised working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers (in line with meeting document RAC/65/2023/02).	**SECR** to publish the updated working procedure on ECHA website.
9.2. Restriction Annex XV dossiers	
9.2.1. Key issues and recommendations to the DS	
9.2.1.1. Universal per- and polyfluoroalkyl substances (U-PFAS)– key issues and recommendations to the DS and the stakeholder statements	
The Chair welcomed the Dossier Submitter representatives from Denmark, Germany, the Netherlands, Norway and Sweden, as well as the occasional stakeholder observers from CHEM Trust, HEAL and EuChemS and the regular stakeholder observers together with their accompanying experts to Cefic, PlasticsEurope, Eurometaux, CropLife Europe and MedTech Europe. The dossier was submitted in January 2023 and proposes to restrict the manufacture, placing on the market and use of PFAS, i.e. universal PFAS (UPFAS). All uses of PFASs are covered by this restriction proposal except for the use of PFASs in fire-fighting foams, which is assessed in a separate restriction proposal.	
RAC took note of and discussed the key issues and recommendations to the Dossier Submitter.	**SECR** to forward the recommendations to the Dossier Submitter. **Rapporteurs** to prepare the first draft opinion focusing on hazard and food contact material and packaging for discussion at RAC-66 REST working group in August 2023 and at RAC-66. **Interested stakeholder observers** to submit additional information via the ongoing third-party consultation by 25 September 2023, and to follow the agendas on the ECHA website for the upcoming RAC working group and plenary meetings.
RAC took note of the oral position statements by the relevant stakeholder representatives participating in the meeting. The detailed written statements received are published in the annex of the RAC-65 minutes.	
9.2.2. Opinion development	
9.2.2.1. Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 – adoption of opinion	
The Chair welcomed the Dossier Submitter's representatives from ECHA, the occasional stakeholder from EuChemS as well as the accompanying expert to the Cefic regular stakeholder observer (Regnet). The dossier has been submitted in July 2022 and concerns restricting the manufacture, use and placing on the market of substances, mixtures and articles containing C14-17 chloroalkanes with PBT- and/or vPvB-properties.	

RAC rapporteur presented and RAC discussed the revised third draft opinion with changes made based on the comments provided by the members: <u>Uncertainties:</u> → RAC agrees with the uncertainties identified by the Dossier Submitter related to the tonnage and emissions (at all life cycle stages including the waste stage). → There are uncertainties regarding the RMMs in place and their effectiveness in minimising the risks for industrial uses and specifically in the formulation and use of metalworking fluids. → RAC considers that there are some uncertainties related to the hazards of the congeners identified with vP properties. RAC concludes that the uncertainties identified do not have a significant impact on the conclusions of RAC's evaluation. <u>Proposed restriction:</u> RAC supports the Restriction option A proposed by the Dossier Submitter with the following modifications: → RAC proposes that the substances identified as "other vP congeners" should also be included within the scope of the restriction proposal. → RAC supports the information requirements for suppliers in paragraph 7 but notes that the requirements should be triggered when the concentration of chloroalkanes within the scope of the restriction is equal to or greater than 0.1 % w/w. → This information requirement will apply for 18 months (from six months after the entry into force of the restriction to two years) and would support the effective implementation of the restriction by ensuring that the presence of chloroalkanes is known along the supply chain before their manufacture and use is banned.	**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.

RAC does not support the derogation for metalworking fluids identified in option B by the Dossier Submitter. Should the European Commission consider the derogation appropriate, the ban on manufacturing and formulation as defined in paragraphs 1a and 2 of Option A should enter into force, once the derogation for metalworking fluids has ended. RAC adopted its opinion by consensus (with modifications agreed at RAC-65).	
The expert accompanying the Cefic regular stakeholder observer commented on the uncertainties regarding the composition of the substances.	
10. Authorisation	
10.1. General authorisation issues	
10.1.1Report from the May AFA Working Group	
The Secretariat presented the Report of the 15th Meeting of the Committee for Risk Assessment Applications for Authorisation Working Group which took place on 3-4 May 2023. RAC took note of the Report.	
10.1.2 Update on incoming/future applications and horizontal issues	
The Secretariat presented update on AfA process: 1. AfAs and Review Reports pipeline 2. Opinion-making: streamlining 3. RAC Lines-To-Take (Chromates) • Sludge removal RAC discussed that manual operations should be limited as far as possible and that at least a feasibility study for automation/containment could be requested on a case-by-case basis. RAC discussed if a condition that only well-trained workers equipped with fit-for-purpose PPEs should be added by default in case such condition is not already fulfilled. • Use of liquid vs solid forms The Secretariat suggested to include in the standard text of Section 7.1 a reworded proposal for the feasibility study concerning the preparation of a liquid solution of CrO_3 to adjust the concentration of CrVI in baths. This feasibility study	**SECR** to consider adding information on sludge removal to the RAC Lines-To-Take. **SECR** to add to the RAC Lines-To-Take instruction how to express a ”negative opinion” and/or initiation relevant bodies to reduce workers exposure as soon as possible. For AfAs revealing unacceptable working conditions that need to be addressed urgently, **SECR** to develop a standard text to be included in the opinion text and in sections 1.3 and 7.2 of the justifications. **SECR** to update the RAC Lines-To-Take accordingly.

should focus on the replacement of solid flakes and could also involve the implementation of an automated system to prepare the solution. • Negative opinion RAC discussed when it should not recommend hard conditions as type of "negative opinion". RAC discussed how RAC/ECHA can more efficiently/quickly improve workers exposure in the worst cases identified under the authorisation process.	
10.2. Discussion on key issues	
10.2.1. 14 applications for authorisation (chromium trioxide and OPE) from Nov 2022 submission window	
RAC rapporteurs presented Key issues in 14 applications for authorisation (chromium trioxide and OPE) from Nov 2022 submission window.	**RAC members** to provide comments during RAC consultations on draft opinions.
10.3. Agreement on draft opinions	
10.3.1 Draft opinions for agreement with or without plenary debate (A-list)	
ECHA Secretariat presented the summary of the draft opinions for agreement without plenary debate (A-list): 1. 285_CT_Liebherr-Aerospace_Linden (2 uses) 2. 287_CT_Bacrom (1 use) 3. 288_CT_Leonardo (1 use) 4. 289_CT_Beretta (2 uses) 5. 290_CT_Fir-Italia (1 use) 6. 291_CT_Belloni (1 use) 7. 294_CT_Kludi (2 uses) 8. 295_CT_Ugitech (1 use) RAC agreed by consensus the 11 draft opinions on the Application listed in Annex IV.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinions. **SECR** to send the draft opinions to the applicants for commenting
10.3.2 Draft opinions for discussion and agreement with plenary debate	
286_CT_Hartchrom-Beck (4 uses)	
Use1: *Chromium trioxide-based functional chrome plating of axially/rotationally symmetrical components requiring optimal tribological surface properties (resulting from*	**Rapporteur** together with **SECR** to do the final editing of the draft opinions according to the discussion at the plenary.

microcracked surface) to ensure low surface friction under lubrication. **Use 2:** *Chromium trioxide-based functional chrome plating of axially/rotationally symmetrical components requiring high wear resistant surfaces to withstand abrasive forces occurring in their application.* **Use 3:** *Chromium trioxide-based functional chrome plating of components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring optimal tribological surface properties (resulting from microcracked surface) to ensure low surface friction under lubrication.* **Use 4:** *Chromium trioxide-based functional chrome plating of components with complex 3-dimensional geometry (not axially/rotationally symmetrical) requiring high wear resistant surfaces to withstand abrasive forces occurring in their application.* RAC discussed: - How RAC can inform in the opinion that the working place conditions are not acceptable. - RAC agreed to add in the opinion text, in section 1.3. *RAC's evaluation on the OCs and RMMs* and in section 7.2 that RAC considers that the working conditions in the sites covered by the application are not acceptable in terms of workers' health protection. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement without undue delay, technical improvements to the OCs and RMMs at the manual plating lines (e.g. automated systems to perform the dipping/immersion of the parts and sampling, bath coverage, use of mist suppressant and physical segregation), followed by a measurement campaign to validate the effectiveness of the applied technical improvements. The additional	**SECR** to send the draft opinions to the applicant for commenting.

OCs and RMMs shall be implemented within 12 months of the granting of an authorisation for this use. 2. Until the implementation of the additional OCs and RMMs, the applicant shall ensure that workers involved in chrome plating activities in the proximity of the baths, use appropriate and properly fit-tested RPE, with due consideration for the duration of the tasks and the comfort of the workers during their use. The applicants shall also use the results of Human Biomonitoring (see section 8.1) to validate the appropriateness and effectiveness of the RPEs. 3. Without prejudice to points 1 and 2 above, the applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by liquid solutions of CrO_3 (at 6 sites) to further limit exposure, (b) the implementation of an automated system to perform the bath concentration adjustment (at 8 sites), (c) the implementation of a closed/automated system to perform bath sampling tasks (at all sites), where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented all across the sites and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Non-standard point 7 7. The applicant shall continue their existing [annual] biomonitoring programme for the workers potentially exposed to Cr(VI). This programme must consist, as a minimum, of pre and post shift urine samples (beginning of the week --> end of the week), using valid existing standard methodologies such as e.g. HSE, HBM4EU.	

This annual biomonitoring program must be synchronised with the annual occupational air monitoring campaign specified in 1.a above. The results of the biomonitoring programme can be reported following the "Format for reporting of occupational exposure data by downstream users", in the respective Excel sheet for biomonitoring, as it can be found on the ECHA homepage. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the draft opinions by consensus.	
292_CT_Artech (1 use)	
Use1: *Industrial use of chromium trioxide for the functional chrome plating with decorative character of steel tubes and plates incorporated in machines for the agri-food industry, leisure, household furniture and automotive industries.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement, without delay technical improvements to the OCs/RMMs (e.g. improvement of the LEV functioning, covering the bath during the plating process) to minimize the Cr(VI) concentration nearby the plating bath and the glovebox. These shall be implemented within 12 months of the granting of an authorisation for this use and be followed by a measurement campaign to validate the effectiveness of the applied technical improvements. 2. The applicant shall ensure that workers perform a 'fit check' of the seal, of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately. 3. The applicant shall carry out and document	**Rapporteur** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicants for commenting.

a detailed feasibility study on: a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE; b) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s) in case the local exhaust ventilation is not functioning properly). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the draft opinion by consensus.	
293_CT_Talleres-Aykrom (1 use)	
Use1: *Industrial use of Chromium Trioxide in functional chrome plating of metallic pieces required in different industrial sectors such as corrugated rolls in order to meet hardness, wear resistance, corrosion resistance, good surface condition, low friction coefficient and coating adhesion requirements.* The STO representing ETUC expressed strong support to conclusions of RAC draft opinions clearly stating if the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk and that existing workplace conditions are not acceptable in terms of protection of workers' health. RAC requested the rapporteur to ensure that conditions/monitoring arrangements	**Rapporteur** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicants for commenting.

concerning the emission of wastewater are properly listed in relevant sections of the draft opinion. RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk and that existing workplace conditions are not acceptable in terms of protection of workers' health. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall implement the following technical measures within 12 months after the decision on the present authorisation case is taken: a) As an immediate priority, the installation of an effective LEV system (lip extraction) and an effective air abatement system connected to the LEV, to prevent uncontrolled releases of Cr(VI) to the air and to minimize releases into the environment is installed b) The installation of a system for covering of the baths when the plating process takes place and an effective LEV system (lip extraction) are installed c) The installation of an effective system that continuously controls correct functioning of the LEV and triggers an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s) in case the local exhaust ventilation is not functioning properly) is installed. 2. Show with appropriate measurements (see section 8.1) that these control measures are effective in minimizing the workers' exposure and the exposure of the general local population to Cr(VI) 3. Ensure that workers perform a 'fit check' of the seal of their RPE before performing relevant tasks with risk of Cr(VI) exposure and that workers are trained to perform this test adequately. 4. Carry out and document a detailed	

feasibility study: a. on the automation of the concentration adjustment of the baths using either solid or liquid CrO_3 within a closed system. b. on the implementation of an automated or closed system to perform the bath sampling. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. With additional biomonitoring arrangement in point 7 Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the draft opinion by consensus.	
296_CT_Mahle-2 (1 use)	
Use1: *Functional chrome plating of piston rods for shock absorbers for automotive applications.* RAC agreed that the rapporteur and the secretariat will edit Section 7.1 and align text Sections 1.3 and 7.2 according to the RAC discussion on the horizontal issues. 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. RAC agreed: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study for a. the substitution of solid CrO_3 flakes by liquid solutions of CrO_3 to further limit exposure under WCS 5 b. the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.	**Rapporteurs** together with **SECR** to do the final editing of the draft opinion according to the discussion at the plenary. **SECR** to send the draft opinion to the applicants for commenting.

c. the 4 day process of tank cleaning/desludging tasks performed under WCS 6, to implement additional measures to reduce further the exposure of workers, considering the hierarchy of control principles, such as improved cleaning practices to minimise the exposure to Cr(VI) (e.g., reduce it to Cr(III) before workers can enter/access the bath to remove the sludge and remaining liquid). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC agreed the draft opinion by consensus.	
10.4. Adoption of opinions	
261_CT_Metalbrass (1 use)	
Use1: *Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.* RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by liquid solutions of CrO_3 to further limit exposure, (b) the implementation of an automated system to perform the bath concentration	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinion by consensus.	
263_CT_Orelec (1 use)	
Use1: *Industrial use of chromium trioxide for the hard chrome plating of injection moulds in order to provide hardness, wear resistance and good demoulding properties, critical for the manufacture of high-quality plastic parts.* RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk. RAC agreed: Section 7: additional conditions for the authorisation The Applicant shall implement without delay increased local enclosure (with partially closed lid, during use) as described by the Applicant in response to questions from RAC on the feasibility of additional risk management measures of the bath to ensure that workers who are not performing activities directly associated with the bath (WCS 4), are protected from inhalation exposure. The applicant shall carry out and document a detailed feasibility study on segregation of the bath from the rest of the workshop or	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

segregation of other activities from the bath (i.e. other activities when the bath is in use) to further reduce inhalation exposure of workers. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, segregation to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and its effectiveness reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinion by consensus.	
265_TXP_EDF (2 uses)	
Use 1: *Industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines.* **Use2:** *Industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves.* RAC concluded that the risk assessment presented in the application demonstrates adequate control of risks from the use applied for, provided that the operational conditions and risk management measures described in the application are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation 1. The applicant shall continue the following occupational inhalation exposure monitoring programmes for TXP, which shall: (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to TXP	**SECR** to send the final opinions to the applicant, the European Commission and MS CAs.

(ii) be based on relevant standard methodologies or protocols (iii) ensure a sufficiently low limit of quantification (iv) comprise personal and/or static inhalation exposure sampling (v) be representative of: a. the full range and duration of tasks undertaken where exposure to TXP is possible b. the OCs and RMMs typical for each of these tasks c. the number of workers potentially exposed (vi) include contextual information about the tasks performed during sampling. 2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the OCs and RMMs in place and, if needed, to introduce measures to further reduce workplace exposure to TXP and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers. 3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles. 4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place. 5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of	

the Member State where the use takes place, that exposure of humans has been reduced to as low a level as technically and practically possible and that the OCs and RMMs corresponding to the specific exposure scenarios developed in the chemical safety report function appropriately. 6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues to be reduced to as low a level as technically and practically possible. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinions by consensus.	
267_CT_SPGPrints (1 use)	
Use1: *Use of Cr(VI) in an integrated process to create a hard surface with selective adhesion properties on mandrels used to manufacture screens for Rotary Screen Printing (RSP) for textile and other (printing) applications.* RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation None Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinion by consensus.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.

271_CT_Villeroy (1 use)	
Use1: *The use of chromium trioxide for electroplating of metal substrates with the purpose to create a long-lasting high durability surface with bright look for kitchen and bathroom sanitary ware.* RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by liquid solutions of CrO_3 to further limit exposure (at the FMMMG site); (b) the implementation of an automated system to perform the bath concentration adjustment (at the FMMMG site), and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE (at both sites). The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. No point 7 Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinion by consensus.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.
272_CT_RIGHI (1 use)	
Use1: *Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.*	

RAC concluded that the operational conditions and risk management measures described in the application are generally appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation The applicant shall carry out and document a detailed feasibility study on: (a) the substitution of solid CrO_3 by a liquid solution of CrO_3 to further limit exposure. (b) the implementation of an automated system to perform the bath concentration adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of RPE. The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. RAC adopted the final opinion by consensus.	**SECR** to send the final opinion to the applicant, the European Commission and MS CAs.
11. Drinking Water Directive	
11.1 Report from the June DWD Working Group	
The Secretariat presented an oral of the 1st Meeting of the Committee for Risk Assessment Applications for Drinking Water Directive Working Group which took place on 1-2 June 2023. RAC took note of the Report.	**SECR** to distribute the report and to publish on the ECHA website.
13. AOB	

13.1. Any other business – Introduction of new processes	
RAC took note of the presentation on the introduction of the potential new processes that may be transferred to ECHA in the future and which might involve RAC.	
14. Minutes of RAC-65	
14.1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-65	
RAC adopted the final minutes by consensus at the plenary meeting.	**SECR** to upload the table with Summary Record of the Proceedings and Conclusions and Action points from RAC-65 to CIRCA BC.

CLH opinions at RAC-65

1. 9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3]

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	9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3]	271-843-1 [1]; - [2]; 267-966-5 [3]	68609-93-8 [1]; - [2]; 67968-63-2 [3]	Repr. 1B	H360D	GHS08 Dgr	H360D			
RAC opinion	TBD	9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3]	271-843-1 [1]; - [2]; 267-966-5 [3]	68609-93-8 [1]; - [2]; 67968-63-2 [3]	Repr. 1B	H360D	GHS08 Dgr	H360D			
Resulting Annex VI entry if	TBD	9-Octadecenoic acid (Z)-, sulfonated, potassium salts [1];	271-843-1 [1]; - [2];	68609-93-8 [1]; - [2]; 67968-63-2 [3]	Repr. 1B	H360D	GHS08 Dgr	H360D			

agreed by COM		Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt [3]	267-966-5 [3]								

2. 2,3-epoxypropyl isopropyl ether

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	2,3-epoxypropyl isopropyl ether	223-672-9	4016-14-2	Repr. 1B	H360F	GHS08 Dgr	H360F			
RAC opinion	TBD	2,3-epoxypropyl isopropyl ether	223-672-9	4016-14-2	Repr. 1B	H360F	GHS08 Dgr	H360F			
Resulting Annex VI entry if agreed by COM	TBD	2,3-epoxypropyl isopropyl ether	223-672-9	4016-14-2	Repr. 1B	H360F	GHS08 Dgr	H360F			

3. Tetrahydrofurfuryl methacrylate

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	tetrahydrofurfuryl methacrylate	219-529-5	2455-24-5	Repr. 1B Skin Sens. 1A	H360FD H317	GHS08 GHS07 Dgr	H360FD H317			
RAC opinion	TBD	tetrahydrofurfuryl methacrylate	219-529-5	2455-24-5	Repr. 1B Skin Sens. 1A	H360Df H317	GHS08 GHS07 Dgr	H360Df H317			
Resulting Annex VI entry if agreed by COM	TBD	tetrahydrofurfuryl methacrylate	219-529-5	2455-24-5	Repr. 1B Skin Sens. 1A	H360Df H317	GHS08 GHS07 Dgr	H360Df H317			

4. Bixlozone (ISO);2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one

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

	Index No	Chemical name	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	TBD	bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	-	81777-95-9	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	
RAC opinion	TBD	bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	-	81777-95-9	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	bixlozone (ISO); 2-(2,4-dichlorobenzyl)-4,4-dimethyl-1,2-oxazolidin-3-one	-	81777-95-9	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410		M = 1 M = 10	

5. Trimethyl phosphate

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	trimethyl phosphate	208-144-8	512-56-1	Carc. 1B Muta. 1B Repr. 1B Acute Tox. 4 STOT RE 2	H350 H340 H360FD H302 H373 (nervous system)	GHS08 GHS07 Dgr	H350 H340 H360FD H302 H373 (nervous system)		oral: ATE = 1257 mg/kg bw	
RAC opinion	TBD	trimethyl phosphate	208-144-8	512-56-1	Carc. 1B Muta. 1B Repr. 1B Acute Tox. 4 STOT RE 2	H350 H340 H360FD H302 H373 (nervous system)	GHS08 GHS07 Dgr	H350 H340 H360FD H302 H373 (nervous system)		oral: ATE = 1300 mg/kg bw	
Resulting Annex VI entry if agreed by COM	TBD	trimethyl phosphate	208-144-8	512-56-1	Carc. 1B Muta. 1B Repr. 1B Acute Tox. 4 STOT RE 2	H350 H340 H360FD H302 H373 (nervous system)	GHS08 GHS07 Dgr	H350 H340 H360FD H302 H373 (nervous system)		oral: ATE = 1300 mg/kg bw	

6. Barium chromate

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	barium chromate	233-660-5	10294-40-3	Carc. 1B	H350	GHS08 Dgr	H350			
RAC opinion	TBD	barium chromate	233-660-5	10294-40-3	Carc. 1B	H350	GHS08 Dgr	H350			
Resulting Annex VI entry if agreed by COM	TBD	barium chromate	233-660-5	10294-40-3	Carc. 1B	H350	GHS08 Dgr	H350			

7. 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate

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	615-008-00-5	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate	223-861-6	4098-71-9	Acute Tox. 3* STOT SE 3 Skin Irrit. 2 Eye Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Chronic 2	H331 H335 H315 H319 H334 H317 H411	GHS06 GHS08 GHS09 Dgr	H331 H335 H315 H319 H334 H317 H411	-	Resp. Sens. 1; H334: C ≥ 0,5 % Skin Sens.1; H317: C ≥ 0,5 %	Note 2
Dossier submitters proposal	615-008-00-5	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate	223-861-6	4098-71-9	**Modify** Acute Tox. 1 Skin Corr. 1 Eye Dam. 1 Skin Sens. 1A **Remove** STOT SE 3	**Retain** H317 **Modify** H330 H314 H318 **Remove** H335	**Retain** GHS06 GHS08 GHS09 Dgr **Add** GHS05	**Retain** H317 **Modify** H330 H314 **Remove** H335	**Add** EUH071	**Add** inhalation: ATE = 0,031 mg/L (dusts or mists) **Modify** Skin Sens. 1A: H317: C ≥ 0,05 %	
RAC opinion	615-008-00-5 or TBD	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate	223-861-6	4098-71-9	**Modify** Acute Tox. 1 Skin Corr. 1 Eye Dam. 1 Skin Sens. 1A **Remove** STOT SE 3	**Retain** H317 **Modify** H330 H314 H318 H317 **Remove** H335	**Retain** GHS06 GHS08 GHS09 Dgr **Add** GHS05	**Retain** H317 **Modify** H330 H314	**Add** EUH071	**Add** inhalation: ATE = 0,03 mg/L (dusts or mists) **Modify** Skin Sens. 1A: H317: C ≥ 0,001 %	**Retain** Note 2
Resulting Annex VI entry if agreed by COM	615-008-00-5 or TBD	3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate	223-861-6	4098-71-9	Acute Tox. 1 Skin Corr. 1 Eye Dam. 1 Resp. Sens. 1 Skin Sens. 1A Aquatic Chronic 2	H330 H314 H318 H334 H317 H411	GHS06 GHS05 GHS08 GHS09 Dgr	H330 H314 H318 H334 H317 H411	EUH071	inhalation: ATE = 0,03 mg/L (dusts or mists) Resp. Sens. 1; H334: C ≥ 0,5 % Skin Sens. 1A; H317: C ≥ 0,001 %	Note 2

8. Folpet (ISO); *N*-(trichloromethylthio)phthalimide

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	613-045-00-1	folpet (ISO); *N*-(trichloromethylthio)phthalimide	205-088-6	133-07-3	Carc. 2 Acute Tox. 4 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1	H351 H332 H319 H317 H400	GHS08 GHS07 GHS09 Wng	H351 H332 H319 H317 H400		M = 10	
Dossier submitters proposal	613-045-00-1	folpet (ISO); *N*-(trichloromethylthio)phthalimide	205-088-6	133-07-3	**Retain** Carc. 2 Aquatic Acute 1 **Add** STOT RE 1 Skin Irrit. 2 Aquatic Chronic 1 **Modify** Acute Tox. 2 Eye Dam. 1 Skin Sens. 1A	**Retain** H351 H400 **Add** H372 H315 H410 **Modify** H330 H318	**Retain** GHS08 GHS09 **Add** GHS05 GHS06 **Modify** Dgr **Remove** GHS07	**Retain** H351 H317 **Add** H372 H315 **Modify** H330 H318 H410		**Retain** M = 10 **Add** inhalation: ATE = 0,39 mg/L (dusts or mists) Skin Sens.: C ≥ 0,001 % M = 1	
RAC opinion	613-045-00-1	folpet (ISO); *N*-(trichloromethylthio)phthalimide	205-088-6	133-07-3	**Retain** Carc. 2 Aquatic Acute 1 **Add** STOT RE 1 Aquatic Chronic 1 **Modify** Acute Tox. 2 Eye Dam. 1 Skin Sens. 1A	**Retain** H351 H317 H400 **Add** H372 (respiratory tract) H410 **Modify** H330 H318	**Retain** GHS08 GHS09 **Add** GHS05 GHS06 **Modify** Dgr **Remove** GHS07	**Retain** H351 H317 **Add** H372 (respiratory tract) **Modify** H330 H318 H410	**Add** EUH066	**Retain** M = 10 **Add** inhalation: ATE = 0,30 mg/L (dusts or mists) STOT RE 1: C ≥ 5 % STOT RE 2: 1 % ≤ C < 5 % Skin Sens. 1A; H317: C ≥ 0,001 % M = 10	
Resulting Annex VI entry	613-045-00-1	folpet (ISO); *N*-(trichloromethylthio)phthalimide	205-088-6	133-07-3	Carc. 2 Acute Tox. 2 STOT RE 1	H351 H330	GHS08 GHS06 GHS05	H351 H330	EUH066	inhalation: ATE = 0,30 mg/L (dusts or mists)	

if agreed by COM					Eye Dam. 1 Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H372 (respiratory tract) H318 H317 H400 H410	GHS09 Dgr	H372 (respiratory tract) H318 H317 H410		STOT RE 1: C ≥ 5 % STOT RE 2: 1 % ≤ C < 5 % Skin Sens. 1A; H317: C ≥ 0,001% M = 10 M = 10	

9. 2-bromo-2-(bromomethyl)pentanedinitrile [DBDCB]

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	2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]	252-681-0	35691-65-7	Acute Tox. 2 Acute Tox. 4 Eye Dam. 1 Skin Sens. 1 Aquatic Chronic 2	H330 H302 H318 H317 H411	GHS06 GHS05 GHS09 Dgr	H330 H302 H318 H317 H411			
RAC opinion	TBD	2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]	252-681-0	35691-65-7	Acute Tox. 2 Acute Tox. 4 STOT RE 2 Eye Dam. 1 Skin Sens. 1A Aquatic Chronic 2	H330 H302 H373 (thyroid, central nervous system) H318 H317 H411	GHS06 GHS08 GHS05 GHS09 Dgr	H330 H302 H373 (thyroid, central nervous system) H318 H317 H411		inhalation: ATE = 0,27 mg/L oral: ATE = 500 mg/kg bw Skin Sens. 1A; H317: C ≥ 0,001 %	
Resulting Annex VI entry if agreed by COM	TBD	2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]	252-681-0	35691-65-7	Acute Tox. 2 Acute Tox. 4 STOT RE 2 Eye Dam. 1 Skin Sens. 1A Aquatic Chronic 2	H330 H302 H373 (thyroid, central nervous system) H318 H317 H411	GHS06 GHS08 GHS05 GHS09 Dgr	H330 H302 H373 (thyroid, central nervous system) H318 H317 H411		inhalation: ATE = 0,27 mg/L oral: ATE = 500 mg/kg bw Skin Sens. 1A; H317: C ≥ 0,001 %	

10. 1,1-dichloroethylene; vinylidene chloride

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	602-025-00-8	1,1-dichloroethylene; vinylidene chloride	200-864-0	75-35-4	Flam. Liq. 1 Carc. 2 Acute Tox. 4*	H224 H351 H332	GHS02 GHS08 GHS07 Dgr	H224 H351 H332			D
Dossier submitters proposal	602-025-00-8	1,1-dichloroethylene; vinylidene chloride	200-864-0	75-35-4	**Retain** Flam. Liq. 1 **Modify** Carc. 1B Acute Tox. 1 **Add** Muta. 2 Acute Tox. 3 STOT RE 1 Aquatic Chronic 3	**Retain** H224 **Modify** H350 H330 **Add** H341 H301 H372 (respiratory tract, kidney, liver) H412	**Retain** GHS02 GHS08 Dgr **Add** GHS06 **Remove** GHS07	**Retain** H224 **Modify** H350 H330 **Add** H341 H301 H372 (respiratory tract, kidney, liver) H412		**Add** inhalation: ATE = 0,5 mg/L (vapours) oral: ATE = 200 mg/kg bw	**Retain** D
RAC opinion	602-025-00-8	1,1-dichloroethylene; vinylidene chloride	200-864-0	75-35-4	**Retain** Flam. Liq. 1 **Modify** Carc. 1B Acute Tox. 1 **Add** Muta. 2 Acute Tox. 3 STOT RE 1 Aquatic Chronic 3	**Retain** H224 **Modify** H350 H330 **Add** H341 H301 H372 (respiratory tract, kidney, liver) H412	**Retain** GHS02 GHS08 Dgr **Add** GHS06 **Remove** GHS07	**Retain** H224 **Modify** H350 H330 **Add** H341 H301 H372 (respiratory tract, kidney, liver) H412		**Add** inhalation: ATE = 0,5 mg/L (vapours) oral: ATE = 300 mg/kg bw	**Retain** D
Resulting Annex VI entry if agreed by COM	602-025-00-8	1,1-dichloroethylene; vinylidene chloride	200-864-0	75-35-4	Flam. Liq. 1 Carc. 1B Muta. 2 Acute Tox. 1 Acute Tox. 3	H224 H350 H341 H330 H301	GHS02 GHS08 GHS06 Dgr	H224 H350 H341 H330 H301		inhalation: ATE = 0,5 mg/L (vapours)	D

					STOT RE 1 Aquatic Chronic 3	H372 (respiratory tract, kidney, liver) H412		H372 (respiratory tract, kidney, liver) H412		oral: ATE = 300 mg/kg bw	

11. Fluoroethylene

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	fluoroethylene	200-832-6	75-02-5	Carc. 1A Muta. 2	H350 H341	GHS08 Dgr	H350 H341			
RAC opinion	TBD	fluoroethylene	200-832-6	75-02-5	Carc. 1A Muta. 2	H350 H341	GHS08 Dgr	H350 H341			D
Resulting Annex VI entry if agreed by COM	TBD	fluoroethylene	200-832-6	75-02-5	Carc. 1A Muta. 2	H350 H341	GHS08 Dgr	H350 H341			D

12. Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]

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	barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]	225-935-3	5160-02-1	Carc. 2	H351	GHS08 Wng	H351			
RAC opinion	TBD	barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]	225-935-3	5160-02-1	Carc. 2	H351	GHS08 Wng	H351			
Resulting Annex VI entry if agreed by COM	TBD	barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]	225-935-3	5160-02-1	Carc. 2	H351	GHS08 Wng	H351			

13. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2

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	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2	289-699-3	89997-63-7	Acute Tox. 4 Acute Tox. 4 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H317 H400 H410	GHS07 GHS09 Wng	H332 H302 H317 H410		inhalation: ATE = 2,5 mg/L (dusts or mists) oral: ATE = 700 mg/kg bw M = 100 M = 10	
RAC opinion	TBD	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2	289-699-3	89997-63-7	Acute Tox. 4 Acute Tox. 4 STOT SE 1 STOT RE 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H400 H410	GHS07 GHS08 GHS09 Dgr	H332 H302 H317 H370 (nervous system) H373 (respiratory tract) (inhalation) H410		inhalation: ATE = 2,5 mg/L (dusts or mists) oral: ATE = 700 mg/kg bw M = 100 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical CO_2	289-699-3	89997-63-7	Acute Tox. 4 Acute Tox. 4 STOT SE 1 STOT RE 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H400 H410	GHS07 GHS08 GHS09 Dgr	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H410		inhalation: ATE = 2,5 mg/L (dusts or mists) oral: ATE = 700 mg/kg bw M = 100 M = 10	

14. *Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvent

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	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvent	289-699-3	89997-63-7	Acute Tox. 4 Acute Tox. 4 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H317 H400 H410	GHS07 GHS09 Wng	H332 H302 H317 H410		inhalation: ATE = 2,5 mg/L (dusts or mists) oral: ATE = 700 mg/kg bw M = 100 M = 10	
RAC opinion	TBD	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvent	289-699-3	89997-63-7	Acute Tox. 4 Acute Tox. 4 STOT SE 1 STOT RE 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H400 H410	GHS07 GHS08GHS09 Dgr	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H410		inhalation: ATE = 2,5 mg/L (dusts or mists) oral: ATE = 700 mg/kg bw M = 100 M = 10	
Resulting Annex VI entry if agreed by COM	TBD	*Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvent	289-699-3	89997-63-7	Acute Tox. 4 Acute Tox. 4 STOT SE 1 STOT RE 2 Skin Sens. 1B Aquatic Acute 1 Aquatic Chronic 1	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H400 H410	GHS07 GHS08 GHS09 Dgr	H332 H302 H370 (nervous system) H373 (respiratory tract) (inhalation) H317 H410		inhalation: ATE = 2,5 mg/L (dusts or mists) oral: ATE = 700 mg/kg bw M = 100 M = 10	

Part III. List of Attendees of the RAC-65 meeting

RAC members	
Aquilina	Gabriele
Angeli	Karine
Baranski	Boguslaw
Biró	Anna
Brovkina	Julija
Chiurtu	Elena-Ruxandra
Christodoulou	Sotirios
Deviller	Genevieve
Doak	Malcolm
Docea	Anca Oana
Esposito	Dania
Facchin	Manuel
Geoffroy	Laure
Ginnity	Bridget
Hakkert	Betty
Hartwig	Andrea
Kadiķis	Normunds
Karadjova	Irina
Leinonen	Riitta
Losert	Annemarie
Lund	Bert-Ove
Martinek	Michal
Menard Srpčič	Anja
Mendas Starcevic	Gordana
Moeller	Ruth
Mohammed	Ifthekhar Ali
Moldov	Raili
Murray	Brendan
Neumann	Michael
Peczkowska	Beata
Piña	Benjamin
Pribu	Mihaela
Rakkestad	Kirsten Eline
Rodriguez	Wendy
Santonen	Tiina
Schlüter	Urs
Schulte	Agnes
Schuur	Gerlienke
Sørensen	Peter Hammer
Spetseris	Nikolaos
Tekpli	Nina Landvik
Tobiassen	Lea Stine
Užomeckas	Žilvinas
van der Haar	Rudolf
Varnai	Veda Marija
Viegas	Susana

Apologies RAC members	
Fernández	Mariana F.

Members' advisers		
		Nominated by
Beestra	Renske	Hakkert Betty and Schuur Gerlienke
Capolupo	Marco	Esposito Dania
Hoffmann	Frauke	Schulte Agnes
Liadakis	Georgios	Tsitsimpikou Christina
Marinkovic	Marino	Hakkert Betty
Moilanen	Marianne	Leinonen Riitta
Rehrl	Anna-Lena	Facchin Manuel
Russo	Maria Teresa	Aquilina Gabriele
Saksa	Jana	Moldov Raili
Stalter	Daniel	Schulte Agnes
Suutari	Tiina	Leinonen Riitta

SEAC Rapporteurs		
Cogen	Simon	UPFAS
Fankhauser	Simone	UPFAS

Invited experts		**Role/Substance**
Dubois	Celine	Replacing RAC member Karin Angeli 5-7 June
Levy	Patrick	WPC, Government Interest group (OELs)
Manusadzianas	Levonas	New RAC member nominee
Musu	Tony	WPC, Workers Interest group (OELs)
Saarikoski	Sirkku	WPC, Government Interest group (OELs)
Scazzola	Roberto	RAC Chair (starting 16 June)

Dossier submitters		**Substance**
August	Christina	(DE) - UPFAS
Baumbusch	Angelika	(NO) - UPFAS
Borg	Daniel	(SE) - UPFAS
Charles	Sandrine	(FR) – VDC
Dannenberg	Carl	(DE) - UPFAS
De Blaeij	Arianne	(NL) - UPFAS
De Kort	Thijs	(NL) – UPFAS
Deweird	Juliette	(FR) - VDC
Drost	Wiebke	(DE) - UPFAS
Heggelund	Audun	(NO) – UPFAS
Ivarsson	Jenny	(SE) – UPFAS
Johansson	Tommy	(SE) – UPFAS
Kupprat	Franziska	(DE) – UPFAS
Nielsen Juhl	Peter	(DK) - UPFAS
Sanders	Marion	(DE) - UPFAS
Sehbar	Khalaf	(DK) - UPFAS

Regular stakeholder observers		
Barry	Frank	ETUC
Di Caprio	Elisabetta	Concawe
De Backer	Liisi	Cefic - CLH
Duguy	Hélène	ClientEarth
Hermann	Christine	EEB
Robin	Nicolas	PlasticsEurope - UPFAS
Robinson	Jan	AISE
Romano Mozo	Dolores	EEB
Ruelens	Paul	CropLife Europe
Santos	Roumiana	MedTech Europe
Van de Broeck	Steven	Cefic – restriction and AFA
Verougstraete	Violaine	Eurometaux

Occasional stakeholders		**Substance**
Cingotti	Natacha (HEAL)	UPFAS
Glüge	Juliane (EuChemS)	UPFAS, MCCP
Loebel	Oliver (EurEau)	DWD WG report
Schneider	Julie (CHEM Trust)	UPFAS

Stakeholder experts		**Substance**
Barber	David (CropLife Europe)	UPFAS
Bock	Ronald (PlasticsEurope)	UPFAS
Consoli	Elisa (Eurometaux)	UPFAS
Dekant	Wolfgang (Cefic)	Art 77(3)c Silanamine
Henry	Barbara (MedTech Europe)	UPFAS
Jaques	Henry (Cefic)	MCCP
Nödler	Karsten (EurEau)	DWD WG report
Prieto	Miguel (Cefic)	DWD WG report
Van Wely	Eric (Cefic)	UPFAS

European Commission		**DG**
Beekman	Martijn	DG GROW
Bertato	Valentina	DG ENV
Heras-Palomar	Nerea	DG EMPL (OELs)
Morris	Alick	DG EMPL (OELs)
Pedersen	Finn	DG ENV
Roebben	Gert	DG GROW
EU Agency Observers		
Lopez-Galvez	Gloria	EFSA

ECHA staff	
Ahtiainen	Heini
Alami-Eerikinharju	Wafa
Barnewitz	Greta
Bercaru	Ofelia
Bowmer	Tim (Chair)
Broere	William
Cornú	Catherine
De la Flor	Ignacio
Di Bastiano	Augusto
Doyle	Simone
Gmeinder	Michael
Hammer	Jort
Hautamäki	Anne
Hellsten	Kati
Henricsson	Sanna
Hoffstadt	Laurence
Karjalainen	Ari
Kokkola	Leila
Lazic	Nina
Lisboa	Patricia
Lefevre	Sandrine
Ludborzs	Arnis
Marquez-Camacho	Mercedes
Mäkelä	Petteri
Nygren	Jonas
Nyman	Anna-Maija
Orispää	Katja
O'Rourke	Regina
Pillet	Monique
Prevodouros	Kostas
Regil	Pablo
Ryan	Paul
Sadam	Diana
Salo	Marta
Sosnowski	Piotr
van Broekhuizen	Fleur
Wilk	Mateusz
Zarogiannis	Panos
Zeiger	Bastian

List of Attendees of the Joint RAC and SCCS symposium on Wednesday 7 June

Bernauer	Ulrike	SCCS
Bodin	Laurent	SCCS
Chaudhry Mohammad	Qasim (Chair)	SCCS
Coenraads	Pieter-Jan (Vice-Chair)	SCCS
Dusinska	Maria	SCCS
Ezendam	Janine	SCCS
Gaffet	Eric	SCCS
Galli	Corrado Lodovico	SCCS
Panteri	Eirini	SCCS
Rogiers	Vera (Vice Chair)	SCCS
Rousselle	Christophe	SCCS
Stępnik	Maciej Marek	SCCS
Vanhaecke	Tamara Alida R	SCCS
Wijnhoven	Susanne Wilhelmina Petronella	SCCS
Kratke	Renate	SCCS/ SCHEER
Manikas	Rizos-Georgios	DG GROW
Grenier	Natacha	DG GROW
Herold	Diana	DG GROW
Meroni	Donata Angela	DG GROW

Part III. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-65 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-65 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-65 meeting

ANNEX IV List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-65 meeting without plenary debate (A-list)

ANNEX V RAC-SCCS joint symposium - Agenda

5 June 2023
RAC/A/65/2023

Final Agenda
65th meeting of the Committee for Risk Assessment
(RAC-65)

5-8 June 2023

Face-to-face meeting[1]

Monday, 5 June starts at 14.00
Thursday, 8 June ends at 18.00

Times are Helsinki times

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

RAC/A/65/2023
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 – Work plan

5.1 RAC Work Plan for all processes

For information

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

6.1 Article 77(3)(c) request on Silanamine (SAS-HMDS): review of the acute toxicity classification of Silanamine as adopted by RAC in its opinion of 5 December 2019.

For adoption

[1] Members are expected to attend in person.

Item 7 –Health based exposure limits at the workplace

7.1 Opinions for discussion

1. 2,3-epoxypropyl methacrylate (glycidyl methacrylate) (EC: 203-441-9; CAS: 106-91-2)

For discussion

Item 8 – Harmonised classification and labelling (CLH)

8.2 General CHL issues

1. Report from the April CLH Working Group

RAC/65/2023/01
For information

8.3 CLH dossiers

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

- **9-Octadecenoic acid (*Z*)-, sulfonated, potassium salts [1]; Reaction products of fatty acids, C18 (unsaturated) alkyl with sulfur trioxide, potassium salts [2]; 9(or 10)-sulphooctadecanoic acid, potassium salt:** *mutagenicity, carcinogenicity, reproductive toxicity*
- **2,3-epoxypropyl isopropyl ether:** *reproductive toxicity*
- **Tetrahydrofurfuryl methacrylate:** *skin sensitisation, reproductive toxicity, STOT RE*
- **Bixlozone (ISO):** *physical hazards, acute toxicity via all routes, skin irritation, eye irritation, skin sensitisation, STOT SE, STOT RE, mutagenicity, carcinogenicity, reproductive toxicity, hazards to the aquatic environment*
- **Trimethyl phosphate:** *acute toxicity via oral and dermal routes, mutagenicity, carcinogenicity, reproductive toxicity, STOT RE*
- **Barium chromate:** *mutagenicity, carcinogenicity, reproductive toxicity*
- **3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate; isophorone di-isocyanate:** *acute toxicity, STOT SE, EUH071, skin irritation, eye irritation, skin sensitisation*
- **Folpet (ISO); N-(trichloromethylthio)phthalimide:** *acute toxicity, skin irritation, eye irritation, skin sensitisation, carcinogenicity, mutagenicity, reproductive toxicity, STOT SE, STOT RE, hazards to the aquatic environment*
- **2-bromo-2-(bromomethyl)pentanedinitrile; [DBDCB]:** *physical hazards, acute toxicity, skin irritation, eye irritation, respiratory sensitisation, skin sensitisation, mutagenicity, carcinogenicity, reproductive toxicity, STOT SE, STOT RE, hazard to the aquatic environment, hazards to the ozone layer*
- **1,1-dichloroethylene; vinylidene chloride:** *acute toxicity, eye irritation, carcinogenicity, STOT RE, hazards to the aquatic enviornment*
- **Fluoroethylene:** *mutagenicity, note D*
- **Barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]; C.I. Pigment Red 53:1:** *carcinogenicity*
- **Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbon dioxide (HH) (EC: 289-699-3; CAS: 89997-63-7)/ Chrysanthemum cinerariaefolium, extract from open and mature**

flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents: *STOT SE, STOT RE*

2. Hazard classes for agreement with plenary debate

1. **Fluoroethylene** (EC 200-832-6; CAS 75-02-5): *carcinogenicity*
2. **1,1-dichloroethylene; vinylidene chloride** (EC 200-864-0; CAS 75-35-4): *mutagenicity*

For discussion and adoption

Item 9 – Restrictions

9.1 General restriction issues

1. Report from the May Restriction Working Group

For information

2. Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers and changes in the opinion template

RAC/65/2023/02
For information and agreement

9.2 Restriction Annex XV dossiers

1. Key issues and recommendations to the DS
   1. Universal per- and polyfluoroalkyl substances (U-PFAS)– key issues and recommendations to the DS
      - stakeholder statements

For discussion

2. Opinion development

   1. Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 – adoption of opinion

For discussion and adoption

   2. BPA+ - ***not*** *for discussion at RAC-65*
   3. Creosote, and creosote related substances – ***not*** *for discussion at RAC-65*

Item 10 – Authorisation

10.1 General authorisation issues

1. Report from the May AFA Working Group

RAC/65/2023/03
For information

2. Update on incoming/future applications and horizontal issues

For information/discussion

10.2 Authorisation applications

1. Discussion on key issues

1. 14 applications for authorisation (chromium trioxide and OPE) from Nov 2022 submission window

For discussion

10.3 Agreement on draft opinions

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

9. 285_CT_Liebherr-Aerospace_Linden (2 uses)
10. 287_CT_Bacrom (1 use)
11. 288_CT_Leonardo (1 use)
12. 289_CT_Beretta (2 uses)
13. 290_CT_Fir-Italia (1 use)
14. 291_CT_Belloni (1 use)
15. 294_CT_Kludi (2 uses)
16. 295_CT_Ugitech (1 use)

For agreement

2. Draft opinions for agreement with plenary debate

1. 286_CT_Hartchrom-Beck (4 uses)
2. 292_CT_Artech (1 use)
3. 293_CT_Talleres-Aykrom (1 use)
4. 296_CT_Mahle-2 (1 use)

For discussion and agreement

10.4 Adoption of opinions

1. 261_CT_Metalbrass (1 use)
2. 263_CT_Orelec (1 use)
3. 265_TXP_EDF (2 uses)
4. 267_CT_SPGPrints (1 use)
5. 271_CT_Villeroy (1 use)
6. 272_CT_RIGHI (1 use)

For discussion and adoption

Item 11 – Drinking Water Directive

1. Report from the June DWD Working Group

For information

Item 12 – Joint RAC and SCCS symposium

RAC/65/2023/04
For information

Item 13 – AOB

1. Introduction of new processes

Item 14 – Minutes of RAC-65

1. Table with Summary Record of the Proceedings, and Conclusions and Action points from RAC-65

For adoption

Annex II

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-65 meeting.

RAC/A/65/2023	RAC-65 final Draft Agenda
RAC/65/2023/01	General CHL issues: Report from the April CLH Working Group
RAC/65/2023/02	Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers and changes in the opinion template
RAC/65/2023/03	General authorisation issues: Report from the May AFA Working Group
RAC/65/2023/04	Joint RAC and SCCS symposium Agenda

ANNEX III

The following participants, including those for whom the Chairman declared the interest on their behalf, declared potential conflicts of interest with the Agenda items (according to Art 9 (2) of RAC RoPs)

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
ALREADY DECLARED AT PREVIOUS RAC PLENARY MEETING(S)		
Applications for Authorisation		
All chromates	Urs SCHLUTER	Institutional & personal involvement; asked to refrain from voting in the event of a vote on this group of substances - other mitigation measures may be applied by the Chairman.
Harmonised classification & labelling		
1) ***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with supercritical carbon dioxide** 2) ***Chrysanthemum cinerariaefolium*, extract from open and mature flowers of *Tanacetum cinerariifolium* obtained with hydrocarbon solvents** **ES**	Marieta FERNANDEZ	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.
	Benjamin PINA	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.
Restrictions		
Universal PFAS **DE**	Michael NEUMANN Urs SCHLUETER	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.
DE	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		voting in the event of a vote on this substance - no other mitigation measures applied.
DK	Peter Hammer SOERENSEN 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. No personal involvement.
NL	Betty HAKKERT 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.
NO	Kirsten Eline RAKKESTAD Nina TEKPLI	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
SE	Bert-Ove LUND Ifthekhar Ali MOHAMMED	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.
BPA+ **DE**	Agnes SCHULTE Urs SCHLUETER 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.
Creosote, and Creosote related substances **FR**	Karine ANGELI 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.
Harmonised classification & labelling		

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
1) **Bixlozone (ISO)** 2) **Barium chromate** 3) **9-Octadecenoic acid (*Z*)-, sulfonated, potassium salts** **NL**	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.
	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.
1) **Isophorone di-isocyanate** 2) **C.I. Pigment Red 53:1** **DE**	Agnes SCHULTE	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. Personal involvement.
	Michael NEUMANN	Working for the CA submitting the dossier; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	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.
1) **Fluoroethylene** 2) **Vinylidene chloride** **FR**	Karine ANGELI	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

AP/Dossier / DS	RAC Member	Reason for potential CoI / Working for
		measures applied. No personal involvement.
1) **Tetrahydrofurfuryl methacrylate** 2) **Trimethyl phosphate** 3) **Folpet (ISO)** **AT**	Annemarie LOSERT	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.
	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.
2-bromo-2-(bromomethyl)pentane dinitrile; [DBDCB] **CZ**	Michal MARTINEK	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.
2,3-epoxypropyl isopropyl ether **SE**	Bert-Ove LUND	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
	Ifthekhar Ali MOHAMMED	Working for the CA submitting the dossiers; asked to refrain from voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.

Annex IV

Table 1. List of Draft opinions on AFAs agreed by the Committee for Risk Assessment at the RAC-65 meeting without plenary debate (A-list).

Conclusions / agreements / adoptions
285_CT_Liebherr-Aerospace_Linden (2 uses) **Use1:** *Industrial use of chromium trioxide for functional chrome plating of actuation and landing gear systems for the aviation industry.* RAC concluded that the operational conditions and risk management measures described in the draft opinion are appropriate and effective in limiting the risk, provided that they are implemented and adhered to. RAC agreed: Section 7: additional conditions for the authorisation 1. The applicant shall ensure that appropriate RPE is worn during baths sampling (WCS 5.1), due to the potential for exposure to Cr(VI). The use of RPE could stop if the task starts being performed with an automated system or closed sampling system. 2. The applicant shall ensure that workers perform a 'fit check' of the seal of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately. 3. The applicant shall carry out and document a detailed feasibility study on: a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure; b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen. the installation of a system that triggers automatically appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly).The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period. Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2. Section 9: recommendations for the review report as given in Annex IV Table 2. **Use2:** *Industrial use of chromium trioxide for surface treatment of aluminium alloys for applications in the aerospace industries unrelated to functional chrome plating.*

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to workers.
RAC concluded that the OCs and RMMs related to environmental release minimisation are appropriate and effective in limiting the risk to the general population via the environment.

RAC agreed:
Section 7: additional conditions for the authorisation

1. The applicant shall implement without undue delay, technical improvements to the OCs and RMMs at the manual plating lines as well as during weighing of solid CrO_3 and surface treatment of aluminium alloys by brushing or pen-stick, within 12 months of the granting of an authorisation for this use, followed by a measurement campaign to validate the effectiveness of the applied technical improvements.
2. Until the implementation of the additional OCs and RMMs, the applicant shall ensure that workers involved in surface treatment activities (manual plating line and manual brushing) use appropriate RPE, with due consideration for the duration of the tasks and the comfort of the workers during their use.
3. The applicant shall ensure that appropriate RPE is worn during bath sampling due to the increased potential for exposure to CrO_3. The use of RPE could stop if the task starts being performed with an automated system or closed sampling system.
4. The applicant shall ensure that workers perform a 'fit check' of the seal of their RPE before taking on relevant tasks and workers shall be trained to do this test adequately.
5. Without prejudice to points 1, 2, 3 and 4 above, the applicant shall carry out and document a detailed feasibility study on:
    - the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure;
    - the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen; the installation of a system that triggers automatically appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly).

   The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.
Section 9: recommendations for the review report as given in Annex IV Table 2.

287_CT_Bacrom (1 use)

Use1: *Industrial use of chromium trioxide for the hard plating of various end-products made of steel for the industry manufacturers to provide hardness, corrosion resistance, low friction coefficient, good surface roughness, thickness, and excellent surface condition.*

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to workers.
RAC concluded that the OCs and RMMs related to environmental release minimisation are appropriate and effective in limiting the risk to the general population via the environment.

RAC agreed:
Section 7: additional conditions for the authorisation

1. The applicant shall implement without delay additional OCs and RMMs to reduce the manual intervention for some of the activities near the plating bath (i.e. dipping/immersion of the parts and removal operations in chromium and rinsing baths), to minimise the exposure to Cr(VI) and to eliminate the over-reliance on RPE.
2. The applicant shall implement as planned, the segregation of the loading/unloading area.
3. Without prejudice to point 1 above, the applicant shall carry out and document a detailed feasibility study on:
   (a) the substitution of solid CrO_3 by a liquid solution of CrO_3 to further limit exposure;
   (b) the implementation of an automated system to perform bath concentration adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE;
   (c) the installation of a system that triggers automatically appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s), in case the local exhaust ventilation is not functioning properly).

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use.
In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.
Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.
Section 9: recommendations for the review report as given in Annex IV Table 2.

288_CT_Leonardo (1 use)

Use1: *Functional chrome plating of military gun barrels and outer jacket surfaces using chromium trioxide.*

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

RAC agreed:
Section 7: additional conditions for the authorisation
The applicant shall carry out and document a detailed feasibility study on:

(a) the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use.

In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

289_CT_Beretta (2 uses)

Use1: *Chromium trioxide based functional plating of gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses.*
Use2: *The use of Chromium trioxide based functional chrome plating of gun barrel bores and auxiliary parts for semi-automatic shotguns, over/under, side-by-side shotguns, pistols and carbines for civilian uses.*

RAC concluded that the operational conditions and risk management measures described in the application are appropriate and effective in limiting the risk to workers and general population, provided that they are adhered to.

RAC agreed:

Section 7: additional conditions for the authorisation

1. The applicant shall ensure that appropriate RPE is worn during baths sampling (WCS 6), due to the potential for exposure to Cr(VI).

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

290_CT_Fir-Italia (1 use)

Use1: *Industrial use of chromium trioxide for the functional chrome plating with decorative character of items for the hydrosanitary sector.*

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

RAC agreed:

Section 7: additional conditions for the authorisation

The applicant shall carry out and document a detailed feasibility study on:

(a) the substitution of solid CrO_3 with a liquid solution of CrO_3 to further limit the exposure

(b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE"

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use.

In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.

No point 7

Section 9: recommendations for the review report as given in Annex IV Table 2.

291_CT_Belloni (1 use)

Use1: *Industrial use of chromium trioxide for the plating of coffee machine parts in contact with water and food.*

RAC concluded that the operational conditions and risk management measures described in the application are not appropriate and effective in limiting the risk to workers.

RAC agreed:

Section 7: additional conditions for the authorisation

1. The applicant shall implement without undue delay, technical improvements to the OCs and RMMs at the manual plating lines (e.g. further automation and/or segregation), followed by a measurement campaign to validate the effectiveness of the applied technical improvements. The additional OCs and RMMs shall be implemented within 12 months of the granting of an authorisation for this use.
2. The applicant shall ensure that workers perform a 'fit check' of the seal, of their respiratory protective equipment (RPE) before taking on relevant tasks and workers shall be trained to do this test adequately.
3. The applicant shall carry out and document a detailed feasibility study on:
   (a) the substitution of solid CrO3 flakes by liquid solutions of CrO3 to further limit exposure;
   (b) the implementation of an automated system to perform the bath adjustment, and the implementation of a closed/automated system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE;
   (c) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s)), in case the local exhaust ventilation is not functioning properly.

   The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented all across the sites and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.

Section 9: recommendations for the review report as given in Annex IV Table 2.

294_CT_Kludi (2 uses)

Use 1: *Functional chrome plating with decorative character of metal and plastic substrates for sanitary applications.*
Use 2: *Pre-treatment ("etching") of plastic substrates using chromium trioxide in electroplating processes for sanitary applications.*

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

RAC agreed:
Section 7: additional conditions for the authorisation

1) The applicant shall carry out and document detailed feasibility studies on:
   a) the substitution of solid CrO_3 flakes with liquid CrO_3 to further limit exposure;
   b) the implementation of an automatic system with liquid CrO_3 solution to perform concentration adjustment of the chromium baths and the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) may occur.
   c) The implementation of a physical segregation between the plating areas and the loading/unloading areas.

   The feasibility studies shall be concluded within 12 months of granting an authorisation for this use. In accordance with the conclusion of the feasibility studies, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.
Section 9: recommendations for the review report as given in Annex IV Table 2.

295_CT_Ugitech (1 use)

Use1: *Industrial use of chromium trioxide for the functional chrome plating of stainless steel bars, mainly designed to be cylinder rods, used in aggressive and corrosive environments in diverse sectors such as transportation.*

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.

RAC agreed:
Section 7: additional conditions for the authorisation

The applicant shall carry out and document a detailed feasibility study on:
   a) the implementation of an automated or closed system to perform bath sampling tasks, where exposure to Cr(VI) is foreseen and which currently rely on the use of PPE;
   b) the installation of a system that controls continuously the local exhaust ventilation and triggers automatically an alarm and appropriate and effective measures to reduce the exposures to workers (e.g. the shutdown of the relevant Cr(VI) plating bath(s) in case the local exhaust ventilation is not functioning properly.

The feasibility study shall be concluded within 12 months of the granting of an authorisation for this use. In accordance with the conclusion of the feasibility study, OCs and RMMs to further reduce workplace exposure to Cr(VI) to as low a level as technically and practically feasible must be implemented and reviewed during the review period.

Section 8: monitoring arrangements for the authorisation as given in Annex IV Table 2.

No point 7

Section 9: recommendations for the review report as given in Annex IV Table 2.

Table 2. Standard text for Section 8: monitoring arrangements for the authorisation and Section 9: recommendation for the review report.

Section 8: monitoring arrangements for the authorisation

1. The applicant shall implement the following monitoring programmes for Cr(VI):
   (a) Occupational inhalation exposure monitoring programmes, which shall:
      (i) be conducted at least annually. The frequency of the measurements should be sufficient to capture any potential increase in exposure of workers to Cr(VI).
      (ii) be based on relevant standard methodologies or protocols;
      (iii) ensure a sufficiently low limit of quantification;
      (iv) comprise personal and/or static inhalation exposure sampling;
      (v) be representative of:
         a. the full range and duration of tasks undertaken where exposure to Cr(VI) is possible;
         b. the OCs and RMMs typical for each of these tasks;
         c. the number of workers potentially exposed;
      (vi) include contextual information about the tasks performed during sampling.
   (b) Environmental releases:
      (i) the applicant shall continue conducting their (or "implement a") monitoring programme for Cr(VI) emission to wastewater;
      (ii) the applicant shall conduct air emission measurements at least annually or more frequently following any possible changes in the process;
      (iii) the monitoring programmes for wastewater and air emissions shall:
         a. be based on relevant standard methodologies or protocols; and
         b. be representative of the OCs and RMMs used at the applicant's site.
         c. ensure a sufficiently low limit of quantification.
2. The information gathered via the measurements referred to in paragraph 1 and related contextual information shall be used annually by the applicant to confirm the effectiveness of the RMMs and OCs in place and, if needed, to introduce measures to further reduce workplace exposure to Cr(VI) and emissions to the environment to as low a level as technically and practically feasible. While doing so, the applicant shall also review and, if needed, update their assessment of the combined exposure for the different groups of workers.
3. The applicant shall use the monitoring results to further ensure that the application of RMMs at their site is in accordance with the hierarchy of control principles.
4. The information from the monitoring programmes referred to in paragraph 1, including the contextual information associated with each set of measurements as well as the outcome and conclusions of the review and any action taken in accordance with paragraph 2, shall be documented, maintained and be made available by the applicant, upon request, to the competent national authority of the Member State where the authorised use will take place.
5. The applicant may reduce the frequency of measurements, once they can demonstrate to the competent authority of the Member State where the use takes place, that exposure of humans (i.e. workers and general 0population) has been reduced to as low a level as technically and practically possible and that the risk management measures and operational conditions corresponding to the specific exposure scenarios developed in the chemical safety report

function appropriately.

6. Where the frequency of a monitoring programme has been reduced in accordance with paragraph 5, any subsequent changes to the operational conditions or risk management measures that may affect the exposure of workers and humans via the environment at each of the sites where the use takes place shall be documented. The applicant shall assess the impact of such changes by monitoring to demonstrate that exposure of workers continues and humans via the environment to be reduced to as low a level as technically and practically possible
7. The applicant shall continue their existing [annual] biomonitoring programme for the workers potentially exposed to Cr(VI).

Section 9: recommendation for the review report.

The results of the feasibility study as mentioned in section 7 and the measurements referred to in section 8.1 as well as the outcome and conclusions of the review and any actions taken in accordance with section 8.1 should be documented and included in any subsequent authorisation review report.

Annex V

RAC-SCCS joint symposium

7 June 9.30-13.00

Agenda

Timing	Topic		Presenter	
	1	***Approaches to substance grouping***		
9:30-9:50	a	Substance grouping in general and CLH	Fleur Van Broekhuizen (ECHA)	20
9:50-10:30	b	Grouping for restrictions	Sandrine Lefèvre-Brévart (ECHA)	20 + 20 discussion
10:30-11:00	*Coffee break*			
	2	***The increasing role of non-animal methods in risk assessment***		
11:00-11:15	a	Report back from the ECHA NAMs meeting on 31/5	Ofelia Bercaru (ECHA)	15
11:15-12:10	b	The importance of NAMs for safety assessment of cosmetic ingredients – the current status and gaps, and the outlook for use in NGRA	Pieter Jan Coenraads, Vera Rogiers and Qasim Chaudhry (SCCS)	30 + 25 discussion
	3	***The acceptability of cancer risk***		
12:10-13:00	a	Experience from restrictions and OELs	Tim Bowmer (ECHA)	30 + 20 discussion

RAC/M/65/2023
SEAC/M/59/2023

Appendix

Appendix to

Minutes of the 65th Meeting of the Committee for Risk Assessment (RAC-65) and of the 59th Meeting of the Committee for Socio-economic Analysis (SEAC-59)

Stakeholder observers´ written statements provided for the plenary discussions on UPFAS restriction proposal at RAC-65 and SEAC-59

Disclaimer: The registered stakeholder observers and their experts contributed to the written summary of statements in their capacity as individual organisations. The statements expressed in the document are their own and do not represent the views of the European Chemicals Agency or of the Committee for Risk Assessment/Socio-economic Analysis."

Oral statements given in the RAC-65/SEAC-59 Plenary meetings:

Cefic/FPP4EU statement to RAC on the restriction proposal ("the proposal") (max 500 words)

Thank you, Mr Chair, for allowing Cefic to take the floor.

I would like to cover several points:

Firstly, we have commissioned a scientific overview of several PFAS, looking into their key physicochemical characteristics, human health hazards and ecological risk. This study shows the diversity of PFAS, demonstrating that they are not all the same. We will soon submit this study, hoping that the Committee will consider it as part of their discussions on PFAS hazard, exposure and risk.

We are also inventorying PFAS in the equipment used by the chemical industry. This includes the status of alternatives (where they exist). The inventory will assess the extensive use of PFAS and the dependency on such uses to enable the safe and efficient functioning of our factories. This study will support a request for a derogation on PFAS in chemical industry settings.
Secondly, we are briefing downstream sectors to raise awareness on this restriction. This resulted in the creation of a Collaboration Platform. There are currently more than 130 parties represented in this Platform covering several industrial sectors including mobility-transport-automotive, aerospace and defence, health, life sciences, textile, digital, agri-food, construction, electronics, renewable energy, retail, energy intensive industries and creative and cultural industries. The Platform has demonstrated the significant number of industries that use PFAS and their approach to the restriction proposal. There remains concern within the Platform about how to contribute to this process, especially considering their role in the Green Deal, EU Chips Act, EU4Health, EU Renovation Wave, etc. which will be heavily impacted by this restriction. The six-month consultation period is short for something which covers 10,000 substances used in long and widespread value chains. Additionally, not all parties, especially SMEs, have the resources to understand and assess the impact of this at national, EU and regional levels. Also, due to the limited industry seats to follow these discussions, there is an additional risk that many stakeholders will not have the opportunity to fully understand the process, and to have their concerns heard.

We call on the Committee to consider ways to enable the participation of all parties to the restriction process by allocating sufficient seats to industry representatives, by holding additional meetings to fully assess the different uses covered by the restriction and by exceptionally permitting delayed submissions of information.

Finally, we request the Committee considers the advice of the Enforcement Forum when looking into the enforceability of the proposal as a level playing field for EU companies needs to be considered. We believe that attention is needed here to avoid non-EU materials being given preferential treatment over local versions for derogated products. In addition, we believe that there are also enforcement challenges associated with measuring the proposed concentration limits (across multiple media and product types) to ensure the equal implementation of the law. This is particularly challenging for environmental matrices which are not uniform with respect to emissions to various compartments.
Thank you.

Submitted on 26 May 2023

HEAL and CHEM Trust joint statement - 6-7 June 2023 RAC discussion on the universal PFAS restriction

Introduction:

HEAL and CHEM Trust would like to thank the committee for giving us the opportunity to present our statement. HEAL is a non-profit organisation addressing how the natural and built environments affect health in Europe and beyond, representing over 90 organisations across the European continent. CHEM Trust is a charity working to prevent human-made chemicals from causing long-term damage to humans and wildlife.

HEAL and CHEM Trust would like to thank the dossier submitters for preparing this very comprehensive and broad PFAS restriction proposal. This is the most efficient way to reduce PFAS emissions to a minimum and protect present and future generations from the irreversible impacts of PFAS contamination.

The joint European research programme HBM4EU recently evidenced frequent and high PFASs exposure and recommended taking *"all possible measures to prevent further contamination of the European population"* [1]. This shows that this restriction is long overdue as the contamination was allowed to happen despite knowledge of PFAS high persistence and concerns about their harmful effects.

In that regard, we ask RAC to limit the derogations to an absolute minimum and only in cases where industry provides clear justification including details on planned use(s) and exposure(s) throughout their lifecycle.

Scope and unacceptable risk:

We fully support the grouping approach adopted by the dossier submitters, based on the OECD 2021 PFAS definition[2] and covering all very persistent PFAS and their precursors, with high persistence being the key hazardous property. The dossier presents an extensive assessment of the hazardous properties reported for PFAS in addition to their very high persistence (eg. mobility, bioaccumulation, ecotoxicity, effects on human health), and the concerning effects resulting from their combination. The dossier makes a very strong case of the unacceptable risk due to continuous emissions of highly persistent PFAS in the environment, leading to increasing levels and therefore increasing likelihood of irreversible adverse effects. Only a full grouping approach can minimise the potential for regrettable substitution and comprehensively address present and future sources of highly persistent PFAS.

As clearly demonstrated in the dossier and supported by independent peer-reviewed

scientific literature, the production, use and end of life of fluoropolymers are associated with emissions of PFAS which pose an unacceptable risk to human health and the environment[3-5]. In addition, as extremely persistent materials, fluoropolymers represent a long-term reservoir for the emissions of associated PFAS in the environment. Therefore, we fully support their inclusion in the scope of the restriction as the overall aim to reduce emissions of highly persistent PFAS to a minimum is scientifically justified.

Risk management options and derogations:

It is absolutely crucial to keep in mind when considering potential derogations what the dossier highlights in this regard, that "...*even if further releases of PFASs were immediately prevented, existing environmental stocks as well as technical stock (stock of PFASs in existing articles) and PFAS-containing waste would continue to be a source of exposure for generations.*" Just last month, a study was published demonstrating how stock of arrowheads precursors at a contaminated site remains a source of PFAS emissions for centuries[6]. This stresses the urgency to act to prevent adding more to the vast PFAS stock that is already present in our environment and economy.

This is why, in theory, we prefer RO1. However, we recognise the need for extended transition periods where no alternatives are currently available and for which the uses are critical for health, safety and functioning of society. With that said, the transition periods should remain as short as possible as any continued use of PFAS will lead to increasing the PFAS environmental stock that will impact generations to come.

Recent research also indicates that PFAS migration from food contact materials may contribute substantially to individuals tolerable weekly intake (TWI), especially for infants and young children.[7-10] Therefore, it is critical that any derogations or potential derogations for uses related to direct human consumption (i.e. non-stick coatings in industrial and professional bakeware) be limited as much as possible.

Time unlimited derogations and exemptions:

In our view, there are at present no justifications for time unlimited derogations with the exception of, "*...calibration of measurement instruments and as analytical reference materials*[11]," which are necessary for monitoring PFASs for the purpose of tracking progress, identifying hot spots, informing public health interventions, and further regulatory action. Due to the extreme persistence of PFAS, such actions will be necessary for decades to come and therefore a time unlimited derogation is justified for only this use.

PPP/BP/MP time unlimited derogations:

We strongly concur with the dossier submitters that PFAS emissions and exposure to it through PPPs and BPs need to be addressed and we support the inclusion of co-formulants within the scope of the restriction. We also acknowledge the legal rationale for addressing PFAS active ingredients in PPPs and BPs under their respective legislative frameworks, but we are concerned about the lack of practical guarantees about how and when this will take place - this potentially leaves a huge regulatory loophole in terms of direct human and environmental exposure to PFAS.[12,13]

Information requirements and mandatory management reports:

Finally, we strongly support the dossier submitters prioritising transparency in mandating information reporting requirements and mandatory management reports tied to derogations. However, we urge the committee to apply these same requirements not just to the 13.5 year time- limited derogations and all applications of fluorinated gases, but also to 6.5 year time-limited derogations which are currently exempt from this requirement.[14]

Reporting requirements for all derogations would provide more data to authorities with which they could more efficiently and effectively assess and regulate all chemicals' use derogations.

Final remarks:

We will provide further data in our response to the public consultation for consideration by the risk assessment committee. As a final note, we want to once again stress our strong support for this incredibly important restriction which has the potential to set a global precedent in tackling PFAS.

References:

[1] Uhl et al. (2023). PFASs: What can we learn from the European Human Biomonitoring Initiative HBM4EU.
International Journal of Hygiene and Environmental Health. 250, 114168. DOI: 10.1016/j.ijheh.2023.114168.

[2] OECD. (2021). Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance (oecd.org)

[3] Lohmann, R., Cousins, I.T., Dewitt, J.C. et al. (2020). Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?. *Environ. Sci. Technol.* 2020, 54, 20, 12820−12828. DOI: 10.1021/acs.est.0c03244.

[4] Kwiatkowski. C.F., Andrews, D.Q., Birnbaum, L.S., et al. (2020). Scientific Basis for Managing PFAS as a Chemical Class. *Environ. Sci. Technol. Lett.* 2020, 7, 8, 532–543. DOI: 10.1021/acs.estlett.0c00255.

[5] Brandsma, S.H. (2019). The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. *Chemosphere.* 220, 493-500. DOI: 0.1016/j.chemosphere.2018.12.135.

[6] Ruyle et al. (2023). Centurial Persistence of Forever Chemicals at Military Fire Training Sites. *Environ. Sci. Technol.* DOI: 10.1021/acs.est.3c00675.

[7] Lurch, M., Fengler, R., Mbog, G. (2023). Food simulants and real food – What do we know about the migration of PFAS from paper based food contact materials? *Food Packaging and Shelf Life.* 35. 100992. DOI: 10.1016/j.fpsl.2022.100992.

[8] Zabaleta,I., Blanco-Zubiaguirre, L., Baharli, E.N., et al.. (2020). Occurrence of per- and polyfluorinated compounds in paper and board packaging materials and migration to food simulants and foodstuffs. *Food Chemistry,* 321: 126746, DOI: 10.1016/j.foodchem.2020.126746.

[9] Geueke, B. et al. (2022). "Systematic evidence on migrating and extractable food contact chemicals: Most chemicals detected in food contact materials are not listed for use." *Critical Reviews in Food Science and Nutrition,* DOI: 10.1080/10408398.2022.2067828.

[10] Whitehead, H.D. and Peaslee, G.F. (2023). "Directly fluorinated containers as source of perfluoroalkyl carboxylic acids." *Environmental Science and Technology Letters*. DOI: 10.1021/acs.estlett.3c00083.

[11] Annex XV. Pg.6.

[12] Sonne, C., Jenssen, B.M., Rinklebe, J. (2023). EU need to protect its environment from toxic per- and polyfluoroalkyl substances. *Science of Total Environment.* 876(10): 162770. DOI: 10.1016/j.scitotenv.2023.162770.

[13] Farmers' use of PFAS pesticides could be a ticking time bomb - Nyheder.dk. Published 9 Feb 2023.

[14] Annex XV. Pg.182.

Brussels, 26.05.2023

Joint statement by the European Environmental Bureau and ClientEarth on the U-PFAS restriction proposal to the RAC Committee

Dear Chair, thank you for the floor,

dear Members of the Committee,

The European Environmental Bureau and ClientEarth as civil society representatives would like to thank the Dossier Submitters for the great work they've done by preparing this proposal in a joint effort. We largely support the scope and the suggested restriction option as they support a high level of protection for human health and the environment. Safeguarding this high level of ambition is needed now more than ever considering the multiple planetary crisis humanity is currently facing, including the exceedance of the chemical pollution planetary boundary.

We would like to make three general comments to the attention of RAC members.

First, on the hazard assessment. The Annex XV dossier really well substantiates the hazardous properties of all PFASs, and, as a consequence, the need to ban them as a group. Their persistence, leading to potential irreversible pollution, should suffice on its own to justify strict regulatory action. In this regard, we appreciate that scientists, the Court of Justice of the EU (in the GenX case), but also RAC supported this reasoning in previous opinions. In the context of the PFAS in firefighting foams restriction for example, the members of this committee acknowledged that "the high persistence of PFAS in combination with other hazards present grounds for significant concern"[1]. This also applies, in our opinion, to fluoropolymers and fluorinated gases.

Strong evidence of polluted water bodies, soil and air worldwide confirms that PFAS endangers the health and wellbeing of humans and the environment, not only theoretically based on potential hazards, but also in real life, already for decades and with probable long-term effects on future generations. A recent report has mapped thousands of polluted sites in Europe. PFAS are not only forever chemicals but also everywhere chemicals, as "The Forever Pollution Project" proves.

Industry tends to frame the PFAS groups of fluorinated gases and fluoropolymers as much more harmless than they are. Scientific evidence proves that representatives of these heterogenous groups are harmful, and that therefore they shall not be exempted from this restriction. The group approach proposed by the Dossier Submitter is the only right answer to uncertainties regarding the extent of the danger posed by these chemicals, the objective being to avoid regrettable substitution. Any

[1] Committee for Risk Assessment (RAC), Committee for Socio-economic Analysis (SEAC) – Opinion on an Annex XV dossier proposing restrictions on Per- and polyfluoroalkyl substances (PFAS) ECHA/RAC/RES-O-0000007226-75-01/F; Draft date: [16/03/2023]; (p. 11)

exemption of substances from the scope should therefore be strictly justified by the companies claiming the need for such derogations.

Fluoropolymers are a good example of chemicals posing a concern due to their hazards, because of, notably, their persistence, potential bioavailability, contribution to the formation of microplastics, as well as additional hazards visible throughout their lifecycle. Their problematic chemical entourage, including harmful substances such as PFAS processing aids, monomers, oligomer and synthesis by- products, is used and emitted in the production, use-phase and at the end-of-life treatment, which poses a risk to human health and the environment. It is critically important to take into account the risks throughout the entire life cycle, to grasp the full picture of its impact. This chemical entourage of fluoropolymers has given rise to important pollution scandals, for example in the Veneto region of Italy following heavy contamination by PFAS of surface and ground waters.

Therefore, it is more than right that the proposed restriction aims for a complete ban of PFAS use, a ban already required by the Chemical Strategy for Sustainability. We support the Dossier Submitters' understanding that the concerns which justify drastic regulatory action are not limited to the group of arrowhead PFAS and their precursors, but also apply to F-gases and fluoropolymers. Irreversible pollution justifies the most ambitious type of action, following the same line of thinking as the one applied in the microplastics restriction.

Second, concerning missing information in the dossier. The dossier rightly underlines the existence of data gaps, depending on the application, PFAS types and single substances. But despite those gaps, what we get from the publicly available data is a clear justification for concern. We would like to remind the Committee that the responsibility to reduce those gaps and uncertainties on the exposure and emissions of PFAS relies on the industry. In line with the basic principles of REACH regarding the burden of proof, industry alone is responsible for providing reliable and representative hazard and emission data. We see no reason to give them the benefit of the doubt, as long as available evidence confirms uncontrolled emissions and increasing environmental stocks of PFAS, with likely long lasting effects on the state of the environment and health of Europeans.

Third and finally, talking about the End of Life appears ironic in the context of PFAS due to their obvious persistence, but the End of Use of PFAS applications is a serious issue, which is in many facets not well understood yet. The fate of PFAS products and how their waste streams are actually managed is not well documented and promising safe treatment methods are not yet in place. What is however understood, is that recycling streams of e.g. metal articles that are coated with PFAS are contaminated and a potential source of uncontrolled emissions. Incineration is in the context of the Green Deal and its circular economy ambitions obviously no preferable treatment option. Even if this treatment method is more established so far, it does not come without risk, and the technology to safely destroy the limited volume of PFAS which can be collected and treated, is not in place yet.

We want to close our statement with the expression of our hope that the RAC committee, despite the challenges with respect to analysis and existing data gaps, contributes to set a milestone in the protection of human health and the environment by supporting the wide ban of PFAS proposed in the dossier.

Thank you very much for your attention.

May 26th, 2023

SEAC 59, June 2023.

ChemSec statement on PFAS

On behalf of European citizens and over a hundred companies from the PFAS movement, we would like to **thank the dossier submitters** for three years of intensive work in preparation of the PFAS restriction proposal. In line with the strong commitment of the Commission's Chemicals Strategy to ban PFAS in all non-essential uses, you have set in motion a process with the potential to create a better future for us all.

The situation is urgent and calls for strong measures. **A universal restriction is the only way forward**. PFAS levels in both humans and the environment are now in many cases above the levels of documented adverse effects. These levels will increase as long as PFAS chemicals are produced and used.

Many stakeholders have been aware of the extreme persistence of PFAS and their presence in human blood for many decades. Still, the production of numerous similar an equally problematic molecules has continued**.** This must be stopped. PFAS must be regulated as a group and **we need industry to increase its efforts** and put more resources into innovation to identify safer alternatives. There is a great potential and business opportunity for new solutions!

Alternatives have already been found in many different sectors and we are confident **it will be possible to find more alternative solutions** in the coming years. For example, viable alternatives have been found for uses for which it was thought that it would be impossible, such as for the semiconductor manufacturing process.

We should aim for limiting the number of derogations rather than increasing them. We call on SEAC to make sure all potential alternatives are thoroughly assessed, and we call on both industry organisations and competent authorities to **reach out to your national companies and support them** in their search for

alternative solutions. If you are looking for inspiration, you are welcome to follow ChemSec's webinar on June 19th about alternatives in four different sectors: semiconductor manufacturing, fuel cells, technical textiles for PPE, and refrigerants.

PFAS affects us all and the socioeconomic consequences needs to be seen in the broad perspective. **ChemSec has just published an investigation** that shows that the majority of PFAS chemicals are produced by only twelve companies at an average market price of €19 per kg. But these companies would quickly go bankrupt if they were to **pay the full price** of their products - a staggering €18,374 per kg, if we include the societal costs.

It is clear to us that society is looking for new solutions**.** A recent example is when **47 investors with US**
$8 trillion under management asked the world's biggest chemical producers to phase out PFAS. Another example is Denmark, where there are strong calls in Parliament for a national ban because the EU process is considered too slow. Therefore, we urge ECHA's committees to **ensure that their work is not delayed** so that we can have a broad efficient and EU wide restriction in place as soon as possible. We all need it.

CropLife Europe (CLE) would like to provide the following statement to RAC. 26 May 2023

CLE appreciates the complexity of the task of the Dossier Submitter on the universal PFAS restriction proposal. The proposal includes a derogation for active substances in Plant Protection Products (PPP), which avoids double regulation, which honours the principles of one substance one assessment and which acknowledges and respects the robustness of the EU PPP framework. Regarding the latter CLE have provided an additional explanation in to the public consultations (9th May*) as to how Persistence is being taken into account as a fundamental part of the PPP evaluation and approval framework. In the exceptional case of unanticipated effects identified after approval, Regulation 1107/2009 has provisions that require immediate reporting of such effects, allows authorities to request additional data, and even to suspend or cancel approvals as a precautionary measure. Considering the comprehensive data requirements, the strict approval criteria, and the wide range of regulatory options both pre- and post-approval, the pesticide authorization framework is considered to adequately address the concerns regarding persistence that are behind the proposed PFAS REACH Restriction.

CLE wish to note that for Restrictions Article 68(1) requires an unacceptable risk to human health or the environment to be demonstrated, and that the detailed risk assessment opinions from EFSA which underpin current active substance approvals run counter to this requirement.

CLE welcomes the evolution of the proposed PFAS definition that scopes the restriction, and now includes certain functional groups which are exempted on the basis that they can and do degrade in the environment. Additional confirmatory information including recent experimental results have been made available in the first CLE submission to the Public Consultation. We remain committed to continue additional studies and we will share the results to RAC as soon as available. It is essential to realize that these experiments are only intended to prove that not all PFAS functional groups are extremely persistent. As such, the **precise details of the experimental conditions used here do not matter** (20°C vs 12°C). This is because the observed degradation rate will anyway vary with each parent molecule which contains one of these functional groups (e.g. -OCF3, -NCF_3), depending on the broader chemical structure. The essential and key point is that **the identified functional groups do not confer persistence on a larger molecule**, and hence there is no basis for an a priori ban. Protection is in no way lowered, because it remains incumbent on any REACH registrants to investigate potential persistence, including of any metabolites, in the respective REACH registrations.

CLE wish to point out three derogations which are missing:

- An adequate (time-limited) derogation for fluorinated packaging essential for safe handling of chemicals in regulated sectors (e.g. PPP) which do not permit unapproved changes.
- Derogations for intermediates that are essential to produce derogated substances should be introduced in order to avoid unintended loss of such substances.
- A time-unlimited derogation for PPORD and not-yet-approved active substances to avoid unintended loss of innovation as volumes exceeding 1 ton are needed to develop, test and register these substances.

CropLife Europe (CLE) would like to provide the following statement to SEAC. 26 May 2023

The proposal includes a derogation for active substances in Plant Protection Products (PPP). While we welcome this development confirming the robustness of the EU PPP framework, we would like to provide further explanations as to how Persistence is being taken into account as a fundamental part of the PPP evaluation and authorization framework. In that regard a dedicated document has also been submitted via the Public Consultation portal on 26th May**.

CLE welcomes the progress made when it comes to the definition of PFAS being proposed. Scientific elements have been considered to further adjust it – and therefore confirm that certain groups initially considered as persistent can and do degrade in the environment. This will help fine tuning and better scoping the restriction proposal. Further elements including newer test study results are available in the CLE submission to the Public Consultation made on 9th May*. We remain committed to continuing with additional studies and we will share the results openly with RAC as soon as available.

We also want to point out three derogations which are missing:

- An adequate (time-limited) derogation for fluorinated packaging essential for safe handling of chemicals in regulated sectors (e.g. PPP) which do not permit unapproved changes.
- Derogations for intermediates should be introduced to avoid unintended loss of derogated substances.
- A time-unlimited derogation for PPORD and not-yet-approved active substances to avoid unintended loss of innovation.

Regarding the first point, we would like to highlight that the vertical legislation dedicated to PPP puts a significant cost and time constraints on the speed at which alternatives can be put on the market, if available or after they have been developed & approved. For the registration of a given plant protection product, studies on the suitability of packaging material are required (including min. 2 years storage stability). A change to an alternative barrier technology replacing surface fluorination would require new studies to be performed and provided as an update to the product registration. Member State PPP authorities then need to process such requests and deliver an updated authorization. This is alongside the continuous evaluation/update of registrations made by national authorities as imposed by the PPP framework. As demonstrated by European Commission own survey and REFIT exercise of the framework, national authorities are often the bottle neck with frequent delays compared to legal timelines. We believe the proposed 18-month transition is inadequate to roll out replacement of fluorinated packaging for PPP. Because packaging forms part of a PPP registration, it cannot be changed without approval, and hence these PPP would be lost from the market. Further details are made available in the CLE submission to the Public Consultation made on 9th May* .

*CropLifeEurope (CLE) Scientific input to the consultation on the Restriction proposal on the manufacture, placing on the market and use of PFAS (submitted 9 May 2023)
**CLE Document #34672 Persistence scientific assessment and risk management safeguards under the Pesticide authorization framework (submitted 26 May 2023)

EuChemS statement

As the representative of EuChemS, I welcome the PFASs restriction proposal and would like to thank the drafters of the proposal for their hard work. I also welcome the broad scope of the proposal and support the regulation of PFASs based on their persistence in addition to other concerns.

The persistence of PFASs is a sufficient concern for their management as a chemical class because the continual release of highly persistent substances will result in increasing concentrations. These increasing concentrations will increase the probability of the occurrence of known and unknown effects that can only be undone with huge efforts. From the past we have learned that many effects such as the formation of the ozone hole and many different toxic effects were not known when the respective chemicals were introduced to the market. Releasing persistent chemicals is therefore always of high risk and is actually the root cause of the most serious cases of environmental contamination (such as the contamination with PCBs) in the last 50 years.

I noticed however that a number of comments submitted to the public consultation had differing views. For example, some comments propose that fluoropolymers are different from all other PFASs and should be exempted from the PFASs restriction because they are considered safe. However, I would like to highlight that the production of fluoropolymers and the handling and disposal of fluoropolymers as waste has often resulted in emissions of non-polymeric PFASs to the environment. The emissions from fluoropolymer production include emissions of monomers, oligomers, synthesis by-products and polymer processing aids and even with current abatement systems, emissions are not even close to zero. This can be seen in the permits and emission reports of the fluoropolymer manufacturer in the EU. I cannot therefore support the argument put forward by the fluoropolymer industry that it is possible to manufacture fluoropolymers safely.

In addition, Chemours has also started a discussion about F-gases and argues that these are critical for our daily life. It has also been mentioned that F-gases are already addressed in the Regulation (EU) No 517/2014 of the European Parliament and of the Council on fluorinated greenhouse gases (the European F-gas regulation). However, the F-gas regulation addresses only the concern of the high global warming potential of fluorinated gases. Other concerns such as the formation of persistent degradation products, such as trifluoroacetic acid (TFA), and their release to the environment are not addressed. Especially for TFA, concentrations are increasing in many parts of the world. Some of the measured concentrations are orders of magnitude higher than the revised drinking water health guidance value of 60 µg/L TFA that was set by Germany in 2020. It is therefore important that fluorinated gases are also included in the PFASs restriction to address these other problems as well.

Kind regards,
Dr. Juliane Glüge

Representative of EuChemS
Senior Researcher at ETH Zürich in Environmental Science
Member of the Global PFAS Science Panel

MedTech Europe Statement for the ECHA Risk Assessment Committee on the Universal PFAS REACH Restriction

6 June 2023

MedTech Europe welcomes the opportunity to share its views on the PFAS Restriction proposal. PFAS are used extensively in medical technologies (medical devices, *in vitro* diagnostic devices, and device parts of drug-device combination products) and often have no safe and effective alternative. Medical technologies are to be distinguished from *medicinal* ones. Given the extensive grouping of substances this proposal encompasses, companies have been working with suppliers to map the uses of PFAS and will keep finding uses over time. We welcome the proposed derogations thus far for some of the medical technology applications. However, many essential medical applications are not covered and a no-derogation scenario (where there is no alternative and/or a PFAS is found in the future) will have serious consequences for end-users - patients and practitioners across Europe.

PFAS, including fluoropolymers, are used in medical technologies as they have a combination of properties no other materials/chemicals have: enable strength, flexibility, durability, lubricity, biocompatibility, chemical compatibility (with other device materials, processing chemicals and sterilant/sterilization methods), and processability which all allow minimally invasive surgeries and improve patient outcomes. In addition, fluorinated polymer processing aids are used upstream in the supply chain. The low intrinsic hazard of PFAS in medical technologies is important and is proven by testing in accordance with the ISO 10993 series. Fluoropolymers have 45+ years of safe clinical use globally and many fluoropolymers have not been proven to pose a hazard in the environment. Medical technologies containing fluoropolymers are disposed of as clinical waste and are incinerated. In accordance with Article 68(1) REACH and because the PFAS Restriction proposal grouping is so broad, the focus should be on the inherent risk.

Case study on implantable medical devices: such as interventional cardiac occluders and endoprostheses, surgical vascular grafts, cardiovascular patches, surgical sutures, implantable ophthalmic applications, hernia mesh, etc. Fluoropolymer-containing medical devices have been implanted in patients for 45+ years safely and effectively. Fluoropolymers are biocompatible, bioinert, stable when implanted, durable, non-toxic, chemically inhert, heat resistant, provide a low coefficient of friction, allow tissue growth, strong, and flexible. Replacement of materials used in implantable [and invasive] medical technologies is a drastically more complex and resource-intensive undertaking than in most other applications and industries. It is estimated that development, validation, clinical studies, and regulatory approval of material substitution in implantable medical devices would take ~20 years for a single device. Currently, there are no alternatives that meet all these properties and/or have successful clinical history like fluoropolymers. Alternatives that do not currently exist may not be able to serve as diverse a patient population as what is currently served by fluoropolymers. Unknown adverse effects may occur if using an alternative with limited history and this will not be fully realized for decades after the proposed derogation restriction concludes.

Furthermore, the newly adopted CLP hazard classes lack a hazard class for substances with inherent persistence properties. Considering the unique properties of PFAS (e.g. fluoropolymers), they should be treated differently.

Can RAC provide the source(s) of data in the dossier indicating the medical technology sector is one of the highest users of PFAS?

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

www.medtecheurope.org.

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PlasticsEurope statement

FPG's views on the PFAS REACH Restriction proposal.

The Fluoropolymers Product Group believes that fluoropolymers and applications containing a fluoropolymer should be not regulated within the REACH restriction. A total ban on fluoropolymers is notproportionate.

The concerns related to fluoropolymers raised in the restriction proposal can be appropriately managedthrough the implementation of different regulatory frameworks together with responsible manufacturing and End-of-Life risk-management practices. Regulatory frameworks such as the Industrial Emissions Directive, the Waste Framework Directive, and the Occupational Health and Safety Directive can addressthe concerns related to fluoropolymers effectively and quickly.

- A segmentation of the PFAS family according to known physico-chemical and (eco)toxicological properties rather than a structure-based classification alone is needed for a risk-based regulatory approach which is scientifically sound. Fluoropolymers should not be grouped together with other PFAS.
- Given their benign hazard profile, which has been demonstrated,[1,2] fluoropolymers are intrinsically safe and have been used for decades without safety concerns in industrial, commercial, and consumer applications. Fluoropolymers do not pose a risk to human health or the environment as they are non-toxic, not bioavailable, non-water soluble, non-mobile and do not bio-accumulate.
- Fluoropolymers are critical materials and are enablers of the European Green Deal, the Chips Act, the Hydrogen Strategy, the Sustainable and Smart Mobility Strategy, and are central to the EU's strategic autonomy agenda. DG Grow in its March 2023 final report on Foresight for Chemicals highlights "*PFAS being among the top 20 Critical Chemicals*".[3]
- The lack of recognized alternatives could open the door for regrettable substitution to alternatives thatdo not sufficiently perform compared to fluoropolymers, may be potentially hazardous, less durable and as such would mean applications are unable to meet stringent safety standards. DG Grow recognizes the importance of considering derogations to allow continued use of PFAS in the EU as "there are in some cases no suitable alternatives for PFAS in certain parts of the value chain".[3]
- The proposed restriction creates general uncertainty already undermining investment decisions andinnovation undermining important EU ambitions and strategic goals. This could result in the completerelocation of the fluoropolymer industry outside the EU with significant impacts and unpredictable consequences for critical European sectors that rely heavily on these materials.

Therefore, by way of derogation, fluoropolymers and applications containing a fluoropolymer shall not berestricted. We ask for different regulatory measures to be implemented to address potential concerns raised by the regulators in relation to fluoropolymers.

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[1] Henry B. J., Carlin P. J., Hammerschmidt J. A., Buck, R. C., Buxton W., Fiedler H., Seed J., Hernandez O. (2018). A Critical Review of the Application ofPolymer of Low Concern and Regulatory Criteria to Fluoropolymers, Integr Environ Assess Manag2018:316–334 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4035

[2] Korzeniowski S.H., Buck, R. C., Newkold R. M., El kassmi A., Laganis E., Matsuoka Y., Dinelli B., Beauchet S., Adamsky F., Weilandt K. ,Soni V., Kapoor D., Gunasekar P., Malvasi M., Brinati G., Musio S. (2022). A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers, Integr Environ Assess Manag2022:1–30 https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646

[3] DG Grow. Final Report on Foresight for chemicals. March 2023. Chem4EU - Publications Office of the EU (europa.eu)

Written statements submitted for the RAC-65/SEAC-59 Plenary meetings:

APPLiA statement

APPLiA acknowledges that there are negative impacts on the environment and human health from some chemicals within the wide PFAS family, but we are concerned with an approach to universally restrict all PFAS without any distinctionbetween the many different types, properties, risk levels and without consideringif suitable alternatives are available for critical applications.

PFAS includes a broad variety of chemicals. The home appliance industry is widelyusing fluoropolymers within the PFAS family due to their unique combination of properties e.g. non-stick, self-lubricating, resistance to high temperature and highpressure, durability, heat conductivity, resistance to abrasion and to friction. Fluoropolymers have different property profiles compared to many other chemicals in the PFAS family, such as PFOA or PFOS. In addition, the Restriction dossier shows that differences exist between polymerized and non-polymerized PFAS. For instance, some fluoropolymers such as PTFE are authorised under requirements as laid down in Regulation (EU) no 10/2011 on plastic food contactmaterials and other specific national requirements and can be further safely usedfor food preparation. The Restriction Proposal should therefore take into these differences, while allowing fluoropolymers and other PFAS such as PFOA or PFOSto be assessed under separate risk-management approaches.

The Proposal is based on a generalised and partly inconclusive assessment and itoverestimates the availability of suitable alternatives for fluoropolymers used bythe Home Appliances industry. The evaluation of alternatives for fluoropolymers shall be reconsidered. Derogations for fluoropolymers are needed for a limited number of specific but critical home appliance applications, for which there are nosuitable alternatives e.g. lubricants, electronics and components that are in contact with food for the main function in small domestic cooking appliances.

The home appliance industry is actively searching for solutions to tackle PFAS wherever needed. In any case, if a substitution is required, it will take significantlymore time than foreseen in the RP to develop and secure functional alternatives. There is no guarantee that, for all applications, alternatives can be found withoutcompromising the high performance, durability and functionality of household appliances. We would plead for sufficient time and a stepwise approach for the industry to develop possible alternatives to substitute PFAS, while final performance of the components containing PFAS must remain a vital and highly relevant criterion.

Furthermore, it is necessary to secure the continuous supply of spare parts to enable repair and refurbishment of appliances that were produced some years agoand would need to be used for repair in the future. For this reason, we are againsta inclusion of spare parts in the restriction, that could undermine the circularity objectives by discarding parts as waste and resulting in the replacement of complete appliances instead of repairing them.

With such a universal proposed restriction, the home appliances industry would be heavily impacted economically. We are asking for a RP that is based on a differentiated risk-management approach addressing the different types of PFAS in the different applications and their related suitable alternatives.

EPEE Alliance statement

F-gas industry joint statement on U-PFAS proposed restriction

The 7 signatories associations representing the F-gas industry sector are aware of the importance of the proposed Universal PFAS restriction, and came together to select some key issues for the sector and share suggestions regarding the main aspects to keep into account during the discussion:

1. ***Consider trade-offs and costs of further reducing emissions of F-gases through a ban versus through the containment provisions put in place by the EU F-gas Regulation.***
2. ***Consider a careful assessment of the feasibility of the proposed concentration limits for the different substances and sectors. In the case of F-gases, standard distillation and purification methods used for F-gases (virgin and recycled) allow impurities in the range of 0,5%. For other substances the proposedthreshold values will make the recycling process almost impossible.***
3. ***Consider the potential impacts of a restriction on fluoropolymer substances in devices' components (e.g., fluoropolymers used in sealants, bearings, O-rings, motors, electronics), such as a possible reduction in safety, leakage control, and overall product performance (for instance, lower energy efficiency and higher indirect emissions, lower reliability and shorter longevity of the equipment).***
4. ***Consider the possibility of a clear derogation for whole value chain of the Heating Ventilation Air Conditioning and Refrigeration sector (HVAC-R), as well as the placing on the market and using reclaimed and recycled F-gases, as provided for by F-gas Regulation 517/2014 and its current draft revision, to ensure circular economy and avoid unnecessary waste.***
5. ***Consider the amount of waste that early decommissioning of equipment using F-gases might cause. A derogation covering both the refrigerants and the spare parts to secure maintenance is crucial to ensure energy efficiency, operational continuity, and to avoid unnecessary waste due to premature disposal.***
6. ***Carefully consider on a case-by-case basis whether non-fluorinated alternatives are indeed technically and economically feasible for the specific applications when discussing transitional periods and set the appropriate duration for these. The direct and indirect environmental impacts from the use of non-fluorinated alternatives should also be carefully assessed to avoid regrettable substitution.***
7. ***Emissions calculations should be carefully cross-checked with the most recent data, and the trends offuture emissions should take into account technological developments such as the shift to electric vehicles.***

To complement the information already collected by the dossier submitters, the sector has started a large workof **data collection** through several studies (including the ones listed below), and the issues presented in this document will be supported by submission to the ongoing public consultation.

- **Socio-Economic Analysis** on the impact of the PFAS restriction on the F-gas sector (EFCTC – **CONCLUDED**)
- **Regulatory Management Options Analysis** on a group of 8 F-gases (EFCTC – **ONGOING**; *results expected July/Aug 2023*)
- HFCs **Outlook Data** for PFAS Analysis (EPEE – **ONGOING**; *results expected May/June 2023*)

All the signatory associations remain available to answer any follow-up questions in the context of this REACH restriction process.

ETRMA Contribution on Proposed PFAS Restriction to RAC 65

The European Tyre and Rubber Manufacturers' Association (ETRMA) represents the European tyre and general rubber goods (GRG) manufacturing industry in Europe. Our Members employ more than 350.000 workers directly and sustain many more indirectly. The industry has a turnover in excess of €60 billion per annum producing many critical products for Europe's economy and society. We are pleased the have the opportunity to provide our comments to RAC on the proposed PFAS Restriction.

Firstly, it should be noted that the impact of the Restriction will be felt mainly by the general rubber goods sector rather than the tyre sector. This industry is characterised by its diversity, complexity and dominance by SMEs. **Approximately 2.8 million tonnes of rubber goods are produced in Europe with the automotive sector being the main user. Around 14 – 50 kilotonnes requires the use of fluoropolymers accounting for 0.5 -2% of production**. The use of fluoropolymers is essential for performance and there are currently no alternatives. The following characteristics of rubber goods containing fluoropolymers allow them to play a critical role:

- Low coefficient of fraction/surface tension;
- Temperature range;
- Clinical compatibility;
- High surface speed; and
- Resistance to degradation over time.

Critical applications include the aerospace, pharmaceutical, e-mobility and renewable energy sectors, all of which are critical for the dual transition.

ETRMA would recommend the following derogations from the proposed Restriction for the following applications:

Derogation for use of PFAS in <u>industrial rubber goods</u> not placed on the market for consumers:

- This uses are essential for rubber articles to perform to extreme conditions, and releases are limited if any as they are included inside other complex articles, or under controlled conditions.
- Industrial uses include some articles that are in contact with food, such as hoses.
- This does not hamper that other threshold limits on groups of PFAS salts / acids that are present as impurities in fluoropolymers, such as PFHxA.

Derogation for Medical devices, as the use is also essential

- Risk and releases are controlled under Regulation 2017/745.

Rubber articles used by consumers

- Set up a threshold on the maximum allowed content of free PFAS salts in line with the detection limit potential of current methods. For instance, if there are 4000 PFAS substances identified, and the current tests detection limit by substance is 0,5 ppb, then set a threshold for the whole group of 4000*0,5 ppb.

Tyres do not contain fluoropolymers. During the manufacturing of rubber goods, including tyres, fluoropolymers performances in machinery are needed.

- Fluoropolymers (generally thermoplastics) are used in some bulk pieces and coatings in contact with rubber, to ensure no friction and no sticking during all the steps of the manufacturing process in a plant (rubber compounding, rubber conveying operations, tire assembly, curing…);
- As examples, these fluoropolymers pieces or coatings can be found in guides, galley rollers, rolling disks, tables, blades, metallic rolls coating and curing moulds coating. They are essential for the production of rubber compounds and tires, in particular to ensure proper demoulding of the tire after the curing step, in order not to damage tread sculptures; and
- Today, there are no alternatives demonstrating the same anti-sticking and anti-friction properties, without polluting the rubber surface. On this last point, as a tire is made from a superposition of different green rubber layers, any presence of such an anti-adhesive polymer at the interfaces could lead to a further split of the rubber parts during the life of the tire, which is not acceptable regarding safety and lifetime.

ETRMA stands ready to elaborate further on these point.

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EURATEX statement to RAC and SEAC on PFAS restriction

26 May 2023

The European textile and apparel industry represents diverse manufacturing. This also includes specialised textiles, which require fluorinated substance finishing as these are critical uses that need to fulfil the highest degree of safety and performance standards. EURATEX is concerned about the limited derogations for the textile applications in the UPFAS proposal. This is because no alternatives have been developed yet for these protective or high-performance applications.

EURATEX will submit information to ECHA consultation, however for the discussions in the Committees, we provide the following general input:

Personal protective equipment (PPE)

PPE is needed to minimise exposure to hazards that cause serious injuries and illnesses, which may result from contact with chemical, radiological, physical, electrical, mechanical, or other hazards. PFAS substances are needed to guarantee the level of safety that is required by different standards.

Under the PFHxA restriction, the final opinion of the ECHA[1] acknowledges the diversity of the textile sector and SEAC supports a derogation for certain PPE Regulation Categories (Regulation (EU) 2016/425).

While EURATEX welcomes the derogations in UPFAS on PPE Category III (a) and (c) and PPE in firefighting activities for Category III (a)-(m), these derogations need to be broadened to cover PPE in general. All PPE Categories must to provide a certain level of protection based on agreed standards. Therefore EURATEX requests a derogation until alternatives are developed and readily available.

Armed forces, law and order

Regulation (EU) 2016/425 does not apply to PPE specifically designed for armed forces or for the maintenance of law and order. Therefore it is fundamental that a specific derogation is granted for PPE meant for armed forces, law and order and other emergency response workers. The need for this separate derogation is supported by ECHA's opinion on PFHxA.

Medical textiles

Surgical fabrics must provide effective barrier characteristics to prevent splashes of fluid and droplets, possibly carrying viable micro-organisms, penetrating the fabric under mechanical pressure. Accepted test method for evaluating barrier characteristics to liquid penetration is EN 13795-1:2019 with a minimum performance requirement of >20 cm hydrostatic head throughout the lifecycle of the medical device.

[1] ECHA's Opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances -

This separate exemption should include all types of textile fabrics (woven, knitted, laminates, non- woven) as the standard does not specify the type of the fabric and the restriction should not hinder future developments or use of new textiles for medical purposes.

Technical textiles

There are many specific applications where PFAS substances are needed to guarantee protection against hazardous liquids, radioactive dust, infection/aerosols, fire, UV-radiation. EURATEX proposes technical textiles[2] derogation with clear requirement of minimum surface tension of 27.5 (mN/m) according to ISO 14419 and/or Oil number 3 or better.

This level of requirement ensures that these technical textiles will withstand extreme conditions and remain functional over the entire service life, which is only possible with fluorocarbons. Example - thiswould be the case for construction products (awnings, textile roofs, wall covering, building envelopes),where alternatives cannot guarantee the same technical properties.

EurEau statement on the Universal PFAS Restriction

EurEau calls for a **full ban** of all PFAS uses, thus applying the Precautionary and Control- at-Source Principles. **Transition periods** for uses for which there is no alternative today, should be short to encourage innovation. If a complete ban cannot be achieved,any exceptions should be subject to strict governance and control. No release to the environment should be permitted.

The **Polluter-Pays Principle** must be applied to remedy any existing or future contamination of drinking water resources.

Reasons:

~ Due to their mobility, **PFAS have become ubiquitous in the environment**, including in surface water and groundwater. Their persistency means that each nanogram released during production, use and end-of-life adds to the environmental and health burden for many decades.

~ PFAS are increasingly regulated **'end-of-pipe'**. However, once in the environment, it is too late to remove them.

~ Drinking water is a minor but non-negligible exposure pathway of consumers to PFAS. The revised **Drinking Water Directive** sets a threshold of 0.5 µg/litre for PFAS total or 0.1 µg/litre for the sum of 20 PFAS in drinking water.

Following the 2020 EFSA opinion on four PFAS (PFOA, PFOS, PFNA and PFHxS), some countries are considering moving towards even stricter values for the sum of thesefour PFAS. Denmark already adopted a limit value of 0.002 µg/l. For Germany, thisthreshold would mean that 20% of the raw drinking water needs extra treatment. These energy- and resource-intensive processes generate PFAS-contaminated brineor activated carbon.

Costs are passed on to the water consumers while the polluters are not held responsible.

~ The draft revised **Groundwater** and **Environmental Quality Standards Directives** propose 0.0044 µg/l for 24 PFAS (PFOA equivalents). Many water bodieswill take decades to meet these standards, making a full PFAS ban indispensable.

~ **Wastewater** is one of the pathways conveying PFAS from domestic and industrial premises

to the environment. Today's treatment technologies transfer some (longer chain) PFAS from the aqueous phase into sewage solids, while many (shorter chain) PFAS cannot be removed.

The draft revised **Urban Wastewater Treatment Directive** introduces quaternary treatment for micro-pollutants. However, even this additional treatment step will notretain many PFAS. Simultaneously, wastewater operators will have to consider the environmental quality standards in their risk assessments. Consequently, pressure will increase to address PFAS although viable technologies are not available today.

~ PFAS seriously **jeopardise nutrient and material recovery from wastewater and sewage sludge**. If sludge is applied on farmland to increase its phosphorus, nitrogen and carbon content, a certain quantity of PFAS might be transferred to thesoil. The Commission will soon revise the **Sewage Sludge Directive** and set thresholds for sludge-to-farmland applications.
Sludge may also be thermally treated in mono-incinerators to recover phosphorus.This happens at temperatures of no more than 900°C, leaving doubts about the fateof PFAS.

Reading:

EurEau Position on PFAS in the urban water cycle
https://www.eureau.org/resources/position-papers/6094-position-paper-on-pfas-in- urban-water-dec-2021-update/file

EurEau Briefing Note on PFAS and Drinking Water
https://www.eureau.org/resources/briefing-notes/5236-briefing-note-on-pfas-and- drinking-water/file

EurEau Briefing Note on PFAS and Waste Water
https://www.eureau.org/resources/briefing-notes/5612-briefing-note-on-pfas-and- waste-water/file

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IOGP Europe statement on the ECHA proposed PFASs restriction proposal

IOGP Europe acknowledges that PFASs due to their characteristics need to be controlled to prevent health risks for people and the environment. However, due to their characteristics, some PFASs, provide the safest operating parameters for Subsea Flexible Pipes used in the oil and gas fields offshore.

Flexible pipes are made of an assembly of polymeric barriers with corrosion-resistant steel wires. In many applications, they are the only viable solution for oil and gas field development.

Fluoropolymers, such as polyvinylidene fluoride (PVDF) and polytetrafluoroethylene (PTFE) are required within the design of the construction of flexible pipes to ensure safety. Despite significant research, currently, there is no known substitute for extruded PVDF or current uses of PVDF and PTFE in flexible pipe design and manufacturing. Any restriction or ban could have a devastating effect on energy affordability and security.

PVDFs are the only solution for High Pressure High Temperature (HPHT) applications and to date, there are no alternatives. Barriers in flexible pipes comprised of PVDF are used between 90-130°C, while PFASs free alternatives, polyethylene and polyamide materials, are limited and used in only lower temperatures (between 60-90°C). In addition, various PTFE-based sealing elements are typically used on the interfaces between metallic components.

Any restriction of PVDF and PTFE would affect the manufacturing of flexible pipes in Europe resulting in the closure of numerous manufacturing facilities, severely disrupting the supply chain, and resulting in economic impact of billions of Euros per year.

Despite the proposed derogation for petroleum and mining industry, oil and gas exploration and production would be still impacted due to disruption in the supply chain, shortages in raw materials caused in the production of flexible pipes.

The existing and new oil and gas fields rely on these products as enabling technology. During the lifetime of a field, some replacement products and maintenance parts are required. If the industry is not able to supply necessary spares, this may lead to premature field closure which could affect energy security and energy affordability for decades to come.

In most cases, whenever alternative materials are technically feasible, these are already in use. Furthermore, it should be highlighted that materials considered as alternatives in the proposal are not technically feasible replacements for the abovementioned application. Whereas, as acknowledged in section 2.15 of annex E of the restriction proposal, the development of alternative products could take several decades, if even possible.

As an oil and gas industry, we strongly encourage to assess in detail the full ban of fluoropolymers for the reasons stated above and we would like to keep a continuous dialogue regarding the derogation period and alternative materials availability and development.

25th of May 2023

To: **ECHA's Risk Assessment (RAC) and Socio-Economic (SEAC) Committees**

Subject: **Restriction Proposal on "Universal PFAS"**

ORO understands the need for regulating PFAS that pose an unacceptable risk to human health and the environment but we disagree on the inclusion of PFAS substances in the proposal, which do not pose an unacceptable risk, in particular fluoropolymers.

Fluoropolymers are very stable materials that are safe and have an outstanding combination of properties that makes them extremely valuable materials in a wide variety of critical applications. Fluoropolymers do not pose a risk to human health or the environment as they are not toxic, not bioavailable, not bio-accumulative, not mobile and insoluble in water and other biological fluids. Furthermore, fluoropolymers meet the polymers of low concern (PLC) criteria as established by OECD.

We understand that the regulators have concerns on PFAS emissions during the lifecycle of fluoropolymers mainly during manufacturing and end of life phases. Recent developments from the industry in the manufacturing of fluoropolymers, including the use of non-fluorinated polymerization aidsand efficient abatement technologies ensure minimal small-molecular weight PFAS emissions. At the same time, fluorinated polymerization aids being the major source of PFAS pollution in the environment,the use of fluorinated polymerization aids during fluoropolymer manufacturing should be regulated instead of Fluoropolymers in itself.

At the end of life, 85% of Fluoropolymer waste is incinerated; a recent study on fluoropolymer incineration shows that fluoropolymers can be completely thermally destroyed under standard operating conditions. Moreover, industry is committed and has made significant progress in developing technologieson recyclability of fluoropolymers.

These measures during manufacturing and end of life ensure the final objective of achieving negligeable small-molecular weight PFAS emissions from the Fluoropolymer life cycle, we strongly believethat a total ban on fluoropolymers is disproportionate and hence fluoropolymers should be exempted from the restriction proposal under REACH.

A ban on substances without proven risk would mean a move away from risk-based substance legislation. Other countries, such as the UK and the US are taking a science- and risk-based approach, resulting in significant disadvantages for the EU economy.

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Hydrogen Europe

European Chemicals Agency SEAC
Secretariat

Brussels, 26th May 2023

Subject: Hydrogen Europe's statement on U-PFAS restriction ahead of SEAC meeting of June 2023

Reaching the net-zero emission target enshrined in the Climate Law is an absolute priority and will completely transform our economy. To do so, the European Union and its Member States have set to rely on some key technologies (amongst which renewables and hydrogen) to enable this change. In the context of this extreme challenge, the regulatory framework for products needed to manufacture the hydrogen technologies (electrolysers, fuel cells and many more) cannot become an obstacle for the achievement of this goal, on the contrary.

Yet, the restriction proposal on per- and polyfluoroalkyl substances (PFAS) in its current form does exactly that. The group approach chosen to ban up to 10,000 highly varied chemical types jeopardises the hydrogen economy and crucial energy and climate (Green Deal) ambitions, as it fails to sufficiently consider essentiality of uses, availability and readiness of alternatives, value chains and spillovers, socioeconomic impacts, and policy consistency and proportionality.

Fluoropolymers, which have been proven to meet OECD criteria of “polymers of low concern”, are extensively used in electrolysers and fuel cell technologies and all across the hydrogen value chain from production to infrastructure (e.g., in grids technologies and hydrogen refuelling stations) and storage to end use. These highly specialised products are particularly used in (proton exchange) membranes, and also in gaskets and sealings and more.

Their inclusion under the PFAS ban based on their persistency and their alleged lifecycle emissions is ill- guided as the former is required for the product’s durability (making both economic and environmental sense) and the latter can (and should) be addressed by emissions monitoring and abatement measures and not a disproportionate ban. Additionally, no alternatives are foreseen that could reach the necessary KPIs for the ramp-up of the hydrogen industry in the short-to-mid term (incompatible with derogations’ timelines). Due to their unique chemical and physical properties, the availability of fluoropolymers is key for the nascent hydrogen sector. While we support the rationale of a PFAS restriction, it should acknowledge the various risk profiles of fluoropolymers and regulate them accordingly.

The proposed 5-year derogation only for proton exchange membrane (PEM) fuel cells not only excludes PEM electrolysers and non-PEM technologies (fluoropolymers are essential in alkaline water electrolysis to manufacture its electrolyte of potassium hydroxide) but also the uses more upstream and downstream in the value chain. This means that even with derogations on more uses (such as those highlighted above), the proposal would still ban essential uses in fluoropolymer production, hydrogen distribution and transmission infrastructure (including compressors, pipelines and storage, hydrogen refuelling stations.) and the various sectors where hydrogen is / will be consumed, such as energy intensive industries or the transport sector as now mandated in binding national targets under the revised Renewable Energy Directive. With fluoropolymers’ lifecycle emissions rightly addressed by an appropriate policy framework, an exemption for fluoropolymer production (including relevant raw materials) and use should be granted under the PFAS restriction. Our industry remains available to further support with additional data.

Jorgo Chatzimarkakis CEO,
Hydrogen Europe

ACEA is a professional association uniting 14 major mobility actors on the European market. The automotive industry wishes to express its great concern if the implementation of the restriction were to continue as is and proposes an alternative implementation approach that integrates the technical and economic constraints on the one hand and preserves the objectives of electromobility on the other. Material assessment is a complex process and requires sufficient lead time for validation and introduction of alternatives. We request:

- **Application of the PFAS ban should be in two phases for the automotive industry**:
  1. Only in vehicles type-approved after entry into force +X years (depending on application), in accordance with the rules of implementation of the regulations applicable to the automotive sector (Regulation (EU) 2018/858). This prevents the scrapping of already-registered vehicles, including millions of properly functioning used vehicles sold mainly by brand dealers and used vehicle dealers per year.
  2. An extension to all vehicle production after entry into force X+Y years (dates to be confirmed in updated submission).
- **Guarantee the maintenance and reparability of the vehicles** that will no longer be in production at the entry in force of the restriction (including lifetime serviceability of refrigerants). This would enable a more sustainable industry and be in accordance with the Green Deal.
- **Guarantee the maintenance and reparability of machinery producing vehicles** and automotive parts in industrial settings during their long lifetime under high industrial standards and regulations.
- And for the items below:
  - **Fluoropolymers (incl. fluoroelastomers):** Removal from the scope of the restriction. Concerning the manufacturing phase, the risks of PFAS emissions to the environment can be controlled with alternative Risk Management Options. Concerning the use phase, they are considered non-toxic, non-bioaccumulative, non-mobile and as such, are classed as polymers of low concern. Concerning the end-of-life phase, incineration of fluoropolymers does not contribute to environmental PFAS emissions and is a safe method of disposal.
  - **Lubricants:** More time to analyze the impacts, specifically the PFPE lubricants (stable, not classified as hazardous and as bio-accumulative, lifetime lubricant), as automotive uses should be considered as falling under the “harsh conditions” derogation.
  - **Batteries:** Derogations and respective transition times until the battery industry has identified and implemented alternative non-PFAS solutions.
  - **Fuel cells:** Removal of PTFE and PFSA (fluoropolymers) from the scope of the proposed restriction to enable the hydrogen economy to develop and secure the EU’s decarbonization policy.
  - **Hardchrome Plating:** Derogation of 13.5 years to not conflict with EU POP and other parts under EU REACH.
  - **PTFE membrane:** see fluoropolymers.
  - **Refrigerants**:
    - Transition period of 7 years for new passenger vehicle types and 17 years for new registrations. For heavy-duty vehicles, transition period should be 10 years for new types and 22 for new registrations.

- Vehicles with internal combustion engines (ICE) and belt-driven compressors should receive an unlimited derogation as there is no viable alternative.
- European production for export should receive an unlimited derogation as alternatives are not suitable for all markets.

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RECHARGE STATEMENT TO SEAC-59 meeting

RECHARGE is the association for advanced rechargeable and lithium batteries representing over 60 members spanning the entire battery value chain[1]. RECHARGE would like to highlight:

1. Errors in the Restriction Proposal published 22 March 2023 and
2. A PFAS restriction without derogations for batteries will seriously limit the Green Deal and prevent Europe from achieving a net zero economy by 2050.

Errors in the Restriction Proposal

Contrary to what is stated in Annex E (page 416), solid state batteries and lead acid batteries **are not potential** non-PFAS alternatives to Lithium ion batteries. This is because:

- Solid state batteries use PFAS, specifically PVDF and PTFE:
  - in the binder within the active material
  - in solid electrolytes and
  - in gel polymer electrolytes.
- Although lead acid batteries do not use PFAS, they are not a technically feasible solution, because they have a low energy density and cannot be used in applications which require high energy, high power, very long life, superior reliability, and the ability to withstand extreme temperatures. In addition, lead compounds used for battery manufacturing and lead metal have been recommended by ECHA for authorization under REACH Annex XIV. Lead acid batteries cannot be used for technologies such as smartphones, tablets, power tools, hearing aids, defibrillators, and many other portable applications used by EU citizens today. They cannot be used for powertrain systems in mobility solutions such as electric vehicles, fork-lift trucks, e-bikes and e-scooters.

The points above are further explained in RECHARGE's first submission to the consultation (Ref. 3925).

A PFAS restriction without derogations for batteries will seriously limit the Green Deal and prevent Europe from achieving a net zero economy by 2050

The European Green Deal is one of the world's most ambitious climate policies to usher the European Union and its Member States into a net zero economy by 2050 by decoupling economic growth from fossil fuel dependency. The Green Deal relies on batteries to achieve objectives for low-emission mobility, decarbonized energy generation and digitalization.

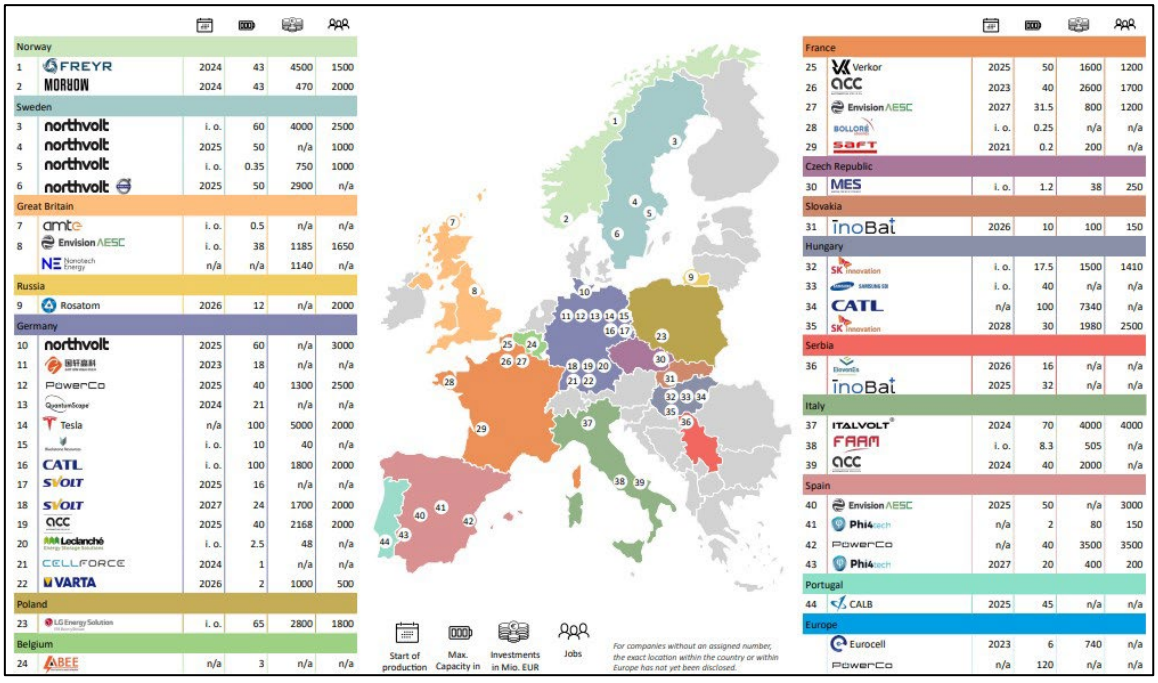
Batteries have been identified by the European Commission as a strategic value chain. The Commission states:

'*Batteries are thus an important source of energy and one of the key enablers for sustainable development, green mobility, clean energy, and climate neutrality*'[2].

Batteries are critical to enable electric vehicles to replace sales of new combustion engine vehicles by 2035. On 29 June 2022, all climate ministers of the 27 EU Member States agreed to the European Commission's proposal (part of the 'Fit for 55' package) to effectively ban the sale of new internal combustion vehicles by 2035. Most EU Member States have also signed up to the COP26 declaration on accelerating the transition to 100% zero emission cars and vans in leading markets by 2035.

Approximately 45 battery cell production sites in Europe that are in planning, under construction or partly already in operation represent 56 billion Euros of investment and 43,000 jobs[3] (See Figure 1). This will aid Europe to become self-sufficient in battery cells as early as 2028 as an integrated value chain. **Without PFAS derogations for batteries, these battery production sites will stop operating in Europe**.

Figure 1: Indicative overview of cell production sites in Europe[4]



[2] Page 4, Provisionally agreed Battery Regulation, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CONSIL:ST_5469_2023_INIT&from=EN

[3] Figures include EU Member States and European Economic Area countries – therefore Russia, UK & Serbia have not been included in our calculations. Figures obtained from IPCEI Market Analysis Q4 2022, https://www.ipcei-batteries.eu/fileadmin/Images/accompanying-research/publications/2023-02- BZF_Kurzinfo_Marktanalyse_Q4_22-ENG.pdf.

SEAC meeting 59 – Contribution from the veterinary medicines sector.

AnimalhealthEurope and Access VetMed represent the veterinary medicines sector. We welcome the proposed time unlimited derogation for active pharmaceutical ingredients (APIs) in human and veterinary medicinal products (Art 4.c). The derogation for veterinary APIs is justified in the restriction dossier based on sectoral legislation, the importance for animal and human health and the food supply, and the need to safeguard availability of medicines.

However, we would like to inform SEAC that as worded, this derogation does not achieve its very aim of allowing manufacturing of neither these active substances nor even of non-PFAS active substances and associated veterinary medicines in general in the EEA for the following reasons:

- To introduce fluorine into the API molecules, starting materials and chemical intermediates that qualify as PFAS are used, which are imported and/or manufactured, and these are not derogated.
- The same is true for processing aids and process chemicals, including solvents and reagents.
- In production of any veterinary medicines including vaccines, polyfluorinated polymers such as e.g., polytetrafluoroethylene (PTFE) are often used as seals for chemical reactors, vials and in equipment such as membrane filters, gaskets, liners, O-rings, piping etc. Electronics are embedded in production equipment and are indispensable to correct functioning of any given production line.
- Likewise, polyfluorinated polymers are widely used in packaging materials (blisters, vial stoppers etc.) as they are extremely efficient in preventing interaction between product and packaging materials, which is a regulatory requirement.

All the above listed uses of PFAS chemicals are not currently listed as specific uses in the restriction dossier nor derogated under the current wording.

Without additional derogations, the Animal Health Industry will, very abruptly, no longer be able to manufacture any of our APIs (both, classifying as PFAS or non-PFAS APIs) or associated veterinary medicines in the EEA and this is valid for the entire sector. As a result, the supply and availability of all veterinary medicines including vaccines in the EEA will be substantially impacted longer term, resulting in new and extensive dependencies upon non-EEA manufacturing and shortages of important medicines and therapeutic gaps in the field of veterinary medicine. Consequently, veterinary healthcare would no longer be possible which will impact the vast majority of veterinarians in the EEA. It would also threaten the food supply as only healthy animals can enter the food chain.

Our sector is committed to phasing out PFAS wherever possible but given our sectoral legislation and long development times, appropriate derogations and transition times will be required. Additionally, no alternatives exist for certain uses.

We will therefore propose additional derogations to ensure a smooth transition without disruption and will provide detailed justifications in a sectoral SEA submitted through the consultation portal.

We are at SEAC's disposal to provide further information where needed, and would support joint meeting attendance with similar sectors, which would include the human pharmaceutical industry and others derogated under Art 4, and the medical device sector as the issues encountered are very similar.