4 September 2023

SEAC/M/59/2023 FINAL

Final

Minutes of the 59th meeting of the Committee for Socio-economic Analysis

6-9 June
and
13-14 June 2023

I. Summary Record of the Proceeding
1) Welcome

María Ottati, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants to the 59th meeting of SEAC.

The Chair informed the participants that the meeting would not be recorded. The list of attendees is given in Part III of the minutes.

2) Adoption of the Agenda

The Chair introduced the final draft agenda of SEAC-59. The agenda was adopted without modifications (in line with SEAC/A/59/2023). The Chair mentioned that the meeting would be partly chaired by the Deputy Chair Kalle Kivelä.

The final agenda is attached to these minutes as Annex III. The list of all meeting documents is attached to these minutes as Annex I.

3) Declarations of conflicts of interest to the Agenda

The Chair requested members and their advisors participating in the meeting to declare any conflicts of interest with any of the specific agenda items. Seven members, three advisors and one regular stakeholder declared potential conflicts of interest regarding the substance-related discussions under Agenda Item 5.2a-1. Two members and one advisor declared potential conflicts of interest regarding the substance-related discussions under Agenda Item 5.2b-5. Two members and one advisor declared potential conflicts of interest regarding the substance-related discussions under Agenda Item 5.2b-4. Two members declared potential conflicts of interest regarding the substance-related discussions under Agenda Item 5.2b-1. These members did not participate in voting under those Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

The Chair declared her absence of conflict of interest for all items of SEAC-59 plenary meeting. She noted that the Deputy Chair was involved in the preparation of the Annex XV dossier for the PFASs in Firefighting Foams restriction proposal, and would therefore not participate in discussions, but that he had no conflict of interest for the other items on the agenda.

The list with declared conflicts of interest is given in Annex II of these minutes.

4) General SEAC procedures
a) Report on SEAC-58 action points and written procedures

The Chair informed the participants that all action points of SEAC-58 had been completed or would be followed up during the ongoing SEAC-59 meeting.

The Chair also informed the Committee that the final minutes of SEAC-58 had been adopted by written procedure and had been uploaded to S-CIRCABC as well as on the ECHA website.

Representatives of the Commission updated the Committee on SEAC-related developments in the REACH Committee and in CARACAL.

5) Restrictions

5.1 General restriction issues

1) Agreement of the updated paper on SEAC's approach to assessment of PBT/vPvB substances

The members of the SEAC working group to update SEAC's approach to the evaluation of restriction reports and applications for authorisation for PBT and vPvB substances provided a presentation on the updated paper (now covering SEAC's approach to assessment of persistent substances). SEAC agreed on the proposed paper. The SEAC working group, together with the Secretariat was requested to take the discussions into account and revise the approach after the SEAC-59 plenary in order to publish the updated document on the ECHA website.

2) Presentation of work on valuation of new health endpoints

A representative of the OECD provided a presentation on their work on valuation of new health endpoints. The Secretariat informed the Committee about an upcoming update of the paper on SEAC reference willingness-to-pay (WTP) values, adding values based on the new valuations presented. The Chair concluded that the Secretariat will develop the figures and table the updated paper for agreement at SEAC-60.

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

SEAC took note of the presentation by the Secretariat and SEAC agreed on the revised working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers (in line with meeting document SEAC/59/2023/03). The Secretariat will publish the updated working procedure on ECHA website.

Furthermore, the Secretariat provided an update on the changes made in the opinion template, which will be used for the ongoing UPFAS restriction opinion from now on.

5.2 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Universal per- and polyfluoroalkyl substances (UPFAS) – recommendations and key issues discussion and the stakeholder statements

The Chair welcomed the Dossier Submitter's representatives from Germany, the Netherlands, Denmark, Norway and Sweden, as well as the occasional stakeholder observer from EuChemS and the regular stakeholder observers (Cefic, PlasticsEurope, Eurometaux, MedTech Europe and ChemSec) together with their accompanying experts. She informed the participants that 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 PFAS are covered by this restriction proposal except for the use of PFAS in firefighting foams, which is addressed in a separate restriction proposal (prepared by ECHA). Due to the complexity of the dossier, the conformity check process is carried out in two steps. Step 1 was the formal agreement of conformity at the RAC and SEAC plenaries in March 2023. Following this, the third-party consultation on the Annex XV report was launched on 22 March 2023. This was now followed by step 2, which consisted of discussions on the key issues and recommendations to the Dossier Submitter at the SEAC-59 plenary.

SEAC took note of and discussed the key issues and recommendations to the Dossier Submitter, as presented by the SEAC (co-)rapporteurs. The rapporteurs were requested to prepare the first draft opinion focusing on food contact materials and packaging for discussion at SEAC-60. The interested stakeholder observer representatives were requested to send their registrations early for the upcoming SEAC-60 plenary meeting.

Furthermore, the Chair requested the stakeholder observers to provide additional information via the six-month consultation of interested parties on the restriction proposal by 25 September 2023.

For discussion

b) Opinion development

1) Creosote, and creosote-related substances – Second draft opinion

The Chair welcomed the Dossier Submitter's representatives from France. She informed the participants that the restriction dossier was submitted in October 2022 and concerns the restriction of creosote and creosote-related substances. The rapporteurs prepared the second draft opinion, on which the SEAC written commenting was carried out between 17 until 26 May. The third-party consultation will end on 22 June 2023.

The Chair informed the Committee that RAC had skipped its discussions at RAC-65, in order to wait for the outcome of third-party consultation.

The SEAC rapporteurs then presented the second draft opinion. The SEAC members supported the approach taken, with some proposals for alignment with RAC conclusions.

SEAC agreed with the rapporteurs' preliminary conclusion on costs and benefits of the proposed restriction; the assessment will be continued in next cycle. Furthermore, SEAC members supported the rapporteurs' conclusions on the analysis of alternatives and cost assessment, subject to final outcome of the third party consultation which will finish by 22 June 2023. SEAC also held preliminary discussions on the proportionality.

The Commission observer asked for clarifications regarding impacts for railway services. The regular stakeholder observer representative from Eurometaux commented on the type of railway sleepers used in practice.

The (co-)rapporteurs were requested to prepare the third draft opinion by August 2023, considering the SEAC-59 discussions, the comments received from the SEAC written commenting round and the comments from the Annex XV report consultation.

For discussion

2) BPA+

Given that further major developments of the opinion are expected as a result of comments received in the (currently still-ongoing) consultation on the Annex XV dossier, no discussion took place in this meeting.

Not for discussion in this meeting

3) Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 – Agreement on draft opinion

The Chair welcomed the Dossier Submitter's representatives from ECHA and the RAC rapporteurs. She informed the participants that the restriction dossier was submitted in July 2022 and concerns the manufacture, use and placing on the market of substances, mixtures and articles containing C14-17 chloroalkanes with PBT- and/or vPvB-properties.

The RAC co-rapporteur summarised the discussions at RAC-65, where RAC had adopted its opinion. The SEAC rapporteurs then presented the revised third draft opinion.

Members supported the rapporteurs' conclusions and commented on the impacts of the inclusion of vP congeners within the scope of the restriction and the ban on manufacturing. The Commission representative asked to clarify what would be the impact of the ban on manufacturing on exports. The occasional stakeholder observer representative from EuPC commented on recycling. The accompanying expert to Cefic commented on the level of emissions resulting from manufacturing.

The Committee agreed on its draft opinion (with editorials agreed at SEAC-59) by consensus. The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. The Secretariat intends to launch the consultation on the SEAC draft opinion on 14 June 2023.

For agreement

4) Terphenyl, hydrogenated – Draft of the SEAC final opinion

The Chair welcomed the Dossier Submitter's representatives from Italy. She informed the participants that the restriction dossier was submitted in April 2022.

She reminded the Committee that the third-party consultation on the agreed SEAC draft opinion ended on 15 May 2023 with 28 comments received. The (co-)rapporteurs updated the opinion based on the comments received, and the draft of the SEAC final opinion was made available to the Committee on 26 May. The SEAC rapporteurs were then invited to present the results of the third-party consultation and their impact on the SEAC opinion.

Members, the Commission and the expert accompanying expert to a regular stakeholder observer (Cefic) commented on the proposed time-unlimited derogation and the need to review the derogation.

SEAC adopted the final opinion by simple majority (with editorial modifications agreed at SEAC-59) with changes related to the scope of the derogation for the use as a heat transfer fluid in industrial installations and the need for a review of the derogation for new installations after 10 years. One member took a minority position, considering that restriction option 3 as suggested by the Dossier Submitter can be considered proportionate

and that a restriction option with a time-limited derogation would be more proportionate than the restriction option adopted by SEAC. The rapporteurs were asked, together with the Secretariat, to make final editorial changes to the opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC opinion. The Secretariat will forward the adopted opinion and its supportive documents to the Commission as well as publish on the ECHA website. The Chair thanked the rapporteurs for their work on this dossier.

5) *N*,*N*-dimethylacetamide and 1-ethylpyrrolidin-2-one – Draft of the SEAC final opinion

This agenda item was chaired by the Deputy Chair. He welcomed the Dossier Submitter's representatives from the Netherlands, the RAC rapporteurs and an accompanying expert to a regular stakeholder observer (Cefic). He informed the participants that the restriction dossier was submitted in April 2022.

The Deputy Chair reminded the Committee that the third-party consultation on the agreed SEAC draft opinion ended on 22 May 2023 with three comments received. The (co-)rapporteurs updated the opinion based on the comments received and the draft of the SEAC final opinion was made available to the Committee on 26 May. The SEAC rapporteurs were then invited to present the results of the third-party consultation and their impact on the SEAC opinion.

The Commission and the Dossier Submitter commented on proportionality.

The Committee adopted its final opinion by consensus. The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted SEAC final opinion.

6) Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams – Draft of the SEAC final opinion

The Chair welcomed the Dossier Submitter's representatives from ECHA and the RAC rapporteurs. She informed the participants that the restriction dossier was submitted in January 2022 by ECHA. She reminded the Committee that the third-party consultation on the agreed SEAC draft opinion ended on 15 May 2023 with 20 comments received. The (co-)rapporteurs updated the opinion based on the comments received and the draft of the SEAC final opinion was made available to the Committee on 26 May.

The SEAC rapporteurs were then invited to present the results of the third-party consultation and their impact on the SEAC opinion.

Members and a regular stakeholder observer (Client Earth) commented on the changes to the opinion based on the comments received during the draft opinion consultation. The Commission commented on the approach to express the length of one of the derogations by referring to a specific end-date, rather than the number of years.

The Committee adopted its final opinion by consensus. The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted SEAC final opinion.

For adoption

5.3 Appointment of (co-)rapporteurs for restriction dossiers (closed session)

SEAC was provided with an update on the upcoming restriction proposals.

6) Authorisation

6.1 General authorisation issues

a) Update on incoming/future applications

The Secretariat presented information on incoming/future applications for authorisation and review reports, expected workload in 2023 and beyond, and timelines. The Committee discussed the role of conformity of applications for authorisation within the process of opinion development, a need for targeting the scope and limiting the number of questions sent to applicants and authorisation holders. A representative of the stakeholder organisation (Eurometaux) contributed to the discussion by supporting sending questions to applicants which are of direct relevance.

SEAC took note of the update on the new applications for authorisation received during the May 2023 submission window and other AfA-related updates and discussed options for streamlining the opinion-making process for AfAs.

b) Update to the technical instructions to the rapporteurs

The Secretariat presented and SEAC discussed proposed changes in technical guidance and standard texts for SEAC rapporteurs.

The Secretariat will consider the discussion and will update the relevant material (such as the technical guidance for rapporteurs), as well as publish it on S-CIRCABC.

6.2 Authorisation applications

a) Discussion on key issues

The SEAC rapporteurs, provided general information regarding the applications for authorisation 297_CT_Acciaierie_Italia (1 use), 298_CT_Bjerringbro_Fornikling (1 use), 299_OPE_MeiraTGX (1 use), 300_CT_Weber-Hydraulic (1 use), 301_CT_SD_Liberty_Liege (1 use), 302_CT_Thoma_Metallveredelung (1 use), 303_CT_Rubinetterie_Stella (1 use), 304_SD_Acciaierie (1 use), 305_CT_Meoni_e_Bartoletti (1 use), 306_CT_Galvanica_Pasotti (1 use), 307_CT_Vinzia (1 use), 309_CT_Cromatura-Staff (1 use) and 310_CT_Cromotecnica_Fida (1 use), and specified the identified key issues in them. SEAC members asked questions of clarifying nature on the identified key issues.

b) Agreement on draft opinion

1. 285_CT_Liebherr-Aerospace_Linden (2 uses)
   This is an application for authorisation on two uses of chromium trioxide:

Use 1: Industrial use of chromium trioxide for functional chrome plating of actuation and landing gear systems for the aviation industry.
Use 2: Industrial use of chromium trioxide for surface treatment of aluminium alloys for applications in the aerospace industries unrelated to functional chrome plating.

SEAC members discussed the scope of the application for authorisation, one of the shortlisted alternatives by the applicant and the additional time which would be needed for its implementation, as well as the length of the review period. A representative of a stakeholder organisation (Eurometaux) contributed to the discussion pointing out potential regrettable substitution, as well as commenting on processes in the substitution plan.

The Committee agreed on the draft opinions by consensus. The rapporteur, together with the Secretariat, will do the final editing of the SEAC draft opinions. The Secretariat will send the draft opinions to the applicant for commenting.

2. 286_CT_Hartchrom-Beck (4 uses)
   This is an application for authorisation on two uses of chromium trioxide:
   Use 1: Chromium trioxide-based functional chrome plating of axially/rotationally symmetrical components requiring optimal tribological surface properties (resulting from 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.

SEAC members discussed scope of the application for authorisation, feasibility of an alternative technology submitted during the third-party consultation, as well as the other shortlisted alternative technologies, relation between the applicants and their work on the alternative methods, as well as the length of the review period. A representative of the European Commission contributed to the discussion on RAC's conclusions and conditions for the authorisation, and the length of the review period. A representative of a stakeholder organisation (Eurometaux) contributed to the discussion by providing a clarification on scaling up.

The Committee agreed on the draft opinions by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinions. The Secretariat will send the draft opinions to the applicants for commenting.

3. 287_CT_Bacrom (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: 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.

SEAC members discussed the scope of the application for authorisation, non-use scenario by the applicant, as well as the length of the review period. A representative of the European Commission contributed to the discussion on the length of the review period.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

4. 288_CT_Leonardo (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: Functional chrome plating of military gun barrels and outer jacket surfaces using chromium trioxide.

SEAC members discussed availability of a technology reported during the third-party consultation, the length of the requalification steps in the substitution plan, technology readiness level of one of the shortlisted alternative methods, as well as the length of the review period. A representative of the European Commission contributed to the discussion on the length of the review period and the current legal framework the applicant is operating within. A representative of a stakeholder organisation (Eurometaux) contributed to the discussion by providing additional information on one of the shortlisted alternative methods.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

5. 289_CT_Beretta (2 uses)
   This is an application for authorisation on two uses of chromium trioxide:
   Use 1: Chromium trioxide based functional plating of gun barrel bores and auxiliary parts for assault rifles, carbines and pistols for non-civilian uses.
   Use 2: 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.

SEAC members discussed availability of a technology reported during the third-party consultation, the length of the requalification steps in the substitution plan, technology readiness level of one of the shortlisted alternative methods, as well as the length of the review period. A representative of the European Commission contributed to the discussion on the length of the review period and the current legal framework the applicant is operating within. A representative of a stakeholder organisation (Eurometaux) contributed to the discussion by providing additional information on one of the shortlisted alternative methods.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

6. 290_CT_Fir-Italia (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: Industrial use of chromium trioxide for the functional chrome plating with decorative character of items for the hydrosanitary sector.

SEAC members discussed potential an alternative method shortlisted by the applicant, timeline of the substitution plan and the length of the review period. A representative of the European Commission contributed to the discussion on the length of the review period.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

7. 291_CT_Belloni (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: Industrial use of chromium trioxide for the plating of coffee machine parts in contact with water and food.

SEAC members discussed an alternative method shortlisted by the applicant, technical infeasibility of an alternative, timeline of the substitution plan and the length of the review period. A representative of the European Commission contributed to the discussion on the length of the review period.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

8. 292_CT_Artech (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: 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.

SEAC members discussed the length of the review period. A representative of the European Commission contributed to this discussion.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

9. 293_CT_Talleres-Aykrom (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: Industrial use of chromium trioxide in functional chrome plating of metallic pieces required in different industrial sectors such as corrugated rolls to meet hardness, wear resistance, corrosion resistance, good surface condition, low friction coefficient and coating adhesion requirements.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

10. 294_CT_Kludi (2 uses)
    This is an application for authorisation on two uses of chromium trioxide:
    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.

A representative of a stakeholder organisation (ChemSec) asked a question about the current legal framework the applicants are operating within.

The Committee agreed on the draft opinions by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinions. The Secretariat will send the draft opinions to the applicants for commenting.

11. 295_CT_Ugitech (1 use)
    This is an application for authorisation on a single use of chromium trioxide:
    Use 1: 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.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

12. 296_CT_Mahle-2 (1 use)
    This is an application for authorisation on a single use of chromium trioxide:
    Use 1: Chromium-trioxide-based functional chrome plating of piston rings for automotive applications.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The Secretariat will send the draft opinion to the applicant for commenting.

c) Adoption of opinion

1. 261_CT_Metalbrass (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.

It was received by the Committee in May 2022. SEAC agreed on the draft opinion during SEAC-57 plenary meeting. On 13 April 2023 the applicant submitted comments on the draft opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with the Secretariat will do the final editing of the SEAC opinion. The Secretariat will send the opinion to the Commission, the Member States and the applicant, and publish it on the ECHA website.

2. 263_CT_Orelec (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: 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.

It was received by the Committee in May 2022. SEAC agreed on the draft opinion during SEAC-57 plenary meeting. On 13 April 2023 the applicant submitted comments on the draft opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with the Secretariat will do the final editing of the SEAC opinion. The Secretariat will send the

opinion to the Commission, the Member States and the applicant, and publish it on the ECHA website.

3. 265_TXP_EDF (2 uses)
   This is an application for authorisation on two uses of trixylyl phosphate:
   Use 1: Industrial use as a hydraulic fluid in closed systems to drive and control the steam inlet valves of turbines.
   Use 2: Industrial use as a hydraulic fluid in closed systems to drive and control main steam isolation valves.

It was received by the Committee in May 2022. SEAC agreed on the draft opinions during SEAC-57 plenary meeting. On 14 April 2023 the applicant submitted comments on the draft opinions.

The Committee adopted the opinions by consensus. The rapporteurs, together with the Secretariat will do the final editing of the SEAC opinions. The Secretariat will send the opinions to the Commission, the Member States and the applicant, and publish them on the ECHA website.

4. 267_CT_SPGPrints (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: 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.

It was received by the Committee in May 2022. SEAC agreed on the draft opinion during SEAC-57 plenary meeting. On 17 April 2023 the applicant submitted comments on the draft opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with the Secretariat will do the final editing of the SEAC opinion. The Secretariat will send the opinion to the Commission, the Member States and the applicant, and publish it on the ECHA website.

5. 271_CT_Villeroy (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: 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.

It was received by the Committee in May 2022. SEAC agreed on the draft opinion during SEAC-57 plenary meeting. On 17 April 2023 the applicants submitted comments on the draft opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with the Secretariat will do the final editing of the SEAC opinion. The Secretariat will send the opinion to the Commission, the Member States and the applicants, and publish it on the ECHA website.

6. 272_CT_RIGHI (1 use)
   This is an application for authorisation on a single use of chromium trioxide:
   Use 1: Electroplating of metal substrates using chromium trioxide to achieve functional surfaces for the sanitary sector.

It was received by the Committee in May 2022. SEAC agreed on the draft opinion during SEAC-57 plenary meeting. On 13 April 2023 the applicant submitted comments on the draft opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with the Secretariat will do the final editing of the SEAC opinion. The Secretariat will send the opinion to the Commission, the Member States and the applicant, and publish it on the ECHA website.

6.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)

SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with SEAC/59/2023/04 Rev.1 restricted room document).

7) Requests under Article 77(3)(c)

None.

8) AOB

Two of the regular stakeholder organisations (ChemSec and EEB) made short verbal announcements of work recently undertaken by their organisations.

a) Update of the work plan

The Secretariat provided an update of the work plan for the future months.

b) Potential new tasks

The Secretariat provided an update of the potential new tasks to SEAC, in the context of ongoing reviews of relevant regulations.

9) Action points and main conclusions of SEAC-59

A table with the action points and main conclusions is given in Part II below.

Main conclusions and action points
SEAC-59, 2023

(Adopted at SEAC-59 meeting)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the agenda	
The agenda was adopted without modifications (SEAC/A/59/2023).	
3. Declarations of conflicts of interest to the Agenda	
Conflicts of interest have been declared and will be included in the minutes.	
4. General SEAC procedures	
a) Report on SEAC-58 action points and written procedures	
SEAC was informed of the status of the action points of SEAC-58. Furthermore, SEAC took note of the oral report from the Commission on SEAC-related developments in the REACH Committee and the CARACAL meetings.	
b) Update of SEAC accredited stakeholders' list (closed session)	
SEAC took note of and discussed the restricted meeting document (SEAC/59/2023/01). SEAC agreed on the current SEAC regular stakeholders list.	**SECR** to publish the list on the ECHA website and to consider whether other stakeholder organisations should be invited to participate.
5. Restrictions	
5.1 General restriction issues	
1. Agreement of the updated paper on SEAC's approach to assessment of PBT/vPvB substances	
SEAC agreed on a paper on SEAC's approach to assessment of persistent substances, which updates and replaces the paper on SEAC's approach to assessment of PBT/vPvB substances.	**SEAC working group**, together with **SECR**, to take the discussions into account and revise the approach after the SEAC-59 plenary. **SECR** to publish the updated document on the ECHA website.
2. Presentation of work on valuation of new health endpoints	

SEAC took note of the presentation by the representative of the OECD regarding their work on valuation of new health endpoints. SEAC took note of the presentation by the Secretariat on the upcoming update of the SEAC reference willingness-to-pay (WTP) values.	**SECR** to continue developing the figures based on these results as reference WTP values, and table them for agreement at SEAC-60.
3. Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers and changes in the opinion template	
SEAC agreed on the revised working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers (in line with meeting document SEAC/59/2023/03). Furthermore, SEAC took note of changes in the opinion template.	**SECR** to publish the updated working procedure on the ECHA website.
5.2 Restriction Annex XV dossiers	
a) Conformity check and key issues discussion	
1. Universal Per- and polyfluoroalkyl substances (UPFAS) - recommendations and key issues discussion	
SEAC took note of and discussed the key issues and the recommendations to the Dossier Submitter.	**SECR** to send the recommendations to the Dossier Submitter. **Rapporteurs** to prepare the first draft opinion focusing on food contact material and packaging for discussion at SEAC-60. **Interested STOs** to submit additional information via the ongoing third-party consultation by 25 September 2023, and to send their registrations early for the upcoming SEAC plenary meeting.
b) Opinion development	
1. Creosote, and creosote related substances – Second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	**Rapporteurs** to prepare the third draft opinion, considering SEAC-59 discussions, the outcome of the third-party consultation and the results of the SEAC written consultation.

2. Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 – agreement on the SEAC draft opinion	
SEAC rapporteurs presented and SEAC discussed the third draft opinion. SEAC agreed on its draft opinion (with editorials agreed at SEAC-59) by consensus.	**Rapporteurs**, together with **SECR**, to do the final editing of the draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. **SECR** to launch a third-party consultation on the agreed SEAC draft opinion on 14 June 2023.
3. Terphenyl, hydrogenated – draft of the final opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the final opinion. SEAC adopted its final opinion (with editorials agreed at SEAC-59) by simple majority. The minority view will be published together with the opinion.	**Rapporteurs**, together with **SECR**, to do the final editing of the final opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted SEAC final opinion. **SECR** to send the compiled package to the Commission. **Member** taking minority opinion should send their scientific and technical reasons for the minority position to SECR by 21 June 2023.
4. N,N-dimethylacetamide and 1-ethylpyrrolidin-2-one – draft of the final opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the final opinion. SEAC adopted its final opinion (with editorials agreed at SEAC-59) by consensus.	**Rapporteurs**, together with **SECR**, to do the final editing of the final opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted SEAC final opinion. **SECR** to send the compiled package to the Commission.
5. Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the final opinion. SEAC adopted its final opinion (with editorials agreed at SEAC-59) by consensus.	**Rapporteurs**, together with **SECR**, to do the final editing of the final opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted SEAC final opinion. **SECR** to send the compiled package to the Commission.
5.3) Appointment of rapporteurs (closed session)	
The Secretariat updated the Committee regarding the upcoming restriction proposals in the Registry of Intentions.	

6. Authorisation	
6.1 General authorisation issues	
a) Update on incoming/future applications	
SEAC took note of the update on the new AfAs received during the May 2023 submission window.	
b) Update of technical guidance for rapporteurs	
The Secretariat presented and SEAC discussed additions and changes to the technical guidance for rapporteurs and AfA opinion template.	**SECR** to consider the discussion and update the technical guidance document (and to publish it on S-CIRCABC) and the AfA opinion template.
6.2 Authorisation applications	
a) Discussion on key issues	
1. 297_CT_Acciaierie_Italia (1 use) 2. 298_CT_Bjerringbro_Fornikling 3. 299_OPE_MeiraTGX (1 use) 4. 300_CT_Weber-Hydraylic (1 use) 5. 301_CT_SD_Liberty_Liege (1 use) 6. 302_CT_Thoma_Metallverdelung (1 use) 7. 303_CT_Rubinetterie_Stella (1 use) 8. 304_SD_Acciaierie (1 use) 9. 305_CT_Meoni_e_Bartoletti (1 use) 10. 306_CT_Galvanica_Pasotti (1 use) 11. 307_CT_Vinzia (1 use) 12. 309_CT_Cromatura-Staff (1 use) 13. 310_CT_Cromotecnica_Fida (1 use)	
SEAC discussed the key issues identified in the 13 applications for authorisation.	**Rapporteurs** to take the discussions into account for the development of the draft opinions.
b) Agreement on draft opinions	
Opinions agreed by consensus without editorials	
1) 292_CT_Artech (1 use) 2) 294_CT_Kludi (2 uses) 3) 288_CT_Leonardo (1 use) 4) 289_CT_Beretta (2 uses) 5) 293_CT_Talleres-Aykrom (1 use) 6) 295_CT_Ugitech (1 use) 7) 296_CT_Mahle-2 (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions.

SEAC agreed on its draft opinions for these applications for authorisation by consensus.	**SECR** to send the draft opinions to the applicants for commenting.
Opinions agreed by consensus with editorials agreed at SEAC-59	
1) 290_CT_Fir-Italia (1 use), 2) 291_CT_Belloni (1 use) 3) 285_CT_Liebherr-Aerospace_Linden (2 uses) 4) 286_CT_Hartchrom-Beck (4 uses) 5) 287_CT_Bacrom (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions (with editorials agreed at SEAC-59) on these applications for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **SECR** to send the draft opinions to the applicants for commenting.
c) Adoption of opinion	
Opinions adopted by consensus	
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)	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinions.	**Rapporteurs**, together with **SECR,** to do the final editing of the SEAC opinions. **SECR** to send the opinions to the Commission, the Member States, and the applicants, and to publish them on the ECHA website.
6.4 Appointment of (co-)rapporteurs for authorisation applications (closed session)	
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with SEAC/59/2023/04rev.1 restricted room document).	**SEAC members** to volunteer to the pool of (co-) rapporteurs for applications for authorisation. **SECR** to upload the updated document to confidential folder on S-CIRCABC IG.
9. Action points and main conclusions of SEAC-59	
SEAC adopted the action points and main conclusions of SEAC-59.	

III. List of Attendees
SEAC-59

SEAC members
ANASTASIOU Christos
ARGYROPOULOS Christos
BRIGNON Jean-Marc
BÜCKER Michael
CASTELLI Stefano
CAVALIERI Luisa (co-opted)
COGEN Simon
DOMINIAK Dorota
DOLENC Darko
FANKHAUSER Simone
FREUDENTHAL Oona
GABBERT Silke
GAIDUKOVS Sergejs
GRACIA Ignacio
ISKRA Jernej
JANSSEN Martien
JOMINI Stéphane
JONES Derrick (co-opted)
JOYCE John
KIISKI Johanna
LEAHY Eimear
LÜDEKE Andreas
MÅGE Marit
NIKOVA Julieta
PIÑEROS Juan
PETERSEN Ida Svostrup
REALE Priscilla
RODRIGUEZ Manuel
ROUW Aart (co-opted)
RUZGYS Karolis
SERRA Alexandra
SOFIKITI Nikoletta
SPITERI Jonathan (co-opted)
THIELE Karen
TŐKÉS Gábor
TURVEY Alex
ŽELJEŽIĆ Davor

ECHA STAFF
AHTIAINEN Heini
ATANASOVA Marina
BARNEWITZ Greta
BIN Essi
DI BASTIANO Augusto
DOYLE Simone
GMEINDER Michael
HAMMER Jort
HENRICHSON Sanna
KIVELÄ Kalle
KLAUSBRUCKNER Carmen
LAZIC Nina
LEHTO HÜRLIMANN Mikko
LIESIROVA Tina
LISBOA Patricia
LOUKOU Christina
LUDBORZS Arnis
MANNERVESI Maija
MARQUEZ-CAMACHO Mercedes
MOTTET Denis
MUSTAQH Fesil
NIEMELÄ Helena
NURMI Väinö
ORISPÄÄ Katja
OTTATI Maria
PELTOLA Jukka
PILLET Monique
POPOVIC Marko
REGIL Pablo
STOYANOVA Evgenia
WILK Mateusz
ZEIGER Bastian

Commission observers
BEEKMAN Martijn
BERTATO Valentina
PEDERSEN Finn
SVÄRD Amie
ROSSI Ludovica

RAC rapporteurs
SANTONEN Tiina
MOLDOV Raili

Stakeholder representatives and accompanying experts		
Name	**Representing**	**Agenda point**
Amaya JANOSI	Cefic: European Chemical Industry Council	
Anna LENNQUIST	Expert to ChemSec	UPFAS
Anna GERDING	Expert to CropLife Europe	PFAS in FFF
Antoine MACKIE	ACEA = European Automobile Manufacturers' Association	MCCP
Chris HOWICK	Ineos-Inovyn, Expert to Cefic	MCCP
Christine HERMANN	EEB: European Environmental Bureau	
Corinna MUTTER	SPECTARIS, Expert to MedTech Europe	UPFAS
Dolores ROMANO MOZO	EEB: European Environmental Bureau	
Elisa CONSOLI	CEFIC, Expert to Eurometaux	PFAS in FFF
Hauke HEINEN	Bayer, Expert to Cefic	Report from the PBT/vPvB working group
Hélène DUGUY	ClientEarth	
Hugo WAETERSCHOOT	Eurometaux	
Geoffroy TILLIEUX	EuPC	MCCP
Jan SCHÜLLER	Eastman, Expert to Cefic	Terphenyl
Jens-Olaf EICHLER-HAESKE	BASF, Expert to Cefic	DMAC, NEP
Juliane GLÜGE	EuChemS = European Chemical Society	UPFAS, PFAS in FFF, MCCP
Mads Boye KØRNER	Koppers, Expert to Cefic	Creosote
Martin KALLER	BASF, Expert to Cefic	PFAS in FFF
Mike HOLLAND	EAERE	
Nicolas ROBIN	PlasticsEurope	PFAS in FFF, UPFAS
Oliver LOEBEL	EUREAU (IWW Water Center)	PFAS in FFF
Paul RUELENS	CropLife	PFAS in FFF
Ronald BOCK	AGC, expert to PlasticsEurope	PFAS in FFF, UPFAS
Roumania SANTOS	MedTech Europe	
Sidsel DYEKJAER	ChemSec	
Susanne VEITH	Dupont, Expert to Cefic	UPFAS
Geoffroy TILLIEUX	EuPC	MCCP
Sandra WERNECKE	Expert to ACEA	MCCP

Dossier Submitters	
Name	**Restriction**
Tiziana CATONE	Terphenyl
Silvia ALIVERNINI	Terphenyl
Maria ORRU	Terphenyl
Sammy DRISSI-AMRAOUI	Creosote
Karine FIORE	Creosote
Elodie PASQUIER	Creosote
Richard LUIT	DMAC-NEP
Angelika BAUMBUSCH	UPFAS
Arianne DE BLAEIJ	UPFAS
Carl DANNENBERG	UPFAS
Sebastiana HARD	UPFAS
Marion SANDERS	UPFAS
Christina AUGUST	UPFAS
Franziska KUPPRAT	UPFAS
Peter Juhl NIELSSEN	UPFAS
Sehbar KHALAF	UPFAS
Thijs DE KORT	UPFAS
Audun HEGGELUND	UPFAS
Jenny IVARSSON	UPFAS

Invited experts		
Name	**Representing**	**Substance**
Eeva LEINALA	OECD: Organisation for Economic Co-operation and Development	
Damien DUSSAUX	OECD: Organisation for Economic Co-operation and Development	Presentation of work on valuation of new health endpoints and agreement on

		their use as SEAC reference values.
Eike PELTZER	WFV Deutschland	PFAS in FFF

Advisors		
Name	**Country**	**Advisor to**
Mervi ASSMANN	FI	Johanna KIISKI
Stephanie CASTAN	AT	Simone FANKHAUSER
Izabela RYDLEWSKA-LISZKOWSKA	PL	Dorota DOMINIAK
Sabrina MORO IACOPINI	IT	Stefano CASTELLI
Sofia ANTONIADOU	GR	Nikoletta SOFIKITI
Achim HELMEDACH Oliver PETERS	DE	Karin THIELE
Arianne DE BLAEIJ	NL	Silke GABBERT
Sebastiana HARD		Martien JANSSEN

IV. List of Annexes

ANNEX I. List of documents submitted to the members of the Committee for Socio-economic Analysis

ANNEX II. Declared conflicts of interest

ANNEX III. Final Agenda

ANNEX I

Documents submitted to the members of the Committee for Socio-economic Analysis

Document	Number
Final Draft Agenda	SEAC/A/59/2023
Update of SEAC accredited stakeholders' list	SEAC/59/2023/01 (restricted meeting document)
Updated SEAC's approach to assessment of PBT/vPvB substances	SEAC/59/2023/02
Updated Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers	SEAC/59/2023/03
Appointment of (co-)rapporteurs for authorisation applications	SEAC/59/2023/04 (Restricted room document)

ANNEX II

DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS

The following participants declared conflicts of interests with the agenda items below (according to Article 9(2) of the SEAC Rules of Procedure):

Name of participant	**Agenda item**	**Interest declared**
Marit MAGE	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Dossier Submitter
Ida SVOSTRUP PETERSEN	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Dossier Submitter
John JOYCE	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Dossier Submitter
Alex TURVEY	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	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.
Karen THIELE	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	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.
Achim HELMEDACH (Adviser to SEAC M Karen Thiele)	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Dossier Submitter
Martien JANSSEN	5.2b-5) N,N-dimethylacetamide; 1-ethylpyrrolidin-2-one (NEP) 5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Dossier Submitter
Silke GABBERT	5.2b-5) N,N-dimethylacetamide; 1-	Working for the CA submitting the dossier; asked to refrain from

	ethylpyrrolidin-2-one (NEP) 5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	voting in the event of a vote on this substance - no other mitigation measures applied. No personal involvement.
Sebastiana HARD (Adviser to SEAC M Silke GABBERT)	5.2b-5) N,N-dimethylacetamide; 1-ethylpyrrolidin-2-one (NEP) 5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Dossier Submitter
Arianne DE BLAEIJ (Advisor to SEAC M Martien JANSSEN)	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS) 5.2b-5) N,N-dimethylacetamide; 1-ethylpyrrolidin-2-one (NEP)	Dossier Submitter 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.
Stefano CASTELLI	5.2b-4) Terphenyl, hydrogenated	Dossier Submitter
Priscilla REALE	5.2b-4) Terphenyl, hydrogenated	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.
Stephane JOMINI	5.2b-1) Creosote, and creosote related substances	Dossier Submitter
Jean-Marc BRIGNON	5.2b-1) Creosote, and creosote related substances	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.
Kalle KIVELÄ (Deputy Chair)	5.2b-6) PFAS in fire-fighting foams	Worked on preparation of the dossier

Mike HOLLAND (regular stakeholder observer representative for EAERE=European Association of Environmental and Resource Economists)	5.2a-1) Universal per- and polyfluoroalkyl substances (UPFAS)	Worked on preparation of the dossier

26 May 2023
SEAC/A/59/2023

Final Draft Agenda
59th meeting of the Committee for Socio-economic Analysis

6-9 June
and
13-14 June 2023

Hybrid meeting

Tuesday 6 June starts at 10.00
Friday 9 June breaks at 13.25
Tuesday 13 June resumes at 10.00
Wednesday 14 June ends at 13.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/59/2023
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – General SEAC procedures

a) Report on SEAC-58 action points and written procedures

For information

b) Update of SEAC accredited stakeholders' list (closed session)

SEAC/59/2023/01
Restricted meeting document
For information and agreement

Item 5 – Restrictions

5.1 General restriction issues

1. Agreement of the updated paper on SEAC's approach to assessment of PBT/vPvB substances

SEAC/59/2023/02
For agreement

2. Presentation of work on valuation of new health endpoints

For information

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

SEAC/59/2023/03
For information and agreement

5.2 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Universal per- and polyfluoroalkyl substances (UPFAS) – recommendations and key issues discussion

For discussion

b) Opinion development

1) Creosote, and creosote related substances – Second draft opinion

For discussion

2) BPA+ - Not for discussion at SEAC-59

Not for discussion at this meeting

3) Medium-chain chlorinated paraffins (MCCP) and other substances that contain chloroalkanes with carbon chain lengths within the range from C14 to C17 – agreement on the draft opinion

For agreement

4) Terphenyl, hydrogenated – Draft of the SEAC final opinion
5) *N*,*N*-dimethylacetamide and 1-ethylpyrrolidin-2-one – Draft of the SEAC final opinion
6) Per- and polyfluoroalkyl substances (PFAS) in fire-fighting foams – Draft of the SEAC final opinion

For adoption

5.3 Appointment of (co-)rapporteurs for restriction dossiers (closed session)

For information

Item 6 – Authorisation

6.1 General authorisation issues

a) Update on incoming/future applications

b) Updates to the Technical Instructions for the rapporteurs

For information

6.5 Authorisation applications

a) Discussion on key issues

1. 297_CT_Acciaierie_Italia (1 use)
2. 298_CT_Bjerringbro_Fornikling (1 use)
3. 299_OPE_MeiraTGX (1 use)
4. 300_CT_Weber-Hydraylic (1 use)
5. 301_CT_SD_Liberty_Liege (1 use)
6. 302_CT_Thoma_Metallverdelung (1 use)
7. 303_CT_Rubinetterie_Stella (1 use)
8. 304_SD_Acciaierie (1 use)
9. 305_CT_Meoni_e_Bartoletti (1 use)
10. 306_CT_Galvanica_Pasotti (1 use)
11. 307_CT_Vinzia (1 use)
12. 309_CT_Cromatura-Staff (1 use)
13. 310_CT_Cromotecnica_Fida (1 use)

For discussion

b) Agreement on draft opinion

1. 285_CT_Liebherr-Aerospace_Linden (2 uses)
2. 286_CT_Hartchrom-Beck (4 uses)
3. 287_CT_Bacrom (1 use)
4. 288_CT_Leonardo (1 use)
5. 289_CT_Beretta (2 uses)
6. 290_CT_Fir-Italia (1 use)
7. 291_CT_Belloni (1 use)
8. 292_CT_Artech (1 use)
9. 293_CT_Talleres-Aykrom (1 use)
10. 294_CT_Kludi (2 uses)
11. 295_CT_Ugitech (1 use)
12. 296_CT_Mahle-2 (1 use)

For discussion and agreement

c) Adoption of opinion

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

6.6 Appointment of (co-)rapporteurs for authorisation applications (closed session)

SEAC/59/2023/04
Restricted room document
For agreement

Item 7 – Article 77(3)(c) requests

None

Item 8 – AOB

a) Update of the work plan

For information

Item 9 – Action points and main conclusions of SEAC-59

Table with Conclusions and Action points from SEAC-59

For adoption

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:

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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.

For more information, please contact: Roumiana Santos

Chemicals Manager, MedTech Europe
rr.santos@medtecheurope.org

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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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.

Please contact: a.mccarthy@etrma.org

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

International Association of Oil & Gas Producers

Avenue de Tervueren 188A
B-1150 Brussels
Belgium

T +32 (0)2 790 7762
reception-europe@iogp.or
www.iogpeurope.org

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.

Only Representative Organisation AISBL
Chaussée de Roodebeek 206
1200 Brussels, Belgium

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.

ADVANCED RECHARGEABLE & LITHIUM BATTERIES ASSOCIATION

168, Avenue de Tervueren – Box 3
B-1150 Brussels, Belgium I +32 2 777 05 60
@RechargeEurope I www.rechargebatteries.org

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.

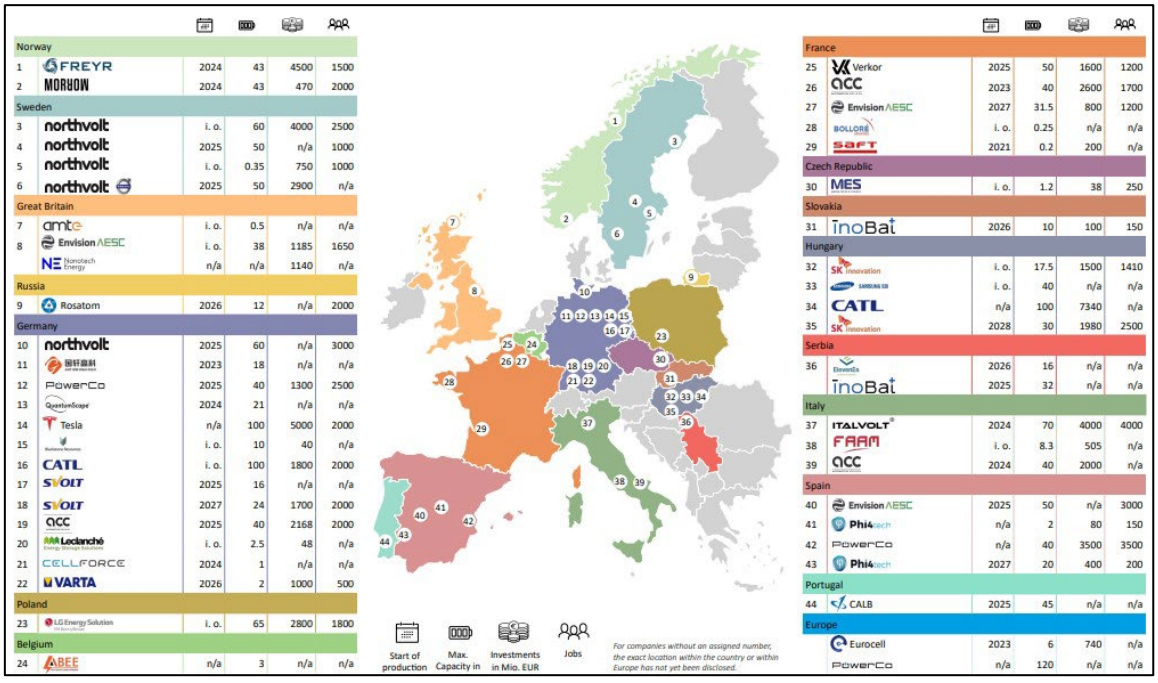
Batteries have been identified by the European Commission as a strategic value chain. The Commission states:

'*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.