16 February 2021

SEAC/M/49/2020 FINAL

Final

Minutes of the 49th meeting of the Committee for Socio-economic Analysis

30-November-4 December 2020
and
8-10 December 2020

I. Summary Record of the Proceeding

1) Welcome and apologies

María Ottati, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the 49th meeting of SEAC. The Chair also informed SEAC that apologies had been received from one member.

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-49. The agenda was adopted with minor modifications (in line with SEAC/A/49/2020rev1). The Chair explained 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 to any of the specific agenda items. Three members, and one advisor, declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2a-1) and 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 and Deputy Chair declared their absence of conflict of interest for all items of SEAC-49 plenary meeting.

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

4) Report from other ECHA bodies and activities

a) Report on SEAC-48 action points, written procedures and update on other ECHA bodies

The Chair informed the participants that all action points of SEAC-48 had been completed or would be followed up during the on-going SEAC-49 meeting.

The Chair also informed the Committee that the final minutes of SEAC-48 had been adopted by written procedure and had been uploaded to S-CIRCABC as well as on the ECHA website. The Chair thanked members for providing comments on the draft SEAC-48 minutes.

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

b) ECHA administrative improvement proposals

The Secretariat gave a presentation about the administrative improvement proposals to be implemented for the upcoming annual review of ECHA declarations of interest for members as well as related to the simplification of the stakeholder involvement in the ECHA Committees.

5) Restrictions

5.1 General restriction issues

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

SEAC took note of and discussed the planned updates in the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals. The Secretariat will launch the written consultations with RAC and SEAC members on the proposed changes in spring 2021 with a view of tabling it for agreement in June 2021.

5.2 Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Substances in single-use diapers

The Chair welcomed the Dossier Submitter's representative from France, the RAC rapporteurs, the occasional stakeholders and their accompanying industry experts. She informed the participants that the restriction dossier had been submitted in October 2020. The Dossier Submitter's representatives provided an introductory presentation on the dossier. They explained that the proposal concerns substances in single-use baby diapers. Members and the occasional stakeholder commented on the DS presentation. The RAC rapporteurs then informed that RAC had concluded that the dossier conforms to the Annex XV requirements at RAC-55.

The SEAC rapporteurs then presented the outcome of the conformity check and the recommendations to the Dossier Submitter. The rapporteurs also provided some recommendations for improving the dossier.

The Committee discussed the case and a occasional stakeholder commented as well. The Committee then agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteurs presented their key issues of the restriction proposal. The Chair informed the Committee that the Consultation on this restriction proposal will be launched on 21 December 2020.

b) Opinion development

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

The Deputy Chair welcomed the Dossier Submitter's representatives from Germany, the RAC rapporteur and the occasional stakeholders and the experts accompanying regular and occasional stakeholder observers. He informed the participants that the restriction dossier had been submitted in December 2019. The opinion development had been extended due to the high volume of consultation comments received and to facilitate the evaluation of the derogation requests.

The RAC rapporteur provided a report from the RAC discussions on this dossier held within RAC-55. The SEAC rapporteurs then presented the third draft opinion to the Committee.

The members generally supported the evaluation of the rapporteurs. The members discussed the restriction's costs and asked some clarifications, e.g. whether loss of functionality is less of a concern for greaseproof paper, costs on fire-fighting foams, whether alternatives are readily available for textiles, and if not whether R&D costs are expected for developing alternatives. The Commission observers asked to provide emission estimates in the same table where cost estimates are presented and commented on the possible impact of functional losses on proportionality for textiles. A final update of the Background Document by the Dossier Submitter is expected by early January 2021, providing further clarification on emission estimates. In case of any substantial changes to the costs' assessment, these will be discussed again at SEAC-50.

During the discussion on proportionality, SEAC touched upon the essential use concept that is used by the Dossier Submitter to justify some derogations, taking into account discussions held on the microplastics dossier. A SEAC member noted that SEAC can discuss only SEA aspects of the essential use concept, but these eventually refer to CEA and the lack of quantified estimates. The Commission observer suggested doing the proportionality assessment sector-by-sector, using a qualitative approach e.g. benefits of use in some sectors can be discussed qualitatively.

The rapporteurs gave an overview of all the derogations proposed by the Dossier Submitter and presented their evaluation of derogations proposed by the Dossier Submitter or requested by stakeholders (photographic coatings, latex and water-based printing inks, watches, filtration and separation media, optical fibres). SEAC did not support the proposal for tentative agreement on the derogations presented. The Committee discussed also the feasibility of the general transitional period of 18 months. Regarding the proposed reporting requirements, the rapporteurs were requested to assess whether reporting requirements are meaningful.

The Commission observer commented on the general transitional period and suggested that SEAC would recommend the exact length, and if this is not possible an assessment of different possible transitional periods should be presented. They also made a remark regarding the reporting requirements and asked what is the intended difference between paragraph 10 and 12 in the proposed restriction.

The regular and occasional stakeholder observers and their experts commented on costs and on derogations (e.g. cost figures for fire-fighting foams are underestimated, wider economic impacts due to relocation of companies outside the EU and job losses, a level-playing field for EU companies should be maintained).

The Deputy Chair concluded that the Committee tentatively agreed on the rapporteurs' assessment of costs and supported the mainly qualitative approach. If there will be further changes on costs, these will be presented at SEAC-50. The derogations presented at the meeting were not agreed upon. Members were reminded that additional comments were

still welcome during the written commenting round on the third draft opinion. Further updates might be needed after the Dossier Submitter provides the updated Background document in early January 2021. The (co-)rapporteurs were requested to prepare the fourth draft opinion, taking into account the SEAC-49 discussions (also on microplastics with regard to the essential use concept) and the results of the SEAC commenting round, by early February 2021. The Secretariat will consider the need to organise an ad hoc Webex meeting in early 2021 to discuss the derogations.

2) Microplastics – draft final opinion

The Chair welcomed the Dossier Submitter's representatives from ECHA, the occasional stakeholders and the industry experts accompanying regular and occasional stakeholder observers. She informed the Committee that the dossier was submitted by ECHA in January 2019. The proposal aims to restrict the placing on the market of intentionally added microplastics and is comprised of various measures.

In order to structure the discussions for adoption, the Chair first gave the floor to some selected stakeholders, representing each of the main sectors / types of organisations participating, to make interventions. These interventions can be found annexed to the minutes.

The SEAC rapporteurs presented and SEAC discussed the draft of final opinion. Following the ad-hoc Microplastics Webex held on 20 October 2020, and based on the outcome of the consultation, which finished on 1 September 2020 (with 211 comments received), SEAC rapporteurs have amended of the draft opinion agreed at SEAC-47.

The rapporteurs' presentation focused on the updates made to the draft opinion. Based on the presentation, the participants discussed and supported the evaluation of the lower size limit issue as presented in the opinion. In addition, SEAC agreed with the evaluation of the remaining scope issues; derogation of polymers without carbon in their structure and additional derogation requests. Furthermore, SEAC supported the rapporteurs' evaluation of the restriction options for infill material (with further modifications as proposed during the discussions) as well as agreed with the rapporteurs' recommendation to review the duration of some of the transitional periods after entry into force. The Commission observer requested that key data elements underlying the SEAC recommendations be duly reflected in the opinion and requested further explanation with regard to the practicalities of the suggested review of derogations. SEAC also supported the rapporteurs' conclusions on cosmetic products and agreed with their evaluation of the paragraph 7 'instructions for use and disposal' and with the evaluation of paragraph 8 (reporting). SEAC discussed the benefits and proportionality and proposed some final modifications in the opinion.

Based on the discussions, the Chair concluded that the following editorials were agreed at the meeting: a) table 4 (on derogations). Clarify which are derogations from scope and which are derogations from the ban on placing on the market (potentially requiring instructions for use and disposal / reporting). b) For synthetic infill, describe how the different proposed options would apply to existing pitches and elaborate on the two scenarios identified where the proposed wording of option A (mandatory RMMs) could allow existing pitches to avoid implementing RMMs after the end of the three year transitional period: (i) stockpiling of replacement infill prior to end of transition and (ii) no further topping up of infill after end of transition. c) In relation to uses where transitional periods

with an interim review is recommended (plant protection products, fragrance encapsulation, medical devices and seed coating), SEAC concluded that the implementation of this approach should not be in the form of open-ended derogations, in other words this would mean that transitional periods should be no longer than 8 years for Plant Protection Products, between 5 and 8 years for fragrance encapsulation, no longer than 6 years for medical devices and no longer than 5 years for other agricultural uses. d) SEAC proposed minor edits to the text on proportionality and the reference to the essential uses concept was removed.

SEAC adopted its final opinion on the restriction proposal by consensus. The rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted SEAC opinion and to ensure that the supporting documentation (Background Document and responses to comments from the consultation) is in line with the adopted SEAC opinion. The SEAC Chair thanked the rapporteurs for their work on this dossier, and informed the Committee that the adopted opinion will be sent to the Commission and published on the ECHA website.

5.2 Appointment of (co-)rapporteurs for restriction dossiers

SEAC was informed about the upcoming restriction proposals to be submitted in the first half of 2021.

6) Authorisation

6.1 General authorisation issues

a) Update on incoming/future applications

The Secretariat presented the information on incoming/future applications for authorisation and review reports, expected workload in 2021 and timelines.

SEAC took note of the update on the new applications for authorisation and the review reports received during the November 2020 submission window and other AfA-related updates.

b) Horizontal AfA issues

The Secretariat presented and SEAC discussed the approach to assessing changes in Producer Surplus in applications for authorisation. The Committee requested the Secretariat to develop the Producer Surplus approach further based on SEAC-49 discussions, and to organise a SEAC written consultation on the paper prior to discussions at SEAC-50 plenary meeting in March 2021.

The Secretariat also presented and SEAC took note of the draft report on the socio-economic findings from the received applications for authorisation and their related SEAC's opinions. The Secretariat will finalise the report for publication in early 2021.

Furthermore, a representative of the European Commission presented and SEAC took note of the update by the Commission on the developments in the role of SEAC in the framework

of Article 60(4) of REACH (Granting of authorisations); and on the technical and economic feasibility thresholds.

6.2 Authorisation applications

a) Discussion on key issues

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

The Secretariat, in cooperation with the SEAC rapporteurs, provided general information regarding the new applications for authorisation and specified the identified key issues in the applications listed below:

- 218_CT_DOURECA (two uses)
- 219_CT_HusqvarnaAB (single use)
- 220_CT_SRG Global (two uses)
- 221_CT_SD_USSK (single use)
- 222_RR1_SD_Colle (single use)
- 223_RR1_EDC_Lanxess (single use)
- 224_RR1_EDC_Eurenco (single use)
- 225_MOCA_LUC (two uses)
- 226_OPE_LETI (single use)

b) Agreement on draft opinion

1) 196_OPE_Becton (1 use)

This is an application for authorisation on one use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (4-tert-OPnEO) as a processing aid in imported diagnostics.

SEAC members discussed the length of the review period, substance substitution activities by the applicant and the information available in the Analysis of Alternatives submitted by the applicant.

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. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

2) 197_OPE_NPE_Phadia (2 uses)

This is an application for authorisation on two uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated and 4-nonylphenol, ethoxylated:

Use 1: Use as component of buffer solutions for the production of purified proteins (cell extraction, chromatographic purification and solvent exchange) and in-process and final

Quality Control testing; intended for use as laboratory reagents in Scientific Research and Development and In Vitro Diagnostic applications at Thermo Fisher Scientific Baltics UA.

The SEAC members discussed the length of the review period, substance substitution activities by the applicant and the information available in the Analysis of Alternatives submitted by the applicant.

Use 2: Coating Thyroid Stimulating Hormone Receptor onto articles used as components of IVD reagent systems at B·R·A·H·M·S GmbH and Phadia GmbH.

The SEAC members discussed quantified emissions by the downstream users for both uses.

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. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

3) 199_OPE_Biokit (2 uses)

This is an application for authorisation on two uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Industrial use of 4-tert-OPnEO as a detergent in the formulation of reagents for incorporation into latex-based, ELISA and CLIA In-Vitro-Diagnostic kits.

Use 2: Professional use of 4-tert-OPnEO as a detergent during the final use of latex-based, ELISA and CLIA IN-Vitro-Diagnostic kits.

A SEAC member reflected on applicant's confidentiality claims on exact quantity of releases of the SVHC substance to the environment.

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. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

4) 202_OPE_Merckle (1 use)

This is an application for authorisation on a single use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: The use of 4-OPnEO as an emulsifier in a silicone oil emulsion for siliconization of pre-filled syringes in a medicinal product.

SEAC members discussed the length of the review period requested by the applicant and substitution activities by the applicant.

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. The rapporteurs and the Secretariat will

consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

5) 203_OPE_NPE_Qiagen (4 uses)

This is an application for authorisation on four uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated and 4-nonylphenol, ethoxylated:

Use 1: Formulation and filling of buffer solutions containing 4-tert-OPnEO/4-NPnEO for the manufacturing of and use in in-vitro Diagnostic and Life Sciences kits of the product groups sample preparation, PCR and sequencing.

Use 2: Industrial use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for the use in in-vitro Diagnostic and Life Sciences kits of the product groups sample preparation, PCR and sequencing.

Use 3: Professional downstream use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for the use in in-vitro Diagnostic and Life Sciences kits with regulatory impact of the product groups sample preparation, PCR, sequencing (and immunoassay for 4-tert-OPnEO only).

Use 4: Professional downstream use of 4-tert-OPnEO/4-NPnEO in the purification of biomaterial and blocking of non-specific bindings for Life Sciences kits without regulatory impact of the product groups sample preparation, PCR and sequencing.

SEAC members discussed differences of the scope of the Uses 3 and 4, non-use scenarios, and very broad publicly available range of costs provided by the applicant.

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. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

6) 208_RR1_TCE_BlueCube (1 use)

This is a review report on a single use of trichloroethylene:

Use 1: Industrial use of trichloroethylene as process chemical (enclosed systems) in Alcantara Material production.

SEAC members discussed claimed health impact calculations by the authorisation holder. SEAC members also discussed briefly the decrease of the substance emissions against the increase of use amounts of the substance due to changes in technology, as well as the alternative trichloroethylene-free process developed by the authorisation holder.

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

Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

7) 209_CT_Safran (1 use)

This is an application for authorisation on a single use of chromium trioxide:

Use 1: Industrial use of chromium trioxide-based mixtures for the surface treatment of legacy spare parts of military aircraft engines, including safety-critical parts whose failure endangers airworthiness.

SEAC members briefly reflected on the scope of the use of this application for authorisation, as well as on a 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. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

8) 210_CT_Hubner (3 uses)

This is an application for authorisation on three uses of chromium trioxide:

Use 1: The use of chromium trioxide in the etching of single-component (1K) plastic articles.

Use 2: The use of chromium trioxide in the selective etching of multi-component (2K/3K) plastic articles.

Use 3: The use of chromium trioxide in the functional electroplating of single-component (1K) and multi-component (2K/3K) plastic articles.

SEAC members discussed tonnage of the substance used per each of the uses, and a length of the review period requested by the applicant. A representative of Eurometaux contributed to the discussion on the length of the review period.

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 applicants for commenting. The rapporteur and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

9) 211_CT_SD_TataSteel (1 use)

This is an application for authorisation on a single use of chromium trioxide:

Use 1: Use of Chromium (VI) Trioxide and Sodium Dichromate for Passivation of Electrolytic Tinplate (ETP).

SEAC members discussed non-use scenarios and job losses estimated by the applicants.

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 applicants for commenting. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

c) Adoption of opinion

1) 143_OPE_bioMerieux (3 uses)

This is an application for authorisation on three uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of reagents for molecular in vitro preparative and testing applications.

Use 2: Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in view of controlling the amount of non-specific reactions in the formulation of in vitro reagents for clinical and industrial in-vitro testing Immunoassays.

Use 3: Industrial use of 4-tert-OPnEO for its non-ionic detergent properties, used for the extraction of biological material which is further formulated and coated on articles intended for clinical and industrial in vitro testing applications.

It was received by the Committee in May 2019. SEAC agreed on the draft opinions during SEAC-44 plenary meeting. On 14 April 2020 the applicant submitted comments on the draft opinions. Some of the applicant's activities have been severely impacted by COVID-19; the demand for 4-tert-OPnEO-containing extraction buffers has increased substantially. Therefore, the applicant provided updated information relevant for Use 1 on 30 September 2020. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the relevant opinion.

The SEAC members briefly discussed decrease of the substance releases to the environment against the increase of use amounts of the substance.

The Committee adopted the opinions by consensus. The rapporteurs, together with Secretariat will to 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.

2) 147_CTPht_Bilbaina (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp.:

Use 1: Use of CTPht as a binder in the manufacture of clay targets.

It was received by the Committee in August 2019. SEAC agreed on the draft opinion during SEAC-46 plenary meeting. On 3 August 2020 the applicant submitted comments on the draft opinion. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinion.

SEAC members discussed economic feasibility assessment and non-use scenarios submitted by the applicant. Representatives of the European Commission contributed to

the discussion, asking for further clarifications as regards the elements and assessment on economic feasiblity. SEAC members also briefly reflected on availability of alternatives.

The Committee adopted the opinion by consensus. The rapporteurs, together with Secretariat will to 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) 148_CTPht_DEZA (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp.:

Use 1: Use of CTPht as a binder in the manufacture of clay targets.

It was received by the Committee in August 2019. SEAC agreed on the draft opinion during SEAC-46 plenary meeting. On 20 July 2020 the applicant submitted comments on the draft opinion. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinion.

SEAC members discussed economic feasibility assessment and non-use scenarios submitted by the applicant. Representatives of the European Commission contributed to the discussion, asking for further clarifications as regards the elements and assessment on economic feasibility. SEAC members also briefly reflected on availability of alternatives.

The Committee adopted the opinion by consensus. The rapporteurs, together with Secretariat will to 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.

4) 149_CTPht_Nalon (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp.:

Use 1: Use of CTPht for manufacture of formulations for various industrial uses.

It was received by the Committee in August 2019. SEAC agreed on the draft opinion during SEAC-45 plenary meeting. On 13 October 2020 the applicant submitted comments on the draft opinion. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with Secretariat will to 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) 150_CTPht_AO_Koppers (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp. and anthracene oil:

Use 1: Use of CTPht/AO for manufacture of formulations for various industrial uses.

It was received by the Committee in August 2019. SEAC agreed on the draft opinion during SEAC-45 plenary meeting. On 14 October 2020 the applicant submitted comments on the

draft opinion. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with Secretariat will to 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) 153_CTPht_AO_Bilbaina (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp. and anthracene oil:

Use 1: Use of CTPht/AO for manufacture of formulations for various industrial uses.

It was received by the Committee in August 2019. SEAC agreed on the draft opinion during SEAC-45 plenary meeting. On 3 August 2020 the applicant submitted comments on the draft opinion. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with Secretariat will to 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.

7) 162_OPE_LFB (1 use)

This is an application for authorisation on a single use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Use as virus inactivation into the manufacture process of plasma-derived immunoglobulins.

It was received by the Committee in November 2019. SEAC agreed on the draft opinion during SEAC-46 plenary meeting. On 13 October 2020 the applicant submitted comments on the draft opinion. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the relevant opinion.

The Committee adopted the opinion by consensus. The rapporteurs, together with Secretariat will to 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.

8) 176_OPE_Abbott_1 (5 uses)

This is an application for authorisation on five uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Industrial use as a surfactant in the formulation of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.

Use 2: Professional use as a surfactant in the final use of In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and ABBOTT PRISM automated analyser systems.

Use 3: Industrial use as a surfactant in the formulation of system solutions (Pre-Trigger and Trigger), for use with In-Vitro Diagnostic Devices (IVDs) on ARCHITECT and Alinity automated analyser systems.

Use 4: Professional use of system solutions (Pre-Trigger and Trigger), in the final use of the In-Vitro Diagnostic Devices (IVDs) on ARCHITECT and Alinity automated analyser systems.

Use 5: Industrial use as a surfactant in the extraction and purification of antigens for incorporation into In-Vitro Diagnostic Devices (IVDs) for clinical testing using ARCHITECT, Alinity and PRISM automated analyser systems.

It was received by the Committee in August 2019. SEAC agreed on the draft opinions during SEAC-47 plenary meeting. On 20 October 2020 the applicant submitted comments on the draft opinions on Uses 1 and 2. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the relevant opinions.

The SEAC members discussed the length of the review period and substitution activities by the applicant. A representative of the European Commission requested the Committee to review the Committee's underlying arguments in the impact assessment part of the opinion.

The Committee adopted the opinions by consensus. The rapporteurs, together with Secretariat will to 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.

9) 184_OPE_Lilly (1 use)

This is an application for authorisation on a single use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Industrial formulation (dilution) of a silicone solution containing 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and its subsequent use as a lubricant in the manufacture of medicinal product delivery devices.

It was received by the Committee in November 2019. SEAC agreed on the draft opinion during SEAC-47 plenary meeting. On 14 October 2020 the applicant submitted comments on the draft opinion. The rapporteur with the Secretariat's assistance reviewed the received comments and updated the relevant opinion.

The Committee adopted the opinion by consensus. The rapporteur, together with Secretariat will to 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.

10) 186_OPE_NPE_Beckman (5 uses)

This is an application for authorisation on five uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated and 4-nonylphenol, ethoxylated:

Use 1: Formulation of NPnEO and OPnEO solutions in European sites for use as laboratory products. Laboratory products are used as intermediate solutions for preparation of finished laboratory products (finished goods) or in-process use.

Use 2: In-process production use of OPnEO as a washing buffer used in the coating of in vitro diagnostic immunoassay particles.

Use 3: Downstream use of OPnEO- or NPnEO-containing clinical laboratory products that require registration, licensing, approval and monitoring by country-based health authorities, designed for use in dedicated clinical chemistry, immunology, haematology and flow cytometry laboratory instruments and assays.

Use 4: Downstream use of OPnEO- or NPnEO-containing laboratory products designed for use in flow cytometry, genomics and particle characterization laboratory instruments and assays for quality control and research and development.

Use 5: Phase out of OPnEO-containing laboratory products from the market due to obsolescence or next generation formulations.

It was received by the Committee in November 2019. SEAC agreed on the draft opinions during SEAC-46 plenary meeting. On 14 October 2020 the applicants submitted comments on the draft opinions. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the relevant opinion.

The SEAC members discussed cost-effectiveness analysis presentation in the opinions. The Committee decided that cost-effectiveness analysis will be presented combined for 4-tert-OPnEO and 4-NPnEO. Members of the Committee also noted few consistency issues, namely tonnage of the substance presentation, which was noted by the SEAC rapporteurs. A representative of the European Commission also contributed to the discussion.

The Committee adopted the opinions by consensus. The rapporteurs, together with Secretariat will to 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.

11) 187_OPE_AGC (2 uses)

This is an application for authorisation on two uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as detergent for the inactivation of viruses in the production of therapeutic proteins using mammalian cell hosts.

Use 2: Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent during the purification process of recombinant biopharmaceuticals derived from microbial expression hosts in projects where processes have been approved by the authorities (GMP compliant).

The SEAC members briefly reflected on the conditions set by RAC in the opinions.

The application for authorisation was received by the Committee in November 2019. SEAC agreed on the draft opinions during SEAC-46 plenary meeting. On 14 October 2020 the applicants submitted comments on the draft opinions. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinions.

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

12) 188_OPE_Wallac_2 (2 uses)

This is an application for authorisation on two uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated:

Use 1: Formulation of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (as Triton X-100) for use in the assay buffer for the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity.

Use 2: Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in the assay buffer of the GSP® Neonatal GALT kit used for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity.

The application for authorisation was received by the Committee in November 2019. SEAC agreed on the draft opinions during SEAC-47 plenary meeting. On 8 October 2020 the applicant submitted comments on the draft opinions. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinions.

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

6.3 Appointment of (co-)rapporteurs for authorisation applications

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/49/2020/01 rev. 01, was agreed by SEAC.

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

7.1) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances

The Chair reminded the Committee about the Article 77(3)(c) request on revision of derogations from proposed restriction on PFOA/PFCAs. The Committees were mandated on 4 August 2020 to prepare supplementary opinions on some derogations from the proposed restriction on C9-C14 perfluorocarboxylic acids (C9-C14 PFCAs), their salts and related substances and on some of the exemptions for perfluorooctanoic acid (PFOA), its salts and related substances included in the POP Regulation. The opinions were developed on the basis of a report prepared by ECHA, which assessed if additional derogations and amendments to existing derogations are justified. The ECHA assessment was based on data collected in a call for evidence by ECHA in May 2020 to which 16 stakeholders provided information.

The Secretariat provided a brief report from the RAC discussions on the Article 77 (3)(c) request held within the ongoing RAC-55, where RAC had adopted its opinion on this request.

The rapporteurs then presented to the Committee the draft opinion that responds to the mandate. Regarding derogation #1, SEAC concluded that the derogation proposed by the ECHA is justified and proportionate especially taking a long-term perspective. The low remaining emissions with 100 ppm limit is not a reason to ban the use of fluoropolymers that contain perfluoroalkoxy groups. SEAC did not support the possibility to reduce the limit and phase out the use in the future. For derogation #2, SEAC supported the derogations proposed by ECHA as justified and proportionate from a socio-economic point of view. With regards to the derogation #3 SEAC supported ECHA's proposal that the derogation is not justified. Derogation #4: SEAC agreed that the limit value should not be lowered at this point (but reviewed and assessed by the Commission no later than 5.7.2022 as already stated in the POP regulation). It is proposed to align the derogations described in paragraph 6 of the RAC and SEAC opinion on the C9-C14 PFCAs restriction to the derogations set out in paragraphs 5 and 6 of the PFOA derogation in the EU POP Regulation. In addition, SEAC supported the alignment (the derogation #5), because PFOA and C9-C14 PFCAs are generated and generally occur simultaneously in PFAS products, and thereby the same applications are governed by both restrictions.

Stakeholder observers asked for clarifying questions (e.g. to clarify between the use of PFOA and C9-C14 PFCAs.) The Chair concluded that SEAC supported all derogations as justified (except in derogation #1 to reduce the limits).

The Committee adopted its opinion on this Article 77(3)(c) request by consensus. The rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted SEAC opinion. The Chair thanked the rapporteur and the ECHA team for their work on this case.

7.2) Substitution plan

The Secretariat reported from the SEAC Working Group meeting on Substitution Plans, which was part of the work related to the ECHA Executive Director's Article 77(3)(c) request on Substitution Plans.

The Committee had some minor discussion. Mostly supportive comments were received from the SEAC members.

8) AOB

a) Update of the work plan

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

b) European Commission presentation on the EU Chemicals Strategy for Sustainability

The representative of the Commission provided a presentation on the EU Chemicals Strategy for Sustainability and its key actions and planned timelines.

9) Action points and main conclusions of SEAC-49

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

II. Main conclusions and action points

SEAC-49, 30 November-3 December 2020 and 8-10 December 2020

(Adopted at SEAC-49 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 with minor modifications (SEAC/A/49/2020_rev1).	
3. Declarations of conflicts of interest to the Agenda	
Conflicts of interest have been declared and will be taken to the minutes.	
4. Report from other ECHA bodies and activities	
a) Report on SEAC-48 action points, written procedures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-48. Furthermore, SEAC took note of the report from other ECHA bodies, including the oral report from the Commission on SEAC-related developments in the REACH Committee.	
5. Restrictions	
5.1 General restriction issues	
a) Updated Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals	
SEAC took note of the plans to update the framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals.	**SECR** to organise SEAC written consultation on the Framework paper in spring 2021.
5.2 Restriction Annex XV dossiers	
a) Conformity check and key issues discussion	
1. Substances in single-use diapers	
SEAC agreed that the dossier conforms to the Annex XV requirements.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG. **SECR** to launch a consultation on the restriction proposal on 21 December 2020.

b) Opinion development	
1. Undecafluorohexanoic acid (PFHxA), its salts and related substances –third draft opinion	
SEAC rapporteurs presented and SEAC discussed the third draft opinion.	**SEAC members** to provide any remaining comments via the written consultation on the third draft opinion (by 13 December 2020). **Rapporteurs** to prepare the fourth draft opinion, taking into account SEAC-49 discussions and the SEAC written consultation, by early February 2021. **Rapporteurs** together with the **Secretariat** to consider arranging an open ad hoc Webex meeting on derogations in early 2021 prior to SEAC-50 (if needed).
2. Microplastics – draft final opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the final opinion. SEAC adopted its final opinion (with modifications agreed at SEAC-49) by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion. **SECR** to compile the adopted RAC and SEAC opinions, and to forward it to the Commission.
5.2 Appointment of (co-)rapporteurs for restriction dossiers	
SEAC was informed about the upcoming restriction proposals to be submitted in the first half of 2021.	
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 November 2020 submission window and other AfA-related updates.	
b) Horizontal AfA issues	
SEAC discussed the approach to assessing changes in Producer Surplus in applications for authorisation. Furthermore, SEAC took note of the draft report on the socio-economic findings from the received applications for authorisation and their related SEAC's opinions.	**SECR** to develop the Producer Surplus approach further based on SEAC-49 discussions, and to organise a SEAC written consultation on the paper prior to discussions at SEAC-50. **SECR** to finalise the report for publication in early 2021.

SEAC also took note of the update by the Commission on the developments in the role of SEAC in the framework of Article 60(4) of REACH; and on the technical and economic feasibility thresholds.	
6.2 Authorisation applications	
a) Discussion on key issues	
1) 9 applications for authorisation (EDC, Cr(VI), MOCA, 4-tert-OPnEO) from August 2020 submission window	
SEAC discussed the key issues identified in the applications for authorisation.	**Rapporteurs** are requested to prepare the first versions of the draft opinions, taking into account the SEAC-49 discussions.
b) Agreement on draft opinions	
1) 196_OPE_Becton (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion (with modifications agreed at SEAC-49) on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the applicant for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion have been agreed by RAC.
2) 197_OPE_NPE_Phadia (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions (with editorials agreed at SEAC-49) on this application 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. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
3) 199_OPE_Biokit (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application 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 applicant for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

4) 202_OPE_Merckle (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together **with SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the applicant for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.
5) 203_OPE_NPE_Qiagen (4 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions (with editorials agreed at SEAC-49) on this application 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. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
6) 208_RR1_TCE_BlueCube (1 use)	
SEAC rapporteur presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion (with editorials agreed at SEAC-49) on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the authorisation holder for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion have been agreed by RAC.
7) 209_CT_Safran (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the applicant for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
8) 210_CT_Hubner (3 uses)	

SEAC rapporteur presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application 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 applicant for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
9) 211_CT_SD_TataSteel (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the authorisation holder for commenting. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion have been agreed by RAC.

c) Adoption of opinion	
1) 143_OPE_bioMerieux (3 uses)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinions. SEAC adopted its opinions on this application for authorisation by consensus.	**Rapporteur** 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 applicant, and to publish them on the ECHA website.
2) 147_CTPht_Bilbaina (1 use)	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinion. SEAC adopted its opinion (with editorials agreed at SEAC-49) on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
3) 148_CTPht_DEZA (1 use)	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinion. SEAC adopted its opinion (with editorials agreed at SEAC-49) on this application for authorisation by consensus.	**Rapporteur** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.

4) 149_CTPht_Nalon (1 use)	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinion. SEAC adopted its opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
5) 150_CTPht_AO_Koppers (1 use)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinion. SEAC adopted its opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
6) 153_CTPht_AO_Bilbaina (1 use)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinion. SEAC adopted its opinion on this application for authorisation by consensus.	**Rapporteur** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
7) 162_OPE_LFB (1 use)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinion. SEAC adopted its opinion on this application for authorisation by consensus.	**Rapporteur** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
8) 176_OPE_Abbott_1 (5 uses)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinions. SEAC adopted its opinions on this application for authorisation by consensus.	**Rapporteur** 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 applicant, and to publish them on the ECHA website.
9) 184_OPE_Lilly (1 use)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinion.	**Rapporteur** together with **SECR** to do the final editing of the SEAC opinion.

SEAC adopted its opinion on this application for authorisation by consensus.	**SECR** to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
10)186_OPE_NPE_Beckman (5 uses)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinions. SEAC adopted its opinions on this application for authorisation by consensus.	**Rapporteur** 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.
11)187_OPE_AGC (2 uses)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinions. SEAC adopted its opinions on this application for authorisation by consensus.	**Rapporteur** 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 applicant, and to publish them on the ECHA website.
12)188_OPE_Wallac_2 (2 uses)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinions. SEAC adopted its opinions on this application for authorisation by consensus.	**Rapporteur** 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 applicant, and to publish them on the ECHA website.
6.3 Appointment of (co-)rapporteurs for authorisation applications	
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with the restricted room document SEAC/49/2020/01_rev1).	**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.
7. Requests under Article 77(3)(c)	
1) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances;	
The SEAC rapporteurs presented and SEAC discussed the draft opinion on the Article 77(3)(c) request on revision of derogations from proposed restriction on PFOA/PFCAs. SEAC adopted its opinion (with modifications agreed at SEAC-49) by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC opinion. **SECR** to prepare the compiled RAC and SEAC opinion package and send it to Commission, and to publish it on the ECHA website.

2) Substitution Plans	
SEAC took note of the report from the meeting of the SEAC Working Group on Substitution Plans held on 6 November 2020.	
8. Any other business	
b) European Commission presentation on the EU Chemicals Strategy for Sustainability	
SEAC took note of the presentation by the Commission on the EU Chemicals Strategy for Sustainability and on the planned actions for its implementation.	
9. Action points and main conclusions of SEAC-49	
SEAC adopted the action points and main conclusions of SEAC-49.	

III. List of Attendees
SEAC-49

SEAC members
ALEXANDRE João
ANASTASIOU Christos
ANTONIADOU Sofia
BERGS Ivars
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
DOMINIAK Dorota
DOLENC Darko
FANKHAUSER Simone
ISKRA Jernej
JANSSEN Martien
JONES Derrick
JOYCE John
KAJIC Silva
KIISKI Johanna
LUIT Richard
LUDEKE Andreas
MUNCRIEF Sandi
MÄGE Marit
NIKOVA Julieta
PETERSEN Ida Svostrup
RODRIGUEZ HERNANDEZ Manuel
ROUW Aart
SCHUCHTAR Endre
SHAKHRAMANYAN Nikolinka
THIELE Karen
URBAN Klaus
ZIEMIENE Jurgita

Commission observers
BENGYUZOV Manol (DG GROW)
BERTATO Valentina (DG ENV)
BLASS-RICO Ana-Maria (DG GROW)
GALLEGO Matteo (DG ENV)
GILLILAND Douglas (JRC)
MONTANI Elena (DG ENV)
PEDERSEN Finn (DG ENV)
SVÄRD Amie (DG GROW)
TOSETTI Patrizia (DG GROW)

ECHA STAFF
ANDERSSON Ida
BLAINEY Mark
DOYLE Simone
ELO Pertti
FRANKE Greta
GERVASUTTI Simone
GMEINDER Michael
GRISHANKOVA Elena
HAN Adela
HENRICHSON Sanna
KAPANEN Anu
KIVELA Kalle
LAZIC Nina
LEFEVRE-BREVART Sandrine
LUDBORZS Arnis
MAJOROS Laszlo
MANNERVESI Maija
MARQUEZ-CAMACHO Mercedes
MATTHES Jochen
MOTTET Denis
NICOT Thierry
NIEMINEN Jarkko
NURMI Väinö
ORISPAA Katja
OTTATI Maria
PELTOLA Jukka
PILLET Monique
REGIL Pablo
RHEINBERGER Christoph
RICHARZ Andrea
RODRIGUEZ UNAMUNDO Virginia
ROGGEMAN Maarten
ROSSI Ludovica
SIHVONEN Kirsi
SIMPSON Peter
STASKO Jolanta
STOCKS Matthew
THIERRY-MIEG Morgane
TORKKELI Hanna
VAZQUEZ Jesus
VAINIO Matti
ZEIGER Bastian

RAC rapporteurs
BORG Daniel
HAKKERT Betty
VARNAI Veda

Stakeholder observers & accompanying experts
ALLAN Dawn (Firmenich) as accompanying expert to IFRA for Microplastics
AZZI-HARTMANN Rola as accompanying expert to MedTech Europe for Microplastics
BALLACH Jochen (CIRFS= European Man-made Fibres Association) as Occasional Stakeholder for Microplastics, Disposable Diapers, PFHxA and PFCAs/PFOAs
BARBU Luminita (EDANA) as Occasional Stakeholder for Substances in single-use diapers and PFHxA
BERG Madeleine (Fidra) as accompanying expert to ClientEarth for Microplastics
BIANCHINI Martina (IFRA) as Occasional Stakeholder for Microplastics
BOCK Ronald (AGC) as accompanying expert to PlasticsEurope for PFHxA and PFCAs/PFOA
CASSART Michel (PlasticsEurope) as Occasional Stakeholder for Microplastics
COLACICCO Rudy (EPPA) as accompanying expert to Cosmetics Europe for Microplastics
DE BOER Steven (SABIC) as accompanying expert to Plastics Europe for Microplastics
de MATOS Olivier (ECETOC = European Centre for Ecotoxicology and Toxicology of Chemicals) as Occasional Stakeholder for Microplastics
DOBE Christopher as accompanying expert to ECPA for Microplastics
DUGUY Hélene (ClientEarth)
HANNEBAUM Peter (Tyco Fire Production) as accompanying expert to Eurofeu for PFHxA
HOLLAND Mike (EAERE = European Association of Environmental and Resource Economists)
HOK Frida (ChemSec)
JANOSI Amaya (Cefic) on day 3
KAFKA Amalia (Euroseeds) as Occasional Stakeholder for Microplastics
KARAGIANNIDOU-ROSIEK Maria (IOGP) as Occasional Stakeholder for Microplastics
KAYSER Martin (BASF) as accompanying expert to ECETOC for Microplastics
LANGEVELD Kees (ICL) as accompanying expert to Eurometaux for Microplastics
LEONHARDT Thomas (Eurofeu) as Occasional Stakeholder for Disposable Diapers and PFHxA

Stakeholder observers & accompanying experts (cont.)
MACAUDIERE Sylvie (Arkema) as accompanying expert to Cefic for Microplastics
MANCINI Giulia (EECA=European Semiconductor Industry Association) as Occasional Stakeholder for PFHxA
MILOIU Emilia (MedTech Europe) as Occasional Stakeholder for Microplastics
MISTRY Rohit (Eftec = Economics for the Environment) as accompanying expert to A.I.S.E. for Microplastics
MUSU Tony (ETUC)
NAVAZAS Alejandro (EuRIC) as Occasional Stakeholder for Microplastics
NICOLAS Robin (PlasticsEurope) as Occasional Stakeholder for PFHxA and PFCAs/PFOAs
OTT Wolfang as accompanying expert to CIRFS for Microplastics
PERFETTI Marco (EUPC=European Plastic Converters) as Occasional Stakeholder for Microplastics
ROBINSON Jan (A.I.S.E.) as Occasional Stakeholder for Microplastics
ROBINSON Nik (EOSCA) as accompanying expert to IOGP for Microplastics
ROMANO Dolores (EEB = European Environmental Bureau)
RUELENS Paul (ECPA=European Crop Protection) as Occasional Stakeholder for Microplastics
SCALIA Mauro (EURATEX = European Apparel and Textile Organisation) as Occasional Stakeholder for Microplastics and PFHxA
SCHLUNDER Klaus as accompanying expert to Euroseeds for Microplastics and PFCAs/PFOAs
SERRANO RAMON Blanca (Cefic)
STRAUSS Markus as accompanying expert to EURATEX for PFHxA
VANDER STRAETEN as accompanying expert to Eurometaux on Microplastics
WIETOR Jean-Luc as accompanying expert to EEB for PFHxA and PFCAs/PFOAs
YADA Makiko (Daikin Chemical Europe) as accompanying expert to Cefic for PFHxA and PFCAs/PFOAs
VITALI Elise as accompanying expert to EEB for Microplastics
WAETERSCHOOT Hugo (Eurometaux = European Association of the Metals Industry)

Advisors, invited experts, observers & dossier submitters (DS)
ASSMANN Mervi as advisor to Johanna KIISKI
DE BLAEIJ Arianne as advisor to Martien JANSSEN
DUBOIS Céline as dossier submitter for Substances in single-use diapers restriction dossier
ERDMANN Christian as dossier submitter for PFHxA restriction
FIORE Karine as dossier submitter for Substances in single-use diapers restriction dossier
FORKMAN Mats as former co-rapporteur for CTPht AfAs
GABBERT Silke as advisor to Richard LUIT
GUERRIERO Lee UEFA) as invited expert for Microplastics
HELMEDACH Achim as advisor to Karen THIELE and as dossier submitter for PFHxA restriction
HILY Emeline as dossier submitter for Substances in single-use diapers restriction dossier
JOMINI Stéphane as advisor to Jean-Marc BRIGNON
MORO IACOPINI Sabrina as advisor to Stefano CASTELLI
JONGENEEL Rob as advisor to Richard LUIT
OLIVER Peters as advisor to Karen THIELE
REALE Priscilla as advisor to Luisa CAVALIERI
SLADKO Thomas, trainer of the course *'Fundamental of diplomatic protocol'*, as invited expert

IV. List of Annexes

ANNEX I

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

Document	Number
Final Draft Agenda	SEAC/A/49/2020_rev1
Appointment of (co-)rapporteurs for authorisation applications	SEAC/49/2020/01 (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**
BRIGNON Jean-Marc	5.2a.1) Substances in single-use diapers	Working for the MS submitting the dossier
JOMINI Stéphane	5.2a.1) Substances in single-use diapers	Working for the MSCA submitting the dossier
LÜDEKE Andreas	5.2b.1 Undecafluorohexanoic acid (PFHxA)	Working for the MSCA submitting the dossier
THIELE Karen	5.2a.1 Undecafluorohexanoic acid (PFHxA)	Working for the MSCA submitting the dossier

ANNEX III

30 November 2020
SEAC/A/49/2020_rev1

Final Agenda
49th meeting of the Committee for Socio-economic Analysis

30 November-3 December 2020
and
8-10 December 2020

Web-based meeting

Monday 30 November starts at 14.00
Thursday 3 December breaks at 17.45
Tuesday 8 December resumes at 10.00
Thursday 10 December ends at 13.45

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/49/2020_rev1
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

c) Report on SEAC-48 action points, written procedures and update on other ECHA bodies

d) ECHA administrative improvement proposals

For information

Item 5 – Restrictions

5.1 General restriction issues

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

For information

5.2 Restriction Annex XV dossiers

b) Conformity check and key issues discussion

1) Substances in single-use nappies

For discussion and agreement

c) Opinion development

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

For discussion

2) Microplastics – draft final opinion

For discussion and adoption

5.2 Appointment of (co-)rapporteurs for restriction dossiers

For information

Item 6 – Authorisation

6.1 General authorisation issues

a) Update on incoming/future applications
b) Horizontal AfA issues

For information

6.4 Authorisation applications

13) Discussion on key issues

a. 9 applications for authorisation (EDC, Cr(VI), MOCA, 4-tert-OPnEO) from August 2020 submission window

For discussion

14) Agreement on draft opinion

1. 196_OPE_Becton (1 use)
2. 197_OPE_NPE_Phadia (2 uses)
3. 199_OPE_Biokit (2 uses)
4. 202_OPE_Merckle (1 use)
5. 203_OPE_NPE_Qiagen (4 uses)

6. 208_RR1_TCE_BlueCube (1 use)
7. 209_CT_Safran (1 use)
8. 210_CT_Hubner (3 uses)
9. 211_CT_SD_TataSteel (1 use)

For discussion and agreement

15) Adoption of opinion

1. 143_OPE_bioMerieux (3 uses)
2. 147_CTPht_Bilbaina (1 use)
3. 148_CTPht_DEZA (1 use)
4. 149_CTPht_Nalon (1 use)
5. 150_CTPht_AO_Koppers (1 use)
6. 153_CTPht_AO_Bilbaina (1 use)
7. 162_OPE_LFB (1 use)
8. 176_OPE_Abbott_1 (5 uses)
9. 184_OPE_Lilly (1 use)
10. 186_OPE_NPE_Beckman (5 uses)
11. 187_OPE_AGC (2 uses)
12. 188_OPE_Wallac_2 (2 uses)

For discussion and adoption

6.5 Appointment of (co-)rapporteurs for authorisation applications

SEAC/49/2020/01

For agreement

Item 7 – Article 77(3)(c) requests

1) Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances

For discussion and adoption

2) Substitution Plans

For discussion

Item 8 – AOB

a) Update of the work plan
b) European Commission presentation on the EU Chemicals Strategy for Sustainability

For information

Item 9 – Action points and main conclusions of SEAC-49

Table with Conclusions and Action points from SEAC-49

For adoption

ANNEX IV

Written statements provided by relevant stakeholder observer organisations in relation to Agenda point 5.2.b.2 Microplastics

1. **IFRA**

IFRA and A.I.S.E.
Speaker Notes (3 minutes)

Interest in Dossier:

I am here to represent the fragrances and the detergents industries. Polymers are used for fragrance encapsulation. Fragrance encapsulates are used predominantly in laundry detergents and fabric softeners but also in some cosmetic products.

Scientific Position:

IFRA and A.I.S.E. welcome the opportunity to provide input to the SEAC process. Encapsulation technology is the most sustainable and resource efficient way of dosing fragrances in consumer products. In the context of the SEAC public consultation on the draft opinion, IFRA has reviewed the availability and the development of viable alternatives to the existing technology in the deepest and most transparent way possible: IFRA highlighted the challenges (CfE#657) in developing and identifying potential alternatives and A.I.S.E. outlined the need for appropriate time needed in R&D (CfE# 666) to make the walls of the perfume microcapsules fully biodegradable as part of the vision in the future. See also document 5 contained in submission #663 (which also included a confidential document on proprietary developments). In addition, IFRA, in close cooperation with A.I.S.E., has provided a detailed and balanced assessment of the timeline for developing suitable alternatives, examining the reformulation products and any other issues that impact the time needed to comply with the proposed restriction. Following review of the existing available encapsulates, we conclude that there are currently **no viable alternatives to the capsules used** at present that provide the performance required and which would be fully exempt from the existing ECHA microplastic restriction proposal.

Identifying, developing and placing on the market substitutes for the current materials which deliver on the multiple **criteria needed for complex encapsulation systems, i.e. biodegradability, consumer performance/acceptance, stability in manufacture and consumer use, ability to work with an extensive palette of fragrance ingredients and viability for commercial-scale manufacture** represents a major challenge to the industry.

It is a complex process with a number of interlinked steps, which creates significant investment risks in terms of commercialisation and testing.
The industry has calculated that **a typical company would require 8.5 years from start of research to having their clients with products containing the technology on the market.**

Some companies are currently developing biodegradable capsules, but most of these:

a. are in the very early stages of R&D and would not be available in the volumes required to cover the market;
b. do not currently meet comprehensively the criteria outlined above for degradable perfume microcapsules that bring perfume onto fabrics without direct losses of it through the wash cycle. A technological breakthrough is needed to fulfil the multiple criteria of these complex fragrance encapsulation systems.

With this in mind, we are maintaining **the need for a minimum transition period of 8 years from entry into force for encapsulated fragrances.** Practical barriers aside, A.I.S.E.'s socio economic analysis submitted in the 2nd public consultation (submission #642) demonstrated that **reducing this to +5 years would only increase the emissions avoided by 1%, but would increase the costs of the restriction by 25%**. Furthermore, an insufficient transition period could result in regrettable product reformulations that trigger changes in consumer behaviour, namely increased frequency of washing, leading to greater environmental impact through increased use of energy and water and increased releases of fibres from synthetic textiles.

To conclude, whilst we require a minimum transition period of 8 years from entry into force for encapsulated fragrances**,** the SEAC rapporteurs' proposal to review the **need for a transition period longer than 5 years after entry into force is welcomed**. This proposal should ensure a smooth transition to alternatives and timely reduction of releases and it would help the regulators understand the progress made by industry.

We thank you for your attention.

2. Cosmetics Europe

Cosmetics Europe Intervention: 49th SEAC Microplastics 8th December 2020

- The cosmetics and personal care industry is a consumer driven sector developing and producing a diverse range of products to serve the needs and expectations of the hundreds of millions of consumers who use our products every day. Our industry provides choice for all consumers whoever they are, wherever they are from, whatever their needs. Consumers love their cosmetics and personal care products. The societal value of cosmetics and personal care products is clear. Multiple studies show our products are essential to Europe's 500 million consumers and consumers across the world, contributing to their quality of life, health, hygiene and mental well-being, self-esteem and social interaction.
- Cosmetics Europe represents the biggest multi-national cosmetics and personal care manufacturers in Europe and more than 4000 SMEs, together representing around 80% of the European market.
- We have appreciated the opportunity to engage in the ECHA Annex XV REACH restriction process throughout and at each step have submitted substantive evidence generated from data and information derived from comprehensive sources and very highly representative of the European market.
- We welcome the conclusions in the SEAC opinion that a derogation for make-up, lip and nail care leave on cosmetic products could be proportionate taking into account the very low contribution to overall emissions as well as the large impact on industry of a ban of microplastics in these products. A comprehensive European study has shown 75% of consumers dispose of these products via the household waste. The significance of low emissions for these products has also been acknowledged by RAC.
- A recent Cosmetics Europe survey[1] on make-up, lip and nail products representing at least 79% of the European market, finds that in respect of these products 177 ingredients and 23,270 formulations would be impacted. This new data also demonstrates that the tonnages are 40% less than those assumed by ECHA for these products and taken forward in the current version of the SEAC Opinion we are discussing today. The direct effect of this is the rise in the cost-effectiveness ratio for leave-on products of about 66% with respect to the cost-effectiveness ratio reported in the current Opinion. We stand prepared to play our part to help inform consumers regarding use and disposal and thus eliminate potential emissions for these products.
- We are however deeply disappointed that the SEAC opinion does not recommend extended transition periods for other leave on cosmetic products. Given the complexity of leave on formulations, the thousands of formulations that would have to be reformulated at the same time, the lack of suitable alternatives and the complex, costly and lengthy reformulation process[2] means that a 6 year

[1] See annex

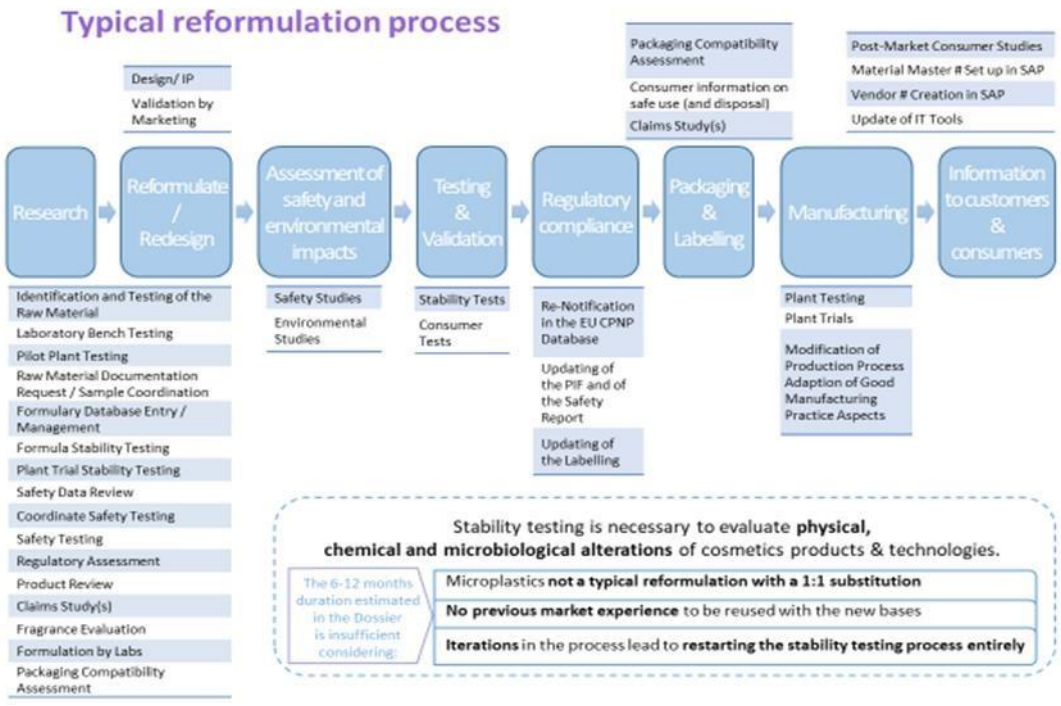
[2] See annex

transition period for other leave on cosmetic and personal care products, is just not realistic.

Microbeads in rinse off cosmetics with up to 2 microplastic ingredients, 1 per formulation and available suitable alternatives, took over 5 years to reformulate. We urge SEAC today to recommend longer transition periods for other leave on cosmetic products to reflect this reality.

ANNEX

Survey make-up lip nail 16 November 202



3. European Crop Protection Association and European Seeds Association

8th December 2020

This intervention in on behalf of the European Crop Protection Association and European Seeds Association. We have four key points.

Firstly, we welcome the SEAC revised restriction wording for the pesticide and seed treatment transition period (paragraph 6, g and h). This now clearly differentiates the derogations between the three cases of pesticides and seed treatments subject to the plant protection regulation, seed treatments which may not be, and the resulting coated seeds.

Secondly, we support the SEAC opinion that it is necessary to review the availability of alternatives prior to the expiry of the relevant transition period. Both ECPA and Euroseeds have requested longer transition periods than have been proposed, based in part on the uncertainty in the reregistration process, how many products are impacted, and how long it will take to find suitable replacements. A review prior to the deadline would be an essential safety net given these uncertainties, and should the R&D efforts for replacements face unexpected setbacks.

Linked to the transition period, Euroseeds wish to again highlight the challenges they expect to face in bringing replacement seed treatments to market within 5 years, and the need to generate data and register in compliance with national Member State legislation. In particular over-yearing is a 1-2 year seed-safety quality control test required to demonstrate continued viability of seeds from one season to the next.

Finally, we wish to again support the dossier submitter proposed lower size limit of 0.1 micron. When considering the lower size limit, it is essential to realise that the microplastic restriction is <u>not</u> defined in terms of plastic. It is defined in terms of polymers, which are large nanoscale molecules. Below 0.1 micron, at the nanoscale, the difference between molecules, colloids, dispersions, their solubility, and what is a solid particle, all become very, very ambiguous. In our view the microplastic definition as written is not fit for purpose at the nanoscale, as we have gone into in great detail previously for the 1nm limit (see #32929, #31756, #31586). Nor can it be measured reliably in the routine real-world context needed for enforcement. While we clearly favour an even more practical higher size limit, we believe the dossier submitter proposal of 0.1 micron is a pragmatic approach, without making the restriction unworkable in an effort to close hypothetical or minor edge-cases perceived as loopholes.

4. European Environmental Bureau (EEB), ChemSec, Clientearth

8 December 2020

On behalf of the EEB, ChemSec and ClientEarth,

I would like to thank SEAC to give us the opportunity to say a few words. We have paid careful attention to the development of your scientific opinion and appreciated your effort to involve stakeholders, including us, throughout this process.

There is compelling scientific evidence that a continued use of microplastics is responsible for irreversible environmental pollution and for potential impacts on humans. Both ECHA and RAC have highlighted those risks and both recommended precaution.

In light of this, SEAC needs to concentrate on socio-economic matters, in accordance with its mandate. It also needs to carefully justify any suggestions to lower the ambition of the restriction. This means:

- **Derogations must not be accepted except when based on reliable and strong evidence**, carefully considered by both RAC and SEAC; and, similarly,
- There should be **no transition period unless justified**. If justified, only that specific use should be granted a delay.
- The **essentiality of the use for society should be taken into account** in the assessment of the relevance of derogations & transition periods.

Considering these imperatives, we **very much welcome some changes made in the SEAC final opinion.**

- The proposal for a 1nm lower size limit will limit the extent of potential regrettable substitution of microplastics by nanoplastics.
- The recommendation for a 5y transition period for fragrance encapsulation (instead of 8) is a step in the right direction although we do not think that the evidence presented to justify a continuous use is sufficiently strong.
- We appreciate that SEAC acknowledges the remaining uncertainties that make it difficult to conclude on some of the transition periods (like seed treatment or cosmetics); however, we believe SEAC should simply not recommend any delay when it is not sufficiently justified.

We would also like to raise the attention of SEAC on **several concerns we have with regard to the latest draft.**

The first one concerns the exclusion of polymers without any carbon C in their chemical structure from the scope of the restriction. We are very worried by this derogation, which was added late in the process, and for several reasons.

- First, the implications of the derogation are not fully assessed and identified: which polymers are being exempted because of it? How many? A definition and list of the polymers that would be covered is indispensable.
- Second, as we understand, some of the polymers that would be exempted, such as ammonium polyphosphates, are, contrary to what is currently claimed, highly persistent. This was for example the conclusion of an assessment performed by the US Environment Protection Agency in 2015. They pose, therefore, the same concerns as organic polymers considered to be restricted.
- Thirdly and very importantly, the way this derogation is treated violates the limits of the SEAC's mandate. The claimed justification to support the derogation is that the

substances concerned do not present an unacceptable risk because they are not persistent. It is the role of RAC, not SEAC - nor the ECHA secretariat - to assess the reliability and strength of the evidence on the claims submitted in the public consultation. The derogation needs to be assessed and voted on by an appropriate RAC quorum.

- Finally, stakeholders need to be provided with all the details of the assessment of the hazards and risks associated with these as well as any other reasons considered to include an additional derogation at that stage.

We therefore invite SEAC members to **reject that new derogation** that is not well justified and clearly belongs to RAC's realm of competence.

The **other points of concern** relate to elements that were already present in SEAC first draft opinion:

- The derogation for liquid and soluble polymers should be taken out as they pose risks to the environment that are not negligible.
- Supporting a temporary 100nm limit when the "reliable characterisation or identification of microplastics is not 'self evident'" is risky: what should be the threshold for assessing when an identification is self-evident or not? Without proper guidance, the lack of clear identification might well serve as an argument for companies to ask for an exemption of their nanoparticles.
- The derogation for biodegradable polymers remains problematic considering their potential impact on aquatic organisms. We advise SEAC to reject that derogation.
- The SEAC draft opinion still supports the derogation of microplastics contained by technical means (Para. 5a) that would include consumer products such as nappies or menstrual pads. We believe there is no justification for continuing to allow using microplastics in such products that are in direct contact with the human body.
- Some of the transition periods, for leave-on cosmetics or plant protection products, are very long, yet not justified enough. They should be removed from the proposal as those would concretely undermine the effectiveness of the restriction. In particular we find it hard to justify the long delays allowed for agricultural uses of microplastics in light of the objectives of the Farm to Fork strategy.
- Reporting requirements for derogated uses should be strengthened, for ex by requiring information on quantities of pellets handled, and not only on the releases.

We invite SEAC to ensure that the derogations and transition periods do not threaten the reduction of microplastics' irreversible impact on the environment. Alternatives to microplastics already exist or are likely to be developed in the near future for the vast majority of uses. Therefore the experience from frontrunners that have already transitioned provides SEAC with strong evidence to support a strict restriction.

But we also want to remind the Commission of its responsibilities in the next step of the procedure. In the 2019 *Sweden v. COM* case, the Court recalled that the Commission has the power to entirely rely on the Committee's opinion, or to not follow them if justified. It is the risk manager that has to take the final decision that is the most fit to the political objectives set.

We look forward to contributing further to the main points of the discussion today with you.

Thank you.

5. European Recycling industries Confederation

Alejandro Navazas - Scientific Officer at The European Recycling Industries' Confederation

From EuRIC, on behalf of our mechanical tyre recycling branch -EuRIC MTR- we thank this committee for the opportunity to take part again into this discussion.

To understand the impact of the restriction on the circular economy, please, remember this:

In Europe, approximately per one tyre that is burned in energy recovery processes there is one tyre that is recycled into rubber granulate (a 1:1 ratio)[3].

This is important to answer the question: **How can this *at least* 500.000 tonnes of end-of-life tyres (ELT)[4], falling under the microplastic restriction, be managed?**

Firstly, the ban affects the largest granulation end market - ELT-derived infill is present in more than 80% of artificial turf pitches installed in EU[5]- and the stability of the whole granulation market for the last 10 years, implies that **no more recycled rubber could be uptake by other granulate applications.**

Then, **could other material recovery alternatives such as pyrolysis be a solution? Pyrolysis is not an option** because the capacity is simply just not there.

Furthermore, in both cases granulation or pyrolysis, we have to take into consideration (again 1:1 ratio in mind) the fact that **why would more than 1 Mt of tyres be burned in the first place if there was a recycling market for it?**

Then, would energy recovery be an alternative option? No, not really because there is a limited capacity for energy recovery in EU[6]. Besides, even if it was an option, it is not the desired one. Incineration is a destructive method that leads to more CO_2 emissions and loss of critical raw materials[7] and we are already almost at 1:1 ratio in EU.

Taking the previous into consideration, EuRIC thinks that the final opinion reflected by ECHA's committees underestimates the problem based on wrong data assumptions.

[3] ETRMA (2019). Europe 92% of all End-of-Life Tyres collected and treated in 2017. Press Release. Retrieved from: https://www.etrma.org/wp-content/uploads/2019/11/20191119-Europe-92-of-all-End-of-Life-Tyres-collected-and-treated-in-2017.pdf

[4] Equivalent to 50 million ELT units, each weighing approx. 10 kg.

[5] GENAN (2018), Market Potential 2018, and According to ANNEX BACKGROUND DOCUMENT TO RAC AND SEAC OPINIONS ON INTENTIONALLY ADDED MICROPLASTICS: *reports by ECHA (2017) and RIVM (2018), 90-95% of the artificial turf pitches in the EU use infill made from ELT rubber granules produced from recycled tyres, which is also referred to as styrene-butadiene rubber (SBR) (EUNOMIA 2018).*

[6] Global cement and concrete association: https://gccassociation.org/gnr/EU28/GNR-Indicator_25aAGF-EU28-alt.html

[7] The Critical Raw Material List can be found at this link: http://eurlex.europa.eu/legalcontent/EN/TXT/PDF/?uri=CELEX:52017DC0490&from=EN

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benefits[56] associated with the re-use of end-of-life tyres as infill material–. Landfilling is not an option due to EU legislation and there is limited capacity in energy recovery (i.e. incineration[57]). There are however alternative markets where this excess infill material could be put to use such as the manufacture of flooring, athletic tracks and other surfaces or in pyrolysis and black carbon manufacture. It is unknown to what extent these alternative markets could absorb the excess infill currently used on artificial pitches[58]. It is therefore also ~~unknown~~ unclear if and to what extent these lost benefits are a significant factor from a cost perspective. SEAC re-iterates this is only part of a larger policy and environmental discussion (e.g. end-of-life) surrounding artificial pitches which falls outside of the committee's current remit. In any case, potential lost benefits should be considered as costs additional to the already mentioned costs due to market impacts. These lost benefits could not be monetized.

[56] Resource efficiency: reuse of tyres as a secondary raw material and reduced energy need compared to manufacture of virgin material.

[57] Incineration can only take place in cement mills due to the high energy content of the granules.

[58] Although research is on-going to find other applications for infill material (e.g. pyrolysis).

[59] Certain producers have indicated that production of non-microplastic alternatives could be ramped up during the ~~6 year~~6-year transition period.

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source of concern (RIVM 2018). However, SEAC reiterates that there are potential lost environmental benefits (related to the use of ELT waste as a secondary raw material) associated with the fact that at least 100 -000 tonnes of ELT waste per year will not be re-used as infill material. Depending on cement kiln capacities a larger part of ELT waste may end up being sent for incineration. There are however alternative markets where this excess infill material could be put to use such as the manufacture of flooring, athletic tracks and other surfaces or in pyrolysis and black carbon manufacture. It is unknown to what extent these alternative markets could absorb the excess infill currently used on artificial pitches. It is therefore also ~~unknown~~ unclear if and to what extent these lost benefits are a significant factor. A key and important difference between these restriction options is that RO2 would still allow the irreversible emission of microplastics to the environment during the transition period.

Extract from SEAC draft final opinion shared by this committee previously to the meeting on the 8th December 2020. Please see the modified changes after public consultation. **Page 65.** States it is unknown if there are alternatives markets to absorb excess tyres falling under the restriction. Reference 57 inaccurate, the problem is not the availability of cement mills, the problem is that the use of tyre is being replace by other types of wastes (See EuRIC response to public consultation). Reference 58. Alternatives such as pyrolysis are mentioned without further science-based reference, this does not reflect market reality. Reference 59. Is a statement without further reference to facts. We provide a well-documented. fact-based arguments on EuRIC submission to SEAC explaining accurately all the factors addressing these points. **Page 76.** Statement about incineration is contradictory with statement on page 65. Again, it is unclear if there are alternative markets to absorb the total tyre waste used as infill material.

This restriction affects at least 500.000 tonnes of tyres[8] (way more than the at least 100.000 tonnes reflected on both RAC and SEAC opinions) and therefore the alternatives will not be able to absorb the current infill used in artificial pitches.

Besides, tyre recycling into artificial turf infill has a lot of benefits because by using recycled materials, virgin materials are preserved and land exploitation is avoided. Furthermore, recycling contributes to **global warming mitigation,** avoids acidification and contributes to better air quality[14].

Under the restriction, for us, the "unknow" impact on the CE, will be translated in an excess of waste tyres and due to the lack of alternatives:

- **The price stability of recycled rubber would be affected**
- **If not exported, excess tyres will be stockpiled**
- **Despite an EU landfilling ban, more and more tyres will be illegally discarded as the actual trends are showing**[9]

And all of this cannot be overcome by any transitional period.

Therefore, at EuRIC we really believe that **a derogation will:**

- **Protect a well-functioning circular value chain**
  and
- **Protect the best available and environmentally friendly end-market option for tyres.**

Last but not least, this derogation must be accompanied by measures to limit microplastic release as proposed in the CEN/CENELEC technical report because in this way microplastic loses can be avoided for this infill application[10].

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EuRIC

EuRIC MTR
Mechanical Tyre Recycling Branch*

[8] The actual surplus would be 400 000 tonnes of ELT infill per year (400 000 tonnes of ELT infill corresponds to 527 000 tonnes of ELT, including steel and textile. Source, ETRMA contribution to the public consultation on Annex XV dossier, dated 05/2019. Data in alignment to that of recyclers based on tyres input and granulate output sold for infill. From the tyre recycler industry we do not agree with this "at least 100 000 tonnes of tyres" number proposed by the Dossier Submitter as the only quantity that gets close to that number is that of the ELT-derived infill destined to the construction of new pitches. However, annually there is a two-times higher quantity of ELT-derived infill than the one used in new pitches construction that needs to be directed to pitch renovation and pitch maintenance as consequence of compaction (i.e., the infill volume reduction due to compression by players/ball impacts).

[9] *Illegale Altreifenentsorgung in Deutschland - ZARE - Die Initiative für zertifizierte Altreifenentsorger (zertifizierte-altreifenentsorger.de)*

[10] Magnusson & Mácsik (2020). Determining the effectiveness of Risk Management Measures to minimize infill migration from synthetic turf sports fields. Please, refer to ESTC reply to SEAC public consultation on microplastic restriction

6. **Cefic**

Microplastics SEAC 49 Statement

Good morning and thank you for the opportunity to comment here today on behalf of PlasticsEurope, Eurometaux, ECETOC and Cefic. Industry welcomes the discussion on the restriction proposal on intentionally added microplastics, and value the opinions of SEAC and RAC. We strongly believe that REACH is an appropriate regulatory tool to address chemical risk EU-wide, however we have some concerns with the restriction proposal that we would like to mention in this occasion.

Firstly, the grouping of all polymers and polymers containing particles as a whole, considering the wide range of properties and behaviours of this materials is not a suitable starting point for a restriction in REACH.

The broad and generic definition makes the restriction extremely difficult to understand, interpret, implement and ultimately, enforce; legislations and in this particular case restrictions, need to be properly enforced and monitored by the Competent Authorities and understood and complied by industry.

Secondly, we would like to would like to reiterate the importance of including a lower limit, as it is necessary to take into account technical feasibility based on state-of-the-art analytical methods. At the same time, **analysis of these microplastics particle sizes still presents a major technical burden for mixtures, specially below 1 micron**. Significant additional research and development efforts will be required to advance available analysis techniques.

inally, I would like to make several points on the reporting paragraph:

- The reporting requirements included affect a very large number of derogated uses, creating significant additional administrative burden **without an effect on Microplastic releases**.
- The effective implementation and enforceability of the reporting requirements in paragraph 8 would represent a big challenge due to the complex supply chains affected (global supply chains, materials could be moving in and out of countries in various stages of their production).
- For many sectors, the information required for reporting is not readily available, the cost for the companies to collect information on something not previously required has not been properly identified and considered.
- New methodologies and models will have to be developed, IT systems modified, and personnel trained that requires time, we are concern the proposed timelines will not be sufficient to have a workable system up and running.

Finally we would like to thank SEAC to for their consideration on the need to preserve CBI when reporting.

7. MedTech Europe

MedTech Europe's statement at SEAC meeting of 8 December 2020

We welcome the adopted opinion of RAC and the draft opinion of SEAC to derogate IVDs from the restriction proposal. Given that releases of microplastics from IVD products are very low and any other measures would have been disproportionate.

For today's meeting we put forward comments for consideration with regards to the Instructions for Use and Reporting requirements.

For the Instructions for Use – the IVD sector will give the appropriate instructions to minimise releases to the environment as far as technically and practically feasible.

For reporting requirements, we would strongly favor introducing a minimum threshold limit for reporting environmental releases. This would reduce administrative costs and increase accurate reporting. There are potentially tens of thousands of downstream users (DUs) in the EU, and this would require each one providing annual release data to each supplier based on their own waste treatment processes. More detailed guidance and clarifications are still needed for our industry. Increase in sales could also affect the amount of microplastics release. It would be important to take into account what is already being done to limit the amount of microplastic release. COVID-19 is a pertinent example, where a new disease causes a surge in demand for products which IVD companies will be striving to support.

We appreciate the flexibility of the rapporteurs to consider our views / input in the final version of the SEAC Opinion.

8. IOGP

SEAC Microplastics meeting 8 December 2020
IOGP intervention (max.3min)

Thank you for the opportunity to make this statement representing IOGP, the International Oil and Gas Producers association.
Oil and gas industry is one of the sectors that would fall under the derogation and would therefore have to comply with the reporting obligation. Therefore, it is essential to understand how this reporting obligation will work in practice.
Thank you for the revision of the SEAC opinion incorporating many positive changes, such as recognition of the business confidential information.
We are happy to see the deadline for reporting obligation to be moved to the end of May, which we hope should give enough time to produce a quality report by the obliged parties.
However, it is still not clear how the reporting obligation will be established in practice including what reporting system will be used, and who exactly will be the obliged parties.
We have previously recommended in our written submission in August, that the most efficient and cost-effective method of reporting for the industry and for the public administration would be incorporating the microplastics releases to one of the existing environmental reporting frameworks submitted to the national competent authorities.
Moreover, in the draft opinion that you have share with us, it is recognized that:

- The overall cost of the reporting requirement can be reduced by cost-effective implementation, for instance by taking into account existing reporting schemes.
- And that the costs of environmental reporting obligations indicate lower costs then harmonised notifications under poison centres legislation.

We would be curious to understand reasoning on why it is recommended to report directly to ECHA, how this system will be set up and what are the next steps in this process.
Thank you