

**11 November 2020**

**SEAC/M/48/2020 FINAL**

**Final**

**Minutes of the 48<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**1-11 September 2020  
and  
15-17 September 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 48th 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-48. The agenda was adopted without modifications (in line with SEAC/A/48/2020). 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. Four members, and one advisor, declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2a-1) and 5.2a-6). These members did not participate in voting under those Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

The Chair declared her absence of conflict of interest for all items of SEAC-48 plenary meeting. The Deputy Chair declared a potential conflict of interest to the substance-related discussions under the agenda item 5.2a)-4 (restriction proposal on five cobalt salts), being part of ECHA's Dossier Submitter team.

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-47 action points, written procedures and update on other ECHA bodies**

The Chair informed the participants that all action points of SEAC-47 had been completed or would be followed up during the on-going SEAC-48 meeting.

The Chair also informed the Committee that the final minutes of SEAC-47 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-47 minutes.

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

## **5) Restrictions**

### **5.1 General restriction issues**

#### **a) Updated report on the costs and benefits of REACH restrictions**

SEAC took note of and discussed the on-going work to update the report on the costs and benefits of REACH restrictions. The previous report on impacts of REACH restrictions covered 2010-2016 (i.e. the first 16 restrictions). The updated report includes the results of the previous report plus estimated costs and benefits of 17 restrictions processed since 2016.

### **5.2 Restriction Annex XV dossiers**

#### **b) Opinion development**

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

The Deputy Chair welcomed the Dossier Submitter's representative from Germany, the RAC rapporteurs 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 RAC rapporteur provided a report from the RAC discussions on this dossier held within RAC-54. The SEAC rapporteurs then presented the second draft opinion to the Committee.

The members supported the evaluation of the rapporteurs. The Committee discussed the feasibility of the transition period and proposed reporting requirements. The Committee also discussed the analysis of alternatives, concentration limit values and the impacts of any restriction on recycling. The members also commented on the costs of the reporting requirements and benefits of the restriction.

The Commission observers commented on the proposed derogations and on the cost-effectiveness of alternatives. They also informed the Committee about the publication of a new report commissioned by ECHA and the Commission on the use of PFAS and fluorine free alternatives in fire-fighting foams. Another report on the use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel will be published soon.

The regular and occasional stakeholder observers commented on analytical methods, enforceability, derogations, and some of them supported the reporting obligations and labelling. The expert(s) accompanying the regular and occasional stakeholders commented on definitions, transitional period and labelling requirements. The Deputy Chair informed the Committee that a discussion on the concept of essential uses in the margins of SEAC-49 was being considered.

The Deputy Chair concluded that the Committee supports the rapporteurs' approach to the evaluation of the costs and benefits, as well as derogations and proportionality. The (co-)rapporteurs were requested to prepare the third draft opinion, taking into account the SEAC-48 discussions and the results of the six-month consultation, by end of October 2020.

## 2) Microplastics – status update

The Chair welcomed the Dossier Submitter's representatives from ECHA, supported by experts from Sweden (KemI), 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.

The SEAC rapporteurs provided a short status update on the comments received from the consultation on the SEAC draft opinion, which finished on 1 September 2020 (with 211 comments received). Based on the evaluation of the comments received, the Secretariat together with the rapporteurs were asked to consider the need for arranging an ad-hoc WebEx meeting on microplastics in October 2020, prior to SEAC-49. SEAC is expected to adopt its final opinion on this restriction proposal at SEAC-49, in December 2020.

## 3) Formaldehyde and formaldehyde releasers – draft final opinion

The Chair welcomed the Dossier Submitter's representatives from ECHA. She informed the participants that the restriction dossier had been submitted in January 2019. The proposed restriction aims to restrict the placing on the market of articles for supply to the general public if the formaldehyde released from them exceeds a concentration of 0.124 mg/m<sup>3</sup> as measured in accordance with specific conditions (specified in an appendix to the restriction). Furthermore, a formaldehyde concentration of 0.1 mg/m<sup>3</sup> shall not be exceeded in the interiors of road vehicles and aircraft. SEAC had agreed on the draft SEAC opinion at SEAC-46.

The SEAC (co-)rapporteurs then presented the draft of the SEAC final opinion and the outcome of the consultation on the SEAC draft opinion. The Commission observers commented on: the scope of the restriction proposal; the justification for the derogation for articles covered by the Directive 2009/48/ EC on toy safety and on that for articles covered by the Biocidal Products Regulation (BPR); the conditions set up in Appendix X and on how they would function in practice; the justification for the evaluation of the proportionality of the restriction proposal. The regular and occasional stakeholder observers and accompanying experts commented on the socio-economic impacts should small parts made of polyoxymethylene (POM) be included in the restriction, while welcoming the Rapporteurs' proposal for a modification of Appendix X to allow for more flexibility of loading factors, on the importance of Appendix X to demonstrate compliance, on the use of DALYs as part of the evaluation on proportionality, as well as on the technical feasibility and the socio-economic impacts of a restriction with the limit value proposed by RAC, which is lower than the value proposed by the Dossier Submitter.

The members noted that the rapporteurs are proposing to exclude aircraft from the scope of the restriction, to modify Appendix X to allow more realistic loading factors for small

articles, and to extend the transition period to 24 months in general and 36 months for trucks and buses. The members also noted the further clarifications given by the rapporteurs in relation to the derogations proposed by the Dossier Submitter, and commented on the difference between cost-effectiveness assessment and affordability assessment.

One SEAC member expressed concerns about the appropriateness of the approach used by the Rapporteurs to evaluate the proportionality of the proposal, specifically the use of break-even analysis. The Rapporteurs agreed to make editorial changes to the opinion to clarify the approach.

The Committee adopted its final opinion by consensus (with editorials as agreed at SEAC-48). The rapporteurs were requested, together with the Secretariat, to do the final editing of the adopted SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.

#### 4) Five cobalt salts – draft final opinion

The Chair welcomed the Dossier Submitter's representatives from ECHA. She informed the participants that the restriction dossier had been submitted in October 2018 and proposes to restrict the placing on the market, manufacture and use of five cobalt salts as substances on their own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications.

The SEAC (co-)rapporteurs then presented the draft of the SEAC final opinion and the outcome of the consultation on the SEAC draft opinion. The rapporteurs had reviewed the comments including the new information provided by industry on the potential cost effectiveness of a B-OEL. The information is considered in the final opinion but rapporteurs had limited time to scrutinize the data presented and not all underlying data was available to the rapporteurs. Industry stakeholder representative responded that underlying data can be made available for authorities if requested.

The Commission observers commented on the uncertainties of the assessment, on the derogations for feedingstuffs, on the impact on the batteries production, on the differences of the conclusions for the different restriction options, in particular, 1 and 10 micrograms/m<sup>3</sup>, on the transitional period and on the conclusion on proportionality.

Members supported the conclusion that it is uncertain whether the proposed restriction as amended by RAC would represent the most appropriate EU-wide action. Members also supported the conclusions regarding costs, benefits and proportionality. Members also discussed the proposed derogation for the animal feed sector.

The Committee adopted its final opinion by consensus (with editorials as agreed at SEAC-48). The rapporteurs were requested, together with the Secretariat, to do the final editing of the adopted SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.

#### 5) Calcium cyanamide – draft final opinion

The Chair welcomed the Dossier Submitter's representatives from ECHA, the occasional stakeholders and the expert accompanying the regular stakeholder observer. She

informed the participants that the restriction dossier had been submitted in July 2019 and concerns the placing on the market of calcium cyanamide used as a fertiliser.

The SEAC (co-)rapporteurs then presented the draft of the SEAC final opinion and the changes made in response to the consultation on the SEAC draft opinion. Members supported the conclusion that it is uncertain whether the proposed restriction would represent the most appropriate EU-wide action. Members discussed the changes proposed by the Rapporteurs in response to the comments received, including those in relation to the plant protection product-like properties of calcium cyanamide, its beneficial effects and possible alternative measures. These matters were commented on by an expert accompanying a regular stakeholder. Impacts on farmers, manufacturers and pharmaceutical businesses were also discussed and commented on by the expert accompanying the regular stakeholder. Members also discussed environmental risks and proportionality, cost-effectiveness and the appropriateness and length of a transition period. The accompanying expert to the regular stakeholder commented on these topics as well.

The Committee adopted its final opinion by consensus (with editorials as agreed at SEAC-48). The rapporteurs were requested, together with the Secretariat, 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.

#### 6) Skin sensitizers – draft final opinion

The Deputy Chair welcomed the Dossier Submitter's representatives from France and Sweden, the occasional stakeholders and the industry experts accompanying regular and occasional stakeholder observers. He informed the participants that the restriction dossier had been submitted in April 2019 and proposes to restrict skin sensitising substances in finished textile, synthetic leather, hide and fur articles, placed on the market for the first time.

The SEAC (co-)rapporteurs then presented the draft of the SEAC final opinion and the outcome of the consultation on the SEAC draft opinion. Members discussed specific skin sensitisers including a variety of dyes. The Commission observers commented on the limits proposed for formaldehyde and chromium VI, as well as on analytical methods, the dynamic link with CLP (including SEAC's recommendation to introduce a 'semi-dynamic' link and on a transitional period after the date of entry into force of the new classification), testing and enforcement costs and proportionality. A regular stakeholder commented on the transitional period proposed for the semi-dynamic link with CLP. The expert accompanying a regular stakeholder commented on alternatives to chromium. The occasional stakeholder observer supported the semi-dynamic link, and commented on analytical methods and testing costs. The expert accompanying the occasional stakeholder said they consider that the proposed semi-dynamic link could be implemented and commented on industry's testing practises.

The Committee adopted its final opinion by consensus (with editorials as agreed at SEAC-48). The rapporteurs were requested, together with the Secretariat, 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.

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

SEAC agreed on the pools of (co-)rapporteurs for the upcoming restriction proposals (in line with the restricted meeting document SEAC/48/2020/01).

Furthermore, SEAC was informed about the selection by the Chair on the rapporteur and co-rapporteur positions for the Article 77(3)(c) request on PFOA/PFCAs derogations.

## **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 2020/2021 and timelines.

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

#### **b) Substitution Plans**

The Secretariat informed the Committee about a request by the European Commission to ECHA to evaluate Substitution Plans. These Substitution Plans are expected to be submitted to ECHA between September and December 2020 by 12 applicants which received letters from the European Commission asking them to consider submitting the Substitution Plans.

The Secretariat informed the Committee that the evaluation will be carried out based on Article 77(3)(c) mandate to SEAC from the ECHA Executive Director. The expected deliverables by SEAC are addenda to the already adopted opinions on the relevant applications for authorisation.

ECHA will publish public versions of the Substitution Plans on the ECHA website for consultations with the third parties and the applicants' responses to the comments. The applicants will have the possibility to comment also on the draft addendum. The Secretariat explained practicalities of the opinion development process, such as involvement of the original rapporteurs on the 12 applications for authorisation, which will be supported by the other SEAC members and the Secretariat by means of a Working Group. Participation at the Working Group will be open both to the SEAC members and the SEAC regular stakeholder observers. In addition, the Secretariat will organise preparatory meetings before plenaries in 2021 for SEAC members. Tasks of the Working Group will include commenting on the format for addenda prepared by the Secretariat, discussing possible horizontal issues identified when reading the first Substitution Plans and commenting on whether the planned evaluation process is fit for purpose considering the submitted Substitution Plans. The preparatory meetings will be used to prepare draft addenda for each of the Substitution Plans or utilisation, and reporting of lessons learnt on evaluation of the Substitution Plans to SEAC for future use.

The Committee members discussed practical issues related to the addenda on the Substitution Plans development, including utilisations of the substance against the uses of the substance, lengths of the review periods in the current draft opinions, involvement of and communications with the applicants during the development of addenda, as well as process' general timeline. Representatives of the European Commission and of the three stakeholder observer organisations contributed to the discussion.

The Committee took note of the Secretariat's presentation. The Secretariat will develop the approach further based on SEAC-48 discussions, and will organise Working Group and preparatory meetings to assist the rapporteurs in the opinion development on Substitution Plans. SEAC members were requested to volunteer for the Working Group and regular stakeholder observers to express their interest to observe the working group meeting.

## **6.2 Authorisation applications**

### **a) Discussion on key issues**

1. 6 applications for authorisation (Cr(VI), diglyme) from May 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:

- 212\_CT\_Lars (two uses);
- 213\_CT\_SteelColor (single use);
- 214\_CT\_Salzgitter (two uses);
- 215\_CT\_Oras (two uses);
- 216\_CT\_Viega (two uses);
- 217\_Diglyme\_Acton\_2 (two uses).

### **b) Agreement on draft opinion**

- 1) 193\_OPE\_PPG (2 uses)

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

Use 1: The formulation of a hardener component containing OPE in Aerospace and Defence (A&D) two-part polysulphide sealants;

Use 2: Mixing, by Aerospace and Defence Companies, and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1 % w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a).



The SEAC members discussed methodology of profit loss calculation by the applicant, the Analysis of Alternatives and substitution activities 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 opinion has been agreed by RAC.

#### 2) 194\_OPE\_Yposkesi (1 use)

This is an application for authorisation on the use of OPE for its non-ionic detergent properties for the cell membrane lysis and viral clearance during the development and manufacturing of viral vectors in medicinal products dedicated to human use (Investigational and Authorized Advanced Therapy Medicinal Product).

The SEAC members discussed substitution activities by the applicant, biowaste collection and incineration method, as well as economic feasibility study 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 rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

#### 3) 195\_OPE\_IL (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a lysing agent for red blood cells in blood analysis diagnostic device.

The SEAC members discussed the non-use scenario, in particular with regard to a number of job losses specified by the applicant, as well as the Substitution Plan.

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

#### 4) 198\_OPE\_Zoetis (4 uses)

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

Use 1: Industrial use as a surfactant in a lysis buffer for the release of proteins and antigens from biological material used in the manufacture of three SERELISA veterinary In Vitro Diagnostic devices (IVDs) for detecting infectious disease in farm animals;

Use 2: Industrial use in formulation of kits, kit reagents and buffer solutions in two WITNESS and three SERELISA veterinary In Vitro Diagnostic devices (IVDs) used for detecting certain diseases in pets and farm animals;

Use 3: Professional use as a surfactant in kits, kit reagents and buffer solutions in 18 veterinary In Vitro Diagnostic devices (IVDs) including one SERELISA, six ProfFLOK, six WITNESS and five VetScan. The use is carried out by professional users in diagnostic laboratories and veterinary clinics to detect certain diseases in pets and farm animals;

Use 4: Industrial use as a viral inactivating agent in the manufacture of two veterinary biologic drugs for treatment of osteoarthritis in cats and dogs.

The SEAC members discussed the length of the review period, substitution activities by the applicants, as well as transfer costs in case of not granting of the authorisation.

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 opinion has been agreed by RAC.

#### 5) 200\_OPE\_RSI (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as surfactant in in-vitro diagnostic device developer solution.

The SEAC members discussed reflection of the consumer use in the Analysis of Alternatives, releases of the substance to the environment from the professional use, 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.

#### 6) 204\_OPE\_Merck\_3 (2 uses)

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

Use 1: Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a surface-active ingredient for the production of two types of mixed cellulose ester membranes (lateral flow and microfiltration membranes);

Use 2: Downstream use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as component of mixed cellulose ester membranes.

The SEAC members discussed content of the SVHC substance in the final products (membranes), naming convention of the alternative substances, length of the review period, and considerations of shelf-life of the products in setting up of the review period.

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 opinion has been agreed by RAC.

#### 7) 205\_OPE\_Pfizer (2 uses)

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

Use 1: The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO)(Triton X-100) as a surfactant in the manufacture of biopharmaceuticals - Viral Inactivation and associated processes;

Use 2: The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO))(Triton X-100) as a surfactant in the manufacture of biopharmaceuticals – Post-Production Cleaning.

The SEAC members discussed substitution activities by the applicant and length of the requested review period, in particular on Use 2. The Commission observer contributed to this discussion.

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 opinion has been agreed by RAC.

#### 8) 206\_OPE\_Sanquin (1 use)

This is an application for authorisation on the use of Triton™ X-100 (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated) in formulation of components for IVD kits.

The SEAC members discussed profit loss figures in the application for authorisation.

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 opinions to the applicants for commenting.

#### 9) 207\_NPE\_Chemetall (2 uses)

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

Use 1: The formulation of a hardener component containing NPE in Aerospace two-part polysulphide sealants;

Use 2: Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulphide sealant components with NPE -containing hardener, resulting in mixtures containing < 0.1 % w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a).

The SEAC members discussed the most likely non-use scenario by the applicants, profit calculations for the applicants, substitution activities by the applicants and issues the applicants are facing in the search for a suitable alternative substance.

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 opinion has been agreed by RAC.

#### 10)211\_CT\_SD\_TataSteel (1 use)

This is an application for authorisation on the use of chromium trioxide and sodium dichromate for Passivation of Electrolytic Tinplate (ETP).

The SEAC members discussed the length of the requested review period, rapporteurs' conclusions on the Analysis of Alternatives, an alternative technology change and the substitution activities by the applicant.

The Committee requested the Secretariat to put the agreement on the updated version of the draft opinion on the agenda of the next SEAC-49 plenary meeting. The rapporteurs will take the SEAC-48 discussions into account in the next version of the SEAC draft opinion. The Secretariat will launch the SEAC consultation on the second version of the SEAC draft opinion and schedule it for discussion and agreement at SEAC-49 in December 2020.

### **c) Adoption of opinion**

#### **1. 155\_OPE\_Siemens\_2 (5 uses)**

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

Use 1: Use of 4-tert-OPnEO in isolation of protein from recombinant cell cultures for the production of IVD kits (protein cell extraction);

Use 2: Use of 4-tert-OPnEO in formulation of IVD kit reagents;

Use 3: Use of 4-tert-OPnEO in formulation of IVD- wash solutions;

Use 4: Use of IVD kit reagents on diagnostic analyser systems;

Use 5: Use of IVD-wash solutions on diagnostic analyser systems.

It was received by the Committee in August 2019. SEAC agreed on the draft opinions during SEAC-46 plenary meeting. On 23 July 2020 the applicant submitted comments on the draft opinions on Uses 4 and 5. 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 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. 171\_OPE\_Wallac (2 uses)**

This is an application for authorisation on the two following 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) into enhancement solutions and DELFIA standard and maintenance solutions used in In Vitro Diagnostic assays and RUO products as well as maintenance of instruments as a critical ingredient for detection process while measuring europium (or other lanthanide) content of the assay solution;

Use 2: Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in enhancement solutions and DELFIA standard and maintenance solutions as a critical

ingredient for detection process while measuring europium (or other lanthanide) content in In Vitro Diagnostic assays and RUO products or during maintenance of instruments.

It was received by the Committee in August 2019. SEAC agreed on the draft opinions during SEAC-45 plenary meeting. On 17 July 2020 the applicant submitted comments on the two draft opinions. The rapporteurs with the Secretariat's assistance reviewed the received comments and updated the opinions.

SEAC members discussed methodology of accounting of job losses by the applicant.

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

### 3. 173\_OPE\_Sobi (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) as a surfactant in manufacture of biopharmaceuticals by Swedish Orphan Biovitrum AB.

It was received by the Committee in August 2019. SEAC agreed on the draft opinion during SEAC-45 plenary meeting. On 15 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.

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

### 4. 175\_OPE\_Rousselot (1 use)

This is an application for authorisation on the use of 4-tert-OPnEO as surfactant in the manufacturing of low endotoxin gelatin.

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.

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

### 5. 181\_OPE\_NPE\_Roche (Uses 2 and 4 only)

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

Use 2: Use of Octyl- and Nonylphenoethoxylates in the formulation and filling of in vitro diagnostic (IVD) assays specified in Appendix 1 to the AoA;

Use 3: Use of Octyl- and Nonylphenoethoxylates in in vitro diagnostic (IVD) assays specified in Appendix 1 to the AoA;

Use 4: Use of Octyl- and Nonylphenoethoxylates in the production of proteins and the conjugation of latex beads, both being used as components or for the production of components of in vitro diagnostic (IVD) assays, research or quality control products and other, e.g. analytical applications (processes specified in Appendix 1 to the AoA).

It was received by the Committee in August 2019. SEAC agreed on the draft opinions during SEAC-45 plenary meeting. On 17 July 2020 the applicant submitted comments on the draft opinions on Uses 2 and 4. 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 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.

#### **d) Status update**

##### **1. AfAs agreed at SEAC-47**

The SEAC Secretariat informed the Committee about the opinion development progress in RAC on those draft opinions, on which SEAC agreed at the SEAC-47 plenary meeting. The agreed SEAC opinions need editorial check before sending them to the applicants for commenting. An additional round of discussion in SEAC need not to be held on any of the SEAC draft opinions as a result of the agreements on RAC draft opinions by RAC.

#### **6.3 Appointment of (co-)rapporteurs for authorisation applications**

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/48/2020/02 rev.1, 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; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances**

SEAC took note of the introductory presentation on the Article 77(3)(c) request on revision of derogations from proposed restriction on PFOA/PFCAs and the planned timelines for the opinion development.

The rapporteurs were requested to provide the draft opinion to Secretariat by 12 October 2020. The Secretariat would launch the SEAC consultations on the technical analysis prepared by ECHA and on the draft opinion prior to SEAC-49. SEAC is expected to adopt its opinion on this case by 15 December 2020.

### **8) AOB**

#### **a) Update of the work plan**

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

**b) Presentation by RIVM on the state of play on a draft publication advancing on the cost effectiveness for PBT and vPvB substances through comparative analysis at emission and environmental stock**

The representative of RIVM (Dutch National Institute for Public Health and the Environment) gave a presentation on the state of play on a draft publication advancing on the cost-effectiveness for PBT and vPvB substances through comparative analysis at emission and environmental stock.

The presentation summarised main results of a reach project conducted at the RIVM. The project examined how different effect indicators impact the results of cost-effectiveness analysis for persistent chemicals. In particular, it compared the use of emission estimates, steady-state mass and stock pollution estimates. The members welcomed the study and discussed the possibilities for Dossier Submitters to implement it in practise.

**c) Workshop on Chromates held on 18 June 2020**

The representative of Eurometaux presented results of the second webinar workshop on suitable alternative and Substitution Plan as indicated in the Commission letter to the challenged application of Functional Chrome plating with decorative character.

Objectives of the workshop were to report back from SEAC-47 discussion on the results of the first webinar workshop, which took place on 28 May 2020, and to explore potential for alignments between the Substitution Plans. The presentation and the related discussions were held jointly together with the agenda point 6.1-b.

**d) Presentation by the Federal Institute for Occupational Safety and Health (BAuA) on the project regarding the technical and economic feasibility of alternatives to the use of chromium trioxide for functional and/or decorative chrome plating**

The representative of BAuA (Federal Institute for Occupational Safety and Health) presented the results of a project regarding the technical and economic feasibility of available alternatives to the use of chromium trioxide on the market for functional and/or decorative chrome plating. The presentation and the related discussions were held jointly together with the agenda point 6.1-b.

**9) Action points and main conclusions of SEAC-48**

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

## II. Main conclusions and action points

### SEAC-48, 7-11 September 2020 and 15-17 September 2020

(Adopted at SEAC-48 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
<b>2. Adoption of the agenda</b>	
The agenda was adopted without modifications (SEAC/A/48/2020).	
<b>3. Declarations of conflicts of interest to the Agenda</b>	
Conflicts of interest have been declared and will be taken to the minutes.	
<b>4. Report from other ECHA bodies and activities</b>	
a) Report on SEAC-47 action points, written procedures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-47. 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.	
<b>5. Restrictions</b>	
<b>5.1 General restriction issues</b>	
<b>a) Updated report on the costs and benefits of REACH restrictions</b>	
SEAC took note of the updated report on the costs and benefits of the REACH restrictions.	
<b>5.2 Restriction Annex XV dossiers</b>	
1) Undecafluorohexanoic acid (PFHxA), its salts and related substances – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	<b>Rapporteurs</b> to prepare the third draft opinion, taking into account SEAC-48 discussions, further clarifications submitted by the Dossier Submitter and the outcome of the consultation, by end of October 2020.
2) Microplastics – status update	
SEAC rapporteurs presented the status update on the consultation comments received.	<b>SECR</b> together with <b>Rapporteurs</b> to consider the need for arranging an ad-hoc Webex in October 2020 prior to SEAC-49.



3) Formaldehyde and formaldehyde releasers – Adoption of final opinion	
<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted its final opinion by consensus (with editorials as agreed at SEAC-48).</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> 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.</p> <p><b>SECR</b> to compile the adopted RAC and SEAC opinions, and forward it to the Commission.</p>
4) Five cobalt salts – Adoption of final opinion	
<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted its final opinion by consensus (with editorials as agreed at SEAC-48).</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> 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.</p> <p><b>SECR</b> to compile the adopted RAC and SEAC opinions, and forward it to the Commission.</p>
5) Calcium cyanamide in fertilisers – Adoption of final opinion	
<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted its final opinion by consensus (with editorials as agreed at SEAC-48).</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> 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.</p> <p><b>SECR</b> to compile the adopted RAC and SEAC opinions, and forward it to the Commission.</p>
6) Skin sensitizers – Adoption of final opinion	
<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted its final opinion by consensus (with editorials as agreed at SEAC-48).</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> 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.</p> <p><b>SECR</b> to compile the adopted RAC and SEAC opinions, and forward it to the Commission.</p>
<b>5.2 Appointment of (co-)rapporteurs for restriction dossiers</b>	
<p>SEAC agreed on the pools of (co-)rapporteurs for the upcoming restriction proposals (in line with the restricted meeting document SEAC/48/2020/01).</p> <p>Furthermore, SEAC was informed about the selection by the Chair on the rapporteur and co-rapporteur positions for the Article 77(3)(c) request on PFOA/PFCAs derogations.</p>	

<b>6. Authorisation</b>	
<b>6.1 General authorisation issues</b>	
a) Update on incoming/future applications	
SEAC took note of the update on the new AfAs received during the August 2020 submission window and other AfA-related updates.	
b) Substitution Plans	
SEAC discussed the proposed approach on processing the further information (including, possibly, Substitution Plans) to be submitted by the applicants as regards certain applications for authorisation.	<p><b>SECR</b> to develop the approach further based on SEAC-48 discussions, and to organise ad-hoc groups to assist the rapporteurs in the opinion development on Substitution Plans.</p> <p><b>SEAC members</b> to volunteer for the ad-hoc groups.</p>
<b>6.2 Authorisation applications</b>	
<b>a) Discussion on key issues</b>	
1) 6 applications for authorisation (Cr(VI), diglyme) from May 2020 submission window	
SEAC discussed the key issues identified in the applications for authorisation.	<b>Rapporteurs</b> are requested to prepare the first versions of the draft opinions, taking account the SEAC-48 discussions.
<b>b) Agreement on draft opinions</b>	
1) 193_OPE_PPG (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
2) 194_OPE_Yposkesi (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.</p> <p><b>SECR</b> to send the draft opinion to the applicant for commenting.</p>

	<p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
3) 195_OPE_IL (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.</p> <p><b>SECR</b> to send the draft opinion to the applicant for commenting.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
4) 198_OPE_Zoetis (4 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together <b>with SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
5) 200_OPE_RSI (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion (with modifications agreed at SEAC-48) on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.</p> <p><b>SECR</b> to send the draft opinion to the applicant for commenting.</p>
6) 204_OPE_Merck_3 (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions (with modifications agreed at SEAC-48) on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
7) 205_OPE_Pfizer (2 uses)	

<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions (for Use 2 with modifications agreed at SEAC-48) on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
<p>8) 206_OPE_Sanquin (1 use)</p>	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion (with modifications agreed at SEAC-48) on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.</p> <p><b>SECR</b> to send the draft opinion to the applicant for commenting.</p>
<p>9) 207_NPE_Chemetall (2 uses)</p>	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions on this application for authorisation by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
<p>10)211_CT_SD_TataSteel (1 use)</p>	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p>	<p><b>Rapporteurs</b> to take the SEAC-48 discussions into account in the next version of the SEAC draft opinion.</p> <p><b>SECR</b> to launch the SEAC consultation on the second version of the SEAC draft opinion and schedule it for discussion and agreement at SEAC-49 in December 2020.</p>

<p><b>c) Adoption of opinion</b></p>	
<p>1) 155_OPE_Siemens_2 (5 uses)</p>	
<p>The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinions.</p>	<p><b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the SEAC opinions.</p>

SEAC adopted its opinions on this application for authorisation by consensus.	<b>SECR</b> to send the opinions to the Commission, the Member States and the applicant, and to publish them on the ECHA website.
2) 171_OPE_Wallac (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.	<b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the SEAC opinions.  <b>SECR</b> to send the opinions to the Commission, the Member States and the applicant, and to publish them on the ECHA website.
3) 173_OPE_Sobi (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.	<b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the SEAC opinion.  <b>SECR</b> to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
4) 175_OPE_Rousselot (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC opinion.  <b>SECR</b> to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
5) 181_OPE_NPE_Roche (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC opinions.  <b>SECR</b> to send the opinions to the Commission, the Member States and the applicant, and to publish them on the ECHA website.
<b>d) Status update</b>	
1) AfAs agreed at SEAC-47	
SEAC took note of the status update on SEAC draft opinions agreed at SEAC-47 plenary meeting.	
<b>6.3 Appointment of (co-)rapporteurs for authorisation applications</b>	
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/48/2020/02rev.1).	<b>SEAC members</b> to volunteer to the pool of (co-) rapporteurs for applications for authorisation.  <b>SECR</b> to upload the updated document to confidential folder on S-CIRCABC IG.

<b>7. Requests under Article 77(3)(c)</b>	
1) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances	
SEAC took note of the introductory presentation on the Article 77(3)(c) request on revision of derogations from proposed restriction on PFOA/PFCAs and the planned timelines for the opinion development.	<p><b>Rapporteurs</b> to provide the draft opinion to SECR by 12 October 2020.</p> <p><b>Members</b> to comment the on the technical analysis prepared by ECHA and on the draft opinion prepared by SEAC rapporteurs prior to SEAC-49.</p> <p><b>SECR</b> to table the draft opinion for discussion and adoption at SEAC-49.</p>
<b>9. Action points and main conclusions of SEAC-48</b>	
SEAC adopted the action points and main conclusions of SEAC-48.	

### III. List of Attendees

#### SEAC-48

<b>SEAC members</b>
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
LÜDEKE Andreas
MÄGE Marit
NIKOVA Julieta
PETERSEN Ida Svostrup
RODRIGUEZ HERNANDEZ Manuel
ROUW Aart
SCHUCHTAR Endre
SHAKHRAMANYAN Nikolinka
THIELE Karen
URBAN Klaus
ZIEMIENE Jurgita

<b>Commission observers</b>
BENGYUZOV Manol (DG GROW)
BERTATO Valentina (DG ENV)
BLASS-RICO Ana-Maria (DG GROW)
GALLEGO Matteo (DG ENV)
HUALDE-GRASA Eva Patricia (DG GROW)
ROZWADOWSKI Jazek (DG GROW)
SVÄRD Amie (DG GROW)
TRLIFAJ Šimon (DG GROW)
ZORGNO Riccardo (DG GROW)

<b>Advisors, invited experts, observers &amp; dossier submitters (DS)</b>
ASSMANN Mervi as advisor to Johanna KIISKI
CARLSSON FENG Mattias as dossier submitter for Skin sensitisers restriction dossier
DE BLAEIJ Arianne as advisor to Richard LUIT
DUBOIS Céline as dossier submitter for Skin sensitisers restriction dossier
ERDMANN Christian as dossier submitter for PFHxA restriction
IORE Karine as dossier submitter for Skin sensitisers restriction dossier
FRANKE Greta as future ECHA staff member
GABBERT Silke as advisor to Richard LUIT
HELMEDACH Achim as advisor to Karen THIELE and as dossier submitter for PFHxA restriction
JOMINI Stéphane as advisor to Jean-Marc BRIGNON
MORO IACOPINI Sabrina as advisor to Stefano CASTELLI
OLIVER Peters as advisor to Karen THIELE
PIROW Ralph as dossier submitter for PFHxA restriction
REALE Priscilla as advisor to Luisa CAVALIERI
STEWART Alexandra as dossier submitter for Skin sensitisers restriction
TURVEY Alex as advisor to John JOYCE
WOLFGRAMM Anne as advisor to Karen THIELE

<b>RAC rapporteurs</b>
BORG Daniel
KARADJOVA Irina

<b>Stakeholder observers &amp; accompanying experts</b>
BALLACH Jochen (CIRFS= European Man-made Fibres Association) as Occasional Stakeholder for Microplastics, Skin sensitisers and PBT and vPvB substances
BELKHIRIA Sami as accompanying expert to Cefic for PBT and vPvB substances
BERNARD Alice (ClientEarth)
BOCK Ronald (AGC) as accompanying expert to PlasticsEurope for PFHxA and PFOA & C-9-C14 PFCA
CASSART Michel (PlasticsEurope) as Occasional Stakeholder for Formaldehyde and Microplastics
CROZIER Jonathan (Cefic)
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 H�elene (ClientEarth)
GREULICH Stefan (Dupont) as accompanying expert to PlasticEurope for Formaldehyde
HADDAD Roberto (COMIPIEL SA) as accompanying expert to EEB (European Environmental Bureau) for Skin sensitisers
HAIDER Sonja (ChemSec) for discussion on substitution plans
HANNEBAUM Peter (Tyco Fire Production) as accompanying expert to EUROFEU for PFHxA
HOLLAND Mike (EAERE = European Association of Environmental and Resource Economists)
H�OK Frida (ChemSec)
INTGIMARSDOTTIR Sigridur (Haldor Topsoe) as accompanying expert to Cefic for Cobalt salts
KAYSER Martin as accompanying expert to ECETOC for Microplastics
KLASSE Hans-J�urgen (AlzChem Trostberg GmbH) as accompanying expert to Cefic on Calcium cyanamide

<b>Stakeholder observers &amp; accompanying experts (cont.)</b>
LEONHARDT Thomas (EUROFEU) as Occasional Stakeholder for Microplastics and PFHxA
MACAUDIERE Sylvie (Arkema) as accompanying expert to Cefic for Microplastics
MANCINI Giulia (EECA=European Semiconductor Industry Association) as Occasional Stakeholder for PFHxA
MISTRY Rohit Eftec = Economics for the Environment) as accompanying expert to A.I.S.E. for Cobalt salts
MUSU Tony (ETUC)
NICOLAS Robin (PlasticsEurope) as Occasional Stakeholder for PFHxA and PFOA & C-9-C14 PFCA
OTT Wolfgang as accompanying expert to CIRFS for Microplastics and Skin sensitisers
PERFETTI Marco (EUPC=European Plastic Converters) as Occasional Stakeholder for Skin sensitisers
ROGER Apolline (ClientEarth)
ROMANO Dolores (EEB = European Environmental Bureau)
RUELENS Paul (ECPA=European Crop Protection) as Occasional Stakeholder for Microplastics
SANTOS OTERO Tatiana (EEB) for discussion on substitution plans
SCALIA Mauro (EURATEX = European Apparel and Textile Organisation) as Occasional Stakeholder for PFHxA and Skin sensitisers
SERRANO RAMON Blanca (Cefic)
STRAUSS Markus (EURATEX = European Apparel and Textile Organisation) as Occasional Stakeholder for PFHxA and Skin sensitisers
ten BRINK Patrick as accompanying expert to EEB for Microplastics
TILLIEUX Geoffrey (EUPC) as Occasional Stakeholder for Formaldehyde and Microplastics
WAETERSCHOOT Hugo (EUROMETAUX = European Association of the Metals Industry)
WIETOR Jean-Luc as accompanying expert to EEB for PFHxA
YADA Makiko (Daikin Chemical Europe GmbH) as accompanying expert to Cefic for PFHxA and PFOA & C9-C14 PFCA



<b>ECHA STAFF</b>
BLAINEY Mark
DOYLE Simone
ELO Pertti
GERVASUTTI Simone
GILIOLI Roberto
GMEINDER Michael
GONZALEZ Arutnev
HAN Adela
HENRICHSON Sanna
KIVELÄ Kalle
LAZIC Nina
LEFEVRE-BREVART Sandrine
LINNA Risto
LIOPA Elina
LOGTMEIJER Christiaan
LUDBORZS Arnis
MAARANEN Janne
MAJOROS Laszlo
MANNERVESI Maija
MBANI Tytti
MOTTET Denis
MUSHTAQ Fesil
NICOT Thierry
NURMI Väinö
ORISPÄÄ Katja
OTTATI Maria
PELLA Katrin
PELTOLA Jukka
PELTOLA-THIES Johanna
PILLET Monique
POPOVIC Marko
RHEINBERGER Christoph
RICHARZ Andrea
ROGEMAN Maarten
ROSSI Ludovica
SIHVONEN Kirsi
SIMPSON Peter
SOSNOWSKI Piotr
VÄÄNÄNEN Virpi
VAINIO Matti
ZEIGER Bastian

#### **IV. List of Annexes**

- ANNEX I. List of documents submitted to the members of the Committee for Socio-economic Analysis
- ANNEX II. Declared conflicts of interest
- ANNEX III. Final Draft Agenda

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

<b>Document</b>	<b>Number</b>
Final Draft Agenda	SEAC/A/48/2020
Appointment of (co-)rapporteurs for authorisation applications	SEAC/48/2020/02 rev.1 (restricted room document)
Appointment of (co-)rapporteurs for restriction dossiers	SEAC/48/2020/01 (restricted meeting document)

## 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):

<b><u>Name of participant</u></b>	<b><u>Agenda item</u></b>	<b><u>Interest declared</u></b>
BRIGNON Jean-Marc	5.2a.6 Skin sensitizers in textile	Working for the MSCA submitting the dossier
JOYCE John	5.2a.6 Skin sensitizers in textile	Working for the MSCA submitting the dossier
KIVELÄ Kalle	5.2a.4 Five cobalt salts	Participation in the preparation of the restriction dossier
LÜDEKE Andreas	5.2a.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
WOLFGRAMM Anne	5.2a.1 Undecafluorohexanoic acid (PFHxA)	Working for the MSCA submitting the dossier

**Final Agenda**  
**48th meeting of the Committee for Socio-economic Analysis**

**7-11 September 2020**  
**and**  
**15-17 September 2020**

**Web-based meeting**

**Monday 7 September starts at 14.00**  
**Friday 11 September breaks at 13.00**  
**Tuesday 15 September resumes at 10.00**  
**Thursday 17 September ends at 13.30**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***SEAC/A/48/2020***  
***For adoption***

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

**Item 4 – Report from other ECHA bodies and activities**

- a)** Report on SEAC-47 action points, written procedures and update on other ECHA bodies

***For information***

**Item 5 – Restrictions**

**5.1 General restriction issues**

- a) Updated report on the costs and benefits of REACH restrictions

## 5.2 Restriction Annex XV dossiers

### a) Opinion development

- 1) Undecafluorohexanoic acid (PFHxA), its salts and related substances – second draft opinion
- 2) Microplastics – status update

***For discussion***

- 3) Formaldehyde and formaldehyde releasers – draft final opinion
- 4) Five cobalt salts – draft final opinion
- 5) Calcium cyanamide – draft final opinion
- 6) Skin sensitizers – draft final opinion

***For discussion and adoption***

## 5.3 Appointment of (co-)rapporteurs for restriction dossiers

***SEAC/48/2020/01***

***For agreement***

## **Item 6 – Authorisation**

### 6.1 General authorisation issues

- a) Update on incoming/future applications
- b) Substitution Plans

***For information***

### 6.4 Authorisation applications

- a) Discussion on key issues

1. 6 applications for authorisation (Cr(VI), diglyme) from May 2020 submission window

***For discussion***

- b) Agreement on draft opinion

1. 193\_OPE\_PPG (2 uses)
2. 194\_OPE\_Yposkesi (1 use)
3. 195\_OPE\_IL (1 use)
4. 198\_OPE\_Zoetis (4 uses)
5. 200\_OPE\_RSI (1 use)
6. 204\_OPE\_Merck\_3 (2 uses)
7. 205\_OPE\_Pfizer (2 uses)
8. 206\_OPE\_Sanquin (1 use)
9. 207\_NPE\_Chemetall (2 uses)
10. 211\_CT\_SD\_TataSteel (1 use)

***For discussion and agreement***

c) Adoption of opinion

1. 155\_OPE\_Siemens\_2 (5 uses)
2. 171\_OPE\_Wallac (2 uses)
3. 173\_OPE\_Sobi (1 use)
4. 175\_OPE\_Rousselot (1 use)
5. 181\_OPE\_NPE\_Roche (Uses 2 and 4 only)

***For discussion and adoption***

d) Status update

1. AfAs agreed at SEAC-47

***For information***

**6.5 Appointment of (co-)rapporteurs for authorisation applications**

***SEAC/48/2020/02***

***For agreement***

**Item 7 – Requests under Article 77(3)(c)**

- 1) Revision of derogations from proposed restrictions on perfluorooctanoic acid (PFOA), its salts and PFOA-related substances; C9-C14 perfluorocarboxylic acids (C9-C14 PFCA), their salts and C9-C14 PFCA-related substances

***For information***

**Item 8 – AOB**

- a) Update of the work plan
- b) Presentation by RIVM on the state of play on a draft publication advancing on the cost effectiveness for PBT and vPvB substances through comparative analysis at emission and environmental stock
- c) Workshop on Chromates held on 18 June 2020
- d) Presentation by the Federal Institute for Occupational Safety and Health (BAuA) on the project regarding the technical and economic feasibility of alternatives to the use of chromium trioxide for functional and/or decorative chrome plating

***For information***

**Item 9 – Action points and main conclusions of SEAC-48**

Table with Conclusions and Action points from SEAC-48

***For adoption***