

**17 August 2020**

**SEAC/M/47/2020 FINAL**

**Final**

**Minutes of the 47<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**1-4 June 2020  
and  
9-11 June 2020**

## **I. Summary Record of the Proceeding**

### **1) Welcome and apologies**

Tomas Öberg, Chairman of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the 47th meeting of SEAC. The Chairman also informed SEAC that apologies had been received from two members.

The Chairman 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 Chairman introduced the final draft agenda of SEAC-47. The agenda was adopted without modifications (in line with SEAC/A/47/2020rev2). The Chairman explained that the meeting is partly co-chaired by the Deputy Chairman Kalle Kivelä. The Chairman explained that Cobalt and Formaldehyde discussions and adoption of the final opinions had been postponed until September 2020 because two stakeholders made justified requests to submit comments later. ECHA has decided to accept input from these stakeholders after the close of the consultation.

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 Chairman requested members and their advisors participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Five members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.1.a-1, 5.1a-3, 5.1a-7. These members did not participate in voting under those Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

The Chairman and the Deputy Chairman declared the absence of conflict of interest for all items of SEAC-47 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-46 action points, written procedures and update on other ECHA bodies**

The Chairman informed the participants that all action points of SEAC-46 had been completed or would be followed up during the on-going SEAC-47 meeting.

The Chairman also informed the Committee that the final minutes of SEAC-46 had been adopted by written procedure and had been uploaded to S-CIRCABC as well as on the ECHA website. The Chairman thanked members for providing comments on the draft SEAC-46 minutes.

A representative of the Commission was invited to update the Committee on SEAC related developments in the REACH Committee and in CARACAL.

### **5) Restrictions**

#### **5.1 Restriction Annex XV dossiers**

## **a) Opinion development**

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

The Chairman 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 Secretariat provided to the Committee a report from the RAC discussions on this dossier held within RAC-53. The rapporteurs then presented the first draft opinion to the Committee. The regular and occasional stakeholder observers commented on derogations, concentration limits and transition periods. The expert accompanying the occasional stakeholder commented on the use of firefighting foams and their alternatives. The members pointed out that information was lacking and asked industry to submit more data in the ongoing consultation.

The Chairman concluded that the Committee supports the approach of the rapporteurs so far. The (co-)rapporteurs were requested to prepare the second draft opinion, taking into account the SEAC-47 discussions and the results of the SEAC written consultation, by early August 2020. The members were requested to provide remaining comments via the commenting round on the first draft opinion by 3 July 2020.

### 2) Microplastics – revised sixth draft opinion

The Chairman 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. He 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 Secretariat provided to the Committee a report from the RAC discussions on this dossier held in RAC-53, where RAC had adopted its opinion. The rapporteurs then presented the revised sixth draft opinion to the Committee. The draft opinion had been updated with discussions held in the SEAC Microplastics Webex on 28 April 2020. One member suggested editorials and commented on the infill material used on indoor sports fields. The Commission observer commented on the impact of RAC's recommendation for a revised biodegradability testing scheme and a ban on the placing on the market of infill material used on artificial sports surfaces. The regular and occasional stakeholders, as well as experts accompanying regular stakeholder commented about the transitional periods, alternatives and derogations. The Chairman reminded stakeholders to submit new additional information via the upcoming consultation on the SEAC draft opinion.

The Committee agreed on its draft opinion by simple majority. One member had a dissenting view claiming a lack of sound socio-economic analysis upon which to base a conclusion on the proportionality of the proposed restriction. The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. The Secretariat intends to launch the consultation on the SEAC draft opinion on 1 July 2020. SEAC is expected to adopt its final opinion on this dossier at SEAC-49 in December 2020.

### 3) Skin sensitizers – fifth draft opinion

The Chairman welcomed the Dossier Submitter's representatives from France and Sweden and 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, leather, hide and fur articles, placed on the market for the first time.

The Secretariat informed the Committee that RAC had adopted its opinion at RAC-52 in March 2020. The rapporteurs then presented the fifth draft opinion to the Committee. Members commented on the enforceability and testing costs, and one member proposed a consultation question on the impact of labelling to support enforcement. A regular stakeholder observer, together with its expert, commented on the derogation for personal protection equipment, and labelling. An occasional stakeholder observer supported the dynamic link, and its accompanying expert commented on alternatives to chromium for tanning leather and analytical methods.

The Committee agreed on its draft opinion by consensus (with editorials as agreed at SEAC-47). The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. The Secretariat intends to launch the consultation on the SEAC draft opinion on 24 June 2020.

#### 4) Calcium cyanamide – third draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA and the occasional stakeholders and the expert accompanying the regular stakeholder observer. He 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 Secretariat provided to the Committee a report from the RAC discussions on this dossier held in RAC-53, where RAC had adopted its opinion. The rapporteurs then presented the third draft opinion to the Committee. One member commented on the proportionality of the proposal. The expert accompanying the regular stakeholder observer contributed to the discussion on proportionality. The Chairman reminded stakeholders to submit new additional information via the upcoming consultation on the SEAC draft opinion. The Commission observer informed about the new Fertilising Products Regulation and commented on the proportionality and the proposed transition period.

The Committee agreed on its draft opinion by consensus (with editorials as agreed at SEAC-47). The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. The Secretariat intends to launch the consultation on the SEAC draft opinion on 24 June 2020.

#### 5) Perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances – draft final opinion

The Chairman welcomed the Dossier Submitter's representatives from Norway, the RAC rapporteurs and the occasional stakeholder and the accompanying expert to the occasional stakeholder. He informed the participants that the restriction dossier had been submitted in April 2019 and proposes to restrict the manufacture, use and placing on the market of PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof.

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 regular stakeholder observer and the Commission observer commented on the derogation for firefighting foams.

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 Chairman 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**

The Secretariat presented and SEAC took note of the update on the upcoming restriction proposals to be submitted within the October 2020 submission window. ECHA will submit a restriction proposal on lead chromate; lead sulfochromate yellow (C.I. Pigment Yellow 34); lead chromate molybdate sulphate red (C.I. Pigment Red 104) in October 2020. The pool was agreed at SEAC-44 for this dossier. A second ECHA dossier is expected in October 2020 on lead in ammunition (gunshot and bullets) and fishing tackle. A third ECHA dossier is also scheduled, as a 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 (this dossier will be processed as an Article 77(3)c request). Furthermore, in October, France will submit a restriction proposal on substances of concern in disposable baby nappies. The Netherlands is also working on a restriction proposal for N,N-dimethylacetamide (DMAC) and 1-ethylpyrrolidin-2-one NEP.

The calls for expression of interest for these dossiers will be launched in summer 2020.

## **6) Authorisation**

### **6.1 General authorisation issues**

#### **a) Update on incoming/future applications**

The Secretariat presented the information on incoming/future applications, expected workload in 2020/2021 and timelines. The Secretariat informed also about impact of Covid-19 related research to some current applications for authorisation. In addition, the Secretariat also informed the Committee about update in the Substitution Plan format to make it compliant with the European General Court ruling on lead chromate pigments in March 2019 and the "Suitable Alternatives that are Generally Available (SAGA)" concept. Review of the Analysis of Alternatives (AoA) and the Socio-economic analysis (SEA) formats will follow.

#### **b) Update on the Lines to take document on OPnEO/NPnEO**

The Secretariat presented an update on the Lines to take document on applications for authorisation on uses of OPnEO and NPnEO. Objective of the document is to harmonise approaches and outcomes in the OPnEO and NPnEO opinions, not excluding case-specific reasoning, if appropriate. The document is based on past and on-going approaches taken by the rapporteurs in coordination with ECHA Authorisation teams. Current updates in the document regards Substitution Plans, information on the SVHC substance releases to the environment and the cost-benefit ratio, as well as assessment period. SEAC members contributed to the discussion on the updates to the Lines to take document.

#### **c) Update on how SEAC can proceed with the suitable alternatives that are generally available (SAGA)**

The Secretariat presented its view on the SAGA concept, which emerges from the above mentioned European General Court ruling on lead chromate pigments. During the discussion, which followed the Secretariat's presentation, SEAC members in general supported the Secretariat's views on the issue. They acknowledged that the presentation is a good thought starter while asking for more discussion in SEAC. Two representatives of the stakeholder observer organisations and the Commission observer also contributed to this discussion. The Secretariat will provide further information on SAGA to SEAC when it is available.

## 6.2 Authorisation applications

### a) Discussion on key issues

1. 11 applications for authorisation (OPE/NPE, Cr(VI)) and a review report (TCE) from February 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:

- 193\_OPE\_PPG (two uses);
- 196\_OPE\_Becton (single use);
- 197\_OPE\_NPE\_Phadia (two uses);
- 198\_OPE\_Zoetis (four use);
- 199\_OPE\_Biokit (two uses);
- 202\_OPE\_Merckle (single use);
- 203\_OPE\_NPE\_Qiagen (four uses);
- 207\_NPE\_Chemetall (two uses);
- 208\_RR1\_TCE\_BlueCube (single use);
- 209\_CT\_Safran (single use);
- 210\_CT\_Hubner (three uses);
- 211\_CT\_SD\_TataSteel (single use).

### b) Agreement on draft opinion

1. 154\_OPE\_Siemens\_1 (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a detergent for virus inactivation via Solvent/Detergent treatment in recombinant and plasma-derived medicinal products.

One SEAC member noted that the applicant did not consider impact on patients in this application for authorisation. Another SEAC member raised a question about a discontinued use of the substance in the non-use scenario.

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.

2. 164\_OPE\_Baxter (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as detergent in the production of bead components for in-vitro diagnostic kits for an immunoassay platform.

SEAC members discussed about investment costs, which are estimated qualitatively and claimed confidential, substitution activities by the applicant, and exceptional length of the regulatory period, which is indicated by the applicant to obtain necessary approvals in order to comply with the requirements of other legal acts than the REACH Regulation. The SEAC members also reflected on market share of the company products.

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. 165\_OPE\_bioMerieux\_2 (1 use)

This is an application for authorisation on the industrial use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated for its non-ionic detergent properties, consisting in the filling of 4-tert-OPnEO-containing solutions into specific single-use ampoules to be included in clinical and industrial in vitro testing applications as part of the BioFire and BioFire Next Gen FA products.

Two SEAC members made editorial remarks on the text of the SEAC draft opinion.

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. 170\_OPE\_DiaSorin (1 use)

This is an application for authorisation on the industrial use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as non-ionic surfactant, employed in the purification of antigens in in vitro diagnostics tests for infectious diseases, auto-immunity markers, bone metabolism, hepatitis and retrovirus, oncology and endocrinology.

One SEAC member asked a question about indirect job losses in case if the authorisation has not been granted. Another SEAC member made editorial remark on the text of the SEAC draft opinion.

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.

#### 5. 172\_OPE\_DIAGAST (1 use)

This is an application for authorisation on the industrial use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated for its amphiphilic, surfactant and non-haemolytic properties, to create controlled hydrophilic spots on porous hydrophobic membranes (solid form) for in vitro diagnostic kits for blood testing via antigen/antibody reaction in the following product ranges: ABTest Card®, ABD PAD® and M-TRAP® cartridges for the ONYX® system.

One SEAC member asked a question about quality of the Substitution Plan 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 rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

#### 6. 176\_OPE\_Abbott\_1 (5 uses)

This is an application for authorisation on the five following 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 ABBOTT PRISM automated analyser systems.

The SEAC members discussed substitution activities by the applicant, specifically for Uses 2 and 3, the non-use scenario, as well as high numbers of the job losses indicated by the applicant. One SEAC member questioned confidentiality on certain data in the application claimed by the applicant; he asked for higher level of transparency. 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.

#### 7. 182\_NPE\_Abbott (1 use)

This is an application for authorisation on the professional use of 4-nonylphenol, branched and linear, ethoxylated as a surfactant in an onboard solution (Detergent B) as an accessory to In-Vitro Diagnostic Devices (IVDs) to wash the reagent probes, the mixers and the reaction cuvettes between tests to prevent interference with the test result on ARCHITECT and Alinity automated analyser systems.

One SEAC member made a remark on availability of alternatives by the Sunset Date.

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.

#### 8. 184\_OPE\_Lilly (1 use)

This is an application for authorisation on the 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.

The SEAC members discussed the Analysis of Alternatives and economic feasibility study submitted by the applicant, as well as a length of the review period.

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

#### 9. 185\_OPE\_NPE\_Idexx (3 uses)

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

Use 1: Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as detergent in the technical manufacturing of in vitro diagnostic veterinary ELISA Plate tests (plate coating) to prevent the non-specific binding of unwanted macromolecules;

Use 2: Formulation of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated in the manufacture of sample diluents and standard solutions used in in vitro diagnostic veterinary ELISA Plate tests used for the detection of infectious diseases in livestock and poultry;

Use 3: Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and use of 4-Nonylphenol, branched and linear, ethoxylated in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions.

The SEAC members discussed the substitution strategy chosen by the applicant, obstacles in implementation of the Substitution Plan, as well as possible impacts on animal welfare in case of not granting of the authorisation.

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

#### 10. 188\_OPE\_Wallac\_2 (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) 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 SEAC members discussed the substitution strategy chosen by the applicant, confidentiality on certain data in the application, the non-use scenario submitted by the applicant, as well as differences in releases between the downstream users.

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 applicant for commenting.

#### 11. 192\_OPE\_Pfizer\_2 (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a surfactant within a lubricant used in the manufacture of pharmaceutical drug products.

The SEAC members reflected on technological differences in this application comparing to the other similar applications 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 rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

#### 12. 201\_OPE\_Vetter\_2 (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as emulsifier in the siliconisation of glass containers (syringes and cartridges) used as primary packaging material for 44 medicinal products of several pharmaceutical companies listed in the confidential Appendix 1 to the AoA. These products cover several therapeutic areas, and approx. 40 % of them are listed on the WHO Model List of Essential Medicines (EML).

The SEAC members discussed benefits from the use of the substance, costs for the downstream users, number of job losses claimed by the applicant, as well as availability of the alternatives and chosen substitution strategy 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.

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

#### 1. OPE\_Sebia (3 uses)

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

Use 1: Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for its "wetting" detergent properties allowing the dissolution, the dilution and the good spreading of substrates and reagents, necessary to optimize the sensitivity of gel electrophoresis in vitro diagnostic tests;

Use 2: Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for its detergent properties in the production of electrophoresis gels in view of ensuring the positioning of specific proteins necessary for the interpretation of results of gel electrophoresis in vitro diagnostic tests;

Use 3: Industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for its detergent properties resulting in cellular lysis and protein interactions rupture and required for the production of reagents involved in the determination of proteins of interest in gel and capillary electrophoresis IVD test.

It was submitted during February 2019 submission window. SEAC agreed on the draft opinion during SEAC-44 plenary meeting. On 14 April 2020 the applicant submitted comments on the draft opinion. The rapporteur with the Secretariat's assistance reviewed the received comments and updated the opinion. The Committee adopted the opinion by consensus. The rapporteur, together with 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 to publish it on the ECHA website.

#### 2. NPE\_Sebia (1 use)

This is an application for authorisation on industrial use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated for its detergent properties in the production of buffers and reagents in view of ensuring the positioning of specific proteins necessary for the interpretation of gel electrophoresis in vitro diagnostic tests results based on the determination of isoenzymes. It was submitted during February 2019 submission window. SEAC agreed on the draft opinion during SEAC-44 plenary meeting. On 14 April 2020 the applicant submitted comments on the draft opinion. The rapporteur with the Secretariat's assistance reviewed the received comments and updated the opinion.

The Committee adopted the opinion by consensus. The rapporteur, together with 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 to publish it on the ECHA website.

#### 3. OPE\_Stago (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-tert-OPnEO for its detergent properties in the process of cell lysing for the production of in-vitro diagnostic reagents;

Use 2: Industrial use of 4-tert-OPnEO in view of controlling the amount of non-specific reactions in the production of in-vitro diagnostic reagents.

It was submitted during February 2019 submission window. SEAC agreed on the draft opinion during SEAC-44 plenary meeting. On 14 April 2020 the applicant submitted comments on the draft opinion. The rapporteur with the Secretariat's assistance reviewed the received comments and updated the opinion. The Committee adopted the opinion by consensus. The rapporteur, together with 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 to publish it on the ECHA website.

#### 4. SC\_Ariston (1 use)

This is an application for authorisation on the use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr6+) in the refrigerant solution. It was submitted during February 2019 submission window. SEAC agreed on the draft opinion during SEAC-44 plenary meeting. On 14 April 2020 the applicant submitted comments on the draft opinion. The rapporteurs reviewed the received comments and updated the opinion.

The Committee adopted the opinion by consensus. The rapporteur, together with 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 to publish it on the ECHA website.

### **d) Status update**

#### 1. AfAs agreed at SEAC-46

The SEAC Secretariat informed the Committee about the opinion development progress in RAC on those draft opinions, on which SEAC agreed at the SEAC-46 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 made by RAC.

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/47/2020/01\_rev.1, was agreed by SEAC.

## **7) AOB**

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

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

### **b) Status update on IT tools**

The Secretariat provided an update regarding the plans for future IT developments (especially related to Interact and collaboration platform).

### **c) Presentation by the Commission on the concept of Suitable Alternatives Available in General and the Substitution Plan Requirement**

The Commission representative presented Commission's views on the SAGA concept.

### **d) Presentation on webinar workshop on suitable alternatives and Substitution Plan as indicated in the Commission letter to the challenged application of Functional Chrome plating with decorative character**

The representative of Eurometaux presented results of the webinar workshop on suitable alternatives and Substitution Plan as indicated in the Commission letter to the challenged application of Functional Chrome plating with decorative character. He also informed that on 18 June 2020 there will be a second workshop, which will aim at clarification on level of detail on utilisations, Substitution Plans, increase of communication between downstream users and applicants, and promoting of common understandings.

## **8) Action points and main conclusions of SEAC-47**

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

## II. Main conclusions and action points

### SEAC-47, 1-4 June 2020 and 9-11 June 2020

(Adopted at SEAC-47 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 with modifications (SEAC/A/47/2020_rev2).	
<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-46 action points, written procedures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-46. 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 Restriction Annex XV dossiers</b>	
<b>a) Opinion development</b>	
1) Undecafluorohexanoic acid (PFHxA), its salts and related substances – first draft opinion	
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<p><b>SEAC members</b> to provide any remaining comments via the written consultation on the first draft opinion (by 3 July 2020).</p> <p><b>Rapporteurs</b> to prepare the second draft opinion, taking into account SEAC-47 discussions and the SEAC written consultation, by early August 2020.</p>
2) Microplastics – revised sixth draft opinion	
<p>SEAC rapporteurs presented and SEAC discussed the revised sixth draft opinion.</p> <p>SEAC agreed on the draft opinion by simple majority. The dissenting view will be reflected in the minutes.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.</p> <p><b>SECR</b> to launch a consultation on the SEAC draft opinion on 1 July 2020.</p>
3) Skin sensitisers – fifth draft opinion	

<p>SEAC rapporteurs presented and SEAC discussed the fifth draft opinion.</p> <p>SEAC agreed on the draft opinion by consensus (with editorials as agreed at SEAC-47).</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.</p> <p><b>SECR</b> to launch a consultation on the SEAC draft opinion on 24 June 2020.</p>
<p>4) Calcium cyanamide in fertilisers – third draft opinion</p>	
<p>SEAC rapporteurs presented and SEAC discussed the third draft opinion.</p> <p>SEAC agreed on the draft opinion by consensus (with editorials as agreed at SEAC-47).</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.</p> <p><b>SECR</b> to launch a consultation on the SEAC draft opinion on 24 June 2020.</p>
<p>5) Perfluorohexane-1-sulphonic acid, its salts and related substances – draft final opinion</p>	
<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted its final opinion by consensus.</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>
<p><b>5.2 Appointment of (co-)rapporteurs for restriction dossiers</b></p>	
<p>SEAC took note of the update on the upcoming restriction proposals.</p>	
<p><b>6. Authorisation</b></p>	
<p><b>6.1 General authorisation issues</b></p>	
<p>a) Update on incoming/future applications</p>	
<p>SEAC took note of the update on the new AfAs received during the February 2020 submission window and other AfA-related updates.</p>	
<p>b) Update on the lines to take document on OPnEO/NPnEO</p>	
<p>SEAC took note of the update on the lines to take document on OPnEO/NPnEO.</p>	
<p>c) Update on how SEAC can proceed with the suitable alternatives that are generally available (SAGA)</p>	
<p>SEAC took note of the update on how SEAC can proceed with the suitable alternatives that are generally available (SAGA).</p>	<p><b>SECR</b> to provide further information on SAGA to SEAC when available.</p>
<p><b>6.2 Authorisation applications</b></p>	

<b>a) Discussion on key issues</b>	
1) 11 applications for authorisation (OPE/NPE, Cr(VI)) and a review report (TCE) from February 2020 submission window	
SEAC discussed the key issues identified in the applications for authorisation and the review report.	
<b>b) Agreement on draft opinions</b>	
1) 154_OPE_Siemens_1 (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
2) 164_OPE_Baxter (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
3) 165_OPE_bioMerieux_2 (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.

4) 170_OPE_DiaSorin (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
5) 172_OPE_DIAGAST (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
6) 176_OPE_Abbott_1 (5 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.  SEAC agreed on its draft opinions on this application for authorisation by consensus.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.  <b>SECR</b> to send the draft opinions to the applicants for commenting.
7) 182_NPE_Abbott (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
8) 184_OPE_Lilly (1 use)	
SEAC rapporteur presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on its draft opinion on this application for authorisation by consensus.	<b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <b>Rapporteur</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

9) 185_OPE_NPE_Idexx (3 uses)	
SEAC rapporteur presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on its draft opinion on this application for authorisation by consensus.	<b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <b>Rapporteur</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.
10)188_OPE_Wallac_2 (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.  <b>SECR</b> to send the draft opinions to the applicant for commenting.
11)192_OPE_Pfizer_2 (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
12)201_OPE_Vetter_2 (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.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <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.
<b>c) Adoption of opinion</b>	
1) OPE_Sebia (3 uses)	
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.
2) NPE_Sebia (1 use)	
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.
3) OPE_Stago (2 uses)	
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 opinions to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
4) SC_Ariston (1 use)	
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.
<b>d) Status update</b>	
1) AfAs agreed at SEAC-46	
SEAC took note of the status update on SEAC draft opinions agreed at SEAC-46 plenary meeting.	
<b>6.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)</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/47/2020/01).	<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. AOB</b>	
a) European Commission presentation on Suitable Alternatives Available in General and Substitution Plan Requirement	
SEAC took note of the presentation by the Commission on Suitable Alternatives Available in General and Substitution Plan Requirement.	
b) Eurometaux presentation on webinar workshop on suitable alternatives and Substitution Plan as indicated in the Commission letter to the challenged application of Functional Chrome Plating with decorative character	
SEAC took note of the presentation by Eurometaux on the webinar workshop on suitable alternatives and Substitution Plan as indicated in the Commission letter to the challenged application of Functional Chrome Plating with decorative character.	
<b>8. Action points and main conclusions of SEAC-47</b>	
SEAC adopted the action points and main conclusions of SEAC-47.	

### III. List of Attendees

#### SEAC-47

SEAC members	Advisors, invited experts, observers & dossier submitters (DS)
ALEXANDRE João	ASSMANN Mervi as advisor to Johanna KIISKI
ANTONIADOU Sofia	CARLSSON FENG Mattias as dossier submitter for Skin sensitisers restriction dossier
BERGS Ivars	CORREL MYHRE Ingunn Espen as dossier submitter for PFHxS restriction dossier
BLAHA Karel	DE KORT Mattheus Josephus as advisor to Martien JANSSEN
BRIGNON Jean-Marc	DOLENC Darko a nominee for SEAC member as ECHA Invited Expert
CASTELLI Stefano	ERDMANN Christian as dossier submitter for PFHxA restriction
CAVALIERI Luisa	FIORE Karine as dossier submitter for Skin sensitisers restriction dossier
COGEN Simon	FOTLAND Tor Oysten as dossier submitter for PFHxS restriction dossier
DELCOURT Benjamin	HEGGELUND Audun as dossier submitter for PFHxS restriction
DIAZ MORENO Ismael	HELMEDACH Achim as advisor to Karen THIELE and as dossier submitter for PFHxA restriction
DOMINIAK Dorota	JERNEJ Iskra a nominee for SEAC member as ECHA Invited Expert
FANKHAUSER Simone	KACAN Stefan as dossier submitter for PFHxA restriction
JANSSEN Martien	LANGTVET Espen as dossier submitter for PFHxS restriction
JONES Derrick	Mc GROARTY Liam acting as invited expert for dossier submitter for Microplastics restriction
JOYCE John	MORO IACOPINI Sabrina as advisor to Stefano CASTELLI
KAJIC Silva	MUNCRIEF Sandi a nominee for SEAC member as ECHA invited expert
KIISKI Johanna	OLIVER Peters as advisor to Karen THIELE
KNOFLACH Georg	PETERSEN Ida Svostrup a nominee for SEAC member as ECHA Invited Expert
LUIT Richard	PIROW Ralph as dossier submitter for PFHxA restriction
LÜDEKE Andreas	REALE Priscilla as advisor to Luisa CAVALIERI
MÅGE Marit	SCHULZE Jona as dossier submitter for PFHxA restriction
NIKOVA Julieta	STEWART Alexandra as dossier submitter for Skin sensitisers restriction
RODRIGUEZ HERNANDEZ Manuel	ZEIGER Bastian as future ECHA staff member
ROUW Aart	
SCHUCHTAR Endre	
SHAKHRAMANYAN Nikolinka	
THIELE Karen	
THIERRY-MIEG Morgane	
URBAN Klaus	

<b>Stakeholder observers &amp; accompanying experts</b>	
BALLACH Jochen (CIRF) as Occasional Stakeholder for Microplastics	LANGEVELD Kees as accompanying expert to EUROMETAUX for Microplastics
BARBU Luminita (EDANA) as Occasional Stakeholder for Microplastics	LAROCHE Charles (IFRA = International Fragrance Association) as Occasional Stakeholder for Microplastics
BERG Madeleine as accompanying expert to ClientEarth for Microplastics	LENNQUIST Anna as accompanying expert to ChemSec for PFHxA
BERNARD Alice (ClientEarth)	LEONHARDT Thomas (EUROFEU) as Occasional Stakeholder for Microplastics and PFHxA
BROSCHE Sara as accompanying expert to ClientEarth for PFHxA	MACAUDIERE Sylvie (Arkema) as accompanying expert to Cefic for Microplastics
BUIJS Nathalie (MedTech Europe) as Occasional Stakeholder for Microplastics and all AfAs	MISTRY Rohit as accompanying expert to A.I.S.E. for Microplastics
CASSART Michel (PlasticsEurope) as Occasional Stakeholder for Microplastics	OTT Wolfgang as accompanying expert to CIRFS for Microplastics
CHAVE John (Cosmetics Europe) as Occasional Stakeholder for Microplastics	PALKONEN Susanna (EFA) as accompanying expert to EEB for Skin sensitisers
CHIDLEY Jo-Anne as accompanying expert to ChemSec for Microplastics	ROBINSON Jan (A.I.S.E.) as Occasional Stakeholder for Microplastics
COLACICCO Rudy as accompanying expert to Cosmetics Europe for Microplastics	ROBINSON Nik (European Oilfield Speciality Chemicals Association) as accompanying expert to IOGP for Microplastics
COLLOT Anne Gaëlle as accompanying expert to PlasticsEurope for Microplastics	ROGER Apolline (ClientEarth)
de MATOS Olivier (ECETOC = European Centre for Ecotoxicology and Toxicology of Chemicals) as Occasional Stakeholder for Microplastics	ROMANO Dolores (EEB = European Environmental Bureau) on week 2
DOBE Christopher as accompanying expert to ECPA for Microplastics	SANTOS OTERO Tatiana (EEB) on week 1
DRMAČ Dunja (EURATEX = European Apparel and Textile Organisation) as Occasional Stakeholder for PFHxA and Skin sensitisers	SCHLÜNDER Klaus (KWS) as accompanying expert to Euroseeds for Microplastics
HANNEBAUM Peter (Tyco Fire Production) as accompanying expert to EUROFEU for PFHxA	SERRANO RAMON Blanca (Cefic)
HARTMANN Rola Azzi as accompanying expert to MedTech Europe for Microplastics	ten BRINK Patrick as accompanying expert to EEB for Microplastics
HÖK Frida (ChemSec)	WAETERSCHOOT Hugo (EUROMETAUX = European Association of the Metals Industry)
KAFKA Amalia (Euroseeds) as Occasional Stakeholder for Microplastics	WEILANDT Karl as accompanying expert to Cefic for PFHxA
KAYSER Martin as accompanying expert to ECETOC for Microplastics	WIETOR Jean-Luc as accompanying expert to EEB for PFHxA
KARAGIANNIDOU-ROSIEK Maria (IOGP = International Association of Oil and Gas producers) as Occasional Stakeholder for Microplastics	YADA Makiko (Daikin Chemical Europe GmbH) as accompanying expert to PlasticsEurope for PFHxA
KLASSE Hans-Jürgen (AlzChem Trostberg GmbH) as accompanying expert to Cefic on Calcium cyanamide	

<b>ECHA STAFF</b>	<b>Commission observers</b>
BLAINEY Mark	BENGYUZOV Manol (DG GROW)
BIN Essi	BERTATO Valentina (DG ENV)
BERGES Markus	BLASS-RICO Ana-Maria (DG GROW)
GMEINDER Michael	GALLEGO Matteo (DG ENV)
HAN Adela	HUALDE-GRASA Eva Patricia (DG GROW)
HENRICHSON Sanna	PEDERSEN Finn (DG ENV)
KIVELA Kalle	SVÄRD Amie (DG GROW)
LAZIC Nina	TRLIFAJ Šimon (DG GROW)
LEFEVRE-BREVART Sandrine	<b>RAC rapporteurs</b>
LOGTMEIJER Christiaan	BORG Daniel
LUDBORZS Arnis	
MAJOROS Laszlo	
MANNERVESI Maija	
MARQUEZ-CAMACHO Mercedes	
MAZZEGA SBOVATA Silvia	
MBANI Tytti	
MOTTET Denis	
MUSHTAQ Fesil	
NICOT Thierry	
NURMI Väinö	
ÖBERG Tomas	
ORISPÄÄ Katja	
OTTATI Maria	
PELLA Katrin	
PELTOLA Jukka	
PELTOLA-THIES Johanna	
POPOVIC Marko	
REGIL Pablo	
REHL Anna-Lena	
RHEINBERGER Christoph	
RICHARZ Andrea	
ROBERTS Julian	
ROSSI Ludovica	
SEGARD Audrey	
SIMPSON Peter	
STASKO Jolanta	
VAINIO Matti	

#### **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

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

<b>Document</b>	<b>Number</b>
Final Draft Agenda	SEAC/A/47/2020rev2
Appointment of (co-)rapporteurs for authorisation applications	SEAC/47/2020/01 (restricted room 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>
THIERRY-MIEG Morgane	5.2b.2 Skin sensitizers in textile	Working for the MSCA submitting the dossier
BRIGNON Jean-Marc	5.2b.2 Skin sensitizers in textile	Working for the MSCA submitting the dossier
JOYCE John	5.2b.2 Skin sensitizers in textile	Working for the MSCA submitting the dossier
MÅGE Marit	5.2b.4 Perfluorohexane-1-sulphonic acid, its salts and related substances (PFHxS)	Working for the MSCA submitting the dossier
THIELE Karen	5.2a.1 Undecafluorohexanoic acid (PFHxA)	Working for the MSCA submitting the dossier

**Final Agenda**  
**47th meeting of the Committee for Socio-economic Analysis**

**1-4 June 2020**  
**and**  
**9-11 June 2020**

**Webex meeting**

**Monday 1 June starts at 10.00**  
**Thursday 4 June breaks at 16.00**  
**Tuesday 9 June resumes at 10.00**  
**Thursday 11 June ends at 12.30**

***Times are Helsinki times***

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***SEAC/A/47/2020***  
***For adoption***

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

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

**b)** Report on SEAC-46 action points, written procedures and update on other ECHA bodies

***For information***

**Item 5 – Restrictions**

**5.1 Restriction Annex XV dossiers**

**b)** Opinion development

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

***For discussion***



- 2) Microplastics – revised sixth draft opinion
- 3) Skin sensitisers – fifth draft opinion
- 4) Calcium cyanamide in fertilisers – third draft opinion

***For discussion and agreement***

- 5) Perfluorohexane-1-sulphonic acid, its salts and related substances – 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) Update on the lines to take document on OPnEO/NPnEO
- c) Update on how SEAC can proceed with the suitable alternatives that are generally available (SAGA)

***For information***

#### **6.2 Authorisation applications**

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

1. 11 applications for authorisation (OPE/NPE, Cr(VI)) and a review report (TCE) from February 2020 submission window

***For discussion***

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

1. 154\_OPE\_Siemens\_1 (1 use)
2. 164\_OPE\_Baxter (1 use)
3. 165\_OPE\_bioMerieux\_2 (1 use)
4. 170\_OPE\_DiaSorin (1 use)
5. 172\_OPE\_DIAGAST (1 use)
6. 176\_OPE\_Abbott\_1 (5 uses)
7. 182\_NPE\_Abbott (1 use)
8. 184\_OPE\_Lilly (1 use)
9. 185\_OPE\_NPE\_Idexx (3 uses)
10. 188\_OPE\_Wallac\_2 (2 uses)
11. 192\_OPE\_Pfizer\_2 (1 use)
12. 201\_OPE\_Vetter\_2 (1 use)

***For discussion and agreement***

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

1. OPE\_Sebia (3 uses)
2. NPE\_Sebia (1 use)
3. OPE\_Stago (2 uses)
4. SC\_Ariston (1 use)

***For discussion and adoption***

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

1. AfAs agreed at SEAC-46

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

**SEAC/47/2020/01**  
**(restricted room document)**  
**For agreement**

#### **Item 7 – AOB**

- a) Update of the work plan
- b) Status update on IT tools

*For information*

#### **Item 8 – Action points and main conclusions of SEAC-47**

Table with Conclusions and Action points from SEAC-47

**For adoption**