

6 May 2020

SEAC/M/46/2020 FINAL

Final

Minutes of the 46th meeting of the Committee for Socio-economic Analysis

10-12 March 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 46th meeting of SEAC. The Chairman then informed SEAC that Kalle Kivelä, ECHA, had been appointed as the Deputy Chairman of the Committee.

Furthermore, the Chairman informed SEAC that apologies had been received from three 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-46. The agenda was adopted without modifications (in line with SEAC/A/46/2020). 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. The second week of SEAC-46 was cancelled due to the Coronavirus outbreak.

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 5.2a.1, 5.2b.2, and 5.2b.4. 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 declared the absence of conflict of interest for all items of SEAC-46 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-45 action points, written procedures and update on other ECHA bodies

The Chairman informed the participants that all action points of SEAC-45 had been completed or would be followed up during the on-going SEAC-46 meeting.

The Chairman also informed the Committee that the final minutes of SEAC-45 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-45 minutes.

The Commission observer was invited to update the Committee on SEAC related developments in the REACH Committee.

5) Restrictions

5.1) General Restriction issues

a) Report from the Restrictions Task Force

The Secretariat provided a brief report from the most recent activities of the Restrictions Task Force.

b) Revision of the RAC and SEAC working procedure on opinion development

The Secretariat provided a presentation and SEAC took note of the revisions of the RAC and SEAC working procedure on opinion development. The working procedure was revised based on experience gained from recent restriction dossiers in order to streamline the process to help the Committees to cope with the ongoing peak in their workload.

5.2) Restriction Annex XV dossiers

a) Conformity and key issues discussion

1) Undecafluorohexanoic acid (PFHxA), its salts and related substances

The Chairman welcomed the Dossier Submitter's representative from Germany (following via WebEx) and the RAC rapporteur. He informed the participants that the restriction dossier had been submitted in December 2019.

The Dossier Submitter's representative provided an introductory presentation on the dossier. He explained that the proposal concerns the manufacture, use and placing on the market of PFHxA, its salts and the related substances.

The Chairman informed that RAC had concluded that the dossier conforms to the Annex XV requirements at RAC-52. The SEAC rapporteurs then presented the outcome of the conformity check and the recommendations to the Dossier Submitter. The rapporteurs also provided some recommendations for improving the dossier.

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteurs presented their key issues of the restriction proposal. The Chairman informed the Committee that the Consultation on this restriction proposal will be launched on 25 March 2020.

c) Opinion development

1) Calcium cyanamide in fertilisers – second draft opinion

This agenda topic was postponed until the next meeting.

2) Skin sensitisers in textile – third draft opinion

This agenda topic was postponed until the next meeting.

3) Microplastics – fifth draft opinion

This agenda topic was postponed until the next meeting.

4) Perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances – fourth draft opinion

The Chairman welcomed the Dossier Submitter's representatives from Norway (following via WebEx) and the RAC rapporteur. 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 RAC rapporteur then informed that RAC had adopted its opinion at RAC-52. The SEAC (co-)rapporteurs then presented the fourth draft opinion. Members commented on the derogations, transitional periods and uncertainties in the evaluation. The Commission observer commented on the cost calculations for emissions.

The Committee agreed on its draft opinion by consensus. The rapporteurs were requested, together with the Secretariat, to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the Consultation) is in line with the agreed SEAC draft opinion. The Secretariat will launch the Consultation on the SEAC draft opinion on 25 March and SEAC is expected to adopt its final opinion on this dossier at its June plenary meeting.

5) Formaldehyde – fourth draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA. He 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 if the formaldehyde released from them exceeds a concentration of 0.124 mg/m³ as measured in accordance with the conditions specified in an appendix. Furthermore, a formaldehyde concentration of 0.1 mg/m³ shall not be exceeded in the interiors of road vehicles and aircraft. SEAC had provisionally agreed on the SEAC draft opinion at SEAC-45.

The Secretariat then informed the Committee that RAC had discussed and adopted the opinion in RAC-52. The SEAC (co-)rapporteurs then presented the fourth draft opinion. Three SEAC members had questions regarding the proportionality of a restriction with the modified conditions and scope as proposed by RAC and, in particular, regarding the additional costs and benefits of the lower limit values proposed by RAC. The SEAC members also gave advice to the rapporteurs on information that should be requested during the 60-day external consultation on the SEAC draft opinion on this restriction proposal. The Commission observer contributed to the discussion regarding proportionality, scope, derogations and length of the transitional period.

The Committee agreed on the SEAC draft opinion. The rapporteurs were asked to edit the draft opinion, taking into account the SEAC-46 discussions, by middle of March 2020. The Secretariat will launch the external consultation on the SEAC draft opinion on 25 March 2020. The opinion will be tabled for adoption at SEAC-47 in June 2020.

6) Five cobalt salts – fifth draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA. He 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. SEAC had provisionally agreed on the SEAC draft opinion at SEAC-45.

The SEAC rapporteurs then presented the fifth draft opinion. The Commission observer and the regular stakeholder observer commented on the derogations.

The Committee agreed on the SEAC draft opinion by consensus. The rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the agreed draft opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the Consultation) is in line with the agreed SEAC draft opinion. The Secretariat will launch the Consultation on the SEAC draft opinion on 25 March and SEAC is expected to adopt its final opinion on this dossier at its June plenary meeting.

7) Siloxanes (D4, D5 and D6) – draft final opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA and the RAC rapporteur. He informed the participants that this restriction dossier had been submitted in January 2019 and proposes to restrict placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance.

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 derogations requested in the public consultation, and the time-limited derogation for leave-on cosmetic products and on the justification of the length of their transitional period.

The Committee adopted its opinion by consensus. The rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the SEAC final 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 Secretariat will forward the adopted opinion and its annexes to the Commission and publish it on the ECHA website.

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

The Chairman presented and SEAC agreed on the updated pool of (co-)rapporteurs for the calcium cyanamide in fertilisers restriction proposal. The Chairman then appointed a new rapporteur as a replacement due to the previously appointed rapporteurs' retirement from this dossier. Furthermore, SEAC took note of the update on the upcoming restriction proposals.

6) Authorisations

6.1) General authorisation issues

a) Update on incoming/future applications

The Secretariat provided an update on the applications for authorisation received during the February 2020 submission windows and the incoming applications/review reports later in 2020. The Secretariat also informed the Committee members that in the RAC and SEAC opinions adopted by RAC and SEAC in the future, precise amount of SVHC releases will be disclosed to the public. This information will be accompanied by range estimates of release factors and quantities of SVHC used by the applicants.

b) Report from the Commission Workshop on AfAs (3 February 2020)

The Commission observer provided an update on the Commission Workshop on Applications for Authorisation that took place on 3 February in Brussels.

6.2) Authorisation applications

a) Discussion on key issues

1. 11 applications for authorisation from November 2019 submission window (OPE/NPE)

This item was removed from the agenda. The Secretariat will launch a SEAC consultation on the presentation containing the identified key issues in 11 applications for authorisation from the November 2019 submission window.

b) Agreement on draft opinion

1. 147_CTPht_Bilbaina (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp. as a binder in the manufacture of clay targets. The SEAC members discussed the cost effectiveness estimates, advice to the Commission regarding a length of the review period, and possibility to substitute the use of this SVHC. The Commission observer contributed to the

discussion regarding the economic feasibility of alternatives, and the non-use scenario 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 opinions. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

2. 148_CTPht_DEZA (1 use)

This is an application for authorisation on the use of pitch, coal tar, high temp. as a binder in the manufacture of clay targets.

The SEAC members discussed the socio-economic analysis including how the environmental releases are presented in the opinion justification.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinions. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

3. 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 OPE in isolation of protein from recombinant cell cultures for the production of IVD-kits (protein cell extraction);

Use 2: Use of OPE in formulation of IVD-kit reagents;

Use 3: Use of OPE 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.

The SEAC members discussed the socio-economic analysis, including measures implemented by the applicant to reduce releases of the substance to the environment, and a length of the review period for each of the uses applied for. The Commission observer contributed to the discussion on the relationship between the five uses, the cost estimates, the analysis of alternatives, the additional conditions proposed by RAC, the risk from alternatives, and the risk to the environment from the emissions of the 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 rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

4. 156_OPE_Hospira (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a surfactant in the manufacture of one biopharmaceutical protein, a biosimilar product, used to prevent infection and neutropenic fevers.

One SEAC member raised a question about the market share of the particular products produced by the applicant, and a question about alternatives related to biosimilar medicines in general. The Commission observer contributed to this discussion.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

5. 160_OPE_Merck_2 (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (technical grade) as raw material for the manufacturing of GMP Triton® X-100 Emprove® Expert according to IPEC standards.

One SEAC member raised a question about a condition for the review report. The Commission observer commented on the impacts on patients and downstream users in the socio-economic analysis.

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. 162_OPE_LFB (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as virus inactivation into the manufacture process of plasma-derived immunoglobulins.

SEAC members discussed different aspects in the socio-economic analysis and the description of releases to the environment. The Commission observer commented on the feasibility assessment in the analysis of alternatives in the 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.

7. 163_OPE_Rentschler (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated in a washing buffer applied during a purification step in the manufacture of the monoclonal antibody Dinutuximab beta.

SEAC members discussed the length of the review period and R&D activities by the applicant.

The Committee agreed on the draft opinion by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinion. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

8. 174_OPE_Eli_Lilly (1 use)

This is an application for authorisation on the industrial use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a patient safety viral inactivation reagent in the manufacture of human medicines produced from biological systems.

The Commission observer commented on the cost-effectiveness analysis in light of the additional conditions proposed by RAC.

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.

9. 175_OPE_Rousselot (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a surfactant in the manufacturing of low endotoxin gelatin.

SEAC members discussed the length of the requested review period in connection to 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.

10. 180_OPE_NPE_Bio-Rad (4 uses)

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

Use 1: Industrial use of 4-tert-OPnEO and 4-NPnEO for their non-ionic detergent properties in view of controlling reactions and chromatography support saturation required in the production of highly specific and sensitive in vitro immunoassays dedicated to the diagnosis of viral (HIV, HCV, Dengue) and parasitic infections;

Use 2: Industrial use of 4-tert-OPnEO for its non-ionic detergent property in the formulation of in vitro reagents dedicated to high-performance microbiological and immunological assays supported on microplates or magnetic particles;

Use 3: Industrial use of 4-tert-OPnEO for its detergent properties used for extraction, viral inactivation and purification of biological material further formulated and /or coated on articles intended for IVD applications;

Use 4: Industrial use of raw material containing 4-tert-OPnEO for protein stabilization for veterinary in vitro diagnostic application.

The SEAC members discussed the confidentiality claims and transparency of the application for authorisation, suggesting to narrow down the ranges of profits and numbers used in the draft opinions to make them more meaningful for the assessment. The Commission observer contributed to this discussion, and made a note on overall consistency of the four draft opinions.

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

11. 186_OPE_NPE_Beckman (5 uses)

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

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

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

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

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

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

The SEAC members discussed the release factors for Uses 3, 4 and 5, and type of diagnostics used by different downstream users and corresponding impacts. 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 rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

12. 187_OPE_AGC (2 uses)

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

Use 1: Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as Triton X-100 as detergent for the inactivation of viruses in the production of therapeutic proteins using mammalian cell hosts in projects where processes have been approved by the authorities (GMP compliant);

Use 2: Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as Triton X-100 as a detergent during the purification process of recombinant biopharmaceuticals derived from microbial expression hosts in projects where processes have been approved by the authorities (GMP compliant).

One SEAC member noted absence of the Substitution Plan in the application for 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 rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

13.189_OPE_Lonza (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated for virus inactivation via solvent/detergent treatment in the manufacture of recombinant medicinal active pharmaceutical ingredients (APIs) from mammalian cell cultures.

The Commission observer commented on the wording used in SEAC's assessment and the Slough plant.

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.

14.190_OPE_TEVA (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a nonionic surfactant for bacteria cells disruption and washing of inclusion bodies in Biological Drug Substance manufacturing process.

The SEAC members discussed the alternatives, job losses presented in the non-use scenario, and the applicant's efforts to substitute SVHC. The Commission observer contributed to the discussion on the assessment of alternatives for biosimilar medicines.

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.

15.191_NPE_Sekisui (1 use)

This is an application for authorisation on the industrial use of 4-nonylphenol, branched and linear, ethoxylated as polymer additive in the manufacture of interlayer polymer films for laminated safety glass.

The Commission observer commented on the evaluation of the analysis of alternatives by the Committee, including advantages and disadvantages of the proposed alternative technology.

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. CT_TES (1 use)

This is a downstream user's application for authorisation on the use of chromium trioxide as surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, in particular magnetic cores of high-performance transformers. It was submitted during February 2019 submission window. SEAC agreed on the draft opinion during SEAC-44 plenary meeting. On 13 January 2020 the applicants submitted comments on the draft opinion.

The Committee adopted the opinion by consensus. The rapporteurs, 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 applicants, and to publish it on the ECHA website.

2. OPE_Boehringer (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated in a washing buffer to purify biological active pharmaceutical ingredients during the production of Palivizumab and Moxetumomab pasudotox-tdfk. It was submitted during February 2019 submission window. SEAC agreed on the draft opinion during SEAC-44 plenary meeting. On 16 January 2020 the applicants submitted comments on the draft opinion.

The Commission observer commented on the evaluation of the analysis of alternatives by the Committee.

The Committee adopted the opinion by consensus. The rapporteurs, 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 applicants, and to publish it on the ECHA website.

d) Status update

- 1. AfAs agreed at SEAC-45**
- 2. 165_OPE_bioMerieux_2 (1 use)**
- 3. 170_OPE_DiaSorin (1 use)**
- 4. 172_OPE_DIAGAST (1 use)**
- 5. 176_OPE_Abbott_1 (5 uses)**
- 6. 182_NPE_Abbott (1 use)**
- 7. 184_OPE_Lilly (1 use)**
- 8. 185_OPE_NPE_Idexx (3 uses)**

The agenda points were removed from the agenda.

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

This item was postponed until the next meeting.

7) AOB

a) Update of the work plan

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

8) Action points and main conclusions of SEAC-46

Due to the exceptional circumstances surrounding the Coronavirus outbreak and to retain quorum, the Chairman decided to allow WebEx voting during the last day of SEAC-46 (12 March 2020). Written confirmations were received via the Chat functionality of the WebEx application to be counted for the quorum, together with the votes of those physically present in the meeting room.

The exceptional arrangements were valid for the following agenda points 5.2a1 and 5.2.b.6 and their related Table with Conclusions and Action points from SEAC-46 (only relevant to the remaining issues 5.2a1 and 5.2.b.6 as outlined above).

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

II. Main conclusions and action points

SEAC-46, 10-12 March 2020

(Adopted at SEAC-46 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the agenda	
The agenda was adopted with minor modifications (SEAC/A/46/2020_rev1).	
3. Declarations of conflicts of interest to the Agenda	
Conflicts of interest have been declared and will be taken to the minutes.	
4. Report from other ECHA bodies and activities	
a) Report on SEAC-45 action points, written procedures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-45. Furthermore, SEAC took note of the report from other ECHA bodies, including the oral report from the Commission on SEAC related developments in the REACH Committee.	
5. Restrictions	
5.1 General restriction issues	
a) Report from the Restrictions Task Force	
SEAC took note of the report from the Restrictions Task Force.	
b) Revision of the RAC and SEAC working procedure on opinion development	
SEAC took note of the revisions of the RAC and SEAC working procedure on opinion development.	
5.2 Restriction Annex XV dossiers	
a) Conformity and key issues discussion	
1) Undecafluorohexanoic acid (PFHxA), its salts and related substances	
SEAC agreed that the dossier conforms to the Annex XV requirements.	<p>SECR to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG.</p> <p>SECR to launch a consultation on the restriction proposal on 25 March 2020.</p>

b) Opinion development	
2) Calcium cyanamide in fertilisers – second draft opinion	
This item was postponed until the next meeting.	
3) Skin sensitisers in textile – fourth draft opinion	
This item was postponed until the next meeting.	
4) Microplastics – fifth draft opinion	
This item was postponed until the next meeting.	
5) Perfluorohexane-1-sulphonic acid, its salts and related substances – fourth draft opinion	
SEAC rapporteurs presented and SEAC discussed the fourth draft opinion. SEAC agreed on the draft opinion by consensus.	Rapporteurs together with SECR 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. SECR to launch a consultation on the SEAC draft opinion on 25 March 2020.
6) Formaldehyde and formaldehyde releasers – fourth draft opinion	
SEAC rapporteurs presented and SEAC discussed the fourth draft opinion. SEAC agreed on the draft opinion by consensus.	Rapporteurs together with SECR 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. SECR to launch a consultation on the SEAC draft opinion on 25 March 2020.
7) Five cobalt salts – fifth draft opinion	
SEAC rapporteurs presented and SEAC discussed the fifth draft opinion. SEAC agreed on its draft opinion by consensus.	Rapporteurs together with SECR 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. SECR to launch a consultation on the SEAC draft opinion on 25 March 2020.
8) Siloxanes (D4, D5 and D6) –draft final opinion	

<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted its final opinion by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.</p> <p>SECR to compile the adopted RAC and SEAC opinions, and forward it to the Commission.</p>
<p>5.3 Appointment of (co-)rapporteurs for restriction dossiers</p>	
<p>SEAC agreed on the updated pool of (co-) rapporteurs for the calcium cyanamide in fertilisers restriction proposal.</p> <p>The Chairman then appointed a new rapporteur as a replacement due to the previously appointed rapporteurs' retirement from this dossier.</p> <p>SEAC took note of the update on the upcoming restriction proposals.</p>	
<p>6. Authorisation</p>	
<p>6.1 General authorisation issues</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.</p>	
<p>b) Report from the Commission Workshop on AfAs (3 February 2020)</p>	
<p>SEAC took note of the report from the Commission workshop on AfAs which took place on 3 February 2020 in Brussels.</p>	
<p>6.2 Authorisation applications</p>	
<p>a) Discussion on key issues</p> <p>1) 11 applications for authorisation from November 2019 submission window (OPE/NPE)</p>	
<p>The agenda point was removed from the agenda.</p>	<p>SECR to launch a SEAC consultation on the key issues presentation.</p>
<p>b) Agreement on draft opinions</p> <p>1) 147_CTPht_Bilbaina (1 use)</p>	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p>

<p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>2) 148_CTPht_DEZA (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>3) 155_OPE_Siemens_2 (5 uses)</p>	
<p>SEAC rapporteur 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>Rapporteur together with SECR to do the final editing of the SEAC draft opinions.</p> <p>Rapporteur and SECR to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
<p>4) 156_OPE_Hospira (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>5) 160_OPE_Merck_2 (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>6) 162_OPE_LFB (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>7) 163_OPE_Rentschler (1 use)</p>	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p>

<p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>8) 174_OPE_Eli_Lilly (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>9) 175_OPE_Rousselot (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>10) 180_OPE_NPE_Bio-Rad (4 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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinions.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
<p>11) 186_OPE_NPE_Beckman (5 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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinions.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
<p>12) 187_OPE_AGC (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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinions.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.</p>
<p>13) 189_OPE_Lonza (1 use)</p>	

<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>14) 190_OPE_TEVA (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>15) 191_NPE_Sekisui (1 use)</p>	
<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>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion.</p> <p>Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.</p>
<p>c) Adoption of opinion</p>	
<p>1) 135_CT_TES (1 use)</p>	
<p>SEAC adopted its opinion on this application for authorisation by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC opinion.</p> <p>SECR to send the opinion to the Commission, the Member States and the applicants, and to publish it on the ECHA website.</p>
<p>2) 138_OPE_Boehringer (1 use)</p>	
<p>SEAC adopted its opinion on this application for authorisation by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC opinion.</p> <p>SECR to send the opinion to the Commission, the Member States and the applicants, and to publish it on the ECHA website.</p>
<p>d) Status update</p>	

- | |
|---|
| <ol style="list-style-type: none"> 1) AfAs agreed at SEAC-45 2) 165_OPE_bioMerieux_2 (1 use) 3) 170_OPE_DiaSorin (1 use) 4) 172_OPE_DIAGAST (1 use) 5) 176_OPE_Abbott_1 (5 uses) 6) 182_NPE_Abbott (1 use) 7) 184_OPE_Lilly (1 use) 8) 185_OPE_NPE_Idexx (3 uses) |
|---|

The agenda points were removed from the agenda.	
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8. Action points and main conclusions of SEAC-46	
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SEAC adopted the action points and main conclusions of SEAC-46.	SECR to upload the action points and main conclusions to S-CIRCABC IG.
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III. List of Attendees

SEAC-46

SEAC members
ALEXANDRE Joao
ANASTASIOU Christos
ANTONIADOU Sofia
BERGS Ivars
BLAHA Karel (Webex)
BRIGNON Jean-Marc (Webex)
CASTELLI Stefano (Webex)
CAVALIERI Luisa
COGEN Simon
DELCOURT Benjamin (Webex)
DIAZ MORENO Ismael
DOMINIAK Dorota
FANKHAUSER Simone
FOCK Lars
JANSSEN Martien
JONES Derrick
JOYCE John
KIISKI Johanna
LUIT Richard (Webex)
LÜDEKE Andreas
MÅGE Marit
NIKOVA Julieta
RODRIGUEZ HERNANDEZ Manuel
ROUW Aart
SCHUCHTAR Endre (Webex)
SHAKHRAMANYAN Nikolinka
THIELE Karen
THIERRY-MIEG Morgane (Webex)
URBAN Klaus
Commission observers
BENGYUZOV Manol (DG GROW) (Webex)
GALLEGO Matteo (DG ENV) (Webex)
SVÄRD Amie (DG GROW)

Advisors, invited experts, observers & dossier submitters (DS)
ASSMANN Mervi as advisor to Johanna KIISKI (Webex)
CORREL MYHRE Ingunn Espen as dossier submitters for PFHxS restriction dossier (Webex)
ERDMANN Christian acting as Dossier Submitter for PFHxA restriction (Webex)
IORE Karine acting as advisor to Morgane THIERRY -MIEG (Webex)
FORKMAN Mats acting as an invited expert/ co-rapporteur for CTPht_Bilbaina and CTPht_DEZA
FOTLAND Tor Oysten as dossier submitters for PFHxS restriction dossier (Webex)
HELMEDACH Achim acting as advisors to Karen THIELE and as Dossier Submitter for PFHxA restriction (Webex)
LANGTVET Espen as dossier submitters for PFHxS restriction dossier (Webex)
MUNCRIEF Sandi acting as advisors to Lars FOCK
PETERS Oliver acting as advisor to Karen THIELE (WebEx)
REALE Priscilla acting as advisor to Luisa CAVALIERI (WebEx)
WIEBKE Drost acting as Dossier Submitter for PFHxA restriction (Webex)

Stakeholder observers & accompanying experts (cont.)

BUIJS Nathalie (MedTech Europe) as Occasional Stakeholder for D4/D5/D6, Microplastics, DMF and Cobalt salts restrictions and all AfAs

MUSU Tony (ETUC = European Trade Union Confederation);
--

WAETERSCHOOT Hugo (EUROMETAUX = European Association of the Metals Industry)
--

RAC rapporteurs

BORG Daniel

NEUMANN Michael

ECHA STAFF

BLAINEY Mark

BIN Essi

BERGES Markus

DI BASTIANO Augusto

FIGUIERE Romain

GMEINDER Michael

HENRICHSON Sanna

KIVELA Kalle

KVATCHADZE Giorgi

LAZIC Nina

LEFEVRE-BREVART Sandrine

LOGTMEIJER Christiaan

LUDBORZS Arnis

MAJOROS Laszlo

MÁK Éva

MARQUEZ-CAMACHO Mercedes

MATTHES Jochen

MAZZEGA SBOVATA Silvia

MOTTET Denis

MUSHTAQ Fesil

NICOT Thierry

NURMI Vaino

ÖBERG Tomas

ORISPAA Katja

OTTATI Maria

PELTOLA Johanna

PELTOLA Jukka

REGIL Pablo

RHEINBERGER Christoph

RODRIGUEZ UNAMUNO Virginia

ROGGEMAN Maarten

SADAM Diana

SIHVONEN Kirsi

SIMPSON Peter

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

Document	Number
Final Draft Agenda	SEAC/A/46/2020
Appointment of (co-)rapporteurs for authorisation applications (closed session)	SEAC/46/2020/02 (restricted room document)
Appointment of (co-)rapporteurs for restriction applications	SEAC/46/2020/01_rev.1 (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):

<u>Name of participant</u>	<u>Agenda item</u>	<u>Interest declared</u>
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
46th meeting of the Committee for Socio-economic Analysis

10-12 March 2020
and
17-19 March 2020

**ECHA Conference Centre, Sisu meeting room (Telakkakatu 6,
Helsinki)**

Tuesday 10 March starts at 14.00
Thursday 12 March breaks at 16.30
Tuesday 17 March resumes at 14.00
Thursday 19 March ends at 16.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/46/2019
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-45 action points, written procedures and update on other ECHA bodies

For information

Item 5 – Restrictions

5.1 General restriction issues

- d)** Report from the Restrictions Task Force
e) Revision of the RAC and SEAC working procedure on opinion development

5.2 Restriction Annex XV dossiers

b) Conformity and key issues discussion

- 1) Undecafluorohexanoic acid (PFHxA), its salts and related substances

For agreement

c) Opinion development

- 1) Calcium cyanamide in fertilisers – second draft opinion

For discussion

- 2) Skin sensitisers in textile – fourth draft opinion

- 3) Microplastics – fifth draft opinion

- 4) Perfluorohexane-1-sulphonic acid, its salts and related substances – fourth draft opinion

- 5) Formaldehyde and formaldehyde releasers – fourth draft opinion

- 6) Five cobalt salts – fifth draft opinion

For discussion and agreement

- 7) Siloxanes (D4, D5 and D6) – draft final opinion

For discussion and adoption

5.3 Appointment of (co-)rapporteurs for restriction dossiers

For agreement

Item 6 – Authorisation

6.1 General authorisation issues

- a) Update on incoming/future applications

- b) Report from the Commission Workshop on AfAs (3 February 2020)

For information

6.2 Authorisation applications

- e) Discussion on key issues

1. 11 applications for authorisation from November 2019 submission window (OPE/NPE)

For discussion

- f) Agreement on draft opinion

1. 147_CTPht_Bilbaina (1 use)

2. 148_CTPht_DEZA (1 use)

3. 155_OPE_Siemens_2 (5 uses)
4. 156_OPE_Hospira (1 use)
5. 160_OPE_Merck_2 (1 use)
6. 162_OPE_LFB (1 use)
7. 163_OPE_Rentschler (1 use)
8. 174_OPE_Eli_Lilly (1 use)
9. 175_OPE_Rousselot (1 use)
10. 180_OPE_NPE_Bio-Rad (4 uses)
11. 186_OPE_NPE_Beckman (5 uses)
12. 187_OPE_AGC (2 uses)
13. 189_OPE_Lonza (1 use)
14. 190_OPE_TEVA (1 use)
15. 191_NPE_Sekisui (1 use)

For discussion and agreement

- g) Adoption of opinion
1. CT_TES (1 use)
 2. OPE_Boehringer (1 use)

For discussion and adoption

- h) Status update
1. AfAs agreed at SEAC-45
 2. 165_OPE_bioMerieux_2 (1 use)
 3. 170_OPE_DiaSorin (1 use)
 4. 172_OPE_DIAGAST (1 use)
 5. 176_OPE_Abbott_1 (5 uses)
 6. 182_NPE_Abbott (1 use)
 7. 184_OPE_Lilly (1 use)
 8. 185_OPE_NPE_Idexx (3 uses)

For information

6.3 Appointment of (co-)rapporteurs for authorisation applications

For information

Item 7 – AOB

- a) Update of the work plan

For information

Item 8 – Action points and main conclusions of SEAC-46

Table with Conclusions and Action points from SEAC-46

For adoption