

29 January 2020

SEAC/M/45/2019 FINAL

Final

Minutes of the 45th meeting of the Committee for Socio-economic Analysis

26-28 November 2019

and

3-5 December 2019

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 45th meeting of SEAC. The Chairman also informed SEAC that apologies had been received from five 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-45. The agenda was adopted without modifications (in line with SEAC/A/45/2019). 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. Six members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.1b.2, 5.1b.3, and 5.1b.8. 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-45 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-44 action points, written procedures and update on other ECHA bodies

The Chairman informed the participants that all action points of SEAC-44 had been completed or would be followed up during the on-going SEAC-45 meeting.

The Chairman also informed the Committee that the final minutes of SEAC-44 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-44 minutes.

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

b) Revised rules of procedure

The Secretariat presented to the Committee the proposed revisions to the SEAC Rules of Procedure, which are related to the minutes of SEAC plenary meetings (in line with the meeting document SEAC/45/2019/03). The Committee agreed to the proposed revisions

and the Secretariat was requested to forward the revised SEAC RoPs to the ECHA Management Board for their adoption.

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. The next step is to finalise the documents prepared in the context of the Task Force, and to find ways on how to implement these in the dossiers and in the Committee work.

5.2) Restriction Annex XV dossiers

a) Opinion development

1) Calcium cyanamide in fertilisers – first draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA 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 the report from the RAC discussions on this dossier held within RAC-51. The rapporteurs then presented the first draft opinion to the Committee. The expert accompanying a regular stakeholder observer commented on the assessment of alternatives. The Commission observer commented on the benefits and costs and highlighted that calcium cyanamide is not approved as a plant protection product under Regulation (EC) 1107/2009. 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-45 discussions and the results of the SEAC written consultation, by the end of January 2020. The Secretariat will open a commenting round on the first draft opinion after SEAC-45 and will keep it open until 7 January 2020.

2) Skin sensitisers in textile – second draft opinion

The Chairman welcomed the Dossier Submitter's representatives from France and Sweden, the RAC co-rapporteur and the occasional stakeholder observer. 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 RAC co-rapporteur provided to the Committee the report from the RAC discussions on this dossier held within RAC-51. The rapporteurs then presented the second draft opinion to the Committee. The Commission observers commented on proportionality, enforcement, costs and benefits and the links between this proposal, CLP and the Cosmetics Regulation.

The Chairman concluded that the Committee supports the approach of the rapporteurs so far. The (co-)rapporteurs were requested to prepare the third draft opinion, taking into

account the SEAC-45 discussions and the results of the consultation, by the end of January 2020.

3) Perfluorohexane-1-sulphonic acid, its salts and related substances – second 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 Secretariat informed that RAC had received an update on state of play at RAC-51. The SEAC (co-)rapporteurs then presented the second draft opinion. One SEAC member had questions regarding the proportionality.

The Committee members supported the rapporteurs' approach on the benefits and practicality. The rapporteurs were asked to prepare the third draft opinion, taking into account the SEAC-45 discussions and the results of the public consultation, by end of January 2020.

4) Microplastics – third draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, supported by experts from Sweden (KemI) via WebEx, 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 and use of intentionally added microplastics and is comprised of various measures.

The RAC rapporteurs then informed the Committee that RAC had discussed the fourth version of the draft opinion in RAC-51. The SEAC (co-)rapporteurs then presented the third draft opinion. Members commented on the infill material and proportionality. One of the Commission observers commented on the derogations for cosmetic products. The other Commission observer asked for further elaborations on the costs, benefits and proportionality sections. The expert accompanying an occasional stakeholder commented on the costs. The occasional stakeholder observers commented on the costs, transitional periods and proportionality.

The rapporteurs were asked to prepare the fourth draft opinion, taking into account the SEAC-45 discussions, by end of January 2020.

5) Siloxanes (D4, D5 and D6) – third draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the RAC rapporteurs, the industry expert accompanying the regular stakeholder observer and the occasional stakeholder observer. 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 RAC rapporteur informed the Committee that RAC had adopted its opinion on this restriction proposal within the ongoing RAC-51. The SEAC (co-)rapporteurs then presented the third draft opinion. The expert accompanying the regular stakeholder observer commented on industrial use. The Commission observer commented on the derogations and asked for more analysis and justifications to support the reasoning.

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 (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 18 December 2019.

6) Formaldehyde – third draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the industry expert accompanying the regular stakeholder observer, and the RAC rapporteur. 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 releasing formaldehyde at rates resulting in concentrations greater than 0.124 mg/m³ in a test chamber.

The RAC rapporteurs then informed the Committee that RAC had discussed the fourth version of the draft opinion in RAC-51. The SEAC (co-)rapporteurs then presented the third draft opinion. Four SEAC members had questions regarding the comparison table of different testing methods, scope of the restriction specifically, and about the cost-benefit analysis and the proportionality of the restriction. The expert accompanying the regular stakeholder observer contributed to the discussion regarding feasibility and impact of the restriction proposal. One Commission observer commented on the extension of the scope to airplanes and vehicles and asked for an assessment of the costs and benefits.

The Committee provisionally agreed on the SEAC draft opinion. The rapporteurs were asked to prepare the fourth draft opinion, taking into account the SEAC-45 discussions, by end of January 2020. The Secretariat will table the draft opinion for the final agreement at SEAC-46 in March 2020.

7) Five cobalt salts – fourth draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the RAC rapporteur, two experts accompanying the regular stakeholder observers, as well as one occasional stakeholder observer. 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 (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate) as substances on their own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications.

The RAC rapporteur provided a brief update from the RAC discussion on this dossier held within RAC-51 and informed that RAC will adopt its opinion on this restriction proposal by written procedure in January 2020. The SEAC rapporteurs then presented the fourth draft opinion. The expert accompanying the regular stakeholder observer commented on uncertainties and on the transitional period. The Commission observers commented on the analysis of the proposed restriction as well as on derogations.

The Committee provisionally agreed on the SEAC draft opinion. The rapporteurs were asked to update the fourth draft opinion, taking into account the SEAC-45 discussion, by early January 2020. The Secretariat will table the draft opinion for the final agreement at SEAC-46 in March 2020.

8) *N,N*-dimethylformamide – draft final opinion

The Chairman welcomed the Dossier Submitter's representative from Italy, the occasional stakeholder observers, and the industry experts accompanying the regular and occasional stakeholder observers. He informed the participants that the restriction dossier had been submitted in October 2018 and proposes to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3 %.

The SEAC rapporteur then presented the draft final opinion. Three SEAC members and representatives from the European Commission had questions regarding the introduced changes in the SEAC opinion due to comments, which were received during the consultation on the SEAC draft opinion, such as proportionality and costs. The Commission observers asked the rapporteur to further clarify the proportionality section. The expert accompanying the regular stakeholder observer contributed to the discussion and pointed out that the given technical measure cost figures in the consultation for the man-made fibres sector are higher than the overestimated benefits.

SEAC adopted its final opinion on the restriction proposal for *N,N*-dimethylformamide 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 public consultation) is in line with the adopted SEAC opinion. The SEAC Chairman thanked the rapporteur for his work on this dossier, and informed the Committee that the adopted opinion will be sent to the Commission and published on the ECHA website.

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

The Secretariat presented and SEAC agreed on the pool of (co-)rapporteurs for the restriction dossier on PFHxA (undecafluorohexanoic acid and its salts and related substances) in line with the restricted meeting document SEAC/45/2019/01_rev1.

In October 2020, France will submit a restriction proposal on identification of substances of concern that may be present in single use nappies for infants and children. In the same submission window, ECHA will also submit a restriction proposal on lead in ammunition (gunshot and bullets) and fishing tackle. The calls for expression of interest for these dossiers will be launched in spring/summer 2020.

6) Authorisations

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 inform also about OPE/NPE AfAs: technical guidance and standard texts for RAC and SEAC rapporteurs.

b) Emerging practices in SEAC opinions on OPE and NPE

During the preparation of the opinions on uses of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (4-tert-OPnEO) and 4-nonylphenol, ethoxylated (4-NPnEO), members and the Secretariat identified several horizontal issues where a harmonised approach would be beneficial. These horizontal issues had been presented by the Secretariat together with proposed approaches to support the rapporteurs in drafting the opinions on uses of 4-tert-OPnEO and 4-NPnEO. During the discussion SEAC members and representatives of the stakeholder observer organisations, including the European Commission, welcomed the initiative and provided to the Secretariat comments to consider. The representative of the Commission recalled the criteria of a 'suitable alternative in general' set by the Court, noted that the analysis on the relevant elements were necessary for decision-making, and restated the reservation on the current version of the opinion conclusions.

6.2) Authorisation applications

a) Discussion on key issues

1. 16 applications for authorisation from August 2019 submission window (OPE/NPE)

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:

- 156_OPE_Hospira (single use);
- 160_OPE_Merck (single use);
- 162_OPE_LFB (single use);
- 163_OPE_Rentschler (single use);
- 165_OPE_bioMerieux_2 (single use);
- 170_OPE_DiaSorin (single use);
- 172_OPE_DIAGAST (single use);
- 180_OPE_NPE_Bio-Rad (four uses);
- 182_NPE_Abbott (single use);
- 184_OPE_Eli-Lilly (single use);
- 185_OPE_NPE_Idexx (three uses);
- 186_OPE_NPE_Beckman (five uses);
- 187_OPE_AGC (two uses);
- 189_OPE_Lonza (single use);
- 190_OPE_TEVA (single use);
- 191_NPE_Sekisui (single use).

b) Agreement on draft opinion

1. 146_CT_TataSteel (1 use)

This is an application for authorisation on the use of chromium trioxide for the manufacture of Electrolytic Chromium/Chromium oxide Coated Steel (ECCS).

The SEAC members discussed about the Substitution Plan and the Analysis of Alternatives. A representative of the European Commission contributed to the discussion regarding the substitution plan.

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

2. 147_CTPht_AO_Bilbaina (1 use)

3. 149_CTPht_Nalon (1 use)

4. 150_CTPht_AO_Koppers (1 use)

5. 151_CTPht_AO_Rutgers (1 use)

6. 152_CTPht_AO_RainCarbon (1 use)

These are five applications for authorisation on the use of pitch, coal tar, high temp. and anthracene oil (except 149_CTPht_Nalon) for manufacture of formulations for various industrial uses.

The Committee agreed on the five 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.

7. 157_OPE_Kedrion (1 use)

This is an application for authorisation on the use of 4-tert-OPnEO as Triton X-100 as detergent for virus inactivation in the manufacturing process of the human plasma-derived medicinal products Plasmagrade/Plasmasafe and Resusix, as well as Plasminogen (pre-commercialization name) and any subsequent commercialization brand.

The SEAC members discussed cost effectiveness, as well as relatively high release factors to the environment.

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. 158_OPE_Sanofi (1 use)

This is an application for authorisation on the use of Octoxynol-9 for virus splitting and inactivation step in the manufacturing of influenza vaccines.

The SEAC members discussed about analysis of alternatives, specifically on technical and economic feasibility of alternatives, the Substitution Plan, and non-use scenario 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.

9. 159_OPE_Merck (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated as a detergent in the purification process of G-CSF (Granulocyte Colony Stimulating Factor) inclusion bodies.

SEAC discussed possible negative impacts on patients in the socio-economic analysis, release factor to the environment, and the Substitution Plan.

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

10.161_OPE_Swords (1 use)

This is an application for authorisation on the industrial use of the substance as a surfactant in the purification of the biopharmaceutical drug Orencia, used for the treatment of Rheumatoid Arthritis, Juvenile Idiopathic Arthritis and Adult Psoriatic Arthritis.

One SEAC member raised a question about economic infeasibility of the alternatives.

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.

11.166_OPE_Ompi (1 use)

This is an application for authorisation on the use of octylphenoethoxylates as emulsifier in the siliconisation of glass containers used as primary packaging for one specific medicinal product (NeoRecormon®) of one pharmaceutical company.

The SEAC members discussed about technical and economic feasibility of alternatives.

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.

12.167_OPE_Roche (1 use)

This is an application for authorisation on the use of octylphenoethoxylates as emulsifier in the siliconisation of glass containers used as primary packaging for medicinal products (NeoRecormon® and MIRCERA®).

The SEAC members discussed about availability of alternatives.

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.

13.168_OPE_Vetter (1 use)

This is an application for authorisation on the use of Octylphenoethoxylates as emulsifier in the siliconisation of glass containers used as primary packaging for two specific medicinal products (NutropinAq® and Lucentis®) of one pharmaceutical company.

A representative of the European Commission contributed to the discussion regarding the identified alternatives.

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.

14.169_OPE_Nordisk (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a solvent/detergent agent for virus inactivation in the manufacture of pharmaceutical products used in the treatment of rare bleeding disorders.

The SEAC members discussed about technical and economic feasibility of alternatives.

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.

15.171_OPE_Wallac (2 uses)

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

Use 1: Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) into enhancement solutions and DELFIA standard and maintenance solutions used in In Vitro Diagnostic assays and RUO products as well as maintenance of instruments as a critical ingredient for detection process while measuring europium (or other lanthanide) content of the assay solution;

Use 2: Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in enhancement solutions and DELFIA standard and maintenance solutions as a critical ingredient for detection process while measuring europium (or other lanthanide) content in In Vitro Diagnostic assays and RUO products or during maintenance of instruments.

The SEAC members discussed about the Substitution Plan submitted by the applicant. A representative of the European Commission noted that downstream users' impact should be part of the cost effectiveness analysis.

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.

16.173_OPE_Sobi (1 use)

This is an application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a solvent/detergent agent for virus inactivation in the manufacture of pharmaceutical products used in the treatment of rare bleeding disorders.

One SEAC member raised a question about the scope of the use. A representative of the European Commission contributed to this discussion regarding the scope of the use.

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.

17.178_OPE_Janssen (1 use)

This is an application for authorisation on the use of 4-tert-Octylphenol ethoxylate as a lysing agent for the permeabilization of the host cell membrane to release adenovirus particles used for the manufacture of vaccines. Its use allows the selective elimination of enveloped adventitious viruses and is compatible with the chemicals needed to control the host cell DNA precipitation in the next process step.

SEAC discussed length of the requested review period. A representative of the European Commission contributed to this discussion regarding applicability of the criteria for longer review period.

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

18.177_OPE_Abbott_2 (1 use)

This is an application for authorisation on the professional use as a surfactant, in wash buffer components used in conjunction with Fluorescence In Situ Hybridisation (FISH) test kits and/or their Laboratory Developed Test (LDT) equivalents, in clinical diagnostic use for medical analysis of human tissue and blood samples to identify characteristic genetic abnormalities related to specific disease conditions.

SEAC discussed high releases to the environment, incineration costs and its economic feasibility.

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.

19.179_OPE_Octapharma (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 detergent for a virus inactivation step (solvent/detergent treatment) during the manufacture of plasma-derived and recombinant medicinal products;

Use 2: Use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as component of a chromatography column regeneration solution during the manufacture of a recombinant-derived Factor VIII.

One SEAC member noted relatively high release factor.

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.

20.181_OPE_NPE_Roche (3 uses)

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

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

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

Use 3: Use of Octyl- and Nonylphenoethoxylates in the production of proteins and the conjugation of latex beads, both being used as components or for the production of components of in vitro diagnostic (IVD) assays, research or quality control products and other, e.g. analytical applications (processes specified in Appendix 1 to the AoA).

SEAC discussed possible collection of waste containing SVHC, as well as calculated health impacts in the socio-economic analysis.

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.

21.183_NPE_GEHC_Bio-Sciences (1 use)

This is an application for authorisation on the industrial use of emulsifiers containing nonylphenols ethoxylated for the manufacture of chromatography resins used by the biopharmaceutical industry, food & beverage sector and academia.

SEAC members discussed costs of releases to the environment reduction, as well as lost profits and job losses provided 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.

c) Status update

- 1. 147_CTPht_Bilbaina (1 use)**
- 2. 148_CTPht_DEZA (1 use)**
- 3. 155_OPE_Siemens_2 (5 uses)**
- 4. 176_OPE_Abbott_1 (5 uses)**

SEAC rapporteurs updated the Committee members on the progress with the opinion development of the draft opinions on these applications for authorisation.

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/45/2019/02_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.

8) Action points and main conclusions of SEAC-45

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

II. Main conclusions and action points

SEAC-45, 26-28 November and 3-5 December 2019

(Adopted at SEAC-45 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the agenda	
The agenda was adopted without modifications (SEAC/A/45/2019).	
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-44 action points, written procedures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-44. 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 and CARACAL.	
b) Revised Rules of Procedure	
SEAC agreed to the proposed revisions to the SEAC RoPs (in line with the meeting document SEAC/45/2019/03).	SECR to forward the revised SEAC RoPs to the MB for their adoption.
5. Restrictions	
5.2 Restriction Annex XV dossiers	
a) Opinion development	
1) Calcium cyanamide in fertilisers – first draft opinion	
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<p>Rapporteurs to prepare the second draft opinion, taking into account the SEAC-45 discussions and the results of the SEAC written consultation, by end of January 2020.</p> <p>SECR to launch a written commenting round for members to provide comments on the first draft opinion</p> <p>SEAC members to provide comments by 7 January 2020.</p>

2) Skin sensitisers in textile – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	Rapporteurs to prepare the third draft opinion, taking into account the SEAC-45 discussions and the results of the public consultation, by end of January 2020.
3) Perfluorohexane-1-sulphonic acid, its salts and related substances – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	Rapporteurs to prepare the third draft opinion, taking into account the SEAC-45 discussions and the results of the public consultation, by end of January 2020.
4) Microplastics – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the third draft opinion.	Rapporteurs to prepare the fourth draft opinion, taking into account the SEAC-45 discussions, by end of January 2020.
5) Siloxanes (D4, D5 and D6) – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the third 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 public consultation on the SEAC draft opinion on 18 December 2019.
6) Formaldehyde and formaldehyde releasers – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the third draft opinion. SEAC provisionally agreed on its draft opinion (on the scope, derogations and costs, benefits and proportionality based on limit value proposed by DS).	Rapporteurs to prepare the fourth draft opinion, taking into account the SEAC-45 discussions, by end of 7 February 2020. SECR to table the dossier for final agreement at SEAC-46.
7) Five cobalt salts – fourth draft opinion	
SEAC rapporteurs presented and SEAC discussed the fourth draft opinion. SEAC provisionally agreed on its draft opinion.	Rapporteurs to update the fourth draft opinion, taking into account the SEAC-45 discussions, by early January 2020. SECR to make it available to SEAC. SECR to table the dossier for final agreement at SEAC-46.
8) N,N-dimethylformamide – draft final opinion	

<p>SEAC rapporteurs presented and SEAC discussed the draft of the final opinion.</p> <p>SEAC adopted the final opinion (with modifications agreed at SEAC-45) 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 pool of (co-)rapporteurs for the PFHxA restriction proposal to be submitted in December 2019 (in line with the restricted meeting document SEAC/45/2019/01_rev.1).</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 incoming/future applications.</p>	
<p>b) Emerging practices in SEAC opinions on OPE and NPE</p>	
<p>SEAC took note of the presentation on the Technical guidance and standards texts to support in developing opinion for the uses of OPE/NPE in a harmonised and consistent manner.</p>	
<p>6.2 Authorisation applications</p>	
<p>a) Discussion on key issues</p>	
<p>1) 16 applications for authorisation from August 2019 submission window (OPE/NPE)</p>	
<p>SEAC discussed the key issues identified in the applications for authorisation.</p>	
<p>b) Agreement on draft opinions</p>	
<p>1) 146_CT_TataSteel (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>

2) 147_CTPht_AO_Bilbaina (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
3) 149_CTPht_Nalon (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
4) 150_CTPht_AO_Koppers (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
5) 151_CTPht_AO_Rutgers (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
6) 152_CTPht_AO_RainCarbon (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
7) 157_OPE_Kedrion (1 use)	

<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>8) 158_OPE_Sanofi (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) 159_OPE_Merck (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)161_OPE_Swords (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>11)166_OPE_Ompi (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>12)167_OPE_Roche (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>
13) 168_OPE_Vetter (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
14) 169_OPE_Nordisk (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
15) 171_OPE_Wallac (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions for Uses 1 and 2 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>
16) 173_OPE_Sobi (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
17) 177_OPE_Abbott_2 (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>

18) 178_OPE_Janssen (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
19) 179_OPE_Octapharma (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions for Uses 1 and 2 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>
20) 181_OPE_NPE_Roche (3 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on its draft opinions for Uses 2, 3 and 4 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>
21) 183_NPE_GEHC_Bio- Sciences (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on its draft opinion on this application for authorisation by consensus.</p>	<p>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>
c) Status update	
1) 148_CTPht_DEZA (1 use)	
<p>SEAC took note of the status of the opinion development process.</p>	
2) 153_CTPht_Bilbaina (1 use)	
<p>SEAC took note of the status of the opinion development process.</p>	

3) 155_OPE_Siemens_2 (5 uses)	
SEAC took note of the status of the opinion development process.	
4) 176_OPE_Abbott_1 (5 uses)	
SEAC took note of the status of the opinion development process.	
5) AfAs agreed at SEAC-44	
SEAC took note of the status update on the AfAs agreed on at SEAC-44.	
6.3 Appointment of (co-)rapporteurs for authorisation applications	
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with the restricted room document SEAC/45/2019/02).	<p>SEAC members to volunteer to the pool of (co-) rapporteurs for applications for authorisation.</p> <p>SECR to upload the updated document to confidential folder on S-CIRCABC IG.</p>
8. Action points and main conclusions of SEAC-45	
SEAC adopted the action points and main conclusions of SEAC-45.	SECR to upload the action points and main conclusions to S-CIRCABC IG.

III. List of Attendees

SEAC-45

SEAC members
ALEXANDRE Joao
ANASTASIOU Christos
ANTONIADOU Sofia
BERGS Ivars
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
DIAZ MORENO Ismael
DOMINIAK Dorota
FIORE Karine
FOCK Lars
FORKMAN Mats
JANSSEN Martien
JONES Derrick
JOYCE John
KIISKI Johanna
KNOFLACH Georg
LEAHY Eimear via Webex
LUIT Richard
LÜDEKE Andreas
MÅGE Marit
NIKOVA Julieta
RODRIGUEZ HERNANDEZ Manuel
ROUW Aart
SCHUCHTAR Endre
SHAKHRAMANYAN Nikolinka
THIELE Karen
URBAN Klaus
Commission observers
BENGYUZOV Manol (DG GROW)
BERTATO Valentina (DG ENV) via Webex
GALLEGO Matteo (DG ENV)
SVÄRD Amie (DG GROW)
TOSETTI Patricia (DG GROW) via Webex
WODLI Jordane (DG ENV)
Stakeholder observers & accompanying experts
ALLAN Dawn (Firmenich) as accompanying expert to IFRA for Microplastics restriction
ANGIULLI Francesca (AISE = International Association for Soaps, Detergents and Maintenance Products) as Occasional Stakeholder for Microplastics restriction

Advisors, invited experts, observers & dossier submitters (DS)
ASSMANN Mervi as advisor to Johanna KIISKI
CARLSSON FENG Mattias acting as dossier submitter for Skin sensitizers restriction dossier
CORREL MYHRE Ingunn Espen as dossier submitters for PFHxS restriction dossier via Webex
De BLAEIJ Arianne acting as advisor to Martien JANSSEN
DORFH Helena acting as dossier submitters for Skin sensitizers restriction dossier via WebEx
FIORE Karine acting as dossier submitter for Skin sensitizers restriction dossier
FOTLAND Tor Oysten as dossier submitters for PFHxS restriction dossier via Webex
GABBERT Silke acting as advisor to Martien JANSSEN via WebEx
HELMEDACH Achim acting as advisors to Karen THIELE
IACOPINI MORO Sabrina acting as advisor to Stefano CASTELLI via WebEx
LANGTVET Espen as dossier submitters for PFHxS restriction dossier via Webex
LERCHE BJERREGAARD Dorte acting as advisors to Lars FOCK
PETERS Oliver acting as advisor to Karen THIELE via WebEx
REALE Priscilla acting as advisor to Luisa CAVALIERI via WebEx
STEWART Alexandra acting as dossier submitters for Skin sensitizers restriction dossier via WebEx
THIERRY-MIEG Morgane acting as advisor to Karine FIORE via WebEx
THORS Åsa acting as dossier submitters for Skin sensitizers restriction dossier via WebEx

Stakeholder observers & accompanying experts (cont.)
BALLACH Jochen (IVS = Industrievereinigung Chemiefaser), accompanying expert to EUROMETAUX for Microplastics and DMF restrictions
BUIJS Nathalie (MedTech Europe) as Occasional Stakeholder for D4/D5/D6, Microplastics, DMF and Cobalt salts restrictions and all AfAs
COLLACICO Rudy (EPPA) as accompanying expert to Cosmetics Europe for Microplastics restriction
DOBE Chris (ECPA = European Crop Protection Association) as accompanying expert to ECPA for Microplastics restriction
DRMAC Dunja (EURATEX = European Apparel and Textile Organisation) as Occasional Stakeholder for Skin sensitizers restriction
EGGERMONT Bruno (EURATEX = European Apparel and Textile Organisation) as accompanying expert to EURATEX for DMF
INGISMARSDÖTTIR Sigrídur (Haldor Topsoe) as accompanying expert to CEFIC for Cobalt salts
HOLLAND Mike (EAERE = European Association for Environmental and Resource Economists)
JÁNOSI Amaya (CEFIC = European Chemical Industry Council)
KLASSE Hans-Juergen (AlzChem Trostberg GmbH) as accompanying expert to CEFIC for Calcium Cyanamide restriction
LANGVELD Kees (Fertilizers Europe) as accompanying expert to AISE for Microplastics restriction
Charles LAROCHE (IFRA = International Fragrance Association) as Occasional Stakeholder for Microplastics restriction
MACAUDIERE Sylvie (ARKEMA), accompanying expert to CEFIC for Microplastics restriction
MISTRY Rohit (EFTEC = Economics for the Environment), accompanying expert to EUROMETAUX for Cobalt salts restriction
MUSU Tony (ETUC = European Trade Union Confederation);

ECHA STAFF
BLAINEY Mark
BIN Essi
BERGES Markus
DI BASTIANO Augusto
FIGUIERE Romain
GILIOLI Roberto
GMEINDER Michael
HENRICHSON Sanna
KIVELA Kalle
KVATCHADZE Giorgi
LEFEVRE Remi
LEFEVRE-BREVART Sandrine
LINNA Risto
LIOPA Eelina
LOGTMEIJER Christiaan
LUDBORZS Arnis
MAJOROS Laszlo
MÁK Éva
MARQUEZ-CAMACHO Mercedes
MATTHES Jochen
MAZZEGA SBOVATA Silvia
MOTTET Denis
MUSHTAQ Fesil
NICOT Thierry
NOGUEIRO Eugénia
ÖBERG Tomas
ORISPÄÄ Katja
OTTATI Maria
PELTOLA Johanna
PELTOLA Jukka
PENNESSE Daniele
REGIL Pablo
RHEINBERGER Christoph
RODRIGUEZ UNAMUNO Virginia
ROGGEMAN Maarten
SADAM Diana
SIHVONEN Kirsi
SIMON Rupert
SIMPSON Peter
STOYANOVA Evgenia
SOSNOWSKI Piotr
VAANANEN Virpi
VAINIO Matti

Stakeholder observers & accompanying experts (cont.)
Rocky ROWE (ECPA= European Crop Protection Association) as Occasional Stakeholder for Microplastics restriction
SHAEFER Dietmar (Evonik Nutrition & Care GmbH) as accompanying expert to CEFIC for D4/D5/D6 restriction
WAETERSCHOOT Hugo (EUROMETAUX = European Association of the Metals Industry)
WATSON Diane (Cosmetics Europe) as Occasional Stakeholder
WIJNENDAELE Kris (European Panel Federation), accompanying expert to CEFIC for Formaldehyde restriction

RAC rapporteurs
ANDREOU Kostas
BRANISTEANU Radu
BORG Daniel
BROVKINA Julija
CARVALHO Joao
CHIURTU Elena
DUNAUSKIENE Lina
GEOFFROY Laure
KAPELARI Sonja
KARADJOVA Irina
LEINONEN Riitta
LUND Bert-Ove
MENARD Anja
MOELLER Ruth
MOLDOV Raili
NEUMANN Michael
PARIS Pietro
RUCKI Marian
SANTONEN Tiina
SCHULTE Agnes
SCHLÜTER Urs
SEBA Julie
SOGORB Miguel
TOBIASSEN Lea Stine
VAN DER HAAR Rudolf

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/45/2019
Appointment of (co-)rapporteurs for authorisation applications (closed session)	SEAC/45/2019/02 (restricted room document)
Appointment of (co-)rapporteurs for restriction applications	SEAC/45/2019/01_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>
CAVALIERI Luisa	5.1b.8–N,N-dimethylformamide (DMF)	Contract with the MSCA submitting the dossier
CASTELLI Stefano	5.1b.8–N,N-dimethylformamide (DMF)	Working for the MSCA submitting the dossier
FIORE Karine	5.1b.2 Skin sensitizers in textile	Participation in the preparation of the restriction dossiers
FORKMAN Mats	5.1b.2 Skin sensitizers in textile	Working for the MSCA submitting the dossier
JOYCE John	5.1b.2 Skin sensitizers in textile	Working for the MSCA submitting the dossier
MÅGE Marit	5.1b.3 Perfluorohexane-1-sulphonic acid, its salts and related substances (PFHxS)	Working for the MSCA submitting the dossier

FINAL DRAFT AGENDA

15 November 2019
SEAC/A/45/2019

Final Draft Agenda
45th meeting of the Committee for Socio-economic Analysis

26-28 November 2019
and
3-5 December 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Tuesday 26 November starts at 14.00
Thursday 28 November breaks at 17.00
Tuesday 3 December resumes at 14.00
Thursday 5 December ends at 17.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/45/2019
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

c) Report on SEAC-44 action points, written procedures and update on other ECHA bodies

For information

d) Revised rules of procedure

SEAC/45/2019/03
For agreement

Item 5 – Restrictions

5.1 General restriction issues

- b) Report from the Restrictions Task Force

For information

5.2 Restriction Annex XV dossiers

- b) Opinion development

- 1) Calcium cyanamide in fertilisers – first draft opinion
- 2) Skin sensitisers in textile – second draft opinion
- 3) Perfluorohexane-1-sulphonic acid, its salts and related substances – second draft opinion
- 4) Microplastics – third draft opinion

For discussion

- 5) Siloxanes (D4, D5 and D6) – third draft opinion
- 6) Formaldehyde and formaldehyde releasers – third draft opinion
- 7) Five cobalt salts – fourth draft opinion

For discussion and agreement

- 8) *N,N*-dimethylformamide – draft final opinion

For discussion and adoption

5.3 Appointment of (co-)rapporteurs for restriction dossiers

*SEAC/45/2019/01
(restricted document)
For agreement*

Item 6 – Authorisation

6.1 General authorisation issues

- c) Update on incoming/future applications

For information

- d) Emerging practices in SEAC opinions on OPE and NPE

6.2 Authorisation applications

d) Discussion on key issues

1. 18 applications for authorisation from August 2019 submission window (OPE/NPE)

For discussion

e) Agreement on draft opinion

1. 146_CT_TataSteel (1 use)
2. 149_CTPht_Nalon (1 use)
3. 150_CTPht_AO_Koppers (1 use)
4. 151_CTPht_AO_Rutgers (1 use)
5. 152_CTPht_AO_RainCarbon (1 use)
6. 153_CTPht_AO_Bilbaina (1 use)
7. 157_OPE_Kedrion (1 use)
8. 158_OPE_Sanofi (1 use)
9. 159_OPE_Merck (1 use)
10. 161_OPE_Swords (1 use)
11. 166_OPE_Ompi (1 use)
12. 167_OPE_Roche (1 use)
13. 168_OPE_Vetter (1 use)
14. 169_OPE_Nordisk (1 use)
15. 171_OPE_Wallac (2 uses)
16. 173_OPE_Sobi (1 use)
17. 177_OPE_Abbott_2 (1 use)
18. 178_OPE_Janssen (1 use)
19. 179_OPE_Octapharma (2 uses)
20. 181_OPE_NPE_Roche (3 uses)
21. 183_NPE_GEHC_Bio-Sciences (1 use)

For discussion and agreement

f) Status update

1. 147_CTPht_Bilbaina (1 use)
2. 148_CTPht_DEZA (1 use)
3. 155_OPE_Siemens_2 (5 uses)
4. 176_OPE_Abbott_1 (5 uses)
5. AfAs agreed at SEAC-44

For information

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

Item 7 – AOB

- a) Update of the work plan

For information

Item 8 – Action points and main conclusions of SEAC-45

Table with Conclusions and Action points from SEAC-45

For adoption