

30 August 2021

SEAC/M/51/2021 FINAL

### <u>Final</u>

Minutes of the 51<sup>st</sup> meeting of the Committee for Socio-economic Analysis

31 May-4 June 2021 and 7-9 June 2021

### I. Summary Record of the Proceeding 1) Welcome

María Ottati, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants at the 51<sup>st</sup> meeting of SEAC.

The Chair informed the participants that the meeting would not be recorded. The list of attendees is given in Part III of the minutes.

### 2) Adoption of the Agenda

The Chair introduced the final draft agenda of SEAC-51. The agenda was adopted with minor modifications (in line with SEAC/A/51/2021). The Chair mentioned that the meeting would be partly chaired by the Deputy Chair Kalle Kivelä.

The final agenda is attached to these minutes as Annex III. The list of all meeting documents is attached to these minutes as Annex I.

### 3) Declarations of conflicts of interest to the Agenda

The Chair requested members and their advisors participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Five members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2b-1), 5.2b-2) and 5.2b-3). These members did not participate in voting under those Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

The Chair and Deputy Chair declared their absence of conflict of interest for all items of SEAC-51 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-50 action points, written procedures, and update on other ECHA bodies

The Chair informed the participants that all action points of SEAC-50 had been completed or would be followed up during the on-going SEAC-51 meeting.

The Chair also informed the Committee that the final minutes of SEAC-50 had been adopted by written procedure and had been uploaded to S-CIRCABC as well as on the ECHA website. The Chair mentioned that there were no comments received on them.

Representatives of the Commission updated the Committee on SEAC-related developments in the REACH Committee and in CARACAL and provided an update on ECJ ruling on lead chromates

### b) Update of SEAC accredited stakeholders' list (closed session)

The Committee reviewed the SEAC accredited stakeholders list. The Committee took note of and discussed the restricted meeting document (SEAC/51/2021/03). Following the discussions, SEAC agreed on the update of the list.

The Chair informed SEAC that the Secretariat will publish the updated list on the ECHA website.

### 5) Restrictions

### 5.1 General restriction issues

### a) Framework paper on opinion development on Restrictions

The Secretariat presented and the Committee discussed the revisions made in the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals. Following the RAC and SEAC plenary meetings, the Secretariat will publish the revised document on the ECHA website. Some members proposed that the Secretariat consider re-opening the paper describing the SEAC approach on evaluating restrictions and applications for authorisation for PBT and vPvB substances.

Furthermore, the members were informed about the upcoming training of newcomers and other interested experts to be held on 23 June 2021.

### b) Update from the Restriction Task Force Meeting

SEAC took note of the update provided by the Secretariat on the recent Restrictions Task Force meeting which took place on 29 April 2021. The topics covered included guidance on uncertainty analysis in scientific assessment, best practices in analysis of alternatives, and the draft Restrictions Roadmap.

### 5.2 Restriction Annex XV dossiers

### a) Conformity check and key issues discussion

### 1,6,7,8,9,14,15,16,17,17,18,18-Dodecachloropentacyclo-[12.2.1.16,9.02,13.05,10]octadeca-7,15-diene ("Dechlorane Plus"™)

The Chair welcomed the Dossier Submitter's representatives from Norway and the RAC rapporteur. She informed the participants that the restriction dossier had been submitted in April 2021.

The Dossier Submitter's representatives provided an introductory presentation on the restriction proposal. They explained that the proposal concerns the risks for human health and the environment from emissions of Dechlorane  $Plus^{TM}$ . Members commented on the DS presentation. The RAC rapporteurs then informed SEAC that RAC had concluded that the dossier conforms to the Annex XV requirements at RAC-57.

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

The Committee discussed the case. The Committee then agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteurs presented the key issues they have identified in the restriction proposal. The Chair informed the Committee that the Consultation on this restriction proposal will be launched on 23 June 2021.

### b) Opinion development

### 2) Undecafluorohexanoic acid (PFHxA), its salts and related substances – fifth draft opinion

The Deputy Chair welcomed the Dossier Submitter's representative from Germany, the RAC rapporteur and the occasional stakeholders and the experts accompanying regular and occasional stakeholder observers. He summarised the state of play of the opinion-making process.

The RAC rapporteur provided a report from the RAC discussions on this restriction proposal held during RAC-57, where RAC adopted its opinion. The SEAC rapporteurs then presented the revised fifth draft opinion to the Committee. SEAC members agreed on the costs and other impacts as proposed by rapporteurs.

SEAC discussed and agreed on the conclusions for benefits, proportionality as presented by the rapporteurs, with further changes proposed during the discussions. SEAC also discussed whether a review clause would be needed and agreed to the proposal by the rapporteurs, with additional changes proposed during the discussions. Furthermore, SEAC agreed on the derogations as presented by the rapporteurs with the following amendments: a derogation for PPEs specifically designed for the armed forces to be added to the conditions, and the derogation for medical face shields to be deleted from the proposed restriction conditions (pending the submission of information on the availability of alternatives in the consultation on the draft SEAC opinion). For the consultation on the SEAC draft opinion, in addition to the questions already proposed by the rapporteurs, SEAC agreed to include a question on the number of sites that would benefit from the derogation for firefighting foams used in large tanks.

SEAC also supported the conclusions on practicality, including the general transitional period and reporting requirements as presented by the rapporteurs. In addition, rapporteurs were asked to check and consider clarifying, where necessary, the following points: the terminology used in the proportionality conclusions for different sectors, the justification of why specific categories of PPEs are proposed for derogation, the justification for the start date of the reporting requirements and whether the manufacture of firefighting foams for derogated uses would still be allowed. Furthermore, it was agreed that RAC conclusions on derogations for specific sectors as agreed in RAC-57 will be aligned in the SEAC opinion.

The Committee agreed on its draft opinion by consensus (with changes as agreed at SEAC-51). 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 7 July 2021. Furthermore, recognising that the RAC opinion diverges significantly from the restrictions suggested, SEAC will extend its decision making by 90 days based on Article 71.3 (i.e. SEAC is expected to adopt its opinion at SEAC-53 in December 2021).

### 3) Substances in single-use diapers – second draft opinion

The Chair welcomed the Dossier Submitter's representatives from France, the RAC (co-)rapporteurs and the occasional stakeholders. She summarised the state of play of the opinion-making process.

The RAC rapporteur provided to the Committee a report from the RAC discussions on this dossier held at RAC-57 and responded to questions from the SEAC members. The SEAC rapporteurs then presented the second draft opinion to the Committee. SEAC members asked the Chair and the Commission for clarification regarding how to proceed with the dossier given RAC's preliminary finding that the Dossier Submitter had not sufficiently demonstrated a risk to justify an EU-wide restriction. The ECHA secretariat and the Commission informed SEAC members that a complete SEAC opinion on this dossier is required to inform future decision-making.

The accompanying expert of the occasional stakeholder observer from EDANA commented on the impact on costs of any future more sensitive testing methods, given that the detection limits required for the proposed concentration limits may also detect background contamination. The occasional stakeholder observers from FECC commented on one of the studies quoted by the Dossier Submitter and referenced in the opinion. The Dossier Submitter provided clarifying comments regarding price competition and more generally appealed to industry to submit additional well-substantiated information via the consultation on the Annex XV report. The members also pointed out that information was still lacking and asked industry to submit more data in the ongoing consultation.

The Chair concluded that the Committee agrees with the approach of the (co-)rapporteurs so far. She noted agreement regarding the conclusion that the need for action on an EUwide basis has not been demonstrated as well as the lack of information to conclude on whether there are suitable alternatives. She also noted that the Committee agreed with the (co-)rapporteurs' preliminary evaluation of costs and benefits, and that it supported their approach to assessing proportionality.

The (co-)rapporteurs were requested to prepare the third draft opinion by early August 2021, taking into account the SEAC-51 discussions, RAC-57 conclusions and any additional comments received during the remainder of the consultation (the deadline for comments is 21 June).

### 4) Lead and its compounds in outdoor shooting and fishing- first draft opinion

The Chair welcomed the Dossier Submitter's representative from ECHA, the regular and occasional stakeholders and their accompanying industry experts as well as the members of the SEAC support group which was established to support the rapporteurs during the opinion development. She summarised the state of play of the opinion-making process.

The Secretariat informed the Committee that RAC had discussed its first draft opinion at RAC-57. The rapporteurs then presented the first draft opinion to the Committee. Members commented on the scope of the restriction (exclusion of all indoor uses; effectiveness of information/labelling obligations; aspects of the optional conditional derogation for lead

gunshot used in sports shooting, including effectiveness, implementation of permitting systems, and the need for time-limited derogations). SEAC also discussed the availability and costs of alternatives as well as the costs of implementing RMMs at shooting ranges. The regular stakeholder observers, together with their experts, commented on the scope, availability of alternatives, costs, and transition periods. An occasional stakeholder observer commented on the scope in relation to voluntary military training and on costs. The invited experts commented on the optional conditional derogation of gunshot used in sports shooting and on costs.

The Chair concluded that there was general support by SEAC that action on a Union-wide basis is justified and that the proposed restriction in principle is the most appropriate regulatory action to control the identified risks. However, further clarification on the delineation between 'civilian' and 'non-civilian' uses would be beneficial, as would further evidence of the effectiveness of information and labelling obligations, the appropriateness of the proposed transition periods, as well as several aspects related to the optional conditional derogation for lead gunshot used in sports shooting. Regarding the cost assessment, the Chair concluded that there was general support for the approach taken by the Dossier Submitter but that the work will continue as several clarifications and further scrutiny are needed to conclude on cost calculations. She welcomed the relevant stakeholder observers' stated intention to submit additional information via the consultation on the Annex XV report.

The (co-)rapporteurs were requested – with the support from the SEAC support group members – to prepare the second draft opinion by late July 2021, taking into account the SEAC-51 discussions, the outcome of the SEAC written consultation and any comments received during the consultation (the deadline for comments is 24 September).

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

The Secretariat provided a presentation on the incoming restriction dossiers expected to be submitted in October 2021. The Chair informed the Committee that the call for expression of interest for the pool(s) of (co-)rapporteurs will be launched after the plenary and interested members were encouraged to come forward as volunteers to the pools of (co-) rapporteurs for upcoming restriction proposals by 16 August 2021.

### 6) Authorisation

### 6.1 General authorisation issues

### a) Update on incoming/future applications

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

SEAC took note of the update on the new applications for authorisation received during the May 2021 submission window and other AfA-related updates.

### b) SEAC's approach to evaluation of review reports

The Secretariat presented and SEAC discussed the draft document on RAC and SEAC's Approach to Evaluating Review Reports.

The purpose of the document is to describe RAC and SEAC's approaches for evaluating review reports to ensure consistency in the Committees' evaluations. The Secretariat held an orientation discussion at the RAC-56 and SEAC-50 plenary meetings. In addition, following the plenary discussions the Secretariat organised a consultation with members and stakeholder observer organisations of the two Committees. A revised version of the document was presented at RAC-57 and at this SEAC-51 plenary meeting.

During the discussion on the new version of the document a few SEAC members proposed some editorial changes. Among other topics the SEAC members discussed how to evaluate the progress of substitution if a company covered by a granted authorisation submits a new application instead of a review report, that the number of questions sent to authorisation holders should be determined on a case-by-case basis, and non-conformity issues. Representatives of the stakeholder organisations Eurometaux and ClientEarth contributed to the discussion.

SEAC agreed on the document by consensus. The Secretariat will consider the discussion and update the document, and will publish it on the ECHA website.

### c) Update on opinion format

The Secretariat presented to the Committee the updated version of the opinion format. The Committee members briefly discussed the presentation by the Secretariat. Representatives of the stakeholder organisations Client Earth and the European Environmental Bureau (EEB) contributed to the discussion.

### d) SEAC's approach to dealing with issues related to geographical boundaries

The Secretariat presented and SEAC discussed various aspects in the approach to dealing with issues related to geographical boundaries in the socio-economic assessment of applications for authorisation. A representative of the European Commission contributed to the discussion. The Committee requested the Secretariat to consider the discussion. In addition, SEAC requested the Secretariat to consider preparing a note on the issues related to geographical boundaries and to include elements from the discussion.

### e) SEAC's approach to assessing changes in producer surplus

The Secretariat presented and SEAC discussed the approach to assessing changes in Producer Surplus in applications for authorisation. The Committee discussed the document and considered that additional work is needed to improve the practical instructions in the document. The Committee requested the Secretariat to establish a working group to draft practical instructions and to amend the theoretical approach if necessary. The practical approach should present 1, 3 and 5 years of profit losses as options and clarify under which conditions each option would be used by SEAC. The option of 1 year should be presented as the starting point when no information is available that would support using a higher number of years, and the practical guide should recognise that it is a conservative assumption, giving a lower bound estimate of the changes in producer surplus. The practical guide should provide the possibility for different periods to be supported, based

on the information that is provided by the applicants. A representative of the European Commission also contributed to the discussion.

The Secretariat will table the updated document for agreement at SEAC-52 in September 2021.

### 6.2 Authorisation applications

### a) Discussion on key issues

1. 4 applications for authorisation/review reports (chromium trioxide, chromic acid) from February 2021 submission window

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

- 231\_CT\_Kesseboehmer (single use)
- 232\_DtC\_Monroe (single use)
- 233\_CT\_Betz-Chrom (single use)
- 234\_CT\_Kwalter (2 uses)
- 235\_CA\_Neoperl (single use).

### b) Agreement on draft opinion

1) 218\_CT\_DOURECA (2 uses)

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

Use 1: Industrial use of hexavalent chromium trioxide for a pre-treatment step (etching) in the electroplating process for automotive applications

Use 2: Industrial use of chromium trioxide for the electrolytic step to create a long-lasting and high durability chromium decorative surface on plastic substrates in the electroplating process for automotive applications

The SEAC members discussed the applicant's substitution activities and the length of the review period.

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

### 2) 219\_CT\_HusqvarnaAB (1 use)

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

Use 1: Industrial use of a mixture containing Chromium Trioxide in functional chrome plating of the saw chain cutter links in order to meet stay sharp and durability requirements for use with chainsaws

One SEAC member noted importance of a safety aspect for cutter chains moving at high velocity. Another SEAC member reflected on a comparatively large proportion of

confidential information in this application for authorisation. A representative of the stakeholder organisation Eurometaux asked a question about RAC's potential contribution in the assessment of the risk of alternative substances listed in the Analysis of Alternatives by the applicant.

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

### 3) 220\_CT\_SRG Global (2 uses)

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

Use 1: Chromium trioxide-based etching as pre-treatment step for electroplating of plastics for transportation applications

Use 2: Functional chrome plating with decorative character for transportation applications

SEAC members discussed availability of alternatives, the applicant's substitution activities, terminology used by the applicant in naming of the potential alternative processes, economic and technical feasibility of alternatives. One SEAC member did not agree that there was enough evidence on the applicants' customer's requirements to support the SEAC rapporteurs' conclusions on the availability of alternatives and credibility of the substitution plan. He therefore chose to take a minority position on this case. The minority position is available in Annex III of these minutes. One SEAC member expressed explicit support to the draft opinions as they are prepared by the SEAC rapporteurs.

The Committee agreed on the draft opinions by a simple majority. The rapporteurs, together with the Secretariat, will do the final editing of the SEAC draft opinions. The Secretariat will send the draft opinions to the applicant for commenting. 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) 221\_CT\_SD\_USSK (1 use)

This is an application for authorisation on one a single use of chromium trioxide and sodium dichromate:

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

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

5) 222\_RR1\_SD\_Colle (1 use)

This is a review report on a single use of sodium dichromate:

Use 1: Use of sodium dichromate as mordant in wool dyeing with dark colours

The Secretariat briefed the Committee about the outcome of discussion on the draft opinion in RAC. A representative of the European Commission contributed to the discussion by clarifying some aspects of and the information needs for the decision-making process, in particular as regards the clarity of the opinion and conclusion on the availability of suitable alternatives. One SEAC member raised issues about availability of alternatives with regard to requirements set by some of the applicant's customers, as well as the nonuse scenario submitted by the applicant, and a length of the review period. A representative of the stakeholder organisation Eurometaux contributed to the discussion by reminding the Committee that each of the applications for authorisation and review reports should be considered on its own merits, and made a remark on the SEAC rapporteurs' presentation in general. Another SEAC member asked a question about alternatives available in the EU. A representative of the stakeholder organisation ClientEarth also contributed to the discussion by reflecting on provisions of Article 64 of the REACH Regulation.

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

6) 223\_RR1\_EDC\_Lanxess (1 use)

This is a review report on a single use of 1,2-dichloroethane (EDC):

Use 1: Industrial use as a swelling agent during the sulphonation reaction of polystyrenedivinylbenzene copolymer beads in the manufacturing of strong acid cation exchange resins

SEAC members discussed a length of the review period and the authorisation holder's substitution plans. The SEAC members acknowledged that any assessment for contingency periods should be done by the Committee on a case by case basis.

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

### 7) 224\_RR1\_EDC\_Eurenco (1 use)

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

Use 1: Industrial use of 1,2-Dichloroethane as a solvent for the synthesis of Polyepichlorohydrin used as a precursor in the production of Glycidyl Azide Polymer, an oligomer with hydroxyl terminations used to increase the energetic performance of propellants and explosives

SEAC members discussed availability of alternatives, credibility of the substitution plan submitted by the authorisation holder and a length of the review period. Representatives of the European Commission contributed to the discussion by clarifying some aspects of and the information needs for the decision making process, in particular as regards the justification for the proposed condition, definition of progress report, conclusion on suitable alternatives and the justification for the review period.

The Committee advised that changes should be made in the review period recommended in the opinion, and in the conditions proposed. The rapporteurs will take the SEAC-51 discussions into account in the next version of the SEAC draft opinion, and the Secretariat will launch the SEAC consultation on the second version of the SEAC draft opinion and will schedule it for discussion and agreement at SEAC-52 in September 2021.

8) 225\_MOCA\_LUC (2 uses)

This is an application for authorisation on two uses of 2,2'-dichloro-4,4'-methylenedianiline (MOCA):

Use 1: Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for custom-made rollers with high reliability requirements for steel and aluminium sectors

Use 2: Industrial use of 2,2'-Dichloro-4,4'-methylenedianiline (MOCA) in the manufacture of high-performance polyurethanes specifically for heavy-duty rollers, tensioner pads and spring blocks with high reliability requirements for offshore energy and renewables sectors

The SEAC members discussed substitution activities by the applicant, independence of the two uses, and non-use scenario submitted by the applicant. A representative of the stakeholder organisation Eurometaux also contributed to the discussion.

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

9) 226\_OPE\_LETI (1 use)

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

Use 1: Use of 4-tert-OPnEO in aqueous buffers during the manufacturing process of the active pharmaceutical ingredient (Protein Q) of the veterinary vaccine LetiFend<sup>®</sup>

SEAC members discussed substitution activities by the applicant and alternatives in the analysis 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 Secretariat will send the draft opinion to the applicant for commenting. The rapporteurs and the Secretariat will consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

### c) Adoption of opinion

1. 196\_OPE\_Becton (1 use)

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

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

It was received by the Committee in February 2020. SEAC agreed on the draft opinion during SEAC-49 plenary meeting. On 9 April 2021 the applicant submitted comments on the draft opinion.

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

2. 198\_OPE\_Zoetis (4 uses; comments on Use 4 only)

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

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

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

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

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

It was received by the Committee in May 2020. SEAC agreed on the draft opinions during SEAC-49 plenary meeting. On 12 April 2021 the applicant submitted comments on the draft opinion on Use 4 only.

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

3. 199\_OPE\_Biokit (2 uses; comments on Use 2 only)

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

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

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

It was received by the Committee in February 2020. SEAC agreed on the draft opinions during SEAC-49 plenary meeting. On 12 April 2021 the applicant submitted comments on the draft opinion on Use 2 only.

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

### 4. 203\_OPE\_NPE\_Qiagen (4 uses)

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

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

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

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

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

It was received by the Committee in February 2020. SEAC agreed on the draft opinions during SEAC-49 plenary meeting. On 12 April 2021 the applicants submitted comments on the four draft opinions.

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

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/51/2021/01 was agreed by SEAC.

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

a) Substitution Plans – agreement on draft addenda

### 1. CT\_Hapoc\_2

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in November 2018. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum. The Secretariat will send the draft addendum to the applicant for commenting.

### 2. CT\_Gerhardi

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in March 2017. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum. The Secretariat will send the draft addendum to the applicant for commenting.

### 3. DEHP\_DEZA

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in January 2015. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

The Committee members asked questions about number of downstream users covered by this application for authorisation, and briefly discussed the approach taken by the applicant in compiling the submitted substitution plan.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum to reflect the points raised in the discussion. The Secretariat will send the draft addendum to the applicant for commenting.

### 4. SD\_Ormezzano

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in May 2017. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

The Committee members discussed overall quality of the submitted Substitution Plan. A representative of the stakeholder organisation ChemSec contributed to the discussion.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum to reflect the points raised in the discussion. The Secretariat will send the draft addendum to the applicant for commenting.

### 5. CT\_Schell

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in September 2019. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

One SEAC member commenting on factors affecting substitution noted that aesthetic preferences of consumers cannot be enforced by regulatory changes. A representative of the European Commission also contributed to the discussion.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum to reflect the points raised in the discussion. The Secretariat will send the draft addendum to the applicant for commenting.

### 6. CT\_Keuco

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in September 2019. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

One SEAC member commenting on factors affecting substitution noted that aesthetic preferences of consumers cannot be enforced by regulatory changes.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum to reflect the points raised in the discussion. The Secretariat will send the draft addendum to the applicant for commenting.

### 7. CT\_Aloys

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in September 2019. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

One SEAC member commenting on factors affecting substitution noted that aesthetic preferences of consumers cannot be enforced by regulatory changes.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum to reflect the points raised in the discussion. The Secretariat will send the draft addendum to the applicant for commenting.

### 8. CT\_Ideal

The rapporteurs presented and SEAC discussed a draft addendum to the Committees' opinion on the application for authorisation adopted in September 2019. The draft addendum contains the evaluation of the Substitution Plan submitted by the applicant to ECHA following a request by the European Commission.

One SEAC member commenting on factors affecting substitution noted that aesthetic preferences of consumers cannot be enforced by regulatory changes.

The Committee agreed on the draft addendum by consensus. The rapporteurs, together with the Secretariat, will do the final editing of the draft addendum to reflect the points

raised in the discussion. The Secretariat will send the draft addendum to the applicant for commenting.

### b) Substitution Plans – adoption of addenda

### 1. CT\_Hapoc\_1

The rapporteurs presented comments on the draft addendum agreed by SEAC at the previous SEAC-50 plenary meeting. The applicant submitted comments on 26 April 2021. One SEAC member asked a question on the conclusion regarding credibility of the

substitution plan submitted by the applicant.

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

### 2. CT\_Chemservice

The rapporteurs presented comments on the draft addendum agreed by SEAC at the previous SEAC-50 plenary meeting. The applicant submitted comments on 16 April 2021. SEAC discussed comments on the draft addendum submitted by the applicant. Representatives of the European Commission contributed to the discussion, highlighting the fact that REACH does not distinguish between applications up or down the supply chain.

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

### 3. CT\_REACHLaw

The rapporteurs presented comments on the draft addendum agreed by SEAC at the previous SEAC-50 plenary meeting. The applicant submitted comments on 16 April 2021. SEAC discussed comments on the draft addendum submitted by the applicant. Representatives of the European Commission contributed to the discussion.

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

### 4. MOCA\_REACHLaw

The rapporteurs presented comments on the draft addendum agreed by SEAC at the previous SEAC-50 plenary meeting. The applicant submitted comments on 16 April 2021. SEAC briefly discussed responses by the rapporteurs to the applicant's comments on the draft addendum. One SEAC member explicitly supported the rapporteurs' conclusions.

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

### 8) AOB

### a) Update of the work plan

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

### 9) Action points and main conclusions of SEAC-51

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

# II. Main conclusions and action points SEAC-51, 31 May-4 June 2021, and 7-9 June 2021

(Adopted at SEAC-51 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/51/2021).	
3. Declarations of conflicts of interest to the Agen	da
Conflicts of interest have been declared and will be included in the minutes.	
4. Report from other ECHA bodies and activities	
a) Report on SEAC-50 action points, written pro	cedures, and update on other ECHA bodies
P = = = = = = = = = P = = = = P = = P = P	
SEAC was informed on the status of the action points of SEAC-50.	
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 their presentation on the ECJ judgment on lead chromate cases.	
b) Update of SEAC accredited stakeholders' list	(closed session)
SEAC took note of and discussed the restricted meeting document (SEAC/51/2021/03).	<b>SECR</b> to publish the updated list on the ECHA website.
SEAC agreed on the update of SEAC accredited stakeholders' list.	
5. Restrictions	
5.1. General restriction issues	
a) Framework paper on opinion development	t on Restrictions
SEAC took note of and discussed the revisions made in the Framework for RAC and SEAC in	SECR to publish the revised document on ECHA website.
checking conformity and developing opinions on restriction proposals. SEAC was informed about the upcoming training of newcomers and other interested experts to be held	<b>SEAC members</b> to propose topics to be covered in the training by 11 June.
on 23 June 2021.	<b>SECR</b> to consider re-opening the SEAC paper on evaluating restriction proposals and applications for authorisation for PBT and vPvB substances.
b) Update from the Restriction Task Force Me	

5.2 Restriction Annex XV dossiers	
a) Conformity check and key issues discussio	n
1. 1) 1,6,7,8,9,14,15,16,17,17,18,1 [12.2.1.16,9.02,13.05,10]octadeca-2	
SEAC agreed that the dossier conforms to the Annex XV requirements.	<b>SECR</b> to compile the RAC and SEAC final outcome of the conformity check and upload this to S CIRCABC IG.
SEAC took note of the recommendations to the dossier submitter.	<b>SECR</b> to launch a six-month external consultatio on the restriction proposal on 23 June 2021.
b) Opinion development	
1. Undecafluorohexanoic acid (PFHxA), its sa opinion	Its and related substances – Revised fifth draft
SEAC rapporteurs presented and SEAC discussed the revised fifth draft opinion. SEAC agreed on the draft opinion by consensus (with modifications agreed at SEAC-51).	<b>Rapporteurs</b> together with <b>SECR</b> to do the finated iting of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.
	<b>SECR</b> to launch an external consultation on th SEAC draft opinion on 7 July 2021.
2. Substances in single-use diapers – Second	draft opinion
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	<b>Rapporteurs</b> to prepare the third draft opinior considering SEAC-51 discussions and the outcom of the external consultation, by early August 2021
3. Lead and its compounds in outdoor shooting	ng and fishing– First draft opinion
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<b>Rapporteurs</b> to prepare the second draft opinior considering SEAC-51 discussions and the SEA written consultation, by late July 2021.
	<b>SEAC members</b> to provide any remainin comments on the first draft opinion by 2 July 2021
5.3 Appointment of (co-)rapporteurs for restric	ction dossiers
SEAC was provided with an update on the upcoming restriction proposals to be submitted in October 2021.	<b>SEAC members</b> to come forward as volunteers t the pools of (co-) rapporteurs for upcomin restriction proposals by 16 August 2021.

. Authorisation	
6.1 General authorisation issues	
a) Update on incoming/future applications	
SEAC took note of the update on the new AfAs received during the May 2021 submission window and other AfA-related updates.	
b) SEAC'S approach to evaluation of review report	rts
The Secretariat presented and SEAC discussed the draft document on SEAC's Approach to Evaluation of Review Reports.	The Secretariat to consider the discussion and updat the document and to publish it on the ECHA website
SEAC agreed on the document by consensus.	
c) Update on the opinion format	
SECR informed SEAC about the ongoing work on updating the opinion format.	
SEAC discussed the presentation by the Secretariat.	
d) SEAC's approach to dealing with issues related	to geographical boundaries
The Secretariat presented and SEAC discussed the draft document on SEAC's Approach to dealing with issues related to geographical boundaries.	<ul> <li>SECR to consider the discussions and to update the document.</li> <li>SECR to consider making a lines to take note on the issues related to geographical boundaries and improve on elements from the discussion.</li> </ul>
e) SEAC'S approach to assessing changes in prod	lucer surplus
The Secretariat presented and SEAC discussed the draft document on SEAC's Approach to Assessing Changes in Producer Surplus. SEAC considered that additional work is needed to improve the practical instructions in the document.	<b>SECR</b> to establish a working group to draft practic instructions and to amend the theoretical approach necessary. The practical approach should present 3 and 5 years of profit losses as options and clari under which conditions each option would be used to SEAC. The option of 1 year should be presented a the starting point when no information is availab that would support using a higher number of year and the practical guide should recognise that it is conservative assumption, giving a lower bour estimate of the changes in producer surplus. The practical guide should provide the possibility for different periods to be supported, based on the information that is provided by the applicants.

	<b>SEAC members</b> to indicate their interest in joining the working group by contacting SEAC Secretariat by 11 June 2021.
6.2 Authorisation applications	1
a) Discussion on key issues	
	oxide, chromic acid, dichromium tris(chromate)) from
SEAC discussed the key issues identified in the applications for authorisation.	<b>Rapporteurs</b> are requested to prepare the first versions of the draft opinions, taking into account the SEAC-51 discussions.
b) Agreement on draft opinions	
1) 218_CT_DOURECA (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.
SEAC agreed on its draft opinions (with modifications agreed at SEAC-51) on this	<b>SECR</b> to send the draft opinions to the applicants for commenting.
application for authorisation by consensus.	Rapporteurs and SECR to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
2) 219_CT_HusqvarnaAB (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.
SEAC agreed on its draft opinion (with editorials agreed at SEAC-51) on this application for	<b>SECR</b> to send the draft opinion to the applicant for commenting.
authorisation by consensus.	<b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.
3) 220_CT_SRG Global (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.
SEAC agreed on its draft opinions (with editorials agreed at SEAC-51) on this application for	<b>SECR</b> to send the draft opinions to the applicant for commenting.
authorisation by a simple majority. Minority view will be reflected in the minutes.	<b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.

4) 221_CT_SD_USSK (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the finated and the search of the SEAC draft opinion.
SEAC agreed on its draft opinion (with editorials agreed at SEAC-51) on this application for	<b>SECR</b> to send the draft opinion to the applicant for commenting.
authorisation by consensus.	<b>Rapporteurs</b> and <b>SECR</b> to consider the need t come back to discussions in SEAC after the opinio have been agreed by RAC.
5) 222_RR1_SD_Colle (1 use)	<b>5</b> /
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the finated and the search of the SEAC draft opinion.
SEAC agreed on its draft opinion (with editorials agreed at SEAC-51) on this review report by consensus.	<b>SECR</b> to send the draft opinion to the authorisatio holder for commenting.
6) 223_RR1_EDC_Lanxess (1 use)	
SEAC rapporteur presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the find editing of the SEAC draft opinion.
SEAC agreed on its draft opinion (with editorials agreed at SEAC-51) on this review report by	<b>SECR</b> to send the draft opinion to the authorisatic holder for commenting.
consensus.	<b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.
7) 224_RR1_EDC_Eurenco (1 use)	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> to take the SEAC-51 discussions int account in the next version of the SEAC dra opinion.
	<b>SECR</b> to launch the SEAC consultation on th second version of the SEAC draft opinion an schedule it for discussion and agreement at SEAC 52 in September 2021.
8) 225_MOCA_LUC (2 uses)	· · · · · · · · · · · · · · · · · · ·
The SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the fin editing of the SEAC draft opinions.
SEAC agreed on its draft opinions on this review report by consensus.	<b>SECR</b> to send the draft opinions to the application for commenting.

	<b>Rapporteurs</b> and <b>SECR</b> to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
9) 226_OPE_LETI (1 use)	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the finated and the finated and the SEAC draft opinion.
SEAC agreed on its draft opinion on this review report by consensus.	<b>SECR</b> to send the draft opinion to the applicant fo commenting.
	<b>Rapporteurs</b> and <b>SECR</b> to consider the need t come back to discussions in SEAC after the opinio has been agreed by RAC.
c) Adoption of opinion	
1) 196_OPE_Becton (1 use)	
The SEAC rapporteur presented and SEAC discussed the SEAC draft final opinion.	<b>Rapporteur</b> together with <b>SECR</b> to do the finate disting of the SEAC opinion.
SEAC adopted its opinion on this application for authorisation by consensus.	<b>SECR</b> to send the opinion to the Commission, th Member States and the applicant, and to publish on the ECHA website.
2) 198_OPE_Zoetis (4 uses; comments on Use 4 o	only)
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the finate disting of the SEAC opinions.
SEAC adopted its opinions on this application for authorisation by consensus.	<b>SECR</b> to send the opinions to the Commission, th Member States and the applicant, and to publis them on the ECHA website.
3) 199_OPE_Biokit (2 uses; comments on Use 2 o	nly)
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the finate disting of the SEAC opinions.
SEAC adopted its opinions on this application for authorisation by consensus.	<b>SECR</b> to send the opinions to the Commission, th Member States and the applicant, and to publis them on the ECHA website.
4) 203_OPE_NPE_Qiagen (4 uses)	

The SEAC rapporteurs presented and SEAC	
discussed the SEAC draft final opinions.	editing of the SEAC opinions.

SEAC adopted its opinions on this application for authorisation by consensus.	<b>SECR</b> to send the opinions to the Commission, the Member States and the applicants, and to publish them on the ECHA website.
6.3 Appointment of (co-)rapporteurs for authori	
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/51/2021/01_rev1).	<b>SEAC members</b> to volunteer to the pool of (co-) rapporteurs for applications for authorisation. <b>SECR</b> to upload the updated document to confidential folder on S-CIRCABC IG.
7. Requests under Article 77(3)(c)	
a) Substitution Plans – agreement on draft adder	Ida
1. CT_Hapoc_2	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
SEAC agreed on the draft addendum on this application for authorisation by consensus.	<b>SECR</b> to send the draft addendum to the applicant for commenting.
2. CT_Gerhardi	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
SEAC agreed on the draft addendum on this application for authorisation by consensus.	<b>SECR</b> to send the draft addendum to the applicant for commenting.
3. DEHP_DEZA	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
SEAC agreed on the draft addendum on this application for authorisation by consensus.	<b>SECR</b> to send the draft addendum to the applicant for commenting.
4. SD_Ormezzano	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
SEAC agreed on the draft addendum on this application for authorisation by consensus.	<b>SECR</b> to send the draft addendum to the applicant for commenting.
5. CT_Schell	1
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.

application for authorisation by consensus.	for commenting.
6. CT_Keuco	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
SEAC agreed on the draft addendum on this application for authorisation by consensus.	<b>SECR</b> to send the draft addendum to the application for commenting.
7. CT_Aloys	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
SEAC agreed on the draft addendum on this application for authorisation by consensus.	<b>SECR</b> to send the draft addendum to the application for commenting.
8. CT_Ideal	
The SEAC rapporteurs presented and SEAC discussed the draft addendum.	<b>The rapporteurs</b> , together with SECR, to do the final editing of the draft addendum.
	final editing of the draft addendum.
discussed the draft addendum. SEAC agreed on the draft addendum on this	final editing of the draft addendum. <b>SECR</b> to send the draft addendum to the applican
discussed the draft addendum. SEAC agreed on the draft addendum on this application for authorisation by consensus.	final editing of the draft addendum. <b>SECR</b> to send the draft addendum to the applicar
discussed the draft addendum. SEAC agreed on the draft addendum on this application for authorisation by consensus. b) Substitution Plans – adoption of addenda	final editing of the draft addendum. <b>SECR</b> to send the draft addendum to the application for commenting.
discussed the draft addendum. SEAC agreed on the draft addendum on this application for authorisation by consensus. b) Substitution Plans – adoption of addenda 1) CT_Hapoc_1 The SEAC rapporteurs presented and SEAC	final editing of the draft addendum.  SECR to send the draft addendum to the application for commenting.  Rapporteur together with SECR to do the finediting of the final addendum.
<ul> <li>discussed the draft addendum.</li> <li>SEAC agreed on the draft addendum on this application for authorisation by consensus.</li> <li>b) Substitution Plans – adoption of addenda <ol> <li>CT_Hapoc_1</li> </ol> </li> <li>The SEAC rapporteurs presented and SEAC discussed the SEAC draft final addendum.</li> <li>SEAC adopted the addendum on this application</li> </ul>	final editing of the draft addendum.  SECR to send the draft addendum to the application for commenting.  Rapporteur together with SECR to do the finediting of the final addendum.  SECR to send the opinion to the Commission, the Member States and the applicant, and to publish
discussed the draft addendum. SEAC agreed on the draft addendum on this application for authorisation by consensus. b) Substitution Plans – adoption of addenda 1) CT_Hapoc_1 The SEAC rapporteurs presented and SEAC discussed the SEAC draft final addendum. SEAC adopted the addendum on this application for authorisation by consensus.	final editing of the draft addendum.  SECR to send the draft addendum to the application for commenting.  Rapporteur together with SECR to do the finediting of the final addendum.  SECR to send the opinion to the Commission, the Member States and the applicant, and to publish on the ECHA website.

The SEAC rapporteurs presented and SEAC discussed the SEAC draft final addendum. SEAC adopted the addendum on this application for authorisation by consensus.	<ul><li><b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the final addendum.</li><li><b>SECR</b> to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.</li></ul>
4) MOCA_REACHLaw	
The SEAC rapporteurs presented and SEAC discussed the SEAC draft final addendum.	<b>Rapporteur</b> together with <b>SECR</b> to do the final editing of the final addendum.
SEAC adopted the addendum on this application for authorisation by consensus.	<b>SECR</b> to send the opinion to the Commission, the Member States and the applicant, and to publish it on the ECHA website.
8. Any other business	
a) Update of the work plan	
SEAC took note of the presentation on the work plan for future months.	
9. Action points and main conclusions of SEAC-5	1
SEAC adopted the action points and main conclusions of SEAC-51.	

### III. List of Attendees SEAC-51

SEAC members
ALEXANDRE João
ANASTASIOU Christos
ANTONIADOU Sofia
BERGS Ivars
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
DOMINIAK Dorota
DOLENC Darko
FANKHAUSER Simone
GABBERT Silke
GAIDUKOVS Sergejs
ISKRA Jernej
JANSSEN Martien
JOMINI Stéphane
JONES Derrick
JOYCE John
KAJIC Silva
KIISKI Johanna
LADARU Raluca
LEAHY Eimear
LIBERSKA Ewa
LÜDEKE Andreas
MUNCRIEF Sandi
MÅGE Marit
NIKOVA Julieta
PETERSEN Ida Svostrup
RODRIGUEZ HERNANDEZ Manuel
ROUW Aart
SCHUCHTAR Endre
SHAKHRAMANYAN Nikolinka
THIELE Karen
TURVEY Alex
URBAN Klaus
ZIEMIENE Jurgita

Commission observers
BERTATO Valentina (DG ENV)
BLUMTRITT Kaja (DG GROW)
GALLEGO Matteo (DG ENV)
PEDERSEN Finn (DG ENV)
SVÄRD Amie (DG GROW)
TOSETTI Patrizia (DG GROW)
ZORGNO Riccardo (DG GROW)

#### ECHA STAFF

ANAGNOSTAKIS Kostas
BLAINEY Mark
DOYLE Simone
FRANKE Greta
GERVASUTTI Simone
GMEINDER Michael
GODINA PENT Daniele
HENRICHSON Sanna
HÄMÄLÄINEN Eva
KANNOSTO MAK Eva
KIVELÄ Kalle
LADARU Raluca
LAZIC Nina
LEGZDINA Ilze
LIBERSKA Ewa
LUDBORZS Arnis
MAJOROS Laszlo
MANNERVESI Maija
MARQUEZ-CAMACHO Mercedes
MUSHTAQ Fesil
MÄKELÄ Petteri
NICOT Thierry
NURMI Väinö
NYGÅRD Daniel
ORISPÄÄ Katja
OTTATI Maria
PELTOLA Jukka
PILLET Monique
REGIL Pablo
RICHARZ Andrea
ROSSI Ludovica
SIHVONEN Kirsi
SIMPSON Peter
SOSNOWSKI Piotr
STOYANOVA Evgenia
THIERRY-MIEG Morgane
VAINIO Matti
VAZQUEZ RODRIGUEZ Jesus
VÄÄNÄNEN Virpi
WILK Mateusz
ZEIGER Bastian

### **RAC rapporteurs**

BORG Daniel
FACCHIN Manuel
HAKKERT Betty
VARNAI Veda

	Advisors, invited experts, observers & dossier submitters (DS)		Stakeholder observ accompanying exp
A	ABEYSINGHE Amanda as advisor to	to	BALLACH Jochen (CIRFS= Eu made Fibres Association) as (
	ARGYROPOULLOS THE Pristons as a fullet to mmitt	ee	Stakeholder for Substances in diapers
	SEAC member Socio-economic Analysis ASSMANN Mervi as advisor to Johanna KIISKI		BARBU Luminita (EDANA) as Stakeholder for Substances in
A	MULEX II. MYERE Inguint as interest		diapers and PFHxA
A	submitter for "Dechlorane Plus"™ CROMIE Ruthe (UNEP/AEWA = African-		BOCK Ronald (AGC) as a expert to PlasticsEurope for F
	Eurasian Migratory Waterbird Agreement) as invited expert for Lead		CASSART Michel (Plastics Occasional Stakeholder for S single-use diapers
	DAHLBERG PERSSON Marie as dossier submitter for "Dechlorane Plus"™		DE GRAAFF Rene (Lyonde
	DE BLAEIJ Arianne as advisor to Martien JANSSEN		accompanying expert to Plast Substances in single-use diap
	DERELIEV Sergey (UNEP/AEWA) as invited expert for Lead		DI PIETRA Marco (EU Occasional Stakeholder for Pf
	DUBOIS Céline as dossier submitter for		DUGUY Hélene (ClientEarth)
	the Substances in single-use diapers		GREEN Rhys (University of Ca accompanying expert to EEB
	ERDMANN Christian as dossier submitter for PFHxA		HANNEBAUM Peter (Johnson
	FILTVEDT Anne Line as dossier		accompanying expert to
	submitter for "Dechlorane Plus"™		PFHxA
	FIORE Karine as dossier submitter for		HÖK Frida (ChemSec)
	the Substances in single-use diapers FOTLAND Tor Øystein as dossier		JANOSI Amaya (Cefic)
	submitter for "Dechlorane Plus"™		LEONHARDT Thomas (Eurofe
	HELMHEDACH Achim as advisor to Karen		Occasional Stakeholder for PF PUUSTINEN Seppo (FACE – E
	THIELE and dossier submitter for PFHxA		Federation for Hunting and C
	HILY Emeline as advisor to Stéphane		as Occasional Stakeholder for
	JOMINI JONGENEEL Rob as advisor to Silke		RITO Elias (Fecc = European
	GABBERT		of Chemical Distributors) as ( Stakeholder
	KOPANGEN Marit as dossier submitter		ROBIN Nicolas (PlasticsEurop
	for "Dechlorane Plus"™		Occasional Stakeholder for Pl
	LANGTVET Espen as dossier submitter for "Dechlorane Plus" <sup>™</sup>		ROMANO Dolores (EEB = Eur
	LEFEVRE-BREVART Sandrine (ECHA) as		Environmental Bureau)
	dossier submitter for Lead		SALAU Amélie (ACEA = Europ Automobile Manufacturers' As
	LEINALA Eeva (OECD) as invited expert		as Occasional Stakeholder for
	LOGTMEIJER Christiaan (ECHA) as		SEBASTIANI Giuliana (AFEMS
	dossier submitter for Lead		Association of European Man
	MAZZOLINI Anna (ECHA) as dossier submitter for Lead		Sporting Ammunition) as acc
	MORO IACOPINI Sabrina as advisor to		expert to Eurometaux for Lea
	Stefano CASTELLI		THELIN Anders as expert to E Substances in single-use diag
	PETERS Oliver as advisor to Karen		THUMM Stefan (VTB and Süd
	THIELE		as expert to EURATEX for PFI
	PINEROS Juan as a future SEAC member REALE Priscilla as advisor to Luisa		VANDER STRAETEN Michel (E
	CAVALIERI		on Friday 4 June 2021
	RHEINBERGER Christoph (ECHA) as		WAETERSCHOOT Hugo (Euro YADA Makiko (Daikin Chemic
	dossier submitter for Lead		as expert to Cefic for PFHxA

#### lder observers & panying experts

n (CIRFS= European Mansociation) as Occasional Substances in single-use (EDANA) as Occasional Substances in single-use xА (AGC) as accompanying sEurope for PFHxA nel (PlasticsEurope) as eholder for Substances in ers ene (LyondellBasell) as xpert to PlasticsEurope for ngle-use diapers Marco (EURATEX) as eholder for PFHxA ClientEarth) niversity of Cambridge) as xpert to EEB for Lead ter (Johnson Controls) as expert to Eurofeu for mSec) (Cefic) omas (Eurofeu) as eholder for PFHxA po (FACE – European unting and Conservation) akeholder for Lead = European Association ributors) as Occasional PlasticsEurope) as eholder for PFHxA es(EEB = European)Bureau) ACEA = Europeanufacturers' Association) akeholder for PFHxA Iliana (AFEMS = uropean Manufacturers of nition) as accompanying etaux for Lead as expert to EDANA for ngle-use diapers VTB and Südwesttextil) RATEX for PFHxA TEN Michel (Eurometaux) e 2021 T Hugo (Eurometaux) aikin Chemical Europe)

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

Document	Number
Final Draft Agenda	SEAC/A/51/2021
Appointment of (co-)rapporteurs for authorisation	SEAC/51/2021/01
applications	(restricted room document)
Paper on SEAC'S approach to assessing changes in	SEAC/51/2021/02
producer surplus	(room document)
Update of SEAC accredited stakeholders' list	SEAC/51/2021/03
	(restricted meeting document)

## DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS

The following participants declared conflicts of interests with the agenda items below (according to Article 9(2) of the SEAC Rules of Procedure):

Name of participant	Agenda item	Interest declared	
BRIGNON Jean-Marc	5.2b-2)	Working for the MS	
	Substances in single-use	submitting the dossier	
	diapers		
JOMINI Stéphane	5.2b-2)	Working for the MSCA	
	Substances in single-use	e submitting the dossier	
	diapers		
LÜDEKE Andreas	5.2b-1)	Working for the MSCA	
	Undecafluorohexanoic	submitting the dossier	
	acid (PFHxA)		
THIELE Karen	5.2b-1)	Working for the MSCA	
	Undecafluorohexanoic	submitting the dossier	
	acid (PFHxA)		
MÅGE Marit	5.2b-3)	Working for the MSCA	
	Lead and its compounds	submitting the dossier	
	in ammunition and		
	fishing tackles		

ANNEX III

### Minority Position on CT\_SRG GLOBAL AFA by SEAC member Jean-Marc BRIGNON

### Minority Position on CT SRG GLOBAL AfA

I, the undersigned, take a minority position based following on the arguments/justifications:

The AoA and SEAC draft opinion state that, for both Uses, that there are no available alternatives before the sunset date, and SEAC also concluded that the substitution plan (up to 2027 for Use 2) is credible. These conclusions have been reached, especially for Use 2, to an important extent, on the basis that alternatives cannot deliver the performance required by all OEMs regarding the critical issue of aesthetic aspects. These aesthetic aspects are especially related to

- acceptability of color of alternative (especially Cr-III) coatings compared to Cr-VI based coatings, and stability over time of the color.
- "cool touch" feel that, as explained in the AfA, should make end consumers believe that the material used for the items is not plastic, but plain metal.

However, the applicant did not provide information (customer survey, market research,...) regarding the consequences if the performance in terms of color (either specific color difference for alternative coatings, or color stability) or touch is modified by the alternatives. Issues in terms of final customer acceptance are only claimed and not demonstrated.

Possibilities for OEMs to mitigate customer acceptance issues do not appear to have been studied. For instance, information on the technical and economic possibility for OEMs to inform consumers about risks of Cr-VI processes, about the real materials used instead of trying to "hide" their nature, and therefore contribute to a progressive acceptance over time, is not envisaged. In the same way, possibilities for OEMs to organize differently so that color discrepancies in a single car are minimized are not studied.

Regarding the issue of color change over time, the applicant quotes an "USCAR study" to justify the claim that Cr-III coatings are less stable than Cr-VI coatings. The reference of the study does not appear to be provided in the application dossier, and I was not able to find it on USCAR website or another one. However a summary appears to be available on a professional news website and provides some insights<sup>1</sup>. According to this summary, the chloride trivalent system tested by USCAR had in fact the best color stability over time, superior to hexavalent chromium, followed by the sulfate Chromium trivalent system. From the test results provided in this summary, it seems that the difference between the hexavalent and sulfate trivalent systems would rather be statistically non-

<sup>1</sup> https://www.pfonline.com/articles/summary-report-uscar-field-test-ontrivalent-chromium accessed 8th June 2021

significant. These elements are indirect and limited, but they appear to contradict to some extent the claims by the applicant.

Without more information from the applicant and analysis by SEAC on the color and touch performance issues, the SEAC Draft Opinion (DO) conclusions that there are no available alternatives and that the substitution plan is credible appear to be far more uncertain than recognized in the DO. In my view, there are also significant uncertainties regarding whether the review periods could be shorter, the credibility of non-use scenarios, and the costs of non-use.

Analysis of the consequences of a possible change in performance is warranted in REACH Annex XVI on SEA : "An SEA may include the following elements: [...] impacts of a granted or refused authorisation, [...] on consumers. For example, [...] changes in [...] performance of products, [...]". SEA Guidance document by ECHA also states that "If the supply of the Annex XIV substance stops, the downstream users might anyway switch to the alternative although it will cause drawbacks in terms of technical performance and socio-economic impact."

Changes in performance set by downstream users should not therefore be rejected as impossible as such without proper justification by applicants or their supply chains, and, when critical for the outcome, should be assessed in the SEA, and therefore in the AoA as a first step.

For all of the above, I do not agree with the SEAC DO conclusion that the substitution plan and the non-use scenarios are credible, and I raise the point that, given uncertainties, a shorter review period might have been more adequate.

8<sup>th</sup> June 2021

Jean Day Brip

Jean-Marc Brignon

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These aesthetic aspects are especially related to

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<sup>1</sup> <u>https://www.pfonline.com/articles/summarv-report-uscar-field-test-on-</u> <u>trivalent-chromium</u> accessed 8<sup>th</sup> June 2021