

12 November 2018

SEAC/M/40/2018 FINAL

Final

Minutes of the 40th meeting of the Committee for Socio-economic Analysis

11 - 13 September 2018

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 fortieth meeting of SEAC. The Chairman also informed SEAC that apologies had been received from three members.

The Chairman informed the participants that the meeting would be recorded solely for the purpose of writing the minutes and the recordings would be destroyed once no longer needed.

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-40 (SEAC/A/40/2018). The agenda was adopted without modifications. 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 informed the Committee about the specific interests expressed prior to the meeting and requested members and their advisors participating in the meeting to declare any conflicts of interest to any of the specific agenda items. The Chairman declared the absence of conflict of interest for all items of SEAC-40 plenary meeting. Six members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.1a.1, 5.1b.1 and 5.1b.2. These members did not participate in voting under those Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

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-39 action points, written procedures and update on other ECHA bodies

The Chairman informed the participants that all action points of SEAC-39 had been completed or would be followed up during the on-going SEAC-40 meeting. The Chairman also informed the Committee that the final minutes of SEAC-39 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-39 minutes.

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

b) Annual update of SEAC accredited stakeholders' list (closed session)

The Secretariat presented to SEAC the annual update of SEAC accredited stakeholders' list. The Committee agreed with the proposal by the Secretariat in line with the restricted meeting document SEAC/40/2018/02. The Chair informed that the Secretariat will publish the updated list on the ECHA website.

c) General SEAC procedures (closed session)

The Chair presented to the Committee the proposed list of nominees for appointment as co-opted members of SEAC in line with Article 85(4) of REACH. The Committee agreed on the appointment as proposed by the Secretariat (in line with the restricted room document SEAC/40/2018/02). The Chair informed SEAC that the Secretariat will proceed with the contractual arrangement of the new co-opted members.

5) Restrictions

5.1) Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Plastic and rubber granules containing PAHs

The Chairman welcomed the dossier submitter representatives from the Netherlands. He informed the participants that the restriction dossier had been submitted by the Netherlands on 20 July 2018, in cooperation with ECHA.

The representative of the dossier submitter provided an introductory presentation on the dossier. The restriction dossier focusses on granules and mulches used as infill material in synthetic turf pitches and in loose form on playgrounds and in sport applications. The basis for this dossier is a concern for human health resulting from current concentration limits for polycyclic aromatic hydrocarbons (PAHs) in End-of-Life Tyre (ELT) derived rubber infill granules used in synthetic turf pitches. The primary concern is to address risks to individuals playing and performing sports activities (e.g. football) on artificial turf pitches with rubber granules (rubber crumb) made of recycled tyres. Recent evaluations by RIVM (2017) and ECHA (2017) concluded that PAH levels found in granules on synthetic turf pitches currently in use are assessed to have a relatively low excess cancer risk. However the reports highlighted that the current concentration limits permitted in entry 28 of Annex XVII of REACH are insufficient for protecting those who come into contact with the granules and mulches while playing at sports facilities and playgrounds.

The Chairman then informed the Committee that RAC discussed the conformity of this dossier within RAC-46, and concluded that the dossier is in conformity from the RAC point of view.

The SEAC rapporteurs presented the outcome of the conformity check and the recommendations to the dossier submitter, and proposed to the Committee that they consider the dossier to be in conformity. The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteurs presented their key

issues of the restriction proposal. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 19 September 2018.

b) Opinion development

1) Substances used in tattoo inks and permanent make-up – third draft opinion

The Chairman welcomed the SEAC rapporteurs, the dossier submitter representatives present in person or via WebEx (from Denmark, Norway and ECHA) and its experts from Germany. The restriction proposal was submitted by ECHA together with Denmark, Italy and Norway on 6 October 2017. In addition, Germany contributed significantly to the proposal. The proposal aims to restrict the intentional use of certain substances in tattoo inks or to impose concentration limits for selected substances (impurities). These substances include those with harmonised classifications as carcinogenic, mutagenic, reprotoxic, skin sensitising/corrosive/irritant, eye damaging/irritant as well as other substances prohibited in cosmetic products (under the Cosmetic Products Regulation, (EC) 1223/2009) and selected impurities. The (co-)rapporteurs had developed the third draft opinion on this dossier, taking into account the discussion held at SEAC-39 and the results of the public consultation (that ended on 20 June 2018 with 27 submissions received), which was made available for written consultation prior to SEAC-40 and comments were received from four SEAC members. The rapporteurs had updated the third draft opinion (following the comments by the members) and the updated version had been made available to SEAC on 31 August 2018.

The Secretariat gave a short update from RAC-46 discussions, where RAC had not yet adopted its opinion. RAC had agreed that the only way to manage risks from chemicals in tattoo inks is to limit their concentration. In addition, RAC agreed that there is a justification that action is required on an EU wide measure to harmonise the level of protection across the EU, and to decrease non-compliance. More specifically, RAC supported a dynamic link with the CPR. RAC did not support to derogate 19 colorants as proposed by dossier submitter. However, RAC did not manage to agree on a number of additional metal impurities and a proposed derogation for two key colourants, where further information was requested to be elaborated by the rapporteurs.

The SEAC rapporteurs then presented the third draft opinion, taking into account the discussions held in SEAC-39 and the comments provided during the public consultation. SEAC supported the conclusions of the rapporteurs that the proposed restriction is practical (implementable, manageable, and enforceable). There were no compelling socio-economic arguments favouring either RO1 or RO2, however SEAC members showed preference for concentration limits introduced by RAC due to feasibility arguments (pending on consultation on SEAC draft final opinion). One of the representatives of the Commission asked for more elaborated assessment of each impact element for all three ROs and requested that a summary table of all impacts for each of the ROs (RO1, RO2 or RO as modified by RAC) is included in the opinion. Furthermore, SEAC concluded that the proposed restriction is monitorable. SEAC discussed static vs dynamic link with the CPR and concluded that the advantages and disadvantages of both options need to be outlined in the draft opinion. SEAC considered

that there were no clear socio-economic arguments supporting any specific transitional period, but flagged in conclusion uncertainty with development of analytical methods. SEAC discussed the proposed derogation by the dossier submitter on pigment blue 15:3 and pigment green 7. The need for derogation is to be discussed again at the next plenary meeting when RAC's conclusion on risk is available. Regarding the other 19 pigments proposed to be derogated by the dossier submitter, SEAC agreed with RAC's conclusions that these should not be derogated.

The Chairman concluded that due to the continuing work on the RAC opinion, SEAC was not ready to agree the draft opinion in SEAC-40. The rapporteurs were requested to take the discussion of SEAC-40 into account in the revised SEAC opinion. After SEAC-40, a written SEAC consultation round will be started on the further revised draft opinion. The Committee is expected to agree on the draft opinion in November 2018 and to adopt its final opinion in March 2019.

2) C9-C14 PFCAs, their salts and related substances – third draft opinion

The Chair welcomed the dossier submitters' representatives from Germany and Sweden (following via WebEx) and the RAC rapporteurs. The Chairman reminded the participants that the restriction dossier proposes to restrict the use, placing on the market and import of C9-C14 PFCAs, on their own or in a mixture or in an article or parts therein in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA related substances. The (co-)rapporteurs had developed the third draft opinion on this dossier, taking into account the discussion held at SEAC-39 and the result of the public consultation (that ended on 20 June 2018 with 27 submissions from 17 stakeholders received), which was made available for written consultation prior to SEAC-40 and comments were received from two SEAC members. The rapporteurs had updated the third draft opinion (following the comments by the members) and the updated version had been made available to SEAC on 5 September 2018.

The Secretariat provided a brief report from the RAC discussions on the PFCAs dossier held within the ongoing RAC-46, where RAC had adopted its opinion on this restriction proposal.

The (co-)rapporteurs then presented to the Committee the updated third draft opinion, indicating that the discussion at this plenary should focus on the scope of the restriction, in particular on derogations. They reminded the Committee that the derogations for short-chain (\leq C6) fluorotelomers, 'second-hand' market and products in the supply chain were included in the proposal by the dossier submitter and proposed to SEAC to agree with these. The rapporteurs explained that several additional derogation requests had been received within the public consultation. With regard to semiconductors, they proposed to SEAC that, taking into account the very limited quantities made available on the EU market, SEAC could consider the time limited derogation requested for this sector acceptable. In relation to fluoropolymers, the rapporteurs found the evidence presented in the public consultation insufficient and thus proposed not to accept this additional derogation request. With regard to pressurised metered-dose inhalers, the rapporteurs proposed to accept the requested derogation because of the low volumes (few grams) involved and the important medical use. Furthermore, the rapporteurs proposed to derogate the same uses as covered by the PFOA restriction with the same time-limits and conditions. The rapporteurs continued with presenting the updates to the socio-

economic analysis and recommended to the Committee that the restriction can be considered proportional. Furthermore, the proposed restriction can be considered implementable, enforceable and manageable.

Several members asked for clarifications with regard to not accepting the derogation for fluoropolymer manufacturing. The rapporteurs highlighted that the company concerned had asked both time-limited derogation as well as higher limit value, without providing sufficient information to support their request. The company concerned can come back with further evidence during the public consultation on the SEAC draft opinion.

SEAC agreed on its draft opinion on the restriction proposal on PFCAs by consensus. The (co-)rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the agreed SEAC draft opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the public consultation) is in line with the agreed SEAC draft opinion. The Chair informed the Committee that the Secretariat will launch a public consultation on the SEAC draft opinion on 19 September and SEAC is expected to adopt its final opinion on this dossier at SEAC-41 in November 2018.

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

The Chairman informed the Committee regarding the upcoming restriction proposals that had been included in the Registry of Intentions (RoI). In January 2019, ECHA on request of the Commission, will be submitting five restriction proposals on D4/D5/D6; calcium cyanamide as a fertiliser; formaldehyde and formaldehyde releases in mixtures and articles for consumer uses; intentional use of microplastic particles in consumer/professional use products and on oxo-degradable plastics in various products for consumer and professional use. In addition, France together with Sweden will submit a restriction proposal on substances meeting the classification criteria as skin sensitizers and skin irritants (expected submission January 2019).

The Chairman reminded that the calls for expression of interest for January dossiers are ongoing and invited interested SEAC members to volunteer by 26 October 2018.

6) Authorisations

6.1) General authorisation issues

a) Update on incoming/future applications

The Secretariat informed the Committee that one new review report was received during the August 2018 submission window. It is the review report on the use of trichloroethylene (TCE) as an extraction solvent in caprolactam production. Key issues in the new review report will be discussed at SEAC-41 plenary meeting in November 2018.

The Secretariat also informed that six new applications for authorisation are expected to be received during the November 2018 submission window. The Secretariat noted high increase in number of applications for authorisation to be received during 2019.

6.2) Authorisation applications

a) Discussion on key issues

- 1. CT_Mahle (1use)**
- 2. CT_Doosan (1 use)**

The Chairman introduced the applications for authorisation. At this plenary meeting the Secretariat presented the identified key issues in the applications for authorisation.

The Secretariat in cooperation with the SEAC rapporteurs provided general information regarding these new applications. In the presentations of the cases, the Secretariat outlined the key issues identified by the rapporteurs and asked the Committee for comments and further suggestions.

The Committee noted those key issues. SEAC will request further clarifications from the applicants on the issues identified and discussed by the rapporteurs and the Secretariat. The SEAC rapporteurs will draft the opinions on the applications for authorisation for discussion and agreement at the next SEAC plenary meeting in November 2018.

b) Adoption of final opinions

- 1. DtC_Wesco (1use)**
- 2. SC_Wesco (1 use)**
- 3. PCO_Aviail (2 uses)**
- 4. CT_Hapoc (2 uses)**

The Chairman introduced these applications for authorisation. At the SEAC-37 plenary meeting the Committee had agreed on the draft opinions. The draft opinions were sent to the applicants, who commented on the draft opinions. The rapporteurs updated the draft opinions based on the comments from the applicants. The most substantial change was to remove a condition specifying that the authorisation would apply only for corrosion protection purposes in the two applications by Wesco. Regarding CT_Hapoc, and in view of the broad scope, one of the representatives of the Commission requested that the key functionalities of the substance for the use applied for as relevant for the analysis of alternatives are specified in the opinion. Other changes in the opinions were mostly of an editorial nature.

The SEAC rapporteurs presented the draft SEAC final opinions. Members supported the changes made by the rapporteurs. The final opinions were subsequently adopted by consensus. The opinions will be sent to the applicants, the European Commission and the Member States. The Chairman thanked the rapporteurs for their work on the applications.

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/40/2018/03, was agreed by SEAC.

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

a) Request to review a derogation request for the PFOA restriction (entry 68 of Annex XVII to REACH)

The Chair reminded the Committee that the Commission had received a request for re-examination of the existing restriction of PFOA and related substances (entry 68 of Annex XVII to REACH) in view of including a derogation for the use of PFOB (containing PFOI as an impurity) for the manufacturing of pressurised metered-dose inhalers for the treatment of pulmonary diseases. RAC and SEAC were requested to prepare an opinion in view of a possible derogation from the existing Annex XVII restriction of PFOA, its salts and the related substances, by 1 December 2018.

The Secretariat provided a brief report from the RAC discussions on the Article 77 (3)(c) request held within the ongoing RAC-46, where RAC had adopted its opinion on this request.

The rapporteur then presented to the Committee the draft opinion that responds to the mandate. She recommended SEAC to consider this additional derogation justified. Furthermore, the rapporteur suggested not to set any time limit for this derogation, as the minimisation of risk has been demonstrated (confirmed by RAC), released volumes are low and it is consistent with earlier derogations with minimisation of risks.

One stakeholder observer pointed out that if there is no time limit set for such derogation, innovation is not encouraged. The rapporteur explained that it is always possible to review any restriction at any point of time in the future.

The Committee adopted its opinion on this Article 77(3)(c) request by consensus. The rapporteur was requested, together with the Secretariat, to make the final editorial changes to the adopted SEAC opinion. The Chair thanked the rapporteur and the ECHA team for their work on this case.

8) AOB

a) Update of the work plan

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

b) Report from the Forum project on restrictions

The Secretariat provided to the Committee a presentation of the results of the Forum project on restrictions. The Secretariat informed SEAC that a new project on restrictions is foreseen for the near future and that SEAC could be provided with the results of this new project as well.

c) Study for the development of an evidence-based approach as support to regulators when assessing how to manage the presence of substances of

concern in recycled materials (presentation of RIVM of the project and initials results)

A representative from RIVM provided an update from an ongoing, joint RIVM and Ramboll study commissioned by the European Commission.

d) Overview of upcoming restrictions (closed session)

The Secretariat provided to SEAC more details concerning the many upcoming restriction proposals, with a view to find suitable (co-)rapporteurs.

e) Economic surplus losses in non-use scenarios

The Secretariat presented a room document SEAC/40/2018/04 containing a draft note on the valuation of economic impacts on firms in authorisation non-use scenarios. The purpose of the draft note was to consider what a more specific estimation methodology might look like, in the hope of improving consistency across applications and opinions. The focus initially was on closure and relocation non-use scenarios, but principles for valuing firm impacts more generally were drawn where possible and appropriate.

During the discussion the SEAC members who took the floor acknowledged the high quality of the document. They also suggested further considerations and improvements to the draft note. Representatives of the stakeholder observer organisations who contributed to the discussion also noted the good quality of the document and made proposals for the next version.

The Committee agreed that the Secretariat will launch a two-week consultation on the draft note for the SEAC members and the observers from the stakeholder organisations. The Secretariat will update the paper based on SEAC comments for possible agreement at SEAC-41 plenary meeting.

f) Efficiency in SEAC consultations

The Secretariat initiated discussion on activity of SEAC members in committees' consultations and proposed improvement in this area. During discussion members pointed that the main reason of low activity in commenting is workload related to rapporteurs' tasks and workload not directly related to SEAC. Looking at possible improvements members asked to consider in the development of IT tools possibility to provide comments directly in a document submitted for consultations.

9) Action points and main conclusions of SEAC-40

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

II. Main conclusions and action points

SEAC-40, 11 - 13 September 2018
(Adopted at SEAC-40 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 no modifications.	SECR to upload the adopted agenda to SEAC S-CIRCABC IG as part of the meeting minutes.
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	
<i>a) Report on SEAC-39 action points, written procedures and update on other ECHA bodies</i>	
SEAC was informed on the status of the action points of SEAC-39. 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 in the CARACAL.	
<i>b) Annual update of SEAC accredited stakeholders' list (closed session)</i>	
SEAC agreed on the annual update of SEAC accredited stakeholders' list (restricted meeting document SEAC/40/2018/01).	SECR to publish the updated list on ECHA website.
<i>c) General SEAC procedures (closed session)</i>	
SEAC agreed on the appointment of the co-opted members as proposed by the Secretariat (restricted room document SEAC/40/2018/02).	SECR to proceed with the contractual appointment of the new co-opted members.
5.1 Restriction Annex XV dossiers	
a) Conformity check and key issues discussion	
1. Plastic and rubber granulates containing PAHs	

SEAC agreed that the dossier conforms to the Annex XV requirements. SEAC took note of the recommendations to the dossier submitter.	SECR to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG. SECR to inform the dossier submitter on the outcome of the conformity check.
b) Opinion development	
1. Substances used in tattoo inks and permanent make-up – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the revised draft opinion.	Rapporteurs to update the draft opinion in line with SEAC-40 discussion, for agreement at SEAC-41.
2. C9-C14 PFCAs, their salts and related substances – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the revised third draft opinion. SEAC agreed on the draft opinion by consensus (with modifications agreed at SEAC-40).	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 in September 2018.
5.2 Appointment of (co-)rapporteurs for restriction dossiers	
SEAC was updated on the upcoming restriction proposals to be submitted in January 2019.	SEAC Members to volunteer for six restriction proposals by 26 October 2018.
6. Authorisation	
6.1 General authorisation issues	
a) Update on incoming/future applications	
SEAC took note of the update on the incoming/future applications.	
6.2 Authorisation applications	
a) Discussion on key issues	
1. CT_Mahle (1 use) 2. CT_Doosan (1 use)	
SECR presented the key issues in the applications	Rapporteurs to prepare the draft opinions for

for authorisation.	discussion and agreement at SEAC-41 plenary meeting in November 2018.
b) Adoption on final opinions	
1. DtC_Wesco (1 use) 2. SC_Wesco (1 use) 3. PCO_Aviail (2uses) 4. CT_Hapoc (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinions. SEAC adopted its final opinions on these applications for authorisation by consensus.	Rapporteurs together with SECR to do the final editing of the adopted opinions. SECR to send the final opinions to COM, MSs and the Applicants.
6.4 Appointment of (co-)rapporteurs for authorisation applications (closed session)	
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/40/2018/03).	SEAC members to volunteer to the pool of (co-) rapporteurs for applications for authorisation. SECR to upload the updated document to confidential folder on S-CIRCABC IG.
7. Requests under Article 77(3)(c)	
a) the PFOA restriction	Request to review a derogation request for
SEAC rapporteur presented and SEAC discussed the revised draft opinion. SEAC adopted its opinion on this Article 77(3)(c) request by consensus.	Rapporteur together with SECR to make the final editorial changes to the adopted SEAC opinion. SECR to forward the adopted RAC and SEAC opinions to COM and publish on ECHA website.
8.e AOB: Economic surplus losses in non-use scenarios	
SECR presented the discussion paper on Economic surplus losses in non-use scenarios.	SECR to organise a written commenting round in SEAC on the discussion paper after SEAC-40. SECR to update the paper based on SEAC comments for possible agreement at SEAC-41.
9. Action points and main conclusions of SEAC-40	
SEAC adopted the action points and main conclusions of SEAC-40.	SECR to upload the action points and main conclusions to S-CIRCABC IG.

III. List of Attendees

SEAC-40

SEAC members
ALEXANDRE Joao
ANASTASIOU Christos
BERGS Ivars
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
DELCOURT Benjamin
DOMINIAK Dorota
DOUGHERTY Gary
FANKHAUSER Simone
FIORE Karine
FOCK Lars
GEORGIOU Stavros
JANSSEN Martien
KAJIC Silva
KIISKI Johanna
KNOFLACH Georg
KRAJNC Karmen
LUIT Richard
LÜDEKE Andreas
NARROS SIERRA Adolfo
NICOLAIDES Leandros
NORING Maria
RUZGYS Karolis
SCHUCHTAR Endre
STOYANOVA VELINOVA Elina
THIELE Karen
URBAN Klaus
ZAMFIR Adrian-Stefan
Commission observers
BENGYUZOV Manol (DG GROW)
GALLEGO Matteo (DG ENV)
Stakeholder observers & accompanying experts
HAIDER Sonja (CHEMSEC)
JAMIESON Matthew (Astrazeneca – expert accompanying EFPIA for the discussion on a derogation request for PFOA)
JÁNOSI Amaya (CEFIC)

Advisors, invited experts, observers & dossier submitters (DS)
ANDERSSON Wiktor as advisor to Maria NORING via WebEx
AVERBECK Frauke as DS for PFCAs via WebEx
BERNHEIM Teresa as advisor to Karen THIELE
DE BLAEIJ Arianne as advisor to Richard LUIT
FURLAN Janez as co-rapporteur for CT HAPOC via WebEx
HELMEDACH Achim as advisor to Karen THIELE
JANS Jenny as advisor to Maria NORING
JONGENEEL Rob as advisor to Richard LUIT via WebEx
LAMARCA Victoire as advisor to Karine FIORE via WebEx
LERCHE Dorte as advisor to Lars FOCK
LINDQVIST Martin as DS for PFCAs via WebEx
OYSTEIN FOTLAND Tor as DS for tattoo inks via WebEx
STAUDE Claudia as DS for PFCAs via WebEx

Stakeholder observers & accompanying experts (cont.)
PEREZ Laia (European Tyre and Rubber Manufacturers' Association – expert accompanying CEFIC for discussion on Plastic and rubber granulates)
REID Kirsty (EFPIA – European Federation of Pharmaceutical Industries and Associations) - SEAC occasional observer for the discussion on a derogation request for PFOA
ROGER Apolline (ClientEarth)
TEN BRINK Patrick (EEB)
WAETERSCHOOT Hugo (EUROMETAUX)
YADA Makiko (Daikin Chemical Europe GmbH – expert accompanying CEFIC for discussion on a derogation request for PFOA)
RAC rapporteurs
DUNAUŠKIENE Lina
KADIKIS Normunds
PARIS Pietro

ECHA STAFF
BLAINEY Mark
CALVO-TOLEDO Juan Pablo
GHAZANFARI Sara
GMEINDER Michael
HOLLINS Stephen
KIVELA Kalle
JACQUEMIN Katline
KOSK-BIENKO Joanna
LOGTMEIJER Christiaan
LUDBORZS Arnis
MARQUEZ-CAMACHO Mercedes
MOTTET Denis
MUSHTAQ Fesil
NICOT Thierry
ORISPÄÄ Katja
OTTATI Maria
PILLET Monique
RHEINBERGER Christoph
ROGGEMAN Maarten
SADAM Diana
SIMPSON Peter
SJOBORG Thomas
SOSNOWSKI Piotr
STOYANOVA Evgenia
ÖBERG Tomas

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/40/2018
Annual update of SEAC accredited stakeholders' list (closed session)	SEAC/40/2018/01 (restricted)
General SEAC procedures (closed session)	SEAC/40/2018/02
Appointment of (co-)rapporteurs for authorisation applications (closed session)	SEAC/40/2018/03 (restricted)
Economic surplus losses in non-use scenarios	SEAC/40/2018/04

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>
LUDEKE Andreas	5.1b.1 Substances used in tattoo inks and permanent make-up 5.1b.2 C9-C14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossiers
LUIT Richard	5.1a.1 Plastic and rubber granulates containing PAHs	Participation in the preparation of the restriction dossier
FOCK Lars	5.1b.1 Substances used in tattoo inks and permanent make-up	Participation in the preparation of the restriction dossier
NORING Maria	5.1b.2 C9-C14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossier
JANSSEN Martien	5.1a.1 Plastic and rubber granulates containing PAHs	Participation in the preparation of the restriction dossier
THIELE Karen	5.1b.2 C9-C14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossier

Final Draft Agenda

40th meeting of the Committee for Socio-economic Analysis

11-13 September 2018

ECHA Conference Centre (Annankatu 18, Helsinki)

11 September starts at 13.00

13 September ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/40/2018
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Report from other ECHA bodies and activities

- a) Report on SEAC-39 action points, written procedures and update on other ECHA bodies

For information

- b) Annual update of SEAC accredited stakeholders' list (closed session)

SEAC/40/2018/01

(restricted meeting document)

For agreement

- c) General SEAC procedures (closed session)

SEAC/40/2018/02

(restricted room document)

For agreement

Item 5 – Restrictions

5.1 Restriction Annex XV dossiers

- a) Conformity check and key issues discussion
 - 1) Plastic and rubber granulates containing PAHs

For agreement

- b) Opinion development

- 1) Substances used in tattoo inks and permanent make-up – third draft opinion
 - 2) C9-C14 PFCAs, their salts and related substances – third draft opinion

For discussion and agreement

5.2 Appointment of (co-)rapporteurs for restriction dossiers

For information

Item 6 – Authorisation

6.1 General authorisation issues

- a) Update on incoming/future applications

For information

6.2 Authorisation applications

- a) Discussion on key issues

- 1. CT_Mahle (1 use)
 - 2. CT_Doosan (1 use)

For discussion

- c) Adoption of final opinions

- 1. DtC_Wesco (1 use)
 - 2. SC_Wesco (1 use)
 - 3. PCO_Aviall (2 uses)
 - 4. CT_Hapoc (2 uses)

For discussion and adoption

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

**SEAC/40/2018/03
(restricted room document)
For agreement**

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

- a) Request to review a derogation request for the PFOA restriction (entry 68 of Annex XVII to REACH) – draft opinion

For discussion and adoption

Item 8 – AOB

- a) Update of the work plan
- b) Report from the Forum project on restrictions
- c) Study for the development of an evidence-based approach as support to regulators when assessing how to manage the presence of substances of concern in recycled materials (presentation by RIVM of the project and initial results)
- d) Overview of upcoming restrictions (closed session)
- e) Economic surplus losses in non-use scenarios
- f) Efficiency in SEAC consultations

For information

**SEAC/40/2018/04
(room document)
For discussion**

For discussion

Item 9 – Action points and main conclusions of SEAC-40

Table with Conclusions and Action points from SEAC-40

For adoption