

29 January 2019

SEAC/M/41/2018 FINAL

**Final**

**Minutes of the 41<sup>st</sup> meeting of the Committee for Socio-economic Analysis**

**27-29 November 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 41<sup>st</sup> meeting of SEAC. The Chairman also informed SEAC that apologies had been received from two members.

The Chairman informed the participants that the meeting would 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-41 (SEAC/A/41/2018). 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 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-41 plenary meeting. Eight members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2a.1, 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 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-40 action points, written procedures and update on other ECHA bodies**

The Chairman informed the participants that all action points of SEAC-40 had been completed or would be followed up during the on-going SEAC-41 meeting. He added that the discussion paper on Economic surplus losses in non-use scenarios (that had been presented to SEAC for the first discussion at the previous SEAC plenary and the update to which the Secretariat had planned to present for possible agreement at this meeting) had been postponed until 2019 due to other priorities.

The Chairman also informed the Committee that the final minutes of SEAC-40 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-40 minutes. Furthermore, the Chairman informed the Committee that ECHA had received and responded to a complaint regarding the selection procedure for co-opted members. Additionally, the updated list of stakeholder observers regarded as observers of SEAC had been agreed by written procedure and published on the ECHA website.

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

## **5) Restrictions**

### **5.1) General restriction issues**

#### **a) Update of the work of the Restriction Task Force (RTF)**

The Secretariat provided an update on the Restriction Task Force which will start up again following the REACH review recommendations and action points (specifically 8, 9, 10 and 11). There will be meetings arranged for RTF members on 18 December 2018 (via WebEx) and on 24 January 2019. Additional meetings will also be scheduled. Further work will be reported back to RAC, SEAC and CARACAL as the discussions continue.

### **5.2) Restriction Annex XV dossiers**

#### **a) Conformity check and key issues discussion**

The Chairman introduced the REACH Restrictions part of the agenda with a presentation on the background and legal requirements for conformity checks, informing SEAC that a simpler and more effective approach is required to assessing and agreeing the conformity of incoming restriction dossiers. The Commission has requested ECHA to prepare a large group of restrictions in 2019 and 2020. In the Restriction Task Force (2015) and since then, Member States made clear that the bar for preparing a restriction in an efficient manner has been set too high. To meet this challenge, RAC and SEAC will need to review their approach to the evaluation of restriction dossiers and conformity is one key aspect of this.

He informed that the RTF (Commission, ECHA, Member States and Committee representatives) had confirmed that conformity should be limited to a check of the legal requirements, i.e. whether the components defined by Annex XV are present or not and that this should be separated from the later evaluation of the dossier. A restriction should be built with the contents of the relevant registration dossiers at its core. Should information in the registration dossiers be missing or deemed inadequate, and has not been supplemented during the dossier development, the public consultation is the place to request this. In turn, should the public consultation not fill the gaps seen as critical to the restriction, then the preferred course of action is to: "*ensure that ...[RAC/SEAC] opinions indicate when scientific data do not permit a complete evaluation....*". RAC and SEAC outline the role and importance of the missing information, describing clearly the uncertainties that this creates. They then describe the steps considered necessary to recover/generate that information and suggest a timeline. They advise the Commission accordingly, allowing the latter to apply the precautionary principle as appropriate. The

Chairman concluded that this uses REACH as it was intended and could greatly shorten the time taken to agree a restriction.

Several members expressed the view that the legal requirements are not very specific and that for SEAC it is important that the dossier provides useful information that serves the purpose. One member added that it is important to remember that considering the dossier not in conformity is not stopping the process, but should rather be seen as a possibility to improve the dossier, so that the input received in the public consultation could be more specific. A stakeholder observer also stressed the need to have a proper debate in the Committee at the stage of the conformity check – in order to pose the right questions in the public consultation.

### **1) N,N-dimethylformamide**

The Chairman welcomed the dossier submitter representatives from Italy. He informed the participants that the restriction dossier had been submitted by Italy on 5 October 2018.

The representative of the dossier submitter provided an introductory presentation on the dossier. The proposed restriction aims to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3 %. The substance is used as an intermediate and for the following uses: scientific research and development (including laboratory use) and for the manufacture of chemicals, machinery and vehicles. The dossier submitter proposes a harmonised Derived No Effect Level (DNEL) value for long-term inhalation exposure of 3.2 mg/m<sup>3</sup> and a harmonised DNEL for long-term dermal exposure of 0.79 mg/kg bw/day for use in chemical safety assessments and in safety data sheets.

The SEAC members made comments on the scope of the restriction proposal and completeness of the information in the Annex XV restriction dossier.

The rapporteur then presented the outcome of the conformity check and the recommendations to the dossier submitter, and proposed to the Committee that he considers the dossier to be in conformity.

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteur presented his key issues of the restriction proposal. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 19 December 2018.

### **2) Five cobalt salts**

The Chairman welcomed the dossier submitter representatives from ECHA and two industry experts, accompanying the regular stakeholder observers. He informed the participants that the restriction dossier had been submitted in October 2018 and is intended to restrict the placing on the market, manufacture and use of the cobalt salts as substances on their own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications. The five cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)) are manufactured and used in a variety of sectors within the European Economic Area, including the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. The

cobalt salts are classified as Carc. 1B (inhalation), Muta. 2, Repr. 1B and skin and respiratory sensitisers.

The representative of the dossier submitter provided an introductory presentation on the dossier. The Chairman then informed the Committee that RAC had discussed the conformity of this dossier within RAC-47 last week and that the proposal was considered in conformity from the RAC point of view.

The (co-)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. Several SEAC members supported the views of the (co-)rapporteurs. One stakeholder observer pointed out that in his view, this dossier is lacking transparency on how the dossier submitter has arrived to certain conclusions. Furthermore, the analysis of the other RMOs seem to be limited and the proportionality assessment is not based on the classical cost-benefit analysis. The rapporteurs responded that these are indeed the critical points in the dossier, but they do not see these as conformity issues, but will consider them in the further evaluation of the dossier within the opinion development.

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the (co-)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 December 2018.

## **b) Opinion development**

### **1) C9-C14 PFCAs, their salts and related substances – draft of final opinion**

The Chairman welcomed the dossier submitters' representatives from Germany (following via WebEx), the RAC rapporteurs and two industry experts, accompanying the regular stakeholder observers. 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 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 public consultation on the agreed SEAC draft opinion ended on 19 November with 15 comments received. The (co-) rapporteurs updated the opinion based on the comments received and the draft of the SEAC final opinion (together with the ORCOM) was made available to SEAC on 23 November.

The (co-)rapporteurs were then invited to present the results of the public consultation and their impact on the SEAC opinion. Based on the information provided by 3M, the rapporteurs considered a derogation for a higher limit value justified. However, they proposed to limit it only to the relevant fluoropolymer groups and that the generic threshold of 25 ppb should be applied to articles manufactured from these materials, as the final articles already comply with that threshold. The concentration limit shall be 2000 ppb for the sum of C9-C14 PFCAs in fluoropolymers that contain perfluoropropoxy-groups or perfluoromethoxy-groups and are used in the following products groups: PTFE fine powders, fluoroelastomers and aqueous dispersions until 36 months after the entry into force. Thereafter, the concentration limit shall be 400 ppb for the sum of C9-C14 PFCAs.

One SEAC member pointed out that the SEAC conclusions on enforceability of this restriction proposal seem not to be in line with the Forum advice, which had considered

this restriction proposal not enforceable. The rapporteurs responded that for the Forum the main problem was the lack of the available analytical methods, but they reminded the Committee that these are currently under development. The Secretariat added that also for the PFOA and the Lead in consumer articles restriction dossiers, the SEAC final opinions were adopted without having a harmonised analytical method developed. Also two industry experts emphasised the challenges in analytical testing. However, they also recognised that the work to develop suitable analytical methods is ongoing also from their side for both PFOA and the current restrictions. The rapporteurs received several editorial suggestions for both the proposed entry as well as the justification part of the opinion.

SEAC adopted the final opinion by consensus. The rapporteurs were asked, together with the Secretariat, to make final editorial changes to the opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC opinion. The Secretariat will forward the adopted opinion and its supporting documents to the Commission as well as publish on the ECHA website. The Chairman thanked the rapporteurs for their work on this dossier.

## **2) Substances used in tattoo inks and permanent make-up – revised draft opinion**

The Chairman welcomed the SEAC rapporteurs, the dossier submitter representatives present in person or via WebEx (from Denmark, Norway and ECHA) and their experts from Germany. The restriction proposal was submitted by ECHA together with Denmark, Italy and Norway in October 2017. In addition, Germany contributed significantly to the proposal. The proposal aims to restrict the intentional use of certain substances in tattoo inks by imposing concentration limits. 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 (CPR), (EC) 1223/2009) and selected impurities. The (co-)rapporteurs had developed the fourth draft opinion on this dossier, taking into account the discussion held at SEAC-40. The draft opinion was made available for written consultation prior to SEAC-41 and comments were received from eight SEAC members. The rapporteurs incorporated these comments and the updated version had been made available to SEAC on 16 November 2018.

The RAC rapporteur gave a short update from RAC-47 discussions, where RAC had adopted its opinion. At its meeting, RAC agreed the remaining concentration limits for all substances in the scope. However, RAC could not conclude on a proposed derogation on two colourants (Pigment Green 7 and Pigment Blue 15:3) due to uncertainties stemming from the limited available information on hazards and risks and their potential alternatives (as well as on the technical feasibility for some alternatives). Furthermore, RAC supported a transitional period of one year and the requirement for tattoo artists/practitioners to ensure that non-compliant inks are not used for tattooing procedures. In addition, RAC supported clear definitions of tattoo and permanent make-up practices, which are a prerequisite for enforcement. RAC also agreed that the proposed restriction is effective in reducing the identified risk as technically feasible and less hazardous alternatives are likely to be available, despite stated uncertainties. Lastly, RAC agreed that the proposed restriction is implementable, enforceable, manageable and monitorable.

The SEAC rapporteurs then presented the revised fourth draft opinion. SEAC rapporteurs presented and SEAC supported the concentration limits modified by RAC. Further information on the concentration limits will be requested during the public consultation on the SEAC draft opinion.

Regarding the derogating Pigment Green 7 and Pigment Blue 15:3, SEAC rapporteurs noted the information received during on the public consultation from industry on the lack of technically feasible alternatives for these pigments. However, taking into account RAC's conclusions, SEAC concluded to ask industry to provide additional information during the public consultation on the SEAC draft opinion to further evaluate the need for such a derogation on socio-economic grounds.

In addition, SEAC supported labelling requirements and showed slight preference for a static link with CPR Annex II and IV. SEAC supported the one year transitional period as reasonable timeframe to implement the restriction, although SEAC discussed arguments both for shorter and longer transitional period compared to the one year proposed by dossier submitter.

Furthermore, SEAC members supported rapporteurs' proposals for editorial revisions on benefits and proportionality conclusions.

The representatives from the European Commission asked for further elaboration on the comparison between the restriction options, as well as a comparison of the socio-economic impacts between static and dynamic links with the CPR and CLP. They also requested further elaboration on the assessment of the two pigments blue and green proposed for a derogation.

While discussing enforcement costs, one SEAC member stated his disagreement with the use of fixed budget approach and its application in all restriction dossiers that SEAC provides opinion on. The Secretariat clarified that work on this issue was planned with the assistance of the disagreeing member.

SEAC agreed on its draft opinion on the restriction proposal on tattoo inks 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 Chairman informed the Committee that the Secretariat will launch a public consultation on the SEAC draft opinion on 12 December and SEAC is expected to adopt its final opinion on this dossier at SEAC-42 in March 2019.

### **3) PAHs in granules and mulches used as infill material – first draft opinion**

The Chairman welcomed the Dossier Submitter representatives from the Netherlands (present both in person and via WebEx). He informed the participants that the restriction dossier had been submitted by the Netherlands on 20 July 2018, in cooperation with ECHA. 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 Tyres (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 (co-)rapporteurs had developed the first draft opinion on this dossier, which was made available to SEAC on 19 November 2018. There was no written consultation prior to SEAC-41 but three comments were received from SEAC members on the Annex XV dossier.

The RAC rapporteurs provided a brief update from the RAC discussion on this dossier held within RAC-47, where RAC agreed that a restriction under REACH with a concentration limit of 20 mg/kg is the most appropriate EU wide measure, noting the uncertainty on the end of waste status of the granules and mulches.

The SEAC rapporteurs then presented the first draft opinion. They outlined the main scope of the restriction proposal and concluded that a restriction under REACH is an appropriate EU wide measure. With regard to costs, the SEAC rapporteurs considered the estimated tonnages of ELT-derived infill in the baseline scenario as well founded and plausible. Furthermore, the rapporteurs considered the economic impact related to RO1 as plausible based on the evidence provided. On the other hand, the rapporteurs identified a number of uncertainties around the economic impact associated with RO2 as it is based on an extreme scenario which would benefit from further evidence.

SEAC members discussed a number of issues, including the potential need for assessing the economic impact of a limit value in between RO1 (17 mg/kg) and RO2 (6.5 mg/kg) and the economic impact of the limit value agreed by RAC (20 mg/kg). It was noted by the rapporteurs that the cost estimate for the 17 mg/kg limit value could be used as an upper bound. SEAC also noted that the lower concentration limit proposed by RO2 would lead to more tyres being incinerated, hence causing emissions. SEAC reminded itself not to assess acceptable risk levels but rather to assess what has been proposed by the dossier submitter. In the discussion on other risk management options it was noted that RMO6 (limiting PAHs in carbon black) and RMO7 (further limiting PAHs in extender oils) would only have limited effectiveness as these would be too slow to show (limited) results. SEAC also noted uncertainties on the effectiveness of the proposed measure due to the lack of harmonised end of waste criteria.

In addition, a stakeholder observer representative pointed out that exposure of children under the age of two has not been addressed in the dossier and there was evidence of granules being used in Crèche play areas in Belgium.

The Committee supported the conclusions of the (co-)rapporteurs as presented. It was agreed that the Secretariat will launch a written commenting round for members to provide remaining comments on the first draft opinion. The rapporteurs were requested to prepare the second draft opinion, taking into account the discussions in SEAC-41, by beginning of February 2019.

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

The Secretariat presented the pools of (co-)rapporteurs for six restriction dossiers expected to be submitted in January 2019 (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, skin sensitizers and skin irritants).

SEAC agreed on the pools of (co-)rapporteurs for the upcoming restriction proposals to be submitted in January 2019 (in line with the restricted meeting document SEAC/41/2018/01). SEAC members were still encouraged to volunteer for the pool of (co-) rapporteurs for skin sensitisers in textiles.

Furthermore, the Chairman informed the Committee regarding the upcoming restriction proposals that had been included in the Registry of Intentions (RoI). The Chairman reminded that the calls for expression of interest for upcoming dossiers will be launched early 2019 and encouraged members to volunteer.

## **6) Authorisations**

### **6.1) General authorisation issues**

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

The Secretariat informed the Committee that five new applications for authorisation were received during the November 2018 submission window. Four of them are on uses of chromium trioxide for sanitary sector products. The fifth new application is for the use of chromium trioxide for passivation and coating of tin-plated steel. Key issues in the new applications for authorisation will be discussed at RAC-48 plenary meeting in March 2019.

The Secretariat also informed about high numbers of applications for authorisation expected to be received during 2019 and the beginning of 2020 amounting to ca. 120 applications for authorisation on more than 200 uses of chromium (VI) substances, octyl- and nonylphenol ethoxylates, coal tar pitch, high temperature, and trichloroethylene.

#### **b) Report from the workshop with the Commission on authorisation (15-16 November 2018)**

The Secretariat informed the Committee that an ECHA-Commission workshop on applications for authorisation was held on 15-16 November 2018 in Brussels. Representatives of DG GROW, DG Environment and ECHA participated in the workshop. Objectives of the event were to analyse the nature and perception of the issues and to propose actions for improvement. Based on the Secretariat's preliminary conclusions, the following actions may emerge: the use of 'standardised' phrases for certain parts of the opinions (e.g. for the additional conditions and conclusions), identification of alternative suppliers who can comment during the public consultations, review of formats and guides where relevant, organisation with stakeholders of a lessons learnt exercise to improve the process, and explore how to deal with elements that may require 'political judgement'. On request of SEAC members' the Secretariat clarified that some particular aspects (such as the review periods or the precautionary principle) were not specifically

considered during the workshop, and that the AfA Task Force would be the appropriate group to work on the proposed actions.

## **6.2) Authorisation applications**

### **a) Agreement on draft opinions**

#### **1) CT\_MAHLE (1 use)**

The Chairman introduced the application for authorisation. At SEAC-40, the Committee discussed the key issues for this application. At this plenary, SEAC members were asked to agree on the SEAC draft opinion.

The Chairman invited the Secretariat to inform SEAC about the status of the RAC draft opinion. The rapporteurs then presented the SEAC draft opinion. SEAC members discussed about the availability of the alternatives and the scope of the application for authorisation.

The draft opinion was subsequently agreed by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat.

#### **2) CT\_Doosan (1 use)**

The Chairman introduced the application for authorisation for the industrial formulation of a chromium trioxide solution below 0.1% w/w concentration for the passivation of copper foil used in the manufacture of Lithium-Ion Batteries (LiB) for motorised vehicles. At SEAC-40, the Committee discussed the key issues for this application. At this plenary, SEAC members were asked to agree on the SEAC draft opinion.

The Chairman invited the RAC rapporteur to inform SEAC about the status of the RAC draft opinion. The Secretariat and the rapporteur presented the SEAC draft opinion reminding the Committee that this is a downstream application for a future use in a future plant to be built in Hungary. The scope of the application is narrow and well defined, covering one use for one clear market segment. The applicants will use 15 tonnes per year and have requested a review period of 15-year. Following the responses to the rapporteurs' questions, a dialogue was held on 16 October 2018.

The discussion focused mainly on the length of the review period and on the non-use scenario presented by the applicants. The draft opinion was subsequently agreed by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat.

### **b) Adoption of final options**

#### **1) CT\_Hapoc\_2 (1 use)**

The Chairman introduced this application for authorisation. At the SEAC-39 plenary meeting the Committee had agreed on the draft opinion. The draft opinion was sent to the applicant, who commented on the draft opinion. All of the comments received from the applicant related to the length of the review period. The rapporteurs considered the

comments of the applicant and altered the recommendation on the review period based on the supportive information provided by the applicant.

The SEAC rapporteurs presented the draft SEAC final opinion. The Committee members discussed the opinion as proposed by the rapporteurs. A majority of members supported the changes made by the rapporteurs. The final opinion was subsequently adopted by simple majority. The minority positions by five SEAC members will be published together with the opinion. The opinions will be sent to the applicant, the European Commission and the Member States. The Chairman thanked the rapporteurs for their work on the application.

### **6.3) Review reports**

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

##### **1) RR1\_TCE\_Spolana (1 use)**

The Chairman introduced the review report on the use of Trichloroethylene by Spolana a.s. At this plenary meeting the Secretariat presented the general information related to the review report. The Secretariat also outlined the key issues identified by the rapporteurs and asked the Committee for comments and further suggestions.

SEAC noted the key issues and will request further clarifications on these from the authorisation holder. The SEAC rapporteurs will draft the opinions on the review report for the discussion and agreement at the next SEAC plenary meeting in March 2019.

#### **c) Adoption of final opinions**

##### **1) RR1\_DEHP\_PP (2 uses)**

The Chairman introduced this review report. At the SEAC-39 plenary meeting, the Committee had agreed on the two draft opinions. The draft opinions were sent to the authorisation holder. The authorisation holder commented on the draft opinions. All of the received SEAC-specific authorisation holder's comments related to a length of the review period. The rapporteurs considered the comments from the authorisation holder.

The SEAC rapporteurs presented the draft SEAC final opinions. The Committee members discussed the opinions as proposed by the rapporteurs. SEAC members broadly supported the changes made by the rapporteurs. The final opinions were subsequently adopted by simple majority. The minority positions by five SEAC members will be published together with the opinion. The opinions will be sent to the authorisation holder, the European Commission and the Member States. The Chairman thanked the rapporteurs for their work on the review report.

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/41/2018/02, was agreed by SEAC.

## **7) AOB**

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

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

### **b) INTERACT Project**

The Secretariat provided to SEAC an update on the progress of the ECHA Interact Project, the release of which is scheduled for April 2019.

## **8) Action points and main conclusions of SEAC-41**

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

## II. Main conclusions and action points

SEAC-41, 27 - 29 November 2018  
(Adopted at SEAC-41 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
<b>2. Adoption of the agenda</b>	
The agenda was adopted with no modifications.	<b>SECR</b> to upload the adopted agenda to SEAC S-CIRCABC IG as part of the meeting minutes.
<b>3. Declarations of conflicts of interest to the Agenda</b>	
Conflicts of interest have been declared and will be taken to the minutes.	
<b>4. Report from other ECHA bodies and activities</b>	
<i>a) Report on SEAC-40 action points, written procedures and update on other ECHA bodies</i>	
SEAC was informed on the status of the action points of SEAC-40. SEAC was also informed about a complaint against the selection procedure for co-opted members. 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.	
<b>5. Restrictions</b>	
<b>5.2 Restriction Annex XV dossiers</b>	
a) Conformity check and key issues discussion	
1) N,N-dimethylformamide	
SEAC agreed that the dossier conforms to the Annex XV requirements.  SEAC took note of the recommendations to the dossier submitter.	<b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG.  <b>SECR</b> to inform the dossier submitter on the outcome of the conformity check.
2) Five cobalt salts	
SEAC agreed that the dossier conforms to the Annex XV requirements.	<b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload this

SEAC took note of the recommendations to the dossier submitter.	to S-CIRCABC IG.  <b>SECR</b> to inform the dossier submitter on the outcome of the conformity check.
b) Opinion development	
1. C9-C14 PFCAs, their salts and related substances – draft of final opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the SEAC final opinion and the results of the public consultation on the SEAC draft opinion.  SEAC adopted its final opinion by consensus (with editorial modifications agreed at SEAC-41).	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.  <b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.
2. Substances used in tattoo inks and permanent make-up – revised draft opinion	
SEAC rapporteurs presented and SEAC discussed the revised fourth draft opinion.  SEAC agreed on the draft opinion by consensus (with editorial modifications agreed at SEAC-41).	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.  <b>SECR</b> to launch a public consultation on the SEAC draft opinion in December 2018.
3. PAHs in granules and mulches used as infill material – first draft opinion	
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<b>SECR</b> to launch a written commenting round for members to provide remaining comments via the S-CIRCABC newsgroup (until 13 December 2018).  <b>Rapporteurs</b> to prepare the second draft opinion, taking into account the SEAC-41 discussions, by the beginning of February 2019.
<b>5.3 Appointment of (co-)rapporteurs for restriction dossiers</b>	
SEAC agreed on the pools of (co-)rapporteurs for the upcoming restriction proposals to be submitted in January 2019 (in line with the restricted meeting document SEAC/41/2018/01).	<b>SEAC Members</b> to volunteer for the pool of (co-) rapporteurs for skin sensitisers in textiles.
<b>6. Authorisation</b>	
<b>6.1 General authorisation issues</b>	

a) Update on incoming/future applications	
SEAC took note of the update on the incoming/future applications.	
<b>6.2 Authorisation applications</b>	
a) Agreement on draft opinions	
1. CT_Mahle (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on its draft opinion on this application for authorisation by consensus.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <b>SECR</b> to send the draft opinion to the applicant for commenting.
2. CT_Doosan (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on its draft opinion on this application for authorisation by consensus.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.  <b>SECR</b> to send the draft opinion to the applicant for commenting.
b) Adoption on final opinions	
1. CT_Hapoc_2 (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinion.  SEAC adopted its final opinion on the application for authorisation by simple majority. The minority views will be reflected in the minutes.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the adopted opinion.  <b>SECR</b> to send the final opinion to COM, MSs and the Applicant.  <b>Members</b> taking minority opinions should send their scientific and technical reasons for their minority positions to SECR by 7 December 2018.
<b>6.3 Review reports</b>	
a) Discussion on key issues	
1. RR1_TCE_Spolana (1 use)	
SEAC discussed the key issues identified in the application for authorisation.	<b>Rapporteurs</b> to prepare the first version of the draft opinion, taking into account the SEAC-41 discussions.
b) Adoption of final opinions	
1. RR1_DEHP_PP (2 uses)	

<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft final opinions for uses 1 and 2.</p> <p>SEAC adopted its final opinions by simple majority. The minority views will be reflected in the minutes.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the adopted opinions.</p> <p><b>SECR</b> to send the final opinions to COM, MSs and the Applicant.</p> <p><b>Members</b> taking minority opinions should send their scientific and technical reasons for their minority positions to SECR by 7 December 2018.</p>
<p><b>6.4 Appointment of (co-)rapporteurs for authorisation applications (closed session)</b></p>	
<p>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/41/2018/02).</p>	<p><b>SEAC members</b> to volunteer to the pool of (co-) rapporteurs for applications for authorisation.</p> <p><b>SECR</b> to upload the updated document to confidential folder on S-CIRCABC IG.</p>
<p><b>8. Action points and main conclusions of SEAC-41</b></p>	
<p>SEAC adopted the action points and main conclusions of SEAC-41.</p>	<p><b>SECR</b> to upload the action points and main conclusions to S-CIRCABC IG.</p>



### III. List of Attendees

#### SEAC-41

<b>SEAC members</b>
ALEXANDRE Joao
BERGS Ivars
BLAHA Karel
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
DELCOURT Benjamin
DOMINIAK Dorota
DOUGHERTY Gary
FANKHAUSER Simone
FIORE Karine
FOCK Lars
GEORGIOU Stavros
JANS Jenny
JANSSEN Martien
JOYCE John
KAJIC Silva
KIISKI Johanna
KNOFLACH Georg
KRAJNC Karmen
LEAHY Eimear
LOCS Janis
LUIT Richard
LÜDEKE Andreas
NARROS SIERRA Adolfo
RONKAINEN Dora
ROUW Aart
RUZGYS Karolis
SCHUCHTAR Endre
SHAKHRAMANYAN Nikolinka
STOYANOVA VELINOVA Elina
THIELE Karen
URBAN Klaus
ZAMFIR Adrian-Stefan
<b>Commission observers</b>
BENGYUZOV Manol (DG GROW)
GALLEGO Matteo (DG ENV)
<b>Stakeholder observers &amp; accompanying experts</b>
BOCK Ronald (Chemours International) as accompanying expert to CEFIC for PFCAs
MC CARTHY Adam (Albemarle) as accompanying expert to CEFIC for 5 Cobalt salts

<b>Advisors, invited experts, observers &amp; dossier submitters (DS)</b>
ANDERSSON Wiktor as advisor to Jenny JANS via WebEx
AVERBECK Frauke as DS for PFCAs via WebEx
BERNHEIM Teresa as advisor to Karen THIELE
CATONE Tiziana as DS for DMF via WebEx
DE BLAEIJ Arianne as DS for Plastic and rubber granulates via WebEx
HELMEDACH Achim as advisor to Karen THIELE via WebEx
JONGENEEL Rob as advisor to Richard LUIT via WebEx
OYSTEIN FOTLAND Tor as DS for tattoo inks via WebEx
REALE Priscilla as advisor to Luisa Cavalieri via WebEx
TRUBIROHA Achim as an expert supporting the DS for Tattoo inks via WebEx
VAN DER HAGEN Marianne as DS for Tattoo inks via WebEx
VERHOEVEN Julia as DS for Plastic and rubber granulates via WebEx

<b>Stakeholder observers &amp; accompanying experts</b> (cont.)
HOLLAND Mike (EAERE = European Association for Environmental and Resource Economists)
JÁNOSI Amaya (CEFIC = European Chemical Industry Council)
MISTRY Rohit (EFTEC = Economics for the Environment) as accompanying expert to EUROMETAUX for Cobalt salts restriction
MUSACCHI Ettore (ETRA = European Tyre Recycling Association) as Occasional Stakeholder for Plastic and rubber granulates restriction dossier
MUSU Tony (ETUC = European Trade Union Confederation)
SANTOS Tatiana (EEB = European Environmental Bureau)
WAETERSCHOOT Hugo (EUROMETAUX)
WEILANDT Karl (3M) as accompanying expert to EUROMETAUX for PFCAs
<b>RAC rapporteurs</b>
DUNAUSKIENE Lina
KADIKIS Normunds
PARIS Pietro
VARNAI Veda
BARAŃSKI Boguslaw
KAPELARI Sonja
MULLOOLY Yvonne

<b>ECHA STAFF</b>
BLAINEY Mark
GMEINDER Michael
HOLLINS Stephen
JACQUEMIN Katline
KIVELA Kalle
KOSK-BIENKO Joanna
LOGTMEIJER Christiaan
LUDBORZS Arnis
MAZZOLINI Anna
MARQUEZ-CAMACHO Mercedes
MOTTET Denis
MUSHTAQ Fesil
NICOT Thierry
ORISPÄÄ Katja
OTTATI Maria
PELTOLA Jukka
PILLET Monique
RHEINBERGER Christoph
ROGGEMAN Maarten
SIMPSON Peter
SJOBERG 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

## ANNEX I

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

Document	Number
Final Draft Agenda	SEAC/A/41/2018
Appointment of (co-)rapporteurs for restrictions dossiers	SEAC/41/2018/01 (restricted)
Appointment of (co-)rapporteurs for authorisation applications (closed session)	SEAC/41/2018/02 (restricted room document)

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

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

<b><u>Name of participant</u></b>	<b><u>Agenda item</u></b>	<b><u>Interest declared</u></b>
LUDEKE Andreas	5.2b.2 Substances used in tattoo inks and permanent make-up 5.2b.1 C9-C14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossiers
FOCK Lars	5.2b.2 Substances used in tattoo inks and permanent make-up	Participation in the preparation of the restriction dossier
THIELE Karen	5.2b.1 C9-C14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossier
LUIT Richard	5.2b.3 Plastic and rubber granulates containing PAHs	Participation in the preparation of the restriction dossier
JANSSEN Martien	5.2b.3 Plastic and rubber granulates containing PAHs	Working for the MSCA submitting the dossier
CAVALIERI Luisa	5.2a.1 -N,N-dimethylformamide (DMF)	Contract with the MSCA submitting the dossier
CASTELLI Stefano	5.2a.1 -N,N-dimethylformamide (DMF)	Participation in the preparation of the restriction dossier
JANS Jenny	5.2b.1 C9-C14 PFCAs, their salts and related substances	Working for the MSCA submitting the dossier

27 November 2018  
SEAC/A/41/2018

## **Final Agenda**

### **41<sup>st</sup> meeting of the Committee for Socio-economic Analysis**

**27 – 29 November 2018**

**ECHA Conference Centre (Annankatu 18, Helsinki)**

**27 November starts at 14.00**

**29 November ends at 12.30**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

*SEAC/A/41/2018*  
*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-40 action points, written procedures and update on other ECHA bodies

*For information*

**Item 5 – Restrictions**

#### **5.1 General restriction issues**

- a) Update on the work of the Restrictions Task Force (RTF)

*For information*

#### **5.2 Restriction Annex XV dossiers**

a) Conformity check and key issues discussion

- 1) *N,N*-dimethylformamid
- 2) Five cobalt salts

*For discussion and agreement*

b) Opinion development

- 1) C9-C14 PFCAs, their salts and related substances – draft of final opinion

*For discussion and adoption*

- 2) Substances used in tattoo inks and permanent make-up – revised draft opinion

*For discussion and agreement*

- 3) PAHs in granules and mulches used as infill material – first draft opinion

*For discussion*

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

*SEAC/41/2018/01*

*(restricted meeting document)*

*For agreement*

**Item 6 – Authorisation**

**6.1 General authorisation issues**

- a) Update on incoming/future applications
- b) Report from the workshop with the Commission on authorisation (15-16 November 2018)

*For information*

**6.2 Authorisation applications**

- b) Agreement on draft opinions

1. CT\_MAHLE (1 use)
2. CT\_Doosan (1 use)

*For discussion and agreement*

- c) Adoption of final opinions

1. CT\_Hapoc\_2 (1 use)

*For discussion and adoption*

### **6.3 Review reports**

a) Discussion on key issues

- 1) RR1\_TCE\_Spolana

*For discussion*

b) Adoption of final opinions

- 1) RR1\_DEHP\_PP (2 uses)

*For discussion and adoption*

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

*SEAC/41/2018/02*

*(restricted room document)*

*For agreement*

#### **Item 7 – AOB**

a) Update of the work plan

b) INTERACT Project

*For information*

#### **Item 8 – Action points and main conclusions of SEAC-41**

a) Table with Conclusions and Action points from SEAC-41

*For adoption*