

**29 August 2017**  
**SEAC/A/35/2017**

**Final**

**Minutes of the 35<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**12 - 15 June 2017**

## **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 thirty-fifth meeting of SEAC. The Chairman informed the participants that one new member has joined the Committee. The Chairman also informed SEAC that apologies have been received from five 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-35. The agenda was adopted with minor modifications under AOB. 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. Two members declared potential conflicts of interest to the substance-related discussions under the Agenda Item 5.2. These members did not participate in voting under the respective 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-34 action points, written procedures and update on other ECHA bodies**

The Chairman informed the participants that all action points of SEAC-34 had been completed or would be followed up during the on-going SEAC-35 meeting. The Chairman also informed the Committee that the final minutes of SEAC-34 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-34 minutes.

The Chairman then explained that a report covering the developments in the ECHA MB, RAC, MSC, the Forum and BPC had been compiled and distributed to SEAC as a meeting document (SEAC/35/2017/01).

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) Report from the Restriction workshop held in Helsinki 17-18 May 2017**

The Secretariat provided a report from the Restriction workshop held in Helsinki on 17-18 May 2017 and a general update related to work of the Restriction Efficiency Task Force. SEAC discussed the key observations proposed to the restriction process e.g. lack of data on risk and costs and the need to improve the stakeholder engagement during the public consultation. The Secretariat will report back on the developments at a later stage.

#### **b) ECHA study on enforcement costs**

The Secretariat provided a presentation on ECHA's study on enforcement costs. SEAC welcomed the approach taken as a good starting point but some members asked for careful consideration when using averages. One member suggested that Forum could be specifically asked about the enforcement costs. Another participant provided alternative approach with time perspective. Members noted the constraints related to compliance costs associated with enforcement costs. In addition, enforcement costs differ from one Member State to another. The Secretariat took note of the discussions.

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

#### **a) Conformity check**

##### **1) Lead and lead compounds in shot – outcome of the conformity check and presentation of the key issues**

The Chairman welcomed the dossier submitters' representatives from ECHA. He informed the participants that the dossier was submitted in April 2017, the conformity check process was launched in the Committees on 17 May 2017 and the SEAC commenting round finished on 23 May 2017 (there were no comments received from SEAC members).

The dossier submitter's representative (ECHA) provided a brief introductory presentation on the dossier. The dossier proposes restriction on the use of lead shots over wetlands. The harmonisation of the conditions of use of lead in shot in wetlands is a priority at EU level, as national legislation has already been enacted by some Member States (or regions in some Member States) further to international action through the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of the UN Environment Programme (UNEP) to which the EU is a Party.

The Secretariat gave a short update from RAC-41 discussions, where RAC concluded that the dossier is in conformity. The SEAC rapporteurs presented the outcome of the conformity check and the recommendations to the dossier submitter and proposed to the Committee that the dossier can be considered in conformity from the SEAC point of view. After the short discussion, the Committee agreed that the dossier does conform to the Annex XV requirements. In addition, the rapporteurs presented the key issues identified by them in the dossier.

The Committee discussed different aspects of the proposed restriction, such as scope, enforceability of the proposed restriction, calculated benefits from the restriction and proposed restriction implementation measures. Some SEAC members questioned whether the REACH Regulation is the appropriate EU regulation to restrict possession of lead gunshot for persons in wetlands. Other SEAC members asked, why the scope of the restriction proposal is limited to wetlands only. The Secretariat responded that ECHA drafted the restriction proposal based on the request by the Commission. Some SEAC members raised concerns about who would be a national enforcement authority in their Member States. The SEAC rapporteurs responded that the Forum advice on enforceability of the restriction will be available during the restriction opinion development process. Other SEAC members proposed practical solutions with regard to enforcement of the restriction, e.g. use of wetlands-labelled GPS maps by hunters, and labelling against the use in wetlands of lead-containing shot. A representative of the European Commission confirmed that the Commission sees the REACH Regulation as the appropriate legal instrument for the restriction. He also confirmed that broadening of the scope of the restriction going beyond prohibition of the lead-containing shot in the wetlands only will be considered at a later stage. He also expressed appreciation of the practical ideas by the SEAC members regarding the implementation and enforcement of the restriction proposal.

The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 21 June 2017.

## **b) Opinion development**

### **1) TDFAs – final SEAC opinion**

The Chairman welcomed the dossier submitter representatives from Denmark and an industry expert accompanying a regular stakeholder observer. The Chairman reminded the participants that the dossier submitter proposes a restriction on the use of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives in mixtures containing organic solvents placed on the market or used in spray products for consumers (aerosol dispensers, hand pump and trigger sprays and mixtures marketed for spray application). The restriction is targeted at mixtures with organic solvents in spray products for supply to the general public. TDFAs with organic solvent have been shown to cause serious acute lung injury in mice exposed to aerosolised mixtures. The Chairman explained that the public consultation on the SEAC draft opinion ended on 22 May with two comments received. The draft final opinion, taking into account the comments of the public consultation, was made available to SEAC on 1 June.

The rapporteur presented the results of the public consultation and explained the revisions made in the draft final opinion. The changes made were mainly editorial and

had not changed the main conclusions made during SEAC-34. Some SEAC members restated their concerns regarding insufficient information on alternatives as well as for cost-benefit assessment.

SEAC adopted its opinion on the dossier by simple majority. One member took a minority position to the opinion based on concerns related to the availability of the alternatives and the scope of the restriction (to be included in a separate document which will be published on the ECHA website). In addition, one of the members raised reservations regarding the socio-economic analysis.

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 supportive documents to the Commission as well as publish them on the ECHA website. The Chairman thanked the rapporteurs for their work on this dossier.

## **2) 4 phthalates – final SEAC opinion**

The Chairman welcomed the dossier submitters' representatives from ECHA and Denmark, and two experts accompanying the regular stakeholder observers. The Chairman reminded the participants that the dossier proposes a restriction on articles containing the four phthalates (diisobutyl phthalate (DIBP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP)) for: i) indoor use and ii) outdoor use, if in contact with human skin or mucous membranes. The Chairman explained that the public consultation on the SEAC draft opinion ended on 22 May with 13 comments received. The draft final opinion, taking into account the comments of the public consultation, was made available to SEAC on 7 June.

The rapporteurs presented the results of the public consultation and explained the revisions made in the draft opinion. Having considered the 13 comments received during the public consultation on the SEAC draft opinion agreed in March, they proposed additional derogations (for certain parts, products or appliances of aircraft and for certain articles for automotive vehicles) and made minor adjustments in the justification for its opinion.

SEAC adopted its opinion on the dossier by consensus (with modifications introduced at SEAC-35). One member raised reservations regarding the assessment of benefits.

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 supportive documents to the Commission as well as publish them on the ECHA website. The Chairman thanked the rapporteurs for their work on this dossier.

## **3) Diisocyanates – first draft opinion**

The Chairman welcomed the dossier submitter's representatives from Germany (following via WebEx), the RAC rapporteurs (following via WebEx) and an industry expert accompanying a regular stakeholder observer. He reminded the participants that this restriction proposal had been resubmitted by Germany in February 2017 and had been

considered in conformity by SEAC in its March plenary. The proposal limits the use of diisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures as well as a minimum standardised training package have been implemented. Information how to get access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of diisocyanates in the substance or mixture placed on the market or used is less than 0.1% by weight, as well as for mixtures containing diisocyanates at higher levels than 0.1% by weight which fulfil criteria that show that the potential risks using such products are very low. The rapporteurs had developed the first draft opinion on this dossier, taking into account the discussion on key issues held at SEAC-34, which was made available to SEAC on 24 May. The commenting round ended on 31 May with comments received from five SEAC members. At this SEAC-35 meeting, the Committee was invited to discuss the first draft opinion and to provide feedback sufficient to enable the rapporteurs to formulate a next version of the draft opinion.

The Secretariat briefly reported to SEAC on the RAC discussion on this dossier held within RAC-41. The rapporteurs then presented the first draft opinion, in which they mainly had focused on the costs. Several SEAC members shared the concerns raised by the rapporteurs that already existing OSH measures alone appear sufficient, if properly implemented, and that it is not clear from the dossier why the implementation of the proposed measure would be expected to be more successful noting that in the hierarchy of OSH measures, the technical measures are on top, and thus should be considered first by the DS as a RMO. A stakeholder observer pointed out that training is already an obligation for employers under the worker protection legislation and therefore it can be foreseen that training as specified in the proposed restriction would in practice be combined with existing safety and health trainings, which would affect the costs of the restriction. Another stakeholder observer indicated that the restriction imposes a training requirement by the supplier, which is clearly different and complementary to the requirements for employers (at the user level), concluding this would result in additional costs. It was agreed that the rapporteurs will address these issues with the dossier submitter and update the discussion on costs in the second SEAC draft opinion in line with comments received at SEAC-35 (as well as possible comments in the ongoing public consultation).

The Chairman informed the Committee that the second draft opinion should be developed by the rapporteurs by early August 2017.

#### **4) Lead and lead compounds in PVC – first draft opinion**

The Chairman welcomed the dossier submitter's representatives from ECHA, as well as an industry expert accompanying the regular stakeholder observer. He reminded the participants that this restriction proposal had been submitted by ECHA in February 2017 and had been considered in conformity by SEAC in its March plenary. The dossier proposes a restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15 year derogation for certain building and construction articles produced from recycled PVC (with a higher restriction limit of 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries. The rapporteurs had developed the first draft opinion on this dossier, taking into account the discussion on key issues held at SEAC-34, which was made available to SEAC on 31 May. The commenting round ended on 5 June with comments received from four SEAC members. At this SEAC-35 meeting, the Committee was invited to discuss the first draft opinion

and to provide feedback sufficient to enable the rapporteurs to formulate a next version of the draft opinion.

The Secretariat briefly reported to SEAC on the RAC discussion on this dossier held within RAC-41. The rapporteurs then presented the first draft opinion, in which they mainly had focused on the approach towards costs. Several members supported carrying out the cost-effectiveness analysis in the assessment of this proposal and recommended to perform a comparison with other lead restrictions. One member noted that it is not clear to him why the derogation for lead stabilisers in PVC separators for lead acid batteries is limited to 10 years. The only basis for this appears to be an estimate from the supplier on the time they may need to find a substitute. However, as currently drafted, when the time limit is up, the derogation will cease regardless of whether a substitute is available. Instead of a time limit, there could be a review clause to reconsider the derogation after 10 years. A stakeholder observer indicated that the separators are in contact with other Pb-compounds when in use in the battery and at the end of life of the battery recovered/recycled together with the Pb-acid batteries. Eliminating Pb-stabilisers to reduce the risk at the EOL phase does therefore not provide any benefit neither is there a specific risk associated with this which is a requirement to justify a restriction”.

The rapporteur agreed that the information available to conclude on the derogation is limited and that a better evidence base is needed to underpin the justification (including the time limit) of the derogation. The Secretariat informed the Committee that they have approached the company concerned asking for more information to assess the derogation. One SEAC member highlighted that the cost for sampling and analysis should also be included in the calculation of the enforcement costs. The stakeholder observer recommended to look at the enforcement costs of previous lead restrictions, e.g. lead in jewellery. Another member pointed out that it would be good to see more description of the rapporteurs' scrutiny and evaluation of the proposal in the future drafts of the opinion. The rapporteur confirmed that they will carry out a more in-depth evaluation of the proposal and include it in the development of future drafts of the opinion, also taking into account information received in the public consultation. The Chairman emphasised the importance of being consistent with the previous SEAC assessments on lead, unless there is new information available.

The Chairman informed the Committee that the second draft opinion should be developed by the rapporteurs by early August 2017.

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

The Secretariat presented and the Committee agreed on the pool of (co-)rapporteurs (in line with the restricted meeting document SEAC/35/2017/03) for two restriction proposals on substances used in tattoo inks and permanent make-up, which will be submitted by ECHA and on C9-C14 PFCAs, their salts and related substances to be submitted by Germany.

In addition, the Chairman informed the Committee about another ECHA dossier which is expected to be submitted in April 2018 proposing a restriction on leave on personal care products and other consumer/professional products containing D4/D5. The call for expression of interest for this dossier will be launched in autumn 2017.

## **6) Authorisations**

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

#### **a) Update on incoming/future applications and report from the Authorisation workshop held in Helsinki 18-19 April**

The Secretariat informed the Committee that five applications for authorisation were received during the May 2017 submission window. Three out of the five are upstream applications on the uses of chromium (VI) substances in the aviation sector. One of the new applications is on the downstream use of chromium trioxide in piston rods for vehicles shock absorbers. And the remaining application is also submitted by a downstream user of 1,2-dichloroethane (EDC) for manufacturing of beads for filtration units to treat nuclear wastes.

In addition, the Secretariat informed the Committee that in the August 2017 submission window it is expected to receive two review reports on the uses of two phthalates (DBP and DEHP). In the November 2017 submission window, one review report for the use of lead chromate pigments may be submitted to ECHA, as well as one new application for authorisation by a downstream user for the use of diglyme.

#### **b) Review reports**

The Secretariat presented to the Committee main principles of the review reports and the modified templates, which will be used by the applicants for submission of the review reports. The review report process in terms of content, processing and timelines in RAC and SEAC is very similar to the applications for authorisation process. Review reports have to specify all the changes and progress that took place during the authorisation period e.g. in terms of hazards, exposure (Operational Conditions/Risk Management Measures, monitoring programs), or substitution activities, or any change in business activities that may affect the original SEA. In addition to the chemical safety report, the analysis of alternatives and the socio-economic analysis, a new format of an explanatory note is added to the package to be submitted by the applicants. The explanatory note is a high level document to facilitate reading and to understand changes and progress made. Some SEAC members expressed their views on the scope of the uses re-applied for in the review reports, the evaluation by RAC/SEAC on whether the conditions for the authorisation were met, whether conditions for the review report are fulfilled, etc. Some SEAC members and a representative of the stakeholder organisations asked about the steps in the opinion development process on the review reports. The Secretariat clarified that e.g. public consultation will systematically take place, as well as dialogues as necessary.

#### **c) Review periods longer than 12 years**

The Secretariat introduced the draft document prepared by the Commission and already discussed by CARACAL. The aim of the discussion in RAC and SEAC was to collect views of the Committees on how the criteria could be implemented in practice, and not on the proposed criteria themselves. During the SEAC consultation prior to the SEAC plenary

meeting the Secretariat received comments from 14 SEAC members, most of them being of general nature.

During the discussion some SEAC members expressed wish to use the document as a guidance for SEAC and use it when necessary. This view was supported by some others. Some SEAC members reminded the participants that SEAC as a scientific committee should formulate its opinion based on scientific conclusions. The draft document raises many questions of technical nature about applicability of the proposed criteria, e.g. how would it be possible to assess if substitution is highly unlikely, etc. One of the representatives of the stakeholder organisations told that they in general oppose long review periods because the development of markets and new alternatives can happen within short timelines.

The representative of the European Commission took note of the views of the SEAC members delivered both during the plenary discussion and the written commenting round prior to the SEAC plenary for further consideration. The Secretariat will forward the CARACAL document, when it is adopted.

## **6.2) Authorisation applications**

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

#### **1. PC\_SC\_Saes (2 uses)**

The Secretariat, in cooperation with the SEAC rapporteurs, provided general information regarding the new application for authorisation PC\_SC\_SAES. In the presentation of the case, the Secretariat outlined the key issues identified by the rapporteurs, which would need further clarification by the applicant and asked the Committee for comments and further suggestions.

The Committee discussed these key issues. Where needed, further clarifications will be requested from the applicant on the issues identified and discussed by the Committee.

### **b) Agreement on draft opinions**

#### **1. Diglyme\_Acton (2 uses)**

The Chairman introduced the application for authorisation. The SEAC members were asked to consider the agreement on the draft opinions at this plenary.

The Chairman invited the Secretariat to inform SEAC about the discussion held at RAC-41. The Secretariat briefly presented the main points of the discussion and informed the Committee that the draft opinions have been agreed at this plenary. The SEAC rapporteurs then presented the SEAC draft opinions.

In the following discussion, SEAC mainly focused on how to clearly express in the opinions that the conclusions of the cost-benefit analysis are correct for the current workforce gender structure and how its potential change in the future, would affect the conclusion of SEAC.

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

#### **2. CT\_Haas (1 use)**

#### **3. PD\_Haas (1 use)**

#### **4. SD\_Haas (1 use)**

#### **5. SC\_Aviall (2 uses)**

The Chairman introduced the applications for authorisation. The SEAC members were asked to consider the agreement on the draft opinions at this plenary.

The Chairman invited the Secretariat to inform SEAC about the discussion held at RAC-41. The Secretariat briefly presented the main points of the discussion and informed the Committee that the draft opinions have been agreed at this plenary. The SEAC rapporteurs then presented the SEAC draft opinions.

In the following discussion, SEAC mainly discussed the length of the review period and the need of a condition.

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

#### **6. CT\_ZFL (2 uses)**

#### **7. SD\_ZFL (1 use)**

The Chairman introduced the applications for authorisation. The SEAC members were asked to consider the agreement on the draft opinions at this plenary.

The Chairman invited the Secretariat to inform SEAC about the discussion held at RAC-41. The Secretariat briefly presented the main points of the discussion and informed the Committee that the draft opinions have been agreed at this plenary. The SEAC rapporteurs then presented the SEAC draft opinions.

In its discussion, SEAC members focussed on the analysis of alternatives in relation to the use applied for. In addition, the Committee addressed some aspects of the socio-economic analysis, which are specific in the aviation sector. SEAC also discussed the length of the review period to be recommended in the Committee's opinions.

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

After the agreement of the draft opinion one stakeholder observer expressed the industry's view that the decision would not ensure a level playing field with other applications. In his view the decision was reached in a non-transparent manner. The Chairman replied and explained the procedure for agreement of opinions on applications for authorisation, and the overall obligation for the Committee to strive for consensus in its decisions.

#### **8. MOCA\_Reachlaw (1 use)**

The Chairman introduced the application for authorisation. The SEAC members were asked to consider the agreement on the draft opinion at this plenary.

The Chairman invited the Secretariat to inform SEAC about the discussion held at RAC-41. The Secretariat briefly presented the main points of the discussion and informed the Committee that the draft opinion has been agreed at this RAC plenary. The SEAC rapporteurs then presented the SEAC draft opinion.

In its discussion, SEAC members focussed on the broadness of the described use in the submitted application. Consequently, they discussed the availability of alternatives for

the products/parts covered by the use applied for. The Committee members also discussed the length of the review period to be recommended in the SEAC opinion.

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

After the agreement of the draft opinion one stakeholder observer expressed his view that the decision would not ensure a level playing field with other applications.

#### **9. SD\_Colle (1 use)**

The Chairman introduced the application for authorisation. The SEAC members were asked to consider the agreement on the draft opinion at this plenary.

The Chairman invited the Secretariat to inform SEAC about the discussion held at RAC-41. The Secretariat briefly presented the main points of the discussion and informed the Committee that the draft opinion has been agreed at this plenary. The SEAC rapporteurs then presented the SEAC draft opinion.

SEAC members discussed the submitted analysis of alternatives and the length of the review period to be recommended.

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

#### **10. CT\_Hansgrohe (2 uses)**

The Chairman introduced the application for authorisation. The SEAC members were asked to consider the agreement on the draft opinions at this plenary.

The Chairman invited the Secretariat to inform SEAC about the discussion held at RAC-41. The Secretariat briefly presented the main points of the discussion and informed the Committee that the draft opinions have been agreed at this plenary. The SEAC rapporteurs then presented the SEAC draft opinions.

SEAC members discussed the submitted analysis of alternatives and the length of the review period to be recommended in the Committee's opinions. One SEAC member remarked that the use name provided by the applicant was general/broad. It was clarified that the Broad Information on Uses package contains detailed and specific information to supplement the information included in the use name.

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

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

#### **1. Diglyme\_Isochem (1 use)**

The Chairman introduced the application for authorisation. At SEAC-34, the Committee agreed on the draft opinion. At this plenary, the SEAC members were asked to consider the adoption of the SEAC final opinion.

The Chairman invited the RAC rapporteur to inform SEAC about the updated RAC final opinion which was adopted at RAC-41. The SEAC rapporteurs presented the draft of the final opinion. The Committee then discussed the updated draft of the final opinion, considering the RAC conclusion that the RMMs and OCs described in the application are appropriate and effective in limiting the risks.

The final opinion was subsequently adopted by consensus, and will be sent to the applicant, the European Commission as well as the Members States.

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

The pool of (co-)rapporteurs, as outlined in the amended restricted room document SEAC/35/2017/05 rev.1, was agreed by SEAC.

## **7) AOB**

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

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

### **b) Outcome of the 2016 stakeholder survey and report from the Chair's teleinterviews with SEAC members**

The Secretariat first provided to the Committee a brief report on the outcome of 2016 stakeholder survey. This was followed by the report of the SEAC Chairman from his teleinterviews conducted recently with SEAC members and accredited stakeholder observers. After the presentation, SEAC was invited to discuss the identified areas of improvement (presentations and needs for capacity building) in smaller break out groups. After the break out group discussions, the conclusions from the groups were presented and further discussed in the plenary. The Chairman concluded that the Secretariat will continue to develop the presentation format and plan further capacity building activities based on these identified needs.

## **8) Action points and main conclusions of SEAC-35**

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

## II. Main conclusions and action points

**SEAC-35, 12-15 June 2017**

(Adopted at SEAC-35 meeting)

<b>Agenda point</b>	
<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>2. Adoption of the agenda</b>	
The agenda was adopted with minor modifications under AOB.	<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-34 action points, written procedures and update on other ECHA bodies</i>	
SEAC was informed on the status of the action points of SEAC-34. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/35/2017/01), 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>	
<b>a) Conformity check</b>	
1. Lead and lead compounds in shot – outcome of the conformity check and presentation of the key issues	
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.
<b>b) Opinion development</b>	
1) TDFAs – final SEAC opinion	
SEAC rapporteur presented and SEAC discussed	<b>Rapporteurs</b> together with <b>SECR</b> to do the final

<p>the draft of the SEAC final opinion and the results of the public consultation on the SEAC draft opinion.</p> <p>SEAC adopted its final opinion on the TDFAs proposal by simple majority. The minority view will be reflected in the minutes.</p>	<p>editing of the SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
2) 4 Phthalates (DIBP, DBP, BBP, DEHP) – final SEAC opinion	
<p>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.</p> <p>SEAC adopted its final opinion on the 4 Phthalates proposal by consensus (with modifications introduced at SEAC-35).</p>	<p><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.</p> <p><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
3) Diisocyanates – first draft opinion	
<p>SEAC rapporteurs presented and SEAC discussed the first draft opinion.</p>	<p><b>Rapporteurs</b> to prepare the second draft opinion, taking into account the SEAC-35 discussions and the results of the public consultation, by the beginning of August.</p>
4) Lead and lead compounds in PVC – first draft opinion	
<p>SEAC rapporteurs presented and SEAC discussed the first draft opinion.</p>	<p><b>Rapporteurs</b> to prepare the second draft opinion, taking into account the SEAC-35 discussions and the results of the public consultation, by the beginning of August.</p>
<b>5.3 Appointment of (co-)rapporteurs for restriction dossiers</b>	
<p>SEAC agreed on the pool of (co-)rapporteurs for restriction proposal on substances used in tattoo inks and permanent make-up as well as on C9-C14 PFCAs, their salts and related substances (in line with restricted meeting document SEAC/35/2017/03).</p>	
<b>6. Authorisation</b>	
<b>6.1 General authorisation issues</b>	
c) Review periods longer than 12 years	

SEAC discussed the practical implementation of criteria for review periods longer than 12 years. Commission took note of the different views expressed on the draft paper.	<b>SECR</b> to forward CARACAL paper to SEAC when adopted.
<b>6.2 Authorisation applications</b>	
a) Discussion on key issues	
1. PC_SC_Saes (2 uses)	
SEAC discussed the key issues identified in the application for authorisation.	<b>Rapporteurs</b> to prepare the first versions of the draft opinions.
b) Agreement on draft opinions	
1. Diglyme_Acton (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.  SEAC agreed on the draft opinions for Uses 1 and 2 by consensus.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.  <b>SECR</b> to send the draft opinions to the applicant for commenting.
2. CT_Haas (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on the draft opinion 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.
3. PD_Haas (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on the draft opinion 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.
4. SD_Haas (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.  SEAC agreed on the draft opinion 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.

5. SC_Aviail (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on the draft opinions for Uses 1 and 2 by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p>
6. CT_ZFL (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on the draft opinions for Uses 1 and 2 by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p>
7. SD_ZFL (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on the draft opinion by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.</p> <p><b>SECR</b> to send the draft opinion to the applicant for commenting.</p>
8. MOCAReachlaw (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on the draft opinion by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p>
9. SD_Colle (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.</p> <p>SEAC agreed on the draft opinion by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.</p> <p><b>SECR</b> to send the draft opinion to the applicant for commenting.</p>
10. CT_Hansgrohe (2 uses)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.</p> <p>SEAC agreed on the draft opinions for Uses 1 and 2 by consensus.</p>	<p><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</p> <p><b>SECR</b> to send the draft opinions to the applicant for commenting.</p>

c) Adoption of final opinions	
1. Diglyme_Isochem (1 use)	
<p>SEAC rapporteurs presented and SEAC discussed the SEAC final opinion.</p> <p>SEAC adopted the final opinion by consensus.</p>	<p><b>Rapporteurs</b>, together with SECR, to do the final editing of the adopted opinion.</p> <p><b>SECR</b> to send the final opinion to the Commission, Member States and the applicant.</p>
<b>6.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)</b>	
<p>SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with SEAC/35/2017/05 Rev.1 restricted room document).</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>
<b>8. Action points and main conclusions of SEAC-35</b>	
<p>SEAC adopted the action points and main conclusions of SEAC-35.</p>	<p><b>SECR</b> to upload the action points and main conclusions to S-CIRCABC IG.</p>

### III. List of Attendees

#### SEAC-35

<b>SEAC members</b>
ALEXANDRE JOAO (via webex)
ANASTASIOU Christos
BERGS Ivars
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
CSERGÓ Robert (co-opted)
DELCOURT Benjamin
DOUGHERTY Gary
FANKHAUSER Simone
FIGLIORE Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
JANSSEN Martien
JONES Derrick (co-opted)
KIISKI Johanna
KNOFLACH Georg
KRAJNC Karmen
LOČS Jānis
LÜDEKE Andreas
LUIT Richard
NARROS SIERRA Adolfo
NICOLAIDES Leandros
NORING Maria (via webex)
OLTEANU Maria
SCHUCHTAR Endre
STOYANOVA-LAZAROVA Elina
THIELE Karen
THORS Åsa
URBAN Klaus
ZAMFIR Adrian-Stefan
<b>Commission observers</b>
BENGYUZOV Manol (DG GROW)
BORRAS Anna (DG GROW via WebEx)
GALLEGO Matteo (DG ENV via WebEx)
<b>Stakeholder observers &amp; accompanying experts</b>
BERNARD Alice (ClientEarth)
CAVALLERO Alain (ESPA European Stabiliser Producer Association, accompanying CEFIC for the discussion on Lead in PVC)
HAIDER Sonja (ChemSec)
JANOSI Amaya (CEFIC)

<b>Advisors, invited experts, observers &amp; dossier submitters (DS)</b>
AVERBECK Frauke (DS for Diisocyanates via webex)
BERNHEIM Theresa (advisor to Karen THIELE)
FOCK Lars (DS for TDFAs)
HEESCHE-WAGNER Kerstin (DS for Diisocyanates)
HELLER-HUTORAN Svetlana (DS for Diisocyanates)
HELMEDACH Achim (Advisor to Karen THIELE via webex)
JONGENEEL Rob (advisor to Richard LUIT via WebEx)
LERCHE Dorte (advisor to Lars Fock)
MORO LACOPINI Sabrina (advisor to Stefano CASTELLI)
REALE Priscilla (Advisor to Luisa CAVALIERI via WebEx)
ROUW Aart (DS for Diisocyanates)
RUZGYS Karolis (nominee to become member of SEAC)
THEODORI Demi (advisor to Richard LUIT via WebEx)
VERHOEVEN Julia (advisor to Richard LUIT)
WALENDZIK Gudrun (DS for Diisocyanates)
WINTHER Toke (DS for TDFAs)
WODLI Jordane (advisor to Karine FIGLIORE)
<b>RAC (co-)rapporteurs</b>
DUNAUSKIENE Lina
DUNGEY Steve (via webex)
LUND Bert-Ove (via webex)
NEUMANN Michael (via webex)
SCHULTE Agnes (via webex)
VARNAI Veda (via webex)
<b>ECHA STAFF</b>
BLAINEY Mark
FESIL Mushtaq
HENRICHSON Sanna
JACQUEMIN Katline
KANELLOPOULOU Athanasia

KROESCHE Christoph (EVONIK Industries, accompanying CEFIC for the discussions on TDFAs only)
LUCKE-BRUNK Gudrun (Covestro Deutschland AG, accompanying CEFIC for the discussions on Diisocyanates only)
MARTIN Olwenn (Brunel University London, accompanying ClientEarth for discussions on phthalates)
MERVART Jan (DEZA, accompanying CEFIC for the discussion on Phthalates)
MUSU Tony (ETUC)
TILLIEUX Geoffroy (EUPC = European Plastics Converters, for the discussion on Phthalates and Lead and its compounds in PVC)
WAETERSCHOOT Hugo (EUROMETAUX)

KIVELÄ Kalle
KOSK-BIENKO Joanna
KOULOUMPOS Vasileios
LOGTMEIJER Christiaan
LUDBORZS Arnis
MARQUEZ-CAMACHO Mercedes
MAZZOLINI Anna
MERKOURAKIS Spyridon
NICOT Thierry
ORISPÄÄ Katja
PELTOLA Jukka
REGIL Pablo
RHEINBERGER Christoph
SADAM Diana
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**

<b>Document</b>	<b>Number</b>
Final Draft Agenda	<i>SEAC/A/35/2017</i>
Report on SEAC-34 action points, written procedures and update on other ECHA bodies	<i>SEAC/35/2017/01</i>
ECHA study on Enforcement costs	<i>SEAC/35/2017/02</i>
Appointment of (co-)rapporteurs for applications for authorisation (closed session)	<i>SEAC/35/2017/03</i> <i>(restricted room document)</i>
Review periods longer than 12 years	<i>SEAC/35/2017/04</i>

**ANNEX II****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>
FOCK Lars	5.2b-1 TDFAs	Working for the MSCA submitting the restriction dossier
FOCK Lars	5.2b-2. Phthalates	Participation in the preparation of the restriction dossier
LUDEKE Andreas	5.2b-3 Diisocyanates	Participation in the preparation of the restriction dossier

31 May 2017  
SEAC/A/35/2017

**Final Draft Agenda**

**35<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**12 – 15 June 2017**

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

**12 June starts at 14.00**

**15 June ends at 18.00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

***SEAC/A/35/2017***  
***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-34 action points, written procedures and update on other ECHA bodies

***SEAC/35/2017/01***  
***For information***

**Item 5 – Restrictions**

**5.1 General restriction issues**

- a) Report from the Restriction workshop held in Helsinki 17-18 May 2017
- b) ECHA study on enforcement costs

***SEAC/35/2017/02***

***For information***

## **5.2 Restriction Annex XV dossiers**

- a) Conformity check
  - 1) Lead and lead compounds in shots – outcome of the conformity check and presentation of the key issues

***For agreement***

- b) Opinion development
  - 1) TDFAs – final SEAC opinion
  - 2) 4 phthalates – final SEAC opinion
  - 3) Diisocyanates – first draft opinion
  - 4) Lead and lead compounds in PVC – first draft opinion

***For adoption***

***For discussion***

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

***SEAC/35/2017/03***

***(restricted document)***

***For agreement***

## **Item 6 – Authorisation**

### **6.1 General authorisation issues**

- a) Update on incoming/future applications and report from the Authorisation workshop held in Helsinki 18-19 April 2017
- b) Review reports
- c) Review periods longer than 12 years

***For information***

***SEAC/35/2017/04***  
***For discussion***

### **6.2 Authorisation applications**

- b) Discussion on key issues
  - 1. PC\_SC\_Saes (2 uses)
- c) Agreement on draft opinions
  - 1. Diglyme\_Acton (2 uses)
  - 2. CT\_Haas (1 use)
  - 3. PD\_Haas (1 use)
  - 4. SD\_Haas (1 use)
  - 5. SC\_Aviail (2 uses)
  - 6. CT\_ZFL (2 uses)
  - 7. SD\_ZFL (1 use)
  - 8. MOCA\_Reachlaw (1 use)

***For discussion***

- 9. SD\_Colle (1 use)
- 10. CT\_Hansgrohe (2 uses)

***For discussion and agreement***

- d) Adoption of final opinions
  - 1. Diglyme\_Isochem (1 use)

***For discussion and adoption***

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

***SEAC/35/2017/05  
(restricted room document)  
For agreement***

**Item 7 – AOB**

- a) Update of the work plan
- b) Outcome of 2016 stakeholder survey and report from the Chair's teleinterviews with SEAC members

***For information***

**Item 8 – Action points and main conclusions of SEAC-35**

Table with Conclusions and Action points from SEAC-35

***For adoption***