

26 August 2015 SEAC/M/27/2015 FINAL

## <u>Final</u>

Minutes of the 27<sup>th</sup> meeting of the Committee for Socio-economic Analysis

8-11 June 2015

## 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 twenty seventh meeting of SEAC.

The Chairman briefly introduced one newly appointed Committee member. He then informed the Committee that apologies had been received from five members and four stakeholder observers. Seven advisors to the members, four invited experts, two representatives of the European Commission, observers of six stakeholder organisations and three accompanying experts present at the meeting were introduced. The Chairman informed the participants that two members, four members' advisors and four representatives of the European Commission were to follow the relevant parts of the meeting via WebEx, and that the RAC rapporteurs, the dossier submitter representatives and the experts following specific agenda items would be presented at the beginning of the relevant discussions.

The Chairman also 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 draft agenda of SEAC-27. 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, their advisors and invited experts participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Eight members, two advisors and one stakeholder observer declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2 and 6.2. 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-26 action points, written procedures and other ECHA bodies

The Chairman informed the participants that all action points of SEAC-26 had been completed or would be followed up during the on-going SEAC-27 meeting. The Chairman also informed the Committee that the final minutes of SEAC-26 had been adopted by written procedure and had been uploaded to CIRCABC as well as on the ECHA website. The Chairman thanked members for providing comments on the draft SEAC-26 minutes.

The Chairman 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/27/2015/01).

The representative of the Commission was then invited to update the Committee on SEAC related developments in the REACH Committee and in the CARACAL. In addition, the Commission observer provided an update from the Commission project on assessing competitiveness, innovation and SMEs impact in the context of socio-economic analysis under REACH (i.e. SEA toolkit).

## b) General SEAC procedures

#### Appointment of co-opted members to RAC and SEAC

The Chairman reminded the Committee that the draft paper on appointment of coopted members to RAC and SEAC and the draft call for expression of interest was distributed to both Committees for comments in April (SEAC/27/2015/04). Following supportive reaction of five RAC members and one SEAC member, the call for expression of interest for co-opted members was launched on 6 May, ahead of SEAC-27, in order to speed up the process and to make sure suitable candidates are available for SEAC review and agreement in September.

The Chairman explained that at this SEAC-27 meeting, the Committee is invited to agree on the draft paper on appointment of co-opted members, which confirms the selection procedure and the required competences. In parallel, SEAC is invited to agree on a proposed revision of the Rules of Procedure concerning removal of voting rights of co-opted members.

The Secretariat then presented the paper on appointment of co-opted members as well as briefly summarized the outcome of the call that finished on 4 June. SEAC agreed on the proposed required competences and the selection procedure for coopting additional members to the Committee.

#### **Revised Rules of Procedure of the Committee for Socio-economic Analysis**

The Chairman introduced the topic by reminding the members that the Rules of Procedure for RAC and SEAC were first agreed in March 2008, with some adjustments in the following year. Since then, only minor revisions have been proposed by the Secretariat with the Committees' agreement and approved by the Management Board.

The Secretariat presented the proposed revisions in the SEAC Rules of Procedure (SEAC/27/2015/02). Beside revisions concerning the voting rights for co-opted members, several other items were included in order to update the Rules of Procedure to give more flexibility in organising the meetings with respect to handling voting in the event of lack of consensus. It aims at the improved clarity on concurrent employment in relation to Conflict of Interest declarations, and alignment of the Committee's Rules of Procedure with ECHA's policy on confidentiality. The Chairman invited the meeting to agree on the proposed revisions of the Rules of Procedure.

SEAC members asked clarifying questions regarding the proposed revisions such as changes in voting rules, meeting participation and membership. The Secretariat responded to them one by one. More specifically, one member expressed his concern regarding the proposal for not giving co-opted members the right to vote. Furthermore he proposed that also EEA and EFTA members should be allowed to vote as they are actively contributing to the work of the Committee. Another member requested that before measures are taken due to lack of participation in three consequent meetings, the Secretariat would need to proceed by first prewarning the relevant member. Two members suggested that also members participating via Webex could be considered as being present at the meeting. The Chairman took note of the views and mentioned that he would always first talk to a member that showed lack of participation.

SEAC agreed with the proposed revisions in the SEAC Rules of Procedure. One member expressed his dissenting views from the legal point of view regarding the proposed text in Article 9(3). After agreement by RAC and by SEAC on their respective Rules of Procedures, the proposed revisions are scheduled for approval by the Management Board at their forthcoming meeting.

#### <u>Revised general approach for admission of accredited stakeholder</u> organisations to RAC and SEAC (closed session)

The Secretariat presented the draft revised general approach for admission of accredited stakeholder organisations (ASOs) to RAC and SEAC. The aim of this revision was to harmonise the ECHA Committees' procedures for admission of ASOs to the work of MSC, RAC, SEAC and BPC; to further increase the transparency of the Committees' opinion development process and to ensure active and engaged ASO participation in the work of the Committees.

SEAC agreed on the new approach for admission of ASOs to its work. The Chairman noted that the Secretariat will inform the other ECHA Committees on the SEAC decision and will publish the revised document on the ECHA website. The Secretariat will apply the revised procedure and propose an updated list of SEAC stakeholders for agreement of SEAC at SEAC-28.

## 5) Restrictions

#### 5.1) General restriction issues

The Secretariat informed the participants of the meeting on the outcome of the Restriction Workshop held on 7 and 8 May 2015. The recommendations and the key outcomes from the Restriction Task Force (RETF), which involved Member States, ECHA's Committees and the Secretariat, were presented, as well as the progress of the implementation of the RETF recommendations and several proposals for continuous improvement.

The Chairman reminded the Committee about the on-going commenting round on CIRCABC on the draft Common Approach paper for Restrictions (the outline of which had been presented to SEAC at SEAC-26). The Secretariat will update the paper based on comments received and present it for discussion and possible agreement at September RAC and SEAC plenaries.

### 5.2) Restriction Annex XV dossiers

#### a) Opinion development

#### 1) Ammonium salts – final opinion

The Chairman welcomed the dossier submitter representative (France), who followed the discussion remotely via WebEx. He informed the Committee that the public consultation on the SEAC draft opinion, agreed at SEAC-26, had been launched on 18 March and finished on 18 May with three comments received. The (co-) rapporteurs had provided the draft of the SEAC final opinion and the responses to the public consultation comments on 29 May.

The rapporteurs were invited to present to the Committee the results of the public consultation as well as their impact on the SEAC opinion. They recommended to give the manufacturers sufficient time to find fire retardant suppliers with appropriate blends or develop more stabilized blends and proposed to extend the transitional period from 12 to 24 months after the entry into force of the restriction in line with the comments provided by industry within the public consultation on the SEAC draft opinion.

The Commission observer briefly updated SEAC about the CEN workshop held in Brussels on 4 May concerning the testing method on the ammonia emission.

SEAC adopted its opinion on the dossier by a simple majority. One member took a minority position based on reasons included in a separate document which has been published on the ECHA website. The rapporteurs were asked, together with the Secretariat, to make final editorial changes to the opinion and to ensure that the BD 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 on the ECHA website. The Chairman thanked the rapporteurs for their work on this dossier.

## 2) 4,4-Isopropylidenediphenol (bisphenol A) – revised draft opinion

The Chairman welcomed the dossier submitter representatives (France) and then introduced the state of play regarding the restriction dossier on the placing on the market of thermal paper containing BPA. The Chairman explained that at RAC-33, RAC adopted its opinion by consensus. The SEAC rapporteurs' third revised draft opinion was made available on 13 May. The written commenting round finished on 29 May with one comment received from a SEAC member. Taking into account the draft final opinion of RAC and the reply from RAC on questions by the SEAC rapporteurs, the SEAC rapporteurs updated the revised draft opinion. The fourth revised draft opinion was made available on 5 June.

The Secretariat summarised the conclusions of the RAC opinion and the SEAC rapporteurs then presented the fourth revised draft opinion. The discussion focussed on the health impact assessment and on the proportionality of the restriction proposal. The rapporteurs explained that a break-even analysis was performed in order to estimate at which incidence rates the monetised disease burden equals the costs of the proposed restriction on bisphenol-A. RAC's input concerning the likelihood of observing these calculated break-even incidences was requested. RAC's conclusion was that in the absence of a dose-relationship, the incidences of the relevant effects in the population at risk cannot be estimated. RAC was only able to provide a reply to SEAC on the basis of general

considerations and responded that such disease incident rates were extremely unlikely.

The main discussion in SEAC-27 was on the proportionality of the proposed restriction. Several members expressed their view that the uncertainties were high and that further time is needed to scrutinize the cost-calculations and the assumptions in the break-even analysis. Several members suggested ways to further address the uncertainties to the assessment. Several members were of the view that other elements to proportionality of the restriction are important (e.g., distributional effects) and needed to be reflected more thoroughly in the opinion.

The Chairman concluded that SEAC was not ready to agree the draft opinion in SEAC-27. The rapporteurs were requested to take the discussion of SEAC-27 into account in the revised SEAC opinion. After SEAC-27, a written SEAC consultation round will be started on the further (fifth) revised draft opinion. The Committee is expected to agree on the draft opinion in September and adopt its final opinion in December 2015.

#### 3) DecaBDE – revised draft opinion

The Chairman welcomed the dossier submitters' representatives (ECHA and Norway), and an industry expert accompanying stakeholder observer to the meeting. He reminded the participants that decaBDE was identified as an SVHC and included in the Candidate List as PBT/vPvB. DecaBDE has a widespread occurrence in the environment and in wildlife. This bromine saturated diphenyl ether debrominates in the environment to lower homologues which are PBTs/vPvBs or act as precursors to substances with PBT/vPvB properties. In addition to PBT/vPvB concerns, other potential impacts of exposure to decaBDE may result in neurotoxicity in mammals, including humans. The proposal focuses on the hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles.

The Chairman noted that a preliminary SEAC agreement on the main elements in the SEAC opinion took place at SEAC-26, where SEAC concluded that action is required on an EU wide basis and that the restriction is the most appropriate EU wide measure. SEAC also supported the overall approach to use the substitution costs as a proxy of the compliance costs of the proposed restriction. Based on the discussions held at SEAC-26 and on the public consultation comments received by 17 March 2015 (there were 13 public consultation comments submitted), the rapporteurs prepared the revised draft opinion which was submitted for SEAC comments in May (four comments received from SEAC members during the written commenting round). No final Forum advice has been submitted (i.e. the draft Forum advice can be considered as final).

The RAC co-rapporteur was invited to report back from RAC-33 discussions, where RAC had adopted its opinion. The focus of the RAC discussions had mainly concentrated on the derogations proposed by the public consultation, where RAC agreed not to include the derogation for automotive vehicles.

The SEAC rapporteurs then presented the revised draft opinion to the Committee, more specifically on recycling and proposed derogations. The rapporteurs considered that the arguments for the derogation proposed for the aviation sector were plausible. With regard to the derogation for the automotive sector the rapporteurs concluded that more information would be needed as no data on costs or emissions had been received from the industry via the public consultation and due to the higher tonnage used compared to the aviation industry. The Secretariat informed the Committee that some additional cost information was provided by the automotive industry prior to the meeting, and that the stakeholders would be asked to submit the information in the public consultation on the SEAC draft opinion. In relation to the recycling issue, the rapporteurs considered there is no sufficient evidence to justify derogation for recycling.

SEAC continued its discussions on the revised draft opinion in an ad hoc group who reported back to the plenary next day with some further modifications to the opinion.

SEAC agreed with the rapporteurs' proposal to include a specific public consultation question regarding the automotive sector to ask further information from the industry before concluding on derogation. In addition, despite no information on recycling had been received via public consultation, one member informed that additional studies regarding recycling should be taken into account. He reserved his right to come back to the derogation for recycling sector later on in the opinion development. Consequently, SEAC agreed also to include a question regarding recycling into the public consultation on the SEAC draft opinion.

Furthermore, taking into account the SEAC discussions on the cost-effectiveness of the proposed restriction and the qualitative arguments presented by the rapporteurs, SEAC concluded that the proposed restriction is a proportionate measure to minimise the emissions of decaBDE.

SEAC agreed its draft opinion on the dossier on decaBDE by consensus. It was agreed that the rapporteurs, together with the Secretariat, will make the final editorial changes to the agreed draft opinion and will 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 Secretariat will launch the 60-day public consultation on the SEAC draft opinion on 17 June 2015.

## 4) PFOA – first draft opinion

The Chairman welcomed the dossier submitters' representatives (Germany and Norway), the RAC rapporteur (following via WebEx) and an industry expert accompanying a stakeholder observer. The Chairman reminded the Committee that the dossier on Perfluorooctanoic acid (PFOA) was submitted by Germany jointly with Norway in October 2014. The dossier submitters propose a restriction on manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances. The Chairman informed the participants that the draft opinion prepared by the (co-)rapporteurs was made available to SEAC on 7 May and comments were received from four SEAC members in the following written consultation.

The RAC rapporteur was invited to briefly update SEAC on the discussions on this dossier held within RAC-33.

The SEAC (co-)rapporteurs then presented their draft opinion to the Committee. They were interested in the views of SEAC members regarding whether they agree with the general approach to cost calculation, which approach to use for costeffectiveness of PFOA-related substances, whether "Weight of Evidence" approach is consistent with the approach for PBTs agreed by SEAC and whether they agree with the current status of foreseen derogations (especially recycling and secondhand articles). One member questioned the need for derogations for recycling and second-hand market and compared this restriction with decaBDE, where such derogations have not been established. The rapporteurs proposed to finalise discussion on derogations later, after the ongoing public consultation has ended (also the concentration limit is proposed to be fixed after knowing the final results of the public consultation). An industry expert explained that if Europe wants an efficient restriction, it should include in the scope what has been included now. The major source is treated textiles coming from Far East – the easiest way to cover them would be to set a concentration limit at low level. The vast majority of textile industry in Europe has already switched to alternatives from C8 to C6.

One SEAC member said that in his view this restriction has not been demonstrated to be proportionate. The rapporteurs responded that they would welcome clear advice by the Committee on how to provide sufficient reasons for the proportionality of the restriction. However, the rapporteurs will try to apply some of the approaches taken in the decaBDE opinion.

The Commission observer was interested in the view of industry towards an openended list of substances. The industry expert responded that they would not like to have an open-ended list. 'He also said that the proposed limit value (2ppb) could prevent the use of some C6 alternatives since PFOA or PFOA-related substances might be present as impurities at higher levels – they therefore have requested a derogation for this, as otherwise the production would need to move outside Europe. The rapporteurs confirmed that they will try to solve this issue by moving the concentration limit higher.

The Chairman summarised that the Committee takes note of the support by industry towards this restriction and also different views among members on how to deal with uncertainties in the dossier. The (co-)rapporteurs were asked to prepare the revised draft opinion, taking into account the SEAC-27 discussions and the results of the public consultation, by early August (for discussion and agreement at SEAC-28).

#### 5) Methanol -key issues document

The Chairman welcomed the dossier submitter representative from Poland and the RAC rapporteur, who followed the meeting remotely via WebEx. The Committee was informed that the Key Issues Document was made available on 11 May and that the SEAC commenting round finished on 22 May, with no comments received from SEAC members. SEAC is invited to give their view on the key issues identified by the rapporteurs of the restriction proposal of methanol, submitted by Poland. The Committee is expected to provide sufficient feedback to enable the rapporteurs to formulate a draft opinion.

The SEAC rapporteur then presented the key issues identified. SEAC agreed with the proposed approach to collect further information from the MSCAs regarding the national legislation in place affecting the supply of methanol to the general public and how this legislation will be affected if any by the entering into force of the CLP classification of mixtures as of 1 June 2015. This information is intended to be used to define the baseline which in turn allows the assessment of cost and benefits of the restriction in the different EU countries.

Concerning the identified key issue on the lack of data to analyse the role of methanol in denaturated alcohol, the Secretariat mentioned that in light of upcoming new EU legislation, it needs to be assessed, whether this might affect the scope of denaturated alcohol in the restriction proposal.

SEAC supported the approach that in case the market information for further cost calculations at EU level does not become available, to describe the baseline based on the available data from Finland and Poland and taking into account available information at EU level regarding e.g.: 1) market of methanol, 2) average winter temperatures, 3) population, and 4) vehicles per capita (and applying some simplifying assumptions). One member informed that additional data on the use of methanol could be available from the Czech Republic where the use of methanol cause 42 deaths in 2012 and was invited to provide the data to the rapporteurs.

In summary, SEAC agreed on the main elements presented by the rapporteurs. The Chairman informed that the rapporteurs will need to deliver their first draft opinion on this dossier by early August 2015 (to be discussed at SEAC-28). The Chairman encouraged SEAC members to comment on the first draft opinion during the consultation round in advance of SEAC-28.

### b) Conformity check

## 1) D4/D5- outcome of the conformity check(and key issues presentation)

The Chairman welcomed the dossier submitter representatives from UK (following via WebEx). He informed the participants that the restriction dossier on D4/D5 had been submitted by UK on 17 April 2015. The conformity check procedure was launched in SEAC on 13 May and the (co-)rapporteurs' draft conformity check outcome was made available on 20 May. The SEAC commenting round finished on 25 May with no comments received from SEAC members. The Chairman informed the Committee that, as agreed at SEAC-26 in March, the Committee would be invited to discuss the key issues for further opinion development identified by the (co-)rapporteurs directly after the agreement on conformity.

The dossier submitter representative provided a brief introductory presentation on the dossier. Both D4 and D5 have PBT/vPvB properties and MSC has recently provided an opinion that both substances are vPvB. The restriction proposal is aimed specifically at reducing emissions to the aquatic environment and is targeted on uses that lead to the greatest waste water emissions according to the registration CSRs. The dossier proposes that D4 and D5 shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions.

The RAC rapporteur was then invited to briefly present the outcome of the RAC conformity check to SEAC. RAC had agreed at RAC-33 that the dossier is in conformity with Annex XV requirements.

The SEAC (co-)rapporteurs presented the outcome of the conformity check and the recommendations to the dossier submitter and informed the Committee that the dossier can be considered in conformity from the SEAC point of view. The Committee agreed that the dossier conforms to Annex XV requirements.

The rapporteurs were then invited to present the key issues identified by them in the dossier. According to the rapporteurs, overall the dossier is well-written and contains a solid and thorough analysis (Annex F), where most cost elements are quantified and multiple approaches are used for assessing proportionality, including a specific willingness to pay (WTP) study.

After a brief discussion, the Chairman informed the Committee that the public consultation on the Annex XV report will be launched on 18 June and the first draft

opinion should be prepared by the rapporteurs by early August (replacing the previous key issues document).

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

The Secretariat presented the members who volunteered for SEAC (co-) rapporteurships for the restriction dossiers on Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2-ethylhexyl) phthalate (DEHP) (to be submitted by ECHA). SEAC agreed on the pool of (co-)rapporteurs as outlined in the meeting document SEAC/27/2015/05 RESTRICTED.

## 6) Authorisations

### 6.1) General authorisation issues

The Chairman invited a representative of the Secretariat to present the summary and the observations of the RAC and SEAC draft opinions on the 13 applications for authorisation for the 19 uses of trichloroethylene. The Secretariat focused on the consistency with the use of standard phrases' catalogue, the new templates as well as earlier access to the incoming application for the rapporteurs. Members welcomed and supported the improvements in the opinion making.

Furthermore, the Secretariat informed SEAC about the big peak of the incoming applications for authorisation in the November 2015 and February 2016 submission windows. The Secretariat also informed the Committee about four new applications for authorisation submitted within the May submission window.

## 6.2) Authorisation applications

## a) Authorisation applications – third version of SEAC draft opinion

1) Trichloroethylene 12:

<u>Use 1</u>: Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

The Chairman introduced the application for authorisation. He reminded members that at the previous meeting, SEAC discussed the first version of the SEAC draft opinion and in the following period the rapporteurs have prepared the second version of the SEAC draft opinion, taking into account the SEAC-26 discussions and the views expressed in RAC. The SEAC members were asked to consider the agreement on the SEAC draft opinion at this plenary.

The Secretariat updated the Committee on the discussions held at RAC-33, where RAC had agreed on the draft opinion by consensus. The SEAC rapporteurs then presented the second version of the draft opinion to the Committee.

Following the discussion in the Committee, the Chairman asked members whether they agree on the draft opinion as proposed by the rapporteurs. SEAC agreed on the draft opinion by a simple majority, with two members expressing minority positions. The rapporteurs, together with the Secretariat, will finalise the editorial checking of the draft opinions. The Secretariat will send the combined RAC and SEAC draft opinion to the applicant for their possible comments. The Chairman thanked the rapporteurs for their efficient and thorough work.

## b) Authorisation applications – first version of SEAC draft opinion

1) Lead chromate 1:

<u>Use 1:</u> Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection

The Chairman introduced the application for authorisation. At the previous meeting, SEAC agreed on the conformity of the application and discussed the key issues, as presented by the rapporteurs. The SEAC members were asked to consider the agreement on the SEAC draft opinion at this plenary.

The SEAC rapporteurs presented the first version of the SEAC draft opinion. The Committee agreed with the conclusions of the rapporteurs that SEAC had no reason to disagree with the applicant stating that substitution was not possible, as no alternative substance, mixture or technology, which fulfilled all the needed characteristics and which would be available and feasible had been identified. The Committee also discussed the quality of the submitted data and the socio-economic analysis by the applicant.

The Committee discussed the length of the review period in the light of the RAC recommendation and then agreed on the draft opinion by consensus. The Chairman thanked the rapporteurs for their efficient and thorough work.

#### c) Authorisation applications – report from RAC discussion

1) Trichloroethylene 2a:

<u>Use 1</u>: Use of Trichloroethylene in industrial parts cleaning by vapour degreasing in closed systems where specific requirements (system of use-parameters) exist <u>Use 3</u>: Use of trichloroethylene in packaging

<u>Use 4</u>: Use of trichloroethylene in formulation

The Secretariat informed SEAC about the outcome of the discussion at the RAC-33 plenary meeting. Regarding use 1 the Secretariat highlighted that RAC is of the view that a more than normal review period would seem inappropriate. Furthermore, RAC considered that the risk estimates for man via environment as provided by the applicant are overestimated. SEAC considered that these points alone were insufficient to reopen the discussion on this use butthat following the potential comments received by the applicant on the draft opinion the Committee will reconsider the need to reopen the discussion.

With regard to uses 3 and 4, RAC did not propose any recommendations to SEAC regarding the review period. The refinement of some aspects in the RAC draft opinion (excess risk numbers and estimated statistical cancer cases) was judged to have very little or no effect on the monetised risk estimates prepared for the SEAC draft opinions. The rapporteurs were of the view that there is no need to reopen the SEAC discussion on the draft opinions for these uses. This view was supported by SEAC.

The Secretariat will send the combined RAC and SEAC draft opinions to the applicant for their possible comments. The Chairman thanked the rapporteurs for their efficient and thorough work.

2) Trichloroethylene 2b:

<u>Use 1</u>: Use of trichloroethylene in formulation <u>Use 2</u>: Use of trichloroethylene in packaging

The Secretariat informed SEAC about the outcome of the RAC discussion. RAC did not propose any recommendations to SEAC regarding the review period. The refinement of some aspects in the RAC draft opinion (excess risk numbers and estimated statistical cancer cases) was judged to have very little or no effect on the monetised risk estimates prepared for the SEAC draft opinions. The rapporteurs were of the view that there is no need to reopen the SEAC discussion on the draft opinions for these uses. This view was supported by SEAC.

The Secretariat will send the combined RAC and SEAC draft opinions to the applicant for their possible comments. The Chairman thanked the rapporteurs for their efficient and thorough work.

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

The pool of rapporteurs, as outlined in the amended restricted room document SEAC/28/2015/06\_rev.1, was agreed by SEAC.

## 8) AOB

## a) Update of the workplan

The Secretariat provided an update of the workplan for the future months.

## b) Report from the Dutch PBTs project

The Chairman invited the advisors of the Dutch SEAC member to present the final results within their project plan on 'Development of a benchmark applicable for the SEAC approach to evaluate restriction proposals and authorisation applications for PBT/vPvB substances'.

The Chairman invited SEAC to discuss the preliminary results and members were asked to send their comments on the draft report by 19 June. Taking into account the comments received, the Dutch project group will finalise the report in July. The final report will be distributed to SEAC.

## c) Extension of the mandate of PBT working group

The Chairman proposed to the Committee to extend the mandate of the SEAC PBT working group until the end of 2015. After the June plenary, the SEAC PBT working group will evaluate the results of the Dutch benchmarking project and collect feedback from SEAC members on how the framework has worked with the

ongoing/past PBT-cases and see if this framework should be updated. SEAC agreed with this extension.

## 9) Action points and main conclusions of SEAC-27

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

#### **MAIN CONCLUSIONS & ACTION POINTS** SEAC-27, 8-11 June 2015

(Adopted at SEAC-27 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the agenda	
The agenda was adopted without modifications.	<b>SECR</b> to upload the adopted agenda to SEAC CIRCABC IG as part of the meeting minutes.
3. Declarations of conflicts of interest to the Age	nda
Conflicts of interest have been declared and will be taken to the minutes.	
4. Report from other ECHA bodies and activities	
a) Report on SEAC-26 action points, written procedu	Ires and other ECHA bodies
SEAC was informed on the status of the action points of SEAC-26. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/27/2015/01), including the oral report from the Commission on SEAC related developments in the REACH Committee.	
In addition, SEAC took note of the update from the Commission project on assessing competitiveness, innovation and SMEs impact in the context of Socio-economic analysis under REACH (i.e. SEA toolkit).	
b) General SEAC procedures	
SEAC agreed on the revised general approach on the admission of accredited stakeholder organisations to SEAC (closed session).	<ul> <li>SECR to inform the other ECHA Committees on the SEAC decision and publish the revised document on the ECHA website.</li> <li>SECR to apply the revised procedure and propose an updated list of SEAC stakeholders for the agreement of SEAC in SEAC-28.</li> </ul>
SEAC agreed on the proposed required competences and the selection procedure for co-opting additional members to SEAC.	
Furthermore, SEAC agreed on the revised Rules of Procedure of the Committee for Socio-economic Analysis. Dissenting views will be reflected in the minutes.	<b>SECR</b> to inform the Management Board on the agreement of SEAC on the proposed revised Rules of Procedures.
5. Restrictions	
5.1 General restriction issues	

5.2	Restriction Annex XV dossiers	
a)	Opinion development	
1)	Ammonium salts – final opinion	
opir on t SEA salt	AC rapporteurs presented the SEAC final nion and the results of the public consultation the SEAC draft opinion. AC adopted its final opinion on the Ammonium as dossier by simple majority. The minority w will be reflected in the minutes.	<ul> <li><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the adopted SEAC fin opinion.</li> <li><b>SECR</b> to forward the adopted opinion and i annexes to COM and publish it on the ECH website.</li> </ul>
2) Isopropylidenediphenol (Bisphenol A) – revised draft opinion		
	AC rapporteurs presented and SEAC discussed revised SEAC draft opinion.	<b>SECR</b> to arrange a written commenting rour on the revised SEAC draft opinion before the September plenary meeting.
3) DecaBDE – revised draft opinion		
the SEA dos	AC rapporteurs presented and SEAC discussed revised SEAC draft opinion. AC agreed on the draft opinion on decaBDE sier by consensus (with modifications oduced during SEAC-27).	<ul> <li><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC dramopinion.</li> <li><b>SECR</b> to launch a public consultation on the SEAC draft opinion in June 2015. Two public consultation questions will be included of possible derogations for recycling and automotive industry.</li> </ul>
4) Perfluorooctanic acid (PFOA) - first draft opinion		
	AC rapporteurs presented and SEAC discussed first draft opinion.	<b>Rapporteurs</b> to prepare the revised SEA draft opinion, taking into account the SEAC-2 discussions and the results of the publiconsultation, by early August.
5)	Methanol – key issues document	
the	AC rapporteurs presented and SEAC discussed key issues document for the SEAC draft nion.	<b>Rapporteurs</b> to prepare the first SEAC dra opinion, taking into account the SEAC-2 discussions, by early August.

1) D4/D5 – outcome of the conformity check (and key issues presentation)		
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 to CIRCABC IG.	
SEAC took note of the recommendations to the dossier submitter.	<b>SECR</b> to inform the dossier submitter on the outcome of the conformity check.	
SEAC rapporteurs presented and SEAC discussed the key issues for the SEAC draft opinion.	<b>Rapporteurs</b> to prepare the first SEAC draft	
	opinion, taking into account the SEAC-27 discussions, by early August.	
5.3 Appointment of (co-)rapporteurs for restriction dossiers		
SEAC agreed on the pool of (co-)rapporteurs for the Diisobutyl phthalate (DIBP), Dibutyl phthalate (DBP), Benzyl butyl phthalate (BBP), Bis(2- ethylhexyl) phthalate (DEHP) restriction proposal (as presented in the restricted meeting document SEAC/27/2015/05).	<b>SEAC members</b> to volunteer to the pool of (co-)rapporteurs for the restriction proposal.	
6. Authorisations		
6.1 General authorisation issues		
SEAC took note of the presentation by the Secretariat on the overview of trichloroethylene applications. Furthermore, SEAC took note of the update on the		
applications received within the May/June 2015 submission window.		
6.2 Authorisation applications		
a) Authorisation applications – third version of the SEAC draft opinion		
1. TCE 12:		
SEAC rapporteurs presented and SEAC discussed the third version of the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion.	
SEAC agreed on the draft opinion by simple majority. The minority views will be reflected in the minutes.	<b>SECR</b> to send the draft opinion to the applicant for commenting.	
b) Authorisation applications – first version of the	SEAC draft opinion	
1. Lead chromate 1		
SEAC rapporteurs presented and SEAC discussed the first version of the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion.	
SEAC agreed on the draft opinion by consensus.	<b>SECR</b> to send the draft opinion to the applicant for commenting.	
c) Authorisation applications – report from RAC di	scussion	
1. TCE 2a uses 1, 3 and 4		
	<b>SECR</b> to send the draft opinions to the applicant for commenting.	

2. TCE 2b uses 1 and 2		
SEAC took note of the RAC discussions on TCE 2a (uses 1, 3 and 4) and TCE 2b (uses 1 and 2) applications for authorisation.		
SEAC agreed that no modifications (except minor editorial modifications) are needed to the SEAC draft opinions on the applications for authorisation.		
6.3 Appointment of (co-)rapporteurs for autho	risation applications (closed session)	
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with SEAC/27/2015/06 RESTRICTED room document).	<ul> <li>SEAC members to volunteer to the pool of (co-)rapporteurs for applications for authorisation.</li> <li>SECR to upload the updated document to confidential folder on CIRCABC IG.</li> </ul>	
8. AOB 8.b) Report from the Dutch PBT project		
SEAC took note of the presentation on the final report from the Dutch PBT project.	<b>SEAC members</b> to provide comments on the PBT project via the CIRCABC Newsgroup by 19 June 2015.	
8.c) Extension of the mandate of PBT working gr	oup	
SEAC discussed and agreed to extend the mandate until the end of 2015.		
9. Action points and main conclusion of SEAC-27		
SEAC adopted the action points and main conclusions of SEAC-27.	<b>SECR</b> to upload the action points and main conclusions to CIRCABC IG.	

## **III. List of Attendees**

#### SEAC-27

SEAC members	Advisors, invited experts & dossier submitters (DS)
ALEXANDRE Joao	ANTHON Signe (advisor to L. Fock)
BERGS Ivars	BERNHEIM Theresa (advisor to K. Thiele)
BOUSTRAS George	BROUWER Roy (invited expert, NL)
BRIGNON Jean-Marc	CASTELLI Stefano (advisor to F. D'Amico)
COGEN Simon	CORRELL MYHRE Ingunn, KOPANGEN Marit, HUSE Stina [Norway], and STARKE Sue Martina, STAUDE Claudia, BIEGEL-ENGLER Annegret and NIEDERSTRAβER Bernd [Germany] (DS representatives for PFOA restriction dossier, via WEBEX)
CSERGŐ Robert	FEYAERTS Jean-Pierre (advisor to S. Cogen, via WEBEX)
D'AMICO Flaviano	DELCOURT Benjamin (advisor to C. Dantinne)
DANTINNE Catheline	FAYAERTS Jean-Pierre (advisor to S. Cogen)
DOUGHERTY Gary	FOTLAND Tor Øystein, TOLFSEN Christina Charlotte and KOPANGEN Marit (experts for decaBDE restriction dossier, via WEBEX)
FANKHAUSER Simone (via WEBEX)	KOPANGEN Marit, FOTLAND Tor Øystein and TOLFSEN Christina (Norwegian Environment Agency, via WEBEX – as experts for decaBDE restriction dossier)
FIORE Karine (also DS representative for BPA restriction dossier)	LE COQ Pierre (DS representative for Inorganic ammonium salts restriction dossier, via WEBEX)
FOCK Lars	GODALA Mariusz (DS representative for Methanol restriction dossier, via WEBEX)
FURLAN Janez	MARTIN Sara (DS representative for D4/D5 restriction dossier, via WEBEX)
GEORGIOU Stavros (also DS representative for D4/D5 restriction dossier)	MARTINUSSEN SNEVE Marie (advisor to T.M. Sletten)
GRANDI Silvia (via WEBEX)	OLTEANU Maria (invited expert, RO)
KAJIĆ Silva	RASMUSSEN BAAD Louise (advisor to L. Fock)
KIISKI Johanna	RYDLEWSKA-LISZKOWSKA Izabela (invited expert, PL)
KNOFLACH Georg	URBAN Klaus (invited expert, replacing SEAC member F.G. Simon)
KRAJNC Karmen	VERHOEVEN Julia and OOSTERHUIS Frans (in person), JONGENEEL Rob and LUIT Richard (via WEBEX) (advisors to C. Luttikhuizen)
LOČS Jãnis	
	DAC (co.) romortouro
LUTTIKHUIZEN Cees	RAC (co-)rapporteurs
LÜDEKE Andreas	DUNAUSKIENE Lina
LÜDEKE Andreas	DUNAUSKIENE Lina DUNGEY Stephen (via WEBEX, also DS
LÜDEKE Andreas MEXA Alexandra	DUNAUSKIENE Lina DUNGEY Stephen (via WEBEX, also DS representative for D4/D5 restriction dossier)
LÜDEKE Andreas MEXA Alexandra NARROS SIERRA Adolfo	DUNAUSKIENE Lina DUNGEY Stephen (via WEBEX, also DS representative for D4/D5 restriction dossier) LUND Bert-Ove (via WEBEX)
LÜDEKE Andreas MEXA Alexandra NARROS SIERRA Adolfo NICOLAIDES Leandros	DUNAUSKIENE Lina DUNGEY Stephen (via WEBEX, also DS representative for D4/D5 restriction dossier) LUND Bert-Ove (via WEBEX) KADIĶIS Normunds (via WEBEX)
LÜDEKE Andreas MEXA Alexandra NARROS SIERRA Adolfo NICOLAIDES Leandros PALOTAI Zoltán	DUNAUSKIENE Lina DUNGEY Stephen (via WEBEX, also DS representative for D4/D5 restriction dossier) LUND Bert-Ove (via WEBEX) KADIĶIS Normunds (via WEBEX) NEUMANN Michael (via WEBEX)
LÜDEKE Andreas MEXA Alexandra NARROS SIERRA Adolfo NICOLAIDES Leandros PALOTAI Zoltán PÍŠKOVÁ Martina	DUNAUSKIENE Lina DUNGEY Stephen (via WEBEX, also DS representative for D4/D5 restriction dossier) LUND Bert-Ove (via WEBEX) KADIĶIS Normunds (via WEBEX) NEUMANN Michael (via WEBEX)

STOYANOVA-LAZAROVA Elina Velinova

THIELE Karen (also DS representative for PFOA restriction dossier) THORS Åsa

#### Commission observers BENGYUZOV Manol (DG GROW)

GALLEGO Mateo (DG ENV)

BERTATO Valentina (DG GROW)

FERNANDES DE BARROS Mariana (DG GROW, via WEBEX)

LUVARA` Giuseppina (DG GROW, via WEBEX)

PROKES Pavel (DG GROW, via WEBEX) ROZWADOWSKI Jacek (DG GROW, via WEBEX)

STRECK Georg (DG GROW, via WEBEX)

#### Stakeholder observers and accompanying experts

HAIDER Sonja (EEB)

HUESTEBECK Ken (CLIENT EARTH)

HOLLAND Michael (EAERE)

JANOSI Amaya (CEFIC)

MUSU TONY (ETUC)

VANDER STRAETEN Michel (EUROMETAUX)

BOCK Ronald (Chemours (DuPont), FluoroCouncil representative), accompanying CEFIC observer -PFOA restriction dossier MICHAUX Michel (Brominated Compounds

Consortium), accompanying CEFIC observer -DecaBDE restriction dossier VERBIESE Nicole (Reconsile), accompanying

CEFIC observer – D4/D5 restriction dossier

#### ECHA staff

BERGES Markus BLAINEY Mark HENNIG Philipp HENRICHSON Sanna JACQUEMIN Katline KANELLOPOULOU Athanasia KIOKIAS Sotirios KIVELÄ Kalle KOSK-BIENKO Joanna KOSTIKA Ismini Polyxeni LEGZDIŅA Ilze LIOPA Elīna LOGTMEIJER Christiaan LUDBORŽS Arnis MAZZOLINI Anna

MERKOURAKIS Spyridon

NICOT Thierry

ORISPÄÄ Katja ÖBERG Tomas

PELTOLA Jukka

RODRIGUEZ IGLESIAS Pilar

ROGGEMAN Maarten

SADAM Diana

SHUQOM Natasha

SIMPSON Peter

STOYANOVA Evgenia

VAINIO Matti

VAN HAELST Anniek

#### **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 Agenda

#### Documents submitted to the members of the Committee for Socioeconomic Analysis

Final Draft Agenda	SEAC/A/27/2015
Report on SEAC-26 action points, written	SEAC/27/2015/01
procedures and other ECHA bodies (AP 4.a)	
Revised Rules of Procedure of the Committee for	SEAC/27/2015/02
Socio-economic Analysis	
General RAC/SEAC procedures:	SEAC/27/2015/03
Revised general approach for admission of	RESTRICTED
accredited stakeholder organisations to RAC and	
SEAC (AP 4b)	
Appointment of co-opted members to RAC and	SEAC/27/2015/04
SEAC (AP 4b)	
Appointment of (co-)rapporteurs for restriction	SEAC/27/2015/05
dossiers (AP 5.3)	RESTRICTED
Appointment of (co-)rapporteurs for	SEAC/27/2015/06
authorisation applications (AP 6.3)	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):

Name of participant	Agenda item	Interest declared
BERNHEIM Teresa	5.2a-4 PFOA	Working for the MSCA submitting the restriction dossier
BRIGNON Jean-Marc	5.2a-2 Bisphenol A 5.2a-1 Ammonium salts	Participation in the preparation of both restriction dossiers
CSERGŐ Robert	6.2a-1 Trichloroethylene 12	Previous position of MSCA in REACH Committee in favour of a longer sunset date for TCE
DOUGHERTY Gary	5.2b-1 D4/D5	Working for the MSCA submitting the restriction dossier
FIORE-TARDIEU Karine	5.2a-2 Bisphenol A 5.2a-1 Ammonium salts	Working for the MSCA submitting the restriction dossiers
GEORGIOU Stavros	5.2b-1 D4/D5	Working for the MSCA submitting the restriction dossier
HOLLAND Michael	5.2b-1 D4/D5	Participation in the preparation of the restriction dossier
KIISKI Johanna	5.2a-5 Methanol	Participation in the preparation of the restriction dossier
MARTINUSSEN SNEVE Marie	5.2a-3 DecaBDE	Participation in the preparation of the restriction dossier
	5.2a-4 PFOA	Working for the MSCA submitting the restriction dossier
SLETTEN Thea Marcelia	5.2a-3 DecaBDE	Participation in the preparation of the restriction dossier
	5.2a-4 PFOA	Working for the MSCA submitting the restriction dossier
THIELE Karen	5.2a-4 PFOA	Participation in the preparation of the restriction dossier



## Final Agenda

## 27<sup>th</sup> meeting of the Committee for Socio-economic Analysis

## 8-11 June 2015 ECHA Conference Centre (Annankatu 18, Helsinki) 8 June: starts at 14:00 11 June: ends at 17:30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/27/2015 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-26 action points, written procedures and other ECHA bodies

SEAC/27/2015/01 For information

b) General SEAC procedures

SEAC/27/2015/02 SEAC/27/2015/03 (restricted document) SEAC/27/2015/04 For discussion and agreement

#### Item 5 – Restrictions

**5.1 General restriction issues** 

For information

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

- a) Opinion development
  - 1) Ammonium salts final opinion

	2)	Isopropylidenediphenol (Bisphenol A) – revised draft opinion	
			For agreement
	3)	DecaBDE - revised draft opinion	<b>F</b>
			For agreement
	4)	Perfluorooctanic acid (PFOA) – first d	raft opinion <b>For discussion</b>
			FOF discussion
	5)	Methanol - key issues document	For discussion
			FOI discussion
b)	Confo	mity check (and key issues presentat	ion)
	1)	D4/D5	
		F	or agreement and discussion

5.3 Appointment of (co-)rapporteurs for restriction dossiers SEAC/27/2015/05 (restricted document) For agreement

#### Item 6 – Authorisations

#### 6.1 General authorisation issues

For discussion

#### 6.2 Authorisation applications

- a) Authorisation applications third version of SEAC draft opinion
  - 1. The use of trichloroethylene submitted by *Chimcomplex SA Borzesti* (Trichloroethylene 12):

<u>Use 1</u>: Industrial use of trichloroethylene as a solvent as a degreasing agent in closed systems

#### For agreement

- b) Authorisation applications first version of SEAC draft opinion
  - 1. Lead chromate 1: submitted by Etienne Lacroix Tous Artifices SA

<u>Use 1</u>: Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection

#### For agreement

- c) Authorisation applications report from RAC discussion
  - 1. Three (of five) uses of trichloroethylene submitted by *DOW Deutschland Anlagengesellschaft mbH* (Trichloroethylene 2a):

<u>Use 1</u>: Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist <u>Use 3</u>: Use of tricholoroethylene in packaging

Use 3: Use of tricholoroethylene in packaging

- Use 4: Use of tricholoroethylene in formulation
- 2. Two uses of trichloroethylene submitted by *Richard Geiss GmbH* (Trichloroethylene 2b):

Use 1: Use of Trichloroethylene in formulation

<u>Use 2</u>: Use of tricholoroethylene in packaging

For information

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

SEAC/27/2015/06 (restricted room document) For agreement

Item 7 – Capacity building on SEA

#### Item 8 – AOB

- a) Update of the work plan
- b) Report from the Dutch PBT project

For information

c) Extension of the mandate of the PBT working group

For agreement

#### Item 9 – Action points and main conclusions of SEAC-27

Table with Conclusions and Action points from SEAC-27

For adoption