

**Final**

**Minutes of the 14<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**13-15 March 2012**

## **I. Summary Record of the Proceeding**

### **1) Welcome and apologies**

Mr Tomas Öberg, recently appointed Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, introduced himself and welcomed the participants of the fourteenth meeting of SEAC.

The Chair informed the Committee that apologies had been received from eight members, two invited experts, two international observers, three stakeholder observers, one European Commission observer and two RAC co-rapporteurs. Three invited experts, members' advisors present at the meeting as well as an observer of the European Commission, observers of five stakeholder organisations and two dossier submitter representatives were introduced. The Chair informed the Committee that two SEAC members, two advisors, two European Commission observers and two RAC rapporteurs were to follow the relevant parts of the meeting via teleconference. The Chair also mentioned that the meeting would be recorded and the records would be destroyed after the adoption of the minutes.

The list of attendees is given in Part III of the minutes.

### **2) Adoption of the Agenda**

The Chair introduced the draft Agenda of SEAC-14. The following suggestion for an additional item to discuss under AOB was made at the meeting:

- Dutch environmental impact assessment.

The Agenda was adopted with the modification mentioned above (SEAC/A/14/2011\_rev.1). The final Agenda is attached to these minutes as Annex III. The list of all meeting documents is attached to these minutes as Annex I.

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

The Chair requested members and their advisors to declare any conflicts of interest to any of the specific agenda items. One member and one advisor declared potential conflicts of interest to the substance-related discussions under the agenda items 7.2. These members did not participate in voting on 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) Administrative issues**

#### **a) Changes in the SEAC composition**

The Chair informed the Committee that since the last SEAC meeting, the following members had joined the Committee:

Portugal	ALEXANDRE Joao
Romania	CSERGO Robert

#### **b) Outcome of written procedures**

The Chair informed the Committee that the appointment of (co-)rapporteurs for 1,4-Dichlorobenzene restriction dossier had been agreed by consensus. He also informed the participants that the final SEAC-13 minutes had been adopted by SEAC by consensus.

## **c) Results of the satisfaction survey**

The Secretariat reported on the results of the satisfaction survey for 2011. From SEAC, 15 out of 29 members and one stakeholder observer responded to the questionnaire. Most of the respondents were satisfied with the support provided by the Secretariat but they gave some additional comments concerning further improvement.

One member suggested that those Committee members who normally do not participate in the discussions actively should also be encouraged to become more active. The Chair replied that it is indeed important for such committees to make everyone active and that the members' suggestions on this issue would be appreciated. Another member pointed out that over the past few years respondents seem to be becoming less satisfied, and asked whether the Secretariat plans to develop some ideas as to how to increase the level of satisfaction. The Secretariat will analyse the results of the survey further and consider further actions to improve the support provided to the Committees. One stakeholder observer appreciated the degree of transparency in this Committee.

## **How to fill the updated Annex 2 – Declaration of Interest form**

The Chair informed SEAC of the renewal of annual declarations based on the new declaration of interest template agreed by SEAC at SEAC-13 and included in the Rules of Procedure adopted by the ECHA Management Board on 31 January 2012. The process of renewal of the members' declarations was launched on 6 March 2012. The new declaration of interest was presented and clarified further in detail by the Secretariat. The Chair invited the SEAC members to fill in and return the signed forms to the Secretariat in the margins of the plenary or latest by 31 March 2012.

## **5) Status report of the action points of SEAC-13**

The Chair informed the Committee that all action points of the SEAC-13 meeting had been completed.

## **6) Feedback from other bodies and activities**

The Chair explained that a report covering the developments in the ECHA Management Board, the Committee for Risk Assessment (RAC), the Member States Committee (MSC) and the Forum had been compiled and distributed to the Committee as a meeting document (SEAC/14/2012/01). Oral reports of the RAC-20 meeting (6-9 March 2012) and the Forum-11 meeting (28-29 February 2012) were then provided by the Secretariat.

One member suggested, and the Secretariat agreed, to consider including updates from other relevant EU bodies (e.g. Article 133 Committee and CARACAL) in the report from now on.

## **7) Restrictions**

### **7.1) General restriction issues**

#### **a) Update on intended restriction dossiers**

The Secretariat informed the Committee about two intentions currently included in the Registry of Intentions: 1,4-Dichlorobenzene (DCB) prepared by ECHA (submission foreseen in April 2012) and Nonylphenol (three substances in one dossier) prepared by Sweden (submission foreseen in August 2012 but with information on possible delay).

#### **b) Update on the review of the restriction process**

Under this agenda point, a brief introductory presentation was first given by the Secretariat. The Secretariat reminded the Committee that the revision of the restriction process had been quite extensively discussed in the margins of the previous SEAC-13 meeting. Three break-out groups had been organised with the involvement of two RAC members (on conformity check, on issues related to opinion development and on

Background Document). A report summarising the discussions had been compiled and distributed to both RAC and SEAC at the end of January 2012. The Secretariat also recalled that it had been agreed at SEAC-13 that a group of volunteers would be established to discuss the revision of the restriction process further. The informal joint RAC-SEAC group held a teleconference meeting on 15 February 2012 and their suggestions have been provided in the meeting documents distributed for this agenda point.

- **Prioritisation of recommendations during the conformity check**

The Secretariat presented the meeting document "Prioritisation of recommendations during the conformity check" (SEAC/14/2012/02). It was emphasised that the conformity check is only a technical and legal check of Annex XV requirements, while the recommendations document can give indications on what more may be needed by the Committee in order to facilitate it in issuing an opinion. It would also help to flag at an early stage areas that are vital for the dossier submitter to work on to increase possibilities to facilitate the Committee in issuing an opinion. The suggestions from the informal group regarding when and how to prioritise recommendations during the conformity check were presented. The group suggested having a tentative priority ordering prepared for the Committee meeting, leaving the final prioritisation for the rapporteurs to agree following the 1<sup>st</sup> rapporteurs' dialogue. The group also supported flexible case by case approach to the indication of priority levels.

Members emphasised that the priorities need to be communicated clearly and that it is of vital importance to have a good dialogue between the rapporteurs and the dossier submitter, so that the dossier submitter clearly understands the needs of the rapporteurs. One member asked whether the recommendations document would be prepared if the dossier is found not in conformity. The Secretariat responded that it would indeed be useful to prepare the recommendations document also for a non-conforming dossier and to communicate it to the dossier submitter.

The Chair concluded that the Secretariat would take note of the discussion and consider the appropriate way to document the conclusions. The update on any further work regarding the revision of the restriction process will be given at the next SEAC meeting in June 2012.

- **How to document an opinion not supporting the restriction proposal?**

The Secretariat presented the meeting document "How to document an opinion not supporting the restriction proposal?" (SEAC/14/2012/03). Different options for documenting an opinion not supporting the restriction proposal as well as the suggestions of the informal group were explained. The group had preferred an option of an opinion with the elaborated self-standing justification.

One member expressed the view that it should not be the task of the rapporteurs to change the Background Document (irrespective of whether an opinion is supportive or not), but it should rather be the task of the Secretariat, together with the dossier submitter, to align the Background Document to the opinion of the Committee.

One stakeholder observer representative pointed out that from the industry perspective it is important that each opinion is transparently explained and expressed support for the presented proposal (i.e. the observer supported the opinion with elaborated self-standing justification). He also emphasised that it is important to indicate where the Committee does not agree with the proposal.

The Chair concluded that the Secretariat would take note of the discussion and consider the appropriate way to document the conclusions. The update on any further work regarding the revision of the restriction process will be given at the next SEAC meeting in June 2012.

- **Revision of the restriction process in the Forum**

SEAC was informed about the revision of the restriction process in the Forum. Due to some difficulties experienced in processing of the first restriction dossiers and to improve the efficiency the Forum proposes to reduce the number of occasions when formal Forum advices is given to one. The formal Forum advice can be provided in the middle of the opinion forming process of RAC and SEAC (weeks 12-16) or at a later stage (just before

RAC or SEAC opinion). In both options, the Forum will be involved in the process from the beginning (from the start of the public consultation) and would informally advise the rapporteurs and the Committees. It was mentioned that the RAC members, to whom a similar presentation had been provided at the RAC-20 meeting, had been in favour of the second option.

The SEAC members also expressed preference for the second proposed option. They stressed the importance of informal co-operation and advice by the Forum to the rapporteurs and the Committees throughout the whole opinion forming process.

Finally, the Secretariat informed the Committee that the Forum Working Group on Enforceability of Restrictions is meeting on 21 March 2012 to finalise the revision of the guide for drafting the Forum advice and to agree on the option to revise the procedure for drafting the Forum advice. The final results will be communicated to both Committees.

- **Update on the project on improving the quality of future restriction dossiers**

The Secretariat provided an update on the project on improving the quality of future restriction dossiers as well as presented the follow-up actions (based on the meeting document SEAC/14/2012/04).

One member expressed support for the targeted approach and addressing only critical elements in the dossier, pointing out that some of the previous dossiers had been too long. The Secretariat explained that it is difficult to agree on the level of detail needed in the restriction reports and that the Secretariat is looking for ways to justify the targeting decisions. Another member asked whether something can be done to improve the lack of information and data in the dossier preparation. He suggested setting incentives to improve the ability of the dossier submitter to get more data (e.g. from industry). One SEAC member suggested a review of the whole restriction process and to consider how to improve it for every single step of the process.

The Chair concluded that the Secretariat would take note of the suggestions provided by members in its further work on improving the quality of dossiers.

- **Revised procedure for the appointment of (co-)rapporteurs for restriction dossiers**

The Secretariat presented the revised draft procedure for the appointment of (co-) rapporteurs for restriction dossiers. The purpose of the revision is to align the SEAC appointment procedure with the one for RAC. Elements that are new for SEAC were introduced.

One SEAC member recommended including a reference to the service contract under step h of the procedure – with this modification the procedure was agreed (SEAC/14/2012/08\_rev.1).

## **7.2) Restriction Annex XV dossiers**

### **a) Phthalates – 2nd version of SEAC draft opinion**

The (co-)rapporteurs gave a brief overview of the comments received from the SEAC members on the 1<sup>st</sup> version of the SEAC draft opinion, the 1<sup>st</sup> Forum advice, comments from the public consultation, and introduced the 2<sup>nd</sup> version of the SEAC draft opinion. The presentation was complemented by the report from RAC-20 discussions given by the Secretariat. The discussion on the issues raised took place in three plenary sessions and in three ad hoc working group meetings.

With regard to the costs assessment, the SEAC members observed that the **baseline** assuming authorisations granted for 1% of phthalates manufactured in EU needs to be improved so that it reflects more realistically potential industry authorisations. SEAC agreed on the need to refine the baseline by developing a set of scenarios implying plausible amount of phthalates in restricted articles on the market considering concurring effects of authorisation and import volumes. The dossier submitter agreed to calculate the costs on the basis of the new realistic scenarios with the support and guidance of the (co-)rapporteurs.

The quantification of the **reformulation costs** was found to be a priority by SEAC. Also one stakeholder observer suggested that these costs could be significant. The dossier submitter agreed to consult with some stakeholders to obtain information on the reformulation costs and the (co-)rapporteurs agreed to give necessary guidance to the dossier submitter. Members suggested that the results would be expressed as a percentage of raw material costs of given article groups. Reformulation costs born outside the EU are to be assumed to be passed onto importers in the EU. A stakeholder observer representative brought up also potentially significant wider economic impacts in relation to the supply of alternatives and production of phthalates precursors and higher substitution costs for SMEs.

Several SEAC members were questioning using the RoHs Directive as a basis for the estimates of the **administrative costs** for the restriction proposal at hand. SEAC therefore agreed that another assessment of administrative costs is needed. The documentation related to the restriction on phthalates in toys could provide relevant information.

SEAC agreed also that a **substitution scenario** with a basket of alternatives is needed. Such a scenario would give a more realistic picture of the impact of the proposal, both in terms of costs and benefits. SEAC agreed also on the need for a more thorough assessment of the impact of the proposal on **recycled PVC** and the associated costs.

With regard to benefits assessment, SEAC agreed that the information on the **costs of assisted reproductive treatments (ART)** is useful. Nevertheless, one member pointed out that ART costs are not the same as the willingness to pay (WTP) for reduction of the risk of infertility and care is needed when associating externalities with ART that may lead to overestimation in ART costs. These are rather a consequence of the treatment and not related to the impact concerned (infertility). Some members suggested that adoption costs and their relevance could be explored.

Participants questioned whether the aggregate **WTP** figures presented in the draft opinion were realistic and one member suggested a need to check the multiplier used with the unit WTP. The (co-)rapporteurs agreed to take into account other studies on WTP proposed by the SEAC members.

Several participants said that establishing a **link between the phthalates and infertility** would be important in order for the benefits assessment to be meaningful. SEAC suggested that if a quantitative link between phthalates and infertility cannot be made, it is important to have a qualitative and informative description of the severity and significance for society.

Besides reduced fertility, SEAC agreed that it is important to describe **other effects** of phthalates in the opinion and to seek at least qualitative assessment of the significance of those effects. The (co-)rapporteurs noted that the choice of reduced infertility as a basis for the benefits calculation mirrors RAC's agreement on the reprotoxicity as a relevant endpoint for this dossier.

The (co-)rapporteurs agreed to request the RAC rapporteurs to assist in quantifying and describing the link between phthalates and infertility and other health impacts as soon as possible.

SEAC exchanged their **views on the proposed restriction** with the assumption that no additional information would be available. The discussion confirmed the priorities for further work listed above.

SEAC discussed a new restriction proposal wording based on a total ban with general exemptions. Few comments with regard to clarity of the wording were made but overall no objections were expressed by members. One member suggested that the proposal should be checked for potential overlaps with the scope of the RoHs Directive. The SEAC members were invited to provide further comments on the new restriction proposal wording by 6 April 2012 via CIRCABC Newsgroup. The Secretariat would request the 2<sup>nd</sup>

Forum advice (to be requested no later than 16 March 2012) on the basis of the modified restriction proposal wording discussed at the meeting.

The dossier submitter agreed to address the recommendations of SEAC-14 with support of the (co-)rapporteurs. The dossier submitter should record the outcome of the work in a separate document and submit it by 10 April 2012. The paper should address also relevant comments from the public consultation.

The (co-)rapporteurs were requested to prepare the 3<sup>rd</sup> version of the draft opinion by early May 2012. In the next version of the draft opinion, the (co-)rapporteurs should take into account, amongst other things, the inputs of members (to be) submitted via CIRCABC Newsgroup on the 2nd version of the draft opinion (open until 30 March 2012).

## **b) Chromium VI – outcome of the conformity check**

The Chair welcomed the RAC rapporteurs, who were following the discussion as remote meeting participants. The Secretariat presented the outcome of discussions on Chromium VI at RAC-20, where RAC had concluded that the dossier conforms to the requirements of Annex XV of the REACH Regulation.

The Chair invited the SEAC (co-)rapporteurs to give a presentation on the outcome of the conformity check. The (co-)rapporteurs recommended to the Committee to agree that the dossier conforms to the requirements of Annex XV of the REACH Regulation. The (co-)rapporteurs also informed the Committee that they have a few recommendations for the dossier submitter, but that these should not affect the agreement of the Committee on conformity. The main recommendations to the dossier submitter were presented to SEAC.

After a brief discussion, SEAC agreed that the dossier is in conformity.

The Secretariat will compile the RAC and SEAC outcomes of the conformity check, and upload this to CIRCABC. The Secretariat will also inform the dossier submitter on the Committees' recommendations. The (co-)rapporteurs were invited to start developing the opinion in accordance with the procedure on opinion development. The Secretariat will launch a public consultation on the restriction proposal on 16 March 2012.

After the conformity check was completed, the dossier submitter presented the dossier in detail. The SEAC members were invited to comment on the restriction proposal in writing via CIRCABC Newsgroup (open until 16 May 2012).

## **8) Authorisations**

### **a) Common approach of RAC and SEAC in opinion development on applications for authorisation**

The Secretariat gave an overview of the comments of RAC and SEAC members received on the earlier version of the meeting document tabled under this agenda point, and then presented the resulting changes mainly in relation to the contacts between the Committees and applicants, the possibility to impose different conditions of use and review periods in case there is incomplete and missing information, and clarification of how to deal with cumulative effects.

There was a discussion of a paragraph (Section 9) describing that RAC and SEAC should not consider other discharges, emissions and issues for the same substance when evaluating an application for authorisation. The Secretariat clarified it is the obligation of the Commission to consider these issues when granting authorisations (Article 60(2) of the REACH Regulation).

SEAC agreed to the concept provided in the document including the modifications made in SEAC plenary in Section 9 of the document (SEAC/14/2012/05\_rev.1). The Secretariat agreed to inform RAC about the modification and to upload the agreed document to RAC and SEAC CIRCABC.

## **Reporting from RAC-20 break-out groups on the preparation for the first substances and uses**

The Secretariat gave a brief report from the break-out group discussions at RAC-20 on the usefulness of the background information contained in a registration dossier (including Chemical Safety Report (CSR)), technical report (Annex XIV Recommendation), RCOMs (response to comments tables in relation to Annex XIV Recommendation), Background document (Annex XIV Recommendation) and EU Risk Assessment Report.

RAC found the information in general useful and made a few proposals to improve its preparedness for the applications that concern also SEAC. The RAC members expressed that it would be helpful to get the information in a condensed and extracted form that focuses on key information on uses, exposures and hazards of alternatives. Also presentations about data assessed in the previous steps of the authorisation procedure by the MSC were considered as another possible valuable contribution to the capacity building, in the future.

The RAC members mentioned also a potential synergy effect attributed to similar uses of different substances. A communication pool ensuring the information flow and collaboration between the groups on substances, hazards and exposure installed on CIRCABC were considered important.

RAC also suggested making information on possible alternatives available although (very) limited information is currently available on alternatives or socio-economic factors in the background documentation referred to above.

### **b) Economic feasibility**

The Secretariat presented a meeting document (SEAC/14/2012/06) written as a follow-up of the presentation given on the topic of economic feasibility in the context of authorisation at SEAC-13. The note starts by assuming that all alternatives the applicant is aware of can be regarded as economically infeasible if they would increase costs for the applicant. An option could be considered 'weakly infeasible' if the applicant could potentially bear the associated increase in costs without its business being fundamentally undermined, and 'strongly infeasible' if the applicant could not bear the costs and would simply shut down the associated activity. It then presents two options for dealing with economic feasibility. Under Option A, SEAC would attempt to judge which alternatives an applicant might be able to bear in terms of the cost increase, and which alternatives the applicant could not – i.e. SEAC would attempt to identify the threshold between weakly and strongly infeasible alternatives. Under Option B all alternatives that lead to an increase in costs would be classed as economically infeasible, and there would be no attempt to distinguish between those alternatives which were weakly infeasible and those which were strongly infeasible. The paper recommended the adoption of Option B where there would be no 'separate' test of infeasibility as part of the application evaluation process. It presented a number of arguments in favour of this option. In particular, it argued that Option A effectively represents a cost-benefit test of alternatives where the existing risks are implicitly given a value (of at least the threshold between 'bearable' and 'unbearable' costs) which would not necessarily be consistent. The application evaluation process would identify explicitly those applications where the costs of alternatives are greater than the risks associated with the existing substance. Option A was described as being inconsistent with REACH principles and serving to circumvent a key aspect of the REACH decision-support system, and the Secretariat recommended following Option B. The consequence of following option B is that SEAC's remit with respect to economic feasibility should be focused largely on ensuring that the applicant identifies the full range of alternatives and that the costs of alternatives are fully and accurately estimated.

The participants gave some initial comments on the paper during the discussion: there was a suggestion to cover also joint applications, to clarify how the Committee will be able to judge that costs are accurately estimated and to explore the issue of technical feasibility. One member questioned whether it is correct to consider alternatives always more expensive and one stakeholder observer representing trade unions challenged the ECHA's interpretation of REACH where it says that the feasibility should only be judged

from the perspective of the applicant while the public consultation will provide evidence that an alternative is technically and economically feasible for somebody on the market.

The Secretariat proposed to open a CIRCABC Newsgroup for further comments of the SEAC members, advisors and observers until 16 April 2012. The Secretariat informed it intends to distribute the final document for agreement at SEAC-15 in June 2012 and to make the agreed principles known to applicants in an appropriate manner.

### **c) Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications**

The Secretariat presented the draft terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications. The Secretariat recalled that the first draft of the terms of reference had been presented and discussed by RAC and SEAC at RAC-11 and SEAC-7 in May-June 2010, followed by a written commenting round for both Committees. A few revisions had been made in the draft terms of reference to take into account members' comments and to align the terms of reference with other (agreed) RAC and SEAC procedures for the authorisation process. The Secretariat reminded the Committee that this is the last procedural document RAC and SEAC need to agree on in order to be ready to process authorisation applications. It was also mentioned that RAC had preliminarily agreed on the proposed terms of reference at the RAC-20 meeting.

One member suggested making the text of task e more clear and indicate that it is actually the ECHA Secretariat who is contacting the applicant, and not the rapporteurs. With this clarification the procedure was agreed by SEAC (SEAC/14/2012/07\_rev.1).

### **Amount of registration dossiers received for eight new substances on the Annex XIV**

The Secretariat informed SEAC about the amount of registration dossiers for non intermediate uses received so far for the eight new substances which were added to Annex XIV of REACH in February 2012. The numbers can be seen as a first indicator to the potential for receiving applications for authorisations for these substances, but must be read with great care when trying to estimate the actual amount of applications to be received, due to various factors that are not reflected in the figures which were presented (e.g. possible applications for uses below the registration threshold of 1 t/y, reasons for prioritising certain substances of a group for authorisation, potential variations in the assessment of the intermediate status of certain uses).

## **9) AOB**

- Update of the workplan

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

- Nanomaterials

SEAC was informed about the work on nanomaterials, both by a SEAC member and by the ECHA Secretariat. It was agreed that the Secretariat would continue updating the Committee on the activities in this field in the future.

- Dutch environmental impact assessment

SEAC was updated on the Dutch environmental impact assessment. It was agreed that the Secretariat would consider including an update on the project on SEAC-15 agenda.

## **10) Action points and main conclusions of SEAC-14**

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

## II. Main conclusions and action points

### MAIN CONCLUSIONS & ACTION POINTS - SEAC-14, 13-15 March 2012 (SEAC-14 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
<b>2. Adoption of the agenda</b>	
The agenda was adopted with one addition under any other business (Dutch environmental impact assessment).	SEAC-Secretariat to upload the revised agenda to SEAC CIRCA 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. Administrative issues</b>	
<i>a) Changes in the SEAC composition/nominations</i>	
SEAC was informed about the recent changes in the composition of SEAC.	
<i>b) Outcome of written procedures</i>	
SEAC was informed on the outcome of two written procedures (appointment of (co-) rapporteurs for 1,4-Dichlorobenzene and adoption of SEAC-13 minutes).	
<i>c) Results of the satisfaction survey</i>	
SEAC was informed about the results of the annual satisfaction survey 2011.	Secretariat to consider further action to improve the support provided to the Committees.
<i>How to fill in the updated Annex 2 - Declaration of Interest Form</i>	
SEAC was provided further instructions on how to fill in the updated Annex 2 - Declaration of Interest form, as included in the Rules of Procedure adopted by the ECHA Management Board on 31 January 2012.	SEAC members were invited to fill in and return the signed forms to the Secretariat in the margins of the plenary or latest <b>by 31 March 2012</b> .
<b>5. Status report of the action points of SEAC-13</b>	
SEAC was informed on the status of the action points of SEAC-13.	
<b>6. Feedback from other bodies and activities</b>	
SEAC took note of the report from other bodies and activities.	Secretariat to consider including update from other relevant EU Committees (e.g. Article 133 Committee and CARACAL) in the report from now on.

<b>7. Restrictions</b>	
7.1 General restriction issues	
<i>a) Update on intended restriction dossiers</i>	
SEAC was informed about two intentions currently included in the Registry of Intentions.	
<i>b) Update on the review of the restriction process</i>	
SEAC was informed about the suggestions of the group of interested members on i) how to document an opinion not supporting a restriction proposal and ii) how to prioritise recommendations during the conformity check. The proposals are also included in the documents distributed before the meeting (SEAC/14/2012/03 and SEAC/14/2012/02).	Secretariat to take note of the discussion and consider the appropriate way to document the conclusions. The update on any further work regarding the review of the restriction process will be given at the next SEAC meeting in June 2012.
SEAC was updated about the review of the restriction process in the Forum.	Secretariat to provide further update on the revision process in the Forum in the upcoming meetings.
The report of ECHA's project on improving the quality of future restriction dossiers (SEAC/14/2012/04) was presented to SEAC.	Secretariat to take note of the suggestions provided by members in its further work on improving the quality of dossiers.
SEAC reached an agreement on working procedure on appointment of (co-)rapporteurs for restriction dossiers (SEAC/14/2012/08_rev.1) with one amendment.	Secretariat to upload the revised working procedure to CIRCABC IG.
7.2 Restriction Annex XV dossiers	
<i>Phthalates – Second version of draft opinion</i>	
<p>SEAC rapporteurs presented the second version of the draft opinion.</p> <p>With regard to costs SEAC agreed on the need to</p> <ul style="list-style-type: none"> <li>• Improve the baseline by developing a set of scenarios implying plausible amount of phthalates in restricted articles on the market;</li> <li>• Quantify reformulation costs;</li> <li>• Perform another assessment of administrative costs;</li> <li>• Develop a substitution scenario with a basket of alternatives;</li> <li>• Assess the impact on recycled PVC.</li> </ul> <p>With regard to benefits and proportionality SEAC agreed that</p> <ul style="list-style-type: none"> <li>• ART costs are useful;</li> <li>• Adoption costs and their relevance need to</li> </ul>	<p>Dossier submitter agreed to turn to some stakeholders to obtain information on reformulation costs and to address other recommendations of SEAC-14. Rapporteurs to give necessary guidance to the dossier submitter.</p> <p>Rapporteurs to request RAC rapporteurs to assist in quantifying and describing the link between phthalates and infertility and other health impacts ASAP.</p> <p>Dossier submitter to record the outcome of the work in a separate document and submit it <b>by 10 April 2012</b>. The paper should address also relevant comments from the public consultation.</p> <p>Rapporteurs to prepare the third version of draft opinion by <b>early May 2012</b>. Rapporteurs</p>

<p>be looked at;</p> <ul style="list-style-type: none"> <li>• It is important to have a qualitative and informative description of the severity and significance for society especially if a quantitative link between phthalates and infertility cannot be made;</li> <li>• Other effects of phthalates (besides reduced fertility) need to be described and their significance needs to be assessed at least on qualitative level.</li> </ul> <p>SEAC exchanged their views on the proposed restriction with the assumption that no additional information would be available. This confirmed the priorities listed above.</p>	<p>to take into account inputs of the members (to be) submitted via CIRCABC Newsgroup on the 2nd version of draft opinion (open until <b>30 March 2012</b>).</p> <p>SEAC members to comment on the new restriction proposal wording <b>by 6 April 2012</b> via CIRCABC Newsgroup.</p> <p>Secretariat to request the 2nd Forum advice (to be requested no later than <b>16 March 2012</b>).</p>
<p><i>Chromium VI – outcome of the conformity check</i></p>	
<p>SEAC agreed on the outcome of the conformity check.</p>	<p>Secretariat to compile the RAC and SEAC outcomes of the conformity check and upload this to CIRCABC.</p> <p>Secretariat to inform the dossier submitter on the outcome of the conformity check.</p> <p>The rapporteurs to start developing the opinion in accordance with the procedure on opinion development.</p> <p>Secretariat to launch a public consultation on the proposed restriction on 16 March 2012.</p>
<p><b>8. Authorisations</b></p>	
<p><i>a) Common approach of RAC and SEAC in opinion development on applications for authorisations</i></p>	
<p>SEAC agreed to the concepts provided in the document including the modifications made in SEAC plenary in section 9 of the document (SEAC/14/2012/05_rev.1).</p>	<p>Secretariat to inform RAC about the modification and to upload the agreed document to RAC and SEAC CIRCABC.</p>
<p><i>b) Economic feasibility</i></p>	
<p>SEAC received a presentation on the economic feasibility in the context of applications for authorisation (room document SEAC/14/2012/06).</p>	<p>Secretariat to open a CIRCABC Newsgroup for SEAC members', advisors' and observers' comments until <b>16 April 2012</b>.</p> <p>Secretariat to distribute the final document for agreement at SEAC-15 in June 2012 and make the agreed principles known to applicants in an appropriate manner.</p>
<p><i>c) Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications</i></p>	
<p>SEAC agreed on the document prepared by Secretariat including the proposed editorial modification (SEAC/14/2012/07_rev.1).</p>	<p>Secretariat to upload the agreed terms of reference to RAC and SEAC CIRCABC.</p>
<p>Amount of registration dossiers received for eight new substances on the Annex XIV</p>	
<p>SEAC was informed about the ranges of</p>	<p>SEAC members to take note of the written call</p>

<p>numbers of (non-intermediate) registration dossiers received for the eight new substances on Annex XIV to the REACH Regulation (Authorisation List).</p>	<p>for expression of interests of rapporteurs to be appointed to the pool (Call for rapporteurs is open until <b>16 April 2012.</b>)</p>
<p><b>10. Action points and main conclusion of SEAC-14</b></p>	
<p>SEAC agreed on the action points and main conclusions of SEAC-14.</p>	<p>Secretariat to upload the action points and main conclusions to CIRCABC IG.</p>

### III. List of Attendees

<b>SEAC Members</b>
ALEXANDRE João
BENDL Jiri
BRIGNON Jean-Marc
CSERGO Robert
DANTINNE Catheline
FANKHAUSER Simone (via Webex)
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz-Georg
SKARŽINSKAS Vitalius
STOYANOVA-LAZAROVA Elina Velinova
THORS Åsa
VOIVONTAS Dimosthenis

<b>Invited Experts</b>
D'AMICO Flaviano
HENNIG Philipp
PAPPONEN Hinni

<b>European Commission</b>
BENGYUZOV Manol

<b>RAC (co)-Rapporteurs</b>
SCHLÜTER Urs (Via Webex)
SMITH Andrew (Via Webex)

<b>Advisors, Dossier Submitters (DS), Forum representatives &amp; Observers</b>
BEEKMAN Martijn (Advisor to C. Luttkhuizen)
BRUINEN DE BRUIN Yuri (Advisor to C. Luttkhuizen)
JENSEN Frank (Advisor to L. Fock, Phthalates DS representative and RAC Member)
SCHOU Jørgen Peter (Advisor to L. Fock, Via Webex)
VERHOEVEN Julia (Advisor to C. Luttkhuizen, via Webex)

<b>Stakeholder Observers</b>
COCKCROFT Linda-Jean (Arkema, CEFIC)
HOLLAND Mike (EEB)
JÀNOSI Amaya (CEFIC)
KÜHN Ingolf (Business Europe)
MUSU Tony (ETUC)
WATERSCHOOT Hugo (EUROMETAUX)

<b>ECHA staff</b>
ANFÄLT Lisa
CALVO TOLEDO Juan Pablo
CSAK Viktoria
DUBOURG Richard
FUHRMANN Anna
KIVELA Kalle
LE CURIEUX Frank
LEFÈVRE Rémi
LIPKOVA Adriana
MATTHES Jochen
MOSSINK Jos
NICOT Thierry
ORISPÄÄ Katja
ÖBERG Tomas
PELTOLA Jukka
RÖCKE Timo
RODRIGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
SADAM Diana
SIHVONEN Kirsi
SHUQOM Natasha
SOSNOWSKI Piotr
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

**ANNEX I****Documents submitted to the members of the Committee for Socio-economic Analysis**

Final Draft Agenda	<i>SEAC/A/14/2011</i>
Outlined Final Draft Agenda	<i>SEAC/A/14/2011_outlined</i>
Feedback from other bodies and activities	<i>SEAC/14/2011/01</i>
Prioritisation of recommendations during the conformity check	<i>SEAC/14/2012/02</i>
How to document an opinion not supporting the restriction proposal?	<i>SEAC/14/2012/03</i>
Update on the project on improving the quality of future restriction dossiers	<i>SEAC/14/2012/04</i>
Common approach of RAC and SEAC in opinion development on applications for authorisation	<i>SEAC/14/2012/05</i>
Economic feasibility	<i>SEAC/14/2012/06 (room document)</i>
Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications	<i>SEAC/14/2012/07</i>
Revised procedure for the appointment of (co-) rapporteurs for restriction dossiers	<i>SEAC/14/2012/08</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 Art 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	7.2a Phthalates 7.2b Chromium VI	Dossier submitter
JENSEN Frank	7.2a Phthalates 7.2b Chromium VI	Dossier submitter

**Final Agenda**  
**14<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**13-15 March 2012**  
**ECHA Conference Centre (Annankatu 18, Helsinki)**  
**13 March: starts at 10:00**  
**15 March: ends at 13:00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

**SEAC/A/14/2012**  
**For adoption**

**Item 3 – Declarations of conflicts of interest to the Agenda**

**Item 4 – Administrative issues**

- a) Changes in the SEAC composition/nominations
- b) Outcome of written procedures
- c) Results of the satisfaction survey

**For information**

**Item 5 – Status report of the action points of SEAC-13**

**For information**

**Item 6 – Feedback from other bodies and activities**

**SEAC/14/2012/01**  
**For information**

**Item 7 – Restrictions**

**7.1 General restriction issues**

- a) Update on intended restriction dossiers
- b) Update on the review of the restriction process

**For information**

- Prioritisation of recommendations during the conformity check  
**SEAC/14/2012/02**  
**For discussion**
- How to document an opinion not supporting the restriction proposal?  
**SEAC/14/2012/03**  
**For discussion**
- Revision of the restriction process in the Forum  
**For information**
- Update on the project on improving the quality of future restriction dossiers  
**SEAC/14/2012/04**  
**For information**
- Revised procedure for the appointment of (co-)rapporteurs for restriction dossiers  
**SEAC/14/2012/08**  
**For agreement**

## 7.2 Restriction Annex XV dossiers

- a) Phthalates – 2nd version of SEAC draft opinion  
**For discussion**
- b) Chromium VI – outcome of the conformity check  
**For agreement**

### Item 8 – Authorisations

- a) Common approach of RAC and SEAC in opinion development on applications for authorisation  
**SEAC/14/2012/05**  
**For agreement**
- b) Economic feasibility  
**SEAC/14/2012/06 (room document)**  
**For discussion**
- c) Terms of reference for (co-)rapporteurs of RAC and SEAC for authorisation applications  
**SEAC/14/2012/07**  
**For agreement**

### Item 9 – AOB

- Update of the work-plan
- Nanomaterials
- Dutch environmental impact assessment  
**For information**

**Item 10 – Action points and main conclusions of SEAC-14**

Table with Conclusions and Action points from SEAC-14

***For adoption***