26 November 2012

SEAC/M/16/2012 FINAL

Final

Minutes of the 16th meeting of the Committee for Socio-economic Analysis

12-14 September 2012

I. Summary Record of the Proceeding

1) Welcome and apologies

Tomas Öberg, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the sixteenth meeting of SEAC.

The Chair informed that apologies had been received from five members, one Croatian observer, one international observer and one stakeholder observer. Five members' advisors present at the meeting as well as one representative of the European Commission, observers of four stakeholder organisations and one dossier submitter representative were introduced. The Chair informed that one SEAC member, one advisor to a SEAC member, one representative of the European Commission and four dossier submitter representatives were to follow the relevant parts of the meeting via Webex. 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-16. The Chair explained that the item on overview of the time spent by (co-)rapporteurs on processing the first restriction dossiers would be postponed for the next SEAC-17 meeting. The Chair also mentioned that an additional item had been introduced under AOB – Feedback on the first four restrictions from the Commission's Impact Assessment point of view.

The Agenda was adopted with the above-mentioned 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 Chair requested all participants to declare any conflicts of interest to any of the specific agenda items. Three members and one advisor declared potential conflicts of interest to the substance-related discussions under the agenda items 5.2. The 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 bodes and activities

a) Report on SEAC-15 action points, written procedures and other ECHA bodies

The Chair reported that the majority of the action points of SEAC-15 had been completed or would be followed up during the ongoing SEAC-16 meeting. The update on the ECHA confidentiality policy for documentation would be provided to the Committee in December 2012. In December, the Secretariat will also report back from the discussions with the Commission about the remits of RAC and SEAC. Regarding an analysis of needs of expertise in relation to co-opting members, this issue will be revisited at a later stage after experience gained from RAC.

The Chair also informed that the final minutes of SEAC-15 had been adopted by written procedure and had been uploaded to CIRCABC as well as on the ECHA website. The Chair thanked members for providing comments on the draft SEAC-15 minutes.

The Chair explained that a report covering the developments in the ECHA Management Board (MB), the Committee for Risk Assessment (RAC), the Member States Committee (MSC) and the Forum had been compiled and distributed to SEAC as a meeting document (SEAC/16/2012/01).

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

b) Implementation of the Conflict of Interest Policy

- General principles and guidance for Committee members

The Chair informed that following up a recommendation of the Court of Auditors, the Secretariat had drafted a proposal for general principles and guidance for Committee members of the Agency. The Secretariat then introduced to SEAC the meeting document SEAC/16/2012/02 containing the draft general principles and guidance for Committee members of ECHA. The Secretariat noted that the document had been introduced also to RAC within RAC-22 and would be presented to MSC at its 25th meeting.

One member questioned why the paragraph on relations with media, stakeholders and the general public does not say anything regarding participation of Committee members in workshops, conferences, etc. Another member suggested including in the document a paragraph regarding members working for the Competent Authorities (CAs) in their MSs (particularly their contacts with industry) and possible conflict of roles.

The Chair concluded that the Secretariat would take note of the discussion and would consider the appropriate way to document the proposal.

- Eligibility criteria

The Secretariat provided an update on the eligibility criteria for ECHA bodies. The draft eligibility criteria was briefly presented to RAC and SEAC in their June 2012 meetings. The document was then discussed by the MB in its June meeting, but the final decision was postponed to its September plenary meeting (28-29 September 2012). The Secretariat explained the revised eligibility criteria and emphasised that this criteria would be applicable to new appointments and renewals only and not to current members of the Committees.

The SEAC members asked for clarification on several aspects of the presentation (e.g. what does an "active member" of an association or other body actually mean, what is meant by "current" contractual obligations on slide 5 of the presentation, etc).

It was agreed that the Secretariat would take note of the discussion and submit the proposal for revised eligibility criteria to the ECHA MB.

c) Co-opted members

The Chair reminded that in the last RAC and SEAC plenary meetings, the need for co-opting additional members to the Committee (based on Article 85(4) of REACH) had been discussed by both RAC and SEAC. SEAC then concluded that there is no immediate need to co-opt additional members to the Committee. As agreed at SEAC-16, the Secretariat provided to SEAC an update on the RAC discussions on this issue. The Secretariat reported that RAC had agreed on the need to co-opt additional members to RAC.

It was agreed that the issue of co-opting additional members to SEAC would be revisited at a later stage, after experience gained from RAC. The members of SEAC also requested to be briefed on financial aspects related to co-opting additional members.

d) Facilitation of plenary discussions and written commenting rounds

The Chair gave a brief introduction to the topic, explaining the background for this agenda item in response to comments given by SEAC members in surveys, CIRCA newsgroups and in margins of meetings. Some possible actions were mentioned and members were then asked to join one of the three break-out groups for further discussion. ECHA staff did not participate in these discussions.

Summary of the reports from the break-out groups:

- Meeting documents should be distributed to the Committee members on time (to facilitate preparation of members for the plenary discussion).
- It would be useful if the Secretariat and the (co-)rapporteurs highlighted specific topics for discussions.
- Organisation of break-out groups within plenary meetings.
- Focus of plenaries should be on dossiers, and not on administrative matters.
- Encourage more members to become (co-)rapporteurs, consider "shadow" rapporteurs.
- The Secretariat to be more selective with regard to topics presented to the Committee for discussion.
- The Secretariat should also try to gather more information directly from the members on these issues.

5) Restrictions

5.1) General restriction issues (joint RAC/SEAC session)

a) Update on intended restriction dossiers

The Secretariat provided an update on up-coming restriction dossiers. As already informed in June 2012, there are currently two new substances in the Registry of Intentions:

- lead and lead compounds in articles intended for consumer use prepared by Sweden and
- 1-methyl-2-pyrrolidone (NMP) prepared by the Netherlands.

Submission of both dossiers is currently foreseen in April 2013.

The Secretariat noted also that the Commission has asked ECHA to investigate certain applications of cadmium in relation to the current restriction entry. The request from the Commission to prepare an Annex XV dossier for cadmium in plastics (and possible other applications) is expected to come in November 2012.

b) Update on the review of the restriction process

The Secretariat reminded the Committees that in the March plenary meetings of RAC and SEAC, the plans to revise the Forum procedure for elaboration of the Forum advice on enforceability of restriction proposals had been introduced while in June, some further explanation on this topic had been provided. The revised Forum procedure was then adopted by the Forum at its 12th meeting in June 2012. The Secretariat introduced changes reflecting the revised Forum procedure to the RAC and SEAC working procedures on opinion development (room document RAC/22/2012/04 for RAC and room document SEAC/16/2012/03 for SEAC). The Secretariat then provided an overview of modifications and explained that as the Forum had agreed to start applying the new system to all future and current restriction dossiers starting from the dichlorobenzene (DCB) dossier, the same is proposed to RAC and SEAC.

The Committees agreed to start applying the revised working procedures on opinion development to all restriction dossiers starting from the DCB dossier.

5.2) Restriction Annex XV dossiers

a) Phthalates – comments from the public consultation on the SEAC draft opinion

The SEAC (co-)rapporteurs gave an overview of the comments received from the public consultation on the SEAC draft opinion concerning the four phthalates. The main issues raised in the public consultation were related to the baseline calculation (one comment suggested that there would be some new information on imports which could have an impact on the baseline), to the impacts on PVC recycling (industry concurring with the view that there would be negative impact) and to the role and content of SEAC opinions. The rest of the comments were either making minor proposals to modify wording of the draft opinion's justification and many of the comments were related to the RAC opinion.

The (co-)rapporteurs, supported by one member, explained that the comment suggesting that there was new information on imports was unclear and further clarification needs to take place in order to assess its potential impact on the SEAC draft opinion.

One comment on the role and content of SEAC opinions arrived after the deadline for the public consultation, and thus the Committee was informed it would not be included in the response to comments (RCOM) table. Nevertheless, the Chair observed that the horizontal issue raised is planned to be discussed at the SEAC-17 meeting in December 2012. The Chair agreed that the comment could be distributed to SEAC as a discussion paper prior to the next meeting.

The (co-)rapporteurs, supported by the Secretariat, informed that the comments related to the RAC opinion would not be dealt with as the RAC opinion had been adopted already.

It was agreed that the (co-)rapporteurs would prepare a revised version of the SEAC draft opinion by 26 October 2012 which would be distributed by the Secretariat to SEAC members for written comments. SEAC is expected to adopt its final opinion by 16 December 2012 (deadline extended based on Article 71(3) of REACH).

b) Chromium VI – 2nd version of SEAC draft opinion

The Chair informed the Committee that the restriction dossier on Cr VI was submitted for public consultation on 16 March 2012. The public consultation ends on 16 September 2012. The Chair underlined that the discussion on the 2nd version of the SEAC draft opinion is the most crucial in the opinion development process. In the next SEAC-17 meeting in December 2012, SEAC is expected to agree on the SEAC draft opinion. The adoption of the final opinion is foreseen for March 2013. Additionally, the Chair informed that the 2nd rapporteurs' dialogue took place in August 2012 and included discussion with an expert on contact dermatitis. The Chair invited the (co-)rapporteurs to present the 2nd version of the SEAC draft opinion.

After the presentation by the (co-)rapporteurs, the ECHA Secretariat provided some information concerning the scope of the German ban of Cr VI in leather articles. The issue is still under investigation and the outcome will be reflected in the Background Document (BD) as well as in the opinion. For the time being the ECHA Secretariat is of the opinion that the present German legislation will not have a major impact on the assessment of the number of new allergy cases.

SEAC then discussed the different RMOs (RMO1 - restriction of Cr VI in leather articles into direct and prolonged contact with the human skin; RMO2 - restriction of Cr VI in all leather articles). The Chair invited the RAC rapporteurs to explain to SEAC the reason why they proposed to delete the words "direct and prolonged" from RMO1. The rapporteurs informed that the word "direct" may be misleading considering that also the indirect contact can cause the allergic reaction. The word "prolonged" is difficult to define (as confirmed by the recent investigation performed by the ECHA experts). Moreover, repetitive short contact with the skin may cause very severe allergic reactions, especially for hypersensitive people who are already sensitised to Cr VI. The RAC rapporteurs'

opinion was supported by representatives of industry (Eurometaux STO). Keeping in mind the RAC rapporteurs' proposal concerning changes in RMO1, some of the SEAC members, however, were still in favour of RMO2 (both for reason of improved enforceability and because of the fact that industry will change processes anyhow (and RMO2 is thus what will happen in practice)). The SEAC rapporteurs were requested to prepare the comparison of the cost-benefit analysis of RMO1 and RMO2. The rapporteurs informed the Committee that they do not have enough information in the dossier to prepare such detailed comparison, but in their opinion the cost-benefit balance in both cases would be very similar.

In relation to the rapporteurs' presentation, the dossier submitter informed that generally they agree with the approach of the rapporteurs. The dossier submitter is open to the discussion how more precisely the figures could be calculated, but in their opinion the overall conclusion will not change dramatically. The dossier submitter could also agree with the new wording presented by the RAC (co-)rapporteurs.

SEAC members expressed different opinions about consumers' behaviour. Some SEAC members were of the opinion that the consumers choice as to whether to buy leather articles that may result in allergic problems is indicative of the welfare losses associated with the allergy. Need for assessment of the welfare losses associated with the non leather sources of the exposure to Cr VI was also mentioned. Other members were of the opinion that the Committee does not have enough information to assess the consumer's behaviour and that the information currently available to consumers is not sufficient to prevent the contact with the leather article which causes the allergic reaction.

SEAC discussed the cost-benefit analysis. Some members questioned the validity of the net benefit analysis presented by the rapporteurs using the consumer surplus approach. The (co-)rapporteurs were requested to do more specific calculation as the current benefit level is overestimated according to the view of some SEAC members. The assessments of the prevalence of the allergic cases (number of existing cases in the population) and the welfare assessments were questioned as not scientifically supported. In the opinion of one SEAC member the multiplying 10-years prevalence rate by factor 4 (remaining life time expectancy) is not supported and 10-years prevalence rate is approaching complete prevalence rate in the population. On the other hand, other SEAC members were of the opinion that the cost-benefit analysis presented by the dossier submitter is satisfactory and further adjustments will not change the general conclusion. The same members were of the opinion that the assessment of prevalence of Cr VI allergy is based on the epidemiology information and such assessment is in the remit of RAC.

Answering to the SEAC questions concerning the post-formation of Cr VI, the RAC rapporteurs informed that there is no scientific evidence for the post-formation of Cr VI from Cr III in the leather articles in normal conditions of use. There is also no scientific evidence that Cr III causes allergy.

It was agreed that the (co-)rapporteurs would prepare the 3rd version of the SEAC draft opinion in accordance with the discussion in SEAC, taking into account the input from members, and submit it to the Secretariat by 3 October 2012 for distribution to SEAC members. The rapporteurs will also prepare (in co-operation with the Secretariat) a response to comments on the 2nd version of the draft opinion and submit it to the Secretariat for distribution to SEAC members (including comments submitted after the deadline). Immediately after the SEAC meeting the Secretariat will ask the Forum for the second advice.

c) Dichlorobenzene – 1st version of SEAC draft opinion

The Chair welcomed the RAC (co-)rapporteurs and the dossier submitter to the plenary. The SEAC (co-)rapporteurs provided a presentation on the 1st version of the SEAC draft opinion. It was pointed out that several aspects of the RAC assessment would have a direct impact on the SEAC opinion development. More specifically, the SEAC view on

proportionality was pending on the RAC conclusion of unacceptable risk on the basis of evidence in the dossier.

The following issues were brought up by the (co-)rapporteurs for further discussion.

The SEAC rapporteurs asked if a restriction on domestic use only is a better justified approach. The rapporteurs explained that according to the evidence in the report, the domestic use restriction is the most appropriate option. Several members, however, expressed their reservation about excluding professional use from the restriction as workers are often considered the most vulnerable in work places. The ECHA Secretariat, representing the dossier submitter, pointed out that for the socio-economic analysis, the impact of only one health outcome was estimated. It may therefore be necessary to take into account the possible partial nature of this analysis, and thereby a minimum representation of the health benefits, and that further calculations could modify the outcome.

The SEAC rapporteurs asked whether a qualitative assessment of health benefits is a sufficient justification for the domestic use restriction option, given the cost savings associated with this option. SEAC members concurred with this view. Furthermore, if RAC concluded that there is unacceptable risk, there may not be a requirement for any health benefit impact assessment for this option.

SEAC discussed different views on the consumer surplus approach and its impact on the outcome of the assessment. A short comparison between the consumer surplus approach and financial cost approach was provided to SEAC by the rapporteur.

Regarding the impact on the environment of 1,4 dichlorobenzene in toilet blocks, the RAC (co-)rapporteurs confirmed that as the substance is not soluble it would not pose a concern to the environment.

One SEAC member informed on a recent US study which had concluded a relation between dichlorophenol (note: 2,5-dichlorophenol is the metabolite of 1,4-dichlorobenzene) and the early age of puberty in teenage girls. This was brought to the attention of the RAC rapporteurs.

Based on the debate, it was summarised that SEAC members shared the view that a community wide restriction is motivated. There was support to include both professional and domestic uses in the restriction. Additionally practicality, enforceability and monitorability aspects of the restriction were supported by SEAC hence any further discussion on the draft opinion should focus on the justification.

It was concluded that the (co-)rapporteurs, in co-operation with the Secretariat, would prepare a response to comments of SEAC members on the 1st version of the SEAC draft opinion to be distributed to SEAC members. The (co-)rapporteurs should take the comments into account while preparing the 2nd version of the SEAC draft opinion.

d) Nonylphenol – outcome of the conformity check

The Chair welcomed the RAC (co-)rapporteurs and the dossier submitter representatives (the dossier submitter representatives were following the discussion remotely (via Webex) as observers).

The Chair reminded SEAC that the restriction dossier on nonylphenol and nonylphenol ethoxylate was submitted to ECHA on 3 August 2012. The conformity check in RAC and SEAC was launched on 16 August 2012 and the Committees are expected to reach conclusion on the conformity of the dossier by 14 September 2012 at the latest. The final drafts of the conformity check outcomes, prepared by the (co-)rapporteurs, take into account comments submitted by two SEAC members during the conformity check.

The Chair invited the RAC rapporteurs to brief SEAC on the RAC discussion on the conformity of the nonylphenol dossier. The RAC rapporteurs reported that RAC had agreed that the dossier does not conform to the requirements of Annex XV of the REACH Regulation and explained the key reasons for non-conformity in the dossier from the RAC point of view.

The SEAC (co-)rapporteurs presented the SEAC outcome of the conformity check. The rapporteurs explained why they recommend to the Committee to agree that the nonylphenol restriction dossier is not in conformity. The rapporteurs found that the Annex XV report on nonylphenol does not allow an evaluation of the proposed restriction and other identified RMOs against their effectiveness, practicality and monitorability (question E2 of the conformity check report) and that this assessment does not appear to give sufficient background on the defined scope and conditions of the restriction (question E4 of the conformity check report). The recommendations to the dossier submitter as well as the comments received by two SEAC members in the initial written commenting round were described.

Several members expressed support for the views of the (co-)rapporteurs. One member questioned the argumentation of SEAC in responding "no" to question E2 of the conformity check report, in particular their reference to the RAC views on the hazard and risk assessment. The SEAC rapporteurs responded that based on the information presented in the dossier, it is not possible for SEAC to evaluate the proportionality of the proposed restriction. The same member also felt that with regard to question E4, the dossier submitter has done the minimum required: a concentration limit is provided. The issue in his view is more on the quality side and could be resolved during the public consultation. The (co-)rapporteurs responded that the dossier does not give sufficient background on the conditions of the restriction and the concentration limit is viewed as a condition for a restriction.

SEAC agreed by consensus that the dossier does not conform to the requirements of Annex XV of REACH.

The Chair pointed out that the Secretariat would communicate the results of the conformity check to the dossier submitter and would inform the Committee about the dossier submitter's plans regarding resubmission of their dossier.

5.3 Appointment of (co-)rapporteurs for restriction dossiers

The Secretariat introduced the meeting document SEAC/16/2012/04 containing the Chair's recommendation regarding the pools for appointment of (co-) rapporteurs for the 1-methyl-2-pyrrolidone and lead and lead compounds restriction dossiers. The Secretariat informed that the dossiers are expected to be submitted by April 2013 and the formal appointment of the (co-)rapporteurs will follow later on this year and at the latest when ECHA receives the dossiers. SEAC took note of the pools of the (co-) rapporteurs for the above-mentioned dossiers and welcomed the new candidates for the (co-) rapporteurships.

6) Authorisations
a) Capacity building

- **Economic feasibility**

The Chair reminded that the document on economic feasibility had been provided to SEAC for discussion for SEAC-14 in March 2012 (room document SEAC/14/2012/06). The discussion on the revised version of the document had originally been planned for SEAC-15, but had to be postponed. For this SEAC-16 meeting, the Secretariat had provided the response to comments made by SEAC members on the original document (was distributed as a room document SEAC/16/2012/06). The Secretariat then provided a presentation to the Committee the aim of which was to clarify what the original document did and did not mean to say.

Several members felt that the presentation helped to bring more clarity into the issue. However, members expressed the wish to see the revision of the document and to hold a further discussion on the revised version at the next SEAC-17 meeting. One stakeholder observer made a remark that also industry would benefit from more clarity on the issue of economic feasibility.

It was agreed that SEAC members and observers could provide their comments/suggestions to the Secretariat by 10 October 2012 (for example, how they would define a "costly but not so costly" alternative if they consider such an approach practical). The Secretariat will elaborate the concept further into a document to be distributed to the Committee by mid November. It was also agreed that the Secretariat would consider organising a discussion in an ad hoc group, in conjunction with the next SEAC meeting, for those members and observers who wish to contribute to the conclusion of the work.

- **Valuation of environmental impacts of PBT (joint RAC/SEAC session)**

A RAC member reported on a project that has been commissioned in co-operation with Luxembourg on the valuation of environmental impacts of Persistent, Bioaccumulative and Toxic (PBT) substances. The project will run until the end of 2012 and is aimed at supporting and structuring the decision-process within the socio-economic authorisation route for non–threshold substances for which no adequate control can be established.

RAC and SEAC members welcomed the initiative, noted the relevance for their work in issuing opinions on authorisation applications in the future and asked to be informed of the results once available.

- **Proportionality in evaluating Applications for Authorisation (AfAs) (joint RAC/SEAC session)**

A SEAC member provided some background information on the basis of the proportionality principle in evaluating applications for authorisation, focusing on the REACH Regulation, the available guidance documents, as well as other relevant EU legislation.

The Secretariat noted that proportionality can be understood in different ways depending on the point of view i.e. whether the analysis is proportionate (meaning targeted analysis - how much we need to know to be able to make an opinion) or whether something is proportional in terms of risks vs benefits for authorisations. The Chair concluded that more practical experience from applications is needed in order to see how this will work in practice.

- **AfAs with 'multiple dimensions' (joint RAC/SEAC session)**

Applications for Authorisation may have multiple dimensions in the sense that they may include a variety of cases, from several distinct applications to joint applications, from one use to several uses, from new applications to subsequent or to review applications, etc. A SEAC member had prepared a discussion document (distributed as a room document RAC/22/2012/07 and SEAC/16/2012/05) outlining some of the cases that RAC and SEAC may need to evaluate.

As a response to questions concerning applications with these "multiple dimensions" brought up by the SEAC member, the Secretariat presented RAC and SEAC with the procedural timelines for processing such applications. The overview explained how the submission windows are synchronised with the frequency of the plenary meetings within the ten month opinion-development period. There is also a mechanism for fitting in applications which are received outside the submission windows.

In addition, the topic of subsequent applications was summarised. ECHA recommends in its data submission manual that the applicants would submit subsequent applications only for the same use with the same substance that was previously submitted. From the procedural point of view, the subsequent applications are to be submitted similarly within the submission windows.

The Secretariat reported that the ECHA policy on the linguistic regime for applications for authorisation has recently been finalised with a view of having applications only in one language. Further considerations or potential need for translations can be discussed.

It was also concluded that when large numbers of applications for the same substance potentially arrive, the current rapporteur pool might not be sufficient to evaluate them. Therefore, the background information packages for Annex XIV substances could be useful for all members to gain familiarity with a given substance in advance of applications arriving.

For the evaluation of the joint applications containing different assessment reports per use and per applicant, the Secretariat reported that it has set the procedure so that the application is submitted by one applicant submitting only one dossier for the whole group. ECHA recommends that joint applications are submitted when all applicants apply for all uses and where there are no CBI or competition law issues between the applicants. Alternatively, it might be preferable for all applicants to develop certain parts in common but to submit them separately.

Some clarifications were asked on the written procedure option. A stakeholder also called for maximization of the use of the submission windows. He said there is a need to streamline the process, otherwise, there could be a potential bottleneck depending on a large number of complex applications.

b) Participation of case-owners and stakeholder observers in opinion development process (joint RAC/SEAC session)

The Secretariat informed RAC and SEAC that a document prepared for the MB on the participation of case-owners and stakeholder observers in the opinion development process had been provided as a room document (RAC/22/2012/08 and SEAC/16/2012/07). The issue was discussed by RAC, SEAC and the MB in June and the previous proposal was revised on the basis of that discussion. The Secretariat then presented the new proposal for the participation of case-owners, stakeholder observers and third parties in authorisation.

Several members noted that it would be necessary for ECHA to clarify the definition of confidential business information (CBI), especially because the Committee members come from different MSs and their views on what is considered CBI and what not might be different. However, one member also remarked that there may not be much time in the opinion-making process for going into details and CBI. The ECHA Secretariat confirmed that the guidance on the definition of CBI would be developed and that training might also be considered. In response to a member, the Secretariat indicated that the policy regarding participation of case-owners and stakeholder observers was within ECHA's mandate and did not need discussion at or agreement from CARACAL.

One NGO stakeholder observer strongly disagreed with the proposal – she felt that as these are hazardous substances, it is important also for observers to know the producers, production volumes, etc. Furthermore, all stakeholder observers of RAC and SEAC have signed the confidentiality declarations. This statement was supported by another NGO stakeholder observer, while an industry stakeholder observer found the new proposal a good solution now providing for as much stakeholder participation as possible.

A Commission representative expressed the appreciation of the Secretariat's efforts in trying to find solutions to the outstanding issues after the June discussion, but also expressed some reservations to the proposed system with regard to the efficiency in protecting CBI and the complexity of the process.

It was agreed that the Secretariat would update both Committees after the MB discussion.

7) AOB

- Update of the workplan

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

- Feedback on the first restrictions from the Commission's Impact Assessment Board point of view (joint RAC/SEAC session)

The Secretariat reported back from the meeting of 12 July 2012 between the ECHA Secretariat and the Commission services on feedback from the Commission on the first four restrictions. The Secretariat pointed out that based on the feedback received from

the Commission ECHA can conclude that it is on the right path. It is important, however, to aim for condensed and clear opinions' justifications and Background Documents, as well as to reduce repetition in the justification of RAC and SEAC opinions.

One member questioned why the Commission had expressed the view that the six month long public consultation should not be used to "improve the dossier". The Secretariat replied that the idea behind this remark is that the MS submitting the dossier should organize a public consultation before submitting the dossier to ECHA, to avoid receiving a lot of new information during the public consultation organized by ECHA. Another member supported the idea of the Commission to limit the size of the Background Documents, however, he stressed the importance of being flexible in this respect.

Application for authorisation – opinion format and what to make public
The Secretariat introduced the technical modifications that are proposed to be included in the template for the public version of RAC and SEAC opinions that had been agreed by both Committees earlier. RAC and SEAC agreed with the proposed technical modifications.

8) Action points and main conclusions of SEAC-16

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-16, 12-14 September 2012
(SEAC-16 meeting)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the agenda	
The agenda was adopted with minor modifications under AOB (addition of Feedback on the first four restrictions from the Commission's Impact Assessment point of view and postponing the overview of time spent by rapporteurs on processing the first restriction dossiers for the next meeting).	Secretariat to upload the revised agenda to SEAC CIRCA IG as part of the meeting minutes.
3. Declarations of conflicts of interest to the Agenda	
Conflicts of interest have been declared and will be taken to the minutes.	
4. Report from other ECHA bodies and activities	
a) Report on SEAC-15 action points, written procedures and other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-15. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/16/2012/01), including the oral report from the Commission on SEAC related developments in REACH Committee and CARACAL.	Secretariat to update the Committee on the confidentiality policy for documentation (in December 2012).
b) Implementation of the Conflict of Interest Policy – General principles and guidance for Committee members – Eligibility criteria	
SEAC took note of the meeting document (SEAC/16/2012/02) and discussed the revised eligibility criteria.	Secretariat to take note of the discussion and to consider the appropriate way to document the proposal. Secretariat to take note of the discussion and submit the proposal for revised eligibility criteria to the ECHA Management Board.
c) Co-opted members	
SEAC was briefed about the RAC discussion on the need for co-opting additional members to the Committee based on Article 85(4) of REACH.	Secretariat to revisit the issue of co-opting additional members to SEAC at a later stage, after experience gained from RAC. Secretariat to brief the Committee on financial aspects related to co-opting additional members to RAC and SEAC.
d) Facilitation of plenary discussions and written commenting rounds	

SEAC reported from the break-out groups on this subject.	Secretariat to consider the comments received and to assess possibilities for improvements to facilitate members' involvement in plenary discussions and written commenting rounds.
5. Restrictions	
5.2 Restriction Annex XV dossiers	
a) Phthalates – comments from the public consultation on the SEAC draft opinion	
SEAC rapporteurs presented the comments on the SEAC draft opinion received within the 60 day public consultation. SEAC discussed the comments made to the draft opinion of SEAC.	Rapporteurs to prepare the 1st version of SEAC opinion by 26 October 2012. Secretariat to distribute the document to SEAC members for written comments. SEAC to adopt its final opinion by 16 December 2012 (deadline extended based on Article 71(3) of REACH).
b) Chromium VI – 2nd version of SEAC draft opinion	
SEAC rapporteurs presented the 2nd version of the SEAC draft opinion, and SEAC discussed the open issues to be implemented in the 3rd version of the SEAC draft opinion.	(Co-)rapporteurs to prepare the 3rd version of the SEAC draft opinion in accordance with the discussion in SEAC and to provide this to the Secretariat for distribution to SEAC members by 3 October 2012. (Co-)rapporteurs in cooperation with the Secretariat to submit a response to comments on the 2nd version of draft opinion for distribution to SEAC members. Secretariat to ask Forum for the second advice.
c) Dichlorobenzene – 1st version of SEAC draft opinion	
SEAC rapporteurs presented the 1st version of the SEAC draft opinion, and comments received from the Committee members so far.	(Co-)rapporteurs to take the comments into account while preparing the 2nd version of the draft opinion. (Co-)rapporteurs in cooperation with the Secretariat to submit a response to comments for distribution to SEAC members.
d) Nonylphenol – outcome of the conformity check	
SEAC agreed that the dossier does not conform to the Annex XV requirements and discussed the recommendations to the dossier submitter.	Secretariat to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC. Secretariat to inform the dossier submitter on the outcome of the conformity check.
5.3 Appointment of (co-)rapporteurs for restriction dossiers	

SEAC took note on the appointment of (co-) rapporteurs for the restriction dossier on 1-Methyl-2-pyrrolidone (NMP) and lead and lead compounds in articles intended for consumer use (confidential room document SEAC/16/2012/04).	SEAC members to come forward as remaining volunteers for the two restriction dossiers.
6. Authorisations	
6.a Capacity building – Economic feasibility	
SEAC was presented with further clarifications by the Secretariat on the concept of economic feasibility as outlined in the room document SEAC/16/2012/06.	SEAC members and observers to give comments/suggestions (for example, how they would define a 'costly but not so costly' alternative if they consider such an approach practical) to the Secretariat by 10 October. Secretariat to elaborate the concept further into a document to be distributed to the SEAC by mid November. Secretariat to consider organising a discussion in an ad hoc group in conjunction with the next SEAC meeting for those members and observers who wish to contribute to the conclusion of the work.
7. AOB	
SEAC was informed about the workplan for the future months.	
8. Action points and main conclusion of SEAC-16	
SEAC adopted the action points and main conclusions of SEAC-16.	Secretariat to upload the action points and main conclusions to CIRCAbc IG.

III. List of Attendees

SEAC-16

SEAC Members
ALEXANDRE João
BENDL Jiri
BRIGNON Jean-Marc
CECCARELLI Federica (via WEBEX)
CSERGO Robert
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GULBRANDSEN Magnus Utne
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SKARŽINSKAS Vitalius
SLEZAK Zbigniew
THIELE Karen
THORS Åsa
TIRCHILA Luminita

Advisors, Dossier Submitters (DS) & Observers
CEDERBERG Inger, IVARSSON Jenny, NYLANDER Anna and VASS Anne Marie (DS representatives)
COGEN Simon (Advisot to J-P. FAYAERTS)
KORHONEN Hanna (Advisor to J. Kiiski)
JENSEN Frank (Phthalates DS representative and RAC Member)
LANGTVET Espen (Advisor to M. Gulbrandsen)
LESTANDER Dag (Advisor to A. Thors)
MCMICKAN Sinead (Advisor to RAC Member Y. Mullooly)
PUES Jonathan (Advisor to C. Dantinne)
VERHOEVEN Julia (Advisor to C. Luttikhuizen)

RAC Members
SØRENSEN Peter Hammer

Stakeholder Observers
COCKCROFT Linda-Jean (Arkema, CEFIC)
BUONSANTE Vito (EEB)
JÀNOSI Amaya (CEFIC)
KÜHN Ingolf (Business Europe)
WATERSCHOOT Hugo (EUROMETAUX)

Representative of the European Commission
KUBICKI Michal (via Webex)
ZIELINSKI Janusz

ECHA staff
BALDUYCK Bo
BOWMER Timothy
DE BRUIJN Jack
DUBOURG Richard
KIOKIAS Sotirios
KIOSK-BIENKO Joanna
KIVELA Kalle
LIPKOVA Adriana
MALM Jukka
MATTHES Jochen
MOTTET Denis
NICOT Thierry
ORISPÄÄ Katja
ÖBERG Tomas
PARADA SUAREZ Diana

RAC (co)-Rapporteurs
DUNAUSKIENE Lina
MULLOOLY Yvonne
DUNGEY Stephen
SCHLÜTER Urs
SMITH Andrew
STOLZENBERG Hans-Christian

PELTOLA Jukka
SADAM Diana
SHUQOM Natasha
SOSNOWSKI Piotr
THUVANDER Ann
VAINIO Matti
VAN HAELST Anniek

Joint RAC/SEAC session

RAC Members
ANDERSSON Alicja
BARANSKI Boguslaw
BARRON Thomasina
BJORGE Christine
BORGES Teresa
BRANISTEANU Radu
DI PROSPERO FANGHELLA Paola
DUNAUSKIENE Lina
DUNGEY Stephen
GREIM Helmut
GRUIZ Katalin
HAKKERT Betty
HALKOVA Zhivka
JENSEN Frank
KADIKIS Normunds
KAPELARI Sonja
LEINONEN Riitta
LOSERT Annemarie
LUND Bert-Ove
MULLOOLY Yvonne
PARIS Pietro
PICHARD Annick
PINA Benjamin
POLAKOVICOVA Helena
RUCKI Marian
RUPPRICH Norbert
SCHLUETER Urs
SCHULTE Agnes
SMITH Andrew
SØRENSEN Peter Hammer (via Webex)
SPETSERIS Nikolaos
STASKO Jolanta
STOLZENBERG Hans-Christian
TADEO José Luis

Advisors to RAC members
BROSCHINSKI Lutz (Advisor to A. Schulte)
GUSTAFSSON Anne-Lee (Advisor to A. Andersson)
McGARRY Helen (Advisor to A. Smith)
McMICKAN Sinead (Advisor to Y.Mullooly)
FLORIDI Elena (Advisor to P. Paris)
HOFER Tim (Advisor to M. van der Hagen)
JANONYTE Agne (Advisor to L. Dunauskiene)
MAHIOUT Selma (Advisor to R. Leinonen)
NUNES Laura (Advisor to J. Tadeo)
PAPPONEN Hinni (Advisor to R.Leinonen)
PECZKOWSKA Beata (Advisor to B. Baranski)
STARKE Sue-Martina (Advisor to H. Stolzenberg)
VIVIER Stéphanie (Advisor to A. Pichard)

RAC Stakeholder observers
ANNYS Erwin (CEFIC)
DMYTRASZ Bohdan (CONCAWE)
MEISTERS Marie-Louise (ECETOC)
MUNARI Tomaso (EuCheMS)
MÜLLER Karsten (Business Europe) (replacing V. Soballa)
REGO Laura (ECEAE)
ROWE Rocky (ECPA)
SANTOS Tatiana (EEB)

Other RAC observers
VARNAI Veda (Croatian observer)

Representatives of the European Commission
LEFEVRE Remi
ROZWADOWSKI Jacek

RAC Invited experts
KORATI Safia
MICHEL Cécile (Invited expert supporting RAC Member Elodie Pasquier who was absent)
TIESJEMA Gitte (Invited expert supporting RAC Member Marja Pronk who was absent)

ECHA staff
BOWMER Timothy
BROERE William
CALVO TOLEDO Juan Pablo
FUHRMANN Anna
KOKKOLA Leila
MOSSINK Jos
RODRIGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
SIHVONEN Kirsi

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	*SEAC/A/16/2012*
Report from other ECHA bodies and activities	*SEAC/16/2012/01*
General principles and guidance for Committee members	*SEAC/16/2012/02*
Revised working procedure for SEAC on developing SEAC opinions on Annex XV proposal for restriction	*SEAC/16/2012/03*
Recommendation to SEAC on the appointment of (co-)rapporteurs for restriction dossiers on 1-methyl-2-pyrrolidone (NMP) and on lead and lead compounds in articles	*SEAC/16/2012/04*
Applications for Authorisation (AfAs) with "multiple dimensions"	*SEAC/16/2012/05*
Authorisations – Capacity building, Economic Feasibility	*SEAC/16/2012/06*
Authorisations - Participation of case-owners and stakeholder observers in opinion development process	*SEAC/16/2012/07*

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):

Name of participant	**Agenda item**	**Interest declared**
FOCK Lars	7.2a Phthalates 7.2b Chromium VI	Dossier submitter
JENSEN Frank	7.2a Phthalates 7.2b Chromium VI	Dossier submitter
LESTANDER Dag	7.2d Nonylphenol	Dossier submitter
SLEZAK Zbigniew	7.2a Phthalates	Previous involvement
THORS Åsa	7.2d Nonylphenol	Dossier submitter

14 September 2012
SEAC/A/16/2012

Final Draft Agenda

16th meeting of the Committee for Socio-economic Analysis

12-14 September 2012
ECHA Conference Centre (Annankatu 18, Helsinki)
12 September: starts at 14:00
14 September: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/16/2012
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-15 action points, written procedures and other ECHA bodies
SEAC/16/2012/01
For information

b) Implementation of Conflict of Interest Policy
- General principles and guidance for Committee members
SEAC/16/2012/02
For discussion
- Eligibility criteria
For information

c) Co-opted members – update from the RAC discussion
For information

d) Facilitation of plenary discussions and written commenting rounds
For discussion

Item 5 – Restrictions

5.1 General restriction issues

a) Update on intended restriction dossiers

For information

b) Update on the review of the restriction process

SEAC/16/2012/03 (room document)
For information

5.2 Restriction Annex XV dossiers

a) Phthalates – comments from the public consultation on the SEAC draft opinion

For discussion

b) Chromium VI – 2nd version of SEAC draft opinion

For discussion

c) Dichlorobenzene – 1st version of SEAC draft opinion

For discussion

d) Nonylphenol – outcome of the conformity check

For agreement

5.3 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/16/2012/04 (room document)
For information

Item 6 – Authorisations

a) Capacity building
   - Economic feasibility

SEAC/16/2012/06 (room document)
For discussion

   - Valuation of environmental impacts of PBTs

For discussion

   - Proportionality in evaluating Applications for Authorisation (AfAs)

For discussion

   - AfAs with 'multiple dimensions'

SEAC/16/2012/05 (room document)
For discussion

b) Participation of case-owners and stakeholder observers in opinion development process

SEAC/16/2012/07(room document)

For discussion

Item 7 – AOB

a) Update of the work plan
b) Feedback on the first four restrictions from the Commission's Impact Assessment point of view

For information

Item 8 – Action points and main conclusions of SEAC-16

Table with Conclusions and Action points from SEAC-16

For adoption