

**Helsinki, 15 March 2011**  
**SEAC/M/09/2010 FINAL**

**Final**

**Minutes of the 9<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**8-10 December 2010**

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

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

Ms Ann Thuvander, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the ninth meeting of SEAC.

The Chair informed that apologies had been received from seven members. Members' advisers present at the meeting as well as observers of the European Commission (COM) and observers of five stakeholder organisations participating to the meeting were introduced. The Chair informed that RAC (co-)rapporteurs and the Chair of the Forum working group on enforceability of proposals for restrictions were to follow relevant parts of the meeting.

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

The Chair informed that Henri Bastos and his advisor Karine Fiore, as well as Silvia Grandi and her advisors Federica Ceccarelli and Lucia Martinozzi were to follow the meeting remotely via Webex. The Chair also mentioned that the meeting would be recorded and the records would be destroyed after the adoption of the minutes.

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

The Chair introduced the Agenda of SEAC-9. The Agenda was adopted without any further changes. The final Agenda is attached to these minutes as Annex II.

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

In earlier meetings two members had declared a conflict of interest with regard to the restriction dossiers on dimethylfumarate and lead in jewellery, and one member a conflict of interest with regard to the restriction dossier on phenyl mercury compounds (Agenda points 8 of the present meeting). No additional conflicts of interest were declared.

### **4) Administrative issues**

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

There were no changes in the composition of SEAC since the last meeting.

#### **b) Renewal of SEAC members' term of office**

SEAC was informed on the status of the renewal exercise. In its new term the number of SEAC members is expected to be 26 (some responses still pending). The new terms of office will start on 14 February 2010 for both new members and renewals to ensure compliance with the REACH regulation (allowing no more than two members per Member State).

#### **c) Outcome of written procedures**

The Chair updated the Committee on the recent written procedure on the adoption of the SEAC-8 minutes which were adopted by consensus.

### **5) Status report of the action points of SEAC-8**

The Secretariat provided an update of the status of the SEAC-7 action points and main conclusions. The Secretariat reported that most actions had been completed on time. Some action points regarding the authorisation had been delayed

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

### Feedback from other ECHA bodies

A document (SEAC/09/2010/32) was distributed with updates from the ECHA Committees and Forum as well as the Management Board. An oral update was given on the more recent meetings, the MSC-15, as well as the meeting of the Forum Working Group on Enforceability of Restrictions.

Concerning the MSC-15 meeting the Chair of the MSC gave a presentation on the identification of SVHC and the adoption of the MSC opinion on ECHA's draft recommendation for the inclusion of eight new substances in Annex XIV that, based on their CMR classification, fulfil the criteria of article 57 of REACH. The Chair of MSC pointed out these substances are expected to be added to Annex XIV in an update that will take place in early 2012. The Chair of MSC highlighted as well that Annex XIV is expected to enter into force in early 2011.

The Secretariat also gave an update on the meeting of the Forum Working group on enforceability of restrictions. This meeting aimed at taking stock of the experiences with the first four advices on enforceability that were given by Forum. The Secretariat stressed the need for Forum to get information from RAC and SEAC about changes proposed to the ongoing restriction proposals to facilitate their assessment of the need of a 2<sup>nd</sup> and 3<sup>rd</sup> advice.

### Feedback from the project on Assessing Health and Environmental Impacts in the Context of Socio-economic Analysis under REACH

SEAC was given a presentation on the recent progress of the DG SANCO working group. The Chair indicated the added value of this WG for the work of SEAC in terms of enhancing the cooperation between EU bodies and increases the visibility of SEAC's work. A table of contents of the final report was presented and discussed. Questions were raised on risk assessment terminology and their 'translation' into socio-economic meaningful concepts. The Chair concluded that the report is of interest to SEAC as it addresses the role of socio-economic analysis in relationship to risk assessment.

## **7) Review of stakeholder participation in the work of SEAC**

Due to lack of time the issue was proposed to be dealt with via written procedure.

## **8) Restrictions**

### **a) General restriction issues**

#### *Update of the ROI*

SEAC was informed about the new entry in the Registry of Intention on four classified phthalates. Three of the substances are already included in Annex XVII (entry 51) concerning different uses. The new intention concerns the use of phthalates in consumer articles. Three of the four phthalates are also in Annex XIV which was voted for favourably by the REACH

Committee and that is currently under scrutiny by Parliament and Council .The fourth phthalate is on the candidate list. The dossier is expected to be submitted in January 2011.

#### *Appointment of rapporteurs*

SEAC was informed on the outcome of the call for expression of interest for rapporteurship for the expected phthalates dossier. Two expression of interest were submitted by SEAC members. SEAC agreed on the nomination of a rapporteur and a co-rapporteur for the phthalates dossier.

#### *Revision of the working procedure on conformity check*

The Secretariat gave an overview on the proposed changes in the working procedure. The main changes were the introduction of agreement on conformity both in oral and in written procedure. The template to document the outcome of the conformity check is now also detached from the procedure in order to be able to update the template independently. Another change was the addition of a clause that would allow the establishment of the conformity in case either of the Committees fails to agree on it conformity within 30 days.

It was pointed out that the current text describes two ways in which the Committees agree on the conformity that are not consistent with each other. SEAC preliminary agreed on the revised document (SEAC/09/2010/28) provided that this inconsistency in the text would be dealt with.

#### *Added value of illustrative examples*

A presentation was given on the added value of illustrative examples and how quantifications can be carried out in the absence of quantitative data in some aspects. The restriction proposal on DMFu was taken as an example.

SEAC concluded that quantifications using assumptions to complement market or other data might be helpful. Quantification could be carried out to complement qualitative information. The added value of the quantification (in the DMFu example) was that it demonstrated the main driving elements in the analysis and helped to better understand the orders of magnitude of both costs and benefits. It was further concluded that quantitative analysis complements qualitative description. Care is needed to avoid a “quantification bias”. With all the caveats an approach such as the one presented for DMFu could be useful as it makes the SEA more explicit. This in turn enables to focus the discussions and the justification for a particular restriction and enhances transparency.

The Chair concluded that the use of illustrative examples in restriction reports may be helpful to complement qualitative description. The rapporteurs may also themselves prepare illustrative examples to support their own work and, for instance, to get a better understanding on how sensitive the proportionality of the proposed restriction is to the changes in assumptions. Further illustrative quantitative examples may also help in reaching a common understanding on information needs and what is analytically desirable for SEA's within the framework of REACH.

## **b) Second version of the SEAC draft opinions – state of play (April dossiers)**

- **DMFu**

The Secretariat gave an update on the discussions in RAC-14 concerning the DMFu proposal. The (co-)rapporteurs gave a presentation on the contents of the 2<sup>nd</sup> draft version of the opinion and comments received from the members. Also comments received in the public consultation so far were presented.

SEAC was informed that RAC agreed on the approach to be followed in the RAC opinion with regard to the wording of the proposed restriction for DMFu. Concerning the wording of the proposed entry, the COM representative indicated that RAC and SEAC are expected to give a scientific and technical opinion as their main contribution, but that it is appreciated to have the scientific and technical argumentations translated into the wordings for an annex XVII entry.

SEAC agreed with the main principles in the 2<sup>nd</sup> version of the draft opinion. Concerning the wording of the restriction, SEAC agreed to use the text proposed by RAC as described in the annex of the opinion of RAC.

SEAC agreed to annex the illustrative example described above (Agenda item 8a) to the background document and to reflect some of the discussion on the presentation in the annex.

The Chair concluded that none of the SEAC members asked for new analysis or new information. The level of information in the 2<sup>nd</sup> version of the SEAC draft opinion seemed to be sufficient and that there would not be a need for new information or new analysis. Some elements of the 2<sup>nd</sup> version of the SEAC draft opinion could benefit from some further work and increased clarity and some additional statements could be made, for example on information sources.

The deadline for SEAC comments on the 2<sup>nd</sup> version of the SEAC draft opinion was extended to 21 December 2010. The Secretariat proposed to request the second Forum advice solely based on the 3<sup>rd</sup> version of the RAC opinion as the wording of the restriction entry included in (the annex of) the 2<sup>nd</sup> version of the SEAC draft opinion is supported also by SEAC.

- **Lead and its compounds in jewellery**

The rapporteur for the restriction dossier presented the 2<sup>nd</sup> version of the SEAC draft opinion. In their presentation the rapporteur also reported from the discussions on the dossier at the RAC-14 meeting and reflected upon the (co-)rapporteurs' views on the responses of the dossier submitter on the first Forum advice and reflected briefly upon early RCOMs. The rapporteur also highlighted the key questions for consideration by SEAC, among others, how to assess economic feasibility when there is lack of information, and whether the restriction should cover only fashion jewellery or only jewellery intended for children.

During the discussion several members expressed their support for the two step approach of enforcing the restriction (content and migration approach) as put forward in the draft opinion. Other members advocated for a concentration limit in the restriction proposal on its own to keep the restriction better enforceable by keeping the wording simple and easy to understand.

During the discussion the (co-)rapporteurs explained that, in addition to the uncertainties on the side of benefits in the Cost Benefits Analysis, there are also uncertainties in the costs calculation that relate to the number of pieces of lead containing jewellery, the content of lead

in jewellery, average price of lead containing jewellery, substitution costs of alloy in jewellery, etc. Some members expressed their concerns about the number of assumptions made in the CBA and called for their clarification. Following a query of one member the Chair explained that if RAC concluded that the risk is negligible, there is no basis for SEAC to form an opinion or it could still produce opinion based on the original restriction proposal. The Secretariat thought that additional monitoring costs were likely to be small as other substances like nickel and cadmium content are monitored in jewellery as well. One stakeholder observer offered to provide data on the testing practices of precious jewellery. SEAC agreed on the general approach for dealing with proportionality set out in the partial CBA.

With regard to the issue of *reducing the scope of the restriction to jewellery intended for children and exempting precious metal jewellery*, the co-rapporteur explained that the motivations for these considerations had been the potential improvement of proportionality of the restriction proposal (the net benefit associated with the restriction increased), desire not to impose unnecessary regulation on industry and regulatory consistency with the US and Canadian regulations. Several SEAC members pointed out the problem of the lack of definitions for different types of jewellery and high likelihood of children having access to jewellery intended for adults. The Chair reminded that, with the two step approach, parts of the precious jewellery sector would not be affected. Should there be an Annex XVII entry based on content of the piece of jewellery, a derogation for crystal glass might be needed. One member questioned the reduced compliance costs for the precious jewellery sector with the exemption should the company have to test the jewellery to confirm that it contains precious metals as well as to confirm that it fulfils the lead content limit. He suggested also taking an example from the restriction on cadmium which concerns metal parts of jewellery and therefore by definition excludes crystal and gem stones. The restriction on cadmium also defines different types of jewellery using custom codes. One stakeholder observer pointed out, however, that such solution should be taken with caution since such restriction would not cover gems containing lead. The Chair reminded that evidence based justifications are needed for SEAC to propose a change to the restriction proposal made by the submitter. Such justifications could for example build on information received in the public consultation.

SEAC concluded that with the current available information it has neither justification to limit the restriction to the jewellery intended for children nor to exempt precious metal jewellery.

The deadline for SEAC comments on the 2<sup>nd</sup> version of the SEAC draft opinion was extended to 21 December 2010. The Secretariat also proposed to request the second Forum advice solely based on the 3<sup>rd</sup> version of the draft RAC opinion with an indication that it contains an annex with the wording of the restriction entry supported by both RAC and SEAC.

### **c) First version of the SEAC draft opinions – state of play (June dossiers)**

- **Phenyl mercury**

The RAC co-rapporteur gave a presentation of the discussion in RAC on the first version of the draft opinion on phenyl mercury. In that discussion members of RAC discussed key issues for the rationale of the restriction such as the PBT character of the substances as well as the global mercury strategy and the difficulty of quantifying emissions.

RAC had also discussed the scope of the restriction and whether it would be appropriate to cover all mercury compounds in polyurethane systems. RAC could however in their opinion point to the relevance of other substances and the possible need for further restrictions of them. Finally regarding the implementation of the restriction, RAC members discussed an alternative option (3 years delay + possibility of an extension to 5 years based on justified request).

The Chairperson of the Forum Working Group on the Enforceability of restrictions gave a presentation on the Forum advice. It was stressed that the main difficulty with the enforcement of this proposal lies in the difficulty of linking mercury measured in articles to the use of the five phenyl mercury compounds during the production phase.

The dossier submitter gave an overview of the main elements where additional clarifications would be included in the background document. A main issue related to SEAC would be a clearer distinction between costs related to a restriction on use from those on manufacture.

The co-rapporteur gave a presentation on the first version of the draft opinion of SEAC. The rapporteur stressed the importance of finding a solution to the definition of articles and its parts in relation to the wording of the Annex XV entry as it is likely to be a returning issue in many restriction dossiers. It was brought forward by one member that in general the definition of articles needs to be addressed, but for the individual restriction cases this is of less importance as the wording of the entry can be adapted to suit the specific needs of the restriction in question.

One member pointed out that the use of the words “most appropriate community wide measure’ might have to be changed to be coherent with the Lisbon treaty. The Secretariat proposed to investigate this issue further.

It was concluded that there were no principle objections to the first draft opinion. SEAC seemed to agree with the main conclusions..

- **Mercury in measuring devices**

The key elements of the first version of the draft RAC opinion was introduced by the RAC rapporteur together with some open questions regarding the dossier presented to RAC during RAC-14 meeting. This was followed by a presentation given by the dossier submitter (ECHA) on the state of play of the dossier.. The Chair of the Forum Working Group on Enforceability of restrictions described the first Forum advice on the enforceability of the proposed restriction on mercury in measuring devices. Subsequently, a presentation was made by the SEAC rapporteur, who introduced the elements of the SEAC draft opinion and summarised the initial comments received from the SEAC members on the proposal, and briefed about the comments received so far from the public consultation.

The following discussion focused on two major issues – the assessment of the proportionality of the proposal and the communication of the need for measures outside the scope of the REACH Regulation.

There was some confusion about the interpretation of proportionality. The Secretariat explained that its view is that proportionality in the REACH Regulation is related to the risk reduction based on Annex XV (Section 3 “(i) effectiveness: the restriction must be... proportional to the risk”).

The Secretariat pointed out that information on income distribution and affordability can be presented in the SEA part (Section F) of the dossier as they relate to e.g. “impacts to consumers” and to “social implications” (see Annex XVI of the REACH Regulation), but that they are not part of the concept of proportionality .

In the assessment of economic feasibility available information on compliance costs faced by actors in the supply chain, financial viability and ability to pass costs down the supply chain needs to be presented. While some members considered the assessment of proportionality a central issue for this dossier, other members argued that due to the specific request of COM

and the Community Strategy Concerning Mercury the focus should be on the availability and feasibility of alternatives and the establishment of proportionality would be a lower priority. COM reminded about the review clause requesting the assessment of the technical and economic feasibility of the alternatives and thus less on the reduction of risks and the related costs.

Several members found the cost-effectiveness benchmarks developed by the dossier submitter to facilitate establishing the proportionality of this restriction dossier (Appendix 2 of the background document) very informative and useful. Other members questioned the basis on which the benchmarks were determined, in particular the lack of any criteria for their determination. The dossier submitter explained that the basis for the benchmarks had been described in a transparent manner so that the Committee could take its stand on their relevance taking all uncertainties into account. The dossier submitter also pointed out that the information in Appendix 2 was complementary. SEAC should be able to conclude on the proportionality of the dossier without such information,. It was agreed that the Secretariat would upload Appendix 2 as revised by the dossier submitter to the SEAC CIRCA.

COM expressed their appreciation of the flagging the waste collection issue in the draft opinion. It was questioned though whether the Committee's opinion is the right means to communicate suggestions to be dealt with under other legal frameworks and whether this is within the SEAC's mandate. The Secretariat reminded that dossier submitters are encouraged to carry out and document a risk management option (RMO) analysis as well as communicate its results to relevant bodies when considering a restriction proposal, and that this is also reflected in the existing guidance for restrictions. One member pointed out that if the assumptions of waste collection rates due to the actions under other legal frameworks affect the proportionality of the restriction proposals, they should be considered in the opinion. It was concluded that COM and the Secretariat are to continue to discuss the communication on the waste issue and find a way forward at a later stages of the opinion development.

With regard to the plea of the Forum in its advice for clear wording of a proposed Annex XVII entry, one member reacted by saying that this is neither a requirement of the Annex XV of the REACH Regulation, nor is it necessarily relevant at the stage of proposal submission or opinion formulation (the restriction proposal may change and specifics of all MS may not be taken into account). It was concluded that the checklist for the development of the Forum advice on enforceability of restrictions could be useful for dossier submitters.

#### *d) Joint RAC&SEAC session*

##### *Role and scope of the conformity check of restriction dossiers*

The Secretariat gave a presentation on the role and scope of the conformity check in light of the experiences gained from the first four restriction dossiers. The Committees were asked for their view on the revised templates and the explanatory documents.

The separation of the recommendations from the questions that cover the legal requirements of the conformity check was further discussed. Members pointed out that by separating the recommendations in a voluntary part, valuable input for the rest of the process would be lost. The recommendations that were made in the past four dossiers have in most cases turned out to be essential elements for the development of the opinion. They were considered to be useful in communication with the dossier submitter on further development on the dossier at an early stage in the process.

The Secretariat responded that the conformity check has its legal basis which limits what can be asked for at that stage of the process; a clear difference is needed between what is required

and what is considered as desirable. Recommendations should be worked on in parallel to the conformity check; they are seen as a useful input for the work of the Committees after the conformity check.

RAC and SEAC agreed on testing the revised conformity check template (RAC/14/2010/61, SEAC/09/2010/30), the template for recommendations on desired information regarding Annex XV dossiers proposing restriction (RAC 14/2010/62, SEAC/09/2010/31) and the explanatory note and guidance for the conformity check of Annex XV dossiers proposing restriction (RAC 14/2010/60, SEAC/09/2010/29) on the next restriction dossier and to adjust the documents further after this if needed.

### *Panel on co-operation between RAC and SEAC – restriction dossiers for DMFu and lead and its compounds*

During the joint RAC and SEAC session, the Secretariat organised a panel discussion on the issue on enhancing the opinion-making process by further improving the collaboration between the two Committees, and in particular the rapporteurs' one on the ongoing restriction dossiers. The aim was also to collect members' views on current experiences, the way practicalities are organised, the liaison with the Secretariat, the usefulness of the communication tools, as well as further needs and suggestions for improvement.

The Secretariat gave an overview of the feedback that had been collected previously concerning the collaboration between SEAC and RAC rapporteurs and the collaboration between the two Committees in general. During the discussion that followed members considered this feedback and made some general recommendations to improve the work in the Committees. It was stressed that a division of work and clear communication benefited the collaboration between rapporteur and co-rapporteur. Differences in backgrounds were in most cases thought to be an advantage as they ensure wider coverage of issues.

The Secretariat indicated the importance of commenting and discussing in the work of the Committees, stressing the need for considering the deadlines dictated by the REACH regulation

The Chair concluded that in general the collaboration between the Committees works well. The Chair also emphasized the interest of other risk assessing bodies into the work of ECHA's Committees and the collaboration between both of them.

Finally, the Chair thanked all the participants for the interesting discussion and the good suggestions provided.

## **9) Authorisations**

### **a) Conformity check**

- **Format to document the outcome of conformity check (incl. conformity check questions)**

The Chair reminded SEAC of the preliminary agreement reached on the Conformity check procedure at the last meeting. In the meantime RAC also agreed on the same procedure resulting in agreement on the procedure from both RAC and SEAC. At SEAC-8 and RAC-13 the Format to document the outcome of the conformity check was discussed.

The Secretariat gave a presentation on the changes in the documents following the commenting round in the CIRCA Newsgroup (see RCOM: SEAC/09/2010/24). During the discussion that followed SEAC members raised their concern about the lack of questions regarding socio-economic information in the conformity check. It was thought that such a question would be useful despite its non-mandatory status to make sure that all necessary information would be available early in the process for SEAC to base its opinion on. This was thought to be especially useful in cases when an application made for the adequate control route would actually have to follow the 'SEA' route (due to e.g. insufficient quality of data on adequate control).

The Secretariat responded that Article 62(5) limits the possibilities to make SEA-related information at the conformity check stage mandatory. In addition, SEA-related information is also expected to be submitted as part of the analysis of alternatives. It is the responsibility and in the interest of the applicant to make their case strong enough to allow RAC and SEAC to justify a (supportive) opinion. Insufficient amount and/or quality of information is expected to be a valid ground for RAC and SEAC not giving a positive opinion on an application for authorisation even if the application might be in conformity.

The Secretariat informed that other vehicles have been put in place in order to accommodate possibilities for getting sufficient information from the applicant. These include for instance the concordance table in which an applicant specifies where information can be found in the application. The Working procedure also includes a step at which additional information can be asked from the applicant. Furthermore, the conformity check allows SEAC to identify desirable information, which will be sent to the applicant. The Secretariat informed SEAC that the possibilities of pre-submission discussion with applicants are also being explored.

SEAC agreed to the format as described in document (SEAC/08/2010/17\_rev.1), provided that no further changes were to be made following discussions in RAC.

### **c) Formulation of SEAC opinion on authorisation applications**

- **Format of an opinion**

The Secretariat gave a presentation on the approach concerning the Format of the opinion on authorisation applications (SEAC/09/2010/34; ROOM DOCUMENT).

In the discussion that followed, members gave feedback on some of the wordings proposed in the document. The definition of threshold substances based on presence of DNEL was questioned, as well as the use of the phrase '*standards of sound and comprehensive evidence based analysis*'. The Secretariat replied to the issue on the DNEL that it had been used in this context as it relates to the definition given in Annex I 6.4 and due to the lack of more appropriate definitions. Better suggestions would, however, be welcome, although the issue on how to define a threshold substance would rather fall under the remits of RAC.

Also the need for SEAC's opinions when dealing with applications following the adequate control route was brought up. The COM representatives indicated that the opinion of SEAC would indeed be useful also in the adequate control route, especially with regards to the analysis of alternatives and the possible substitution plan, which in turn will form a basis for the assessment of the review period.

Members brought up the issue of accumulative exposure in case several applications would be granted for the same substance and whether this could be dealt with in the conditions of the authorisations. The Secretariat pointed to the principle of equal treatment, indicating that it

might be difficult to justify a non-supporting view on one application by the fact that other authorisations had already been granted. The issue has also been brought to the attention of the legal affairs unit of ECHA. The Secretariat promised to come back to the issue once more experience has been gained.

The Chair concluded that there appeared to be consensus about the purpose, scope, general approach and the format of the opinion. It was also evident that some of the issues discussed related to the assessment of the applications, rather than to how the opinion should be drafted.

The Secretariat informed that a CIRCA newsgroup would be opened and invited members to submit comments by 20 January 2011.

A new version of the document will be discussed in SEAC-10 in March 2011.

- **Working procedure for developing opinions on applications for authorisation**

The Secretariat gave a presentation on the comments made during the commenting period on the Working procedure for developing opinions for authorisations and introduced the changes made in the document following these comments. The Chair recalled that the procedure had been discussed in SEAC-8 as well as in RAC-13.

Some member expressed their concern regarding the support to rapporteurs in the analysis of alternatives. The Secretariat explained that the present document was not considered the best place for specifications regarding support to rapporteurs and that the issue would be dealt with in another context.

The Secretariat concurred that analysis of alternatives is a crucial part of an application and that the assessment must be solid. In order to overcome the information asymmetry, the public consultation was thought to be useful. The Secretariat is currently working on a procedure to build up the wording of the “*broad information on uses*” that can be used in the public consultation.

Suggestions were made by members to bring the issue of support to rapporteurs to the attention of higher levels in the ECHA. The Secretariat responded that it has discussed internally how to ensure that relevant information is given by the applicant and intends to test in 2011 how to obtain such information using outside contractors. It also pointed out that other vehicles were being designed to warranty the quality and completeness of incoming applications with regard to information on alternatives. The Secretariat also plans to set up a system for pre-submission discussions with the potential applicants, drawing on the good examples given from other EU institutions.

The Chair also pointed out that in the procedure for appointment of rapporteurs members are invited to express their interest as soon as substances have been placed on Annex XIV. This procedure would allow time for preparations. When relevant, SEAC could invite co-opted members to gain more expert knowledge. The Chair reminded SEAC that the current amounts for remuneration of rapporteurs are unlikely to cover any significant amount of extra help from experts.

One member expressed his wish to submit a reservation related to the lack of specifications regarding the support to rapporteurs in the working procedure. In his opinion the working procedure does not include a clear commitment from ECHA to help rapporteurs to access independent information and advice on the availability of alternatives

One Stakeholder observer mentioned that also for industry information on alternatives is not always available, especially when possible alternatives are produced by other sectors (for example organic alternatives to metal based applications).

SEAC agreed on the Working procedure on the development of an opinion on applications for authorisations (SEAC/08/2010/19\_rev.1), provided that no further changes were to be made following discussions in RAC.

### **c) Assessment of economic impacts**

A presentation was made to clarify the difference between the analysis of alternatives from the point of view of the applicant vs. the decision criteria used by the Commission according to Article 60 (4) which is from the point of view of the society. It was concluded that in practice SEAC will need to assess the economic feasibility of alternatives from the point of view of the applicant but needs to be clear if the application has been made from the point of view of the applicant alone or from the point of view of the (whole) supply chain.

No action was required for SEAC. The Secretariat will give advice on this issue to those who prepare applications for authorisation. The purpose of such advice is to ensure that the applicant understands from whose point of view the application needs to be made.

### **d) Abatement cost curves**

The Secretariat informed about the conclusions of the workshop that took place on 6 October 2010 and how ECHA plans to carry out this work in this respect in 2011. The Secretariat indicated that the aim of the project is to gain better knowledge on costs of alternatives and consequences of substitution that will be helpful in the opinion making stage.

The Secretariat intends to start collecting information about abatement costs of chemicals that have been placed on Annex XIV. Members raised question on the actual availability of information and were highlighting the need to work together with industry. The Secretariat responded that indeed industry and other stakeholder collaboration is needed. It also stated that in order to facilitate this it would select a contractor to collect the information. This would also ensure the handling of data respecting confidentiality rules.

In general SEAC welcomed this development and wished to be informed about results when available.

## **10) AOB**

### *Update of the work plan*

The Secretariat presented an update of the SEAC work plan for the rest of 2010 and 2011 with regard to the four restriction dossiers presently being processed by the Committees and the new dossier on phthalates expected to be submitted in January.

## **11) Action points and main conclusions of SEAC-9**

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

## II. Conclusions and action points

### MAIN CONCLUSIONS & ACTION POINTS - SEAC-9, 8-10 December 2010, (SEAC 9 meeting)

<b>Agenda point</b>	
<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>2. Adoption of the agenda</b>	
The revised agenda (SEAC/A/09/2010_rev.1) was adopted	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>	
In earlier meeting conflicts of interest have been declared for the agenda points 8. restriction dossiers	
<b>4. Administrative issues</b>	
<b>4a. Changes in the SEAC composition/nominations</b>	
<b>4b. Renewal of SEAC member's term of office</b>	
SEAC was informed on the status of the renewal exercise. SEAC was informed that the new members term of office will start on 14/2 in order to accommodate the requirements of REACH (two members per MS)	
<b>4. Outcome of written procedures</b>	
SEAC was informed that the minutes of SEAC-8 had been adopted via written procedure by consensus	
<b>5. Status of the action points of SEAC-8</b>	
SEAC was informed on the status of the action points of SEAC-8	
<b>6. Feedback from Other bodies</b>	
	Secretariat to update the room document with information from RAC-13 and to upload it to circa

<b>7. Review of stakeholders participation in the work of SEAC (closed session)</b>	
	Secretariat to launch written procedure on this agenda item
<b>8. Restrictions</b>	
General restriction issues	
SEAC agreed on the nomination of a rapporteur and a co-rapporteur for expected Phthalates dossier.	
Update of conformity procedure for restrictions	
SEAC preliminary agreed on the revision provided that the inconsistency in the text (on when the c'tees agree on the conformity) will be dealt with.	
b) 2 <sup>nd</sup> version of the SEAC draft opinion	
DMFu	
SEAC agreed with the main principles in the 2 <sup>nd</sup> version of the draft opinion  Concerning the wording, SEAC agreed to the text proposed by RAC as described in the annex of the opinion.  SEAC agreed that the level of information in the opinion seems to be sufficient. SEAC agreed that there would not be a need for new information or new analysis. Some minor elements could benefit from some further work, increased clarity. Among which the justification and some rewording.  SEAC proposed to have the illustrative qualitative analysis on DMFu as an annex to the BD.  The opinion as such will be forwarded to the Forum.	The deadline for comments on the 2 <sup>nd</sup> draft is extended to 21 December 2010
lead	
In general members seem to be supportive for original proposal in French dossier.	Secretariat to check for extension of commenting period: discuss with rapporteurs

<p>SEAC was consulted on the questions raised by the rapporteurs.</p> <p>SEAC agreed the approach set out in the partial CBA in the current opinion</p> <p>SEAC concluded that with the current available information an exemption for precious jewellery would be difficult to justify. The Forum could be consulted on enforceability of possible exemptions.</p>	<p>to extend come back with deadline later during the meeting.</p> <p>The deadline for comments on the 2<sup>nd</sup> draft is extended to 21 December 2010</p>
<p>b) first version of the SEAC draft opinion</p>	
<p>Phenylmercury</p>	
<p>SEAC was given a presentation on the advice of the enforceability of the proposal by the Forum WG Chair.</p> <p>SEAC was given a presentation on the recent work on the background document.</p> <p>It was concluded that there are no overall objections to the first draft opinion, SEAC seemed to agree with main conclusions.</p>	<p>Secretariat to investigate consequences of the Lisbon treaty on the standard wording used in the opinion template (i.e. 'community wide')</p> <p>SEAC is invited to submit comments on first versions of draft opinion by December 17 via CIRCA IG</p>
<p>Mercury in measuring devices</p>	
<p>SEAC was given a presentation on the advice of the enforceability of the proposal by the Forum WG Chair. It was concluded that checklists developed by Forum could be useful for dossier submitters.</p> <p>SEAC also given a presentation on the recent work on the background document</p> <p>Regarding the waste issue it was concluded that COM and Secretariat are to continue to discuss this and find a way forward in later stages of the opinion development.</p> <p>Different views were expressed on the need to further develop issue of proportionality in the dossier</p>	<p>Secretariat to upload Appendix 2 of the dossier to SEAC CIRCA</p> <p>SEAC is invited to submit comments on first versions of draft opinion by December 17 via CIRCA IG</p>
<p><b>9. Authorisations</b></p>	

a) conformity check	
<p>SEAC raised concerns on the non-mandatory status of socio-economic information on the conformity check. The Secretariat pointed out that other vehicles are considered for gathering information.</p> <p>SEAC preliminary agreed to the revised template as presented. Provided no changes due to decisions in RAC.</p>	
b) formulation of SEAC opinion on authorisation applications	
Format of an opinion	
<p>The Chair concluded that there was consensus about the purpose, scope and the general approach concerning the format of making of the opinion. It was also evident that some the issues discussed related to the assessment of the applications, rather than how to document the opinion, which was the agenda item. During the discussion several preliminary suggestions were made to improve the opinion format.</p>	<p>Secretariat to open a CIRCA newsgroup on this document and invite members to submit comments by 20 January 2011.</p> <p>A new version will be discussed in the next SEAC meeting in March 2011.</p>
Working procedure for developing opinions on the applications for authorisations	
<p>SEAC temporarily agreed on the working procedure, provided no further comments come from RAC.</p> <p>Some member expressed their concern on the issue of support for rapporteurs.</p> <p>One member expressed the wish to submit a minority position, which will be submitted in writing after the meeting.</p>	<p>Secretariat to consider further issue of the support for rapporteurs</p>
c) assessment of economic impacts	
<p>A presentation was made to clarify the difference between the analysis of alternatives from the point of view of the applicant vs. the decision criteria that is used by the Commission according to Article 60 (4) which is from the point of view of the society. It was concluded that in practice SEAC will need to assess the economic feasibility of alternatives from the point of view of the applicant but needs to be clear if the application has been made from the point of view of the applicant alone or from the point of view of the (whole) supply chain.</p>	<p>While no action required vs. SEAC, the Secretariat will give as much as guidance as possible to those who prepare applications for authorisation. The purpose is to ensure that the applicant is clear from whose point of view the application has been made.</p>

d) abatement cost curves	
The Secretariat informed about conclusions of a recently held workshop and how it plans to carry out this work in 2011. In particular the Secretariat intends to start collecting information about abatement costs of chemicals that have been placed on Annex XIV	SEAC welcomed this development and wished to be informed about first results when they are available.
<b>AOB</b> ○ <b>Update of the workplan</b>	
SEAC was informed on update of the workplan	
<b>Action points and main conclusion SEAC-9</b>	

### III. List of Attendees

<b>SEAC Members:</b>	CECCARELLI, Federica (advisor to GRANDI, Silvia via webex)
BASTOS, Henri (webex)	HUOTORAN, Svetlana (adviser to THIELE, Karen)
BENDL, Jiri	HENNIG, Phillipp (adviser to THIELE, Karen)
BRIGNON Jean-Marc	SCHOU, Jorgen (advisor to FOCK, Lars)
DALTON, Marie	THORS, Asa (adviser to GUSTAFSSON, Lars)
FANKHAUSER, Simone	MARTINOZZI, Lucia (adviser to GRANDI, Silvia, via webx)
FEYAERTS, Jean-Pierre	
FOCK, Lars	
FORKMAN, Mats	<b>ECHA staff:</b>
FURLAN, Janez	ANFÄLT, Lisa
GEORGIOU, Stavros	JAQUEMIN, Katline
GRANDI, Silvia (webex)	KARHU, Elina
GUSTAFSSON, Lars	KOWALSKI, Ulrike
LANGTVET, Espen	LANKOSKI, Jussi
LUTTIKHUIZEN, Cees	LIPKOVA, Adriana
RYDLEWSKA-LISZKOWSKA, Izabela	LOGTMEIJER, Christiaan
SALONEN, Heikki	MERKOURAKIS, Spyridon
SCHUCHTAR, Endre	MÜLLER, Birgit
SIMON, Franz-Georg	PELTOLA, Jukka
SUSNIK, Marko	RODRIGUEZ IGLESIAS, Pilar
TELLING, Aive	SIHVONEN, Kirsi
THEOHARI, Maria	STOYANOVA, Evgenia
THIELE, Karen	SUNDQUIST, Anna-Liisa
TIRCHILA, Luminita	THUVANDER, Ann
VARIZ, Paolo	VAINIO, Matti
<b>RAC Members:</b>	<b>Stakeholder observers:</b>
BARANSKI, Boguslaw	GUARDIA, Jaime (UEAPME)
JENSEN, Frank	HOLLAND, Michael (EEB)
	LEENAERS, Joeri (Eurometaux)
	MUSU, Tony (ETUC)
<b>Forum Members:</b>	VYBOLDINA, Elena (CEFIC)
CUYPERS, Paul	MAKELA, Kari (EMCEF)
<b>Advisers to the SEAC Members:</b>	
BEEKMAN, Martijn (adviser to LUTTIKHUIZEN, C.)	<b>Representatives of the dossier submitters:</b>
VERHOEVEN, Julia (adviser to LUTTIKHUIZEN, C.)	FIORE, Karine (webex)
DOMINIAK, Dorota (adviser to RYDLEWSKA, I.)	GULBRANDSEN, Magnus Utnus
FIORE, Karine (adviser to BASTOS, H., via webex)	MORKA, Heidi (webex)
GULBRANDSEN, Magnus Utnus (adviser to LANGTVET, E.)	LECOCQ, Pierre, (webex)
KIISKI, Johanna (adviser to SALONEN, H.)	

#### **IV. List of Annexes**

- ANNEX I. List of documents submitted to the Members of the Committee for Socio-economic Analysis
- ANNEX II. Final Agenda

**Documents submitted to the Members of the Committee for Socio-economic Analysis**

Revised draft agenda	SEAC/A/09/2010_rev.1
Feedback from other bodies and activities	SEAC/09/2010/32
Explanatory note and guidance for the conformity check of Annex XV dossiers proposing restriction	SEAC/09/2010/29
Template for recommendations on desired information regarding Annex XV dossiers proposing restriction	SEAC/09/2010/31
Revised template for the outcome of the conformity check of an Annex XV dossiers proposing restriction	SEAC/09/2010/30
Revised RAC and SEAC working procedure on conformity check of Annex XV dossiers proposing restrictions	SEAC/09/2010/28
RCOM on the SEAC-8 meeting document “Draft Format to document the outcome of the conformity check of an application for authorisation”	SEAC/09/2010/24
Revised draft Format to document the outcome of the conformity check of an application for authorisation	SEAC/08/2010/17_rev.1
RCOM on the SEAC-8 meeting document “Draft Working procedure for RAC and SEAC for developing opinions on the applications for authorisation” (SEAC/08/2010/19)	SEAC/09/2010/26
Revised draft working procedure for RAC and SEAC for developing opinions on the applications for authorisation	SEAC/08/2010/19_rev.1
Revised draft working procedure for RAC and SEAC for developing opinions on the applications for authorisation	SEAC/08/2010/19_rev.1
Testing the methodology to estimate the abatement costs of certain chemicals	SEAC/09/2010/27

26 November 2010  
SEAC/A/09/2010\_rev.1

## Revised Draft Agenda

### Ninth meeting of the Committee for Socio-economic Analysis

**8-10 December 2010**

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

**8 December: starts at 16:00**

**10 December: ends at 18:00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

*SEAC/A/09/2010\_rev.1*  
*For adoption*

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

**Item 4 – Administrative issues**

- a) Changes in the SEAC composition/nominations
- b) Renewal of SEAC members' term of office
- c) Outcome of written procedures

*For information*

**Item 5 – Status report of the action points of SEAC-8**

*For information*

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

*SEAC/09/2010/22*

Report from DG Sanco WG on improving risk assessment

*For information*

**Item 7 - Review of stakeholder participation in the work of SEAC (Closed Session)**

*SEAC/09/2010/23*

*For information and decision*

**Item 8 – Restrictions**

a) General restriction issues

- Update on intended restriction dossiers
- Revision of the working procedure on conformity check

*For information*

*SEAC/09/2010/28*

*SEAC/09/2010/29*

*SEAC/09/2010/30*

*SEAC/09/2010/31*

*For discussion and preliminary agreement*

b) Second version of the SEAC draft opinions – state of play (April dossiers)

- Lead and its compounds in jewellery
- DMFu

*For discussion*

c) First version of the SEAC draft opinions – state of play (June dossiers)

- Phenyl mercury
- Mercury in measuring devices

*For discussion*

d) **Joint RAC&SEAC session**

- Presentations on co-operation between RAC and SEAC – restriction dossiers for DMFu and lead and its compounds

*For discussion*

- Role and scope of conformity checks of restriction dossiers

*For discussion*

**Item 9 – Authorisations**

a) Conformity check

- Format to document the outcome of conformity check (incl. conformity check questions)

*SEAC/08/2010/17\_rev.1*

*For agreement*

*SEAC/09/2010/24 (RCOM)*

*For information*

b) Formulation of SEAC opinion on authorisation applications

- Format of an opinion

*For discussion*

- Working procedure for developing opinions on the applications for authorisation

*SEAC/08/2010/19\_rev.1*

*For agreement*

*SEAC/09/2010/26 (RCOM)*

*For information*

c) Assessment of economic impacts (applicant's costs vs. costs to the society)

*For discussion*

d) Abatement cost curves

*SEAC/09/2010/27*

*For discussion*

**Item 10 – AOB**

Update of the workplan

*For information*

**Item 11 – Action points and main conclusions of SEAC-9**

Table with Action points and decisions from SEAC-9  
(to be adopted at the end of each meeting day)

*For adoption*