

Helsinki, 26 November 2010
SEAC/M/08/2010 FINAL

Final

Minutes of the 8th meeting of the Committee for Socio-economic Analysis

14-16 September 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 eighth meeting of SEAC.

The Chair informed that apologies had been received from six members, one of whom had sent an invited expert as a replacement. 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 also informed that the current Head of Unit for the Committees at ECHA Ms Leena Ylä-Mononen would become the Director of Evaluation starting from 1 November 2010. Ms Pilar Rodriguez Iglesias, who would become the new Head of Unit for the Committees, was introduced to the SEAC-8 participants. She is presently working as the Head of Unit for Guidance and Helpdesk at ECHA.

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

The Chair informed that Mr Stavros Georgiou was 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-8. The following suggestions for items to discuss under AOB were made:

- Update of the Committee work plan;
- Presentation of the study on short chain chlorinated paraffins (SCCPs).

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

Two members declared a conflict of interest to the Agenda point 7 with regard to the discussion on the restriction dossiers on dimethylfumarate (DMFu) and lead in jewellery.

One member declared a conflict of interest to the Agenda point 7 with regard to the discussion on the restriction dossier on phenyl mercury compounds.

4) Administrative issues

a) Changes in the SEAC composition/nominations

The Chair informed SEAC that two SEAC members, Mr Kristof Kozak and Mr Martin Hajas, had resigned and that the management board had appointed two members, Ms Marie Dalton and Ms Silvia Grandi, since the previous meeting.

b) Renewal of SEAC members' term of office

The Secretariat recalled that the three years term of office is soon ending for those members of SEAC, the Committee for Risk Assessment (RAC), the Member State Committee (MSC) and the Forum for Exchange of Information on Enforcement who had been appointed at an early stage. Therefore, a letter by the Executive Director of ECHA, addressing all permanent representations, had been drafted and would be sent out in the upcoming days. In this letter, the Member States (MSs) are asked to renominate/reappoint the current members, nominate/appoint new members or nominate additional candidates to the abovementioned bodies. The Secretariat mentioned that the letter would be made available to SEAC for information.

c) Other

Framework agreements

With regard to the framework agreements with the MS Competent Authorities (MSCAs), the Secretariat reported that the agreements with Sweden and the Netherlands had been finalised. The aim is to conclude the agreements with those MSs, where the rapporteurs and co-rapporteurs of the first four restriction dossiers come from, in the upcoming weeks. The rest of the framework agreements will also be finalised as soon as possible.

Written procedures

The Chair updated the Committee on the recent written procedures and consultations of SEAC:

- adoption of the SEAC-7 minutes (were adopted by consensus);
- OECD representative's participation to SEAC meetings as an invited expert (agreement was reached);
- participation of RAC (co-)rapporteurs to SEAC meetings (agreement was reached).

Meeting dates

Move of the December SEAC meeting

The Chair informed that the Secretariat intends to move the SEAC-9 meeting to the week 7-10 December to be able to hold it back-to-back/in parallel with RAC-14. Members were asked to inform the Secretariat during the SEAC-8 meeting should this change lead to scheduling conflicts. It was agreed that the Secretariat would confirm in October the exact meeting dates of the next SEAC meeting.

Book Fridays for 2011 March and September meetings

The Chair asked the SEAC members to book the Fridays of the meeting weeks in March and September 2011 in order to accommodate parallel RAC and SEAC meetings (8-11 March and 12-16 September). The Secretariat will inform SEAC as soon as possible on the exact meeting dates.

Book the second week in June 2011

Members were asked to reserve the second week of June 2011 in order to accommodate parallel RAC and SEAC meetings – 7-10 June in addition to the originally planned 14-16 June. The Secretariat will inform SEAC as soon as possible on the exact meeting dates.

5) Status report of the action points of SEAC-7

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. One

action (distribution of the model service contracts to the members) was proposed to be taken over to the action points of SEAC-8.

6) Feedback from other bodies

The Chair informed that the meeting document SEAC/08/2010/16, containing information on the developments in RAC, MSC and the Forum since the SEAC-7 meeting in June, had been submitted to the Committee.

The Chair of RAC provided an update from the main discussions that had taken place at the RAC-12 meeting which had been held on 7-9 September and therefore had not been covered in the abovementioned meeting document. The Chair of RAC reported that the conformity reports on the two June restriction dossiers (phenyl mercury compounds and mercury in measuring devices) had been agreed by RAC by consensus and that the first discussions on the first versions of the RAC opinions on the two April restriction dossiers (DMFu and lead in jewellery) had been held. It was also mentioned that under authorisation, the main discussion had focused on the content of an authorisation application.

With regard to the report from the Commission, Directorate General for Health and Consumers (DG SANCO) working group on improving risk assessment, the Chair proposed that as no substantial developments had taken place since SEAC-7, a more detailed report would be provided to the Committee in the December meeting.

Feedback from the project on Assessing Health and Environmental Impacts in the Context of socio-economic analysis (SEA) under REACH:

The COM observer briefly recalled the background, objectives and timelines of the project, which had been introduced to SEAC in detail at its last meeting in June, and updated the Committee on the developments of the project since SEAC-7. It was agreed that the final conclusions of this project would be presented to SEAC at the SEAC-9 meeting in December and that the Secretariat would consider organising a workshop on the results of the project prior or after SEAC-9.

Feedback from the project on Abatement Cost Curves:

The Secretariat recalled the background of the abatement cost study, the aim of which had been to develop a methodology to prepare cost curves as well as to test the methodology on the three selected substances. The Secretariat added that based on the experiences of the abatement cost study, the work plan for further work on abatement costs for 2010-2012 had been under preparation and that the Secretariat could present it to SEAC at its next meeting. The workshop planned within this project for 6 October was also mentioned. The aim of the workshop is to review the draft report prepared by the contractor and to discuss the work plan for 2010-2012.

7) Restrictions

a) General restriction issues

The Chair informed that on request of the RAC members, the Secretariat had investigated a possibility to publish the conformity check reports of the restriction dossiers. The Secretariat responded that the legal text only prescribes that the outcome of the conformity check should be communicated to the dossier submitter (and not to the public at large). Once the public consultation starts it should be clear to the public at large that the dossier is found to be in conformity, care should be given to avoid commenting on the conformity report but rather on the restriction proposal itself. Publication of the conformity check reports is therefore not envisaged, unless a suitable format for the publication is found.

b) Conformity check (June dossiers)

- **Phenyl mercury**

The SEAC rapporteur and co-rapporteur presented their views on the conformity of the proposal as well as the members' comments (and the (co-)rapporteurs' response to those) regarding the conformity and the (co-)rapporteurs' recommendations for clarifications on the dossier. SEAC was informed about the discussion in RAC on the same dossier by the RAC co-rapporteur.

The Secretariat highlighted that the conformity check procedure would be revised in the context of an overall review and revision of the restriction procedure. The Secretariat thought that the current discussions on the template would provide a good basis for this review.

The discussion focused on the available information on alternatives. SEAC concluded that this information could be found but is scattered throughout the report and that additional information on alternatives is desirable but is not an issue for conformity as such. The public consultation will be used to gather more information on the technical and economic feasibility of alternatives. Lack of information in the dossier about the socio-economic impacts of alternative Hg-free Polyurethane Systems was mentioned as an example. The discussion also focused on the consequences of this information not being provided in the public consultation. The (co-)rapporteurs were of the opinion that enough information had been provided to start developing an opinion on the proposal. Additional information will affect the quality of the opinion.

SEAC agreed by consensus the conformity check report for the Annex XV dossier proposing restriction of phenyl mercury compounds as prepared by the (co-)rapporteurs.

- **Mercury in measuring devices**

To introduce the Agenda point, the COM reminded the Committee of the content and the review clause under entry 18a of the Annex XVII of the REACH Regulation that is linked to the Community Strategy Concerning Mercury in the context of which the COM had requested ECHA to prepare the restriction proposal on mercury measuring devices.

The (co-)rapporteurs reported about the activities taking place since the submission of the dossier. They recognised the circumstances underlining the approach taken by the dossier submitter and shared with the Committee their general observations of the restriction proposal. In addition, they pointed out items that they considered worthwhile elaborating, namely, the reduction of emission from the waste phase, research and development exemption, inconsistency in the references to exports ban, costs related to the life cycle of alternatives, net benefits to the environment, etc. The (co-)rapporteurs appreciated valuable comments of the SEAC members submitted in timely manner. Comments of one of the members were discussed in further detail as they were of a more horizontal nature. The member reminded the purpose of the conformity check and plead for clarity between the 'need to know' and 'nice to know' information in the conformity check report. He expressed his concerns about rapporteurs' tendency to slip into the evaluation of restriction dossiers already at the time of the conformity check. In addition, he pointed out that the level and type of analysis should be proportional for the case and depend on the data available. Another member concurred with these concerns during the discussion. Nevertheless, as the (co-)rapporteurs reported, another member had voiced support for a wider scope conformity check during the commenting round due to its potential to identify issues relevant for the opinion development early on in the process.

The RAC rapporteur gave his reflections of the discussions on the conformity of this dossier at the RAC-12 meeting. He pointed that they had been very similar to those in SEAC. In particular, the limited risk assessment had been debated in RAC. However, RAC had concluded that the dossier is in conformity. RAC had agreed on clarifications on the data on the risk assessment of mercury measuring devices as well as their alternatives.

During the discussion, the COM clarified that the dossier focuses on cutting of mercury supply and demand in the society which is in line with the Community Strategy concerning Mercury. The international consensus on the hazard profile of mercury as a persistent, toxic and bioaccumulative substance lead to an agreement referred to in the Community Strategy on the need to phase out mercury in a cost-effective way. Consequently, the information on risk assessment and net benefits had been considered not a priority and exclusion of this data as well as focus on the cost-effectiveness of the technology substitution had been conscious choices by the COM. One member reacted by recommending that future dossiers should clearly state the choices made by the dossier submitter having implications on the level of analysis. At the same time, the member supported the (co-)rapporteurs in their request for more information on exposure as it would allow putting the analysis of alternatives into perspective.

After the discussion, on request of the Chair, **SEAC agreed by consensus the conformity check report for the Annex XV dossier proposing restriction of mercury in measuring devices as prepared by the (co-)rapporteurs.**

c) Presentation on dossiers by dossier submitter (June dossiers)

- **Phenyl mercury**

The dossier submitter (Norway) presented the restriction proposal on phenyl mercury compounds. In the discussion that followed the dossier submitter gave clarification on a number of issues.

It is assumed that phenyl mercury compounds are extensively used in third countries but no information could be obtained on the exact import volume of articles containing the substances. Restriction was chosen as a Risk Management Option (RMO) (as opposed to authorisation) so as to also cover the import of articles.

In articles produced with phenyl mercury catalysts the mercury concentration is usually below the waste regulation limit and those articles are therefore not handled as dangerous waste.

Health benefits to workers were not included in the analysis; this is considered to be an extra health benefit that is not evaluated in the report.

A wide range of alternatives is considered to be available, among which there are alternative plastics. Although industry had indicated that some high performance uses might be more difficult to substitute, precise information on this is lacking.

The dossier submitter furthermore clarified that the two years phase out period is not cheaper but reduction in emission is larger and therefore cost effectiveness is seemingly lower for the restriction option 2. Besides this, the quality of the end product for the user is deemed to be an important cost factor. However, this is also the part that is the most difficult to quantify/monetize and on which most uncertainty exists. The dossier submitter pointed out that industry had indicated that with a long enough phase out period industry would be able to substitute phenyl mercury whilst maintaining the same level of quality of end-products. Therefore, the dossier submitter concluded that the five years phase out period is more cost-effective.

- **Mercury in measuring devices**

The ECHA Secretariat as the dossier submitter of the Annex XV dossier proposing restriction of mercury in measuring devices presented the restriction proposal. The presentation focused on the scope of the proposal and reasoning for the analytical approach applied in the dossier.

During the discussion, several members brought up issues related to the scope of the restriction. One member pointed out potential inconsistency in the dossier regarding the relationship between the restriction proposal and restrictions on export under the Regulation (EC) No 1102/2008. The COM confirmed that export of mercury measuring devices is not covered by the restriction proposal due to the export ban on products containing mercury is to be examined under the Regulation (EC) No 1102/2008 and suggested that the issue would be clarified with ECHA before the start of the consultation.

Several members suggested that the wording of the proposed restriction should be presented in the dossier as a direct Annex XVII entry to allow meaningful public consultation. The Secretariat explained that the formulation was intentional as the COM but not ECHA is in position to formulate possible legal amendments, in particular in this case where the possible new restriction has to fit to the existing restriction in entry 18a of the Annex XVII. Nevertheless, the Secretariat ascertained that the wording of the proposed restrictions and derogations are equally precise as entries in the Annex XVII. The Chair reminded SEAC that dossiers may not be modified after submission.

One member brought up the need to address the derogation regarding research and development at an early stage. The Secretariat informed that ECHA is together with the COM working on the clarification of the generic exemption from the Restrictions Title of the REACH Regulation.

Members exchanged also their views on the quality of analysis and sufficiency of data. One member questioned validity of the cost effectiveness ranges to establish proportionality presented in the Appendix 2 of the report and hinted that there might be additional relevant information available. Other members supported this opinion by giving examples of information on treatment of mercury emissions and recommended measures during accidental breakage of mercury measuring devices that could be used to estimate the associated costs. The dossier submitter welcomed this suggestion but noted also that caution should be used as some data might not necessarily be directly comparable due to the technical progress or different nature of 'mercury removal' (emissions to water not directly comparable to replacing mercury in measuring devices).

Some SEAC members suggested also that data on exposure to mercury from the use and breakage of measuring devices is available. The Secretariat encouraged the SEAC members to provide such data but expressed its reservations with regard to the usefulness of this data due to the focus of the restriction report on the availability of alternatives.

The Chair concluded the discussion by reminding members of the commenting round at the beginning of the opinion formulation process where the SEAC members would be invited to submit their further comments on the dossier.

d) First version of the SEAC draft opinion – state of play (April dossiers)

- **DMFu**

The dossier submitter (France) presented the planned major updates in the DMFu background document relevant for SEAC; the further elaboration on the baseline and the precise wording of the Annex XVII entry. SEAC was informed on the recent discussion in RAC as well as given a presentation on the Forum advice on the enforceability of the DMFu proposal. The SEAC (co-)rapporteurs presented the first version of the draft opinion as well as the inclusion of comments of the SEAC members.

Following the presentation on the Forum advice, a discussion on the inclusion of standard test methods in opinions was held. It was thought (and confirmed by the COM) that this should be considered as a ‘nice-to-have’ as restrictions can be imposed without an agreed analytical test method.

As the precise scope and wording of the future biocides regulation is still under discussion, there is no reason for SEAC not to develop an opinion on the DMFu proposal. Furthermore, it was argued in RAC that the future biocides regulation can not be considered as an existing RMO and could therefore be left out of the RMO analysis.

It was pointed out that placing on the market covers any market. Enforcing a DMFu restriction on the second hand market would be left up to the discretion of national enforcement authorities.

SEAC thought that the updated baseline on DMFu, using illustrative numbers (based on plausible assumptions), was useful but care should be given when presenting this. As human health benefits, although not quantified, can be clearly demonstrated, the added value of the illustrative example should be considered taking into account the proportionality of the analysis.

It was brought forward that cost figures from court cases constitute a measure of compensation but they do not constitute a measure of welfare loss as used in the cost-benefit analysis. The (co-)rapporteurs should consider how to include this in the opinion.

It was further pointed out that there had been cases reported in nine European countries which illustrate the justification for action on a Community wide basis. Although the RAPEX¹ notifications do not give information on the number of articles per reported use of DMFu, the number of cases of DMFu-induced dermatitis reported in the UK court cases (1600) demonstrates the scale of the problem.

Some members expressed concern as to what extent a risk analysis had been performed for each alternative mentioned in the proposal. The (co-)rapporteurs responded that the product 9² category in the register for biocidal products contains 135 entries. This indicates that number of alternatives is likely to exist. It was pointed out that alternatives could also constitute different techniques for preventing humidity to allow transportation of non-treated articles.

SEAC concluded that the view on the exact wording of the Annex XVII entry is to be further discussed by the drafting group. The drafting group will not do any additional work as regards inclusion of a standard test method in the Annex XVII entry, as restrictions can be imposed without prior definition of standard test methods. The members of SEAC agreed in general that illustrative scenarios/numbers can be used as long as the assumptions are stated transparently and when possible, sources are given. Care should be taken on how and where to use illustrative examples.

¹ RAPEX is an EU rapid alert system for dangerous non-food consumer products.

² Product-type 9: fibre, leather, rubber and polymerised materials preservatives.

- **Lead and its compounds in jewellery**

The session started with a presentation by the dossier submitter (France) on the planned updates in the first version of the background document, which they are supposed to submit by 15 October. After that, the key elements of the RAC draft opinion were introduced and some open questions explained by the RAC co-rapporteur for this dossier. A representative of the Forum working group on enforceability of proposals for restrictions described the first Forum advice on the enforceability of the proposed restriction on lead in jewellery. The last presentation was made by the SEAC rapporteur for the lead restriction dossier, who introduced the elements of the SEAC draft opinion, and described the initial comments received from the SEAC members on the proposal as well as how these comments had been taken into account in the elements of the draft opinion. The SEAC rapporteur also provided a brief overview of the next steps in the work with the lead dossier.

A member asked the dossier submitter whether it is manageable for them to do all the updates in the background document, considering that both Committees had made quite a lot of suggestions for improving the proposal. The dossier submitter responded that – although willing to take into account all recommendations by the Committees – they might need to prioritise between different issues to be improved in the proposal due to time constraints. The dossier submitter added that it would be useful to get suggestions from the SEAC members regarding prioritisation of the issues to be improved.

One stakeholder observer made a remark that lead producing industry clearly favours the migration limit approach, which is also applied for the nickel restriction in jewellery. However, the two step approach (lead content + migration) proposed by the dossier submitter is also acceptable for industry.

The Chair reminded that the written commenting round on the elements of the SEAC draft opinion is ongoing until 17 September and encouraged the SEAC members to provide comments which could help the (co-)rapporteurs in their further work with the opinion on the lead dossier. The second version of the SEAC draft opinion will be available in the second half of November and will be discussed at the plenary meeting in December 2010.

8) Authorisations

The COM observer provided an update regarding the inclusion of substances in Annex XIV of the REACH Regulation, which is the list of substances subject to authorisation. The COM had prepared a draft decision on the basis of the recommendation by ECHA, according to which six out of seven substances recommended by ECHA were proposed by the COM for inclusion in Annex XIV. The draft decision had been presented to CAs for REACH and CLP (CARACAL) in June and the REACH Committee will vote on this proposal on 21 September 2010. Once the decision is adopted, it will be published in the Official Journal (OJ) and will enter into force three days after the publication.

With regard to the guidance documents concerning authorisation the COM observer reported that the guidance for the preparation of an application for authorisation had been presented and endorsed in the June CARACAL meeting. The COM translation services have informed that they would have the guidance document translated by 22 October. The COM will then publish it in the OJ and hand it over to ECHA. The guidance on SEA in authorisation process had also been presented to CARACAL in June and will soon be proposed for endorsement.

a) Content of an authorisation application

The Secretariat gave a presentation on the content and structure of authorisation applications. The purpose and the legal basis of an application for authorisation were explained. The

Secretariat also described the content of the sections of the applications, including the assessment reports such as analysis of alternatives, substitution plan and socio-economic analysis. A preliminary outline of former two reports was provided in the room documents SEAC/08/2010/22 and SEAC/08/2010/23. The Secretariat briefly described the preparatory activities of the COM and ECHA related to authorisation applications (preparation of user manuals, submission tools, guidance to applicants, etc).

One member emphasised the importance of taking into account that some alternatives, which are feasible for the users of a substance, might not necessarily be feasible for the applicant.

Another participant questioned whether the applicant needs to prepare a separate IUCLID file for each use applied for. The Secretariat clarified that there would be one file per application, but it is suggested that the applicant describes the uses in separate sections of the assessment reports.

One member raised a question whether the substance function would be described in the application, as this information is necessary for the assessment of alternatives. The Secretariat confirmed that it is indeed very important how the use of a substance is defined. Using the use descriptor system as a starting point, the Secretariat is presently developing a more detailed guidance for applicants on how to describe the uses. The Secretariat added that the substance function would be described in the Chemical Safety Report (CSR). For the public consultation, broad information on uses will be provided, which will contain very limited information on the function. The Secretariat explained that it is currently exploring options for how to formulate the information on uses to be provided for the public consultation, including the potential involvement of the applicant. The Secretariat pointed out that it would also be in the interest of the applicant to have a relevant description of the uses in order to avoid the potential need to provide additional information on alternatives that may not be relevant for this particular application.

One participant asked whether the applicant would be asked to indicate the intended route (adequate control route or SEA route) in the application. The Secretariat responded that it had not been foreseen to ask the applicant to tick a box whether the application is based on the adequate control or SEA route, as the Secretariat does not want to encourage applicants to provide the needed information only for one of the routes. This is so as the COM may decide that an authorisation cannot be granted under Article 60(2) but could be granted under Article 60(4) of the REACH Regulation.

Several questions were raised on the relationship between the analysis of alternatives and the assessment of economic impacts of an authorisation and it was agreed that the Secretariat would consider these issues further and would dedicate a special session on these issues at a later stage.

Questions on alternatives:

The Secretariat provided a presentation on the questions on alternatives as an optional tool for (co-)rapporteurs to assist them in conducting an assessment of the information on alternatives. It was emphasised that information on alternatives would be important for the decision-making on granting authorisations and would form a central element in applications for authorisation. Some example questions were shown to the Committee.

The members of SEAC welcomed the development of such tool that would assist the Committee in the assessment of authorisation applications. It was agreed that the Secretariat would develop this tool further and would consult SEAC on this development at a later stage.

b) Conformity check

- **Working procedure**

The Chair reminded that the draft working procedure for RAC and SEAC on conformity check of authorisation applications had been discussed by SEAC twice (at SEAC-6 and SEAC-7). To RAC the draft procedure had been presented for the first time at RAC-11 in May. Based on the comments made by the RAC and SEAC members as well as on further internal discussions in ECHA on the conformity check process the draft procedure had been revised. The Secretariat introduced the main changes in the revised draft procedure.

One member stressed that when informing the applicant about the Committee's decision on conformity of the application, it is important to state that this decision cannot be regarded as final, because the application has not yet been evaluated by the Committee in full detail. The Chair highlighted that according to the revised procedure the timeline for the conformity check has been extended and the Committees therefore have more time to assess an application before deciding on conformity. However, given the limited scope of the conformity check, it is important that the applicant understands that a positive view on conformity does not exclude requests for information by the Committee later on in the opinion-making process.

SEAC agreed the working procedure for RAC and SEAC on conformity check of authorisation applications (SEAC/06/2010/06_rev.2). The procedure will be proposed to RAC for agreement at the RAC-13 meeting in October. It was also agreed that the procedure would be revised in the future taking into account experience of the first authorisation applications.

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

The Secretariat presented a draft format to document the outcome of the conformity check of an authorisation application. The conformity check questions were provided in the room document SEAC/08/2010/17 and discussed after the presentation. The Secretariat proposed to use this format for the first applications and later revise it, if necessary, after some experience has been gained from the processing of the first authorisation applications.

One member pointed out that the proposed format does not include a question on the accordance of the CSR with Annex I of the REACH Regulation. The Secretariat replied that according to its view it is covered by the question 4b of the format. However, the Secretariat suggested to this member to propose a more suitable wording for the question, if necessary, and the Secretariat would consider whether such question could be included in the format from a legal point of view.

Another member proposed to include in the format a tick box to indicate which route (adequate control or SEA) that is to be followed. The Secretariat agreed to consider this suggestion.

Several participants questioned why the format does not include any question related to SEA. The Secretariat responded that as Article 62(5) of the REACH Regulation states that an application may include SEA, it does not constitute part of the conformity check from a legal point of view. It will be very difficult to support an application aiming for the SEA route without a SEA but relevant SEA information might be included in other sections of the application, for example in the analysis of alternatives.

One member recommended including in the same document additional questions to the applicant on alternatives. The Secretariat answered by pointing out that there are three possibilities for the Committee to ask for additional information from the applicant: 1) within the conformity check (to require), 2) additional information on alternatives (to require), 3) content related questions (to request). The Secretariat prefers to keep these three sets of

questions separate due to their different legal basis. However, the Secretariat indeed foresees to send these sets of questions to the applicant as a joint communication.

The COM observer suggested to include a question regarding information on relevant research and development activities by the applicant, which is required as part of an analysis of alternatives based on Article 62(4)(e), if appropriate. The Secretariat replied that because of the words ‘if appropriate’ this information would require an assessment and cannot therefore be considered as part of the conformity check but rather of the opinion development.

The Chair informed that a CIRCA newsgroup would be opened by the Secretariat on the draft format and encouraged the SEAC members to submit further comments on the document. A revised version of the draft format will be presented to SEAC in December.

c) Formulation of SEAC opinion on authorisation applications

- **Content of the final Commission decisions and their effect on the format of the opinions – response to comments**

The Chair recalled that at the last SEAC meeting the Discussion Paper “The content of final Commission decisions and their effect on the format of the opinions of RAC and SEAC on authorisation applications” (SEAC/07/2010/12) had been presented and discussed. After the meeting, the commenting round had been opened in CIRCA on the document. The Secretariat explained that this Discussion Paper would not be revised, but the comments made by RAC and SEAC would be taken into account in the work with the format of an opinion. The Secretariat summarised the main RAC and SEAC comments as well as the questions raised within the commenting rounds.

It was agreed that the Secretariat would upload also the RAC RCOM on SEAC CIRCA for information.

- **Format of an opinion; examples of conditions**

The Secretariat made a presentation on the format of an opinion and examples of conditions in authorisation procedure. The Secretariat informed that discussions with COM on the format of an opinion were still ongoing and therefore no meeting documents had been provided to the Committee prior to SEAC-8. However, the Secretariat is continuing its discussions with COM and may have a document outlining the draft opinion format as well as a discussion note on conditions and monitoring arrangements presented in the RAC-13 meeting in October. The Secretariat explained that on conditions and monitoring arrangements no format or template had been foreseen, but checklists could be developed. SEAC will discuss these documents at SEAC-9 in December. The aim is to conclude the discussions and agree on the opinion format as well as on checklists for conditions and monitoring arrangements by March 2011.

Several participants pointed out that it might be useful to consult the Forum during the authorisation process. It was agreed that the Secretariat would investigate possibilities for the formal involvement of the Forum in processing of authorisation applications.

One member questioned whether through SEAC opinion, COM could indeed force the applicant to apply some high-cost conditions. The Secretariat responded by emphasising that the conditions set by the Committee would need to be balanced and meaningful. According to the REACH Regulation, applicants may comment on the draft opinions of the Committees, which also give them a possibility to react on the proposed conditions.

It was agreed that if the documents on the format of the opinion and on conditions and monitoring arrangements are submitted to RAC, they would also be made available on SEAC CIRCA for written commenting.

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

The Chair reminded that at the SEAC-7 meeting the document “Elements of RAC and SEAC working procedure for developing opinions on the applications for authorisation” (SEAC/07/2010/13) had been introduced to SEAC. Based on this document and taking into account comments received by the RAC and SEAC members, a detailed working procedure had been developed. The Secretariat introduced the draft procedure for developing opinions on the applications for authorisation.

One member questioned whether the (co-)rapporteurs would be allowed to be in contact with the applicants. The Chair replied by stressing that both RAC and SEAC would need to discuss the involvement of applicants in the work of the Committees keeping in mind the principles of transparency and equal treatment of applicants as well as the confidentiality of information. The Chair informed that the Secretariat had started to prepare a document outlining how applicants would be involved in the Committees’ work. The Chair added that presence of regular stakeholder observers at the Committee meetings, while applications for authorisation are discussed, would also have to be discussed by RAC and SEAC.

Another participant asked whether applications could be submitted to ECHA at any time. The Secretariat responded by pointing out its intention to announce to industry submission dates of the applications for authorisation. This would allow for an effective regulatory processing of all applications taking into account the fact that RAC and SEAC meet periodically. The Secretariat informed that in informal discussions with industry stakeholders they had been supporting setting clear submission dates.

It was agreed that a CIRCA newsgroup would be established after the meeting on the draft working procedure and that a revised version of the draft procedure would be presented to SEAC at SEAC-9.

9) Manual of conclusions and recommendations

The Secretariat presented a proposal for a Manual of Conclusions and Recommendations. The manual should serve as a reference of key, generally valid conclusions and recommendations arrived at by SEAC and would be intended for the use of the SEAC members, their advisers, regular observer representatives and the Secretariat. This document is likely to become a useful tool for the SEAC members in order to ensure coherence and consistency and to avoid duplication of work or any other unnecessary efforts when considering similar issues. SEAC agreed on the structure of the manual and the suggested approach for its handling.

10) AOB

SEAC 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.

It was agreed that members would try to submit comments on the second versions of the SEAC draft opinions on the April restriction dossiers (DMFu and lead in jewellery) by 6 December so as to provide input for the discussions at the SEAC-9 meeting³. An additional slot could be provided for commenting after the meeting, if needed.

³ According to the procedure the commenting round is foreseen for 29 November – 17 December 2010.

Presentation of SCCP report:

Mr Martijn Beekman, advisor of the Dutch SEAC member, made a presentation on the RIVM⁴ SEA report on banning SCCPs. The report describes an analysis of the socio-economic consequences of the decision of the United Nations Economic Commission for Europe (UNICE) on the banning of SCCPs. It was agreed that this report would be distributed also to SEAC for information.

11) Action points and main conclusions of SEAC-8

SEAC endorsed the SEAC-8 action points and main conclusions.

⁴ RIVM is the National Institute for Public Health and the Environment of the Netherlands.

II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS - SEAC-8, 14-16 September 2010, Day 1

(Adopted at the SEAC-8 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the agenda	
<p>The revised agenda (SEAC/A/08/2010_rev.1) was adopted with the following additions under AOB:</p> <ul style="list-style-type: none"> • Presentation on the SEA study for the SCCP under UN • Update of the SEAC work plan 	SEAC-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	
A member declared a conflict of interest to agenda point 7, the restriction proposal on phenyl mercury.	
4. Administrative issues	
4a. Changes in the SEAC composition/nominations	
SEAC was informed of the changes in the composition of SEAC.	
4b. Renewal of SEAC member's term of office	
4b. Update on Framework Agreement/ Service requests	
	<p>Secretariat to circulate the template of the service request and all the annexes.</p> <p>Secretariat to conclude service request with current rapporteur's CA as soon as possible.</p> <p>Members to provide assistance to the conclusion of the framework contracts when possible.</p>
4b. Update on the recent written procedures/consultation	
SEAC was updated on the recent written procedures and consultations.	
4b. Move of the December SEAC meeting	

SEAC was informed on the possible change of the December meeting	Members to inform secretariat during SEAC-8 meeting should this lead to scheduling conflicts
4b. Book Fridays for 2011 March and September meeting	
	Members were asked to reserve Fridays of March and September meeting weeks in order to accommodate parallel RAC and SEAC meeting. Secretariat to inform SEAC as soon as possible on exact meeting dates.
4b. Book 2nd week in June	
	Members are asked to reserve this week in order to accommodate parallel RAC and SEAC meetings. Secretariat to inform SEAC as soon as possible on exact meeting dates.
5. Status report of the action points of SEAC-7	
SEAC took note of the status report concerning the action points of SEAC-7.	The action point concerning the distribution of the service contracts is to be taken over to the SEAC-8 conclusions and action point.
6. Feedback from other bodies	
Report from DG SANCO WG on improving risk assessment Feedback from the project on Assessing H&E Impacts in the Context of SEA under REACH Feedback from the project on the Abatement Cost Curve	SEAC secretariat to report from DG SANCO working group in December meeting. Final conclusions of this project to be presented at SEAC-9 (if possible). Secretariat to consider organizing a workshop on the results of this project prior or after SEAC-9. Secretariat to give an update on the abatement cost project and a presentation on the work plan at SEAC-9.
7. Restrictions	
b) Conformity check (June dossiers)	
Phenylmercury	
SEAC agreed on the conformity report.	Secretariat to initiate the revision of the conformity check-questions and procedure, now that the conformity check of the first four dossiers has been carried out.
Mercury in measuring devices	

SEAC agreed on the conformity report	Secretariat to consider, during SEAC-8, publishing the conformity check reports.
Presentations by dossier submitter	
Action points and main conclusion SEAC-8 (day 1)	
SEAC agreed on the main action points and conclusions of day 1.	

MAIN CONCLUSIONS & ACTION POINTS - SEAC-8, 14-16 September 2010, Day 2

(Adopted at the SEAC-8 meeting)

7d) First versions of SEAC draft opinions (April Dossiers)	
DMFu (7d)	
<p>The committee expressed no major concern as regarding the outline presented by the rapporteur.</p> <p>Still some issues to be sorted out regarding exact wording of the Annex XVII entry.</p> <p>Restriction can be imposed without an agreed analytical method</p> <p>Analysis with hypothetical numbers is thought to be useful. However caution is warranted on when and where to present those numbers. Alternative ways of cost/benefit calculations are preferred.</p>	<p>Members are invited to examine the first version of the draft opinion and submit comments via the CIRCA IG Newsgroup.</p> <p>Drafting group to further develop wording of the entry.</p> <p>Secretariat to give an update on the discussion concerning the DMFu restriction proposal in the Forum meeting on 12-14 October at the next SEAC</p>
Lead	
<p>The committee expressed no major concern as regarding the outline presented by the rapporteur</p> <p>Several parts of dossier are presently being updated.</p> <p>The current document called 'elements of the opinion' for this agenda point contains a considerable amount of information that is considered to be useful for the development of the opinion.</p> <p>Important to work in parallel with RAC although RAC is developing its opinion on the RA.</p>	<p>Members are invited to examine the elements of the opinion as posted on CIRCA and submit comments via the CIRCA IG Newsgroup.</p> <p>Members are invited to give input, via CIRCA IG Newsgroup, on prioritisation of issues to be solved by Dossier Submitter</p> <p>Secretariat to give an update on the discussion concerning the lead in jewellery restriction proposal in the Forum meeting on 12-14 October at the next SEAC</p>
8. Authorisations	
8a) Content of an authorisation application	
<p>Questions were raised on the relationship between</p>	<p>Secretariat to consider this issue further and</p>

analysis of alternatives and the assessment of economic impacts of an authorisation.	dedicate a special session on this issue.
-questions on alternatives	
SEAC welcomed the development of a tool / list of questions that would assist SEAC in the analysis of authorisation applications.	Secretariat to develop this tool further and to consult SEAC on this development at a later stage.
8b) Conformity Check	
Working procedure	
SEAC agreed on the revised working procedure on the conformity check for authorisation applications.	
Format to document the outcome of conformity check (incl. conformity check questions)	
	Secretariat to open a CIRCA newsgroup on this document and to present a revised version of the draft format in the December meeting.
Action points and main conclusions of SEAC -8 (day 2)	
SEAC agreed on the main action points and conclusions of day 2.	

MAIN CONCLUSIONS & ACTION POINTS - SEAC-8, 14-16 September 2010, Day 3
(Adopted at the SEAC-8 meeting)

8c) Formulation of SEAC opinion on authorization applications	
Content of the final Commission decisions and their effect on the format of the opinions – response to comments	
<p>SEAC reconfirmed the approach that the Secretariat and the Commission have taken regarding the role of the opinion in the overall decision making concerning authorisation applications.</p> <p>Details of the wording of the opinion would be looked into in the December meeting.</p>	<p>Secretariat to upload RAC RCOM to the SEAC CIRCA.</p> <p>Once discussion paper on opinions is ready Secretariat will upload to CIRCA IG Newsgroup for discussion.</p>
Examples of conditions/ format of an opinion	
<p>SEAC thought that the categorisation that was presented was useful</p> <p>SEAC pointed out that the involvement of the Forum is to be investigated.</p> <p>SEAC thought that the examples that were presented were a good basis for further work.</p> <p>It was left open whether a checklist would be developed.</p>	<p>Secretariat to further develop the draft documents and to aim at presenting those at the next RAC meeting in October.</p> <p>Secretariat to investigate the possibilities of formal involvement of the Forum in the processing of authorisation applications.</p> <p>Once these documents have been submitted to RAC also make these available on SEAC CIRCA for written comments.</p> <p>Present (revised) versions in December meetings (to be finalised, possibly, by March 2011).</p>
Working procedure for developing opinions on applications for authorisation	
<p>SEAC agreed on the main outlines of the working procedure.</p> <p>SEAC recognized the need to discuss the involvement of applicants in the work of the Committees keeping in mind principles of transparency and equal treatment of applicants as well as the (business) confidentiality of information.</p>	<p>Secretariat to open a CIRCA IG Newsgroup on the draft procedure.</p> <p>Secretariat to present a revised version of the draft procedure at the SEAC-9.</p> <p>SEAC to discuss the participation of applicants at SEAC-9 meeting.</p> <p>Secretariat to post the planned RAC-13 meeting document concerning the presence of applicants in meetings to SEAC-CIRCA once this is distributed to RAC.</p>

<p>SEAC welcomed the Secretariat's intention to announce the submission dates of the applications for authorisations as this will allow for an effective treatment of all applications.</p>	
<p>9. Manual of conclusions & recommendations</p>	
<p>SEAC agreed the overall approach presented in the presentation and in the draft document.</p> <p>SEAC agreed to start using the manual of conclusions & recommendations.</p>	
<p>10. AOB</p>	
<p>Workplan</p>	
<p>SEAC agreed to have comments on the 2nd version of the draft opinion of the 'aril' dossiers by the 6th of December so as to provide input to the discussion at SEAC-9.</p> <p>SEAC welcomed to have initial comments from the public consultation at an earlier stage final comments could be submitted later.</p>	
<p>Presentation on SCCP</p>	
	<p>Secretariat to upload report on SCCP on SEAC-CIRCA.</p>
<p>11. Action points and main conclusions of SEAC-8: Day 3</p>	
<p>SEAC agreed on the main action points and conclusions of day 3.</p>	<p>Secretariat to upload action points and conclusions to SEAC- CIRCA.</p>

III. List of Attendees

SEAC Members:	Advisers to the SEAC Members:
BASTOS, Henri	BEEKMAN, Martijn (adviser to LUTTIKHUIZEN, C.)
BENDL, Jiri	DOMINIAK, Dorota (adviser to RYDLEWSKA, I.)
BRIGNON Jean-Marc	FIORE, Karine (adviser to BASTOS, H.)
DALTON, Marie	GULBRANDSEN, Magnus Utnus (adviser to LANGTVET, E.)
DANTINNE, Catheline	KIISKI, Johanna (adviser to SALONEN, H.)
ECONOMIDES Aristodemos	VERMANDE, Emilie (adviser to BASTOS, H.)
FAHERTY Mark	
FANKHAUSER, Simone	Representatives of the Commission:
FEYAERTS, Jean-Pierre	GIL, Sebastian (DG ENV)
FOCK, Lars	KUBICKI, Michal (DG ENTR)
FORKMAN, Mats	VLANDAS, Penelope (DG ENV)
FURLAN, Janez	
GEORGIU, Stavros (via Webex)	
GRANDI, Silvia	ECHA staff:
GUSTAFSSON, Lars	ANFÄLT, Lisa
LANGTVET, Espen	JAQUEMIN, Katline
LUTTIKHUIZEN, Cees	KARHU, Elina
MCNALLY Tara *	KOWALSKI, Ulrike
RYDLEWSKA-LISZKOWSKA, Izabela	LANKOSKI, Jussi
SALONEN, Heikki	LIPKOVA, Adriana
SCHUCHTAR, Endre	LOGTMEIJER, Christiaan
SIMON, Franz-Georg	MERKOURAKIS, Spyridon
SUSNIK, Marko	MÜLLER, Birgit
TELLING, Aive	PELTOLA, Jukka
THEOHARI, Maria	RODRIGUEZ IGLESIAS, Pilar
THIELE, Karen	SADAM, Diana
TIRCHILA, Luminita	SIHVONEN, Kirsi
VOIVONTAS, Dimosthenis	STOYANOVA, Evgenia
	THUVANDER, Ann
RAC Members:	VAINIO, Matti
BARANSKI, Boguslaw (via Webex)	YLÄ-MONONEN, Leena
JENSEN, Frank	
LARSEN, Poul Bo (via Webex)	Stakeholder observers:
LE CURIEUX-BELFOND, Olivier (via Webex)	DIMTCHEVA, Ralitza (UEAPME)
VAN MALDEREN, Karen	HOLLAND, Michael (EEB)
	LEENAERS, Joeri (Eurometaux)
Forum Members:	MUSU, Tony (ETUC)
THORAN, Karin	VYBOLDINA, Elena (CEFIC)
	Representatives of the dossier submitters:
	FIORE, Karine
	GULBRANDSEN, Magnus Utnus
	MORKA, Heidi
	VERMANDE, Emilie
* invited expert replacing GEORGIU, S.	

IV. List of Annexes

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

ANNEX I

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

Provisional Draft Agenda	SEAC/A/08/2010_rev.1
Feedback from other bodies	SEAC/08/2010/16
Analysis of Alternatives	SEAC/08/2010/22 (room document)
Substitution plan	SEAC/08/2010/23 (room document)
Format to document the outcome of the conformity check of an application for authorisation	SEAC/08/2010/17
Revised draft Working procedure for RAC and SEAC on conformity check of authorisation applications	SEAC/06/2010/06_rev.2
Draft working procedure for RAC and SEAC for developing opinions on the applications for authorisation	SEAC/08/2010/19
RCOM on the SEAC-7 meeting document “Elements of RAC and SEAC working procedure for developing opinions on the applications for authorisation” (SEAC/07/2010/13)	SEAC/08/2010/20
RCOM on the SEAC-7 meeting document “The content of final Commission decisions and their effect on the format of the opinions of RAC and SEAC on authorisation applications” (SEAC/07/2010/12)	SEAC/08/2010/18
Proposal for a manual of conclusions and recommendations of the Committee for Socio-economic Analysis (MoCR)	SEAC/08/2010/21

14 September 2010
SEAC/A/08/2010_rev.1

Final Agenda

Eighth meeting of the Committee for Socio-economic Analysis

14-16 September 2010

ECHA Conference Centre (Annankatu 18, Helsinki)

14 September: 09:00 – 18:00

15 September: 09:00 – 18:00

16 September: 09:00 – 14:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/08/2010_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

For information

b) Renewal of SEAC members' term of office

For information

Item 5 – Status report of the action points of SEAC-7

For information

Item 6 – Feedback from other bodies

SEAC/08/2010/16

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

For information

Item 7 – Restrictions

a) General restriction issues

For information

b) Conformity check (June dossiers)

- Phenyl mercury
- Mercury in measuring devices

For decision

For decision

c) Presentation on dossiers by dossier submitter⁵ (June dossiers)

For information

d) First version of the SEAC draft opinions – state of play (April dossiers)

- DMF
- Lead and its compounds in jewellery

For discussion

For information

Item 8 – Authorisations

a) Content of an authorisation application

- Information on alternatives and substitution plan

For information

b) Conformity check

- Working procedure

SEAC/06/2010/06_rev.2

For discussion and possible agreement

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

SEAC/08/2010/17

For discussion

⁵ In case dossiers are found to be not in conformity then the dossier submitter will not be invited to the meeting.

c) Formulation of SEAC opinion on authorisation applications

- Content of the final Commission decisions and their effect on the format of the opinions – response to comments

SEAC/08/2010/18 (RCOM)

For information

- Examples of conditions

For discussion

- Format of an opinion

For discussion

- Working procedure for developing opinions on the applications for authorisation

SEAC/08/2010/19

SEAC/08/2010/20 (RCOM)

For discussion

Item 9 – Manual of conclusions & recommendations

SEAC/08/2010/21

For discussion and agreement

Item 10 – AOB

- Update of the Committee workplan
- Presentation on SCCP study

Item 11 – Action points and main conclusions of SEAC-8

Table with Action points and decisions from SEAC-8
(to be adopted at the end of each meeting day)

For adoption