



**SEAC/M/01/2008 FINAL**

**Final**

**Minutes of the 1st meeting of the Committee for Socio-economic Analysis**

**2-3 April 2008**

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

### **1. Welcome and Introduction**

Ms Leena Yla-Mononen, ECHA, who chaired the meeting, welcomed the participants of the first meeting of the Committee for Socio-economic Analysis (SEAC). The Chair introduced the Executive Director (ED) of the European Chemicals Agency (ECHA), Mr Geert Dancet, and gave him the floor for the opening speech.

#### **a) Welcome by the Executive Director of ECHA**

Mr Dancet congratulated the members on their appointment following nomination by their Member States, and stressed the importance of the work of the SEAC as one of the cornerstones of REACH and hence one of the priorities of ECHA, underlining that the Committee is a part of ECHA. He emphasised that the SEAC is an independent scientific expert panel which supports the decision-making process on chemicals and has thus to define its own ways of working. The first tasks of the SEAC are therefore to agree on the Rules of Procedure (RoPs) and to develop efficient working practices and procedures. The ED underlined that an additional challenge to the Committee is that socio-economic analysis (SEA), as introduced by the REACH Regulation, is a new tool in EU chemicals legislation. He reminded the members that they, according to Article 85 (6) of the REACH Regulation, should be supported by the scientific and technical resources available to the Member States, while they were not supposed to accept any instructions from the Member States in order to maintain their independence.

#### **b) Tour de Table –presentation of members of the SEAC**

The members and other participants of the meeting briefly introduced themselves.

#### **c) Apologies**

For this first meeting, apologies were received from four members, two of whom had sent, in anticipation of the draft rules of procedures, non-voting replacements. The list of attendees is given in Part III of the minutes.

### **2. Adoption of the Agenda**

The Agenda was adopted with the modification proposed by the Secretariat to add a point regarding the action points and conclusions of the first SEAC meeting (see part II of these minutes) as a final Agenda item after AOB. The final Agenda is attached to these minutes as Annex II.

### **3. Administrative Issues**

#### **a) Reimbursement rules**

The legal identity and financial identity forms had been provided to the members of the Committee together with the invitation. The participants were reminded to complete the forms, once only. The Chair also informed participants that normally the reimbursement would be done within 30 days, but the first time it might take longer due to the necessary verification of bank account details.

#### **b) Declarations of conflict of interest**

Under this Agenda point the legal advisor of the Secretariat presented the three types of declarations annexed to the draft Rules of Procedure:

- Annual Declaration of Commitment,
- Annual Declaration of Interests,

- Declaration of Confidentiality.

After the adoption of the RoPs, these declarations will have to be completed and signed by the various participants of the SEAC meetings in accordance with the provisions of the RoPs. However, it was clarified that the duties of commitment, declaring conflicts of interests and confidentiality apply from the first day of their appointment.

Publication of the declarations of interests will be in line with ECHA's commitment to transparency and it will also be in line with the practice of some other European agencies like the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). It was promised to provide the members of the SEAC guidance on conflicts of interest.

It was asked by the SEAC members what will happen in case of a member not acting in conformity with the declarations he/she has signed. The Secretariat explained that the responsibility to ensure conformity lies with the individual concerned and on the Chair of the SEAC and that in exceptional cases the member could be requested to resign from the Committee, but expressed the hope that such situations will be avoided. It was also asked whether the declaration of interests relates to present activities only, or past as well, to which the Secretariat responded that the declaration concerns both the current activities and those in past 5 years.

#### **c) Curriculum vitae for web publications**

The Secretariat had proposed a format for a harmonised short Curriculum Vitae (CV) and had distributed it as a room document. It was agreed that the Secretariat will send the template by e-mail, and the members of the Committee will complete it and return it by the end of April. It was emphasised that only the appointed members have to do that. The CVs will be made publicly available on the website of ECHA, in line with Article 88(1) of the REACH Regulation.

#### **d) Contact details of members**

The Secretariat requested the participants of the meeting to check their contact details in the list circulated at the meeting and make the necessary corrections. The list of contact details will be distributed after the meeting to all the participants, but it will not be released to third parties.

### **4. Background of the SEAC**

The Secretariat presented the legal basis for the SEAC and the vision for the modus operandi for the SEAC. The importance of establishing the interface with the Committee for Risk Assessment (RAC) was stressed. It was explained that the SEAC will be co-ordinated by the Chair supported by the scientific secretariat whose tasks are facilitating communication between the SEAC members, planning, preparing, organising and following-up the activities of the Committee, as well as co-ordinating work with the rest of ECHA. The Agency will also support the SEAC financially by reimbursing the travel, hotel and subsistence expenses for members and invited experts related to participation in the SEAC plenary meetings. Subject to availability of funds, ECHA will support the meetings of the working groups.

The Secretariat also briefly explained the historic background of REACH and gave an overview of key changes compared to the previous EU chemicals legislation.

It was discussed whether it is possible to test a new regulatory system and concluded that in general this is unfortunately not possible but there will be a lot of learning by doing while implementing the REACH Regulation.

## **5. Planning of the work for 2008 and beyond**

### Restriction – process description and timelines

The Secretariat introduced the background, the legal basis, key processes and the main timelines of restrictions.

### SEAC tasks in the restriction process

The Secretariat gave an outline of the restriction process and the specific role of SEA in that process. According to the REACH Regulation, the obligatory parts of an Annex XV dossier include information, assessments and justification that are relevant when shaping an opinion on the socio-economic impacts related to the suggested restriction. It was noted that, according to the REACH Regulation, while Member States *may* prepare an SEA<sup>1</sup> as a part of a restriction dossier, the SEAC *shall* formulate an opinion which takes into account the relevant parts of the dossier and the socio-economic impact” (Article 71(1)). It was noted that without an SEA it may be difficult for the SEAC to give an opinion whether the proposed EU-wide restriction is justified.

It was agreed that the role and the tasks of the Rapporteur and possible Co-rapporteur of the SEAC would need to be discussed in more detail at the next meeting. The outcome of the meetings of the RAC on the same issue could provide valuable input for the SEAC, given that, in restriction proposals, both Rapporteurs would work in parallel and should co-operate closely. It was also noted that MSCAs preparing the Annex XV dossiers are likely to have training needs related to the SEA in general, methodological issues related to the SEA-guidance and other related issues. The Secretariat proposed that these needs could be started to be addressed in a Working Group and tailored training activities.

The relation of the tasks of the SEAC and the decision-making process (by the Commission (COM)) was discussed. The representative of the COM explained that the COM has only 3 months to make a proposal for restricting a substance and will therefore very much rely on the opinions received from the Committees of ECHA. Discussions between the COM and the SEAC are necessary in order that the SEAC understands what is important for the COM regarding drafting the opinions, so that it would be as straightforward as possible for the COM to take decisions based on the opinions received from ECHA. The COM also explained that for any restriction decision, an impact assessment in line with the Commission’s impact assessment rules would be needed. However, given the 3 month time limit it would be impossible for the COM to carry out itself such an Impact Assessment. The importance to link the opinions of the SEAC to the Commission’s Impact Assessment Guidelines was therefore emphasised and the COM was invited to investigate the opportunity to give a presentation on the Commission requirements for Impact Assessments in possible

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<sup>1</sup> Annex XV includes a heading ‘Socio-economic assessment’ information requested under that heading relate to comparing the net benefits of the proposed restriction to its net costs. That is only one aspect of the socio-economic impacts related to the suggested restriction. In particular, the justification that the suggested restriction is the most efficient, practical and monitorable risk management option includes aspects (e.g. whether the suggested restriction is proportionate to the identified risk) that are crucial for the opinion on the socio-economic impacts.

future SEAC meetings or workshops. It was also noted that this issue needs further reflection.

#### Conformity check

The Secretariat gave a presentation on the Conformity Check in the restriction process. According to Article 69(4) of the REACH Regulation, the RAC and SEAC shall check whether the dossier submitted conforms to the requirements of Annex XV. It was explained that the Conformity check should examine whether or not the dossier appears to give sufficient basis for drafting the opinions and for discussions in the Committees. It should not pre-empt any discussions of the Committees nor to be seen as any kind of 'pre-opinion'. It was noted that specific questions to the SEAC are whether the submitted dossier includes an SEA; if an SEA is included, whether it appears to allow evaluating the information on the net benefits and net costs; and whether the dossier appears to allow evaluating whether and how socio-economic information has been used to support the justification for a restriction at Community level. It was proposed by the ECHA Secretariat, if requested by the relevant Committee, to provide support to the RAC and the SEAC in the Conformity Check by producing a "Conformity Report" which could be used by the Committees when concluding on conformity.

Several SEAC members emphasised that it is important to make a clear distinction between i) legal requirements and ii) desirable information. The proposal of the Secretariat to support the Committees by producing a "Conformity Report" was very much welcomed by the members of the SEAC. The Secretariat emphasised that it should not prepare a Conformity Report of Annex XV restriction proposals prepared by ECHA itself based on the request by the Commission. The tasks of the Committee Rapporteur in the compliance check were briefly discussed, but it was recognised that the role of the Rapporteur has to be first outlined at a more general level.

It was agreed that the members of the SEAC will provide, by the end of May 2008, written comments on the 'ECHA discussion paper on conformity checking of Annex XV dossiers in relation to the SEAC tasks' which was distributed to the SEAC as a meeting document ECHA/SEAC-1/2008/04.

#### Transitional dossiers

The Secretariat explained that under the Existing Substances Regulation there are some substances for which the review will not be finalised by 1 June 2008. For those substances (there are around 60 such substances) Member States have to prepare an Annex XV transitional dossier by 1 December 2008. The Secretariat drew the participants' attention to the opportunity to use those submitted dossiers, which identify a need for restriction, to test the procedures in order to, for example, further develop the co-operation between the RAC and the SEAC and the Conformity Check and to test the drafting of an opinion. Furthermore, discussions on those dossiers can facilitate prompt and efficient processing of these dossiers after 1 June 2009 when the Restriction Title enters into operation.

#### Decision Support Document

The Secretariat introduced the rationale for and the purpose of the Decision Support Document (DSD). Three options were presented for the entity that could prepare the DSD. The Secretariat proposed that the entity who prepares the original proposal (MSCA or ECHA Secretariat) should be the most appropriate to do this work. This proposal was based on the assumption that the entity that developed the dossier is

supposed to be the most knowledgeable of underlying literature and has an easy access to the relevant information.

The concept of DSD was found in general useful but some members expressed their concern regarding the transparency and independence as well as financial burden when a MSCA (or ECHA) submitting the dossier is made responsible for the preparation of the DSD. Moreover, more discussion would be needed on the relation of the DSD to meeting minutes, response to comments–table and the opinion of the SEAC. It was agreed to come back to this issue at the next meeting and the Secretariat was asked to inform the SEAC about the outcome of the RAC discussions on the same topic.

A concern was also raised regarding the work of the SEAC if the SEA is not available or the data necessary to allow the SEAC to provide its opinion is missing from the dossier . It was noted that the role of the SEAC is to “formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact” (Article 71(1) of the REACH Regulation) and that “SEAC [...] shall be responsible for preparing the opinion of the Agency on ... proposals for restrictions... relating to the socio-economic impact of possible legislative action on substances.” (Article 76(1)(d) of the REACH Regulation) It was proposed that the SEAC should tackle the question to which degree the SEAC might need to complement the SEA or SEA related data provided in the dossier.

The SEAC decided to establish an intersessional working group (envisaged to operate until SEAC-2) to look in more detail into the challenges related to the tasks of the SEAC. The detailed mandate and the composition agreed in the meeting are included in the attached decision (Annex III). The working group is open to all SEAC members and will mostly work via e-mails. In addition, a meeting was proposed to be organised in Helsinki in early June. The results of the working group would be presented at the next SEAC plenary meeting scheduled for October 2008. It was agreed that the Chair of the RAC and up to five RAC members would also be invited to take part in the working group. It was agreed that the SEAC members will inform the Secretariat about their participation in the working group by the end of April.

In order to start to address the SEA-related training needs, the Secretariat proposed to organise a workshop back-to-back to the SEAC-2 meeting. The intersessional working group could give input to the planning of such workshop.

## **6. Rules of Procedure (RoPs)**

The Chair noted that the Secretariat would appreciate it if the Committee could agree on the text of the RoPs at this meeting, so that they could be forwarded to the MB at ECHA for approval at its next meeting at the end of April, together with the RoPs of the other Committees and the Forum of ECHA. The Secretariat also explained that the RoPs provide a framework in which the Committee will operate and emphasised that more detailed working procedures can be established when necessary. It was proposed to discuss the draft RoPs article by article. The Chair also informed participants that one SEAC member, who could not participate in the meeting, had provided written comments to the draft RoPs and that these comments would be brought forward to the discussion by the Chair.

### *Articles 1 and 2*

It was proposed by the SEAC to add to Article 2(b) and (c), which describe the tasks of the SEAC, that the Committee deals with the tasks listed as far as the socio-economic aspects are concerned. The Secretariat explained that the text of Article 2 comes directly from the REACH Regulation, and therefore it was agreed not to change the text, but to add an appropriate footnote.

### *Article 3*

One SEAC member noted that according to Article 85(8) of the REACH Regulation, the Committee is supposed to reach its opinions by consensus, which suggests that voting is not a requirement. It was added that as the Committee can only provide an expert opinion, the idea of voting seems incorrect. The Secretariat responded that the REACH Regulation does not reject the idea of voting and that it might be beneficial to keep this form of decision making as a final resort for the Committee in order to come to an agreement in unclear situations. One member of the Committee proposed to change the last sentence of the article by deleting the words in brackets, as once the members have been appointed, they are all just members, there should be no difference between “members” and “co-opted members”. Another member suggested keeping the words in brackets, as they make the text more clear. It was finally agreed to maintain the text unchanged.

### *Article 4*

One member proposed that the procedure describing who can propose and how to co-opt a member should be included in the RoPs, and was responded by the Secretariat that such more specific procedures should be left for working procedures of the Committee. It was questioned where the “procedure by two-thirds majority” referred to in Article 4(2) comes from, to which the Chair replied that it is a proposal of the Secretariat, reflecting the importance of the decision. It was suggested by one member, but not agreed by others, that in order to be in line with Article 85(8) of the REACH Regulation, there should be a consensus of the members instead of two-third majority of the members. The wording of the paragraph 4 regarding the time for co-opting the members was considered ambiguous and to clarify the meaning of the sentence it was agreed to delete the part “up to a maximum of five”.

### *Article 5*

It was pointed out by several SEAC members that if there is no possibility to participate in the Committee meeting and a replacement is sent, the replacements should not be treated as “invited experts” but as alternates. One member was of the opinion that the first sentence of paragraph 4 – “as members are appointed for their qualifications and therefore shall not have alternates” – is not relevant as the alternates could also have equally high qualifications. It was suggested that the procedure of appointment should be done for alternates as well and that the person replacing the member of the Committee at the meeting should have the same voting rights as the member. Several members supported the idea that the concept of alternates would be necessary. At the same time, majority of the members were of the opinion that the provision should stay as it stands. It was therefore agreed to ask the opinion of the MB of ECHA with regard to alternates and review the RoPs within one year in this respect.

It was also proposed by some SEAC members that the Chair should give a justification if the resignation of a member is proposed to the ED of ECHA. It was agreed that the Committee will always have to be informed if the disciplinary actions foreseen in

Article 5(2) are launched. One member proposed to use instead of “one or more candidates” in the paragraph 3 of Article 5 “one or two”, but the Secretariat clarified that according to the REACH Regulation each Member State may nominate more than two candidates, but the MB may not nominate more than two members from the nominees of each Member State. It was also proposed to delete “in exceptional cases” from the paragraph 4 of Article 5, but it was explained by the Secretariat that the aim is that the members themselves attend the SEAC plenary meetings as much as possible and therefore justification for the exemption should be given.

#### *Article 6*

One member suggested requiring consensus in paragraph 10 of Article 6 instead of two-thirds majority. It was suggested by one member to add to paragraph 6 of this Article that stakeholder organisations could participate in the meetings as observers only when the agreement within the Committee has been sought. The Chair replied by referring to Article 85(4) of the REACH Regulation which provides that stakeholders may be invited to attend meetings as observers, as appropriate, at the request of a Committee member, or the MB.

#### *Article 7 and 8*

Regarding the Articles which concern the Chair and his/her responsibilities, it was questioned what kind of procedure should be implemented in case the Chair is not fulfilling his/her duties. The Secretariat explained that the members would be free to contact the ED of ECHA who in turn could always assign another Chair.

#### *Article 9*

It was asked why declarations of interest and commitments must be made annually, and not once for the whole term. The Secretariat explained that this requirement is based on Article 88(2) of the REACH Regulation. One member asked what will happen if the Committee later finds out that a member had a conflict of interest in some dossier, but did not inform the Committee about that. The Secretariat responded that having annual declarations, declarations at the beginning of each meeting and declarations of appointed rapporteurs are all preventive actions which are supposed to help avoid such situations and that the Chair’s task is to ensure that the rules are respected.

#### *Article 10*

It was noted and agreed that in the first sentence of Article 10 “invited experts” should be used instead of just “experts”. One member asked whether there is a time frame for how long the confidentiality must last, to which the Secretariat replied that for business secrets and some other data there is no timeline. It was also questioned whether this Article means that SEAC members or the MSCA cannot outsource or get support from private consultants or lawyers. To clarify the issue, it was agreed to record in the meeting minutes the following statement:

“Should the relevant public authorities of a Member State have contracted out public tasks relating to the Regulation 1907/2006 to a private company or other third party, information under Article 10 may be disclosed to the designated representatives of this third party provided that strict confidentiality agreements have been established by and between the public authority and the representatives of the third party and these agreements have been provided to the Secretariat. “

It was also added by the Secretariat, that this Article in fact concerns confidential information and not information that is already publicly available. Based on the

observation by the representatives of the European Commission (COM) participating in the meeting as observers, it was agreed to add “the Commission and Community bodies” to the first sentence of Article 10 to reflect that, confidential information arising from the work in the Committee, may also be disclosed to these entities.

#### *Article 11*

Regarding the documents to be published on the website of ECHA, one member was interested why draft Agendas are supposed to be published and not the final ones. The Secretariat explained that the intention is to publish the draft Agenda before the meeting, so that the public can be made aware of what is going to be discussed. The final Agenda will be included in the minutes of the meeting. The level of detail of a brief CV was also questioned by the members, to which the Secretariat responded that the intention was that all would provide data in harmonised and very brief format proposed by the Secretariat.

#### *Article 14*

One member proposed to add to Article 14 that the meeting documents should be available in English by the given deadline. The Chair explained that such an amendment is not advisable as the Secretariat might not be able to fulfil this requirement in all urgent cases. It was agreed that normally the documents will not be distributed on paper to the participants at the meeting, but in case some documents are made available very late (1-3 days) before the meeting, the Secretariat will also provide them at the meeting as hard copies.

#### *Article 16*

It was asked what will be the level of detail of the meeting minutes. The Secretariat explained that the intention is to take the minutes of the MB of ECHA as an example. Those minutes are normally short, but always reflect the conclusions and the discussion points leading to the conclusions. The Secretariat added that the names of the speakers will not be mentioned but just the discussion would be summarised. One member considered that the minimum deadline of 7 days for commenting the meeting minutes is too short. The Chair explained that the possibility to establish such a short deadline for the members was necessary for the cases where the time between two meetings is very short. As this will not likely be the case for the SEAC meetings, the Secretariat will normally give longer time for giving comments.

#### *Article 17*

One member suggested to delete the words “when the opinions are prepared” from the last paragraph of Article 17 highlighting the fact that the co-operation between the RAC and the SEAC should not only be limited to the preparation of the opinions. It was explained by the Chair that the text of this paragraph should be understood in a wider sense – the process of the opinion making (and thus co-operation between the Committees) starts from the Conformity Check and continues until the final opinions are agreed on. It was also proposed and agreed to allow the establishment of permanent working groups to help the rapporteurs instead of establishing an ad-hoc working group to help one specific rapporteur. One member questioned the possibility to replace the rapporteur at any time provided by the paragraph 4 of Article 17. The Secretariat explained that if the rapporteur is not able to fulfil his/her duties, the possibility of replacement would always be discussed in the Committee.

### *Article 18*

The SEAC members asked who can propose to establish a working group and how the decision will be made regarding the chair of the working group. It was explained by the Secretariat that the initiative to establish a working group should come from one or several members of the Committee. Regarding the working group Chair, it was answered that the Committee should decide on the Chair of the working group. It was also suggested and agreed to use “working group members” instead of “such experts” in the last sentence of the paragraph 3.

### *Articles 19-20*

Several members considered the minimum deadline of five calendar days for the written procedure as being too short. The Chair explained that such short deadline would only be used under exceptional circumstances. It was also questioned by several SEAC members whether “the simple majority of all members” mentioned in Article 19 as well as in Article 20 takes into account those members who have declared a conflict of interests in the issue. It was agreed to clarify in the meeting minutes that members having a conflict of interests are regarded as a part of the quorum but abstentions from the vote.

### *Article 21*

It was proposed by one member to amend the text so that ECHA could reimburse costs to the members or to their employers, to which the Secretariat responded by saying that this issue is subject to the rules established by the MB of ECHA.

### *Annex 3*

It was agreed to modify the wording of Annex 3 to correspond to the modifications made in Article 10.

During the meeting, the Secretariat presented the revised text of the RoPs to the participants, modified based upon the comments received from the Committee. The SEAC agreed on the proposed RoPs, and the Chair informed participants that they will be forwarded to the MB for adoption at its meeting at the end of April.

## **7. Guidance Documents**

### **a) RIP 3.9 – SEA guidance on Restrictions**

After a presentation by the ECHA Secretariat on the Guidance on Restriction, the representative of the COM (Joint Research Centre) gave a presentation on the Guidance on SEA under the REACH restriction procedure. The SEAC confirmed that the SEA guidance is central to its work. The Secretariat confirmed that in future the SEAC will have an active role on the updating of this and other relevant guidance documents. It was also noted that the participants can at any time inform the Secretariat about any issues in the guidance documents which need to be changed. It was agreed that the Secretariat will upload the links to all relevant and useful SEA guidance documents to the SEAC CIRCA Interest Group. The Secretariat also promised to upload the ECHA document on the procedure for updating guidance documents to CIRCA.

### **b) RIP 3.9 – forthcoming SEA guidance on Authorisation**

A state of play was given by the Secretariat regarding the forthcoming SEA guidance on Authorisation.

## 8. Document Management

### a) Platform for distribution of documents to the SEAC – CIRCA

The Secretariat gave a brief overview of the recently established SEAC CIRCA Interest Group (<https://circa.europa.eu/>). The members were informed that after the first meeting the documents will only be distributed to members via CIRCA. It was reminded that those members who have not yet registered in the CIRCA system and who have not yet provided their CIRCA User ID to the Secretariat should do so as soon as possible.

## 9. Working Procedures

### a) Working group(s)

Apart from the intersessional working group the SEAC did not see for the moment any need for ad hoc or longer term working groups. The issue would be discussed again at the next meeting. It was pointed out that all working groups should also be time limited as the Members themselves have a limited term of office.

### b) Interface with the Committee for Risk Assessment (RAC)

The Chair gave the floor to Ms Sharon Munn, the Chair of the Committee for Risk Assessment. She introduced the interface between ECHA Committees and the Forum, highlighting the importance of close cooperation between the RAC and the SEAC. It was noted that both Committees consider *inter alia* the appropriateness and efficiency of the proposed measures and use the same data from Annex XV dossiers, but from different angles. It was noted that the stringent timelines and differences in workload may in practice hinder the smooth cooperation between the Committees. It was re-emphasized that in this situation excellent cooperation and exchange of information between the RAC and SEAC Rapporteurs is essential. It was agreed that the Secretariat will report in the future to the SEAC on the relevant outcome of the other ECHA Committees, the Forum and the MB.

### c) Participation of the EFTA-EEA States in the SEAC as observers

The Chair explained that the REACH Regulation is going to be incorporated in the EFTA-EEA Agreement and from the entry into force of this incorporation the representatives of these countries will have the right to participate in the work of ECHA Committees as members, but without voting rights. At its meeting in February the MB had decided, subject to the approval of the relevant Committee/Forum, to invite the EFTA-EEA States (Norway, Iceland and Liechtenstein) to take part in the work of the Committees and the Forum as observers, pending the entry into force of the REACH rules in these countries.

The SEAC agreed to invite by 11 April the EFTA-EEA States to take part in the work of the Committee as observers. The invitation would include the invitation to take part in the intersessional working group.

### d) Participation of stakeholders in the SEAC as observers

The Secretariat noted that ECHA had recently launched a call for expressions of interest of stakeholder organisations (see <http://echa.europa.eu/opportunities/StakeholderCallRegistration.html>). It was agreed that based on the expressions of interest received by 30 April, the Secretariat will initiate a written procedure for inviting certain stakeholder organisations as observers

already to the second plenary meeting of the SEAC. Provided that the outcome of the written procedure was positive, the invitation could include participation in the intersessional working group. One participant questioned whether the representatives of stakeholder organisations invited as observers will participate in the whole meeting, to which the Secretariat responded that it will be always possible to invite them only for some/relevant parts of the meeting.

## **10. Co-opted Members**

### **a) Competence coverage – SEAC overall competence grid**

The Secretariat gave a presentation regarding the overall competence and expertise of the SEAC based upon the individual competence grids filled in by the members when they were nominated.

### **b) Discussion on the need for co-opted members**

The Chair reminded participants that after the RoPs are adopted by the MB, it will be possible to co-opt additional members to the SEAC. However, it was suggested by the Secretariat to consider this possibility carefully before taking any decisions. It was also explained by the Secretariat that the initiative for co-opting members should come from the members themselves. The format for proposing co-opted members was circulated at the meeting as a room document. The Secretariat drew the participants' attention that expertise should be the main factor when proposing members for co-opting.

The Committee agreed that there is no immediate need to co-opt additional members but that the issue should be revisited after June 2009 when the work of the Committee starts in practice. The Committee took note of the format for proposing co-opted members.

## **11. AOB**

### **a) Next meetings**

The Chair proposed the second week of June for the intersessional working group meeting and informed that the next plenary meeting has been tentatively scheduled for 21-23 October 2008, back-to-back with a workshop on SEA. It was agreed that the Secretariat will circulate the tentative dates for the SEAC meetings in 2009 by 11 April.

## **12. Action points and conclusions agreed at the SEAC-1 meeting**

The Committee agreed on the conclusions of the meeting and the action points to follow the first SEAC meeting as laid down in Part II of these minutes.

## II. Conclusions and action points

### SEAC-1 ACTION POINTS & MAIN CONCLUSIONS – 2-3 April 2008 (as adopted at the SEAC-1 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
<b>3 – Administrative Issues</b>	-	
a) Reimbursement rules	-	
b) Declarations of conflict of interest	-	
c) Curriculum vitae for web publication	-	SECR to submit electronically the template for a mini-CV (by 4 April). All members to fill in the CV and send it electronically to SECR (by 30 April)
d) Contact details of members	-	Corrected list of contact details to be made available to the Members (SECR/15 April)
<b>4 – Background of the SEAC</b>	-	
<b>5 – Planning of the work for 2008 and beyond</b>	<ul style="list-style-type: none"> <li>• Role of rapporteurs to be discussed more in detail at the next meeting, RAC-3 and RAC-4 discussions to be taken into account</li> <li>• Training needs related to the SEA in general, methodological issues related to the SEA-guidance and other related issues to be further discussed in a Workshop to be organised back-to-back SEAC-2</li> <li>• COM invited to investigate the opportunity to have presentation by Impact Assessment specialist in the October Workshop</li> <li>• Inter-sessional WG established; mandate, composition and timeline defined. The WG will be open to all SEAC members and will be chaired by SECR.</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to report at SEAC-2 about the outcome of RAC-3 and -4</li> <li>• SECR to prepare a Workshop, in consultation of the intersessional WG</li> <li>• Members/advisors to subscribe before 30 April by sending an e-mail to SECR</li> </ul>
a) Restriction - process description and timelines		
b) Conformity check	<ul style="list-style-type: none"> <li>• The support by ECHA SECR in the conformity check phase welcomed; dossiers prepared by ECHA would however form an exemption</li> <li>• Further discussion needed on the checklists and level of details and how to communicate to the proposing MEMBER STATE that certain data, whilst not being obligatory, would be highly desirable</li> </ul>	<ul style="list-style-type: none"> <li>• Members to give written comments on document ECHA/SEAC-1/2008/04 (by 31 May)</li> </ul>
c) Transitional dossiers	-	

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
d) Decision Support Document	<ul style="list-style-type: none"> <li>• The concept of DSD found in general useful</li> <li>• Further discussions needed in particular on the actors involved and on the relation of the DSD to meeting minutes, response to comments table and opinion itself and on practicalities (e.g. 1 or 2 DSD in the case of restrictions dossiers)</li> <li>• RAC-3 will deal with examples, conclusions to be provided to the SEAC</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to report at SEAC-2 about the discussions of RAC-3 (and -4)</li> <li>• SECR to work examples relevant to the SEAC and present them (by SEAC-2)</li> </ul>
<b>6 – RoPs</b>	<ul style="list-style-type: none"> <li>• Draft rules endorsed with certain modifications</li> <li>• Certain statements to be recorded in the meeting minutes: <ul style="list-style-type: none"> <li>➤ Concerning Art 5, several members were of the opinion that a concept of alternates would be necessary. Several other members supported the provision as it stands. The Committee agreed to ask the opinion of the MB and review the RoPs within one year in this respect</li> <li>➤ Art 5: SEAC to be always informed in the case the disciplinary actions foreseen in Art 5(2) launched</li> <li>➤ Art 10: statement concerning confidentiality arrangements when a public authority has outsourced public tasks supporting the work of the Committee</li> <li>➤ Art 14: late documentation to be avoided, SECR to provide hard copies of late documents to members</li> <li>➤ Art 19 and 20: a clarifying statement on the impact of a declared conflict of interest to the quorum and voting rules: Members having a conflict of interest regarded part of the quorum but abstentions in the vote.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• SECR to forward the draft RoPs to the MB for approval (by 11 April)</li> <li>• SECR to ask the opinion of the MB on alternates (by 11 April)</li> <li>• SECR to upload the RoPs to Circa (by 11 April)</li> <li>• Meeting minutes to reflect the statements correctly</li> </ul>
<b>7 – Guidance Documents</b> a) RIP 3.9 – SEA guidance on Restrictions b) RIP 3.9 – forthcoming SEA guidance on Authorisation	<ul style="list-style-type: none"> <li>• SEAC confirmed that SEA guidance is central to its work</li> <li>• It was confirmed that in future it will be consulted on the updating of relevant guidance documents. Members and advisors can at any time inform SECR about issues with the guidance that would require work. ECHA will monitor this feedback and manage the necessary updating or</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to establish a CIRCA library section for relevant guidance documents and other background documents that could be regarded as useful for the SEAC (by 31 May)</li> <li>• SECR to upload ECHA document on the procedure for updating guidance documents by 30 April.</li> </ul>

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
	rectification process.	
<b>8 - Document Management</b> (SEAC-CIRCA)	<ul style="list-style-type: none"> <li>• CIRCA to be used as temporary solution.</li> </ul>	<ul style="list-style-type: none"> <li>• All members who have not already done so to subscribe to CIRCA interest group (as soon as possible)</li> </ul>
<b>9 – Working Procedures</b> a) Working group(s)	<ul style="list-style-type: none"> <li>• Except the intersessional ad hoc WG established under Agenda item 5, no immediate needs for working groups identified. All working groups should be time limited.</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to prepare a template for a decision on establishment of a working group (by SEAC-2)</li> </ul>
b) Interface with RAC	<ul style="list-style-type: none"> <li>• Both RAC and SEAC consider i.a. appropriateness and efficiency of the proposed measures and use same data from Annex XV dossiers, but the angle of considerations is different</li> <li>• Problems related to time pressure and difference in workload may in practice hinder the smooth cooperation</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to report to SEAC-plenary meetings on important outcomes of the other Committees</li> </ul>
c) Participation of the EFTA-EEA States in the SEAC as observers	<ul style="list-style-type: none"> <li>• SEAC agreed to invite Norway, Iceland and Lichtenstein to take part in the work of SEAC as observers; this would entail their participation in the inter-sessional WG</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to circulate (by 11 April) the invitation to the countries in question and ask them to express their interest to take part in the WG by 30 April</li> </ul>
d) Participation of stakeholders in the SEAC as observers	<ul style="list-style-type: none"> <li>• SEAC took note of the ongoing call for expression of interest of stakeholder organisations and agreed to use written procedure for seeking agreement on inviting such observers; subject to agreement of the SEAC, this could entail their participation also in the inter-sessional WG</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to launch a written procedure as soon as possible on admission of certain stakeholder organisation observers at SEAC-2, on the basis of expressions of interest received by 30 April.</li> </ul>
<b>10 – Co-opted Members</b> a) Competence coverage – SEAC overall competence grid	-	-
b) Discussion on the need for co-opted members	<ul style="list-style-type: none"> <li>• No immediate need to co-opt additional members; issue to be revisited after June 2009</li> <li>• SEAC took note of the format for proposing co-opted members</li> </ul>	-
<b>11 – AOB</b> a) Next meetings	<ul style="list-style-type: none"> <li>• 21-23 October (tbc), back-to-back to a Workshop</li> <li>• Intersessional WG meeting on the week starting 9 June (tbc)</li> </ul>	<ul style="list-style-type: none"> <li>• SECR to circulate the tentative dates for 2009 meetings (by 11 April)</li> </ul>
<b>General</b>		<ul style="list-style-type: none"> <li>• All pp-presentations to be uploaded on CIRCA (SECR/4 April) Conclusions and action points to be uploaded on CIRCA (SECR/4 April)</li> </ul>

### III. List of Attendees

<b>Members</b>	<b>Representatives of the Commission</b>
BIZKOVA, Ruth	BARTELS, Astrid (DG ENTR)
BRIGNON, Jean Marc	CHRISTENES, Frans (JRC)
BROKAITE, Kristina	GIL, Sebastian (DG ENV)
DANTINNE, Catheline	
DE GIGLIO, Franco	<b>ECHA staff</b>
FANKHAUSER, Simone	BARANSKI, Maciej
FOCK, Lars	CARLON, Claudio
FORKMAN, Mats	DANCET, Geert
GEORGIOU, Stavros	DE BRUJN, Jack
GUSTAFSSON, Lars	HANSEN, Bjørn
HAJAŠ, Martin	HAUTAMAKI, Anne
JUVIN, Philippe*	KREYSA, Joachim
KOURTELLIS, Marios	LIPKOVA, Adriana
KOZAK, Kristof	MAURER, Diana
LARKA ABELLÀN, Maj-Britt	MUNN, Sharon
LUTTIKHUIZEN, Cees	KARHU, Elina
RECCHIA, Luca Maria	RASMUSSEN, Kirsten
RYDLEWSKA-LISZKOWSKA, Izabela	SUNQUIST, Anna-Liisa
SALONEN, Heikki	VAINIO, Matti
SELDERSLAGHS, Katrien**	VASILEVA, Katya
SCHUCHTAR, Endre	YLÄ-MONONEN, Leena
SCHWARZER, Stephan	
SIMON, Franz-Georg	
TELLING, Aive	
THEOHARI, Maria	
VOIVONTAS, Dimosthenis	
* Replacing BASTOS, Henri	
** Replacing FEYAERTS, Jean-Pierre	

#### Advisers to the SEAC members

BOERSMA, Anja (adviser to LUTTIKHUIZEN, C.)  
 KIVELÄ, Kalle (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
- ANNEX III. Decision of the Committee for Socio-economic Analysis establishing the Intersessional Working Group

## ANNEX I

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

Draft Agenda (Agenda Item 2)	ECHA/SEAC-1/2008/01_rev.1
Mini CV template for web publication (Agenda Item 3c)	room document
Background of the Committee for Socio-economic Analysis – legal basis, scope, proposed modus operandus (Agenda Item 4)	ECHA/SEAC-1/2008/01
Conformity check of a submitted dossier (Agenda Item 5)	ECHA/SEAC-1/2008/04
Decision Support Document – Proposal for a supporting document for committee opinions and decisions (Agenda Item 5)	ECHA/SEAC-1/2008/05
Rules of Procedure of the Committee for Socio-economic Analysis (Agenda Item 6)	ECHA/SEAC-1/2008/02
ECHA Policy on co-operation with stakeholder organizations (Agenda Item 9d)	room document
Competence Coverage – SEAC Overall Competence Grid (Agenda Item 10a)	ECHA/SEAC-1/2008/03
Form for Proposing Co-opted Members to the SEAC (Agenda Item 10b)	room document



2 April, 2008  
ECHA/SEAC-1/2008/A/01\_rev. 2

**Final Agenda**  
**First meeting of the Committee for Socio-economic Analysis**

2-3 April 2008  
Valkoinen Sali (Aleksanterinkatu 16-18), Helsinki, Finland  
**2 April: starts at 9:00**  
**3 April: ends at 18:00**

**Item 1 – Welcome and Introduction**

- a) Welcome by the Executive Director of ECHA (Mr Geert Dancet)
- b) Tour de table – presentation of members of the Socio-economic Analysis Committee
- c) Apologies

**Item 2 – Adoption of the Agenda**

*For adoption* ECHA/SEAC-1/2008/A/01 rev.1

**Item 3 – Administrative Issues**

- a) Reimbursement rules
- b) Declarations of conflict of interest
- c) Curriculum vitae for web publication
- d) Contact details of members

*For information*

#### **Item 4 – Background of the SEAC**

Legal basis, scope, proposed modus operandus

*For information* ECHA/SEAC-1/2008/01

#### **Item 5 – Planning of the work for 2008 and beyond**

- a) Restriction - process description and timelines
  - SEAC tasks in the restriction process
  - Conformity check
  - Decision Support Document
- b) Authorisation – process description and timelines
- c) Other possible tasks

*For discussion*

Conformity check ECHA/SEAC-1/2008/04

Decision support document ECHA/SEAC-1/2008/05

#### **Item 6 – Rules of Procedures (ROPs)**

ROPs of the Socio-economic Analysis Committee

*For discussion and endorsement*  
ECHA/SEAC-1/2008/02

#### **Item 7 – Guidance Documents**

- a) RIP 3.9 – SEA guidance on Restrictions (presentation by COM)
- b) RIP 3.9 – forthcoming SEA guidance on Authorisation – state of play

*For discussion/information*

## **Item 8 - Document Management**

- a) Platform for distribution of documents to the SEAC – CIRCA

*For information*

## **Item 9 – Working Procedures**

- a) Working group(s)
- b) Interface with Committee for Risk Assessment (RAC)
- c) Participation of the EFTA-EEA states in the SEAC as observers
- d) Participation of stakeholders in the SEAC as observers

*For discussion*

## **Item 10 – Co-opted Members**

- a) Competence coverage - SEAC overall competence grid
- b) Discussion on the need for co-opted members

*For discussion* ECHA/SEAC-1/2008/03

## **Item 11 – AOB**

- a) Next meetings

*(October 21- 23, 2008 tentative)*

## **Item 12 – Action points and conclusions agreed at the SEAC-1 meeting**

*For endorsement*



3 April 2008

**DECISION OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS  
ESTABLISHING WORKING GROUP**

**Working group name:**

**INTERSESSIONAL WORKING GROUP**

**Mandate:**

The WG will address the following

1. Identification of main challenges and options to resolve them, in relation to i) developing SEAC's opinion on the suggested restriction and socio-economic impacts as well as ii) the interaction between the SEAC and Committee on Risk Assessment.
2. Identification of the training needs in relation to analysing socio-economic impacts including suggestions for the first training workshop to be held tentatively in October 2008.
3. Ways and means to validate or peer review data relevant to the SEAC in terms of a restriction proposal.

The WG will have an initial meeting in Helsinki in early June, 2008, but will otherwise work via electronic means.

**Deliverables:**

	By when:
1. Report on the main challenges and options for solutions in relation to developing the SEAC opinions on the suggested restrictions and socio-economic impacts.	SEAC-2
2. Proposals for organising the coordination with the RAC	SEAC-2
3. Draft training programme/plan for 2008-2009 for the SEAC	SEAC-2
4. Contribution to the drafting of the programme for the first SEAC training workshop to be held	The end of 7/2008

- tentatively in October 2008, back-to-back with SEAC 2
5. Initial ideas on methods for the SEAC to review or validate data relevant to the SEAC in terms of the restriction proposals.
- SEAC-2

**WG composition:**

- Chair:*** ECHA Secretariat
- Members:*** All SEAC members, up to 5 members of the RAC
- Other participants*** All SEAC observers (including EEA-EFTA states' representatives and possible stakeholder observers)  
Chair of the RAC

**Duration of WG activity:**

Until SEAC-2 (intersessional WG)