

SEAC/M/03/2009 FINAL

Final

**Minutes of the 3rd meeting of the Committee for Socio-economic Analysis
23-24 February 2009**

I. Summary Record of the Proceeding

1. Welcome and Apologies

Ms Leena Ylä-Mononen, ECHA, who chaired the meeting, welcomed the participants of the second meeting of the Committee for Socio-economic Analysis (SEAC). New members of the Committee Mr Aristodemos Economides nominated by Cyprus and Mr Janez Furlan nominated by Slovenia were introduced and welcomed.

The Chair informed that apologies were received from four members, three of whom had sent non-voting replacements.

Members` advisors present at the meeting as well as representatives of the European Commission (COM), five stakeholder organisations and one international organisation participating in the meeting as observers were introduced.

The recently appointed Director of the Directorate of Cooperation at ECHA that handles also ECHA`s interface with Committees, Mr Andreas Herdina, introduced himself.

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

2. Adoption of the Agenda

At the meeting some changes were proposed to the Agenda by the Secretariat and SEAC members. The Secretariat proposed to include 2 bis) Status of the Action points from SEAC-2 on the Agenda and also to cover the selection of the SEAC permanent Chair and the access of stakeholder observers to SEAC Circa Interest Group under AOB. It was requested from the Secretariat by the members to report under AOB on the status of the guidance document on SEA in Authorisation and on the status of pre-registrations submitted to ECHA. With these modifications the Agenda was adopted. The final Agenda is attached to these minutes as Annex II.

2 bis) Status of the Action points from SEAC-2

The Chair recalled that the minutes of the second meeting of the Committee had been adopted in a written procedure and had already been published on the ECHA website. The Chair reported that all actions from SEAC-2 meeting had been completed, with the exception of a few issues proposed under the SEAC-2 agenda points 6 and 9 that had been carried over to the actions from this meeting.

Under Agenda point 6 of SEAC-2 meeting, the Secretariat had been requested to finalise the “fictitious case” as well as prepare examples on the application of SEA and together with COM to organise a workshop on a past restriction case. The Chair reported that elements of an updated “fictitious Annex XV restriction report” had been used in the preparation of the crash course on SEA for RAC and SEA refresher course. The Chair reported that the development of a full fictitious case and the organisation of the workshop were under further consideration.

Under the same Agenda point of SEAC-2 meeting, the Secretariat had been asked to develop and maintain a web based portal with information and data sources on costs and benefits of regulating chemicals. The Secretariat informed that this task was outsourced and the web portal would be up and running within a couple of months.

Under SEAC-2 Agenda point 9, the Secretariat had been requested to clarify the implications of not complying with providing the conformity check report within the 30 day deadline. The Chair explained that if the conformity check report is not provided within the deadline whether

due to the failure of the rapporteur or the Committee, the restriction process should continue. Prolonging the conformity check procedure would be unjust for the dossier submitter. Thus, if the Committee did not carry out the conformity check in time, the Annex XV dossier would be considered to be in conformity.

3. Administrative Issues

a) Changes in the SEAC composition/nominations

The Chair informed about changes in the composition of SEAC which had taken place after the second meeting of the Committee. It was noted that the SEAC member Mr Marios Kourtellis nominated by Cyprus had resigned from the Committee. Cyprus had nominated Mr Aristodemos Economides to SEAC, who was appointed by the Management Board at its meeting on 18-19 December 2008. The Chair recalled that the appointment of Mr Janez Furlan nominated by Slovenia had started from 15 December 2008 according to the decision taken by the Management Board at its meeting on 24-25 September 2008.

b) Participation of observers

The Chair recalled that at SEAC-2 meeting in October 2008, the Committee had agreed to invite 16 stakeholder organisations to participate in SEAC as observers, four of which it had decided to be addressed jointly in order to possibly get a joint representation from these four organisations. The Secretariat sent out the invitations to the invited stakeholder organisations in December 2008. So far the following eight organisations had officially nominated their representatives:

- CEFIC (European Chemical Industry Council),
- CONCAWE (Oil Companies` European Association),
- EAERE (European Association of Environmental and Resource Economists),
- EEB (European Environmental Bureau),
- EMCEF (European Mine, Chemical and Energy Workers` Federation),
- ETUC (European Trade Union Confederation),
- Eurometaux (European Association of Metals Industry),
- FECC (European Association of Chemical Distributors).

The Secretariat had also received an informal nomination on behalf of the four environmental organisations which had been addressed jointly; and at the moment an official nomination was awaited from them.

UEAPME (European Association of Craft, Small and Medium-sized Enterprises) had responded and informed that it would nominate its representative to SEAC only at a later stage.

As agreed at SEAC-2, an invitation to nominate an observer had also been sent to the OECD Secretariat which had nominated a regular observer to SEAC.

Following a comment of one stakeholder observer regarding the contribution of stakeholder observers in commenting on the meeting minutes, the Chair clarified that in the future the observers would be invited to comment on the meeting minutes but the adoption of the meeting minutes is in the remit of the Committee members only. Nevertheless, the version of the meeting minutes intended for adoption would also be provided to the observers for information. It was reminded also that the minutes from closed sessions would be released to the members and other closed session participants only.

c) Declarations of conflict of interest

No participants declared having any conflict of interest to the items on the Agenda of the meeting.

d) Revised reimbursement rules

The Chair presented document MB/77/2008 final that had been adopted by the Management Board at its last meeting. The rules apply to all members of the Management Board, Committees and Forum, invited experts, observers fulfilling criteria laid down in the document and to other attendees at ECHA meetings. Principal changes from the previous guide included: payment of accommodation expenses only on the basis of a hotel invoice; reference to pre-paid flight or other tickets, signalling the future use by ECHA of a travel agency for the benefit of participants in meetings; and specific rules concerning reimbursement of certain stakeholder observers.

Members enquired about the financial responsibility for cancelling the trip after the flight ticket had been purchased. The Chair explained that in the case that the flight ticket is bought but for some unforeseen reason the member would not be able to participate in the meeting, it should first be examined whether the participant or his/her institution has an insurance that could cover the unused ticket. In case there is no such insurance and since ECHA itself is not insured against such instances, ECHA would have to pay the flight ticket provided that appropriate justifications for the cancellation of the trip have been received.

e) Remuneration of invited experts serving the Committee working groups

The Secretariat presented a decision adopted by the Management Board at its last meeting on the remuneration of co-opted members and experts invited by the ECHA Committees and the Forum. The decision is intended to implement Articles 87(3) of the REACH Regulation and 15 of Regulation (EC) No 340/2008 ('the Fee Regulation'), respectively. The decision establishes a scale of fees for the remuneration of the work of co-opted members and of experts invited by the Committee or requested by ECHA. Remuneration is not payable to individuals who are employed in the public service of a Member State. A uniform rate of EUR 300 per day has been set which is consistent with the principles of economy and sound financial management.

The Chair noted that the meaning of 'employed in the public service of a Member State' would be clarified by the Secretariat, as already requested by RAC.

4. Feedback from other ECHA bodies

The Chair of the Committee for Risk Assessment informed about the recent developments in RAC. Since SEAC-2, RAC had met twice - in November 2008 and in the beginning of February 2009. The February meeting had been preceded by a Crash course on SEA that widened the understanding of RAC members of what SEAC is dealing with. At its plenary in February, RAC discussed a working procedure for processing a restriction dossier and terms of reference for rapporteurs, which took also into account comments given by SEAC. RAC had also been debriefed about the meeting of the SEAC-RAC arrangement. Under the extensive discussion on C&L proposals, RAC members had expressed their concern about ECHA's support during the accordance checks inhibiting the rapporteur from opposing the view of the Secretariat and questioned the level of detail the rapporteur should go to during the accordance check.

The Chair of the MSC summarised developments in the MSC which met for the sixth time on 17-18 December. She explained the first recommendation of substances to be included in

Annex XIV of the REACH Regulation (Authorisation List) has to be submitted by ECHA to the Commission by 1 June 2009. To this end, a public consultation was underway of ECHA's proposed prioritisation of substances to be included in Annex XIV, recommendations for each inclusion, including corresponding application and sunset dates, and supporting documents. The public consultation was to close on 14 April after which the MSC was to be formally consulted, before ECHA would submit the recommendation to the Commission. In total seven substances have been proposed to be prioritised. It was estimated that this first Authorisation List may be finalised by the end of 2009. According to present plans, the first applications for authorisation could be expected in 2012. The Chair also noted the MSC was to meet four times in 2009 and the next meeting was scheduled for 1-2 April.

One member enquired about the workshop for MS Competent Authorities concerned with the Candidate List and authorisation as a risk management instrument that had taken place on 21-22 January at ECHA's conference facilities. The Secretariat explained that the workshop had been aimed at reaching a first agreement on the intention and scope of the Candidate and Authorisation List and to find a common understanding of the choice between authorisation, restriction and other Community legislation for substances of very high concern. The Secretariat agreed to present the proceedings from the workshop to SEAC once they are available.

The Chair informed that in addition to the issues presented under different Agenda points of this meeting, the Management Board had discussed at its December meeting also the 2009 budget and work programme and the multiannual work programme of the Agency. A comprehensive report of the work of the Committees and Forum had been given at the meeting.

The Chair also noted that Forum had convened in December 2008, to discuss enforcement of REACH in the Member States, immediately following the closure of the pre-registration window. Forum agreed the first co-ordinated enforcement project which will focus on pre-registration, registration and safety data sheets for phase-in substances across 20 countries, including Norway and Iceland and it will start in Spring 2009. It also held a brief discussion on the Forum's role in the restriction process and its interaction with RAC and SEAC.

5. SEAC-RAC arrangement

a) First results of the SEAC-RAC arrangement (including oral report of the 1st meeting of 27 January 2009)

One of the SEAC members reported on the first meeting of the SEAC-RAC arrangement that had taken place on 27 January 2009. The member reminded about the tasks of the SEAC-RAC arrangement. He noted that the meeting was intended to consider the interaction between SEAC and RAC rapporteurs to ensure the opinions of the two Committees are prepared in a co-ordinated manner and with a full understanding of the overall requirements of REACH.

The major highlights of the discussion at the meeting of the arrangement were presented. In the presentation, common issues of interest for both Committees were pinpointed, e. g. effectiveness of risk management options in terms of risk reduction capacity and the treatment of uncertainty. It was stressed that RAC and SEAC rapporteurs should interact informally and exchange their understanding throughout the restriction process, and not merely exchange data; rapporteurs should hold face-to-face meetings and there is also a need for other informal communication. It was suggested that rapporteurs would attend the sister Committee meetings. To facilitate tracking of Committee members' comments, CIRCA newsgroups and communication through the respective rapporteurs should be used as preferred communication

channels. A need to establish joint working groups, and the importance of identifying early on those Committee members who could support the rapporteur(s) with their specific expertise and the need for careful scheduling of plenary meetings to create submission windows in order to manage the workload effectively were mentioned.

Participants particularly noted the tight timeline in which the restriction process takes place and therefore highlighted the importance of receiving comments from RAC and SEAC members on preliminary opinions early, the need for introducing interim milestones (in particular to get comments early from interested parties) and for repeated liaison between rapporteurs and learning from their experience.

It was also noted that technical exchange around a case study would be needed to understand the interfaces and common issues of the two Committees. SEAC-RAC arrangement participants volunteered to use parts of the transitional dossier on medium-chain chlorinated paraffins (MCCPs) to test the procedures.

Criteria for assessing when the RAC opinion diverges significantly from the suggested restriction (pursuant to Article 71(3) of the REACH Regulation) remain to be considered by the SEAC-RAC arrangement.

Members discussed the matters raised and agreed on the usefulness of the work carried out thus far. It was pointed out that the submission windows address the problem of scheduling meetings of RAC and SEAC and allow better coordination of the restriction process. Members raised their concern about the manageability of four submission windows in a year, but since only a few restriction dossiers are expected to be submitted in the first years, this might not cause problems in practice.

A question was raised on the issue of keeping minutes from the meetings of the rapporteurs. The Secretariat recommended keeping records of these meetings e. g. in order to inform the other Committee members what was discussed. These should include the observations of the rapporteurs in order for the members to be able to look into an issue as necessary.

Members discussed the level of involvement of other members than (co-)rapporteurs in the restriction process. It was noted that (co)rapporteurs should be trusted by all members and that too deep involvement of the other members should be avoided to prevent duplication of efforts. Instead, the rapporteur should be able to address specific questions to the other members if needed. Nevertheless, it was stressed that in the first years it would be advisable for the other members to seize the opportunity to learn through a more profound involvement in the process.

On the subject of possible COM's participation in some of the meetings of rapporteurs, COM clarified that it could act merely as an observer in these meetings with view of preparing for the decision-making after it has received the opinions from the Committees. Some members were concerned that such participation could affect the independence of (co-)rapporteurs' work. Some suggested that COM observers would refrain from participating at least in the first meeting as this intended to be merely exchange of initial views of the (co-)rapporteurs.

b) Work Plan till June 2009

The next steps for the arrangement were to continue working together electronically on the outstanding questions and then to meet again on 20 April prior to the RAC-6 meeting.

6. Rules of Procedure (ROPs)

a) Report of the written procedure on the revision of the RoPs

The Secretariat recalled that at SEAC-2 the modifications to the SEAC RoPs proposed by the Secretariat were discussed and these had been taken up. Based on the discussions of other Committees and the Forum, the Secretariat had proposed a few additional minor changes to the text and launched a written procedure in which the RoPs had been adopted. An additional editorial correction was introduced, following a comment of a SEAC member, in Article 15 of RoPs, where the reference to Article 12(4) was replaced with the reference to Article 12(3). The agreed RoPs were to be presented to the meeting of the Management Board on 26-27 February for final adoption.

7. Working Procedures for Restrictions

a) Procedure for appointment of rapporteur and co-rapporteur

The Secretariat presented the proposed working procedure for appointment of rapporteur and co-rapporteur. It was explained that in addition to the main principles and selection criteria taken from a document presented at SEAC-2 (SEAC/02/2008/12), the new document included also a stepwise working procedure to be applied when appointing rapporteurs and co-rapporteurs for restriction dossiers. The modifications proposed by the members at SEAC-2 had been incorporated in this document in the sections on principles and selection criteria. Furthermore, the Secretariat proposed to include an explicit statement that the rapporteur could only in exceptional cases come from the same country as where the dossier is prepared and that a SEAC member who is employed by the MS Competent Authority submitting the dossier cannot be assigned as rapporteur for that dossier.

Following extensive discussion at the meeting, the following major changes were introduced in the document:

The mention that on the receipt of the Annex XV dossier by ECHA, the Secretariat would “prepare the necessary contract” was removed as the appointment letter together with the Terms of Reference is in fact a contract in itself and therefore the statement is redundant.

In the section on considerations for exclusion it was added that since the restriction procedure may last 13-16 months, there should be sufficient time remaining of the rapporteur’s term of office to be able to complete the rapporteurship. The Secretariat agreed to clarify whether a member’s term of office could be extended earlier than just before its end in order for the member to be an eligible candidate for the rapporteurship that is likely to last beyond the member’s term of office.

A clarifying sentence was added in the paragraph regarding the conditions of replacement of a rapporteur stating that the replacement of a rapporteur should be avoided to the extent possible in order not to hamper the process.

In the working procedure section, the time for expressions of interest by members was extended from two to three weeks (step c). Furthermore, a new step was introduced for cases when there are several candidates, allowing the Chair to consult with the candidates informally to clarify their availability, qualifications and any other relevant considerations in order to prepare his/her recommendation.

With these modifications and some other minor corrections and clarifications, SEAC adopted the Procedure for the appointment of rapporteur and co-rapporteur with the provision that the procedure may need to be revised after discussions with RAC on their corresponding Working Procedure.

b) Working procedure on processing of an Annex XV restriction dossier

The Secretariat presented the proposed working procedure on processing a restriction dossier. The working procedure is intended to follow directly after the working procedure for conformity check. A parallel procedure had been developed for RAC which was discussed at RAC's last meeting on 10-11 February 2009. Relevant suggestions proposed by RAC members had been taken into account in the SEAC's working procedure.

An extensive discussion followed the presentation in which a number of issues were considered. Some members expressed their concern about the ability to keep the background document up-to-date throughout the procedure. The Secretariat responded that the background document should be fully in line with the opinion at least before the public consultation on the draft opinion and when the final opinion is adopted. The Secretariat agreed that it would be indicated in the working procedure that keeping the background document up-to-date throughout the procedure should be a good practice but not obligatory at all stages.

Concern was raised regarding the possibility that the dossier submitter would decline to provide an input into the background document and/or response to comments. The Secretariat explained that it is in the interest of the submitter to be co-operative and to prepare the background document and response to comments table. The Secretariat took up the task to approach later on MS Competent Authorities to seek their agreement on their tasks and deadlines given in the working procedure. One member suggested that a simulation of a rapporteur's workload should be carried out.

Clarification was sought on the ownership of the background document and on the responsibilities of the two Committees in evaluating and possibly changing the different sections of the document. To improve clarity the Secretariat is working on revision of the Annex XV report format. The aim is that in the revised version – to the extent possible – one heading is relevant only for one Committee. The Secretariat reminded that both Committees are expected to adopt their own parts in the background document to support their respective opinions.

One member pointed out that according to the working procedure SEAC is provided only with selected draft versions of the RAC opinion. The Secretariat agreed to improve the text of the procedure by adding an indication of the stages at which RAC shares its opinions with SEAC.

The need for the Forum's advice in the early stages of the procedure was questioned. Nevertheless, the Secretariat stressed that it would be useful to know the Forum's opinion early on since the dossier submitter has to include in his Annex XV restriction report the evaluation of the enforceability of the identified risk management options and to suggest a wording to be used in Annex XVII.

Concerns were also raised about having sufficient time for adoption of opinions at plenary meetings when there would be several dossiers processed at the same time. The Secretariat responded that in such cases the opinion could be adopted also in a written procedure as a last resort.

Members raised also some more specific points: the need to indicate the major steps and maximum time windows for these steps in the working procedure, to merge the steps j and k, to clarify the difference between "revise" and "review" in the written procedure, the need to include further flexibility in the procedure, to add in step t that SEAC is to provide comments on the SEAC rapporteur's 4th version of SEAC draft opinion in order to avoid a possible confusion with the opinion of RAC mentioned in the preceding step, to provide explanations

of abbreviations and acronyms used in the document and to amend the document in line with Article 71(3) of the REACH Regulation. The Secretariat agreed to consider these points in the next revision of the working procedure.

On the suggestion of one member, the Secretariat agreed to compile all working procedures adopted by SEAC in a handbook and in a dedicated CIRCA folder to be easily accessible by the members.

To conclude, the Chair proposed to upload the document to CIRCA for a further round of commenting in a newsgroup within three weeks from its launch. SEAC is expected to adopt the procedure at its next meeting in June.

c) Draft terms of reference for (co-)rapporteurs

The Secretariat introduced the revised draft Terms of Reference document (SEAC/03/2009/06) and noted that the drafting of this document was closely linked to progress with the working procedure on processing a restriction dossier and the interaction between the two sister Committees. The document had been revised according to consideration at SEAC-2 and a subsequent newsgroup discussion in SEAC as well as parallel discussions in RAC. For the SEAC newsgroup discussion, a response to comments document had been provided to members (SEAC/03/2009/10).

During the discussion, one member proposed that all means of support, such as working groups, invited experts, advisors, etc., available to the rapporteurs would be spelled out in a separate document. The Secretariat agreed to consider this suggestion. Furthermore, the Secretariat was requested to reconsider its negative position on the possibilities to use external consultants. This was perceived by one member as possibly a need specific to the nature of SEAC's work.

Several members queried who would have the final say on the quality of rapporteur's outputs. The Secretariat explained that the Committee's role in the quality assurance takes place through internal consultations and adoption rounds as described in the working procedures related to restriction. ECHA and ultimately COM also play a role in the quality assurance. The Secretariat agreed that acceptable quality criteria will need to be developed in the future.

Some members enquired whether the rapporteur would take precedence over the co-rapporteur in case of disagreement and how the two would share legal accountability and obligation to deliver the outcomes following from ToR. The Secretariat explained that according to the REACH Regulation, the co-rapporteur "may" be appointed. Furthermore, ECHA envisages that the rapporteur and (co-)rapporteur would agree between each other on the share of the work and responsibilities. The Secretariat agreed that the issue should be clarified further.

The Secretariat was requested to amend the document in line with Article 71(3) of the REACH Regulation and to highlight in ToR the shift of the responsibility from the rapporteur to SEAC when the opinion/background document is revised/reviewed and adopted.

The Secretariat also agreed to consider the recommendation of COM to replace the working procedures enclosed in their full length in the document (i. e. annex 2 and 3 in the document SEAC/03/2009/06) with a reference to the appropriate documents in Circa, and to add that in case of changes to the working procedures during the rapporteur's appointment period, a separate agreement would be made to address the effect of these changes on the processing of a particular dossier.

To close the discussion, the Chair proposed to upload the document to CIRCA for a further round of commenting in a newsgroup within three weeks from its launch. SEAC is expected to adopt the ToR at its next meeting in June.

d) The opinion of SEAC on restriction proposals

The Secretariat presented document SEAC/03/2009/05 describing the main principles of the opinion of SEAC on restriction proposals. The role of SEAC and RAC opinions, background document, the interaction between the RAC and SEAC opinions, the content of the opinions and how to document the opinions were described. The basic combinations of RAC and SEAC opinions were also presented. The Secretariat gave further reasoning behind producing a single background document and documenting the two opinions in one paper.

In the extensive discussion that followed the presentation, several members questioned the way the gist of the SEAC's opinion was presented in the document. Some members argued that SEAC should give an opinion only on the socio-economic consequences of the restriction and not on whether the proposed restriction is appropriate or not or supported by SEAC. In this argument they referred to Article 70 of the REACH Regulation according to which RAC is expected to formulate an "opinion as to whether the suggested restrictions are appropriate", while according to Article 71(1) SEAC is expected to give an "opinion on the suggested restrictions" and felt that socio-economic considerations are easily regarded as political, not scientific or technical considerations and that SEAC should therefore abstain from expressing whether it is for or against the proposal. Some members drew the parallel to an Impact Assessment Board that only assesses the quality of the proposal and the SEA on it. Furthermore, many members expressed their concerns to what extent SEAC's opinion can in practice be "clear yes/clear no" on which the Secretariat agreed to revise the text to capture better the idea behind it. A debate followed on the question whether by drawing such clear cut conclusions SEAC would be making in fact political conclusions instead of scientific ones.

On the other hand, other SEAC members generally supported that the opinions needed to be useful for COM and the final decision-making in the "comitology" procedure and thus the opinions should be as clear as possible. Consequently, providing an opinion merely on the impacts of a restriction and not answering whether – based on the evidence given in the restriction proposal – SEAC would be in favour or not in favour of a restriction might cause significant difficulties for and delays in the decision-making process.

The opinion would need to be clear about what type of restriction (the scope and conditions) is backed by the available information. When formulating the (obligatory) justification for its opinion, SEAC should give in transparent manner its scientific and technical arguments in support of the opinion. Assessing the balance between benefits and costs of a restriction belongs to the remit of SEAC and that should allow SEAC to formulate its opinion clearly using scientific methods. In this respect, SEAC should provide a scientific and technical input to the comitology procedure which then in addition can take into account political and other concerns. What also speaks in support of opinions with clear thrust is the SEAC's possibility to modify the proposed restriction following the additional information obtained through public consultations in such manner that it would reflect the balance between costs and benefits of a restriction. Some members expressed their concern about the time available to understand the impacts if the conditions of the restriction(s) are modified.

Some members pointed out more rare situations, like providing an opinion on the original restriction by SEAC while RAC supports a modified restriction. The Secretariat explained that the paper was not meant to cover all possible cases and that such situations should be and can be avoided through effective communication between the two Committees. The issue of how majority and minority opinions would be presented was also brought up.

A question was also raised about the need to keep MS Competent Authorities who are engaged in the final decision making informed about the discussions in the Committees regarding a dossier and the basis of the arguments influencing the final opinion.

It was noted also that RAC and SEAC opinions are closely inter-linked and could be usefully presented in one document at the end of the process as suggested by the Secretariat.

A few specific comments were raised. One member suggested improvement of the wording in the document on page 5 regarding the suggestion that the opinion of SEAC should focus on justifying that an action on a Community-wide basis is needed from the perspective of a proper functioning of the internal market. It was also agreed that in fact the background document and not Annex XV report is modified during the process, unlike stated on page 3 of the document.

In conclusion, the Chair said that these comments would be taken into account in the next version of the document and proposed to upload the document to CIRCA for a further round of commenting in a newsgroup within three weeks from its launch.

8. Transitional dossiers based on Article 136(3) of the REACH Regulation

a) Overview of transitional dossiers submitted by Member States

The Secretariat presented an overview of the 25 transitional dossiers (for 26 substances) received by ECHA by 1 December 2008 established in accordance with Article 136(3) of the REACH Regulation. None of the submitted transitional dossiers identified a need for a restriction under REACH and instead all proposed an alternative way forward. Alternatives included in the dossiers: a need for other Community-wide measures (21 dossiers); national or industry action (22 dossiers); and the remaining two¹ dossiers did not identify the need for further risk management measures (N.B. a dossier can belong to more than one group). One dossier (MCCPs) refers to the need for a restriction for the specific use of MCCPs in leather fat liquoring but this was not considered in further detail in an Annex XV format but rather in an annex to the dossier.

The Secretariat explained that since none of the dossiers proposed a restriction under REACH, they could not be used as a test case. Nevertheless, some of the transitional dossiers discussed a restriction as one of the risk management options and hence were of interest to SEAC. A characterisation sheet had been prepared providing a history and guide to the content of each dossier.

Several members enquired about the follow-up of the transitional dossiers and some queried whether ECHA could address COM about its conclusions on the transitional dossiers. The Secretariat agreed to consider providing a follow-up on transitional dossiers relevant to SEAC and more formal submission of the transitional dossiers characterisation conclusions to COM to channel further the proposed risk management measures.

¹ After the meeting the MS Competent Authority submitting these two dossiers requested that they be re-categorised into category 2 (need for Community-wide measures) since the current category (category 4) gave the impression of no risk, whereas in fact risks had been identified but the MSCA had proposed that current EU existing legislative measures provided an adequate framework to address the risks and thus no additional specific measures had been proposed.

b) Risk Management Options at the Community level

The Chair introduced the document on risk management options at the Community level as useful reference material for SEAC.

One observer pointed out that there were inaccuracies and too generic conclusions in the document concerning the Carcinogens and Mutagens Directive. One member had similar comments on the text concerning the IPPC Directive. The Chair reminded that the document had been originally prepared by COM based on the Annex XV guidance on restrictions and at the same time it was intended to be a brief presentation of risk management options. The Chair proposed to launch a CIRCA newsgroup for a further round of commenting but noted that the comments might not be followed up by ECHA in the near future as no guidance update is currently planned.

Several members supported the idea of training on risk management options at the Community level to be organised for SEAC. The Secretariat agreed to consider this idea.

c)&d) Dossiers identifying a need for a Community-wide measures other than restriction and Dossiers identifying a need for action at national/local level

The Secretariat presented the dossiers from the perspective of increasing the common understanding of why Community-wide measures, other than restriction, were the most appropriate measures for these substances. The emphasis was placed upon the aspects of the justifications that were most relevant to SEAC. The justification for Community-wide action was considered in terms of the risks to be addressed defined through a baseline and internal market. The various risk management options in the dossiers were then examined in relation to three criteria: effectiveness (proportionality), practicality and monitorability.

One of the advisors presented his experience with a scoping study & transitional dossier (coal tar pitch). In the scoping study it was elaborated whether and what kind of restriction measure would be appropriate or whether authorisation would be a more suitable way forward. In addition, other risk management options were investigated.

The presentations were followed by a brief discussion. Several members expressed that the differences between enforceability, monitorability, implementability and manageability were not very clear. The Secretariat agreed to consider developing further interpretation of these notions as it is important for the assessment of a restriction proposal. Furthermore, the discussion reinforced the need for further exchange of information on other risk management options that was brought to attention already under Agenda point 8b).

9. Planning of the work for the second half of 2009

The schedule of the next SEAC plenary and SEAC-RAC arrangement meetings was presented. The Chair noted that the meeting tentatively planned for September 2009 is likely to be cancelled if there are no restriction dossiers submitted earlier on. The working procedures for the restriction process should be adopted by RAC and SEAC at their joint plenary meeting at the end of June.

10. AOB

a) Next meetings

Agenda point covered under point 9 above.

Following the comment made by one SEAC member, the Chair suggested that plenary meetings would finish earlier on the last day or that the Agenda points that require Committee

quorum would be moved to earlier on the Agenda to ensure that a sufficient number of members is present in the meeting room when agreement of members is sought.

b) New Chair of SEAC

The Chair informed that the selection process for a new Chair of SEAC had been concluded but the recruitment process is still ongoing. The new Chair is likely to chair the SEAC-4 meeting in June.

c) Access of stakeholder observers to SEAC Circa Interest Group

The Chair informed that the non-confidential folders on SEAC Circa IG could be now accessed by stakeholder observers. A folder dedicated for confidential documents and documents not to be shared with stakeholder observers had been created on SEAC Circa IG which is not accessible to stakeholders. Members may access the documents in this folder through links provided in the non-confidential folders.

The Chair reminded the members to sign out from the service and close the browser after having visited the SEAC Circa IG as a security precaution.

d) Status report of the preparation of the guidance document on SEA in Authorisation

COM informed that the guidance document on SEA in Authorisation had been contracted out to an external contractor which had worked under the supervision of the Joint Research Centre. The development of the guidance had been completed last year but some improvements continued to be made by COM in particular concerning clarity of the text and quality of illustrations. At the moment there was one outstanding legal issue being discussed between the COM Services. The guidance would be disclosed to the Competent Authorities and stakeholders in order to provide comments and eventually presented at the Competent Authorities meeting in June.

e) Status report of pre-registrations

On request by one member, the Secretariat reported about the progress of pre-registrations submitted from June till December 2008 and the pre-registration state-of-play.

11. Action points and main conclusions of SEAC-3

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

II. Conclusions and action points

SEAC-3 ACTION POINTS & MAIN CONCLUSIONS – 23-24 February 2009 (as adopted at the SEAC-3 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the Agenda	<p>The following points added to the Agenda:</p> <ul style="list-style-type: none"> - 2bis) Status report of SEAC-2 action points. - Cover within AP 4 “Feedback from other ECHA bodies” feedback from the Workshop for MS CAs on Authorisation held in January 2008. - Under AOB: <ul style="list-style-type: none"> - New Chair of SEAC, - Access of stakeholder observers to SEAC Circa IG, - Status report of the preparation of the guidance document on SEA in Authorisation, - Status report of pre-registrations (if possible). <p>The Agenda was adopted with the proposed modifications.</p>	SECR to upload the adopted SEAC-3 Agenda to Circa.
2bis) Status report of SEAC-2 action points.	SEAC took note of the status report regarding SEAC-2 action points.	Explanation on implications of not meeting the 30 days deadline in the Conformity Check procedure to be recorded in SEAC-3 Minutes.
3. Administrative issues		
a) Changes in the SEAC composition/nominations		
b) Participation of observers		SECR to ensure that stakeholder observers are given the possibility to submit comments on the draft Minutes of SEAC plenary meetings.
c) Declarations of conflict of interest	No declarations of conflict of interest declared.	
d) Revised reimbursement rules		Members and stakeholder observers to take into account the revised reimbursement rules when arranging their travels.
e) Remuneration of invited experts serving the	Members took note of the newly established rules for the remuneration of co-opted members and invited experts.	SECR to clarify the interpretation of “public service” in the MB

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
Committee working groups		Decision MB/77/2008 (by SEAC-4).
4. Feedback from other ECHA bodies (RAC, MSC, Forum, MB)	Members took note of the feedback reports from the recent developments in RAC, MSC, the Forum and the MB.	
5. SEAC-RAC arrangement		
a) First results of the SEAC-RAC arrangement	SEAC took note of the Chair`s written report and the oral report by a Member of SEAC-RAC interaction.	
b) Work Plan till June 2009	<ul style="list-style-type: none"> - Task 1 of the Mandate of SEAC-RAC interaction to be discussed at the next meeting of the interaction. - Criteria for getting a deadline extension for adoption of SEAC opinion pursuant to Art 71(3) to be discussed at the next meeting of SEAC-RAC interaction. - M CCP transitional dossier agreed by SEAC/RAC interaction to be used as a case study. - Next meeting of SEAC-RAC interaction to take place on 20 April 2009, back-to-back with RAC-6 meeting. 	SECR to inform SEAC about the outcome of the 2 nd meeting of SEAC-RAC interaction (by SEAC-4).
6. Rules of Procedure (RoPs) a) Report of the written procedure on the revision of the RoPs	SEAC took note of the report of the written procedure on the revision of SEAC RoPs. SEAC RoPs have been forwarded by the SECR to the MB for final adoption.	SECR to inform SEAC about the outcome of the MB meeting (asap).
7. Working Procedures for Restrictions		
a) Procedure for appointment of rapporteur and co-rapporteur	<p>The following major modifications introduced in the document based on the suggestions received from SEAC members:</p> <ul style="list-style-type: none"> - Time for expressions of interest by members extended from 2 weeks to 3. - The Chair needs to consult with the candidates informally to clarify the availability, qualifications and any other relevant considerations in order to prepare his/her recommendation. - Since the restriction procedure may last 13-16 months, there should be sufficient time remaining of the rapporteur`s term of office to be able to complete the rapporteurship. - Replacement of rapporteur should be avoided to the extent possible not to hamper the process, unless it is justified as described in the document. <p>SEAC adopted the Procedure for appointment of rapporteur and co-rapporteur with the presented</p>	SECR to upload the adopted Working Procedure for appointment of rapporteur and co-rapporteur to SEAC Circa IG (by 5/3/09).

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
	<p>modifications with the provision that the procedure may need to be revised after discussions in RAC on their corresponding Working Procedure.</p>	
<p>b) Working procedure on processing of an Annex XV restriction dossier</p>	<ul style="list-style-type: none"> - It may not be feasible to keep the background document up-to-date throughout the procedure. Indicate that it should be a good practice but not obligatory at all stages. - Indicate in the Procedure major steps and the time foreseen for these steps. - Explain in the document the abbreviations used. - Take into account that several dossiers may be in the pipeline at the same time. - Necessary to consult with MS CAs whether it is possible for them to complete the tasks assigned to the submitting MS CA in the WP within the deadlines set. - Indicate where there can be flexibility in the process and where the deadlines and steps are binding. - Possibly indicate workload for rapporteurs and also for other players. - Consider compiling of all SEAC WPs in a handbook. - Consider the Forum views on its input in the restriction process. - Clarify in the document what is meant by “review” and “revision”. - Note that the compilation of early comments by SECR in the second public consultation seems not to lead to any action. - WP should take into account possible extension of the deadline for SEAC final opinion according to Art 71(3) of the REACH Regulation 	<p>SECR to launch a Circa newsgroup on the document SEAC/03/2009/04. SEAC to provide comments in writing within 3 weeks from launching of a Circa newsgroup.</p> <p>SECR to revise the draft WP so that it could be adopted at the joint session between RAC and SEAC in the end of June, taking into account RAC and SEAC comments.</p> <p>SECR to compile all WPs in one place under SEAC Circa Library by 5 March.</p> <p>SECR to address MS CAs at a later stage to seek their agreement on the tasks foreseen for the submitting MS in the WP.</p>
<p>c) Draft terms of reference for (co-)rapporteurs</p>	<ul style="list-style-type: none"> - SECR to consider the use of invited experts and external consultants in SEAC work due to possible need for specific expertise (e.g. on feasibility of alternatives). - SECR to consider summarising all means of support (working groups, consultants, invited experts, etc) available for a rapporteur to be used during the restriction process. - Committee and ECHA Secretariat have the shared role in assessing whether the quality of documents prepared by the rapporteur is at satisfactory level. COM has its final say on the quality of the SEAC opinion. - SECR to clarify the consequences of disagreement on the draft opinion between rapporteur and co-rapporteur. - Alternative ways to be considered to refer to the relevant WPs (e.g. reference to Circa instead of attaching them). - ToR should take into account possible extension of the deadline for SEAC final opinion according to Art 	<p>SECR to launch a Circa newsgroup on the document SEAC/03/2009/06. SEAC to provide comments in writing within 3 weeks from launching of a Circa newsgroup.</p> <p>SECR to revise the draft ToR so that it could be adopted at the joint session between RAC and SEAC in the end of June, taking into account RAC and SEAC comments.</p>

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
	71(3) of the REACH Regulation	
d) The opinion of SEAC on restriction proposals	<ul style="list-style-type: none"> - Extensive and helpful first exchange of views on the purpose of SEAC opinion. Agreed that the purpose of RAC and SEAC opinions is to support the decision making of the Commission (i.e. comitology decision). - Different views on to what extent SEAC opinion can be „clear yes / clear no“. Noted that it may be difficult for SEAC to give such an opinion. - Political considerations should not be part of an opinion and an opinion does not replace a decision. However, less clear what different members meant by „political“. - It was clarified that SEAC is asked to give a scientifically and technically sound opinion. It needs to be clear what type of restriction (the scope and conditions) is backed by available information according to the opinion of SEAC. In other words, the opinion needs to be clear and include a transparent justification so that it supports the final (political) decision making. - It was noted that RAC and SEAC opinions are closely linked and could be usefully presented in one document at the end of the process. A clear understanding of the remits of the Committees and a good dialogue are prerequisites for successful opinion forming. 	<p>SECR to launch a Circa newsgroup on the document SEAC/03/2009/05. SEAC to provide comments in writing within 3 weeks from launching of a Circa newsgroup.</p> <p>SECR to revise the document, taking into account RAC and SEAC comments received.</p>
8. Transitional dossiers based on Article 136(3) of REACH Regulation		
a) Overview of transitional dossiers submitted by MSs		<p>SECR to consider more formal submission of the transitional dossiers characterisation conclusions to COM to channel further the proposed RMM as appropriate.</p> <p>SECR to consider how to follow-up the transitional dossiers in SEAC.</p>
b) RMOs at Community level	SEAC took note of the description of various Risk Management Options (RMO) at the Community level contained in the document SEAC/03/2009/08.	<p>SECR to consider training for SEAC or further discussion on RMO.</p> <p>SECR to record in the meeting Minutes the comments raised by</p>

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/when)
		<p>participants requiring modification of the presented document.</p> <p>SECR to launch a Circa newsgroup on the document SEAC/03/2009/08. SEAC to provide comments in writing within 2 months from launching of a Circa newsgroup, with the understanding that there is no intention at the moment to revise the document or develop it further.</p>
c) Dossiers identifying a need for a Community-wide measures other than restriction	<p>- SEAC took note of a presentation on transitional dossiers focusing on the considerations and justifications given in 3 of them: styrene, MCCP and coal tar pitch.</p> <p>- The interpretation of i.a. enforceability, monitorability, implementability and manageability important for the assessment of a restriction proposal.</p>	SECR to consider developing further interpretation of the notions.
d) Dossiers identifying a need for action at national/local level	Covered within the previous AP.	
9. Planning of the work for the second half of 2009	<p>- SEAC took note of the provisional meeting dates in 2009 listed in document SEAC/03/2009/09.</p> <p>- SEAC meeting tentatively planned for September 2009 is likely to be cancelled.</p>	
10. AOB		
a) New Chair of SEAC	SEAC took note that the next meeting will likely be chaired already by a newly elected Chair of SEAC.	
b) Access of stakeholder observers to SEAC Circa IG	SEAC took note that SEAC Circa IG can now be accessed also by stakeholder observers and that a confidential folder has been created containing documents not intended to be shared with observers.	
c) Status report of the preparation of the guidance document on SEA in Authorisation	SEAC took note that the guidance on SEA in Authorisation is ready but there is one legal issue being discussed between the COM Services. The guidance document will soon be provided to MS CAs for commenting.	
d) Status report of pre-registrations	SEAC took note of the presentation on status report of pre-registrations submitted to ECHA.	

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
General		SECR to upload all SEAC-3 presentations and the action points to Circa by 27 February.

III. List of Attendees

Members:	Representatives of the Commission:
BIZKOVA, Rut	SCHMAHL, Maik (DG ENTR)
BRIGNON, Jean Marc	CHRISTENSEN, Frans (JRC)
BROKAITE, Kristina	GIL, Sebastian (DG ENV)
DANTINNE, Catheline	
DE GIGLIO, Franco	Stakeholder observers:
DOMINIAK, Dorota*	HOLLAND, Mike (EEB)
ECONOMIDES, Aristodemos	LEENAERS, Joeri (Eurometaux)
FANKHAUSER, Simone	MÄKELÄ, Kari (EMCEF)
FEYAERTS, Jean-Pierre	MUSU, Tony (ETUC)
FIORE, Karine**	VAN SLOTEN, Rene (CEFIC)
FOCK, Lars	
FORKMAN, Mats	International observers:
FURLAN, Janez	BRAATHEN, Nils-Axel (OECD)
GEORGIOU, Stavros	
GUSTAFSSON, Lars	ECHA staff:
KOZAK, Kristof	BLENCOWE, Tom
LANGTVET, Espen	DE BRUIJN, Jack
LOURENÇO, João	FUHRMANN, Anna
LUTTIKHUIZEN, Cees	HAUTAMAKI, Anne
McGUINNESS, Sharon	HERDINA, Andreas
RECCHIA, Luca Maria	HOLLINS, Stephen
SALONEN, Heikki	KARHU, Elina
SCHUCHTAR, Endre	LIPKOVA, Adriana
SIMON, Franz-Georg	MUNN, Sharon
SUSNIK, Marko***	PELTOLA, Jukka
TELLING, Aive	SADAM, Diana
THEOHARI, Maria	SIHVONEN, Kirsi
THIELE, Karen	SUNDQUIST Anna-Liisa
VOIVONTAS, Dimosthenis	VAINIO, Matti
	VASILEVA, Katya
	WILSON, Anthony
	YLÄ-MONONEN, Leena
*replacing RYDLEWSKA-LISZKOWSKA, Izabela	
**replacing BASTOS, Henri	
***replacing SCHWARZER, Stephen	

Advisers to the SEAC members:

BEEKMAN, Martijn (adviser to LUTTIKHUIZEN, C.)
 BENDL, Jiri (adviser to BIZKOVA, R.)
 KIISKI, Johanna (adviser to SALONEN, H.)
 MOSCATO, Isabella (advisor to RECCHIA, L.)

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

Revised Draft Agenda (Agenda Point 2)	SEAC/A/03/2009_rev.1
Changes in the composition of the Committee for Socio-economic Analysis in the period from 26 th September 2008 to 13 th February 2009 (Agenda Point 3a)	SEAC/03/2009/01
Rules for the remuneration of co-opted members and experts (Agenda Point 3e)	SEAC/03/2009/02
Report of the written procedure on the revision of SEAC Rules of Procedure (Agenda Point 6)	SEAC/03/2009/03
Working Procedure for Appointment of rapporteurs and co-rapporteurs for restriction dossiers (Agenda Point 7a)	SEAC/03/2009/11
Preliminary draft working procedure for processing an Annex XV proposal for restriction (Agenda Point 7b)	SEAC/03/2009/04
Timelines, milestones and deliverables following the working procedure for SEAC on Annex XV dossiers for restriction	Room document
Response to comments table on the previous version of ToR (Agenda Point 7c)	SEAC/03/2009/10
Revised draft terms of reference for SEAC (co-) rapporteurs (Restrictions) (Agenda Point 7c)	SEAC/03/2009/06
The opinion of SEAC on restriction proposals (Agenda Point 7d)	SEAC/03/2009/05
Transitional dossiers submitted by Member States according to the Article 136(3) of the REACH Regulation (Agenda Point 8a)	SEAC/03/2009/07
Risk Management Options at the Community level (Agenda Point 8b)	SEAC/03/2009/08
Proposed meeting dates in 2009 (Agenda Point 9)	SEAC/03/2009/09

23 February 2009
SEAC/A/03/2009_rev.2

Final Agenda
Third meeting of the Committee for Socio-economic Analysis

23-24 February 2009
ECHA Conference centre (Annankatu 18, Helsinki)

23 February: starts at 14:00

24 February: ends at 18:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/03/2009_rev.1

For adoption

2bis) Status report of SEAC-2 action points

Item 3 – Administrative Issues

a) Changes in the SEAC composition/nominations

SEAC/03/2009/01

For information

b) Participation of observers

For information

c) Declarations of conflict of interest

For signature

d) Revised reimbursement rules

For information

e) Remuneration of invited experts serving the Committee working groups

SEAC/03/2009/02

MB/77/2008 final (Decision of the MB)

For information

Item 4 – Feedback from other ECHA bodies

Feedback from the last RAC, MSC, Forum and MB meetings.

For information

Item 5 – SEAC-RAC arrangement

- a) First results of the SEAC-RAC arrangement (including oral report of the 1st meeting of 27 January 2009)

For information

- b) Work Plan till June 2009

For discussion

Item 6 – Rules of Procedure (ROPs)

- a) Report of the written procedure on the revision of the RoPs

SEAC/03/2009/03

For information

Item 7 – Working Procedures for Restrictions

- a) Procedure for appointment of rapporteur and co-rapporteur

SEAC/03/2009/11

For adoption

- b) Working procedure on processing of an Annex XV restriction dossier

SEAC/03/2009/04

For discussion

- c) Draft terms of reference for (co-)rapporteurs

SEAC/03/2009/10 (RCOM table on the previous version of ToR)

SEAC/03/2009/06

For discussion

- d) The opinion of SEAC on restriction proposals

SEAC/03/2009/05

For discussion

Item 8 – Transitional dossiers based on Article 136 (3) of REACH Regulation

- a) Overview of transitional dossiers submitted by Member States

SEAC/03/2009/07

For information

- b) Risk Management Options at the Community level

SEAC/03/2009/08

For information

- c) Dossiers identifying a need for a Community-wide measures other than restriction

For discussion

- d) Dossiers identifying a need for action at national/local level

For information

Item 9 – Planning of the work for the second half of 2009

- Outline work plan on restrictions

SEAC/03/2009/09

For information

Item 10 – AOB

- a) Next meetings
- b) New Chair of SEAC
- c) Access of stakeholder observers to SEAC Circa IG
- d) Status report of the preparation of the guidance document on SEA in Authorisation
- e) Status report of pre-registrations

Item 11 – Action points and main conclusions of SEAC-3

Table with Action points and decisions from SEAC-3

For endorsement