

SEAC/M/02/2008 FINAL

Final

Minutes of the 2nd meeting of the Committee for Socio-economic Analysis 22-23 October 2008

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 João Lourenço nominated by Portugal and Ms Karen Thiele nominated by Germany were introduced and welcomed.

The Chair informed that apologies were received from five members, two of whom had sent non-voting replacements. Members` advisors present at the meeting as well as representatives of the European Commission (COM) and the three stakeholder organisations participating in the meeting as observers were introduced. The list of attendees is given in Part III of the minutes.

2. Adoption of the Agenda

The Secretariat proposed to also cover under AOB the selection of the SEAC permanent Chair and the involvement of the OECD Secretariat in the work of the Committee. It was requested from the Secretariat by one member to report on the status of the guidance on authorisation and the preparations for the workshop on Annex XV for MS Competent Authorities (CAs) under AOB. With those modifications the Agenda was adopted. The final Agenda is attached to the minutes as Annex II.

The Chair recalled that the minutes of the first meeting of the Committee had been approved in a written procedure and had already been published on the ECHA website.

3. Administrative Issues

a) Changes in the SEAC composition/nominations

The Chair informed about changes in the composition of the SEAC which had taken place after the first meeting of the Committee. It was noted that Norway had nominated a candidate to the SEAC as the first EEA-EFTA country and the Management Board (MB) of ECHA had subsequently appointed Mr Espen Langtvet.

b) Declarations of conflict of interest

The Secretariat reported that annual declarations were still missing from four SEAC members and CVs from two and encouraged members to submit the missing documents to the SEAC Secretariat as soon as possible. It was explained that all available declarations had already been published on the ECHA webpage and that in the published declarations the signatures of persons had been erased in accordance with the decision of the MB of ECHA.

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

c) Reimbursement rules

The Chair informed that ECHA reimbursement rules had been revised since the first meeting of the Committee. Participants were asked to keep in mind that they should make their travel arrangements within five working days from the date on which the invitation had been sent by ECHA and that only non-flexible tickets should be used, unless there was specific justification presented by the member.

4. Stakeholders' participation (closed session)

a) Report from the written procedure on stakeholders' participation

The Secretariat gave a short presentation summarising the purpose of the written procedure on stakeholders' participation in SEAC meetings. According to the results of the written procedure, the SEAC had adopted the proposed procedure for admission of stakeholder observers which formed the first part of the written procedure. The second part of the written procedure concerned the decision on which specific stakeholder organisations the SEAC members would like to invite as regular observers to the Committee work and it had been decided by the Secretariat that this part of the written procedure was suspended due to unfamiliarity of the members with the procedure and the list of stakeholders, complexity of the question and their ambiguous formulation. It had therefore been decided to discuss the involvement of stakeholder organisations in the SEAC's work at this meeting.

The Chair presented the comments received from members in the written procedure on stakeholders` participation. One member had proposed that the total number of stakeholder observers should not exceed 1/3 of the number of the SEAC members, instead of the proposed 1/2. It had been noted that the distinction between parts 1 and 2 in the list of stakeholder organisations was debatable. One member had complained that a surprisingly large group of stakeholders was regarded as non-eligible. The balanced representation of stakeholder observers had been stressed by several members. A few participants had emphasised that preferably the whole life cycle of chemicals, including the waste phase, should be covered. It had also been questioned by a few members whether some additional organisations could get involved in the work of the Committee at a later stage.

The Secretariat explained that at this meeting the Committee should decide on regular stakeholder observers who would participate in every meeting of the Committee. In addition to these regular observers, the Committee could invite additional organisations on an ad-hoc basis. Regarding the large number of non-eligible organisations, the Secretariat responded that this was the decision of the MB that also established the criteria for eligibility.

b) Update on new registrations for participation to ECHA's work

The Secretariat recalled that in February 2008 the MB had adopted a policy paper on stakeholder participation to ECHA's work, after which the call for expression of interest had been launched by ECHA in March 2008 (the call had remained open). The MB had established the criteria according to which it decided whether each organisation was considered as eligible or not. As of 31 August 2008, 77 expressions of interest had been received by ECHA. 40 organisations had met the MB criteria and had been considered as eligible. 19 of those represented general interest (15 of them interested in the SEAC's work) and 21 were sector specific industrial organisations (9 organisations interested in the SEAC). Gaps had been identified in some fields of interests. For example, the specific interests of SMEs had not been well covered and therefore the Member State Committee (MSC) as well as the Risk Assessment Committee (RAC) had invited UEAPME¹ to also participate in their work.

¹ European Association of Craft, Small and Medium-sized Enterprises

c) Invitation of possible regular stakeholder observers

The Secretariat asked members to consider which stakeholder organisations should be invited as regular observers from the updated list. It was also emphasised that according to the suggestion of the MB the Committees should be concentrating mostly on the organisations from part 1 (organisations representing general interest) when inviting stakeholder observers. The Chair asked members to keep in mind that in addition to the regular stakeholder observers the Committee could invite other stakeholder organisations to the meetings on an ad-hoc basis.

After discussion, the Committee decided to invite the following organisations as regular observers:

- 1) BEUC Bureau Européen des Unions de Consommateurs;
- 2) BusinessEurope The Confederation of European Business (previously UNICE);
- 3) CEFIC European Chemical Industry Council;
- 4) CONCAWE Oil Companies` European Association;
- 5) Eurometaux European Association of Metals Industry;
- 6) European Association of Environmental and Resource Economists;
- 7) European Environmental Bureau *;
- 8) European Trade Union Confederation;
- 9) FECC European Association of Chemical Distributors;
- 10) Friends of the Earth Europe *;
- 11) Greenpeace International*;
- 12) Health and Environmental Alliance (HEAL) *;
- 13) WWF European Policy Office *;
- 14) Women in Europe for a Common Future (WECF);
- 15) EMCEF European Mine, Chemical and Energy Workers` Federation;
- 16) UEAPME European Association of Craft, Small and Medium-sized Enterprises.

It was questioned by members within the discussion of involvement of organisations from part 1 of the list why such organisations as for example CONCAWE or Eurometaux were considered as representing a general interest. The Secretariat replied that the division of the organisations between parts 1 and 2 was thoroughly discussed by the MB. CONCAWE and Eurometaux were placed to part 1 as both are big organisations not represented by CEFIC. Regarding the organisation ECETOC, some members expressed the view that this organisation was more relevant for the RAC, and not for the SEAC. It was agreed that the European Environmental Bureau, Friends of the Earth Europe, Greenpeace International, Health and Environmental Alliance and WWF European Policy Office (marked above with *) would be approached by the Secretariat as a group and asked to consider whether they could be represented in the SEAC by joint representatives. The involvement of the organisation Women in Europe for a Common Future (WECF) was considered as useful due to the possibility to get information on the effects of chemicals on sensitive populations.

From part 2 of the list of stakeholders a few members proposed to invite the European Federation of Waste Management (FEAC). Several members were however against this considering waste sector as not yet being ready for their involvement. It was therefore decided to postpone the invitation of the organisation representing waste sector. Some members expressed their views that representatives of engineering industries as well as importers of articles from third countries should also be covered. The Chair noted that

"green chemistry" groups and others working on the issue of alternatives could be of particular interest to this Committee. It was agreed that in case members find some additional organisations which could be regarded as eligible and be invited to the SEAC as regular observers, they could suggest to them that they contact the Secretariat and express their interest in being involved in ECHA's work.

d) ECHA code of conduct for stakeholder observers

The Secretariat explained the rationale for and the process leading to the code of conduct. Participants were informed that the code of conduct had been adopted by the Executive Director of ECHA and that it was applicable to all ECHA Committees, the Forum for Exchange of Information on Enforcement and informal networks.

5. Rules of Procedure (ROPs) (closed session)

a) Adoption of SEAC Rules of Procedure by the MB

The Chair recalled that the ROPs of the SEAC were adopted by the MB at its meeting in April 2008 with only one small modification in Article 6.

b) Proposal for revised ROPs

The Secretariat introduced proposed modifications to the ROPs based on the meeting document SEAC/02/2008/08. It was suggested by ECHA that the Committee should not conclude on the issue of revising the ROPs yet, but should wait until other Committees had discussed their ROPs as this would give an opportunity to the SEAC to take into account also issues spotted by other Committees. It was agreed that the revised ROPs would finally be adopted using the written procedure.

The Secretariat explained that the proposed modifications were mostly related to the present involvement of EEA-EFTA countries as full members, but having no right to vote. All the changes proposed by the Secretariat were preliminarily approved by the Committee. Concerning Article 20(2), it was agreed that the written procedure could be shortened in other than urgent cases only after the agreement of the Committee by consensus and that Article 20(2) should be modified correspondingly. Regarding Article 20(4), it was agreed that the Secretariat would clarify after the meeting what exactly was meant with the wording "procedural decisions".

6. Report from SEAC Intersessional Working Group and conclusion on the need to continue the Working Group and other follow-up actions

a) Conclusions of the Intersessional Working Group meeting of June 2008: Challenges and options for solutions

The Secretariat recalled the mandate for the SEAC Intersessional Working Group agreed at the first meeting of the Committee. The Working Group held its meeting in June 2008 and the conclusions reached at this meeting were presented. The minutes of the Intersessional Working Group meeting were adopted by the participants of that meeting and the Committee agreed that they would be published on the ECHA webpage. It was decided to close the Intersessional Working Group.

b) Highlights from the SEA Workshop of October 2008

The Secretariat made a brief presentation on the SEA Workshop held just before the second meeting of the SEAC on 21-22 October 2008. The purpose of the Workshop, overall conclusions as well as the follow-up actions were introduced.

Several members found the Workshop organised by ECHA useful and emphasised that it would be important to further clarify the restriction process by applying lessons learned from the workshop in practice. Several members welcomed the idea of a test case and it was agreed that ECHA would prepare a "fictitious case" and examples on application of SEA in a restriction case and in an authorisation case which could be used as training material. One member complained that the cases introduced within the SEA Workshop concentrated more on health than on environmental impacts, and suggested to take also environmental impacts into account while developing a test case for learning purposes of the Committees. One member suggested that with regard to restrictions there could be two MS CAs coming from different countries working on the same substance at the same time. This could help use resources in MSs more effectively and would give an opportunity to gain experience in the preparation of a restriction dossier to more countries. The idea was welcomed by the Secretariat.

c) Training activities for 2008-2010

The Secretariat presented the training needs for different target groups (SEAC, RAC, MS CAs, stakeholders) for the upcoming years in the form of a table. It was noted that many of those training needs were identified by the SEAC Intersessional Working Group but complemented during the SEA Workshop. The discussion focussed on the training needs of the SEAC only.

All agreed that it was important to distinguish in which areas formal "classroom" training was required and where learning could take place through different means (e.g. reading). One member expressed his view that the SEAC as well as MS CAs need training on assessment of alternatives. Some members stressed the importance of getting the SEAC members on the same level of understanding as soon as possible before June 2009. It was agreed that ECHA, together with the COM services, would organise a workshop on a past restriction case to demonstrate how the decision making process - including negotiations with the Council and the European Parliament - had taken place. This workshop would be open to both SEAC and RAC members. It was also agreed that ECHA would organise two training courses - one on risk assessment and another on socio-economic analysis, which would be open to the SEAC members, advisors and observers. It was agreed that ECHA would send the terms of reference to the two training courses to SEAC members for their possible comments. Furthermore, ECHA said that it would propose the organisation of a training course on socioeconomic analysis for the RAC. The Committee tried to identify which training/learning needs presented in the table should be of highest priority for the SEAC. The list with priorities identified is included in the minutes as Annex III.

7. Feedback from other ECHA bodies

Ms Sharon Munn, the Chair of the Committee for Risk Assessment informed about the recent developments in the RAC. The Secretariat also briefly reported from the last MB and MSC meetings.

8. Procedure for appointment of rapporteur and co-rapporteur

a) Procedure for appointment of rapporteur and co-rapporteur

A representative of ECHA introduced the proposed procedure for appointment of rapporteur and co-rapporteur presented in the meeting document SEAC/02/2008/12. The legal basis and general principles of the proposed procedure as well as the suggested selection criteria were explained.

One member proposed to add to the document an explicit mention that SEAC and RAC rapporteurs could come from the same MS. The observer from the COM advised to specify in the title of the document that this procedure applied to restrictions only, as in case of authorisation there might be a need to apply a different procedure. It was also noted that the selection criteria for rapporteurs should take into account member's experience with respect to relevant sector, process, substance, alternatives, instead of the fields presented in the draft document as the fields listed in the document were not relevant for the selection criteria. It was agreed that the Secretariat would redraft the document in line with the received comments and submit to the SEAC at the third meeting of the Committee for eventual adoption.

b) Draft Terms of Reference for (co-)rapporteurs of the SEAC

The Secretariat explained the reason behind the development of the draft Terms of Reference for (co-)rapporteurs of the SEAC. A similar document had been developed for the RAC and was going to be discussed at the fourth meeting of the RAC. ECHA stressed that the current document was a preliminary draft, the aim of which was just to stimulate the discussion regarding the scope of the tasks of rapporteurs and corapporteurs in the Committee. It was agreed that members would have the first exchange of views regarding the document at this meeting but more concrete comments should be submitted in writing (via Circa newsgroup) to the SEAC Secretariat by the end of November 2008.

Members of the Committee found the document useful but acknowledged the need for its further development. It was suggested by several members that a flowchart could be included in the document or annexed to the document to make the process clearer. A few members felt that the involvement of other SEAC members than (co-)rapporteurs in the process should be clarified. One member suggested that responses to comments should be provided just in a structured format and not in the form of a table, as the draft stated. The participants also recognised that the quality criteria needed to be further developed. The Secretariat promised to prepare a new version of the Terms of Reference for (co-)rapporteurs of the SEAC by the third meeting of the Committee, taking into account comments submitted by the SEAC and the RAC.

9. Working Procedures – Restrictions dossiers (including transitional (Article 136(3) dossiers)

Under this agenda point, the Secretariat first gave a general presentation on restrictions, introducing the main steps in the restriction process, roles of the RAC and the SEAC in the process and the key documents for different steps in the restriction procedure.

a) Conformity check

The Secretariat recalled that the original document describing the conformity check of a submitted dossier presented at the first meeting of the SEAC had been provided to members for comments (closed on 31 May 2008). The Secretariat had prepared responses to the comments submitted by the SEAC members (meeting document SEAC/02/2008/14). Based on the comments received, two documents had been prepared: 1) meeting document ECHA/SEAC-1/2008/04_rev.1 containing refined questions (criteria) for conformity check and 2) meeting document SEAC/02/2008/15 on conformity check procedure itself.

Criteria for conformity check

One member considered the conformity check questions related to consultation not sufficient. It was also noted that although the presented questions could help to structure a conformity report, they should not be binding and it should be up to a rapporteur whether to use the proposed structure or not. The document ECHA/SEAC-1/2008/04_rev.1 was adopted by the SEAC. However, it was agreed that the Committee would review the criteria for conformity check in the future, when it had gained more experience.

Procedure for conformity check of a restriction dossier

ECHA introduced the proposed procedure for conformity check of a restriction dossier contained in the meeting document SEAC/02/2008/15.

One member asked whether if a dossier was found to be not in conformity, was modified by the MS and re-submitted it would again be checked for conformity. The Secretariat explained that a re-submitted dossier would go through the whole procedure again starting from the very beginning and would therefore also be re-checked for conformity. It was stressed by several members that all actors in the restriction procedure needed to understand the whole procedure as earlier steps had implications for later ones. It was also emphasised that the conformity check procedure should ensure that all SEAC and RAC members had a chance to see and comment on the dossiers at an early stage of the conformity check. One member questioned what would happen in case a rapporteur failed to meet the deadline set in the conformity check procedure. The Secretariat promised to clarify the implications of not complying with providing a conformity check report within the 30 day deadline. With these comments, the Committee endorsed the procedure for conformity check of a restriction dossier. It was however agreed that the procedure would be reviewed in the future when necessary, after some experience had been gained using it.

b) Proposal for handling transitional dossiers

The Secretariat explained that the meeting document SEAC/02/2008/16 on the hand-over of existing substances to ECHA was provided to the Committee members for information. The Secretariat then introduced the proposal for a procedure for handling of transitional dossiers by the RAC and the SEAC based on the meeting document SEAC/02/2008/17 "Processing of transitional dossiers under Article 136(3) of REACH". The Committee was requested to consider the proposal and agree on the way forward on the handling of transitional dossiers.

It was proposed by a member to appoint more than one test rapporteur from the SEAC (also from the RAC) for each transitional dossier in order to give members the possibility to gain experience in assessing a dossier. This proposal was welcomed by other members as well as by the Secretariat. The Committee suggested that also the transitional dossiers identifying a need for another Community measure could be used for discussion by the SEAC in order to facilitate its learning. It was discussed that simulating the restriction process with transitional dossiers identified for restriction could face hurdles due to tight time schedule and the fact that official public consultation cannot be carried out for transitional dossiers. The Secretariat proposed that the stakeholder organisations which had expressed their interest in participating in ECHA's work could be invited to provide their comments on those dossiers. The proposal was welcomed by the meeting participants. One member did not agree with the provision that the responsibility to communicate to the relevant authorities the

identified needs to take action under other Community legislation than REACH would primarily lie on the MS who prepared the dossier (last sentence on page 4 in the meeting document SEAC/02/2008/17). It was finally agreed to delete this sentence from the procedure as the issue was not relevant for the Committees. With this change the proposed procedure regarding the handling of transitional dossiers was agreed upon by the SEAC.

c) Test rapporteurs for transitional dossiers identifying the need for restriction

The Chair informed that the countries which were the members of the ECHA Costing Methodology Working Group established by the MB (Sweden, UK and Germany) had agreed to volunteer to be test rapporteurs. It was however emphasised that it did not prevent others from volunteering to be test rapporteurs as well.

d) The role of the Forum to give advice on enforceability of a restriction proposal

The Secretariat gave a brief presentation introducing the role of the Forum, its tasks and activities carried out so far. According to the REACH Regulation, one task of the Forum was examining proposals for restrictions with a view to advising on enforceability. It was however mentioned that the working procedure for providing advice on restriction proposals was not yet in place but that the Forum was going to discuss the issue at its third meeting in December 2008.

10. Status of other action points outstanding from the last meeting

a) The draft reporting format, Annex XV report template

The Secretariat recalled that the draft reporting format was uploaded to Circa on 17 July 2008 and that the intention was not to open the discussion on it at this meeting.

b) Draft proposal on requesting comments during consultation of Annex XV dossiers

The Chair informed that ECHA was currently working on the draft and it would be presented to the Committees later.

11. Working groups

a) Conclusion on the need to establish a joint working group between the SEAC and the RAC

The Secretariat presented the draft mandate for a joint working group between the SEAC and the RAC. The objectives of the working group, proposed tasks, scope, membership and working methods as well as timelines and deliverables were introduced.

Several members felt that the approach proposed by the Secretariat was too formal and could lead to unnecessary extra workload. Members however agreed that it was necessary to address the needs and modalities for co-operation between the two Committees. It was suggested by one member to start with less formal approach and see in a test case how the co-operation between the two Committees worked and whether there was a need for establishing of such a working group. One participant suggested that each member could first discuss the issue with the RAC member coming from the same MS and then they could come back to the discussion of this question in the

Committees. Several members shared an opinion that not all the tasks from the presented mandate were important at this point in time and it was therefore suggested to prioritise them.

Based on the comments the Secretariat prepared new draft terms of reference for an informal arrangement to work on three of the topics identified in the meeting document SEAC/02/2008/18 "Draft mandate for a Working Group of Socio-economic and Risk Assessment Committees (SERAC)". The amended, focussed, draft terms of reference for developing interaction between the SEAC and the RAC were endorsed by the SEAC and are attached to the minutes as Annex IV.

It was agreed that the Secretariat would approach eventual candidates for this informal arrangement at the latest after the fourth meeting of the RAC taking place on 18-19 November 2008. Members interested in participating in this work were asked to contact the Secretariat. It was agreed that all SEAC (and RAC) members would be transparently informed on all issues related to the SEAC-RAC arrangement. It was also agreed that the participants could decide themselves on the most appropriate working methods and on the need to hold meetings. It was agreed that no written report was required. Instead, the participants of the arrangement would report orally about progress at the RAC and SEAC meetings and in particular in the joint RAC-SEAC meeting planned for June 2009.

12. Planning of the work for 2008 and 2009

a) Registry of Intentions of MS CAs

The Secretariat reported that the Registry of Intentions of MS CAs was at the moment empty.

b) Preparations for Restriction dossiers – Outline of a work plan for the RAC and the SEAC

Ms Sharon Munn, the Chair of the RAC, introduced the meeting document SEAC/02/2008/19 which described a work plan for the RAC and SEAC in relation to Annex XV restriction dossiers up to June 2009. The SEAC took note of the plan.

13. AOB

a) Next meetings

The Chair recalled that the third meeting of the SEAC was scheduled for 24-26 February 2009, as it was presented in the work plan of the RAC and SEAC under Agenda Item 12b.

b) Current structure of the SEAC Circa interest group and instructions on working with Circa

The Secretariat made an on-line demonstration of the possibilities of Circa system which had been used by the SEAC Secretariat for exchange of documents and comments. It was explained to participants how and where to find documents related to the Committee and its meetings from the SEAC Circa interest group, also how to view other members` messages and to send own messages in newsgroups.

c) Implementing rules for the Fee Regulation

The Chair informed that the work regarding implementing rules for the Fee Regulation was ongoing under the MB.

d) Selection of the SEAC Chair

The Secretariat informed that on the 1 October 2008 ECHA opened a call for expression of interest to fill the post of the Chair of the Committee for Socio-economic Analysis. The call would be open until the end of October. The SEAC should therefore get a permanent Chair in the first half of 2009.

e) Involvement of the OECD Secretariat in the work of the Committee

ECHA informed that the OECD Secretariat had approached ECHA in spring 2008 and expressed its interest to participate in ECHA's work. The RAC as well as the MSC had decided to invite the OECD Secretariat to participate in their meetings as an observer and the OECD Secretariat had already taken part in the meeting of the MSC in October 2008. Several members gave positive feedback on the proposal to invite the OECD Secretariat to the SEAC. It was noted that the OECD Secretariat obviously had a lot of valuable data and the work ongoing in different areas the SEAC could benefit from. The SEAC thus agreed to invite the OECD Secretariat as an observer to its meetings.

f) Guidance on authorisation

The Secretariat reported that finalisation of the guidance on authorisation depended on the final agreement within the COM on certain aspects related to the authorisation process.

g) Preparations for the workshop on Annex XV for MS CAs

The Secretariat informed that the workshop was preliminarily planned for mid-January 2009. The workshop is intended for representatives from the Member States Competent Authorities (including EEA/EFTA countries), the Commission and ECHA. The workshop aims to discuss and increase common understanding of the legal and practical implications of the choice between authorisation and restriction and of the intention and the scope of candidate list and authorisation list under REACH. Furthermore, the aim is to identify needs and find ways to improve the working procedures between all parties involved.

14. Action points and main conclusions of SEAC-2

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

II. Conclusions and action points

SEAC-2 ACTION POINTS & MAIN CONCLUSIONS – 22-23 October 2008 (as adopted at the SEAC-2 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)		
3-Administrative issues a) Changes in the SEAC composition/nominations		<u> </u>		
b) Declarations of conflict of interest c) Reimbursement rules	Few members' declarations and CVs are still missing.	Members to submit the missing documents to SECR ASAP. Members to take into account the revised reimbursement rules when arronging their travels.		
4–Stakeholders` participation a) Report from the written procedure on stakeholders` participation		arranging their travels		
b) Update on new registrations for participation to ECHA's work	It was noted that the following interests are not sufficiently covered by the eligible Stakeholder Organisations (StOs): - importers of articles from third countries - Small and medium size enterprises - engineering of industrial and other processes - "green chemistry" groups and others working on the issue of alternatives.	Members may wish to approach suitable StOs to encourage them to express their interest in the work of ECHA through the open call.		
c) Invitation of possible regular stakeholder observers	 Preferably, whole life cycle of chemicals, including the waste phase, should be covered by the regular StO observers; to this end SEAC will review the list of invited StOs and consider inviting additional observers. In any case, sector specific stakeholder organisations (Part 2) not invited as regular observers can be invited on ad-hoc basis in particular when the restriction dossiers are dealt with. It was decided to invite the following 16 StOs as regular observers to SEAC meetings: BEUC - Bureau Européen des Unions de Consommateurs; 	SECR to send invitations to the mentioned StOs and ask them to nominate a permanent representative to follow the work of SEAC (by 30/11/2008). SECR to approach the stakeholder organisations marked with * in order to seek their views on whether they could be represented by joint representatives (by 30/11/2008).		
	- BusinessEurope - The Confederation of European Business;			

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)				
	- CEFIC; - CONCAWE; - Eurometaux - European Association of the Metals Industry; - European Association of Environmental and Resource Economists; - European Environmental Bureau (EEB); - European Trade Union Confederation (ETUC); - FECC - European Association of Chemical Distributors; - Friends of the Earth Europe*; - Greenpeace International*; - Health and Environmental Alliance (HEAL)*; - WWF European Policy Office*; - Women in Europe for a Common Future (WECF); - EMCEF; - UEAPME.					
d) ECHA code of conduct for stakeholder observers						
5-Rules of Procedure a) Adoption of SEAC Rules of Procedure by the MB						
b) Proposal for revised ROPs	All the changes proposed by the SECR were preliminarily approved by the SEAC. Concerning Art 20(2), it was agreed that the written procedure could be shortened in other than urgent cases only after the agreement of the Committee by consensus. The Article 20(2) should be modified correspondingly.	- SECR to seek to clarify the wording of Article 20(4) regarding so-called procedural decisions SECR to seek the endorsement for similar changes in the RoPs of other C'ttees/Forum and to report back to SEAC if other proposals for changes are brought up SECR to submit the final draft revised RoPs for endorsement in a WP (by end of 2008).				
6-Report from SEAC Intersessional WG and conclusions on the need to continue the WG & other follow-up actions a) Highlights from the SEA Workshop of October 2008	 SEAC took note of the following conclusions of the SEA Workshop: Interdisciplinary work is important for SEAC. RAC and SEAC have to work together. Working arrangements between RAC and SEAC should be made as straightforward as possible. Need to increase understanding between risk assessors, risk managers and economists (could be tested). Methodology (SEA) - technical issues/difficulties are not new. 	- ECHA to finalise the "fictitious case" as well as prepare examples on application of SEA in 1) a restriction case 2) on an authorisation case - ECHA/COM to organise a WS on a past restriction case to demonstrate how the decision making has taken place (WS open for both SEAC and RAC) - SECR to develop and maintain a web based portal with information and data sources on costs and				

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)			
	 SEA will not be perfect but need to agree on what is good enough Need for further clarification of process by applying theory in practice. Scarce resources to prepare restriction dossiers in Member States (identify substance expertise). There are several applied research needs (health, environment, willingness to pay); need to focus on what happens; Principles of collaboration should be established Concrete examples are needed. 	benefits of regulating chemicals.			
b) Conclusions of the Intersessional WG meeting of June 2008: Challenges and options for solutions	 Minutes of the IS WG meeting were adopted by the participants to that meeting. It was agreed to publish the minutes on the ECHA website. 	SECR to publish the minutes.			
options for solutions c) Training activities for 2008-2010	 Many learning needs can be taken care by studying existing written guidance and other material and on the job. E.g. no training needed as such for data collection, a guidance manual would be sufficient Many learning/training needs identified in IS WG/SEA WS can be covered by working on concrete cases and the transitional dossiers Key is to get SEAC members on the same level of understanding as soon as possible but before June/2009 The test cases mentioned in 6a) can be used as training material. 	 SECR to organise crash courses on risk assessment SEA open for SEAC/RAC members and their advisors. SECR to draft Terms of Reference regarding the courses ASAP. SEAC members to be given possibility to provide immediate feedback on the draft. 			
d) Other follow-up actions					
7–Feedback from other ECHA bodies					
8-Procedure for appointment of (co-)rapporteur a) Procedure for appointment of (co-)rapporteur	 SEAC took note of the proposed procedure and concluded the following: The selection criteria for rapporteurs should take into account member's experience in respect to relevant sector, process, substance, alternatives, instead of the fields presented in the draft. The current draft procedure is relevant for appointment of rapporteurs for restriction dossiers only, not for authorisation dossiers. An explicit mention that SEAC and RAC rapporteurs could come from the same MS should be added. 	SECR to redraft the document in line with the received comments and submit to the SEAC in SEAC-3 (for eventual adoption).			

Agenda point	Conclusions / decisions / minority opinions	Action requested after the		
		meeting (by whom/by when)		
b) Draft TOR for (co-)rapporteurs of SEAC	 SEAC had a first exchange of views on the draft and noted the following: Clear ToR will be helpful to better understand the role and the tasks of the rapporteur but the draft requires further elaboration. The deliverables listed in the TOR should be clarified with the help of a flowchart describing the process, including the involvement of other SEAC members and other parties in the process. Quality criteria need to be further developed. 	- SEAC members to comment on meeting document SEAC/02/2008/13 by the end of November 2008 via CIRCA newsgroup that will be established by SECR by 28/10/2008 SECR to prepare a new version of the TOR by SEAC-3, taking into account the comments submitted by the SEAC and the RAC.		
9-Working Procedures – Restriction dossiers a) Conformity check	 The list of conformity check questions (doc ECHA/SEAC-1/2008/04_rev.1) was endorsed. The document may be modified when necessary after some experience has been gained when using it. The procedure for conformity check was endorsed (doc SEAC/02/2008/15) with the following comments: All actors in the restriction procedure have to understand the whole procedure as earlier steps have implications for later ones. The conformity check procedure need to ensure that all RAC and SEAC members have a chance to see and comment on the dossiers in the early stage of the conformity check. The procedure may be modified when necessary after some experience has been gained when using it. 	SECR to clarify the implications of not complying with providing the conformity check report within the 30 day deadline (by SEAC-3)		
b) Proposal for handling transitional dossiers	 The proposed procedure (doc SEAC/02/2008/17) regarding the handling the transitional dossiers was agreed upon with one change (deleting the mention of who should communicate the conclusions to the COM as this issue is not relevant to SEAC as such) Moreover, the following was concluded: Also the transitional dossers identifying a need for another Community measure may be used for discussion by the SEAC to facilitate its learning. More than one test rapporteur from SEAC should be involved in assessing the transitional dossiers. Simulating the restriction process with transitional dossiers identified for restriction 			

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
	faces hurdles of: 1) Timelines 2) Public consultation cannot be carried out. - To simulate the public consultation, the StOs invited to follow the SEAC work and the other eligible StOs should be invited to give their comments on the dossiers to SEAC	
c) Test rapporteurs for transitional dossiers	SEAC took note of that in the context of the ECHA Costing Methodology Working Group established by the Management Board, the members of MB from Sweden, UK and Germany had committed to provide test rapporteurs. Other members than those from these MSs are also welcome to volunteer.	
d) The role of Forum		
10-Status of other action points outstanding from the last meeting a) The draft reporting format, Annex XV report template b) Draft proposal on requesting comments during consultation of Annex XV dossiers		
11-Working groups Conclusion on the need to establish a joint SEAC-RAC WG	 IS WG was decided to be closed. Need for further joint SEAC/RAC activity to address needs for cooperation between the two Committees was agreed SEAC endorsed terms of reference for an informal arrangement to work until mid 2009 on some of the topics identified in the meeting document (doc SEAC/02/2008/18) 	- SECR to present the SEAC-2 outcome to RAC-4 and report back to SEAC-3 on RAC conclusions SEAC members to indicate soon to the SECR of their possible interest to work in the informal arrangement - SECR to approach SEAC members at the latest after RAC-4 by e-mail to enquire on their willingness to participate in the informal arrangement - Participants to the informal arrangement to be identified by end November 2008.
12-Planning of the work for 2008-2009 a) Registry of Intentions b) Outline of a work plan for RAC&SEAC		

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)				
13-AOB						
a) Next meetings						
b) Current structure of SEAC Circa IG						
c) Implementing rules for the fee regulation						
e) OECD	SEAC agreed to invite the OECD Secretariat as an observer to its meetings.	SECR to approach the OECD Secretariat (by 30/11/2008).				
14-Action points and main conclusions of SEAC-2						
General		 All pp-presentations to be uploaded on CIRCA (SECR/24/10/2008). Conclusions and action points to be uploaded on CIRCA (SECR/24/10/2008). 				

III. List of Attendees

Members:	Representatives of the Commission:
BASTOS, Henri	BARTELS, Astrid (DG ENTR)
BENDL, Jiri *	SCHMAHL, Maik (DG ENTR)
BRIGNON, Jean Marc	CHRISTENSEN, Frans (JRC)
BROKAITE, Kristina	GIL, Sebastian (DG ENV)
COSTEA, Ion	
DANTINNE, Catheline	
DE GIGLIO, Franco	Stakeholder observers:
ECONOMIDES, Aristodemos **	FEDRIGO, Doreen (EEB)
FEYAERTS, Jean-Pierre	LEENAERS, Joeri (Eurometaux)
FOCK, Lars	MUSU, Tony (ETUC)
FORKMAN, Mats	
GEORGIOU, Stavros	
GUSTAFSSON, Lars	ECHA staff:
HAJAŠ, Martin	CARLON, Claudio
KOZAK, Kristof	FUHRMANN, Anna
LOURENÇO, João	HAUTAMAKI, Anne
LUTTIKHUIZEN, Cees	HOLLINS, Stephen
McGUINNESS, Sharon	KARHU, Elina
RECCHIA, Luca Maria	LIPKOVA, Adriana
RYDLEWSKA-LISZKOWSKA, Izabela	MUNN, Sharon
SALONEN, Heikki	PELTOLA, Jukka
SCHUCHTAR, Endre	SADAM, Diana
SCHWARZER, Stephan	SIHVONEN, Kirsi
SIMON, Franz-Georg	VAINIO, Matti
TELLING, Aive	VASILEVA, Katya
THEOHARI, Maria	YLÄ-MONONEN, Leena
THIELE, Karen	
VOIVONTAS, Dimosthenis	
* Replacing BIZKOVA, Rut	
** Replacing KOURTELLIS, Marios	

Advisers to the SEAC members:

BLANCHEMANCHE, Sandrine (adviser to BASTOS, H.)

BEEKMAN, Martijn (adviser to LUTTIKHUIZEN, C.)

DALTON, Marie (adviser to McGUINNESS, S.)

DOMINIAK, Dorota (adviser to RYDLEWSKA-LISZKOWSKA, I.)

FIORE, Karine (advisor to BASTOS, H.)

GRANDI, Silvia (advisor to RECCHIA, L.)

KIVELÄ, Kalle (adviser to SALONEN, H.)

LAURIDSEN, Jesper (adviser to FOCK, L.)

SUSNIK, Marko (adviser to SCHWARZER, S.)

IV. List of Annexes

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

ANNEX II. Final agenda

ANNEX III. Training and learning needs identified

ANNEX IV. Draft terms of reference for developing interaction between the Socioeconomic and the Risk Assessment Committees

 $\begin{tabular}{lll} ANNEX\ I \\ Documents\ submitted\ to\ the\ Members\ of\ the\ Committee\ for\ Socio-economic \\ Analysis \end{tabular}$

Draft Agenda (Agenda Item 2)	SEAC/A/02/2008_rev.1
Changes in the composition of the Committee for Socio-	SEAC/02/2008/06
economic Analysis in the period from 3 rd April 2008 to	
25 th September 2008 (Agenda Item 3)	
Written Procedure Report on adoption of the proposed	SEAC/02/2008/09
procedure for admission of stakeholder organisations and	
decision to invite stakeholder organisations to SEAC	
meetings (Agenda Item 4a)	
Annex 1 to the meeting document SEAC/02/2008/09	Room document
(Agenda Item 4a)	
List of eligible stakeholder organisations and invitation of	SEAC/02/2008/10
possible stakeholder observers (Agenda Items 4b & 4c)	
Stakeholders` participation. Code of conduct for observers	SEAC/02/2008/11
from stakeholder organisations at ECHA meetings	
(Agenda Item 4d)	
Rules of Procedure (RoPs) (Agenda Item 5a)	SEAC/02/2008/07
First Revision of the Rules of Procedure of the Committee	SEAC/02/2008/08
for Socio-economic Analysis (Agenda Item 5b)	
Appointment of rapporteurs and co-rapporteurs (Agenda	SEAC/02/2008/12
Item 8a)	
Draft terms of reference for (co-)rapporteurs of the	SEAC/02/2008/13
Committee for Socio-economic Analysis	
Response to Comments regarding ECHA/SEAC-	SEAC/02/2008/14
1/2008/04 Discussion paper for conformity check of an	
Annex XV dossier proposing a restriction (Agenda Item	
9a)	
Criteria for conformity check (Agenda Item 9a)	ECHA/SEAC-1/2008/04_rev.1
Working procedure for RAC and SEAC on conformity	SEAC/02/2008/15
check of Annex XV restriction dossiers (Agenda Item 9a)	
Hand-over existing substances to the European Chemicals	SEAC/02/2008/16
Agency – document of 17 th Joint meeting of the competent	
authorities for the implementation of Directive	
67/548/EEC (new substances) and Council Regulation	
793/93/EEC (existing substances) (Agenda Item 9b)	
Processing of Transitional dossiers under Article 136(3) of	SEAC/02/2008/17
REACH (Agenda Item 9b)	
Draft mandate for a Working Group of Socio-economic	SEAC/02/2008/18
and Risk Assessment Committees (SERAC) (Agenda Item	
11)	
Preparation for Restriction dossiers - Outline of a work	SEAC/02/2008/19
plan for RAC and SEAC in relation to agendas of	
forthcoming meetings up to June 2009 (Agenda Item 12b)	
Using the SEAC CIRCA Interest Group (Agenda Item	SEAC/02/2008/20
13b)	



22 October, 2008 SEAC/A/02/2008_rev.2

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

22-23 October 2008

Finlandia Hall (Mannerheimintie 13 e), Helsinki, Finland

22 October: starts at 14:00 23 October: ends at 18:00

Item 1 – Welcome and Apologies

Item 2 - Adoption of the Agenda

SEAC/A/02/2008_rev.1

For adoption

Item 3 – Administrative Issues

a) Changes in the SEAC composition/nominations

SEAC/02/2008/06

For information

b) Declarations of conflict of interest

For signature

c) Reimbursement rules

For information

Item 4 – Stakeholders' participation (closed session)

a) Report from the written procedure on stakeholders` participation

SEAC/02/2008/09

For information

b) Update on new registrations for participation to ECHA's work

SEAC/02/2008/10

For information

c) Invitation of possible regular stakeholder observers

For decision

d) ECHA code of conduct for stakeholder observers

SEAC/02/2008/11 For information

Item 5 – Rules of Procedure (ROPs) (closed session)

a) Adoption of SEAC Rules of Procedure by the Management Board

SEAC/02/2008/07

For information

b) Proposal for revised ROPs

SEAC/02/2008/08

For discussion

Item 6 – Report from SEAC Intersessional WG and conclusion on the need to continue the WG & on other follow-up actions

- a) Conclusions of the Intersessional WG meeting of June 2008: Challenges and options for solutions
- b) Highlights from the SEA Workshop of October 2008
- c) Training activities for 2008 2010
- d) Other follow-up actions

For information and decision

Item 7 – Feedback from other ECHA bodies

For information

Item 8 – Procedure for appointment of rapporteur and co-rapporteur

a) Procedure for appointment of rapporteur and co-rapporteur

SEAC/02/2008/12

For adoption

b) Draft terms of reference for (co-)rapporteurs of the Committees for Socioeconomic Analysis

SEAC/02/2008/13

For discussion

Item 9 – Working Procedures - Restrictions dossiers (including transitional (Art $136\ (3)$) dossiers)

a) Conformity check

SEAC/02/2008/14 (Response to comments) ECHA/SEAC-1/2008/04_rev.1 (questions) SEAC/02/2008/15 For agreement

b) Proposal for handling transitional dossiers (Article 136(3))

SEAC/02/2008/16 For information

SEAC/02/2008/17 For agreement

- c) Test rapporteurs for transitional dossiers identifying the need for restriction *For discussion*
- d) The role of Forum to give advice on enforceability of a restriction proposal *For information*

Item 10 –Status of other action points outstanding from the last meeting

a) The draft reporting format, Annex XV report template

Draft reporting format uploaded to CIRCA on 17 July 2008 For information

b) Draft proposal on requesting comments during consultation of Annex XV dossiers

For information

Item 11 – Working groups

Conclusion on the need to establish a joint working group between SEAC and RAC

SEAC/02/2008/18

For discussion and provisional decision

Item 12 – Planning of the work for 2008 and 2009

a) Registry of Intentions of MSCAs

b) Preparation for Restriction dossiers - Outline of a work plan for RAC and SEAC
 SEAC/02/2008/19
 For information

Item 13 – AOB

- a) Next meetings
- b) Current structure of the SEAC CIRCA interest group and instructions on working with CIRCA

SEAC/02/2008/20
For information

c) Implementing rules for the fee regulation

For information

- d) Selection of the SEAC Chair
- e) Involvement of the OECD Secretariat in the work of the Committee
- f) Guidance on authorisation
- g) Preparations for the workshop on Annex XV for MS CAs

Item 14 – Action points and main conclusions of SEAC-2

Table with Action points and decisions from SEAC-2

For endorsement

ANNEX III

Training and learning needs identified

	Learning needs identified			Covered in	Priority	Priority	
	SEAC	RAC	MS CA	Stake- holders	SEA Workshop	for all groups	for SEAC in 2009
Topics for learning through (formal) training/workshops							
Common understanding of relevant	X	X	X	X	X		
REAC provisions and whole decision							
making procedure	**	**	**	**	**	**	
Learning from past experience and experience from other regions and	X	X	X	X	X	X	X
fields							
Good consultation practices to obtain	X	X	X	X		X	
relevant information							
Is restriction the best risk management	X	X	X			X	
option?							
Present Commission's needs: how	X	X			X	X	X
opinion will be used?							
Assessment of alternatives	X		X			X	
Using qualitative (and semi-	X		X				
quantitative) methods in analysis							
Assessing health and environmental benefits	X	X	X		X	X	X
Methodological issues, e.g. statistical	X		X			X	X
methods, models, uncertainties,	A		Α			Λ	, A
willingness to pay, etc.							
Data collection (best practices)			X	X		X	
Using examples/case studies for	X	X	X	X	X	X	X
training purposes, including transitional							
dossiers							
Risk management	X	X	X				
Link between risk assessment and SEA	X	<u>. </u>	1 1	•	1	X	X
Topics for learning through other mean				l courses, e	tc)		
proposal	X	X	X				X
Conformity check	X	х	X			X	
Preparing opinions	X	X	A			X	
Drafting Opinion Support Document	X	X					
(e.g. using IA examples)							
Learning from good examples of	X	X	X				
sections of Annex XV (with new							
reporting format)							
Guidance documents	X	X	X				
Data availability at Eurostat, OECD,	X	X	X		X	X	X
EPO, etc		_	_				
Transparency & proportionality	X	X	X				
International trade implications	X		X				
Implications for SMEs	X		X				1



Draft terms of reference for developing interaction between the Socio-economic and the Risk Assessment Committees

Adopted by the SEAC on 23 October and forwarded to the RAC to be discussed on 18-19 November 2008

1. BACKGROUND

1.1. Relationship between the RAC and SEAC and the Comitology process

Given that the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) as well as the REACH regulation are new, it is possible that the members of the RAC and SEAC are not clear on their respective complementary roles in the restriction and authorisation processes. The two Committees will work on the same dossier in parallel. The issues in the remit of the one Committee and its view on those issues will need to be taken into account by and affect the work of the other Committee. In addition, there is a possibility that the two Committees take overlapping tasks (without knowing about this) or leave some parts of the Annex XV dossiers with too little attention (as they think the other Committee deals with this). Furthermore, the decision making process after the ECHA Committees have given their opinion is (completely) new. Finally, the work of the two Committees is complementary and hence good co-ordination and communication will increase effectiveness of their work as well as the scientific basis of the opinions.

The role of rapporteurs and possible co-rapporteurs (referred to below as "rapporteurs") towards the respective Committees, the role of rapporteurs of the RAC and SEAC (between themselves), and the role of the ECHA Secretariat in this process has not been elaborated. It would be important to clarify these roles so that maximum time is allocated to actual work.

1.2. Tight and possibly unsynchronised timelines of the two Committees

The timelines of the two Committees are different in the restriction process. This has been documented elsewhere but essentially the issues are

- Only 30 days for both Committees to carry out a conformity check after an Annex XV restriction proposal has been received by the Committees.
- Information submitted during the 6 month consultation period will be evaluated by both Committees. The RAC has 9 months in all to establish a final opinion, while the SEAC will in parallel develop a draft opinion. Thus, there is a clear time constraint: How to digest possibly a lot of new information (coming in at

month 6) in two separate Committees in a co-ordinated (but not the same) manner.

 Furthermore, the SEAC has an additional time constraint to establish its final opinion by month 12. However, this challenge does not affect RAC and this is outside the mandate of this working group.

The two Committees need to adopt the draft (SEAC) and final (RAC) opinions in a <u>coordinated</u> manner by month 9.

2. Purpose

The purpose of this work is to identify good working practices to ensure that the two Committees opinions are prepared in a coordinated manner and with full understanding of the overall requirements of the REACH Regulation. The specific purpose is to identify on which issues, when and how the two Committees should interact and when the two Committees shall have common working procedures.

3. Possible Tasks

The following tasks concerning issues related to the restriction process may be undertaken:

Task 1: Clarify possible overlaps or gaps in tasks between the RAC and SEAC in relation to restriction processes and suggest how to deal with them. To the extent time allows carry out this task also for authorisations processes.

Task 2: Suggest how the two Committees and in particular the rapporteurs would work together in a well coordinated manner. Suggest communication tools and other practical arrangements to be used to improve communication and coordination (i.e. contributions to the standard Terms of Reference for the rapporteurs' assignments) Note that in the ECHA Secretariat a Scientific Dossier Manager is planned to be nominated to help out in coordination. The SDM will be supported by other Secretariat staff.

Task 3: Recommend ways to ensure that Committees keep each other informed and build on the knowledge concerning risk management options. These recommendations include both the Committees themselves as well as the ECHA Secretariat.

4. PARTICIPATION

ECHA Secretariat, including RAC and SEAC Chairs, facilitates this work. About four members from each Committee² may participate based on expressed interests to the ECHA secretariat. Staff members from the Commission can also participate in this work

5. WORKING METHODS, DELIVERABLES AND TIMELINE

Most appropriate working method will be decided by the participants. Oral reports will be made to the RAC and SEAC meetings. In mid 2009 it may be considered if and how to carry on its activities. About three meetings may be held by mid 2009 (aiming at

² Note: SEAC and RAC member/adviser could come from the same country to facilitate coordination.

back to back meetings with SEAC or RAC meetings to reduce costs and for logistical reasons).

Work will be carried out transparently vis-a-vis the Committees so that members can both contribute to and be informed of the work. ECHA Secretariat will identify the most appropriate means for this.