

**Final**

**Minutes of the 12<sup>th</sup> meeting of the Committee for Socio-economic  
Analysis**

**13-15 September 2011**

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

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

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

The Chair informed that apologies had been received from five members, one observer and one stakeholder observer. Four invited experts, members' advisers present at the meeting as well as observers of the European Commission (COM), observers of seven stakeholder organisations and RAC (co-)rapporteurs participating to the meeting were introduced. The Chair informed that an advisor and two dossier submitter representatives were to follow relevant parts of the meeting via teleconference. The Chair also mentioned that the meeting would be recorded and the records would be destroyed after the adoption of the minutes.

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

The Chair informed that this may be the last meeting she would preside over and she thanked the Committee participants for their serious engagement and contribution to ECHA's goal. The Committee expressed its appreciation for Ms Thuvander's constructive work as Chair in the past years and wished her the best of luck.

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

The Chair introduced the draft Agenda of SEAC-12. The following suggestions for additional items to discuss under AOB had been made prior to the meeting:

- Nanomaterials in the context of SEAC;
- Information on the EAERE Conference;
- Information on the M.Sc. study on SEA in restrictions;
- ECHA new graduate scheme on EU chemical policies;
- Update on University & MSCA collaboration in REACH education in Italy;
- Update on the ECETOC study.

The items had been included in the revised Agenda.

The Agenda was adopted without any further changes. The Agenda is attached to these minutes as Annex I.

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

The Chair requested members and their advisors to declare any conflicts of interest to any of the specific agenda items. Five members, an invited expert, two advisors and one RAC rapporteur who also was a dossier submitter for one of the restriction proposals declared potential conflicts of interest to the substance-related discussions in the agenda items 7.2.a) (one member, one invited expert), 7.2.b) (two members) and 7.2.d) (two members, one advisor, the RAC rapporteur) .

The list with declared conflicts of interest is given in Annex II.

### **4) Administrative issues**

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

The Chair informed that since the last SEAC meeting, the following members have joined the Committee:

Cyprus	BOUSTRAS Georgios
Norway	GULBRANDSEN Magnus Utne
Austria	KNOFLACH Georg

Moreover, the Chair informed that since the last SEAC meeting, the following member's membership has been renewed:

Slovenia	FURLAN Janez
Germany	THIELE Karen

#### **b) Outcome of written procedures**

The Chair updated the Committee on the recent written procedure for the adoption of the SEAC-11 minutes and informed that the minutes were adopted by consensus.

#### **c) Handling of conflict of interest**

The ECHA's Secretariat provided information on the Agency's approach on managing possible conflicts of interest. ECHA's Management Board had asked ECHA's Executive Director to review the management of conflict of interests within the Agency.

The Secretariat informed that a global policy will be submitted for discussion and adoption at the next Management Board meeting in September 2011 and will be applicable to all ECHA's bodies and to ECHA's staff. Moreover, implementing rules will be established. Other measures to support the policy will be taken such as providing training, raising awareness and public information on the issue, and introducing a new declaration of interest form.

#### **d) Commission's transparency register for Stakeholders**

The Committee was informed that ECHA's Management Board, at its June meeting, agreed that one of the eligibility criteria for inviting stakeholder observers that would like to participate in Committee and Forum meetings, is that they are listed in the Register of Interest Representatives maintained by COM.

The Stakeholders Observers were therefore invited to take note of this change, and eventually register, taking into account that those not registered, would not be able to take part in SEAC's future meetings.

#### **e) Demonstration on CIRCABC**

Due to the recent migration of Circa, the Secretariat gave a brief demonstration of CIRCABC and of the most frequently used features. Participants were invited to contact the Secretariat for any assistance and to provide any relevant feedback. They were also reminded of the importance of not distributing any confidential information by e-mail.

#### **f) Participation of Croatia in the work of SEAC**

The Committee was informed of Croatia's request to participate in SEAC's work as an observer country, being the treaty signature for its accession to the EU foreseen for the end of 2011, and its actual accession for July 2013. This option is legally supported by Article 106 of the REACH Regulation and by Article 6(8) of the Rules of Procedure for the Committee for Socio-economic Analysis. Since it is expected that as of the date of the signature of the Accession Treaty, Croatia will be invited to all different EU bodies as an observer, following an agreement in the Treaty as for previous Accession countries, the current request for observer status only refers to the time until the Treaty is signed.

SEAC agreed to accept observers from Croatia to the Committee. However, the decision on Croatia's participation as observer within ECHA will have to be approved by the Agency's Management Board most probably at its next meeting, which is to be held in September 2011.

## **5) Status report of the action points of SEAC-11**

The Secretariat provided an update of the status of the SEAC-11 action points and main conclusions. The Secretariat reported that all actions had been completed on time.

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

The Chair informed that a room document had been distributed with updates from the Risk Assessment Committee and from the Forum.

## **7) Restrictions**

### **7.1) General restriction issues**

#### **a) Review of the restriction process after experience on first dossiers**

The Secretariat presented a plan for the review of the restriction process on the basis of the Committees' request following their experience in relation to the first restriction dossiers.

The Secretariat highlighted that the presentation focused on a summary of main identified elements to serve as a basis for RAC and SEAC members' input. Following the first experiences gained with the opinion development of the four restriction dossiers and one currently ongoing restriction proposal, the Secretariat informed about the planned revision of the Committees' working procedures related to restrictions.

The Committee members were asked to provide their input, which will contribute to the update and review of the restriction process. ECHA would then compile the suggestions received from RAC, SEAC and ECHA staff. The Secretariat would finalise the proposal and will present it to RAC and SEAC in the period between December 2011 and January 2012. The target date for the Committees' agreement on the revised procedure is the 1<sup>st</sup> of October 2012.

The Chair invited the SEAC members to discuss the Secretariat's proposal. Members and observers raised several issues like the need for stakeholders' and external actors' involvement, the demand to use the valuable outcome of the learning process, the usefulness of questionnaires, the important avoidance of atypical cases exemplified by the restriction proposals submitted before the first registration deadline, and how representative the first dossiers in fact were. SEAC members also expressed their concern over the feasibility to separate the qualitative aspects from the procedural ones and underlined the importance of having targeted meetings, and not just discussions on the margins of the plenary meetings of the Committees, in order to discuss and evaluate the proposals before the actual decision is taken in plenaries. Moreover, a proposal for a wider review and consequently, for a longer period of the exercise, was made.

The Secretariat clarified that the Committees' actors would be fully involved in the review process.

The Secretariat concluded that, with the proposal being presented to RAC, inputs from the Committees would be collected either via a questionnaire or via a newsgroup in CIRCABC as a first step towards the review process. This will then evolve into a proposal and consider having targeted working groups in order to reach a final decision on the matter by June 2012. Further information on the following steps will be provided in due time.

#### **b) Update on intended restriction dossiers**

The Committee was informed that two restrictions intentions had been notified to ECHA. Sweden intends to submit a restriction proposal on nonylphenole by August 2012. Denmark intends to submit a restriction proposal on Cr(VI) use in production of leather articles. The registry of intentions is publicly available on the ECHA website.

### **c) Principles for changes of (co-)rapporteurs for ongoing dossiers**

The Chair introduced the current version of the document, improved in clarity and content from the former version as a result of the many and useful comments received from SEAC members in the follow-up of SEAC-11.

The Secretariat presented the main changes in the SEAC/11/2011/02\_rev.1 document. The Chair invited SEAC members to comment on the last version of the document. The Committee proposed the addition of a footnote reminding about the declaration of commitment which is applicable also for rapporteurs not longer being members of SEAC.

SEAC agreed on the document with this modification.

### **d) Dealing with comments coming from the public consultation on SEAC's draft opinion**

The Chair briefly introduced the document SEAC/11/2011/03\_rev.1, and the Secretariat presented the changes made as the result of the received comments and of the experiences from the public consultations of the first restriction proposals. The changes made to the document had made it generally applicable while not mentioning any specific dossiers.

During the discussion one amendment to the document was proposed. The Secretariat agreed to amend the document and upload the amended document to CIRCABC. The Secretariat agreed to ensure that the proposal would be implemented in the future restriction cases.

## **7.2) Restriction Annex XV dossiers**

### **a) Lead and its compounds in jewellery - final draft of SEAC opinion**

The (co-)rapporteurs presented the comments of SEAC members and one stakeholder observer on the first version of the SEAC final opinion. The (co-)rapporteurs introduced how these comments as well as the industry's information on enamel and lead crystal had been taken into account in the revised version of the draft opinion presented to the Committee for adoption. The key issues remaining to be decided upon by the Committee were mainly related to the proposal for a new derogation on vitreous enamels and whether this derogation together with the derogation for lead crystal should be time-limited.

The (co-)rapporteurs proposed an indefinite derogation for vitreous enamels. The justification for this takes into account the issues such as the lack of evidence of health impacts of vitreous enamels, lack of suitable alternatives and the fact the derogation for vitreous enamels would relate to a very narrow group of articles and not to so-called imitation enamels. Similar considerations had been made in relation to the proposal to derogate lead crystals. The (co-)rapporteurs concluded that a time limit for the derogation for lead crystals would not be justified either, as lead-free alternatives seem not to be fully equivalent to the lead crystal and a restriction of lead crystal could result in some competition issues. The labelling of enamel jewellery and lead crystals was said to have been considered but found to have limited basis. The (co-)rapporteurs proposed to include a recommendation for a re-evaluation of the developments in the lead crystal and vitreous enamels sectors in the justification to the opinion. The (co-)rapporteurs defended the derogation for internal parts of watches in spite of the overlap with the RoHS Directive<sup>1</sup> given the different objectives of REACH and this legislation. The (co-)rapporteurs also justified a 12 month transitional period for this restriction proposal as it was found sufficient in order for the manufacturers to adjust their production and to remove their old stocks.

Some members expressed their hesitation or reservation against the derogation for vitreous enamels considering limited scientific evidence available namely with regard to

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<sup>1</sup> Directive 2002/95/EC of the European Parliament and of the Council of the 27 January 2003 on the Restriction of the use of Certain hazardous Substances in electrical and electronic equipment.

the migration test results submitted through the public consultation, modest information on the socio-economic impacts and the possibility of confusing the derogated enamels with synthetic ones. In addition, in the absence of the view by RAC and the advice of the Forum on this derogation, some members called for a stronger message in the opinion regarding the need for a review of the derogation.

To respond to these remarks, the opinion was amended during the meeting to reflect limited quality and relevance of the migration test results submitted during the public consultation and to point out that information on enamels was received during the public consultation of the SEAC draft opinion and thus after the adoption of the opinion by RAC. It was noted during the meeting that the implementation of Classification, Labelling and Packaging (CLP) Regulation<sup>2</sup> related to mixtures (such as enamels) will lead to renewed hazard reviews by 1 June 2015 which will allow the health impacts to be evaluated. Such information might lead to a reassessment of the derogation on vitreous enamels proposed by the opinion. The recommendation for a review in the opinion was therefore replaced with a statement referring to this automatic review under the CLP Regulation. These changes in the opinion were found to give a balance between the limited scientific evidence regarding vitreous enamels, likely low health impact of and indications of lack of alternatives to vitreous enamels.

One member pointed out the inconsistency due to the derogation for vitreous enamels while categories 3 and 4 of crystal glass as defined in the Directive 69/493/EEC were not proposed to be derogated. To clarify the reasons for restricting category 3 and 4 of crystal glass, the (co-)rapporteurs noted that according to the information obtained via the public consultation(s) there were lead-free alternatives to the crystal glass category 3 and 4 on the market. It was also added to the opinion that no comments had been received during the public consultation on the SEAC draft opinion that would justify a derogation of this type of crystal glass.

One member raised the concerns related to the inclusion of machining brass in the restriction, but the argumentations in the Annex E of the background document were considered sufficient and thus did not lead to any changes in the opinion.

Following the comments of the participants, it was clarified in the opinion that the restriction proposal applies also to the individual parts used or placed on the market for jewellery making ("do it yourself jewellery"). Further, it was clarified in the opinion that what was lacking was the standard migration test methods and not migration test methods as such. Some additional minor changes were introduced in the opinion to clarify certain aspects pointed out by members during the meeting.

A general debate also took place regarding wide scope in restriction proposals and how that matches with the content of a restriction dossier. A question was raised on when the information submitted via public consultation on uses that have not been addressed in the original dossier but are implicitly in the scope of the proposal can be considered as robust scientific evidence. At the same time, it was questioned whether such use should be considered out of the scope if the original dossier did not address it in first place. The Chair pointed out that SEAC will need to pay more attention to the clarity of the scope in future dossiers.

**SEAC adopted the final opinion on the restriction proposal for lead in jewellery by majority. One member disagreed with the SEAC opinion in particular on the issue of proposed derogations and expressed a minority position** that the derogations were inconsistent because they included vitreous enamels while categories 3 and 4 of crystal glass as defined in the Directive 69/493/EEC were excluded. He also pointed out that categories 1 and 2 of crystal specified in the above mentioned Directive, proposed to be derogated by the SEAC opinion, contain respectively 30 % and 24 % of

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<sup>2</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH), Article 62

lead, while categories 3 and 4 containing below 10 % of lead were not included in the derogation.

**SEAC took note of the Background Document and ORCOM to this opinion. The Secretariat and rapporteurs agreed to make necessary changes to the Background Document and ORCOM to make it in line with the adopted SEAC opinion. The Secretariat was to forward the opinion to the Commission services together with the minority position.**

**The Secretariat was to publish the final opinion of SEAC on the restriction proposal for lead in jewellery on the ECHA.**

#### **b) Phenylmercury compounds - final draft of SEAC opinion**

A presentation was given by the Rapporteurs on the comments received during the public consultation of the SEAC draft opinion and how these were taken into account into the draft of the final opinion. The two comments received concerned the different length of the implementation period in the RAC and SEAC opinions (3 and 5 years) and the need for measures ensuring that other organomercury compounds are not used as alternatives to the five substances included in the restriction as well as general support for the restriction proposal and the SEAC draft opinion. The rapporteur explained that a shorter implementation time would increase the risk reduction capacity but, from a SEA perspective, it is less proportionate and simple to implement. In the SEAC opinion in the section "Effectiveness in reducing the identified risks, proportionality to the risks" SEAC expressed its support for the recommendation made by RAC to consider measures ensuring that other organomercury compounds are not used as alternatives.

**SEAC adopted the final opinion on the restriction proposal for Phenylmercury compounds by consensus. SEAC took note of the Background Document and ORCOM to this opinion. The Secretariat was to publish the final opinion of SEAC on Phenylmercury compounds on the ECHA website and to forward it to COM.**

#### **c) Mercury in measuring devices - final draft of SEAC opinion**

The rapporteur presented the comments that were received during the public consultation on the draft opinion of SEAC as well as rapporteurs' responses to these comments. The rapporteur explained that the comments lead to minor modifications of the opinion, namely i) the word "public" was added in the wording of the derogation for measuring devices which are to be displayed in exhibitions for cultural and historical purposes in order to clarify its scope and ii) the justifications section was aligned with the RAC opinion as regards the recommendation to COM to look into the use of porosimeters.

The Secretariat also informed that after the public consultation a comment had been received regarding a legal obligation of German pharmacies to have a set of seven mercury-in-glass thermometers in order to be allowed to operate. However, it was stated that technically equivalent mercury-free alternatives were available for this application and the proposed transitional period would be sufficient to modify the relevant legislation in time in the Member States. During the discussion, it was clarified that one electronic device could replace the whole set of seven mercury-in-glass thermometers. Following a query by one member related to a comment on the technical feasibility of the alternatives for high-temperature mercury-in-glass thermometers, the rapporteur explained that the technical feasibility of alternatives had been thoroughly checked against and backed up by extensive data in the Background Document. This information, therefore did not lead to any change of the SEAC draft opinion.

**SEAC adopted the final opinion on the restriction proposal for Mercury in measuring devices by consensus. SEAC took note of the Background Document and ORCOM to this opinion. The Secretariat was to publish the final opinion of SEAC on Mercury in measuring devices on the ECHA website and to forward it to COM.**

#### **d) Phthalates – outcome of conformity check**

The Annex XV dossier proposing a restriction for the four phthalates DEHP, DBP, BBP and DIBP<sup>3</sup> was resubmitted by the Danish authorities in August 2011 following the decision of SEAC on non-conformity of the dossier taken in June. The wording of the restriction proposal was kept unaltered; the proposal aims to restrict the placing on the market of articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes containing the four phthalates in a concentration greater than 0.1% by weight of any plasticised material.

The rapporteurs gave a brief overview of the changes in the resubmitted Annex XV dossier. They clarified that even though no fundamental changes had been made, there had been improvements and clarifications, which lead to their conclusion that the resubmitted dossier was in conformity with the requirements of Annex XV of the REACH Regulation. The rapporteurs explained that while the wording of the restriction proposal did not change, a (non-exhaustive) specification of articles intended to be covered/excluded had been included which made the scope clearer. The resubmitted dossier also includes some reasoning why selected article categories provide sufficient information to assess the proposed restriction, a description of implications for human health, on potential environmental impacts, as well as a discussion on potential impacts on recycled PVC or on alternative plastics included. The rapporteurs found that with these improvements the resubmitted dossier can be seen to conform. Nevertheless, the rapporteurs also highlighted a number of remaining aspects in the dossier that are likely to pose challenges to the Committee during the opinion development process.

During the discussion, members did not express any major concerns regarding the conformity of the dossier. The dossier was observed to be a borderline case, but no specific issues were identified against its conformity. Nevertheless, a few members voiced their concern over the amount of work to be done during the opinion forming process resulting from the broadly defined scope. It was, however, noted that the broadness of scope as such cannot be considered an issue for the conformity check, and that restriction proposals with equally broad scope are likely occur in the future dossiers to come. The members were reminded not to confuse the conformity check with a quality check. As specific questions for the public consultation were thought to be useful in clarifying the scope, members were invited to comment on these questions (drafted by the Secretariat) on the margins of the meeting.

**SEAC agreed by consensus on the conformity of the Annex XV dossier proposing a restriction for the four phthalates. The Secretariat was to publish the dossier for public consultation (pending the outcome of the RAC discussions on this dossier).**

### **8) Authorisations**

#### **a) Pool of (co-)rapporteurs for substances listed in Annex XIV**

The Chair presented to SEAC the meeting document SEAC/11/2011/04\_rev.1 containing the list of volunteers for (co-)rapporteurship for substances listed in Annex XIV. The document represents the result of the call for expression of interest launched in March 2011. The Chair thanked SEAC for the expressions of interest received.

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<sup>3</sup> (Bis(2-ethylhexyl) phthalate, EC No. 204-211-0 CAS No. 117-81-7; Benzyl butyl phthalate, EC No. 201-622-7, CAS No. 85-68-7; Dibutyl phthalate, EC No. 201-557-4, CAS No. 84-74-2; Diisobutyl phthalate, EC No 201-553-2, CAS No. 84-69-5)

## **b) Capacity-building in relation to the authorisation process**

The Chair invited the Secretariat to present an overview of the state of play for the capacity-building to prepare for the authorisation process after consideration of proposals received from RAC and SEAC after SEAC-11.

The Secretariat further presented the next steps which, following the joint discussions of RAC and SEAC, will consist of an update of the plan for capacity-building. An agreement of the work plan for capacity-building is expected to be taken at RAC's and SEAC's meetings in December 2011.

Furthermore, in this context the Committee was informed of a workshop which will be organised in November 2011 on gathering information for restriction and SVHC proposals.

The Chair invited the Committee to discuss the information presented.

## **c) Other general issues**

The Committee was updated on ECHA's preparations for the Authorisation process, and in particular on ECHA's plans to support future applicants in their preparations, on the concept of "submission windows" and on the potential issues relating with the introduction of new restrictions on substances already listed in Annex XIV.

In order to support future applicants for authorisation, ECHA is planning to organise pre-submission activities to which future applicants can adhere on a voluntary basis.

The first aspect of these activities consists in a notification system through which potential applicants are already invited to inform ECHA of their intention to submit an application. It should be done sufficiently in advance to the actual submission so that the Agency can plan its resources in an optimized manner.

Another activity – which is still under development – is the organisation of "pre-submission information sessions" where future applicants will have the opportunity to ask ECHA for clarifications on the preparation and submission of their application files, as well as to provide their initial thoughts on a possible phrasing for "broad information on uses" applied for. It was underlined that these sessions were clearly not intended to turn into ECHA giving advice on the content (assessments, conclusions) of an application for authorisation. In principle, one session will be organised per intended application, and this will be done upon a justified request submitted by the future applicant, and provided that the Agency has the necessary resources available at the time of the request. ECHA intends to implement this activity as a pilot project for about two years, before it is decided whether it continues, taking into account the resources implications and the feedback received from applicants. This system is based on the experience of other European Institutions, such as the European Medicines Agency.

The Secretariat informed that the Agency's activities to support applicants in their preparations also consists of general communication actions, such as the participation in conferences and workshops, regular update of its dedicated webpages, or articles in ECHA newsletters. Based on initial feedback from industry and other stakeholders, topic-specific workshops may also be organised in the future. A global communication strategy on applications for authorisation is under development.

As far as the "submission windows" are concerned, these consist of having pre-fixed submission periods of around 2 weeks, every 3 months, in order to synchronise the reception and processing of applications for authorisation with the meetings of RAC and SEAC.

Regarding the potential issues relating with the introduction of new restrictions on substances which are already listed in Annex XIV and therefore subject to the authorisation requirement, ECHA indicated that, in accordance with the REACH legal text, new restrictions can be introduced on Annex XIV substance-containing articles, given that the authorisation requirement does not apply to the placing on the market or use of an article itself.

The Chair invited the Committee to discuss the information received. A few suggestions were made on the possibility of organising substance-specific workshops, and on the idea to invite the future applicants for the same Annex XIV substance to submit all their

applications at the same period, so that they can be assessed at the same time by RAC and SEAC. A proposal was also made to organise information sessions for third parties who intend to provide comments on possible alternatives in the context of the public consultation.

The Chair thanked the Committee for their comments and suggestions which were considered a good introduction to the RAC and SEAC joint session.

#### **d) Joint RAC-SEAC session – Cooperation between RAC and SEAC during the opinion development**

The session started with introduction by the Secretariat ("How Committees evaluate the Applications for Authorisation"). The presentation focused mainly on the issue of the cooperation between both Committees, it outlined key principles and suggested practical solutions to be followed when evaluating applications by the Committees. After the presentation, the participants of the joint session were divided in four break-out groups to discuss the following topics:

1. The approach focuses on properties specified in Annex XIV, but what about the other risks?
2. In practice, alternatives are SEAC's business alone, do you agree?
3. DMELs cannot be used for demonstration of adequate control, but is useful in customising the SEA. What is your opinion?
4. SEAC should focus its attention on evaluating whether the costs of alternatives are correctly assessed. Do you agree?

The outcomes of the discussion in the groups were presented by the group's rapporteurs in the plenary session.

Additionally, participants were asked also to provide comments on which issues would they consider that further discussion or development is needed and to provide ideas on how to avoid that uncertainties would always lead the Committees to a situation where no clear opinion in favour or against an authorisation can be delivered. The groups presented the following conclusions and proposals for further discussion

- Application template needs to define clearly what aspects relate to SEA/adequate control route.
- Need for legal clarification on what endpoints the Committees can consider. If it is not clear in the legal text can RAC/SEAC decide?
- What are the needs of the Commission?
- Processes where RAC/SEAC wants clarification from the applicant and/or, third party
- Possibilities to use competencies and knowledge of the Forum on technical processes and uses
- Is the information from registration dossiers accessible and reliable?
- Alternatives: what are system boundaries (final product, production process, no production alternatives)?; what economic perspective should be considered (applicant's *versus* society's)?
- Basis for an independent opinion beyond the information from an application and public consultation – may own assessment be included? How to deal with lack of knowledge/information? How much can the Committees trust the information coming during the public consultation from third parties?

The Secretariat concluded that it would further elaborate on the issues in collaboration with COM and it would come back during the Committees' meetings in December 2011.

## **9) AOB**

### **• Update of the workplan**

The Secretariat presented the SEAC workplan for the rest of 2011 with regard to the restriction dossiers.

- **Nanomaterials working group**

An invited expert gave a presentation on nanomaterials and the challenges that may be encountered with the introduction of these materials in REACH. This issue was recently raised at the last CARACAL meeting. These challenges will appear particularly in relation to the four aspects which are taken into consideration when forming and adopting a restriction and/or an authorisation opinion: the identity of the substance(s), the characterisation and assessment of the risks to the human health or the environment, the definition of restriction or authorisation and the socio-economic benefits and costs.

The invited expert indicated that currently, no agreement has been reached on the definition of nanomaterial substances in REACH and between the EU and stakeholders. Moreover, due to the nanomaterials' new characteristics such as increased strength, chemical reactivity or conductivity, more identifiers will be needed. Size and surface treatment have already been proposed as new identifiers.

In addition, the amount of consumer products containing nanomaterials has increased while, the information supplied until today under REACH for a bulk substance might not be sufficient for assessing the potential risks when in nanoform and adequate test are still under development. Therefore new standards and instruments were considered to be needed, as per the invited expert's presentation, to assess these potential risks.

As for the definition of restriction and authorisation, it may need to be examined more carefully and possibly redefined due to the additional parameters characterising nanomaterials.

Finally, the invited expert also indicated that despite the advantages, the current knowledge of nanomaterials is limited and the safety assessment should be done on a case-by-case basis, not to mention the weight of the related ethical issues which is to be taken into account.

Some members and advisors expressed their concern on the lack of knowledge and of clarity on nanomaterials. The Chair informed that, if needed, during the next plenary a member of the Secretariat involved in the topic could intervene.

- **Information on the EAERE Conference**

The Committee was informed of the European Association of Environmental and Resource Economists (EAERE) conference which took place in Rome in July 2011, in particular of the special session on economic analysis of risk management of hazardous chemical substances. The purpose of the special session was to enhance the communication between academia and practitioners when it comes to methodological challenges connected to conducting socio-economic impact assessment of chemicals related to REACH restrictions. Another aim was to increase the interest of economists to take up relevant research topics.

The special session covered issues such as i) childhood exposure to lead in jewellery products and the related economic benefits and costs of restriction under REACH, ii) the costs of reducing mercury from measuring devices, iii) economic benefits from mercury emission reductions, iv) meta-analysis of willingness to pay to reduce risks related to mortality and v) voluntary environmental management programme for hazardous air pollutants in Japan.

The Committee was informed that a similar session is to be organised for the next EAERE conference and was invited to make any proposals and suggestions or to take part in it if interested.

- **Information on the Master of Science study on SEA in restrictions**

The Committee was informed of the study, uploaded to CIRCABC, on cross-comparison of the role of socio-economic analysis in the first Annex XV restriction dossiers. This study was developed by desk study and semi-structured qualitative and quantitative assessment interviews with the Committee and ECHA and was carried out between April and July 2011. Following the answers collected during the interviews, the study shows that there is a need for a more practical guidance on proportionality and a clearer distinction between private-public costs and benefits, more research and practical

guidance on health benefits and an update of ECHA guidance documents with practical experiences.

Moreover, the exchange of information between RAC and SEAC resulted to be crucial although, through the study, it appeared to need better timing, harmonisation of each Committee's approach and improvement of the collaboration on essential issues such as the definition of baseline emission levels.

- **ECHA new graduate scheme on EU chemical policies**

The Committee was informed about the Agency's new graduate scheme currently under development, in cooperation with COM, which aims at providing graduates with the knowledge and tools necessary to find an employment within regulatory institutions. The scheme, which will be launched in November 2011, will be created by developing a network of universities providing adequate graduate courses and by using its links with professional organisations that conduct continuous training and education programmes.

ECHA has already collected information from Member States through the Management Board members. The Committee was asked to provide any useful information on special courses in any fields relevant to the EU chemical policies, which will be published on the ECHA website as from December 2011.

- **Update on university activities & MSCA collaboration in REACH education**

The Committee was informed of the specific educational programmes at university level in Italy in relation to REACH and specifically in the field of socio-economic analysis. A Socio-economic analysis summer school course was organised for September 2011, focusing especially on post-graduates, young researchers, professionals and enterprise managers. This summer school will be organised on a yearly basis and the Committee was informed that participation and/or contribution would be appreciated.

- **Update on the ECETOC Study**

The Committee was informed of the recently published technical report by the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) on the principles and practice of environmental impact assessment for socio-economic analysis of chemicals. From the report it transpires that there is a need to quantify the environmental impacts and it also proposed creating a general and wide forum on socio-economic analysis. The Committee was invited to view the report on ECETOC's website to which the Secretariat will create a link from ECHA's webpage.

## **10) Action points and main conclusions of SEAC-12**

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

## II. Main conclusions and action points

<b>Agenda point</b>	<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>2. Adoption of the agenda</b>		
	The revised agenda (SEAC/A/12/2011_rev.1) was adopted	SEAC-Secretariat to upload the revised agenda to SEAC Circa IG as part of the meeting minutes.
<b>3. Declarations of conflicts of interest to the Agenda</b>		
	Conflicts of interest have been declared and will be taken to the minutes.	
<b>4. Administrative issues</b>		
a) Changes in the SEAC composition		
	SEAC was informed about the recent changes in the composition of SEAC	
b) Outcome of written procedures		
	SEAC was informed on the outcome of the written procedure on the SEAC-11 minutes, which were tacitly adopted by SEAC.	
d) Commission's Transparency Register for Stakeholders		
	SEAC stakeholders observers were informed of the new eligibility criterion for ECHA stakeholders as being on the Commission Transparency Register for Stakeholders	Stakeholders interested in the work of SEAC to sign up in the Register as soon as possible.
f) Participation of Croatia in the work of SEAC		
	SEAC agreed to invite Croatia to participate in its work as a third country observer.	SEAC Secretariat to communicate the SEAC decision, to the ECHA MB prior to its meeting on 29-30 September in order to make a final decision.
e) CIRCABC demonstration		
		Users of SEAC CIRCABC to provide feedback on the SEAC CIRCABC to the SEAC Secretariat. The Secretariat to consider the feedback and improve the service.
<b>5. Status report of the action points of SEAC-11</b>		
	SEAC was informed on the status of the action points of SEAC-11. Three action points from SEAC-11 remained unresolved and are dealt with at SEAC-12	

<b>Agenda point</b>	
<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<b>6. Feedback from other bodies and activities</b>	
<b>7. Restrictions</b>	
7.1 General restriction issues	
<i>a) Review of the restriction process after experiences on first dossiers</i>	
SEAC took note of a framework for the revision of the restriction process as regards the Committees' work presented by the Secretariat.	Secretariat to initiate newsgroups or distribute a questionnaire to RAC and SEAC and their stakeholder observers to identify ideas and issues that should be addressed in the revision process in October 2011.  Following the issues identified, the Secretariat is to propose to SEAC (and RAC) by December 2011 how to proceed.
<i>b) Update on intended restriction dossiers</i>	
SEAC was informed about two new intentions on restriction dossiers from Sweden and Denmark	
<i>c) Principles for changes of (Co-)rapporteurs for ongoing dossiers</i>	
SEAC agreed with the proposal of the Secretariat (SEAC/11/2011/02_rev.1) on how to deal with changes in membership and changes in rapporteurship with one modification.	Secretariat to add a footnote in the meeting document to remind that the former members who continue acting as (co-)rapporteurs are bound by the Declaration of commitment of an ECHA Committee for Socio-economic Analysis (co-) rapporteur.
<i>d) Dealing with comments from the public consultation on SEAC's draft opinion</i>	
SEAC took note of the proposal of the Secretariat (SEAC/11/2011/03_rev.1) on how to deal with comments from the public consultation on SEAC's draft opinion and making possible changes to the background documents. A minor amendment was proposed,	Secretariat to implement the proposal in the future restriction cases dealt with by SEAC. Secretariat to upload amended document to CIRCABC.
<i>e) Other general issues</i>	
7.2 Restriction Annex XV dossiers	
<i>a) Final opinion of SEAC on Lead</i>	
SEAC adopted the final opinion on Lead in jewellery with the amendments made during the plenary,	The Secretariat is to publish the final opinion of SEAC on Lead in jewellery on the ECHA website and to forward the final opinion of SEAC to the Commission.

<b>Agenda point</b>	
<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
<p>One member stated his reservation on the way the derogations are defined</p> <p>SEAC took note of the Background Document and ORCOM to this opinion.</p>	<p>The Member is to formulate this reservation and the Secretariat is to include the member's reservation in the minutes in cooperation with the member and to forward the reservation to the Commission services together with the opinion.</p> <p>Secretariat and rapporteurs to make necessary changes to the BD and ORCOM to make it in line with the adopted SEAC opinion.</p>
<i>b) Final opinion of SEAC on Phenyl mercury compounds</i>	
<p>SEAC adopted the final opinion on Phenyl mercury compounds. SEAC took note of the Background Document and ORCOM to this opinion.</p>	<p>The Secretariat is to publish the final opinion of SEAC on Phenyl mercury compounds on the ECHA website and to forward the final opinion of SEAC to the Commission.</p>
<i>c) Final opinion of SEAC on Mercury in measuring devices</i>	
<p>SEAC adopted the final opinion on Mercury in measuring devices. SEAC took note of the Background Document and ORCOM to this opinion.</p>	<p>The Secretariat to publish the final opinion of SEAC on Mercury in measuring devices on the ECHA website and to forward the final opinion of SEAC to the Commission.</p>
<i>d) Phthalates – outcome of the conformity check</i>	
<p>SEAC agreed on the conformity of the restriction proposal.</p>	<p>The Secretariat to publish the dossier for public consultation (pending the outcome of the RAC discussions on this dossier)</p>
<b>8. Authorisations</b>	
<i>a) Pool of (co-)rapporteurs for substances listed in Annex XIV</i>	
<p>SEAC was informed on the composition of the pool of rapporteurs for authorisation applications.</p>	
<i>b) Capacity-building in relation to the authorisation process</i>	
<p>SEAC was informed on the current status of the planning of the capacity building exercise.</p>	
<b>9. AOB</b>	
<p>SEAC was also informed on the organisation of a information gathering workshop on 15-16 November.</p> <p>SEAC was informed about the ECETOC study on Environmental Impact assessment for Socio-Economic Analysis of Chemicals</p>	<p>The Secretariat to publish a link a to the ECETOC study at the ECHA's webpages on SEA</p>

<b>Agenda point</b>	
<b>Conclusions / decisions / minority opinions</b>	<b>Action requested after the meeting (by whom/by when)</b>
SEAC was informed about the workplan for the future months.	
<b>Action points and main conclusion SEAC-12</b>	
SEAC agreed on the action points and main conclusions of SEAC-12.	Secretariat to upload the action points and main conclusions to CIRCABC IG.

### III. List of Attendees

<b>SEAC Members</b>
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GRANDI Silvia
GULBRANDSEN Magnus Utne
KNOFLACH Georg
LADOPOULOU Angela
LANGTVET Espen
LUTTIKHUIZEN Cees
SCHUCHTAR Endre
SKARŽINSKAS Vitalius
ŚLEŹAK Zbigniew Tomasz
STOYANOVA-LAZAROVA Elina Velinova
THIELE Karen
TIRCHILA Luminita
THORS Åsa
VARIZ Paulo

<b>RAC (co)-Rapporteurs</b>
JENSEN Frank

<b>Invited Experts</b>
ALEXANDRE João
CAVALIERI Luisa
PAPPONEN Hinni
URBAN Klaus

<b>European Commission</b>
KUBICKI Michal
VLANDAS Penelope

<b>Advisors, Dossier Submitters (DS) &amp; Observers</b>
BEEKMAN Martijn (Advisor to C. Luttikhuisen)
HENNIG Philipp (Advisor to K. Thiele)
KOPANGEN Marit (Phenylmercury DS representative, via Webex)
MORKA Heidi (Phenylmercury DS representative, via Webex)
VERHOEVEN Julia (Advisor to C. Luttikhuisen)

<b>Stakeholder Observers</b>
BROUWER Roy (EAERE)
DIMTCHEVA Ralitza (UEAPME)
HOLLAND Mike (EEB)
JÁNOSI Amaya (CEFIC)
KÜHN Ingolf (Business Europe)
MUSU Tony (ETUC)
WATERSCHOOT Hugo (EUROMATAUX)

<b>ECHA staff</b>
ANFALT Lisa
JACQUEMIN Katline
KIVELA Kalle
KNIGHT Derek
LEFEBVRE Alain
LEFEVRE Remi
LIPKOVA Adriana
LOGTMEIJER Christiaan
LOGHIN Sorina
MOSSINK Jos
PELTOLA Jukka
RODRIGUEZ IGLESIAS Pilar
SANDBERG Eva
SIHVONEN Kirsi
SAEZ RIBAS Monica
SHUQOM Natasha
THUVANDER Ann
VAINIO Matti

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

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

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

Revised draft agenda SEAC-12	<i>SEAC/A/12/2011_rev.1</i>
Participation of Croatia in the work of SEAC	<i>SEAC/12/2011/01</i>
Feedback from other bodies and activities	<i>SEAC/12/2011/02</i>
Principles for changes of (co-)rapporteurs for ongoing dossiers	<i>SEAC/11/2011/02_rev.1</i>
Dealing with comments from the public consultation on SEAC's draft opinion	<i>SEAC/11/2011/03_rev.1</i>
Pool of (co-)rapporteurs for substances listed in Annex XIV	<i>SEAC/11/2011/04_rev.1</i>
ECHA new graduate scheme on EU chemical policies	<i>SEAC/12/2011/05</i>

**DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS**

The following participants declared conflicts of interests with the agenda items below (according to Art 9(2) of the SEAC Rules of Procedure):

<b><u>Name of participant</u></b>	<b><u>Agenda item</u></b>
BRIGNON Jean-Marc	7.2.a Lead and its compounds
CAVALIERI Luisa	7.2.a Lead and its compounds
FOCK Lars	7.2.d Phthalates
GULBRANDSEN Magnus Utne	7.2.b Phenylmercury compounds
JENSEN Frank	7.2.d Phthalates
LANGTVET Espen	7.2.b Phenylmercury compounds
ŚLĘZAK Zbigniew Tomasz	7.2.d Phthalates

**Final Agenda**

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

**13-15 September 2011**

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

**13 September: starts at 14:00**

**15 September: ends at 18:00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

*SEAC/A/12/2011\_rev.1*

***For adoption***

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

**Item 4 – Administrative issues**

- a) Changes in the SEAC composition/nominations
- b) Outcome of written procedures
- c) Handling of conflict of interest – update from the Secretariat
- d) Commission's Transparency Register for Stakeholders
- e) CIRCABC demonstration

***For information***

- f) Participation of Croatia in the work of SEAC

***SEAC/12/2011/01***

***For agreement***

**Item 5 – Status report of the action points of SEAC-11**

***For information***

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

***SEAC/12/2011/02***

***For information***

**Item 7 – Restrictions**

**7.1 General restriction issues**

- a) Review of the restriction process after experiences on first dossiers  
*For discussion*
- b) Update on intended restriction dossiers  
*For information*
- c) Principles for changes of (Co-)rapporteurs for ongoing dossiers  
*SEAC/11/2011/02\_rev. 1*  
*For agreement*
- d) Dealing with comments coming from the public consultation on SEAC's draft opinion  
*SEAC/11/2011/03\_rev. 1*  
*For information*
- e) Other general issues  
*For information*

## **7.2 Restriction Annex XV dossiers**

- a) Lead and its compounds in jewellery - final draft of SEAC opinion  
*For adoption*
- b) Phenyl mercury compounds – final draft of SEAC opinion  
*For adoption*
- c) Mercury in measuring devices – final draft of SEAC opinion  
*For adoption*
- d) Phthalates – outcome of the conformity check  
*For agreement*

## **Item 8 – Authorisations**

- a) Pool of (co-)rapporteurs for substances listed in Annex XIV  
*SEAC/11/2011/04\_rev. 1*  
*For information*
- b) Capacity-building in relation to the authorisation process  
*For information*
- c) Other general issues  
*For information*
- d) Joint RAC&SEAC session
  - o Cooperation between RAC and SEAC during the opinion development  
*For discussion*

## **Item 9 – AOB**

- Update of the work-plan
- Nanomaterials in the context of SEAC
- Information on the EAERE Conference
- Information on the Master of Science study on SEA in restrictions
- ECHA new graduate scheme on EU chemical policies

**SEAC/12/2011/05**

***For information***

- Update on university & MSCA collaboration in REACH education in Italy
- Update on the ECETOC Study

## **Item 10 – Action points and main conclusions of SEAC-12**

Table with Action points and conclusions from SEAC-12

***For adoption***