

**21 May 2013**

**SEAC/M/18/2013 FINAL**

**Final**

**Minutes of the 18<sup>th</sup> meeting of the Committee for Socio-economic Analysis**

**6 – 8 March 2013**

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

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

Tomas Öberg, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the eighteenth meeting of SEAC.

The Chair informed the Committee that apologies had been received from two members, two stakeholder observers, one Croatian observer and one international observer. Three invited experts, eight members' advisors present at the meeting as well as two representatives of the European Commission, observers of five stakeholder organisations and two dossier submitter representatives were introduced. The Chair informed the participants that two SEAC members and three dossier submitter representatives were to follow the relevant parts of the meeting via Webex.

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.

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

The Chair introduced the draft Agenda of SEAC-18.

The Agenda was adopted with one addition under AOB (following the proposal by the observer from Eurometaux). The final Agenda is attached to these minutes as Annex III. The list of all meeting documents is attached to these minutes as Annex I.

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

The Chair requested all participants to declare any conflicts of interest to any of the specific agenda items. Two members declared potential conflicts of interest to the substance-related discussions under the agenda items 5.2. These members did not participate in voting under the respective agenda items, as stated in Article 9.2 of the SEAC Rules of Procedure.

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

### **4) Report from other ECHA bodies and activities**

#### **a) Report on SEAC-17 action points, written procedures and other ECHA bodies**

The Chair reported that all action points of SEAC-17 have been completed or would be followed up during the ongoing SEAC-18 meeting. The Chair informed the Committee that the Secretariat had updated the opinion template for restriction dossiers following the proposal made in the SEAC-17 meeting document on the remits of RAC and SEAC and agreed by the Committee at SEAC-17. The revised template was uploaded on CIRCABC in January 2013.

The Chair informed the Committee that the final minutes of SEAC-17 had been adopted by written procedure and had been uploaded to CIRCABC as well as on the ECHA website. The Chair thanked members for providing comments on the draft SEAC-17 minutes.

The Chair explained that a report covering the developments in the ECHA MB, RAC, MSC and the Forum had been compiled and distributed to SEAC as a meeting document (SEAC/17/2012/01).

The representative of the Commission was then invited to update the Committee on SEAC related developments in the REACH Committee. Following the proposal by one SEAC member made at the last SEAC meeting, the Commission representative was also invited to report about the 4 December 2012 workshop on synergies between REACH and other EU regulations. It was agreed that the Commission would provide written report (if available) from this workshop to be distributed to SEAC.

The Secretariat provided a presentation on the results of the Annual Satisfaction Survey and Accredited Stakeholder Workshop 2012. It was agreed that the Secretariat would review and analyse these results and plan possible follow-up actions. As members and stakeholder observers had indicated low satisfaction with ECHA's support in training, the Secretariat invited members and observers to help the Secretariat to identify what kind of training in the context of SEAC work they would see useful.

The Chair reported back from the teleinterviews he had conducted with SEAC members at the end of 2012 by summarising the results of these bilateral discussions and outlining some possible further actions to increase the Committee's capacity to handle dossiers. It was highlighted that it is an obligation of a MS to support the nominated member (in terms of allocating enough time, offering experts to support the nominated member, etc) and possibilities to communicate this better to MSs were discussed. It was also agreed that the Chair would organise similar teleinterviews with SEAC stakeholder observers as had been organised with SEAC members. A stakeholder observer suggested to review the nomination process of experts to the scientific committees of ECHA and referred to a decision by the European Ombudsman on how experts are selected for working groups of the scientific committees of the Commission.

## **5) Restrictions**

### **5.1) General restriction issues**

#### **a) Update on intended restriction dossiers (joint RAC/SEAC session)**

The Secretariat provided an update on upcoming restriction dossiers. There are currently three new substances in the Registry of Intentions (RoI):

- 1-Methylpyrrolidin-2-one (NMP), with wide variation of professional and industrial uses, prepared by the Netherlands (expected submission date - 19 April 2013);
- Cadmium and its compounds in plastics and paints prepared by ECHA on the request of the Commission (expected submission date - 17 January 2014);
- Placing on the market and use of diaphragms containing chrysotile prepared by ECHA on the request of the Commission (expected submission date - 17 January 2014).

The Secretariat mentioned that calls for expressions of interest for (co-)rapporteurships of the chrysotile restriction dossier would be launched in both RAC and SEAC shortly after RAC-24/SEAC-18.

#### **b) Update on the review of the restriction process**

The Chair reminded the participants that at the SEAC-17 meeting, a discussion on the remits of RAC and SEAC concerning their respective considerations related to the justification of a restriction had taken place and one SEAC member had proposed to prepare a discussion note and a presentation to SEAC for the SEAC-18 meeting in order to elaborate on this topic further. The discussion note drafted by this member was distributed to the Committee as the meeting document SEAC/18/2013/05 (titled "Review of the restriction process: The basis for SEAC to form an opinion). The SEAC member was then invited to introduce his views to the Committee. The presentation questioned the

limitations of a legislatively narrow SEA analysis in assessing a restriction proposal, and whether in this respect SEAC is strictly bound by Article 68(1) of the REACH Regulation; or whether it precludes a more holistic approach; and what are the synergies between REACH and other EU legislation. He argued that in cases where no unacceptable risk is identified by RAC, there could be other reasons to justify the restriction by SEAC (e.g. technology change has already taken place, settling equal level playing field for EU manufactures and importers of articles, societal reasons, etc).

Several SEAC members and one stakeholder observer shared the view that REACH is risk-based and therefore, a restriction cannot be supported, if no unacceptable risk is demonstrated. It was also considered important to remember that the final decisions on restrictions are taken by the Commission and the task of the Committees is to provide opinions to support the decision-making. To support that, several members noted that wider socio-economic aspects could be part of the SEAC opinion.

The Secretariat reminded the participants that RAC has the task of evaluating whether a suggested restriction would be appropriate in reducing the risk to human health and/or the environment (Article 70 of REACH). Similarly, SEAC has the task of evaluating the socio-economic impacts (Article 71). Since the identification of a risk is a prerequisite for a restriction it follows that SEAC cannot support a proposal where this as assessed in the evaluation by RAC is not demonstrated. This had already been clarified in the SEAC-17 meeting document on the remits of RAC and SEAC (SEAC/17/2012/03). The representative of the Commission also concurred to this. One member commented that although the identification of risk was a pre-requisite for a restriction to be justified, SEAC could nevertheless provide opinion commentary on other aspects of the restrictions impact, as long as the basis of the justification was not made on other 'non-risk' related aspects.

## **5.2) Restriction Annex XV dossiers**

### **a) Chromium VI – discussion on the 2<sup>nd</sup> version of SEAC final draft opinion and adoption of SEAC opinion**

The Chair welcomed the Danish dossier submitter representatives.

The Chair reminded the participants that the restriction concerns chromium (VI), which can be formed during the chrome tanning process when chromium (III) is oxidised. Chromium (III) compounds are added in some tanning processes to increase the dimensional stability, the resistance to mechanical action and the heat resistance of leather by cross-linking of the collagen subunits. The proposed restriction focuses on the risk to consumers (including workers as consumers) of skin sensitisation from direct or indirect skin contact with leather articles which contain chromium (VI). This includes articles for which there is a relatively short, repetitive skin contact as well as longer term, repeated contact.

The Chair informed SEAC that the SEAC draft opinion on chromium (VI) dossier had been submitted for the public consultation on 14 December 2012. The public consultation ended on 12 February 2013 (comments from three interested parties were received). On 19 February, the Secretariat organised an Extended drafting group meeting on chromium (VI). 14 SEAC members and advisors participated in this meeting. The aim of the meeting was to discuss how to reflect in the opinion the concerns of those members, who had not supported the agreement on the SEAC draft opinion at SEAC-17.

The Chair invited the SEAC (co-)rapporteurs to give a presentation. The presentation focussed on the overview of what had been done between SEAC-17 and SEAC-18, comments received within the public consultation as well as the text of the entry with the lately proposed derogations. They also summarised the SEAC position concerning the prevalence and the final opinion on the costs and benefits.

After the (co-)rapporteurs' presentation the Chair gave the floor to the SEAC member, who had expressed his concerns at the last SEAC plenary meeting, to briefly explain to the Committee how his concerns have been reflected in the 2<sup>nd</sup> version of the SEAC final opinion. The member presented to the Committee the results of his consultations on prevalence with UK allergy experts. Generally, he expressed equivocal acceptance of the prevalence estimation of RAC with the reservation that some of his concerns on the uncertainties in the analysis are still valid.

Another member thanked the Secretariat for organising the Extended drafting group meeting and considered it very useful. Furthermore, he proposed to include a conclusive paragraph in the opinion that "despite all the uncertainties surrounding the estimations, there is sufficient socio-economic information available for SEAC to support the restriction. The mere fact that European industry has already shifted to chromium (VI) reducing technologies on a voluntary basis indicates that costs of these alternative technologies are reasonable and economically feasible to industry." The proposal was supported by the (co-)rapporteurs and the SEAC members and included in the opinion.

The (co-)rapporteurs had proposed derogations for the second hand markets and stocks. Some of the members, while they were supporting the concept of the derogations, expressed concern regarding how the derogations have been proposed and implemented in the opinion. In their view, the derogations were added to the opinion at the last moment and have not been properly discussed by the Committee. Additionally, they have not been consulted by interested parties (as were included in the opinion after the public consultation). The SEAC members asked also if the derogation for stocks could be time limited.

The Secretariat fully agreed with the members on this and confirmed that this fact would be clearly communicated to the Commission when sending the Committees' opinions. However, there were several reasons supporting such a proposal. In its 1<sup>st</sup> advice, the Forum had proposed to exclude second hand market articles from the scope of the restriction. It is not meaningful to take samples of the products on the second hand market as the article is destroyed in the test. Furthermore, the Secretariat pointed out that based on the Background Document (BD) it is not possible to evaluate the impacts if a batch of stocks did not comply with the restriction. In addition the leather articles were initially bought legally. It was also pointed out by the Secretariat that the derogation for the stocks is time limited by its nature as the stocks will finally be sold out. In the view of the Secretariat, the fact that the derogation had not been included in the opinion that was subject to public consultation would not be a problem for industry as the derogation limits the scope of the restriction and therefore has no negative impact on industry.

The dossier submitter informed the Committee that it was not their intention to propose the derogation for the articles placed on the second hand market. They believed that those articles not fulfilling criteria of the restriction should not be placed on the second hand market. However, they understood the arguments for making a time limited derogation for the articles in stocks imported/produced before the restriction became effective.

The Chair asked the Committee to adopt the opinion. The opinion was adopted by consensus with additional statements for inclusion in the meeting minutes being made by two SEAC members. The SEAC members Cees Luttkhuizen and Stavros Georgiou wished it to be recorded that they had significant reservations regarding the methodological and empirical basis of the analysis undertaken to assess the cost and the benefits in this dossier. In this respect the quality of the provided CBA is in their view a cause of concern for the justification of SEAC's opinion.

The (co-)rapporteurs and the Secretariat will make necessary editorial changes to the BD and ORCOM to make them in line with the adopted SEAC opinion. The Secretariat will publish the final opinion of SEAC on chromium (VI) on the ECHA website and will forward the final opinions of SEAC and RAC and the BD to the Commission.

## **b) Dichlorobenzene – discussion on the 4<sup>th</sup> version of SEAC draft opinion and agreement on SEAC draft opinion**

The purpose of the proposed restriction is to ban the use of 1,4-dichlorobenzene (1,4 DCB) in toilet blocks and air fresheners used in toilets or other domestic or public indoor areas, or offices. The scope of the restriction proposal is to restrict consumer and professional use of 1,4 DCB. The dossier submitter is ECHA. The public consultation on the restriction dossier on 1,4 DCB took place between 19 June and 19 December 2012, with six comments received. The rapporteurs' third dialogue took place on 17 January 2013. The SEAC written commenting round on the 4th version of the SEAC draft opinion finished on 17 February. Based on the comments received during the commenting round as well as the further amendments made in the RAC opinion, the (co-)rapporteurs prepared the modified 4th version of the SEAC draft opinion for discussion at SEAC-18.

The final Forum advice was made available to RAC and SEAC on 26 February 2013. The deadline for adoption of the opinion is 19 March 2013.

The RAC rapporteurs were invited to present the update on the RAC discussion at RAC-24 to the SEAC Committee. RAC adopted its opinion considering that the risk characterisation ratios (RCRs), which are above one for reasonable worst cases scenarios, denote a risk for consumers and professionals based on liver tumours. Hence the exposure would need to be reduced for both consumer and professional users. In its opinion, RAC had assessed the different risk management options (such as job rotation, voluntary measures by industry, personal protective equipment, ventilation, temperature control by air condition, and the adjustment of the EU Occupation Exposure Limit - OELs) and concluded that the restriction would be the most appropriate risk management measure to reduce exposure levels for both consumers and professionals.

After this, the SEAC rapporteurs presented the revised draft opinion based on the recently adopted RAC opinion. Since RAC had concluded that exposures need to be reduced for both consumer and professional users, it was concluded that a restriction is an appropriate risk management measure to address both cases. The SEAC rapporteurs took account of the inferred health benefits and the scale of costs involved and concluded that the proposal is not disproportionate, (i.e. according to the consumer surplus approach savings for domestic users (2.8m), costs for professional users (-4m), overall costs (-1.2m) across EU).

The SEAC rapporteurs stated that alternatives are available for most scenarios, even though there might be a lack of direct alternatives for certain professional scenarios. Finally, the comments from public consultation were reviewed by the rapporteurs as well as the final Forum advice.

Two SEAC members felt that based on their views regarding consumer surplus, the SEAC opinion should not favour the approach based on Consumer surplus, but rather – hold the Substitution costs approach with equal standing; other members also supported this as it would strengthen the justification in the opinion. The rapporteurs restated the reasons why they preferred the consumer surplus approach, in particular citing their previous extensive discussion and responses to comments on this issue from members.

The Secretariat recommended that the in depth methodological discussion on the preferred approach could be better addressed in a separate fora e.g. in a special session dedicated to this, and taken out of the opinion development process. Furthermore, the recommendation to the Commission should focus on the SEA conclusions with respect to the specific restriction and not on more general methodological questions/issues related to SEAC approaches. This was agreed by the Committee.

It was agreed to include the results from both approaches in the justification document (-1,2 million costs according to the consumer surplus approach and 1,4 million savings according to the substitution cost approach). The SEAC rapporteurs revised the text based on the discussion on the methodological approach and presented it to the Committee. This was supported by the members.

SEAC agreed on the draft opinion by consensus. The rapporteurs and the Secretariat were asked to make editorial changes to the opinion based on the discussions in the plenary. The rapporteurs will ensure that the supportive documentation (BD and RCOM) is in line with the adopted SEAC opinion. The Secretariat will publish the agreed SEAC draft opinion and its supportive Background Document for a 60-day public consultation.

### **c) Nonylphenol – outcome of the conformity check**

The Chair welcomed the RAC (co-)rapporteurs and the dossier submitter representatives from the Swedish MSCA who followed the discussions as observers.

The Chair reminded the Committee that the restriction dossier on Nonylphenol (NP) and Nonylphenol ethoxylates (NPE) had first been submitted to ECHA in August 2012. In September 2012, both RAC and SEAC concluded that the dossier did not conform to the requirements of Annex XV and the reasons for non-conformity were sent to the dossier submitter (Sweden). The dossier submitter resubmitted the Annex XV restriction proposal on 26 November 2012. The conformity check process in RAC and SEAC was launched on 7 February and the Committees are expected to reach a conclusion on conformity by 8 March 2013 at the latest.

The Annex XV dossier proposes a restriction on the placing on the market of NP and NPE in clothing and household textile articles (including their prints) that can be washed in water, if they contain these substances alone or in combination in concentrations equal or higher than 100 mg/kg textile. The use of NP and NPE in concentrations equal or higher than 0,1% is restricted within the EU in products for among other the processing of leather and textiles, industrial and institutional cleaning, etc (REACH, Annex XVII, Entry 46). However, NP and NPE are still used outside the EU as detergents and auxiliaries in the manufacturing of textile articles. After import to the EU the textile articles will be washed and the residues of NP and NPE will be released into the environment via the waste water treatment.

The RAC (co-)rapporteurs informed the participants that RAC had concluded on the conformity of the dossier on 6 March 2013 and the RAC's conclusion was that the dossier is in conformity with the requirements of Annex XV of the REACH Regulation. They explained that those aspects of the dossier, which had been considered not in conformity previously, have been improved and brought into conformity in the revised proposal. However, several recommendations have been made to the dossier submitter to enhance the dossier further.

The SEAC (co-)rapporteurs presented the outcome of the SEAC conformity check and recommended that the dossier would be considered not in conformity. This was due to the fact that the revised report does not appear to allow an evaluation of the assessment of the proposed restriction against its effectiveness, in particular its proportionality. The SEAC (co-)rapporteurs acknowledged that quantification of environmental benefits is hardly feasible in cases like that, however, a qualitative description of potential gains to society (benefits) would have been a minimum requirement. They found that the dossier contains no argumentation as to why and how gains to society (benefits) outweigh costs (efforts required to implement the restriction) and therefore, no proportionality assessment has been provided which could be evaluated by SEAC. The (co-)rapporteurs mentioned that in the two written commenting rounds organised within the conformity check process, comments had been received from five SEAC members. Four of them supported the (co-)rapporteurs' views and one member expressed the opinion that information in the dossier could allow a cost-effectiveness approach since a cost-benefit assessment was not possible. The (co-)rapporteurs responded that they agree to this in principle, however, this should have been the task of the dossier submitter and not of SEAC. Moreover, demonstration of the proportionality of the restriction would still require additional argumentation even with a cost-effectiveness approach to the analysis.

Several SEAC members indicated support to the (co-)rapporteurs' conclusions on non-conformity of this restriction proposal and expressed the view that in the past, the

Committee, in particular (co-)rapporteurs, had been required to undertake too much additional analytical work to assess the dossiers, and this should be avoided.

One SEAC member was of the opinion that the dossier could be considered in conformity, arguing that proportionality could be evaluated sufficiently to form an opinion. He mentioned that the dossier contains information on risks (considerations on RCR for the marine pelagic compartment and discussion on possibilities for ED effects), emission reduction and costs. Furthermore, he argued that cost-effectiveness is considered (comparison with cost for improvement of waste water treatment plants). Moreover, he argued that whether or not this is sufficiently elaborated, is not a conformity, but an evaluation issue. This member also stated that explicit statements of gains to society are not a requirement for conformity. Rapporteurs and members nevertheless maintained that since no argumentation was given on the proportionality of the restriction in terms of a comparison of costs and benefits, an evaluation of such argumentation regarding proportionality could not be undertaken.

SEAC agreed by majority that the dossier on Nonylphenol and Nonylphenol ethoxylates thus does not conform to the requirements of Annex XV of REACH. One member disagreed with this conclusion as mentioned above.

The Chair informed the participants that the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter. It was also agreed that the Secretariat would review the involvement of dossier submitters when the Committee considers the conformity of an Annex XV dossier and come back on the issue at the next plenary before such elaborations take place.

#### **d) Lead in consumer articles – outcome of the conformity check**

The Chair welcomed the RAC (co-)rapporteurs and the dossier submitter representatives from the Swedish MSCA.

The Chair explained to SEAC that the restriction dossier on lead and lead compounds had been submitted to ECHA on 18 January 2013. The conformity check process in RAC and SEAC was launched on 7 February and the Committees are expected to reach a conclusion on conformity by 8 March 2013 at the latest.

The Annex XV dossier proposes a restriction on the placing on the market of lead and its compounds in articles intended for consumer use. The restriction proposal is targeted to consumer articles that can be placed in the mouth by children, given that children are the most vulnerable group when exposed to lead. The lead compounds (but not elemental lead) are classified as reprotoxic category 1 and 2. Lead, however, has been proven to be a non-threshold toxic substance for neurotoxic and neurodevelopmental effects. The main route through which small children (between ages of 6 and 36 months) are exposed to lead from the consumer articles is by mouthing. This exposure impairs the development of their central nervous system as the most sensitive negative effect. According to the dossier submitter that health risk cannot be adequately controlled with the existing EU legislative measures.

The RAC (co-)rapporteurs were invited to report on the RAC discussions on the outcome of the conformity check where RAC had concluded that the dossier is considered to be in conformity. The (co-)rapporteurs noted that the proposal takes into account the RAC opinion (and the Background Document) on the restriction dossier on lead in jewellery processed by the Committees earlier, and that the same human health hazard information and risk assessment approach had been used.

The SEAC (co-)rapporteurs presented the outcome of the conformity check to the Committee. According to the assessment made by the rapporteurs the proposed restriction and its background are clearly presented and the effects to adults and children from lead exposure are well documented in literature and in the report. Furthermore, during the conformity check consultation three SEAC members had provided comments,

which had been considered by the (co-)rapporteurs. The SEAC members' comments resulted in slight modifications in the recommendations requesting more information on the feasibility of alternatives as well as on the outcome of the stakeholder consultation. Furthermore, the (co-)rapporteurs listed other recommendations to the dossier submitter related to the baseline scenario which could be more clear-cut, and to further clarifications on the logic of comparing the annual costs of the restriction to discounted life-time productivity of children.

One SEAC member pointed out that the baseline is not clear and considered this as a conformity issue. However, the rapporteurs noted that the essential information on the baseline is included in the dossier which could be further developed in line with the recommendations. Other members raised concerns that the lack of information in the dossier as well as the wide scope would require a lot of work by the rapporteurs.

Furthermore, the Eurometaux stakeholder observer noted that whilst the lead manufacturing and recycling industry supports minimization of lead exposure to children, to which this restriction can contribute, in his view it is unclear whether the present proposal covers both lead as additive and as an impurity in articles. This could potentially challenge the clarity of the scope of the restriction. The observer pointed out that the most specialised uses of lead relate to specific downstream sectors, which are not aware of this restriction proposal and have not been covered in the stakeholder consultation presented in the dossier. He also questioned whether derogation for lead in crystal and special glass has been considered in addition to derogations for musical instruments and keys/padlocks. Finally, he asked whether the issues of lead in recycled material and existing stocks of lead containing articles are included in the dossier.

One SEAC member suggested that the recommendations to the dossier submitter should also include the issue of crystal glass (whether it is included or not) and other issues brought up during the discussions related to the wide scope. The member suggested that the agreement on the outcome of the conformity check should also include agreement on the recommendations. In response to this, the Chair explained that it is only the outcome of the conformity check that is agreed by the Committee. It was concluded that any additional recommendations of the SEAC members could be forwarded via the Secretariat to the rapporteurs who would then discuss these with the dossier submitter in the first rapporteurs' dialogue. Therefore, the Chair requested SEAC members to send additional questions to the rapporteurs for the first dialogue by mid April 2013.

After the discussions, SEAC concluded that the dossier on lead in consumer articles conforms to the requirements of Annex XV of REACH.

The Chair informed the participants that the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter and that the public consultation on the proposal would be started shortly after SEAC-18.

#### Joint RAC/SEAC session:

After the dossier was agreed to be in conformity by RAC and SEAC, an introductory presentation was provided by the dossier submitter (Sweden) on the restriction proposal to both Committees within the joint RAC/SEAC session. One participant questioned why keys have been exempted from the scope, as keys are often put in the mouth by children. The dossier submitter representative replied that according to the consultation with industry, it is not technically possible to currently substitute lead in keys. A relevant review clause, however, is foreseen in the restriction proposal. A question was also asked on lead in glass, enamels and ceramics. A clarification was provided by the dossier submitter that the food contact relevant applications are handled within the framework of the food legislation.

### **5.3 Appointment of (co-)rapporteurs for restriction dossiers**

The Secretariat presented and SEAC took note of the pool of (co-)rapporteurs for the restriction dossier on cadmium and its compounds in plastics and paints (to be submitted by ECHA on request of the Commission by 17 January 2014) as outlined in the meeting document SEAC/18/2013/04 CONFIDENTIAL. The Chair encouraged more volunteers to come forward to be included into the pool. The agreement on the appointment of (co-)rapporteurs will follow later on this year.

## **6) Authorisations**

### **a) Capacity building**

- **Economic feasibility**

The Chair reminded the Committee that at the last SEAC meeting conclusions had been drawn and agreed on the discussions about the concept of economic feasibility. The Secretariat then briefly presented the document drafted based on these conclusions (meeting document SEAC/18/2013/03).

Several SEAC members expressed support to the presented discussion paper saying that it clarifies very well how the Committee will assess economic feasibility. It also helps to recognize the difference between SEA in restrictions and authorisations.

One SEAC member suggested some specific edits to the text, adding to one sentence and deleting two others. The Chair explained that further editing at this stage would reopen the process and require a new drafting group meeting.

The stakeholder observer from EEB found that many considerations in the presented document are not useful from the applicant's point of view and do not provide guidance to applicants. Another stakeholder observer, however, felt that it is important for applicants to understand the difference between restrictions and authorisations and considered this discussion paper as good guidance to potential applicants.

SEAC agreed on the approach to assessing economic feasibility outlined in the meeting document. It was also agreed that the Secretariat would find the appropriate way to communicate the approach to possible applicants.

- **Valuation of PBTs (joint RAC/SEAC session)**

The Chair reported that closing the gap between PBT hazard identification, risk assessment and impact assessment is a challenging task, which the Committees may be faced in the near future – in the authorisation but also in the restriction process. For that reason the Secretariat had proposed the following session for the information of RAC and SEAC members.

The Chair welcomed an invited expert to report on the results of their project entitled "A framework for valuing environmental impacts of PBT chemicals to inform decision-making on authorisation under REACH". The Chair mentioned that the project had been funded by Luxembourg and had been initiated by a RAC member. He mentioned that this session should be seen as a thought starter, rather than a presentation of solutions.

The invited expert reported on ways to carry out monetary valuation of environmental impacts as a benchmark cost-benefit analysis (CBA) approach, non-monetary valuation of environmental impacts as a cost-effectiveness analysis (CEA) approach, and illustration of CEA on an example of HBCDD.

Following the presentation the Chair opened the floor for discussions. One RAC member noted that at a policy level vPvB substances are treated equally with PBT substances. However, no toxicity or 'T' parameter is in place for vPvBs. Thus, using the proposed methodology, vPvB chemicals will receive lower scores. The member added that some of the data, which is needed for scoring, may not always be available. One RAC member

noted that the 'T' criterion can also be assigned by the human health toxicity endpoints, such as acute toxicity, STOT SE (specific target organ toxicity after single exposure) or RE (specific target organ toxicity after repeated exposure), CMR or endocrine disrupting properties.

The CEFIC stakeholder observer noted that a hazard-only based assessment does not reflect the true substance profile. He expressed his view that a monetisation factor could play a substantial role in substance identification. He also noted that there may be PBT substances available with a less hazardous profile. Although such gradation of severity of PBT consequences cannot be considered for the PBT identification, he expressed his view that it is extremely important that this is taken into consideration in the socio-economic analysis.

One Commission observer noted that the proposed methodology considers only hazard properties. He suggested introduction of other parameters, too (such as use, etc).

The RAC member, who commissioned the research on behalf of Luxembourg, mentioned that he appreciated the fruitful trans-disciplinary examination done by environmental economists and environmental chemists. He also noted that after two previous projects on impact characterisation, this one strives to achieve a consistent decision-making framework. The CBA benchmark model clarifies limitations of any pragmatic CEA model, he noted.

The Secretariat then introduced the work of the PBT expert group. The PBT expert group is coordinated by ECHA, and consists of approximately 15 experts, who are nominated by MSCAs, industry associations and NGOs. The PBT expert group meets two to three times per year; in 2012 there were two meetings. The aim of this expert group is to provide informal and non-binding scientific advice on questions related to the identification of PBT and vPvB properties of chemicals. It was pointed out that if elements of PBT assessment and "PBT-hazard scoring" are used in documents discussed by RAC, the PBT expert group or a member could be consulted.

At the end of this session, a SEAC advisor reported on the continuation of their project "Economic Valuation of Environmental Impacts of Chemicals: SEA Methodology Development" commissioned by RIVM. The project started in May 2012, and it is expected to conclude in March 2013.

The Chair thanked RAC and SEAC members for the lively discussion in this joint RAC-SEAC session. The aim of the session to initiate the thinking on the PBTs was met and welcomed by RAC and SEAC members. They expressed their interest to follow the developments in this field in the future.

## **7) SEAC Manual of Conclusions and recommendations**

The Secretariat presented a proposal for an update of the SEAC Manual of conclusions and recommendations (MoCR). After a brief discussion, it was agreed that the Secretariat would continue collecting conclusions in the Manual and would table the revised document to SEAC, when a substantial update has been made.

## **8) AOB**

### **a) Update on the workplan**

The Secretariat provided an update on the workplan for the future months. Furthermore, the Chair informed about the planned SEAC meeting dates for 2014.

### **b) Commission's conclusions on the Review of REACH (joint RAC/SEAC session)**

The Commission representative introduced the Commission's conclusions from the Review of REACH. The presentation summarised the context (objectives and legal obligations) of the Review, the scope and evaluation process, conclusions, recommendations as well as next steps. In general, the Commission had concluded that REACH functions well and delivers on all objectives that at present can be assessed. However, in the current framework, there is a need to reduce the impact on SMEs as well as to increase efficiency by all actors involved. Recommendations directly related to RAC and SEAC were listed (e.g. RAC and SEAC should improve their co-ordination; the Committees need to continue looking for more efficient ways of working and must be able to rely on strong support from the MSs, etc). It was also mentioned that a conference on the Review of REACH has been foreseen for March/April 2013.

Several RAC and SEAC members questioned the Commission's recommendation to improve the co-ordination between RAC and SEAC, claiming that in their view this co-ordination has been functioning well. The Commission representative responded that the review had been carried out a year ago and indeed the co-operation of the two Committees has improved since then. The importance of maintaining the current co-ordination when the Committees start to process authorisation applications was also highlighted.

One participant asked how the Commission intends to decrease the impact of REACH on SMEs. The Commission observer replied that the first step has been revising the Fee Regulation, which has already been initiated. A stakeholder observer (CEFIC) noted that it is important to realize that the definition of SME is very strict under REACH and that due to this hardly any companies can be considered as SMEs. Reductions in fees do not improve the situation much.

Several members expressed concern how the Committees would manage their workload in the future, when they start to process applications for authorisation. They explained that often the support of MSs to their nominated Committee members is very limited, although providing such support is an obligation of MSs according to REACH and members consider it very important.

The Commission representative confirmed that the views expressed at the meeting would be taken into account in further development of the follow-up actions of the Review of REACH.

### **c) Follow-up of the workshops on applications for authorisation**

At the last SEAC meeting, the observer from Eurometaux had updated the Committee on the recent workshops on authorisation process. As one conclusion of these workshops, it came out that the expertise on SEA and Analysis of Alternatives is limited. This served as a basis for an idea to create an informal network platform for practitioners on SEA and Analysis of Alternatives, where they could exchange and learn from each other's experiences with methods and concepts related to SEA and Analysis of Alternatives in restrictions and authorisations. He mentioned that Eurometaux is hosting the first such meeting on 9 April 2013 and the observer would provide an outline of this event to the SEAC Secretariat for distribution to SEAC members.

The Chair proposed that a report on this meeting would be provided to SEAC at its next plenary meeting in June 2013. The Secretariat also noted that it supports this idea and would consider hosting such meeting at ECHA in the future.

## **9) Action points and main conclusions of SEAC-18**

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

## II. Main conclusions and action points

### MAIN CONCLUSIONS & ACTION POINTS - SEAC-18, 6 – 8 March 2013 (SEAC-18 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
<b>2. Adoption of the agenda</b>	
<p>The agenda was adopted with one addition under AOB.</p>	<p><b>SECR</b> to upload the adopted agenda to SEAC CIRCABC IG as part of the meeting minutes.</p>
<b>3. Declarations of conflicts of interest to the Agenda</b>	
<p>Conflicts of interest have been declared and will be taken to the minutes.</p>	
<b>4. Report from other ECHA bodies and activities</b>	
<i>a) Report on SEAC-17 action points, written procedures and other ECHA bodies</i>	
<p>SEAC was informed on the status of the action points of SEAC-17. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/18/2013/01), including the oral report from the Commission on SEAC related developments in REACH Committee and on 4 December 2012 workshop about synergies between REACH and other EU regulations.</p> <p>In addition, SEAC took note of the results of the Annual Satisfaction Survey and Accredited Stakeholder Workshop 2012 as well as the Chair's report from the teleinterviews conducted with SEAC members.</p>	<p><b>COM</b> to provide written report (if available) from the 4 December 2012 workshop on synergies between REACH and other EU regulations to be distributed to SEAC.</p> <p><b>SECR</b> to review and analyse the results of the Annual Satisfaction Survey and Accredited Stakeholder Workshop 2012 and plan possible follow-up actions.</p> <p><b>SEAC Members</b> and <b>STOs</b> to help SECR to identify what kind of training in the context of SEAC work they would see useful.</p> <p><b>Chair</b> to organise similar teleinterviews with SEAC STOs as were organised with SEAC members.</p>
<b>5. Restrictions</b>	
<b>5.1 General restriction issues</b>	
<i>b) Update on review of the restriction process</i>	
<p>SEAC took note of a presentation by a SEAC member on the basis for SEAC to form an opinion.</p>	
<b>5.2 Restriction Annex XV dossiers</b>	
<i>a) Chromium VI – 3<sup>rd</sup> version of SEAC final draft opinion</i>	
<p>SEAC rapporteurs presented the modified second version of the SEAC final opinion.</p>	<p><b>SECR</b> to take the statements of the two SEAC members into the minutes of SEAC-18.</p>

<p>SEAC discussed the main changes made to the opinion of SEAC.</p> <p>SEAC adopted the SEAC final opinion by consensus.</p> <p>SEAC took note of the Background Document (BD) and ORCOM to this opinion.</p>	<p><b>Rapporteurs</b> and <b>SECR</b> to make necessary editorial changes to the BD and ORCOM to make them in line with the adopted SEAC opinion.</p> <p><b>SECR</b> to publish the final opinion of SEAC on CrVI on the ECHA website and to forward the final opinions of SEAC and RAC and the BD to the Commission.</p>
<p><i>b) Dichlorobenzene – 4<sup>th</sup> version of SEAC draft opinion</i></p>	
<p>SEAC rapporteurs presented the modified fourth version of the SEAC draft opinion.</p> <p>SEAC discussed the main changes made to the draft opinion of SEAC.</p> <p>SEAC agreed on the draft opinion on 1,4 DCB by consensus.</p>	<p><b>Rapporteurs</b> and <b>SECR</b> to make editorial changes to the opinion in accordance with the discussion.</p> <p><b>Rapporteurs</b> and <b>SECR</b> to ensure that the supportive documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.</p> <p><b>SECR</b> to launch a public consultation on the SEAC draft opinion.</p>
<p><i>c) Nonylphenol – outcome of the conformity check</i></p>	
<p>SEAC agreed that the dossier does not conform to the Annex XV requirements by simple majority. Dissenting views will be reflected in the SEAC-18 minutes.</p> <p>SEAC discussed the recommendations to the dossier submitter.</p>	<p><b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC.</p> <p><b>SECR</b> to inform the dossier submitter on the outcome of the conformity check.</p> <p><b>SECR</b> to review involvement of the dossier submitter in discussions on conformity check.</p>
<p><i>d) Lead in consumer articles – outcome of the conformity check</i></p>	
<p>SEAC agreed that the dossier conforms to the Annex XV requirements and took note of the recommendations to the dossier submitter.</p>	<p><b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC.</p> <p><b>SECR</b> to inform the dossier submitter on the outcome of the conformity check.</p> <p><b>SEAC members</b> to send additional suggestions for recommendations to the rapporteurs by the first rapporteurs' dialogue.</p>
<p><b>5.3 Appointment of (co-)rapporteurs for restriction dossiers</b></p>	
<p>SEAC took note of the pool of (co-) rapporteurs for the restriction dossier on cadmium (meeting document SEAC/18/2013/04 CONFIDENTIAL).</p>	<p>SEAC members to volunteer for (co-) rapporteurship on cadmium to be included in the pool.</p>

<b>6. Authorisations</b>	
a) <i>Capacity building</i>	
<ul style="list-style-type: none"> <li><i>Economic feasibility</i></li> </ul>	
SEAC agreed on the economic feasibility concept outlined in the meeting document SEAC/18/2013/03.	<b>SECR</b> to consider what is the best way to communicate the concept to possible applicants.
<b>7. SEAC Manual of conclusions and recommendations</b>	
SEAC discussed the proposal for SEAC Manual of conclusions and recommendations.	<b>SECR</b> to continue collecting conclusions in the Manual and to table the revised document to SEAC, when substantial update has been made.
<b>9. Action points and main conclusion of SEAC-18</b>	
SEAC adopted the action points and main conclusions of SEAC-18.	<b>SECR</b> to upload the action points and main conclusions to CIRCABC IG.

### III. List of Attendees

#### SEAC-18

<b>SEAC Members</b>
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
CSERGO Robert
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIGLIARO Karine
FOCK Lars
FURLAN Janez
GEORGIU Stavros
GULBRANDSEN Magnus Utne
KIISKI Johanna
KNOFLACH Georg
LADOPOULOU Angela
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SKARŽINSKAS Vitalius
THIELE Karen
THORS Åsa
TIRCHILA Liliana Luminita
VOIVONTAS Dimosthenis

<b>ECHA staff</b>
DUBOURG Richard
JACQUEMIN Katline
KIOKIAS Sotirios
KIOSK-BIENKO Joanna
KIVELA Kalle
LUDBORZS Arnis
MALM Jukka
MATTHES Jochen
MERKOURAKIS Spyridon
MOTTET Denis
ORISPÄÄ Katja
ÖBERG Tomas
PELTOLA Jukka

<b>Advisors, Invited Experts, Dossier Submitters (DS) &amp; Observers</b>
CASTELLI Stefano (Invited Expert, IT)
COGEN Simon (Advisor to J-P. Fayaerts)
D'AMICO Flaviano (Invited Expert, IT)
GOLOVACIOVA Llona (Advisor to V. Skarzinskas)
HENNIG Philipp (Advisor to K. Thiele)
KORHONEN Hanna (Advisor to J. Kiiski)
LESTANDER Dag (Nonylphenol DS representative)
PUES Jonathan (Advisor to C. Dantine)
SCHOU Jorgen Peter (Advisor to L. Fock)
SLETTEN Thea Marcelia (Advisor to M.U.Gulbrandsen)
VASS Anne-Marie (Lead and lead compounds DS representative)
VERHOEVEN Julia (Advisor to C. Luttikhuizen)
CEDERBERG Inger (Nonylphenol DS representative, via Webex)
CARLSSON Mattias (Lead and lead compounds DS representative, via Webex)

<b>Stakeholder Observers</b>
BUONSANTE Vito (EEB)
HOLLAND MIKE (EAERE)
JANOSI Amaya (CEFIC)
MOUCHEBOEUF Jean (UEAPME)
WATERSCHOOT Hugo (EUROMETAUX)

<b>Representative of the European Commission</b>
BENGYUZOV Manol (DG ENTR)
ZIELINSKI Janusz (DG ENV)
ROZWADOWSKI Jacek (DG ENTR)

<b>RAC (co)-Rapporteurs</b>
DUNAUSKIENE Lina
DUNGEY Stephen
JENSEN Frank
MULLOOLY Yvonne
SCHLÜTER Urs
SMITH Andrew
STOLZENBERG Hans-Christian

PENNESE Daniele
RODRIGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
SADAM Diana
SHUQOM Natasha
SOSNOWSKI Piotr
STOYANOVA Evgenia
THUVANDER Ann
VAINIO Matti
VAN HAELST Anniek

**The following participants (in addition to the list of attendees above) attended the Joint RAC-SEAC Session**

<b>RAC members</b>
BARANSKI Boguslaw
BARRON Thomasina
BJORGE Christine
BORGES Teresa
BRANISTEANU Radu
CARVALHO João
DUNAUSKIENE Lina
DUNGEY Stephen
GREIM Helmut
GRUIZ Katalin
HAKKERT Betty
JENSEN Frank
KADIKIS Normunds
KAPELARI Sonja
KORATI Safia
LEINONEN Riitta
LUND Bert-Ove
MULLOOLY Yvonne
PARIS Pietro
PASQUIER Elodie
PINA Benjamin
POLAKOVICOVA Helena
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SCHLUETER Urs
SCHULTE Agnes
SMITH Andrew

<b>Advisors (to the RAC members)</b>
JANONYTE Agne (Dunauskiene) advisor for CLH Rapporteurs for nitric acid
KORHONEN Hanna (Leinonen)
MAHIOUT Selma (Leinonen)
Mc MICKAN Sinead (Mullooly)
NUNES Laura (Tadeo)advisor for CLH Rapporteurs for tembotrione
PAPPONEN Hinni (Leinonen)
PECZKOWSKA Beata (Baranski) advisor for CLH Rapporteurs for flonicamid, nitric acid and tricalcium
ROMOLI Debora (Paris)
SMITH Helen (Smith)
STARKE Sue-Martina (advisor to RAC member Hans-Christian Stolzenberg, via Webex)

<b>Commission observers</b>
GARCIA-JOHN Enrique (Commission observer (ENTR) for restrictions, via Webex)
SCAZZOLA Roberto (DG ENTR)
STRECK Georg (Commission observer (ENTR) for authorisations, via Webex)

<b>Stakeholder observers</b>
HENNES Christa (ECETOC)
ANNYS Erwin (CEFIC)
SANTOS Tatiana (EEB)
VEROUGSTRAETE Violaine (Eurometaux)

<b>Other observers</b>
VARNAI Veda (Croatian observer)

<b>Invited Experts</b>
GABBERT Silke

SOERENSEN Peter
SPETSERIS Nikolaos
STOLZENBERG Hans-Christian
TADEO José Luis
TSITSIMPIKOU Christina
Van der HAGEN Marianne
VIVIER Stéphanie

<b>ECHA staff</b>
PELTOLA-THIES Johanna

#### **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**

Final Draft Agenda	<i>SEAC/A/18/2013</i>
Report from other ECHA bodies and activities (AP 4.a)	<i>SEAC/18/2013/01</i>
Update on the review of the restriction process (AP 5.1.b)	<i>SEAC/18/2013/05</i>
Appointment of (co-)rapporteurs for restriction dossiers (AP 5.3)	<i>SEAC/18/2013/02</i>
Capacity building, Economic feasibility (AP 6.a)	<i>SEAC/18/2013/03</i>
SEAC Manual of conclusions and recommendations (AP 7)	<i>SEAC/18/2013/04</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>	<b><u>Interest declared</u></b>
FOCK Lars	5.2a Chromium VI	Dossier submitter
SCHOU Jorgen Peter	5.2a Chromium VI	Dossier submitter
THORS Åsa	5.2c Nonylphenol 5.2d Lead and lead compounds	Dossier submitter
LESTANDER Dag	5.2c Nonylphenol	Dossier submitter
VASS Anne-Marie	5.2d Lead and lead compounds	Dossier submitter

## Final Agenda

### 18<sup>th</sup> meeting of the Committee for Socio-economic Analysis

**6-8 March 2013**

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

**6 March: starts at 14:00**

**8 March: ends at 13:00**

**Item 1 – Welcome and Apologies**

**Item 2 – Adoption of the Agenda**

**SEAC/A/18/2013**  
**For adoption**

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

**Item 4 – Report from other ECHA bodies and activities**

- a) Report on SEAC-17 action points, written procedures and other ECHA bodies  
**SEAC/18/2013/01**  
**For information**

**Item 5 – Restrictions**

#### 5.1 General restriction issues

- a) Update on intended restriction dossiers  
**For information**
- b) Update on the review of the restriction process  
**SEAC/18/2013/05**  
**For information**

## 5.2 Restriction Annex XV dossiers

- a) Chromium VI – 2<sup>nd</sup> version of SEAC final draft opinion  
*For adoption*
- b) Dichlorobenzene – 4<sup>th</sup> version of SEAC draft opinion  
*For agreement*
- c) Nonylphenol – outcome of the conformity check  
*For agreement*
- d) Lead in consumer articles – outcome of the conformity check  
*For agreement*

## 5.3 Appointment of (co-)rapporteurs for restriction dossiers

**SEAC/18/2013/02**  
**(room document)**  
**For information**

### Item 6 – Authorisations

- a) Capacity building
- Economic feasibility  
**SEAC/18/2013/03**  
**For agreement**
  - Valuation of PBTs  
**For information**

### Item 7 – SEAC Manual of conclusions and recommendations

**SEAC/18/2013/04**  
**For discussion**

### Item 8 – AOB

- a) Update of the work plan
- b) Commission's conclusions on the Review of REACH
- c) Follow-up of the workshops on applications for authorisation  
**For information**

### Item 9 – Action points and main conclusions of SEAC-18

Table with Conclusions and Action points from SEAC-18  
**For adoption**