14 February 2013

SEAC/M/17/2012 FINAL

Final

Minutes of the 17th meeting of the Committee for Socio-economic Analysis

3 – 5 December 2012

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 seventeenth meeting of SEAC.

The Chair informed the Committee that apologies had been received from five members, and two stakeholder observers. Two invited experts, seven members' advisors present at the meeting as well as two representatives of the European Commission, one international observer, a Croatian observer, a Dutch observer, observers of six stakeholder organisations and one dossier submitter representative were introduced. The Chair informed the participants that two SEAC members, one advisor to a SEAC member, three RAC (co-)rapporteurs, one advisor to a RAC rapporteur and one representative of the European Commission 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-17.

The Agenda was adopted without any further changes. 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 6.2. The 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

Report on SEAC-16 action points, written procedures and other ECHA bodies

The Chair reported that the majority of the action points of SEAC-16 had been completed or would be followed up during the ongoing SEAC-17 meeting (such as economic feasibility, reporting back from the discussions with the Commission about the remits of RAC and SEAC with suggestions for actions, statistics on the time spent by (co-) rapporteurs on processing the past restriction dossiers, etc). The update on the ECHA confidentiality policy for documentation will be provided to SEAC next year, due to the fact that it is not only related to SEAC, but also to the Committee for Risk Assessment (RAC) and the Member States Committee (MSC) and should be provided to all three Committees in parallel. The Chair also informed the participants of the plenary meeting that the General principles and guidance for Committee members was pending approval by ECHA's management and that the Management Board (MB) at its last meeting in September 2012 had adopted the provisional Eligibility criteria which would be revisited in due time.

The Chair then provided a brief report from the phone calls that he had had with the SEAC members (as a follow-up action from the discussion at SEAC-16 on Facilitation of plenary discussions and written commenting rounds). One member recommended the Secretariat to compile a written report from these phone calls that could be shared with the Committee. The Secretariat agreed to consider this suggestion.

The Chair informed the Committee that the final minutes of SEAC-16 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-16 minutes. The Chair mentioned that a general comment had been received from one SEAC member regarding the level of detail of the minutes of the Committee meetings. This member was then invited to explain his comments further. He was of the view that summaries in the meeting minutes were sometimes too brief, not giving sufficient background and context of the discussions. He emphasised the importance of the Committee being transparent to the outside world. Another member as well as one stakeholder observer expressed support to these views. It was agreed that the Secretariat would take into consideration the comments made in relation to the SEAC minutes while drafting the minutes from now on.

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). As the RAC-23 meeting had taken place on 27-30 November 2012 and had therefore not been covered in the above-mentioned report, the Secretariat provided a brief oral update on the issues discussed within RAC-23.

The representative of the Commission was then invited to update the Committee on SEAC related developments in the REACH Committee and in the CARACAL.

6) Restrictions

6.1) General restriction issues

a) Update on intended restriction dossiers

The Secretariat provided an update on upcoming restriction dossiers. As already informed in September 2012, there are currently two new substances in the Registry of Intentions:

- Lead and lead compounds in articles intended for consumer use prepared by Sweden and
- 1-Methyl-2-pyrrolidone (NMP) prepared by the Netherlands.

The lead dossier will be submitted to ECHA in January and the NMP dossier in April 2013.

The Secretariat also informed SEAC that the nonylphenol restriction dossier was resubmitted to ECHA on 26 November 2012. However, the processing of this dossier will start with the next (January 2013) submission window, which means that the conformity check process in the Committees will start in February and the agreement on the conformity would have to be reached at the March 2013 plenary.

In addition, SEAC was informed that ECHA had received a request to prepare an Annex XV restriction dossier on cadmium and its compounds used in plastic materials that are not covered by the existing entry 23 and to extend the existing restriction to placing on the market of paints containing cadmium.

b) Update on the review of the restriction process

The Chair reminded the participants that at the SEAC-15 meeting in June 2012, it had been agreed that the Secretariat would discuss with the Commission the remits of RAC and SEAC and would report to SEAC of this discussion after the clarification with possible suggestions for actions. The Secretariat introduced a note that had been produced to

address this request (distributed to the Committee as the meeting document SEAC/17/2012/03) and had been agreed with the Commission services. The Secretariat explained 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 (based on Article 70 of the REACH Regulation). 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. Furthermore, if RAC was of the opinion that there is no risk that needs to be addressed and thus no risk to be reduced, there would be no human health or environmental benefits. A restriction would be expected to incur costs to the society, and therefore it is relevant to provide an opinion on the assessment of those costs, as this is necessary for the further decision making process by the Commission. It has been concluded in the note that it is not possible for SEAC to have a basis for an opinion and – in particular – support a restriction proposal if RAC has concluded that the risks are controlled. To facilitate the decision making in this case it was proposed to the Committee to amend the opinion template for restriction proposals as follows: the sentence *"Therefore there is not a sufficient justification for a restriction and SEAC has no basis to form an opinion."* changed to *"Therefore there is not a sufficient justification for a restriction and SEAC has no basis to support the proposed restriction."*

Two SEAC members and an observer expressed the opinion that even if RAC concludes that there is no risk, there might be other reasons (e.g. societal) for SEAC to consider the restriction justified. They emphasised that RAC would not conclude that there is no risk, but that there is no *unacceptable* risk. Both members agreed with the proposed change to the opinion template, however, they felt that more debate is needed on the issue between the Committees, the Secretariat and the Commission. The Secretariat pointed out that the opinions of RAC and SEAC should be consistent. The Secretariat also drew the attention of SEAC to the fact that the word "unacceptable" is used not in relation to the Committees' opinions but to the Commission's decisions in the REACH Regulation. One SEAC member proposed to prepare a discussion note and a presentation on this issue for the next SEAC plenary meeting in March 2013. An article related to this topic had already been distributed by the member for this SEAC-17 meeting and briefly explained during the meeting.

SEAC agreed that the Secretariat would modify the opinion template as proposed in the meeting document and would upload the revised template to CIRCABC.

6.2) Restriction Annex XV dossiers

a) Phthalates – discussion on the 2nd version of SEAC opinion and adoption of SEAC opinion

The Chair reminded the participants that the SEAC draft opinion agreed on in June 2012 had been published for 60 days public consultation. The consultation period ended on 3 September 2012 and in total ten comments were received. As the RAC opinion diverged significantly from the restriction suggested, the deadline for the opinion of SEAC had been extended by 90 days (based on Article 71(3) of the REACH Regulation) until 16 December 2012. The comments from the public consultation were discussed at the SEAC meeting in September. After that meeting, the SEAC (co-)rapporteurs submitted the 1st version of the SEAC final opinion and the ORCOM on the comments from public consultation, which were provided to SEAC for written comments. Following from that the 2nd version of the SEAC opinion was submitted to the Committee prior to the current SEAC meeting.

The SEAC (co-)rapporteurs gave an overview of the comments received from SEAC members and one stakeholder observer on the 1st version of the SEAC final opinion. With the help of these comments the text of the justification of the opinion had been made clearer and more accurate. The (co-)rapporteurs also explained that the comment from the public consultation on the SEAC draft opinion stating that the amount of phthalates in imported articles is higher than expected was not considered of such nature that it would require changes to the projections of the baseline scenarios in the Background Document

(BD). While the SEAC draft opinion was based on the RAC opinion adopted in June saying that the available data does not indicate a current (2012) risk from combined exposure to the four phthalates, the final opinion of SEAC did not change.

During the following discussion one more suggestion for the clarification of the justification of the opinion was made. The (co-)rapporteurs agreed to modify the text of the justification accordingly.

SEAC adopted the SEAC final opinion by consensus. The SEAC final opinion states that taking into account RAC's conclusions that the proposed restriction is not justified because the available data do not indicate that currently (2012) there is a risk from combined exposure to the four phthalates and that the regulatory requirements and consequent reduction in use are further reducing the risk, as will the authorisation requirements imposed on these phthalates in the next few years, SEAC has no basis to support the proposed restriction. SEAC took note of the BD and ORCOM to this opinion. The Chair noted that the Secretariat and the (co-)rapporteurs would make necessary changes to the BD and ORCOM to make them in line with the adopted SEAC opinion. The Committee was informed that the Secretariat would publish the final opinion of SEAC on phthalates on the ECHA website and forward the final opinions of SEAC and RAC and the BD to the Commission.

b) Chromium VI – discussion on the 4th version of SEAC draft opinion and agreement on SEAC draft opinion

The Chair welcomed the Danish Dossier Submitter.

As background to the SEAC discussion, 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 relatively short, repetitive skin contact as well as longer term, repeated contact.

The Chair reminded SEAC that the restriction dossier on chromium (VI) had been submitted for the public consultation on 16 March 2012. The public consultation ended on 16 September 2012. The SEAC written commenting round on the 3rd version of the SEAC draft opinion finished on 6 November 2012 (five SEAC members submitted comments). The 3rd rapporteurs' dialogue took place on 30 October 2012. The 4th version of the SEAC draft opinion, the BD and the SEAC ORCOM were uploaded to CIRCABC on 9 November 2012. The commenting round was open until 20 November to collect comments and proposals for discussion at SEAC-17.

The Chair welcomed the RAC rapporteur who was connected via phone and asked him to present the RAC opinion adopted at RAC-23.

The RAC rapporteur informed SEAC that within the RAC-23 meeting RAC had concluded on the hazard profile, the exposure assessment and that there is a risk related to use of leather articles containing chromium (VI). RAC had discussed prevalence values taking into consideration uncertainties and key assumptions in the estimates, which were based on expert judgement. RAC had assumed that the Danish data were representative to the whole EU. Furthermore, RAC had used the 10-years prevalence value based on the CE-DUR method and had multiplied it by a factor of 4.2 to reflect the average estimated lifetime of patients after the onset of the allergy (42 years). RAC had also agreed with the Dossier Submitter's estimation that the effectiveness of the restriction would be 80%. This means that even if the concentration of chromium (VI) in leather articles was below 3 mg/kg some people could still suffer from their chromium (VI) allergy, if exposed. During the discussion RAC had recognised that the prevalence estimates related to chromium-induced allergy contained uncertainties (which consequently affect the health impact assessment related to exposure to chromium (VI)). Therefore, RAC had decided

to give a range of prevalence values to reflect various uncertainties in the prevalence estimate.

The Chair then invited the SEAC (co-)rapporteurs to present the 4th version of the SEAC draft opinion.

Cost assessment

The Dossier Submitter estimated the cost of the proposed restriction to be from €83 to €100 million per year. The SEAC (co-)rapporteurs generally concurred with this estimation but they gave several reasons why the value might be overestimated. The Secretariat informed the Committee that calculation of the cost had been based on the information provided by chemicals suppliers and industry associations. The Dossier Submitter added that the main cost for tanneries is related to additional chemicals added during the tanning process.

One SEAC member was of the opinion that the basis of the cost estimation was inadequate given that it was based on a simple calculation multiplying 3 cost component numbers together, and furthermore that it was not possible to scrutinise how these individual components found in the draft opinion and the Background Document had been derived. As the primary sources of the information were not documented in sufficient detail, it was not possible to assess the reliability and validity of the information. The member also questioned if the turnover could be used as a basis for estimating the additional costs of leather products since turnover and production costs are not equivalent. Another SEAC member expressed the view that if the current information is the best available for the Committee, the uncertainties should be clearly reported in the justification of the opinion.

The rapporteur informed the participants that the calculation of the cost had been based on the companies' turnover as the production cost had not been available (and is difficult to get in general) and that the costs therefore in principle are a bit overestimated. The Secretariat reminded SEAC that in the public consultation there had been a question asking for more information on the costs. However, no contributions were received.

A SEAC member considered that the estimated cost of €100 million per annum was relatively high. Therefore, the member explained that the Committee should bear this in mind when considering whether the analysis underpinning the restriction is proportionate and furthermore that given this scale of costs, the Committee should have confidence with the assessment before giving a supportive opinion for the restriction. The Secretariat reminded the Committee that the cost would be shared by all 27 EU Members States (and actually consumers).

Benefit calculation

One SEAC member questioned the estimation of the number of lost working days and the related production loss due to chromate allergy. In his opinion the production loss based on the labour costs would overestimate production disturbance losses as the production would continue during the absence of the worker. Furthermore, he mentioned that people would adapt their behaviour to avoid allergy symptoms over time, and the number of symptom days, as well as healthcare costs, would therefore decrease over time. He did not see that this was considered in the calculations. This view was supported by another SEAC member and by a stakeholder observer. The Secretariat informed the Committee that the estimated number of symptom days and healthcare costs are estimated for an average year. The SEAC member pointed out that this was an assumption.

The rapporteur reported that he had consulted some public insurance companies concerning the estimated healthcare costs. According to insurance companies, it is difficult to estimate the healthcare cost accurately but generally the estimation made by the Dossier Submitter was in their view realistic. The rapporteur added that, in case of sickness and consequent absence, the employer would need to have to find a back-up to keep the production running and this would create additional cost.

The rapporteur clarified that the patients (new cases) are assumed to suffer allergy symptoms for 125 days per year on the average. One SEAC member questioned the basis of this figure and pointed to the lack of empirical evidence to highlight his concerns. The rapporteur presented also information supporting the estimation of the willingness to pay (WTP) to avoid a symptom day of €15. One SEAC member questioned this value pointing out that this value was for entirely different illness symptoms (related to air pollution) than those related to chromate allergy and presented evidence from a study by Navrud (one of the authors of the study deriving the €15 figure) that the WTP per day was not in fact constant (as assumed by the dossier submitter), but would diminish with increasing number of symptom days. The Dossier Submitter responded that the WTP value used in the report had been based on information on air pollution which estimates WTP in 1993 to €14 per day and that later studies used in the CAFE process suggest €38 per day (cf. BD, page 117). In the RPA report "Assessment of the impact of the new chemicals policy on occupational health", 1993, the WTP value for eye itching was estimated to €17 per day. The Secretariat mentioned that additional literature by Lundberg is supporting the estimation of welfare loss presented in the BD. However, one SEAC member raised concerns on the reliability of the method used in the study. The Secretariat also highlighted that the SEA Guidance Document on Restrictions includes WTP estimates to symptoms as well as restricted activity days. These are recommended reference values and could be used if more precise information is not available. The Secretariat added that overall the values in the Guidance document and in the estimates made by the Dossier Submitter are in a similar range.

Prevalence estimation

The SEAC rapporteur presented available information and different methods to estimate the prevalence of chromium allergy in the general population. He noted that the information on prevalence had been assessed by RAC and that SEAC should build their assessment on the prevalence used in the RAC opinion.

One SEAC member was of the opinion that RAC had overestimated the prevalence. He presented the uncertainties in the assessment of RAC and gave also an alternative calculation resulting in a lower end estimate of the prevalence. His main question related to the assumption the Dossier Submitter and RAC had made that the proportion of individuals with positive reactions to chromates in the patch test reported by the Danish Contact Dermatitis Group (DCDG) in the publication of the CE-DUR method by Thyssen et al (2007) would be representative of the prevalence in the whole population. One of the main problems according to the member was that statistically unsupportable inferences were made using this sample data to derive population estimates. In particular, the sample whilst representative of cases of "all contact" allergy were in his opinion not representative of individual allergens, since for example individuals with severe dermatitis could be expected to seek medical care from the more specialised clinics included in the DCDG. He also declared that the study author, in correspondence with the member, had indicated that the CE-DUR methodology was not suited to estimate the prevalence of individual allergens. The study author has suggested that to estimate such prevalences, cross-sectional approaches should be used. Some members supported these critical views regarding the representativeness.

The Secretariat clarified that the calculations presented by the SEAC member to illustrate his concerns with the use of the CE-DUR approach for a specific allergen were different to their understanding of the RAC's use of the CE-DUR-based approach, with the member's calculations being based on a different interpretation of the sampling and other extrapolation parameters of the RAC approach. The calculations presented by the member were based on testing data from 10 out of 89 dermatology clinics in DK (i.e. the clinics of the DCDG network). Only reported positive cases from the 10 clinics were used to illustrate a minimum 'lower bound' number of counted cases that could be identified without having to make assumptions on representativity of data for patients who may have been tested in other clinics. The Secretariat, on the other hand, stated that in order to estimate the population prevalence rate the proportion of positive cases recorded by the DCDG network could be applied across all of the 89 clinics. On the issue of sample selection of patients to be tested and the

representativeness of the clinical sample of the network, the Secretariat agreed to consider seeking further clarification from the DCDG network.

One member of SEAC also described the other main problems with the estimates of prevalence, including for example, an internally inconsistent use of the extrapolation factor of 4.2; the lack of corroborative evidence for the population prevalence estimates; and questions regarding the causality of chromate allergy from leather articles, amongst others.

After considering the information provided by the Secretariat and taking the extrapolation factor for duration of the allergy of 4.2 (used by RAC) into account the results using the alternative calculation would be similar to the prevalence estimated by RAC, with the remaining difference being which criteria one used for deciding on a positive reaction. One SEAC member pointed out the inconsistency that the extrapolation factor used in the RAC estimation had not been proposed for use in the original analysis by the Dossier Submitter.

The SEAC member made a plea to the Dossier Submitter or the Secretariat to confirm the assumption of representativity made by the Secretariat with the Danish dermatology clinics in question. The Secretariat agreed to consider this request.

The Secretariat noted that there are uncertainties in the prevalence estimate. However, it was stressed that the Dossier Submitter had been working with a well-established dermatologist to build their assumptions on clinical experience. Due to the uncertainties (in particular related to the criteria for positive tests) RAC had decided to give a range of prevalence estimations. If SEAC would choose to base its opinion on other considerations than made by RAC these would have to be solid and well justified.

SEAC also discussed the assumption that 45% of the present incidence of chromium allergy are caused by leather articles. According to one SEAC member a publication by Carøe (2010) concluded that only around 36% of the cases are caused by leather articles, and that the study authors (which included one of the authors of the study that derived the 45% figure) had also raised questions regarding the causality of chromate allergy as a result of leather exposure. The rapporteur replied that the Dossier Submitter's expert in dermatology was of the opinion that the majority of the remaining 65% of cases which were reported as unknown origin could in fact be caused by chromium (VI) in leather articles. In addition, there is information from other Member States that the percentage of cases allocated to leather could be higher than 45% (even above 80%).

Conclusions

Following some clarifications in the draft opinion the majority of SEAC members supported the draft opinion in its revised version. Five members did not support the draft opinion, in particular due to the uncertainty and lack of proportionate analysis related to the cost-benefit estimation. One of the members not supporting the draft opinion observed that this was not the same as not supporting the restriction proposal.

The Chair concluded that the draft opinion on the restriction of chromium (VI) in leather articles was agreed by SEAC by absolute majority (a majority of all members having the right to vote).

c) Dichlorobenzene – 2nd version of 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 Dossier Submitter is ECHA. The scope of the restriction proposal is to restrict consumer and professional use of 1,4 DCB. The draft Forum advice was made available to RAC and SEAC on 5 October. The public consultation on the restriction dossier on 1,4 DCB will close on 19 December 2012. SEAC is expected to agree on its draft opinion in March 2013 and to adopt its final opinion in June 2013.

The advisor to the RAC rapporteur presented to SEAC the basis for and elements of the RAC opinion. The risk assessment by RAC had concluded that a risk of concern exists for domestic users under worst case conditions. No risk of concern had been identified for professional users. RAC had not supported the link between nasal lesions and respiratory effects. With regard to the alternatives, RAC had raised concern that the proposed restriction may lead to increased use of camphor products by professionals.

The SEAC (co-)rapporteurs presented the 2nd version of the draft opinion. Based on the draft Forum advice a concentration limit "equal to or greater than 1%" had been included in the wording of the restriction. The (co-)rapporteurs then asked SEAC whether the domestic restriction can be supported without quantified evidence of benefits since the domestic use restriction is associated with cost savings due to cheaper alternatives. The SEAC (co-)rapporteurs concluded that, following the assessment by RAC, there is no basis to support restriction for professional use.

SEAC members discussed the current draft and supported the (co-)rapporteurs' conclusion that a domestic restriction can be supported without quantified evidence of benefits. Several SEAC members also expressed their concern that the restriction on professional use would not be supported, especially because this covers the majority of the use in Europe. One member observed that the worst case RCR estimation for workers is above one. He expressed concern why RAC had despite of that concluded that there is no risk for workers, and asked for clarification. He also questioned the correctness of the estimated number of toilet attendants in Europe, which seems very low. In addition, some SEAC members stated that from an enforcement point of view it may be more efficient to restrict both uses at the same time. The level of exposure of the toilet attendants was discussed. The Chair concluded that exposure calculations would fall within the remits of RAC, and should there be any further changes by RAC in relation to the risks to the professional use, the SEAC (co-)rapporteurs were asked to be prepared for possible amendments in the opinion.

The SEAC (co-)rapporteurs were asked to update the draft opinion into the 3rd version based on the discussions and to bring the BD in line with the 3rd version of the draft opinion for information of SEAC members in due course. SEAC is expected to agree on its draft opinion at the March 2013 plenary.

6.3 Appointment of (co-)rapporteurs for restriction dossiers

SEAC agreed on the appointment of (co-)rapporteurs for the two upcoming restriction dossiers as outlined in the meeting document SEAC/17/2012/04 CONFIDENTIAL: 1-methyl-2-pyrrolidone (NMP) expected to be submitted (by the Netherlands) in April 2013 and lead and lead compounds in articles intended for consumer use (by Sweden) to be submitted in January 2013.

6.4 (Co-)rapporteurs' workload on processing the first restriction dossiers

The Chair mentioned that this topic had been added to the agenda of the meeting based on the request made by SEAC members at the SEAC-15 meeting. The Secretariat then presented a short overview of the time spent by SEAC (co-)rapporteurs on processing the first restriction dossiers. This overview had been compiled based on the timesheets submitted to ECHA by the (co-)rapporteurs of the first four restriction dossiers the processing of which had been completed by now – DMF, lead in jewellery, mercury in measuring devices and phenyl mercury compounds. The Secretariat informed the Committee that this issue is under consideration by the MB in the framework of the review of its Decision on the financial arrangements for transfer of a proportion of fees to the MSs.

The Secretariat pointed out that both the (co-)rapporteurs and the Secretariat tend to spend too much time to give an opinion and suggested to think where it would be possible to cut the time spent and become more efficient. However, it is natural that more time is spent on the first opinions, as the process is new.

7) Authorisations

a) Capacity building

- **Economic feasibility**

The Chair reminded the Committee that economic feasibility had been discussed at the 13th, 14th and 16th meetings of SEAC. For this SEAC-17 meeting, a note was produced by the Secretariat providing a summary state of play of the discussions on the issue of economic feasibility as well as response to comments received from SEAC members following the last discussion at SEAC-16. On 3 December, a breakout group meeting was organised for interested SEAC members to discuss the issues related to economic feasibility identified in the note. The Secretariat then presented the conclusions of the breakout group on how SEAC will scrutinize economic feasibility.

Several members considered the presentation to be a good summary of the discussion of the breakout group. An industry stakeholder observer stressed the importance of the issue for stakeholders, as up to now there has been very limited guidance on the issue of economic feasibility. He also made a suggestion not to assume upfront that applicants will always overestimate the costs, but to phrase it in more neutral way. It was also questioned which perspective is expected to be taken by the applicant for the review of alternatives (his own or societal). The Secretariat replied that the analysis of alternatives should be made from the applicant's point of view, but benefits and risks should be assessed from the societal perspective. One member expressed the view that there is probably an incentive for companies to overestimate costs and not to provide complete information regarding alternatives. He stressed the importance of public consultation to acquire information on alternatives. This member also asked at what point in the process it would be possible to challenge the applicants as to whether all alternatives have been considered or not. The Secretariat responded that the possibilities to communicate with the applicants would be discussed under the next agenda point (7b). One member thought that the slides presented could also be applied to technical feasibility, as economic and technical feasibility are interlinked.

It was agreed that the Secretariat would draft a note on the basis of the slides presented and the discussion at the meeting and would table a note for agreement at the next SEAC-18 meeting.

b) Participation of case-owners and stakeholder observers in opinion development process

The Secretariat presented the document endorsed by the ECHA MB and discussed earlier in RAC and SEAC on ECHA's approach to the participation of applicants, third parties and stakeholder observers in the application for authorisation process, using a "trialogue" meeting of the various parties (SEAC/17/2012/06).

SEAC members expressed the need to well establish beforehand how the information expressed during the trialogue would be reported on in the plenary meeting. The Secretariat replied that just as for the non-confidential briefing of stakeholder observers in open sessions, SEAC would receive reporting from the trialogues.

The Commission observer thanked the Secretariat for the good co-operation in developing the document. Concerning Annex I that outlines an answer to the question of what is confidential business information, he suggested to add also Article 118 of the REACH Regulation as a basis. The Secretariat agreed to this addition.

The Chair concluded that an updated version of the document would be uploaded to the ECHA website in the first quarter of 2013.

c) Communication activities in preparation of authorisation applications – report from workshops

The Secretariat and the observer from Eurometaux provided a report from the following recent workshops on authorisation process:

- 1-2 October ECHA seminar on Authorisation Applications held in Helsinki;
- 2-3 October ECHA-CEFIC-Eurometaux co-organised workshop on analysing alternatives and socio-economic impacts in authorisation applications held in Helsinki;
- 12-13 November CEFIC-Eurometaux Technical Workshop on Authorisation Applications dedicated to Chromate Compounds held in Brussels.

8) SEAC Manual of Conclusions and recommendations

The Secretariat presented a proposal for new entries which had been prepared together with the (co-)rapporteurs of the past restriction dossiers as a proposal for an update of the SEAC Manual of conclusions and recommendations (MoCR). SEAC members were asked to comment on the content of the MoCR in general via the CIRCABC newsgroup commenting round until 20 January 2013.

9) AOB

a) Update of the work plan

The Secretariat provided an update of the work plan for the future months.

b) New concepts in the Commission's Impact Assessment methodology

The Commission observer provided a presentation on the new concepts in the Commission's Impact Assessment Methodology.

One SEAC member asked the Commission to report back at the next SEAC about the 4 December 2012 workshop on synergies between REACH and other Community regulations. The Commission agreed to this.

10) Action points and main conclusions of SEAC-17

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-17, 3 – 5 December 2012
(SEAC-17 meeting)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the agenda	
The agenda was adopted.	**SECR** to upload the adopted agenda to SEAC CIRCA IG as part of the meeting minutes.
3. Declarations of conflicts of interest to the Agenda	
Conflicts of interest have been declared and will be taken to the minutes.	
4. Report from other ECHA bodies and activities	
a) Report on SEAC-16 action points, written procedures and other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-16. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/17/2012/01), including the oral report from the Commission on SEAC related developments in REACH Committee and CARACAL.	**SECR** to take into consideration the comments made in relation to the SEAC minutes while drafting the minutes from now on.
6. Restrictions	
6.1 General restriction issues	
b) Update on review of the restriction process	
SEAC was informed about the discussion with the Commission on the remits of RAC and SEAC (SEAC/17/2012/03) and discussed the update proposal of the opinion template for restriction proposals.	**SECR** to modify the opinion template as agreed and to upload the revised template in CIRCABC IG.
6.2 Restriction Annex XV dossiers	
a) Phthalates – discussion on the 2nd version of SEAC final draft opinion	
SEAC adopted the SEAC final opinion by consensus. SEAC took note of the Background Document (BD) and ORCOM to this opinion.	**Rapporteurs** to make the final editorial changes to the justification of the opinion based on the discussions. **SECR** and **rapporteurs** to make necessary changes to the BD and ORCOM to make them in line with the adopted SEAC opinion. **SECR** to publish the final opinion of SEAC on phthalates on the ECHA website and to forward the final opinions of SEAC and RAC and the BD to the Commission.
b) Chromium VI – 4th version of SEAC draft opinion	

SEAC rapporteurs presented the fourth version of the draft opinion. SEAC discussed the main changes made to the draft opinion of SEAC. SEAC agreed on the draft opinion on Chromium VI by simple majority. Dissenting views will be reflected in the SEAC-17 minutes.	**Rapporteurs** to ensure together with the Secretariat that the supportive documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. **SECR** to launch a public consultation on the SEAC draft opinion.
c) Dichlorobenzene – 2nd version of SEAC draft opinion	
SEAC rapporteurs presented the second version of the SEAC draft opinion.	**Rapporteurs** to prepare the third version of the SEAC draft opinion in accordance with the discussion in SEAC and to provide this to the Secretariat for distribution. **Rapporteurs** together with the **SECR** to update the Background document to be in line with the revised SEAC draft opinion. **SECR** to distribute the revised draft opinion and the updated BD to SEAC for information.
6.3 Appointment of (co-)rapporteurs for restriction dossiers	
SEAC agreed on the appointment of (co-) rapporteurs for the substances NMP (1-mehthyl-2-pyrrolidone), lead and lead compounds in articles intended for consumer use (meeting document SEAC/17/2012/04 CONFIDENTIAL).	
6.4 (Co-)rapporteurs' workload on processing the first restriction dossiers	
SEAC took note of the presentation on the workload of the (co-)rapporteurs processing the first restriction dossiers.	
7. Authorisations	
a) Capacity building – Economic feasibility	
SEAC was presented with further clarifications by the Secretariat on the concept of economic feasibility as outlined in the meeting document SEAC/17/2012/05 as well as with the conclusions of the breakout group.	**SECR** to draft a note on the basis of the slides presented and the discussion at the meeting and to table a note for agreement at the next SEAC-18 meeting.
b) Participation of case-owners and stakeholder observers in opinion development process	
SEAC took note of the update on the participation of the case-owners and stakeholder observers in opinion development process as outlined in the	

meeting document SEAC/17/2012/06.	
c) Communication activities in preparation of authorisation applications – report from workshops	
SEAC was provided with the presentation on the workshops in relation to the preparation for authorisation process.	
8. SEAC Manual of conclusions and recommendations	
SEAC discussed the proposal for SEAC Manual of conclusions and recommendations.	**SECR** to open a Newsgroup for SEAC comments until 20 January 2013 and to report on progress at the next plenary.
10. Action points and main conclusion of SEAC-17	
SEAC adopted the action points and main conclusions of SEAC-17.	**SECR** to upload the action points and main conclusions to CIRCAbc IG.

III. List of Attendees

SEAC-17

SEAC Members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios (via Webex)
BRIGNON Jean-Marc
CSERGO Robert
DALTON Marie (via Webex)
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SKARŽINSKAS Vitalius
SLEZAK Zbigniew
STOYANOVA LAZAROVA Elina Velinova
THIELE Karen
THORS Åsa

ECHA staff
DUBOURG Richard
KIOKIAS Sotirios
KIOSK-BIENKO Joanna
KIVELA Kalle
LIPKOVA Adriana
MATTHES Jochen
MERKOURAKIS Spyridon
ORISPÄÄ Katja
ÖBERG Tomas
PARADA SUAREZ Diana
PELTOLA Jukka
RODRIGUEZ IGLIESIAS Pilar
SADAM Diana
SHUQOM Natasha
SOSNOWSKI Piotr
THUVANDER Ann
VAINIO Matti
VAN HAELST Anniek

Advisors, Dossier Submitters (DS) & Observers
CASTELLI Stefano (Invited Expert, IT)
CAVALIERI Luisa (Advisor to K. Fiore-Tardieu)
COGEN Simon (Advisot to J-P. Fayaerts)
D'AMICO Flaviano (Invited Expert, IT)
HENNIG Philipp (Advisor to K. Thiele)
KORHONEN Hanna (Advisor to J. Kiiski)
LESTANDER Dag (Advisor to A. Thors)
MCMICKAN Sinead (Advisor to RAC Member and rapporteur Y. Mullooly, via Webex)
POKRŠČANSKI LANDEKA Mirta (Observer, Croatia)
PŘICHYSTALOVÁ Radka (Observer, NL)
PUES Jonathan (Advisor to C. Dantinne)
VERHOEVEN Julia (Advisor to C. Luttikhuizen)

Stakeholder Observers
BRAATHEN Nils-Axel (OECD)
BUONSANTE Vito (EEB)
HOLLAND MIKE (EAERE)
JANOSI Amaya (CEFIC)
KUHN Ingolf (Business Europe)
MOUCHEBOEUF Jean (UEAPME)
WATERSCHOOT Hugo (EUROMETAUX)

Representatives of the European Commission
KUBICKI Michal
BENGYUZOV Manol (via Webex)
ZIELINSKI Janusz

RAC (co-)rapporteurs
PRONK Marja (via Webex)
SCHLÜTER Urs (via Webex)
SMITH Andrew (via Webex)

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

ANNEX I

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

Final Draft Agenda	*SEAC/A/17/2012*
Report from other ECHA bodies and activities (AP 4a)	*SEAC/17/2012/01*
Report on the participation of stakeholder organisations in the work of SEAC (period November 2011 - November 2012) and the Secretariat's proposal concerning admission of new stakeholder organisations as observers to SEAC (AP 5)	*SEAC/17/2012/02 (restricted)*
Update on the review of the restriction process (discussion note on the remits of RAC and SEAC) (AP 6.1b)	*SEAC/17/2012/03*
Recommendation to SEAC on the appointment of (co-)rapporteurs for restriction dossiers on NMP and lead and lead compounds (AP 6.3)	*SEAC/17/2012/04 (confidential)*
Economic feasibility (AP 7a)	*SEAC/17/2012/05*
Participation of case-owners and stakeholder observers in opinion development process (AP 7b)	*SEAC/17/2012/06*
SEAC Manual of conclusions and recommendations (AP 8)	*SEAC/17/2012/07*

ANNEX II

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):

Name of participant	**Agenda item**	**Interest declared**
FOCK Lars	6.2a Phthalates 6.2b Chromium VI	Dossier submitter
SLEZAK Zbigniew	6.2a Phthalates	Previous involvement

ANNEX III

3 December 2012
SEAC/A/17/2012

Final Agenda

17th meeting of the Committee for Socio-economic Analysis

3-5 December 2012
ECHA Conference Centre (Annankatu 18, Helsinki)
3 December: starts at 14:00
5 December: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/17/2012
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-16 action points, written procedures and other ECHA bodies
SEAC/17/2012/01
For information

Item 5 – Update of stakeholder participation in the work of SEAC (closed session)

SEAC/17/2012/02
For information and agreement

Item 6 – Restrictions

6.1 General restriction issues

a) Update on intended restriction dossiers
For information

b) Update on the review of the restriction process

SEAC/17/2012/03
For information

6.2 Restriction Annex XV dossiers

a) Phthalates – discussion on the 2nd version of SEAC final draft opinion

For adoption

b) Chromium VI – discussion on the 4th version of SEAC draft opinion

For agreement

c) Dichlorobenzene – discussion on the 2nd version of SEAC draft opinion

For discussion

6.3 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/17/2012/04
For agreement

6.4 (Co-)rapporteurs' workload on processing the first restriction dossiers

For information

Item 7 – Authorisations

a) Capacity building
   - Economic feasibility

SEAC/17/2012/05
For discussion

b) Participation of case-owners and stakeholder observers in opinion development process

SEAC/17/2012/06
For information

c) Communication activities in preparation of authorisation applications – report from workshops

For information

Item 8 – SEAC Manual of conclusions and recommendations

SEAC/17/2012/07 (room document)
For discussion

Item 9 – AOB

a) Update of the work plan
b) New concepts in the Commission's Impact Assessment methodology

For information

Item 10 – Action points and main conclusions of SEAC-17

Table with Conclusions and Action points from SEAC-17

For adoption