

27 February 2014

SEAC/M/21/2013 FINAL

Final

Minutes of the 21st meeting of the Committee for Socio-economic Analysis

10 – 12 December 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 twenty-first meeting of SEAC.

Geert Dancet, Executive Director of ECHA, addressed SEAC on the occasion of reaching the twenty-first meeting of the Committee. He thanked members for the work done so far, pointing out that socio-economic analysis is a new element introduced by REACH and SEAC basically had to start from scratch more than five years ago and do a lot of pioneering work. He stressed the importance of the co-operation between RAC and SEAC for both restriction and the authorisation processes and noted that the interface and dialogue between these two Committees had increased. The Executive Director also encouraged members, together with the ECHA Secretariat, to continue working on maximising efficiency, as this is necessary not only to enable ECHA and the Committees to cope with increasing workload but also to keep them focussed on elements of the highest regulatory relevance. He explained that the functioning and the challenges of the ECHA Committees, in particular the need for rapporteurs in RAC and SEAC, had recently been discussed in the ECHA Management Board and in the MSCA Directors' meeting and had been addressed as an important issue affecting the success of implementation of REACH. As a result, MSCAs are requested to commit a minimum of 50% work time for new or re-nominated members and to provide adequate support to the Committee members. Finally, he also thanked the observers from the Commission and the regular stakeholder observers for their valuable contributions to the SEAC plenary discussions.

The Chair informed the Committee that apologies had been received from three members and one international observer. Seven members' advisors present at the meeting, as well as two representatives of the European Commission and observers of seven stakeholder organisations were introduced. The Chair informed the participants that one member's advisor, four dossier submitter representatives and four representatives 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-21. The Agenda was adopted with a minor addition under AOB (presentation by the Secretariat of the ECHA project on carcinogenicity dose-response analysis of chromium(VI)- and arsenic-containing substances, and trichloroethylene). 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 members, their advisors and invited experts participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Two members and one advisor declared potential conflicts of interest, or had this declared for

them by the Chair on their behalf, 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 (RoPs).

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-20 action points, written procedures and other ECHA bodies

The Chair reported that all action points of SEAC-20 had been completed or would be followed up during the on-going SEAC-21 meeting.

The Chair informed the Committee that the final minutes of SEAC-20 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-20 minutes. The Chair mentioned that the draft minutes of the SEAC-21 meeting would be made available to members for commenting a bit later than foreseen by the SEAC RoPs (due to Christmas holidays).

The Chair explained that a report covering the developments in the ECHA MB, RAC, MSC, the Forum and the BPC had been compiled and distributed to SEAC as a meeting document (SEAC/21/2013/01).

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

5) Restrictions

5.1) General restriction issues

a) Update on intended restriction dossier

The Committee was provided with an update on intended restriction dossiers and informed that the Registry of Intentions currently includes the following notifications:

- **Ammonium salts** in cellulose wadding insulation materials used in buildings. ECHA has received a registration of intent for the submission of an Annex XV restriction proposal. In August 2013, France informed the Commission, ECHA and the other MSs, in accordance with Article 129(1) of the REACH Regulation (safeguard clause), it had justifiable grounds for believing that urgent action was essential to protect the public from exposure to ammonia released from ammonium salts in such building materials. France adopted a provisional measure in June and in September 2013, the Commission authorised this provisional measure. Article 129(1) of REACH states that if the provisional measure taken by the MS consists in a restriction on the placing on the market or use of a substance, the MS concerned shall initiate a Union restriction procedure by submitting to ECHA a dossier, in accordance with Annex XV, within three months of the date of the Commission decision. The expected submission date is 15 January 2014.
- **Chrysotile in diaphragms** (to be submitted by ECHA on request of the Commission in January 2014).

- **Cadmium and its compounds** in plastics (to be submitted by ECHA on request of the Commission in January 2014 – however, ECHA has not been able to get information based on which it could be able to finalise an Annex XV restriction report by 17 January 2014).
- **Cadmium and its compounds** in artist paints (to be submitted by Sweden in January 2014).
- **Bisphenol A** in thermal paper (to be submitted by France in January 2014).
- **Bis(pentabromophenyl) ether (DecaBDE)** (to be submitted by ECHA on request of the Commission in August 2014).

b) Revision of the restriction process

The Secretariat informed SEAC that concerns had been raised about the workload relating to the preparation of restriction proposals and the efficiency of the opinion making process. In addition, that the Commission services and ECHA have discussed to what extent the output of the restriction process, i.e. opinions provided by the two scientific committees of ECHA, satisfies the needs of the Commission for its decision making. In response to these discussions, the Commission and ECHA propose to first carry out a survey to better identify some of the problems. The Committee was informed that during December 2013, a questionnaire would be sent to the members, MSCAs and accredited stakeholder observers of RAC and SEAC. It was also proposed to establish a task force to discuss the issues raised in the questionnaire, to analyse the results to identify the core issues and suggest solutions by spring 2014. The SEAC members interested in taking part in the work of this task force were encouraged to express their interest to ECHA by 21 December 2013.

In relation to the discussion on streamlining of the REACH restriction process and in light of the growing workload of RAC and SEAC, the Secretariat proposed to review and simplify the current Committees' working procedures for processing of restriction dossiers. Several SEAC members welcomed this initiative. As the first part of this review, an amended conformity check procedure was tabled for agreement. The Secretariat explained that this procedure had already been agreed by RAC within RAC-27 with one additional modification – the initial commenting round to last until Day 12 (instead of Day 10, originally proposed by the Secretariat), thus ensuring there would be enough days for members to comment on the (co-)rapporteurs' first draft conformity check report.

Several members expressed concern that five calendar days might not be enough for the (co-)rapporteurs for the preparation of their first draft conformity check report. The Secretariat replied that ECHA provides the dossier to the (co-)rapporteurs as soon as possible after receiving it, which in practice means the dossier is available to the (co-) rapporteurs around two weeks before the start of the conformity check process in the Committees (Day 1). Therefore, the Secretariat considered it feasible for the (co-) rapporteurs to prepare their draft conformity check report by Day 5.

The Committee agreed to the revised working procedure on conformity check of Annex XV restriction dossiers with the modification introduced by RAC. The Secretariat informed that the new procedure would be applied starting from the restriction dossiers submitted to ECHA in January 2014.

The Secretariat then presented the possibilities for simplifying the working procedure for developing opinions on restriction dossiers, which it had been considering with the

intention to table the revised opinion development procedure for discussion and agreement at the March 2014 plenaries of RAC and SEAC.

Several members did not support the proposal to remove from the procedure the initial written commenting round on the dossier, considering it as an important input for the (co-)rapporteurs' scoping document. Several members supported the Secretariat's initiative to reconsider how the Background document is developed, as in their view the (co-)rapporteurs and the Committees should not be modifying the Background documents to such extent as done so far.

It was agreed that a CIRCABC newsgroup would be open after SEAC-21 to collect members' views on the presentation of the Secretariat on the revision of the opinion development procedure. The Secretariat will revise the opinion development procedure taking into account the comments received and table it for agreement at SEAC-22.

5.2) Restriction Annex XV dossiers

a) Lead in consumer articles – 4th version of SEAC draft opinion

The Chair welcomed the RAC rapporteur and the dossier submitter representative (SE) who followed the discussions remotely via WebEx.

He then introduced the state of play with the development of the opinion for the proposed restriction on placing on the market of lead and its compounds in articles intended for consumer use; the SEAC draft opinion should be agreed at this meeting based on the modified 4th version of the SEAC draft opinion. The updated Background document, the responses to the final comments from the public consultation and the final Forum advice were uploaded to the Committee in the second half of November 2013.

The Secretariat then informed about the RAC-27 outcome; RAC had adopted its opinion (followed by an urgent written procedure on the justification text after the plenary).

The SEAC rapporteurs presented the modified 4th version of the SEAC draft opinion with a focus on modifications on a limit value based on migration, the nose piece of writing instruments, and cost and benefit calculations. Following the discussions at the extended drafting group meeting, a break-even approach was taken forward.

SEAC discussed the modifications made in the draft opinion, especially in the scope and the derogations (in relation to musical instruments and migration limit). Several other members brought forward that the current assessment of benefits is only partial as other health problems related to lead were not taken into account. A revised derogation for enamels was asked for. More specifically, it was mentioned that the proposed restriction has a derogation, which would potentially allow an improper use of lead salts for enamels on the ceramic articles; which is dangerous if in contact with acid liquids and fruit juices.

The Commission representative called for more information to be requested within the public consultation of the SEAC draft opinion regarding keys and padlocks. A stakeholder representative supported the inclusion of the migration test based content limit. One member supported this.

The Secretariat responded by assuring that the public consultation would include specific questions on the migration limit, exemption for the noses of writing instruments as well

as for keys, locks and padlocks and musical instruments. Industry stated they would provide more information on the migration limit through the public consultation.

One of the members raised concerns with the analytical scope, whether it matched the legal scope of the restriction and if this might impact the proportionality of the proposed restriction. The member also argued that the break even analysis was a necessary element of demonstrating proportionality in this case, although it could be further refined, but on its own was not sufficient to demonstrate proportionality as it did not consider whether IQ impacts were clinically significant.

Based on the exchange of views, the Chair summarised that the Committee supported the rapporteurs' estimation of costs and break even analysis. However, there were different views among the members on the proportionality, although a majority supported the proportionality of the restriction as proposed by the rapporteurs. The Chair concluded that the draft opinion on the restriction of lead in consumer articles was agreed by SEAC by simple majority. Dissenting views were taken by some members, who asked them to be recorded in the minutes. The rapporteurs and the Secretariat were asked to make editorial changes to the opinion based on the discussions in the plenary and to ensure that the supportive documentation (Background document and RCOM) is in line with the agreed SEAC draft opinion. The Secretariat will publish the agreed draft opinion and its supportive documentation on the ECHA website and CIRCABC and launch the 60 days public consultation on the SEAC draft opinion.

b) 1-Methyl-2-pyrrolidone (NMP) – 1st version of SEAC draft opinion

The Chair welcomed the RAC rapporteur and the dossier submitter representatives (NL) who followed the discussion remotely via WebEx. He reminded participants that the restriction dossier had been submitted in August 2013, RAC and SEAC had concluded the dossier in conformity in September 2013 and the public consultation on the Annex XV report had been launched on 18 September 2013.

The Chair informed the Committee that ECHA had recently received a letter from the Commission regarding the NMP restriction proposal referring in particular to the potential divergence between Derived No Effect Level (DNEL) and the Indicative Occupational Exposure Level (IOEL). This letter was made available to both RAC and SEAC on 28 November. The Chair invited the Commission observers to introduce this letter and their views to the participants.

In the view of the Commission, any proposal for adoption of an exposure limit value at an occupational premise should not be implemented under REACH but under the appropriate workers' protection legislation, which is specifically designed to establish and implement IOELs. As REACH does not contain provisions to stop the discussion on the Annex XV dossier, the proposal should receive a proper assessment by both RAC and SEAC. Based on their final outcome, the Commission will decide whether the issue needs to be transferred to SCOEL for further consideration.

The Secretariat presented a brief summary of the RAC discussions on this dossier at RAC-27. RAC agreed with the dossier submitter on the choice of key studies and on the choice of the No Observed Adverse Effect Concentration (NOAEC) for developmental toxicity. RAC discussed the choice of Assessment Factors (AFs) and agreed to use both the REACH guidance-supported AF of 5 and the AF of 10 used in the dossier for illustrative calculations of the RCRs. RAC noted that using either of the AFs, RCRs are above one in many of the scenarios.

The SEAC (co-)rapporteurs presented their 1st version of the SEAC draft opinion in the form of the issues to be addressed. In relation to the proposed restriction (RMO3), the (co-)rapporteurs suggested that SEAC should, as a consequence of the letter received from the Commission, not spend time on specific wording of the restriction. However, they noted the need to assess both the enforceability of the proposed limit value and whether the proposed transitional period of 5 years is appropriate; some comments have been received from the wire coating industry, in the public consultation, claiming that machinery lasts for more than 20 years.

The (co-)rapporteurs noted that as health impacts are not quantifiable, the number of workers exposed is not known and risk reduction is already required under existing worker protection legislation, it is not possible to perform a traditional proportionality analysis. Assuming risk is confirmed by RAC, how should SEAC judge proportionality? The (co-)rapporteurs concluded that measures implying massive relocation are not proportionate and asked for the views of other SEAC members on whether the principle of comparing additional costs with general turnover of costs is a worthwhile approach. Finally, the (co-)rapporteurs suggested asking for further plant specific information from industry within the public consultation to judge on feasibility and proportionality of the proposal.

One SEAC member challenged the suggestion not to elaborate on the choice of legal instrument in the SEAC draft opinion; the opinion template requires SEAC to express a view on this issue (justification that the suggested restriction is the most appropriate EU wide measure). The same member questioned the statement that measures implying massive relocation are not proportionate. Another member commented that he could not see how the comparison of compliance costs with earnings would help to assess on proportionality of the proposal. One SEAC stakeholder observer questioned why health impacts are not quantifiable in this case and what the missing information is.

The (co-)rapporteurs responded that SEAC would propose a measure related to the choice of legal instrument, but would leave it up to the Commission to decide under which legislation to place it. The (co-)rapporteurs noted that a thorough explanation on quantifiable impacts is provided in the dossier.

The Chair summarised the discussion and encouraged members to provide further comments on the 1st version of the draft opinion; the deadline was extended until 16 December 2013. The (co-) rapporteurs were asked to take comments into account in the next version of the SEAC draft opinion.

c) Nonylphenol – 1st version of SEAC draft opinion

The Chair welcomed the RAC rapporteur and the dossier submitter representatives (SE) who followed the discussion remotely via WebEx. He reminded participants that the restriction dossier had been submitted in August 2013, RAC and SEAC had concluded the dossier in conformity in September 2013 and the public consultation on the Annex XV report had been launched on 18 September 2013.

The RAC rapporteur provided a brief summary of the RAC discussions on this dossier held in RAC-27. In relation to the effects, RAC agreed that the current Predicted No Effect Concentration (PNEC) in the dossier would change as the Committee agreed to combine the marine and freshwater PNEC. In the view of RAC, the Toxic Equivalence Factors (TEF)

approach to take into account the combined toxicity of short chain ethoxylates is fine for the screening level but because of the poor data set RAC would therefore prefer to deal with it in a qualitative manner. With regard to the exposure, as the dossier uses the monitoring data available for NP because of the Water Framework Directive, RAC felt that it is difficult to draw conclusions about the exposure. The RAC (co-)rapporteurs hope that there will be some additional data arriving within the public consultation. The current view of the RAC (co-)rapporteurs is that there is a risk that needs to be addressed.

The SEAC (co-)rapporteurs presented their 1st version of the SEAC draft opinion. The rapporteurs felt that further considerations are necessary related to the suggested limit value, the transition period and wording of the proposed restriction; on the latter issue the draft Forum advice is expected to bring more clarity. The (co-)rapporteurs emphasised that the discussion in SEAC is needed on how to best approach proportionality in this restriction case. The dossier submitter considers benefits to be "substantial", although they have not quantified them, which makes the decision on proportionality of the restriction based on a cost-benefit approach difficult or even impossible. The (co-)rapporteurs were also interested to hear other members' views on the approach of the dossier submitter, in the latest version of the Background document, in providing an analysis of the cost-effectiveness of the proposed restriction compared to previous measures to reduce emissions of NP/NPE that have already been implemented (existing Annex XVII entry 46). On the costs side, there is a need to reconsider the compliance control costs, which the dossier submitter considers as very uncertain and have not been considered in the proportionality assessment by the dossier submitter. Finally, the (co-)rapporteurs asked the SEAC members' views whether it is useful to proceed with the four scenarios, established by the dossier submitter in the update to the Background document, to account for different concentrations of NP/NPE in textiles. These scenarios are then used to calculate the releases to waste water to better assess the substitution and compliance control costs.

Several members supported the suggestion of the (co-)rapporteurs to use cost-effectiveness approach to assess proportionality and that the comparison with the previous measure is a good way forward. One member suggested comparing the proposed restriction with end-of-pipe measures, which could help in drawing conclusions regarding the proportionality. Another member expressed the view that as the articles in question are widely used, there has to be a good explanation for such a long transition period. A further member questioned whether the lower limit value had been considered but discarded by the dossier submitter due to additional costs to industry. In relation to costs, one member questioned whether it is possible that some importers pass the costs of their suppliers outside the EU onto EU customers.

In response, the rapporteurs explained that in relation to the transition period, it is argued in the dossier that the textile sector is very diverse and the supply chains are long, however, they will investigate this issue further together with the dossier submitter. The (co-)rapporteurs clarified that the lower limit value would have covered also unintentional uses of NP/NPE. In relation to compliance control costs, the Secretariat suggested approaching some of the big textile producers and importers to ask what their behaviour would be.

The Chair summarised the discussion and encouraged members to provide further comments on the 1st version of the draft opinion in writing within the ongoing written commenting round. Following the request of the SEAC members, it was agreed to prolong the deadline for the written commenting round until 16 December 2013. The (co-)

rapporteurs were asked to take comments into account in the next version of the SEAC draft opinion that would be discussed at the next plenary meeting.

d) Cadmium in paints – outcome of the conformity check

The Chair opened the agenda item by introducing the general approach to be taken by the Committee for the amendment to an existing restriction. The request from the Commission addresses a need to slightly modify the existing entry. The Chair reminded that after the cadmium and its compounds in paints dossier, it is expected that other similar dossiers will follow in the future; therefore the Committees should prepare themselves to process these dossiers accordingly.

On request of the Chair, a stakeholder representative informed about an official letter to ECHA challenging the legal provisions of this amendment to an existing entry. As the letter had only been sent to ECHA one day before the SEAC-21 meeting, the Secretariat had not been able to provide an official reply. However, the ECHA legal experts provided a brief overview of the relevant legal background and confirmed that the current proposed amendment to an existing entry in Annex XVII could only be done via the restriction procedure initiated by an Annex XV dossier, in accordance with Article 68(1) of the REACH Regulation.

The Chair then reported that the conformity check process had been launched on 14 November with the initial commenting round on the conformity of the dossier (one supportive SEAC comment received). On 21 November 2013, the draft conformity check report by the rapporteurs was uploaded to the Committee and an updated conformity check report by the rapporteurs was uploaded on 29 November 2013.

After the introduction, the Chair asked the representative of the dossier submitter (ECHA) to present the main elements of the proposed restriction to the Committee. The Commission had requested ECHA to propose and justify extending the existing restriction to the placing on the market of paints with certain Integrated Community Tariff (TARIC) codes. For enforceability reasons, the dossier should also propose necessary specific limit values of cadmium for such paints.

The ECHA restriction report proposes to modify the restriction such that 'placing on the market' of cadmium in paints, TARIC codes (3208)(3209), would also be restricted if the level of cadmium in those paints exceeds the limit value of 0.01%. Based on ECHA's consultation with the relevant industry representatives it is apparent that concentrations of cadmium in paints in the EU, including copper-based anti-fouling paints, are currently and also expected to be in the future well below the proposed concentration limit of 0.01%. The positive limit value allows continuing use of recycled copper and having the same limit value as elsewhere in the entry simplifies both entry and the enforcement efforts.

Following the introductory presentations, the SEAC rapporteurs presented the outcome of the SEAC conformity check and recommended that the dossier would be considered in conformity. They furthermore presented a recommendation to the dossier submitter to include information on future market situation.

A short discussion took place on the limit value and on possible alignment with the other upcoming cadmium dossiers.

The Chair concluded that SEAC agreed that the cadmium dossier conforms to the requirements of Annex XV. The Chair informed the Committee that following the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter and launch a public consultation on this dossier on 17 December 2013.

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

The Secretariat presented the recommendation of the Chair for the pool of rapporteurs for the restriction dossier on **Bis(pentabromophenyl) ether (DecaBDE)**, as well as for the appointment of (co-)rapporteurs for **Ammonium salts** in insulation (by France), **Bisphenol A** in thermal paper (by France) and **Chrysotile** in diaphragms restriction dossiers (by ECHA) as outlined in the meeting document SEAC/21/2013/03 CONFIDENTIAL.

SEAC agreed to the appointment of SEAC (co-)rapporteurs as proposed in the recommendation and took note on the pool for (co-)rapporteurs.¹

6) Authorisations

6.1) Authorisation applications

a) Authorisation application on use of DEHP in a stop-off formulation in manufacturing of aero engines – 1st version of SEAC draft opinion

The Chair welcomed the RAC rapporteur who followed the discussion remotely via WebEx.

The discussion took place in an observed session. The Chair also informed the Committee that RAC in its 27th plenary meeting considered that adequate control had been demonstrated by the applicant.

The SEAC rapporteur then presented the 1st version of the SEAC draft opinion on the application for authorisation for the processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades. He also informed the Committee that one SEAC member had commented on the application, and the response to the comments had been provided by the rapporteur. Five comments were received during the public consultation. He also mentioned that no major additional information relevant for SEAC had been provided at the dialogue.

The rapporteur presented the 1st version of the SEAC draft opinion on this application for authorisation. He noted that there are no suitable alternatives available at present. Two alternatives have passed preliminary tests and are likely to be economically feasible, but technical tests are scheduled to end in mid-2016 for the most advanced alternative. Another alternative, based on boron nitride, was suggested for similar use during the public consultation. Due to lack of information SEAC cannot assess this alternative substance, however, validation and testing would still be required. The draft SEAC opinion concludes that at present there is no suitable alternative. The rapporteur also elaborated further on the parameters which were considered to suggest the length of the "normal"

¹ Note from the Secretariat: One member came forward as a volunteer for co-rapporteurship for the ammonium salts in the margins of the SEAC-21 plenary and was appointed by SEAC.

review period of seven years. He also proposed not to introduce any conditions or monitoring arrangements for this application.

Several members argued in favour of recommending the "short" review period of four years or the longer review period of twelve years. The Commission representative also provided his argumentation on the basis of the document on the review period agreed by RAC and SEAC. The majority of members supported the review period proposed by the rapporteur.

Subsequently, SEAC agreed by consensus on the draft opinion of SEAC on the application for authorisation, recommending to the Commission granting the authorisation for a period of seven years.

b) Authorisation applications on Phthalates (submitted within the August submission window) – outcome of the conformity check

The SEAC rapporteurs shortly presented the following applications for authorisation received by ECHA:

- 1) Application for authorisation submitted by *Arkema France* on the following uses of Bis(2-ethylhexyl) phthalate (DEHP): Use #1: Formulation of DEHP in compounds, dry-blends and Plastisol formulations; Use #2: Industrial use in polymer processing by calendaring, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, household items <10cm, clothing intended to be worn against bare skin; toys, cosmetics, food contact material].
- 2) Application for authorisation submitted by *Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna* on the following uses of DEHP: Use #1: Formulation of DEHP in compounds, dry-blends and Plastisol formulations; Use #2: Industrial use in polymer processing by calendaring, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, household items <10cm, clothing intended to be worn against bare skin; toys, cosmetics, FCM].
- 3) Application for authorisation submitted by *DEZA a.s.* on the following uses of DEHP: Use #1: Formulation of DEHP in compounds, dry-blends and Plastisol formulations; Use #2: Industrial use in polymer processing by calendaring, spread coating, extrusion, injection moulding to produce PVC articles [except erasers, sex toys, household items <10cm, clothing intended to be worn against bare skin; toys, cosmetics, FCM]; Use #3: Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements.
- 4) Application for authorisation submitted by *Sasol-Huntsman GmbH & Co. KG* on the following use of Dibutyl phthalate (DBP): Use as an absorption solvent in a closed system in the manufacture of maleic anhydride.
- 5) Application for authorisation submitted by *DEZA a.s.* on the following uses of DBP: Use #1: Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride; Use #2: Use in propellants; Use #3: Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements.
- 6) Application for authorisation submitted by *Roxel (UK Rocket Motors) Ltd* on the following uses of DEHP and DBP: Use #1: Industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles (DEHP); Use #2: Industrial use in manufacture of solid propellants and motor charges for rockets and tactical missiles (DBP); Use #3: Industrial use within a specialty paint in manufacture of motors for rockets and tactical missiles (DBP).

- 7) Application for authorisation submitted by *Vinyloop Ferrara S.p.A.*, *Stena Recycling AB* and *Plastic Planet srl* on the following uses of DEHP: Use #1: Formulation of recycled soft PVC containing DEHP in compounds and dryblends; Use #2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles.

SEAC agreed with the rapporteurs that all seven applications for authorisation are in conformity.

The rapporteurs also briefly reported on some issues which could be relevant in the further evaluation of the applications and on which they intend to formulate specific questions to the applicants.

6.2) Appointment of (co)-rapporteurs for authorisation applications (closed session)

During the plenary meeting the Committee members expressed their interest by applying to the pool of rapporteurs and indicating the absence of conflict of interest. The pool of rapporteurs, as outlined in the amended confidential room document SEAC/21/2013/04 Rev.1, was agreed by SEAC. The Chair appointed rapporteurs for the first, the second and the third applications for authorisation on uses of arsenic oxide and the first application for authorisation on uses of lead chromate pigments.

6.3) Setting-up of a Working Group on PBT evaluation

The Secretariat presented the draft mandate (meeting document SEAC/21/2013/04) to set up a working group to develop an approach for SEAC to evaluate restriction proposals and applications for authorisation for PBT and vPvB substances. The Chair informed the meeting that four SEAC members had expressed their interest in participating in the Working Group on PBT evaluation. In addition, invited experts (including RAC members), could be invited on an ad-hoc basis to contribute to the tasks of the Working Group, depending on the expertise needed. Several SEAC members expressed their support to the initiative of setting up the working group and encouraged the involvement of invited experts in the working group. SEAC agreed with the proposed mandate. The first meeting of the Working Group is scheduled for early 2014.

7) AOB

a) Update on the workplan

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

b) ECHA project on carcinogenicity dose-response analysis of chromium (VI)- and inorganic arsenic-containing substances, and project on trichloroethylene

The Secretariat presented the outcome of the project and two notes agreed by RAC in its 27th plenary meeting (2-5 December 2013) concerning the dose-response relationship for carcinogenicity for chromium(VI)- and inorganic arsenic-containing substances.

The Secretariat also presented the ECHA project "Services to support remaining cancer risks, or adequate control, related to the use of trichloroethylene in Applications for Authorisation". The project contains two work packages:

- 1) Review the relevant scientific literature related to carcinogenicity of trichloroethylene and seek information related to cancer mechanisms and exposure;
- 2) Prepare relevant dose-response curves or threshold-type risk estimates for trichloroethylene.

The presentation of the final report and the end of the project is foreseen for April 2014.

c) Estimating abatement costs

The results and findings of two projects assessing abatement costs of certain hazardous chemicals were presented – one project commissioned by ECHA and another by the German Federal Environment Agency (Umweltbundesamt).

8) Action points and main conclusions of SEAC-21

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-21, 10-12 December 2013 (SEAC-21 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 with a minor addition under AOB.	SECR to upload the adopted agenda to SEAC CIRCABC 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	
<i>a) Report on SEAC-20 action points, written procedures and other ECHA bodies</i>	
SEAC was informed on the status of the action points of SEAC-20. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/21/2013/01), including the oral report from the Commission on SEAC related developments in the REACH Committee and in the CARACAL.	
5. Restrictions	
5.1 General restriction issues	
<i>b) Revision of the restriction process</i>	
<p>SEAC took note of the meeting document on carrying out the questionnaire and setting up a task force on revision of the restriction process (SEAC/21/2013/06).</p> <p>SEAC agreed on the revised working procedure on conformity check of Annex XV restriction dossiers (SEAC/21/2013/02) with a modification introduced by RAC (12 days for initial commenting round).</p>	<p>SEAC members to reply to questionnaire and volunteer to become members of the task force.</p> <p>SECR to upload the agreed procedure to CIRCABC and to apply it starting from restriction dossiers submitted in January 2014.</p> <p>SECR to reflect in the meeting minutes that the rapporteurs receive the dossier around two weeks earlier than the formal start of the process in the Committees.</p> <p>SECR to open a Newsgroup collecting views on the presentation on the revision of the opinion development procedure made at SEAC-21.</p> <p>SECR to revise the opinion development procedure taking into account the comments received and</p>

	table it for agreement at SEAC-22.
5.2 Restriction Annex XV dossiers	
<i>a) Lead in consumer articles – 4th version of SEAC draft opinion</i>	
<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 lead and its compounds by simple majority. Dissenting views will be reflected in the SEAC-21 minutes.</p>	<p>Rapporteurs and SECR to make editorial changes to the opinion in accordance with the discussion.</p> <p>Rapporteurs and SECR to ensure that the supportive documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.</p> <p>SECR to launch a public consultation on the SEAC draft opinion.</p>
<i>b) 1-Methyl-2-pyrrolidone (NMP) – 1st version of SEAC draft opinion</i>	
<p>SEAC rapporteurs presented the first version of the SEAC draft opinion.</p>	<p>SEAC members to provide remaining comments on the first version of the SEAC draft opinion by 16 December 2013.</p> <p>Rapporteurs to take comments into account in the next version of the SEAC draft opinion (due by mid-February 2014).</p> <p>Rapporteurs in cooperation with the SECR to submit a response to comments for distribution to SEAC members.</p>
<i>c) Nonylphenol – 1st version of SEAC draft opinion</i>	
<p>SEAC rapporteurs presented the first version of the SEAC draft opinion.</p>	<p>SEAC members to provide remaining comments on the first version of the SEAC draft opinion by 16 December 2013.</p> <p>Rapporteurs to take comments into account in the next version of the SEAC draft opinion (due by mid-February 2014).</p> <p>Rapporteurs in cooperation with the SECR to submit a response to comments for distribution to SEAC members.</p>
<i>d) Cadmium in paints – outcome of the conformity check</i>	
<p>SEAC agreed that the dossier conforms to the Annex XV requirements.</p>	<p>SECR to upload the final outcome of the conformity check to CIRCABC.</p>

SEAC took note of the recommendations to the dossier submitter.	<p>SECR to inform the dossier submitter on the outcome of the conformity check.</p> <p>SECR to launch a public consultation on the dossier on 17 December 2013.</p>
5.3 Appointment of (co-)rapporteurs for restriction dossiers	
<p>SEAC appointed the (co-)rapporteurs for the restriction dossiers on BPA, Chrysotile and Ammonium salts which will be submitted to ECHA in January 2014 (as presented in the confidential room document SEAC/21/2013/03).</p> <p>Furthermore, SEAC took note of the pool of (co-)rapporteurs for DecaBDE.</p>	
6. Authorisations	
<i>6.1a Authorisation application on use of DEHP in a stop-off formulation in manufacturing of aero engines – 1st version of SEAC draft opinion</i>	
<p>SEAC rapporteur presented the first version of the SEAC draft opinion.</p> <p>SEAC agreed on the draft opinion on the application by consensus.</p>	<p>SECR to send the agreed RAC and SEAC draft opinions to the applicant for commenting.</p>
<i>6.1b Authorisation application on phthalates – outcome of the conformity check</i>	
<p>Rapporteurs presented 7 applications for authorisation (DEHP and DBP) and the draft conformity reports.</p> <p>SEAC agreed on the conformity of the applications for authorisation.</p>	<p>SECR to upload the final outcomes of the conformity check to CIRCABC.</p> <p>SECR to inform the applicants on the outcomes of the conformity check.</p>
6.2 Appointment of (co-)rapporteurs for authorisation applications (closed session)	
<p>SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment) and was informed of the (co-)rapporteurs for the authorisation applications submitted to ECHA.</p>	<p>SEAC members to volunteer to the pool of (co-)rapporteurs for applications for authorisation.</p> <p>SECR to upload the updated document to confidential folder on CIRCABC.</p>
6.3 Setting up of a Working Group on PBT evaluation	
<p>SEAC agreed to establish the working group on PBT evaluation and on the mandate and composition of this working group (meeting document SEAC/21/2013/05).</p>	<p>SECR to upload the agreed mandate to CIRCABC.</p> <p>The working group to report on progress at SEAC-22.</p>

8. Action points and main conclusion of SEAC-21	
SEAC adopted the action points and main conclusions of SEAC-21.	SECR to upload the action points and main conclusions to CIRCABC IG.

III. List of Attendees

SEAC-21

SEAC members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
CSERGO Robert
D'AMICO Flaviano
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
IORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
KIISKI Johanna
KNOFLACH Georg
LADOPOULOU Angela
LUTTIKHUIZEN Cees
PALOTAI Zoltán
POKRŠČANSKILANDEKA Mirta
RODRIGUEZ DE SANCHO Maria Jesus
SLETTEN Thea Marcelia
SLEZAK Zbigniew Tomasz
SCHUCHTAR Endre
SIMON Franz Georg
SLETTEN Thea Marcelia
THIELE Karen
THORS Åsa

RAC (co-)rapporteurs
DUNGEY Steve (via WEBEX)
JENSEN Frank (via WEBEX)
LUND Bert-Ove (via WEBEX)
SCHLÜTER Urs (via WEBEX)
TADEO Jose Luis (via WEBEX)

Advisors, dossier submitters (DS) & observers
BEEKMAN Martijn and VERHOEVEN Julia (NMP DS representatives, via WEBEX)
BERNHEIM Teresa (advisor to K. Thiele)
BIRKELI Kenneth (advisor to T.M. Sletten)
CASTELLI Stefano (advisor to F. D'Amico)
CAVALIERI Luisa (advisor to K. Fiore)
COGEN Simon (advisor to J-P. Fayaerts)
JONGENEEL Rob (advisor to C. Luttikhuisen, via WEBEX)
LESTANDER Dag (NP DS representative, via WEBEX)
LUIT Richard (advisor to C. Luttikhuisen)
NIEMELÄ Hanna (advisor to J. Kiiski)
VASS Anne-Marie (Lead and lead compounds DS representative, via WEBEX)

Stakeholder observers
BUONSANTE Vito (EEB)
HOLLAND MIKE (EAERE)
JANOSI Amaya (CEFIC)
MOUCHEBOEUF Jean (UEAPME)
VANDER STRAETEN Michel (EUROMETAUX)
BINKS Steve (ILZRO, expert accompanying the EUROMETAUX observer – Lead and lead compounds)

Representative of the European Commission
BENGYUZOV Manol (DG ENTR, via WEBEX)
BERTATO Valentina (DG ENTR)
BINTEIN Sylvain (DG ENV)
KUBICKI Michal (DG ENTR)
GALLEGO Mateo (DG ENV)
LUVARA Giuseppina (DG ENTR, via WEBEX)
ROZWADOWSKI Jacek (DG ENTR, via WEBEX)
STRECK Georg (DG ENV, via WEBEX)

ECHA staff
BERGES Markus
BLAINEY Mark
CALVO TOLEDO Juan Pablo
DANCET Geert
DUBOURG Richard
GIORDANO Serena
HENNIG Philipp
JACQUEMIN Katline
KIVELA Kalle
LIOPA Elina
LOGTEMEIJER Christiaan
LUDBORZS Arnis
MAROSVOLGYI Nikoletta
MARQUEZ-CAMACHO Mercedes
MERKOURAKIS Spyridon
MOTTET Denis
NICOT Thierry
ORISPÄÄ Katja
ÖBERG Tomas
PELTOLA-THIES Johanna
ROGEMAN Maarten
SADAM Diana
SHUQOM Natasha
SOSNOWSKI Piotr
STOYANOVA Evgenia
VAINIO Matti
VAN HAELST Anniek

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/21/2013</i>
Report on SEAC-20 action points, written procedures and other ECHA bodies (AP 4.a)	<i>SEAC/21/2013/01</i>
Revision of the restriction process (AP 05.1b)	<i>SEAC/21/2013/02</i> <i>SEAC/21/2013/06</i>
Appointment of (co-)rapporteurs for restriction dossiers (AP 5.3)	<i>SEAC/21/2013/03</i> <i>CONFIDENTIAL</i>
Appointment of (co-)rapporteurs for authorisation applications (AP 6.2)	<i>SEAC/21/2013/04</i> <i>CONFIDENTIAL</i>
Setting up of a Working Group on PBT valuation (AP 6.3)	<i>SEAC/21/2013/05</i>

DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS

The following participants, including those for whom the Chair declared the interest on their behalf, 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
LUIT Richard	5.2b 1-Methyl-2-pyrrolidone (NMP)	Working for the organisation preparing the restriction dossier
LUTTIKHUIZEN Cees	5.2b 1-Methyl-2-pyrrolidone (NMP)	Working for the MSCA submitting the restriction dossier
THORS Åsa	5.2a Lead in consumer articles and 5.2c Nonylphenol	Working for the MSCA submitting the restriction dossier
SLEZAK Zbigniew	6.1 Authorisation application on DEHP	Previous involvement

Final Draft Agenda

21st meeting of the Committee for Socio-economic Analysis

10-12 December 2013

ECHA Conference Centre (Annankatu 18, Helsinki)

10 December: starts at 10:00

12 December: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/21/2013
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-20 action points, written procedures and other ECHA bodies

SEAC/21/2013/01
For information

Item 5 – Restrictions

5.1 General restriction issues

- a) Update on intended restriction dossiers

For information

- b) Revision of the restriction process

SEAC/21/2013/06
For information

SEAC/21/2013/02
For discussion/agreement

5.2 Restriction Annex XV dossiers

- a) Lead in consumer articles – 4th version of SEAC draft opinion
For discussion and agreement
- b) 1-Methyl-2-pyrrolidone (NMP) – 1st version of SEAC draft opinion
For discussion
- c) Nonylphenol – 1st version of SEAC draft opinion
For discussion
- d) Cadmium in paints – outcome of the conformity check
For agreement

5.3 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/21/2013/03
(confidential room document)
For information and agreement

Item 6 – Authorisations

6.1 Authorisation applications

- a) Authorisation application on use of DEHP in a stop-off formulation in manufacturing of aero engines – 1st version of SEAC draft opinion
For discussion/agreement
- b) Authorisation applications on Phthalates (submitted within the August submission window) – outcome of the conformity check
For agreement

6.2 Appointment of (co-) rapporteurs for authorisation applications (closed session)

SEAC/21/2013/04
(confidential room document)
For agreement

6.3 Setting up of a Working Group on PBT evaluation

SEAC/21/2013/05
For discussion/ agreement

Item 7 – AOB

- a) Update of the work plan
- b) Estimating abatement costs
- c) ECHA project on carcinogenicity dose-response analysis of chromium(VI)- and arsenic-containing substances, and trichloroethylene
For information

Item 8 – Action points and main conclusions of SEAC-21

Table with Conclusions and Action points from SEAC-21

For adoption