9 December 2013

SEAC/M/20/2013 FINAL

Final

Minutes of the 20th meeting of the Committee for Socio-economic Analysis

11 – 13 September 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 twentieth meeting of SEAC.

The Chair informed the Committee that apologies had been received from six members, one stakeholder observer, one Croatian observer and one international observer. Three invited experts, five members' advisors present at the meeting as well as two representatives of the European Commission, observers of six stakeholder organisations were introduced. The Chair informed the participants that one member's advisor, four dossier submitter representatives 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-20. The Agenda was adopted with minor modifications. 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 two advisors 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.

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-19 action points, written procedures and other ECHA bodies

The Chair reported that all action points of SEAC-19 had been completed or would be followed up during the on-going SEAC-20 meeting.

The Chair informed the Committee that the final minutes of SEAC-19 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-19 minutes.

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/20/2013/01).

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

Finally, the Chair updated the Committee about the discussions on the functioning of the ECHA Committees that had taken place at the last MB meeting of 19-20 June and the following meeting of the MB Working Group on Planning and Reporting which had taken place on 5 September 2013. One SEAC member asked to reconsider the strict Conflict of Interest policy applied by the Secretariat as this would be in contradiction to the needed increased capacity for SEAC's activities in the coming years. The member also expressed that in his view the current implementation of the CoI policy is hindering active participation of members in the discussions on restriction proposals and thus the effectiveness of RAC and SEAC. The Chair responded that the practice for handling Conflict of Interest has been the same since the very first dossier was brought to the Committee and that the minimum mitigation measure applied is to abstain from voting on your own dossier, but that the Secretariat would come back to this issue at a later stage.

5) Restrictions

5.1) General restriction issues (joint RAC/SEAC session)

The Committees were provided with an update on intended restriction dossiers. In addition **to Cadmium and its compounds** in plastics and paints, **Chrysotile** in diaphragms (both to be submitted by ECHA on request of the Commission, expected submission date 17 January 2014) and **Bisphenol A** in thermal paper (by France, expected submission date 17 January 2014), about which the Secretariat had informed the Committees earlier, the following new intentions have been included into the Registry of Intentions:

- **Cadmium and its compounds** in artist paints. This intention has been submitted by Sweden and the expected submission date is 17 January 2014. The scope of this intention has recently been modified, so that it does not include the use of Cadmium and its compounds in pigments for enamel, ceramics and glasses.

- The Commission has requested ECHA to prepare a proposal for a restriction on the manufacture, use and placing on the market of **Bis(pentabromophenyl) ether (DecaBDE)** and of mixtures and articles containing it. The expected submission date is 1 August 2014. The call for rapporteurs for this dossier will be launched shortly after RAC-26/SEAC-20.

5.2) Restriction Annex XV dossiers

a) Lead in consumer articles – 2nd version of SEAC draft opinion

The Chair welcomed the RAC rapporteurs and the DS representative from the Swedish MSCA (who followed the discussions remotely as an observer).

The restriction dossier on lead and lead compounds was submitted to ECHA in December 2012. Following that RAC and SEAC concluded the dossier was in conformity in March 2013, the public consultation on the dossier was launched on 21 March 2013. The 2nd version of the SEAC draft opinion was provided to the Committee on 16 August 2013, together with the rapporteurs' responses to the comments by the SEAC members on the

1st version of the opinion (ORCOM), and the responses by rapporteurs to early comments from the public consultation. The DS, RAC and SEAC (co-)rapporteurs provided answers to the draft Forum advice which was submitted on 7 June 2013. The updated Background document was delivered by the Dossier Submitter early July and the updates to the BD were included by the Secretariat by 16 August. A major revision of the BD is planned to take place after the SEAC meeting in order to bring the BD in line with the opinion. In order to facilitate the plenary discussions, a separate working group meeting was arranged as a webinar on 3 September with the interested SEAC members.

The Annex XV dossier proposes a restriction on the placing on the market of lead and its compounds in articles intended for consumer use. The restriction proposal is targeted to consumer articles that can be placed in the mouth by children, given that children are the most vulnerable group when exposed to lead. The lead compounds (but not elemental lead) are classified as reprotoxic category 1 and 2. Furthermore, no threshold has been found for the neurotoxic and neurodevelopmental effects of lead. The main route through which small children (between ages of 6 and 36 months) would be exposed to lead from the consumer articles is by mouthing. This exposure impairs their developing central nervous system as the most sensitive negative effect. The dossier concludes that this health risk cannot be adequately controlled with the existing EU legislative measures.

The Chair reminded the Committee that the discussions on the 2nd version of the draft opinion is considered as the most crucial stage of the opinion development process, as ideally only minor changes should be introduced to the draft opinion in the later versions.

After the introduction the RAC rapporteurs were invited to report back from the RAC discussions on the 2nd version of the RAC opinion on lead in consumer articles. RAC had supported the realistic mouthing time of 20 minutes and realistic worst case mouthing time of 60 minutes. In addition, RAC had discussed the issue of migration versus content and agreed on the lead content of 0,5% for brass alloys. In June, RAC had agreed preliminarily on the limit value of 0,05% in metallic and non-metallic articles which can be placed in the mouth of children. Regarding the exemptions, RAC had supported the categories as presented in the previous lead in jewellery restriction (entry 63). However, other articles that have been proposed by public consultation or in the original Annex XV dossier were assessed one by one based on mouth-ability, accessibility and conditions under normal use. Especially with regard to the coated articles, RAC could conclude that there could be a small risk. RAC is still favouring the two ways –approach in its risk assessment, based on lead content and migration of lead.

Questions were raised by SEAC members regarding the usage of the RAC risk assessment mouthing times and their appropriateness for the SEAC benefit assessment. The RAC rapporteurs provided more information to SEAC on how the different calculations were derived by RAC. The Chair made an observation that the realistic daily mouthing time could be used as one of the key parameters for SEAC calculations, but other issues, such as the percentage of lead in different parts of articles, may need to be taken into consideration as well. In other words, it was agreed to further discuss on how this value would be used correctly in the benefit calculations. The Secretariat reminded that the mouthing time falls within the RAC regime, whereas SEAC would have to monetise the IQ loss.

The SEAC rapporteurs presented the 2nd version of the SEAC draft opinion. The first part of the presentation focused on the costs (more specifically with regard to the updated substitution costs, testing and enforcement costs) and on the details of benefit calculations.

SEAC discussed the assumptions and methodology as presented by the rapporteurs. A stakeholder observer asked whether the replacement cost for various sectors of the covered articles have been taken into account in calculations and asked for strengthening the uncertainty analysis in the draft opinion. Furthermore, issues were also raised regarding the testing costs for companies. The Secretariat responded that the cost calculations have focused on articles that are in the scope of the restriction proposal (which are described in the updated BD), and replacement costs have been included in the substitution costs. Furthermore, following the industry comments received from the public consultation, the factors for testing costs for companies will be included in the SEAC draft opinion to reflect the uncertainties.

The Commission asked SEAC for a certain flexibility to change the cost calculations should RAC refine the derogations to be exempted from the restriction. It was also noted that the scope would need to be further elaborated as the basis for the impact assessment, in other words the calculations would be adjusted based on the refined scope.

A SEAC member also expressed concerns that there are limitations regarding the approach taken based on DTI and PRODCOM databases, which are the basis for the cost calculation and the assumptions proposed by the rapporteurs. The uncertainties for the number and type of articles in different categories could potentially result in an under- or overestimation of costs and the underpinning of the selected PRODCOM article categories included in the analysis based upon the DTI study should be improved according to this member. The SEAC rapporteurs responded that the uncertainties will be considered and reflected in the draft opinion.

The Chair concluded that there was support for the general approach and methodology taken forward for costs assessment; there were still some issues with some of the specific detail and parameter values/assumption which needed to be considered and reflected further in the draft opinion. It was further noted that the uncertainty analysis can be taken from the original restriction proposal, and the product categories could be assessed if feasible (i.e. which PRODCOM articles are included in the calculations and which are not).

A stakeholder observer raised a concern that they were not invited to take part at the WebEx discussions with the rapporteurs prior to the plenary. The Chair responded and explained that the extended drafting group was arranged for members only to support the rapporteurs in drafting the opinion text to be further discussed in plenary. However, the concern for transparency is noted and there could also be specific reasons for inviting stakeholders to participate in such a drafting group.

In the context of benefit assessment discussions, SEAC discussed the issue of lifetime of articles (for example estimated lifetime of 1-3 years for baby clothes) as well as volume and categories of articles mouthed by children.

A stakeholder observer called for a probabilistic distribution for exposure, and referred to a study which was provided via the public consultation. This was supported by two SEAC members who considered this study worth looked into further as this could be useful for refining the benefit assessment.

Some discussion took place whether the mouthing time for risk assessment provided by RAC might not be the appropriate mouthing time for SEAC's purposes for the impact assessment. Several members however felt there are no reasons why the value should be challenged and supported the RAC mouthing time as the way forward. No agreement was reached, however, a question was raised again by members how this figure from RAC should be used by SEAC correctly in the benefit assessment.

The Chair concluded that SEAC had raised issues with regard to benefits calculations and called for improvements to be made in the benefit assessment. Furthermore, the rapporteurs would take note of the suggestions of members into the third version of the draft opinion.

SEAC discussed the potential derogations to be excluded from the restriction after the presentation by the SEAC rapporteurs. Furthermore, the RAC rapporteurs provided an update on RAC discussions on the derogations. The Chair asked SEAC to assess the exemptions where RAC has identified a risk, whether socio-economic arguments would still justify an exemption. The Secretariat pointed out that the focus should be on the new exemptions identified from the public consultation requests, as the original scope proposed in the Annex XV dossier that went for public consultation could not be widened.

A SEAC member raised concerns for fishing sinkers and ammunition accessible at homes, but which are out of scope of the restrictions. Furthermore, questions were raised regarding the second hand market, in particular if second hand market was restricted, this could affect negatively and in a disproportionate way (e.g. through cost of testing) associations that recycle various articles and sell them at low cost/no cost to economically disadvantaged people.

Several members welcomed the attempt to narrow the scope (i.e. size of articles, positive and negative lists in the Background document), although it seemed there is still a need to clarify what falls within the scope and what is outside of the scope. Considering that the public consultation is still running until 21 September, SEAC could not conclude on the scope until all elements are being taken into account. The Chair noted that depending on the modifications on the scope, the cost and benefit calculations would be modified respectively.

Following a proposal to derogate musical instruments, one SEAC member questioned the general approach taken for consideration of derogations . The SEAC member argued that the approach undertaken by the dossier submitter in determining the scope and derogations was not in line with an evidence based approach to policy making. Concerns were raised regarding the scope of which the analytical assessment should be made, since the outcome of the analysis would depend precisely on what is included in the scope. If the scope would change, this has implications to the assessment results. Considering that the derogations proposed in the public consultation are assessed case-by-case, in an ad hoc basis, there is a risk that some issues might also have been missed from the public consultation, and not covered in the assessment. Some concerns were raised that SEAC's analysis would not be reliable based on this approach.

The Secretariat responded that the aim was to start from the wide scope to narrowing it down, by focusing on a negative list proposed by the industry. The final list for exemptions are assessed by a size dimension, placing in the mouth -concept and on case by case basis. The scope would be clarified further based on new requests for exemptions.

After extensive discussion on the scope and derogations, the Chair concluded that more work is needed to define them further. A SEAC member pointed out that the parents as consumers should ensure the correct usage of articles. However, the Secretariat responded that it is not reasonable to expect that parents would know what is contained in the articles; a reasonable foreseeable misuse of articles by children is quite likely to happen. Furthermore, the suggestions and issues raised by members will be considered by the rapporteurs to further clarify the scope of the proposed restriction and elaborate potential impact on costs and benefits.

In conclusion, the rapporteurs were invited to take comments received into account in the third version of the SEAC draft opinion and to update the BD to be in line with the opinion. Furthermore, the Secretariat will consider organising an extended drafting group meeting with interested SEAC members prior to SEAC-21 to help the rapporteurs in finalising the SEAC draft opinion.

b) 1-Methylpyrrolidin-2-one (NMP) – outcome of the conformity check

The Chair welcomed the dossier submitter representative from the Netherlands (via WebEx).

The Chair reminded that the restriction dossier on 1-Methyl-2-pyrrolidone (NMP) was first submitted by the Netherlands to ECHA in April 2013. In June this year, SEAC concluded that the submitted dossier conformed to Annex XV requirements, while RAC considered it not in conformity due to insufficient quantitative information on toxicity studies, relevant to DNEL development. The Netherlands resubmitted their proposal on 9 August 2013. The conformity check process in RAC and SEAC was launched on 15 August and the Committees are expected to reach a conclusion on conformity by 12 September.

The representative of the dossier submitter provided a presentation on the main changes introduced in the revised proposal. The Annex XV dossier proposes a restriction on the manufacture and use of NMP by professional and industrial workers. NMP may only be manufactured and used if the exposure (as 8-hr TWA) will remain below 5 mg/m³. Peak exposures (15 min. STEL) must remain below 10 mg/m³. Further NMP may only be manufactured and used if dermal exposure is avoided by use of preventive measures. NMP is classified as a skin, eye and possible respiratory irritant but also is classified as a reprotoxic category 1B, based on developmental toxicity. The dossier identifies that the exposure of pregnant women to NMP may result in e.g. reduced birth weight of the new-borns or stillbirth. The aim of the restriction proposal is to control the risks resulting from the exposure of expecting mothers but also from exposure of the non-pregnant (male and female) workers. According to the dossier submitter, the risks resulting from the exposure of pregnant women and the general workers to the substance cannot be adequately controlled with legislative provisions currently in place in EU.

The RAC rapporteur informed the participants that RAC had concluded that the NMP restriction dossier is in conformity. He explained that the dossier now contains quantitative information on toxicity studies, which was missing from the report last time and was the main reason for non-conformity.

Furthermore, the SEAC (co-)rapporteurs presented the SEAC outcome of the conformity check and recommended that the dossier would be considered in conformity. The SEAC rapporteurs mentioned that one supportive comment had been received in the written commenting round on the conformity of this proposal. In addition, the rapporteurs also briefly explained their recommendations to the dossier submitter.

One SEAC member stated his view that although REACH is also related to workplace safety, some considerations and concerns remain in the case of this NMP dossier. He specified that the definition of a threshold occupational exposure limit (OEL) or the technical concentration (TRC) under the workers' safety legislation seem to be more suitable and less burdensome to industry than a restriction under REACH. However, the member agreed that this is not a conformity issue.

SEAC agreed that the dossier on NMP conforms to the requirements of Annex XV. The Chair noted that the Secretariat would communicate the results of the conformity check

and the recommendations to the dossier submitter. The public consultation on the Annex XV report will be launched on 18 September 2013.

c) Nonylphenol – outcome of the conformity check

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

The Chair reminded that the restriction dossier on Nonylphenol (NP) and Nonylphenol ethoxylates (NPE) was first submitted by Sweden to ECHA in August 2012. In September 2012, both RAC and SEAC concluded that the dossier did not conform to the requirements of Annex XV. The dossier submitter resubmitted their proposal in November 2012, however, in March this year, SEAC again concluded that the proposal was not in conformity, while RAC considered it conforming. This was due to the fact that no proportionality assessment had been provided in the revised report as required by Annex XV of REACH. Sweden submitted their proposal in July 2013 as a new restriction proposal. The conformity check process was launched in RAC and SEAC on 15 August and the Committees are expected to reach a conclusion on conformity by 12 September.

The representative of the dossier submitter provided an introductory presentation on the proposal. The Annex XV dossier proposes a restriction on the placing on the market of NP and NPE in textile clothing, fabric accessories and interior textile articles that can be washed in water, if they contain these substances alone or in combination in concentrations equal or higher than 100 mg/kg textile. The limit value includes prints in the textile articles covered by the proposed restriction. The use of NP and NPE in concentrations equal or higher than 0,1% is restricted within the EU in products for among others the processing of leather and textiles (except with no release to waste water or where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment), industrial and institutional cleaning, etc. (REACH, Annex XVII, Entry 46). However, NP and NPE are still used, primarily outside the EU, as surfactants in the manufacturing of textile articles. When the textile articles are washed in the EU, residues of NP and NPE will be released into the environment via the waste water treatment. NP is toxic to aquatic life. The report identifies a concern for NPs and NPEs in the aquatic environment when considering: (a) the results of the quantitative risk assessment for the NPs on their own; (b) the combined toxicity of NPEs and their degradation products such as NPs and nonylphenol ethoxycarboxylates; (c) the quantitative and qualitative risk assessment based on the endocrine disrupting properties of NPs.

The RAC (co-)rapporteurs informed SEAC that this dossier had already passed the conformity in RAC last time and this time RAC had reached the same conclusion. Several issues will need close scrutiny in the further work on this dossier. The RAC rapporteur informed that in UK, more recent monitoring data is available, which the UK would submit within the public consultation on the Annex XV report and which hopefully would be helpful in the opinion development.

Furthermore, the SEAC (co-)rapporteurs presented the SEAC outcome of the conformity check and recommended that the dossier would be considered in conformity. They noted that substantial efforts had been made by the dossier submitter to improve the dossier, e.g. inclusion of the discussion on benefits, proportionality assessment, etc. The SEAC rapporteurs mentioned that one supportive comment had been received in the written commenting round on the conformity of this proposal. The rapporteurs also briefly explained their recommendations to the dossier submitter, e.g., improved argumentation

of the RMO comparison, transparency of the cost calculations, comparison of cost and benefits, argumentation for the proposed concentration limit, etc.

Several members expressed support to the views of the SEAC rapporteurs. They also noted that the differences between RMO-1 and RMO-2 look marginal and noted further that the recommendations to the dossier submitter have been clearly written and seem to be possible to tackle.

SEAC agreed that the dossier thus conforms to the requirements of Annex XV of REACH. The Chair noted that the Secretariat would communicate the results of the conformity check and the recommendations to the dossier submitter. The public consultation on the Annex XV report will be launched on 18 September 2013.

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

The Secretariat presented the recommendation of the Chair for the pools of (co-) rapporteurs for the restriction dossiers **Cadmium and its compounds** in plastics and paints (to be submitted by ECHA), **Cadmium and its compounds** in artist paints (to be submitted by Sweden), and **Bisphenol A** in thermal paper (by France) as outlined in the meeting document SEAC/20/2013/02 CONFIDENTIAL. SEAC took note on the pools for co-rapporteurs as proposed in the recommendation.

Furthermore, the Secretariat informed the Committee that no volunteers had come forward in the call for expressions of interest for (co-)rapporteurs of the **Chrysotile** in diaphragms restriction dossier (to be submitted by ECHA by 17 January 2014) and strongly encouraged interested members to volunteer to be included in the pool of (co-)rapporteurs for this dossier[1].

The Chair informed the Committee that as four restriction dossiers are expected to be submitted in January 2014, the agreement on the recommendation of the Chair for the appointment of the (co-)rapporteurs for these restriction dossiers will be done via the written procedure before the December plenary.

Furthermore, SEAC was informed that shortly after the SEAC-20 meeting, the Secretariat will launch a call for the appointment of (co-)rapporteurs for the restriction dossier on **Bis(pentabromphenyl) ether (DecaBDE)**.

6) Authorisations

6.1) Authorisation application on phthalates

The Chair provided an introductory presentation, recalling some key aspects concerning the processing of applications for authorisation, i.e. confidentiality rules, dissemination of confidential documents, stakeholders in an observed (open) session, establishment of conformity, questions from the Committees to the applicant and the Committees role in evaluating the application.

One stakeholder observer suggested making the presentation of the Chair available to the ECHA website. Another Stakeholder observer asked for clarification on how the Secretariat decides on the classification of the information being considered. The

[1] Note from the Secretariat: One member came forward as a volunteer for rapporteurship in the margins of the SEAC-20 plenary.

Secretariat reassured them that the general transparency policy of ECHA will be followed, noting that a large amount of the information is made available for the public consultation process in order to make it meaningful. The confidential information in the applications for authorisation is necessary for the opinion making but not necessarily for discussions in the plenary. However, if the confidential content needs to be discussed, this will be done in the non-observed (closed) session.

The Chair welcomed the RAC and SEAC (co-)rapporteurs for the first application for authorisation and reminded the Committees that this application concerned the use of DEHP in the processing of a stop-off formulation containing the substance during the diffusion bonding and manufacture of aero-engine fan blades. The public consultation and also the Committees consultation were launched on 14 August. He mentioned that the discussion on the conformity check would take place in RAC and SEAC separately and then gave the floor to the RAC (co-)rapporteurs to present the first application for authorisation. Following these presentations, the Chair then gave the floor to the SEAC rapporteur for his presentation on the socio-economic aspects of the first application for authorisation.

[End of joint session on this issue]

At the separate SEAC plenary session the Chair welcomed the SEAC and RAC (co-) rapporteurs and reminded the rapporteur and the Committee members not to discuss any confidential information from the application in this open plenary discussion.

Furthermore, the Chair invited the RAC rapporteur to brief SEAC on the discussions in RAC on the conformity of this dossier. The RAC rapporteur informed the Committee that RAC had agreed on the conformity of the application for authorisation. He also noted that the RAC (co-)rapporteurs will prepare questions to the applicant to get further clarification on the exposure assessment. This will be done prior to the Trialogue to be held at the end of October.

The Chair gave the floor to the SEAC rapporteur to present the draft outcome of the conformity check. The SEAC rapporteur recommended to the Committee to agree that the application for authorisation is in conformity with the requirements of Article 62 of the REACH Regulation. He also formulated possible questions for clarification to the applicant to be asked before the Trialogue, which may be relevant for the formulation of the SEAC draft opinion. The Committee briefly discussed the proposed questions for further clarification. One SEAC member noted that the application indicates no harm to the environment on one side and safety of the aircrafts on the other, thus providing good basis for granting the authorisation. At the same time, he noted that the applicant shall be encouraged for searching suitable alternatives. Some SEAC members supported the rapporteur's proposal to ask the applicant to provide narrative description of the Project Plan for Alternative Analysis Program which is submitted as a part of the analysis of alternatives. One SEAC member proposed to ask for a further clarification on the safety requirements of other regulations. The SEAC member also agreed to rapporteur's proposal on necessary clarifications to the Socio-Economic Analysis (SEA) submitted as a part of the application for authorisation. Another SEAC member questioned the time-frame in the Project Plan. He sees it as a too long project, especially when it is indicated that the trial studies for the possible alternative 4 have already started. In response to the comments by the SEAC members, the rapporteur noted that the SEA in its current version contains many vague statements. He also proposed possible interaction with the European Aviation Safety Agency (EASA) to understand safety certification processes and their impacts on the review period. The Commission representative reminded that the Committee shall carefully consider what is needed and essential for drafting its opinion

before asking applicant for further information in addition to the information already submitted in the application.

After the discussion SEAC agreed on the conformity of the application for authorisation.

The Chair reminded that the commenting period on the content of the application for authorisation will remain open until 9 October. Comments shall be submitted by the members to the dedicated newsgroup on CIRCABC.

6.2) Recommendation of the review period in applications for authorisation (joint RAC/SEAC session)

In the joint RAC/SEAC session the Secretariat presented a revised note on the Committees' recommendation of the review period in applications for authorisation. The overall aim is to build an efficient opinion making process and to achieve consistent and transparent opinions. Following the discussion at the RAC-25 and SEAC-19, the Commission had provided comments which proposed a "normal" duration of the review period of seven years, a "long" duration of 12 years and the possibility of a shorter duration (without specifying the number of years). The review period could also be extended under exceptional circumstances.

Several members agreed with the general idea of the proposed review period as a starting point when considering each application. They underlined that this would be a learning process for both Committees and there would be a need for a case by case approach but that a clear indication as to where to begin such considerations would be useful. Some were of the opinion that the review period is a policy issue and the scientific Committees are not the correct bodies to make such decisions. The secretariat pointed out that the Committees, in particular SEAC, would be the only body in possession of appropriate information on this issue to be able to advise the Commission and that this was therefore a scientific and technical issue within the Committees mandate. Some members thought that the proposed timing did not adequately reflect the normal range of investment cycles of industry; others thought that it did.

The proposed approach was thought to be balanced and was generally supported by the stakeholders representing industry associations. Other stakeholders representing NGOs were of the opinion that normal review period is too long, considering that substances have been on the candidate list already for a long time and their use is still possible until the sunset date.

Given that the discussion on RAC related issues were very different from those related to SEAC, the Chair thanked the members of the joint session for a very productive debate and concluded that the discussion would continue in RAC and SEAC separately.

<u>SEAC session</u>

In its separate session, RAC had clarified its role as described in the secretariat note and had added a new section.

SEAC members then proposed some further changes to the text of the note as a whole, e.g. to add a reference to Article 60(8) of the REACH Regulation to reflect that the review period is determined on a case-by-case basis.

Some of the SEAC members still considered that there were policy elements relating to the decision on the review period. The Secretariat added that this was the reason why the

Commission will ultimately decide on this issue, but based on the recommendations of ECHA's scientific committees.

A representative of one of the stakeholder organisations remarked that industry could already start the search for alternatives long before the authorisation has been granted.

The Committee agreed on the changes that were introduced based on the discussion. Two members did not agree to the revised text as presented. One of them observed that as long as a discussion on the review period does not take place between the Commission and Member States, the recommendation is not ready for external use, in particular to be communicated to candidate applicants for authorisation. In his opinion the note would not conform to Article 60(8) of the REACH Regulation. The other member pointed out that the criteria as they are now written are not suitable for use in a scientific assessment and further redrafting is needed in order to fulfil the aim of providing efficiency, transparency and clarity to the work of SEAC. Wording such as very high and very unlikely and other value wording should be avoided. She was of the opinion that criteria for the normal period are also needed in order to be able to fully compare with the criteria for long and short review periods.

The Chair concluded that the SEAC agreed on the document "Setting the review period when RAC and SEAC give opinions on an Application for Authorisation". He noted that the document, including the duration of the review periods, can be revised on the basis of experience gained. The Secretariat will upload the document on the ECHA website.

6.3) 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 absence of conflict of interest. The pool of rapporteurs, as outlined in the amended confidential room document SEAC/20/2013/04 Rev.1, was agreed by SEAC. The Chair expressed his appreciation on the fact that more members have now volunteered for the rapporteurship for the applications for authorisation for the substances in the Annex XIV of the REACH Regulation.

7) AOB

a) Update on the workplan

The Secretariat provided an update on the workplan for the future months.

b) Report from the project on economic valuation of environmental impacts

This agenda item was postponed to SEAC-21. However, a project report and a summarizing presentation were been uploaded on SEAC CIRCABC prior to the plenary for information.

8) Action points and main conclusions of SEAC-20

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-20, 11-13 September 2013
(SEAC-20 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 modification 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	
a) Report on SEAC-19 action points, written procedures and other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-19. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/20/2013/01), including the oral report from the Commission on SEAC related developments in the REACH Committee and in the CARACAL.	
5. Restrictions	
5.2 Restriction Annex XV dossiers	
a) Lead in consumer articles – 2nd version of SEAC draft opinion	
SEAC rapporteurs presented the 2nd version of the SEAC draft opinion. SEAC discussed costs, benefits and exemptions.	**Rapporteurs** to take comments into account in the 3rd version of the SEAC draft opinion (including further elaboration of the scope and what would be the impact on costs and benefits). **Rapporteurs**, in cooperation with SECR, to update the BD to be in line with the 3rd version of the draft opinion. **SECR** to consider organising an extended drafting group meeting with interested SEAC members prior to SEAC-21.
b) 1-Methyl-2-pyrrolidone (NMP) – outcome of the conformity check	
SEAC agreed that the dossier conforms to the Annex XV requirements. SEAC took note of the recommendations to the dossier submitter.	**SECR** to upload the final outcome of the conformity check to CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check.

c) Nonylphenol – outcome of the conformity check	
SEAC agreed that the dossier conforms to the Annex XV requirements. SEAC took note of the recommendations to the dossier submitter.	**SECR** to upload the final outcome of the conformity check to CIRCABC. **SECR** to inform the dossier submitter on the outcome of the conformity check.
5.3 Appointment of (co-)rapporteurs for restriction dossiers	
SEAC took note of the pools of (co-) rapporteurs for the four restriction dossiers which will be submitted to ECHA in January 2014 (as presented in the confidential room document SEAC/20/2013/02).	**SECR** to seek agreement on the appointment of (co-)rapporteurs for these four restriction dossiers by written procedure before the December plenary. **SECR** to launch the call for expression of interest in (co-)rapporteurship for DecaBDE restriction dossier shortly after SEAC-20.
6. Authorisations	
6.1 Authorisation application on phthalates – *outcome of the conformity check*	
SEAC agreed on the conformity of the application for authorisation. SEAC discussed the questions to the applicant.	**SECR** to upload the final outcome of the conformity check to CIRCABC. **SECR** to inform the applicant on the outcome of the conformity check.
6.2 Recommendation of the review period in applications for authorisation	
SEAC agreed on the recommendation for setting the review period in applications for authorisation with modifications introduced during the meeting (revised meeting document SEAC/20/2013/03).	**SECR** to upload the agreed document to CIRCABC and to ECHA website.
6.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)	
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 within the August 2013 submission window.	**SEAC members** to volunteer to the pool of (co-)rapporteurs for applications for authorisation. **SECR** to upload the updated document to confidential folder on CIRCABC.
8. Action points and main conclusion of SEAC-20	
SEAC adopted the action points and main conclusions of SEAC-20.	**SECR** to upload the action points and main conclusions to CIRCABC IG.

III. List of Attendees

SEAC-20

SEAC members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
CSERGO Robert
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
SLEZAK Zbigniew Tomasz
SCHUCHTAR Endre
SIMON Franz Georg
THIELE Karen
THORS Åsa

ECHA staff
DUBOURG Richard
GIORDANO Serena
JACQUEMIN Katline
KIOKIAS Sotirios
KOSK-BIENKO Joanna
KIVELA Kalle
LOGTEMEIJER Christiaan
LUDBORZS Arnis

Advisors, invited experts, dossier submitters (DS) & observers
BEEKMAN Martijn (advisor to C. Luttikhuizen and NMP DS representative, via Webex)
CASTELLI Stefano (advisor to Fredericca Cecarelli)
CEDERBERG Inger (NP DS representative, via Webex)
COGEN Simon (advisor to J-P. Fayaerts)
D'AMICO Flaviano (advisor to S. Grandi)
HENNIG Philipp (advisor to K. Thiele)
HENRIKSSON Jörgen (NP DS representative via WEBEX)
IVARSSON Jenny (NP DS representative via WEBEX)
KORHONEN Hanna (advisor to J. Kiiski)
LESTANDER Dag (advisor to A. Thors and NP DS representative)
PALOTAI Zoltan, invited expert (HU)
SLETTEN Thea Marcelia, invited expert (NO)
VASS Anne-Marie (Lead and lead compounds DS representative, via WEBEX)
VERHOEVEN Julia (advisor to C. Luttikhuizen, via Webex)

Stakeholder observers
HOLLAND MIKE (EAERE)
JANOSI Amaya (CEFIC)
MOUCHEBOEUF Jean (UEAPME)
MUSU Tony (ETUC)
WATERSCHOOT Hugo (EUROMETAUX)
RYMAN Jessica (ILZRO, expert accompanying the EUROMETAUX observer - Lead and lead compounds)

Representative of the European Commission
BENGYUZOV Manol (DG ENTR)
GALLEGO Mateo (DG ENV)
LEFEVRE Remi (DG ENV)
LUVARA Giuseppina (DG ENTR)
ROZWADOWSKI Jacek (DG ENTR) via WEBEX

RAC (co-)rapporteurs
BARRON Thomasina
GREIM Helmut
JENSEN Frank
LUND Bert-Ove

MAROSVOLGYI Nikoletta
MARQUEZ-CAMACHO Mercedes
ORISPÄÄ Katja
ÖBERG Tomas
RODRIGUEZ IGLESIAS Pilar
TASKILA Jonna
SADAM Diana
SOSNOWSKI Piotr
STOYANOVA Evgenia
THUVANDER Ann
VAINIO Matti
VAN HAELST Anniek

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

RAC members	**Advisers (to the RAC members)**
BARANSKI Boguslaw	JANONYTE Agne (Dunauskiene) adviser for CLH Rapporteurs for imidazole
BARRON Thomasina	KORHONEN Hanna (Leinonen)
BJORGE Christine	McGARRY Helen (adviser to Andrew Smith)
CARVALHO João	NÚÑEZ Laura (Tadeo) adviser for CLH Rapporteurs for dodemorph and dodemorph acetate
DI PROPSERO FANCHELLA Paola	PAPPONEN Hinni (Leinonen)
DUNAUSKIENE Lina	PECZKOWSKA Beata (Baranski) adviser for CLH Rapporteurs for TPP and AVK
DUNGEY Stephen	ROMOLI Debora (Paris)
GREIM Helmut	SMITH Helen (Smith) adviser for CHL Rapporteurs for imidazole and dodemorph
GRUIZ Katalin	TIESJEMA Gitte (Hakkert)
HAKKERT Betty	**Commission observers**
JENSEN Frank	BORRAS HERRERO Anna (DG ENTR)
KADIKIS Normunds	De BARROS FERNANDES Mariana (DG ENTR)
KAPELARI Sonja	LUVARA Giuseppina (DG ENTR)
KORATI Safia	POPOVA Temenuzhka (DG ENTR)
LEINONEN Riitta	SCAZZOLA Roberto (DG ENTR)

LUND Bert-Ove	LEFEVRE Remi (DG ENV)
MULLOOLY Yvonne	**Stakeholder observers**
PARIS Pietro	ROWE Rocky (ECPA)
PASQUIER Elodie	POOLE Alan (ECETOC)
PINA Benjamin	ANNYS Erwin (CEFIC)
POLAKOVICOVA Helena	BARRY Frank (ETUC)
PRONK Marja	BUONSANTE Vito
RUCKI Marian	DOLORES Romano (EEB)
RUPPRICH Norbert	MUNARI Tomaso (EuCheMS)
SCHLUETER Urs	REGO Laura (ECEAE)
SCHULTE Agnes	VEROUGSTRAETE Violaine (Eurometaux)
SMITH Andrew	**Other observers**
SOERENSEN Peter	VARNAI Veda, Croatian observer
STOLZENBERG Hans-Christian	**RAC Secretariat**
TADEO José Luis	BOWMER Tim
Van der HAGEN Marianne	FUHRMANN Anna
VIVIER Stéphanie	LUDBORZS Arnis
	SOSNOWSKI Piotr
	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

ANNEX I

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

Final Draft Agenda	*SEAC/A/19/2013*
AP 04a Report from other ECHA bodies and activities (AP 4.a)	*SEAC/20/2013/01*
Appointment of (co-)rapporteurs for restriction dossiers (AP 5.3)	*SEAC/20/2013/02 CONFIDENTIAL*
Recommendation of the review period in applications for authorisations (AP 6.2)	*SEAC/19/2013/03*
Appointment of (co-)rapporteurs for authorisation applications (AP 6.4)	*SEAC/20/2013/04 CONFIDENTIAL*

ANNEX II

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**
LUTTIKHUIZEN Cees	5.2b 1-Methylpyrrolidin-2-one (NMP)	Working for the MSCA submitting the restriction dossier
VERHOEVEN Julia	5.2b 1-Methylpyrrolidin-2-one (NMP)	Working for the organisation preparing the restriction dossier
THORS Åsa	5.2a Lead and lead compounds 5.2c Nonylphenol	Working for the MSCA submitting the restriction dossier
LESTANDER Dag	5.2a Lead and lead compounds 5.2c Nonylphenol	Working for the MSCA submitting the restriction dossier
SLEZAK Zbigniew	6.1 Authorisation application on phthalates	Previous involvement

ANNEX III

30 August 2013
SEAC/A/20/2013

Final Draft Agenda

20th meeting of the Committee for Socio-economic Analysis

11-13 September 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
11 September: starts at 14:00
13 September: ends at 13:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/20/2013
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-19 action points, written procedures and other ECHA bodies
SEAC/20/2013/01
For information

Item 5 – Restrictions

5.1 General restriction issues

For information

5.2 Restriction Annex XV dossiers

a) Lead in consumer articles – 2nd version of SEAC draft opinion
For discussion

b) 1-Methylpyrrolidin-2-one (NMP) – outcome of the conformity check
For agreement

c) Nonylphenol – outcome of the conformity check
For agreement

5.3 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/20/2013/02
(confidential room document)
For information

Item 6 – Authorisations

6.1 Authorisation application on phthalates – outcome of the conformity check and introductory presentation on the application

For agreement

6.2 Recommendation of the review period in applications for authorisation

SEAC/20/2013/03
For agreement

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

SEAC/20/2013/04
(confidential)
For agreement

Item 7 – AOB

a) Update of the work plan
b) Report from the project on economic valuation of environmental impacts

For information

Item 8 – Action points and main conclusions of SEAC-20

Table with Conclusions and Action points from SEAC-20

For adoption