4 September 2013

SEAC/M/19/2013 FINAL

Final

Minutes of the 19th meeting of the Committee for Socio-economic Analysis

5 – 6 June 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 nineteenth meeting of SEAC.

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

The Chair also mentioned that the meeting would be recorded and the records would be destroyed after the adoption of the minutes.

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

2) Adoption of the Agenda

The Chair introduced the draft Agenda of SEAC-19. The Agenda was adopted without 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 their advisors declared potential conflicts of interest to the substance-related discussions under the agenda items 5.2. These members did not participate in voting under the respective agenda items, as stated in Article 9.2 of the SEAC Rules of Procedure. One member asked if working for the competent authority (CA) automatically leads to a potential conflict of interest, even if the member did not contribute to the preparation of the dossier. The Chair responded that working for the CA submitting the restriction proposal by definition leads to a perceived conflict of interest. Participation in discussions with a low profile would be acceptable.

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-18 action points, written procedures and other ECHA bodies

The Chair reported that all action points of SEAC-18 have been completed or would be followed up during the on-going SEAC-19 meeting. The Chair informed the Committee that following the exchange of views at the SEAC-18 meeting, the Secretariat has reviewed the involvement of the dossier submitter in discussions on conformity of restriction dossiers and proposes that the dossier submitter would be allowed to briefly present the proposal before the rapporteurs report on the outcome of the conformity check and the Committee enters into the discussion. However, after such introductory presentation, the dossier submitter should continue to follow the discussion on conformity strictly as an observer. The Secretariat proposed to apply this new system starting from

the NMP restriction dossier, the conformity of which was being discussed within this plenary meeting.

The Chair also informed the participants about a calculation error identified by one SEAC member in the adopted final opinion of SEAC on the Chromium (VI) restriction proposal and the corrective actions taken. The error resulted in a significant underestimation of the cumulative cost. However, the justifications of the opinion regarding the proportionality of the restriction did not change since the estimated benefits are still substantially greater than the costs. The corrected document was made available to the Committee on 20 March 2013 and later on to the Commission. The Chair noted that the Secretariat has taken this mistake seriously and has already started to scrutinise different calculations in the on-going restriction dossiers more carefully to support the (co-)rapporteurs.

The Chair stated that following the action points of the SEAC-18 meeting, the Commission had provided to the SEAC Secretariat a summary of its 4 December 2012 workshop on synergies between REACH and other EU legislation, which had been uploaded to CIRCABC.

The Chair informed the Committee that the final minutes of SEAC-18 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-18 minutes.

The Chair explained that a report covering the developments in the ECHA MB, RAC, MSC, the Forum and for the first time the Biocidal Products Committee (BPC) had been compiled and distributed to SEAC as a meeting document (SEAC/19/2013/01).

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

The Chair provided a brief report from the tele-interviews he had conducted with SEAC stakeholder observers after the SEAC-18 meeting. The feedback received from them was similar to the feedback received from members. The stakeholder observers considered it problematic that not enough members are active in the plenary discussions. They also expressed some concerns regarding the need for specific competencies among members and occasional policy driven interventions as well as uncertainty in relation to the transparency in handling authorisation applications by the Committees. However, the stakeholder observers considered as very positive the openness in discussions, the limited use of closed sessions and the possibility for stakeholder observers to get the floor when they want to contribute. Similarly, appreciation was expressed for the critical debates on restriction dossiers, the possibility to bring additional experts for specific agenda items, the good work done by the rapporteurs and the good interaction between the rapporteurs and the Secretariat.

Finally, the Chair informed the participants about the report being prepared for the ECHA MB on the functioning of the Committees (RAC, SEAC and MSC). The workload in SEAC has so far been acceptable, noting that half of the members have volunteered for rapporteurships. In the future, the workload will rise and SEAC might face lengthier meetings.

5) Restrictions

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

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

- Sweden has submitted a new intention on Nonylphenol and Nonylphenol ethoxylates. Although Nonylphenol (NP) is not used in the manufacturing of the textile it could be unintentionally added to the textile in low concentrations from

the degradation of Nonylphenol ethoxylate (NPE) in the manufacturing process. NPE is used for various purposes in the production of textile. It is a surfactant used for dispersion, emulsification, cleaning, etc. NPE degrades to NP mainly in the waste water treatment plant but this can thus also occur somewhere in the manufacturing process. The use of NPE within the textile sector in EU is restricted in concentrations equal or higher than 0,1% (if not used in closed systems) since 2005. The major part of textiles consumed within the EU is however imported from suppliers outside the Union. The expected submission date is 2 August 2013.

- France has submitted an intention on Bisphenol A (BPA). The opinion from Anses published in April 2013 confirmed the health effects of BPA, particularly for pregnant women in terms of potential risks to the unborn child. Some exposure situations, mainly related to the handling of thermal paper (cash register receipts, credit card receipts, etc), leading to potential risk for human health have been identified. Therefore, the scope of the restriction will be the use of BPA in thermal paper. The expected submission date is 17 January 2014.

The Chair mentioned that the calls for (co-)rapporteurs for the Bisphenol A restriction dossier would be launched shortly after RAC-25/SEAC-19.

The Chair informed the Committees that the Secretariat had done the editorial revision of the opinion template for restrictions and had included in the template a further possibility to describe uncertainties following the recommendation of SEAC. The revised opinion template has been uploaded to CIRCABC Interest Groups of both Committees.

5.2) Restriction Annex XV dossiers

a) Dichlorobenzene – 1st version of SEAC final opinion

As an introductory opening, the Chair reminded the participants that the purpose of the proposed restriction by ECHA is to ban the use of 1,4-dichlorobenzene (DCB) in toilet blocks and air fresheners used in toilets or other domestic or public indoor areas, or offices. According to the opinion adopted by RAC at RAC-24, risk was identified for both consumer and professional uses. The Chair informed the Committee that the Forum Working Group on Restrictions had provided an additional advice on enforceability of this restriction proposal to the SEAC rapporteurs on 17 May 2013. Based on this, the rapporteurs slightly modified the wording of the proposed restriction in the SEAC opinion to reflect the advice given. Furthermore, the public consultation on the SEAC draft opinion was closed on 17 May 2013. However, there were no comments received during this consultation.

The Chair then invited the rapporteurs to present the 1st version of the SEAC final opinion. The rapporteurs explained the minor editorial changes made in the opinion in order to take into consideration the Forum Working Group advice. SEAC members fully supported the changes introduced by the rapporteurs in the wording of the proposed restriction.

After a short exchange of views, SEAC adopted the final opinion on 1,4 DCB by consensus. It was agreed that the rapporteurs and the Secretariat would make the necessary editorial changes in the Background Document (BD) and the Secretariat would publish the final opinion of SEAC on 1,4 DCB and the BD on the ECHA website.

Furthermore, the Secretariat will forward the final opinions of SEAC and RAC and the BD to the Commission.

b) Lead in consumer articles – 1st version of SEAC draft opinion

The Chair welcomed the RAC rapporteurs and the dossier submitter representatives from the Swedish MSCA (one representative followed the discussions in person at the plenary meeting and the rest of the representatives remotely as observers).

The Chair introduced the current state of the opinion development for the restriction proposal on the placing on the market of lead and its compounds in articles intended for consumer use, submitted to ECHA in December 2012. The proposal is targeted at consumer articles that could be placed in the mouth by children, considering that children are the most vulnerable group. Lead compounds (but not elemental lead) are classified as toxic to reproduction, category 1 and 2. The main route through which small children (between ages of 6 and 36 months) are exposed to lead from consumer articles is by mouthing. The key negative effect from such exposure is the impairment of the development of the central nervous system and this health risk cannot be adequately controlled with the existing EU legislative measures. Following that SEAC agreed on the conformity of the dossier in March 2013, the public consultation on the dossier was launched on 21 March 2013. The SEAC commenting round on the dossier closed on 10 May 2013, with three SEAC comments received within the deadline and there were also two late comments received. The 1st version of the SEAC draft opinion was provided to the Committee on 17 May 2013, with the written commenting round finishing by 7 June 2013. The aim of the discussion is to agree on the main elements presented in the 1st version of the SEAC draft opinion, more specifically on the scope and the costs.

After the introduction the RAC rapporteurs were invited to report back from the RAC discussions on the 1st version of the RAC opinion on lead in consumer articles. RAC had supported the general approach taken based on the scientific principles laid down by RAC in the opinion for lead in jewellery in 2010. In addition, RAC had discussed the issue migration versus content. Regarding the scope RAC had discussed the definition on placing in the mouth in great detail, and in relation to mouthing time RAC had decided to take forward two hours of mouthing time for consumer articles mouthed by children of all ages as a more conservative estimate. Furthermore, 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. RAC had concluded that primarily consumer articles based on either metal alloys or plastics that can be placed in the mouth by children are in the scope of the proposed restriction.

As a clarification to SEAC's questions, the RAC rapporteurs confirmed that clothes and textiles as such are considered to be out of the scope of the proposal and that therefore only their parts that could contain lead e.g. buttons, zippers and (coloured) plastics are covered.

An advisor wanted to know whether RAC had discussed a mouthing time that could be used for the benefit calculation, and the RAC rapporteurs responded that RAC had mainly discussed reasonable worst case mouthing times as these are used in the risk assessment. The Secretariat confirmed that also the realistic case scenario would be reviewed for the use within the impact assessment.

The SEAC rapporteurs presented the 1st version of the SEAC draft opinion that focused on the scope and the costs and the main elements in the preliminary draft Forum advice as well as SEAC members' comments on the dossier.

Several SEAC members, including the rapporteurs, considered the wide scope of the proposal challenging and suggested to include indicative lists of articles that fall within the scope (positive list) or out of the scope (negative list) of the proposed restriction further to possible derogations in the Background Document in order to provide clarity on the scope of the proposal. It is expected that the public consultation will provide additional information on these issues, and the discussion will for that reason have to continue in September. The Committee was informed that the dossier submitter is working on the clarification of the articles categories that have been used in the current assessment and reflect the main types of consumer articles to be covered by the proposed restriction. The Secretariat pointed out that articles covered by other EU legislations that regulate lead are considered to be out of the scope of the proposed restriction (i.e. food contact materials, toys, etc). This will be clearly reflected in the updated Background Document and possibly in the wording of the proposal.

Aiming at narrowing the scope, SEAC discussed the definition provided by the rapporteurs for articles which can be placed in the mouth of children. It was concluded also to include the size of the articles. In this context, a reference was made to the guideline on the interpretation of the concept "which can be placed in the mouth" as laid down in the entry 52 of Annex XVII. Some SEAC members noted that this concept, which defines the size and accessibility of articles, can be helpful to define the articles covered by the proposed restriction. In addition, an observer agreed that such definition could also be useful for industry to distinguish the consumer articles that fall within the scope, mainly on the basis of accessibility to small children. In addition, one SEAC member raised an issue of the cost for enforcement due to the wide scope of the proposal.

A SEAC member referred to the US regulation on lead with a focus on children articles, which could be considered worthwhile to look into more in detail. The Secretariat responded that it would not be possible to follow the US approach as a risk management option as such since this is not included in the proposal under public consultation.

Given the complexity of the dossier and the volume of work to be done, a SEAC member proposed that the Secretariat should consider whether a working group should be appointed to assist the rapporteurs. In this context, another member highlighted also the importance of close cooperation between RAC and SEAC due to the interdependencies in the opinion development on this proposal. The Chair explained that the Secretariat in consultation with the rapporteurs would try to find a suitable approach for members to interact in the opinion development process, but that it is premature to decide if a working group is the best format for this.

It was noted that the original cost calculations build on costs for clothes, for example, and not on lead-containing parts of clothes such as buttons and zippers. That leads to an overestimation of the substitution costs associated with these articles. The dossier submitter is currently revising the cost calculations by taking this aspect into account. Some members argued that also benefits were overestimated, and consequently these are now presently being re-assessed and revised by the dossier submitter.

SEAC discussed the methodological approaches taken by the dossier submitter which partly are based on principles laid down by SEAC in their opinion on lead in jewellery (2010). It was felt that the methodology used would need some further justification to check whether the current cost calculation is sufficiently representing costs for different potential uses of lead in articles included in the restriction. It was suggested to select a variation of typically different uses to check whether the costs calculations made hold for these uses. Potentially, further modification of the cost calculation would be required as a result of the proposed analysis. Members also proposed to address the issue of recycled lead and unintended use of lead in the cost calculation.

Some members, as well as a stakeholder observer, questioned the accuracy of the XRF method for measuring lead concentration in certain consumer applications as compared to certain wet chemical methods, and promised to provide the rapporteurs with scientific evidence on this if available. Furthermore, according to a stakeholder observer the methods for migration measurements are yet to be validated.

The Chair reminded the Committee that the Forum advice would address some enforceability relevant issues, including the availability of analytical methods. Furthermore, derogations will be discussed at the September meeting as the public consultation is still going on. In addition, stakeholder observers were encouraged to invite third parties to provide any additional information as early as possible, since the closure of the public consultation (21 September 2013) is after the next SEAC plenary.

Finally, the rapporteurs were invited to take comments received into account in the 2nd version of the SEAC draft opinion which is due by mid-August 2013.

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

The Chair welcomed the RAC (co-)rapporteurs and the dossier submitter representative from the Netherlands.

The Chair reminded the Committee that the restriction dossier on NMP was submitted by the Netherlands to ECHA on 19 April 2013. The conformity check process was launched in RAC and SEAC on 10 May and the Committees are expected to reach a conclusion on conformity by 8 June 2013 at the latest.

The representative of the dossier submitter provided an introductory presentation on the proposal. The Annex XV dossier proposes a restriction on the manufacture and use of NMP by professional and industrial workers. According to the proposal, NMP may only be manufactured and used if it can be guaranteed that the exposure (as 8-hr TWA) will remain below 5 mg/m³, peak exposure would remain below 10 mg/m³ and protective clothing and gloves are used. This Annex XV restriction dossier is targeting both industrial and professional uses of NMP. The consumer use is not included. NMP is classified as a reprotoxic substance category 1B based on developmental toxicity, but is also classified as skin, eye and possibly respiratory irritant. The aim of the restriction proposal is to control the risks resulting from exposure of the general worker and more specifically of expecting mothers. The dossier identifies that the exposure to NMP may result e.g. in reduced birth weight of the newborns or stillbirth. The risk resulting from the exposure of all workers and specifically pregnant women to the substance cannot be adequately controlled with legislative provisions currently in place in EU.

The RAC (co-)rapporteurs informed the participants that RAC had concluded that the NMP restriction dossier is not in conformity with the requirements of Annex XV of the REACH Regulation. This was due to the fact that the submitted Annex XV report does not appear to present sufficient information to allow an independent assessment of the hazards. The RAC (co-)rapporteurs explained that the toxicity studies are generally described quite briefly in section B5.9 of the report, with the effects described as increases or decreases without indicating the magnitude of the effect, thus not allowing an independent assessment of the data. As the proposal is based on establishing new OELs, it is very important for RAC to be able to independently assess the DNELs. In addition, it was felt that the details of the study should also be available for the public consultation.

The SEAC (co-)rapporteurs presented the outcome of the SEAC conformity check and recommended that the dossier would be considered not in conformity. The (co-) rapporteurs explained that evaluation of the assessment of the proposed restriction related to proportionality does not seem possible based on the provided information in the dossier. The conclusion in the dossier on proportionality is that the proposed restriction is proportionate. However, the basis for this statement was according to the rapporteurs not well justified. With regard to information on costs, estimates for 4 out of 18 sectors are presented. For two sectors the costs are said to be minimal without giving any figures or other arguments. For other sectors no information at all is available. Two sectors are not mentioned in the compliance cost table (p. 180) as it is expected that production in these sectors will cease. One of these sectors is wire coating which seems to account for 1/3 of total NMP use. Furthermore, it seems that no attempt has been made to produce an estimate of the total costs. Only costs for the 4 sectors referred to above are summarized and presented as minimum costs for the proposed restriction.

One SEAC member explained that he had a different impression of the dossier compared to the (co-)rapporteurs. According to him, there is a clear analysis made sector by sector. Even if some information is missing, it seems to have been included in the Appendices. This member was of the opinion that having a clear sector by sector approach the Committee would be able to come to a conclusion. The rapporteur, however, stressed the importance of looking at the whole picture.

One member compared this restriction dossier with earlier dossiers processed by SEAC. According to him, the dossiers on Lead, Chromium or Phthalates did not contain much more information, but were still considered in conformity by this Committee. The dossiers referred to above also did not include data on all sectors. Another member emphasised the importance of maintaining a consistent decision making, equal treatment of dossiers

by the Committee and expressed the view that the NMP proposal should be considered in conformity from the SEAC standpoint, acknowledging also that there are some data gaps in the report. Several other members concurred with this view. Following on from this exchange of views, SEAC agreed that the restriction dossier on NMP thus conforms to the requirements of Annex XV of the REACH Regulation.

After the conformity check discussion was concluded the dossier submitter declared that the Netherlands will adapt the dossier based on the RAC conformity check outcome, but that there was no additional information on costs available that could be added to the dossier.

The Chair informed the participants that the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter.

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

The Secretariat presented the recommendation of the Chair for the appointment of (co-) rapporteurs for the restriction dossier on Nonylphenol and Nonylphenol ethoxylates (to be submitted by Sweden by 2 August 2013) as outlined in the meeting document SEAC/19/2013/02 CONFIDENTIAL. SEAC agreed on the appointment as proposed in the recommendation.

The Chair informed the Committee that no volunteers had come forward in the call for expressions of interest for (co-)rapporteurs of the Chrysotile 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.

6) Authorisations

6.1) Capacity building

The Secretariat presented the tasks of SEAC in Application for Authorisation (AfA) process as the introduction to the upcoming work concerning the AfA process in the Committee. The purpose of the presentation was to recap what the Committees have to do to prepare their opinions on applications for authorisation, to provide a summary of the capacity building programme for the members who had no possibility to follow all the steps of the process, and to give a few highlights concerning the AfA process.

The Committee members appreciated the promise that the Secretariat would support the rapporteurs to maximum extent in their work on applications. One participant questioned the difference between the business rules check and the conformity check of an authorisation application, to which the Secretariat responded by clarifying that these two processes are separate steps in the work on an AfA. The business rules check is the task of the Secretariat, who will also prepare a preliminary conformity check report on an AfA.

Several members and stakeholder observers questioned the confidentiality of AfA discussions and STO involvement in trialogues. The Secretariat underlined the importance of the confidentiality in the process and that no CBI is disclosed during the discussions. The participants were informed that some of the trialogues or parts of trialogues can be closed to STOs due to confidentiality reasons. The same applies to plenary discussions.

The SEAC members were also interested in what exactly SEAC can expect from RAC and to which extent they should assess the justification for the adequate control route. The Secretariat pointed out to the Committee that the decision if the adequate control was properly justified is in the remit of RAC. The Secretariat shortly explained on which aspects of an application SEAC can expect input from RAC.

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

The Secretariat presented to RAC and SEAC the note on the Committees' recommendation of the review period in AfA. "Normal", "short" and "long" review periods were proposed as the starting point for the recommendation. The Secretariat had intended to propose 8, 4 or 12 year review periods for agreement at this meeting. However, due to the link between the opinions of the Committees and the Commission decision, the Commission services had requested more time for reviewing the note to ensure that the review period in the opinions matches with their own considerations in the decision.

The representative of the Commission confirmed their support for the general idea of the recommendation and the proposal to differentiate between "normal", "short" and "long" review periods.

One representative from an industry stakeholder organisation (Cefic supported by Eurometaux) remarked that the ECHA proposal recognises differences in the industrial world and would discourage rumours about the length of review periods. He also recognised the recommendation to be helpful for industry in undertaking an analysis of alternatives, and expressed industry's preference for a four year review period as a minimum, taking into consideration the time needed for switching to alternative substances and actions/permits which may be required under other legislations. A representative of another stakeholder organisation (ETUC) expressed the opinion that eight and 12 year periods are too long for granting an authorisation.

The Committee members supported the principal proposal of "normal", "short" and "long" review periods. For some, the starting point might be the "short" as opposed to the "normal". Concerning the length of the review periods, members had different views. Some members thought that the proposed review periods were too long and would not give enough pressure for substitution. Others considered the lengths reasonable. There was some discussion about whether the length of the review period should be based on socio-economic or political considerations. It was noted that any political elements would be taken up by the Commission at the decision making stage, while the Committees needed to base their recommendation on the review period on scientific evaluation of the socio-economic considerations set out in the application.

The Commission confirmed that it expects to receive a clear recommendation by the Committees on the review period based on scientific reasoning.

The Chair concluded that the Committees agreed on the overall approach for setting the review period. The Committees will reflect on the appropriate number of years for the "normal", "short" and "long" review periods, and if there are exceptional circumstances to justify deviating from these. It was agreed that the Secretariat would table the revised document for discussion and agreement at September 2013 plenary meetings.

6.3) Revised working procedure for appointment of (co)-rapporteurs for authorisation applications (joint RAC/SEAC session)

The Secretariat presented to the Committees the revised working procedure for appointment of (co-)rapporteurs for AfA by RAC and SEAC. The Committees agreed on the revised working procedure as proposed.

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

Following the agreement on the new working procedure for appointment of (co-) rapporteurs for AfA by RAC and SEAC, the Committee members expressed their interest in (co-)rapporteurship by applying to the pool of (co-)rapporteurs and indicating the absence of conflicts of interest. The updated pool was agreed by SEAC. The Chair

informed the Committee who from the pool has been selected to rapporteur the first authorisation application that has been submitted to ECHA.

One SEAC member pointed out that only 8 members have put themselves up for (co-) rapporteurships, which is less than 1/3 of the Committee. ECHA expects a big number of applications in the near future and it will be a heavy burden for these 8 members to process the applications. The Chair concurred with this and strongly encouraged other Committee members to volunteer to the pool of rapporteurs.

7) AOB

a) Update on the workplan

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

b) First meeting of the NeRSAP network – a short debrief and potential future of the network

The Chair reminded the participants that at the SEAC-18 meeting, an observer from Eurometaux had provided information to the Committee about the idea of creating an informal network platform for practitioners on SEA and Analysis of Alternatives, where they could exchange and learn from each other's experiences with methods and concepts related to SEA and Analysis of Alternatives in restrictions and authorisations. At SEAC-18, the Committee was informed that Eurometaux had offered to host the first such meeting on 9 April 2013 and it was agreed that a report from this meeting would be provided at the SEAC-19 plenary meeting. The observer from Eurometaux was then invited to give a brief presentation on the results of the first meeting of the network.

The Chair expressed his appreciation for creating this forum for practitioners to meet and discuss about methodology, but reminded about the importance that SEAC members participating are perceived as independent in their decision-making. He therefore welcomed the initiative by the organisers to consider this aspect as well.

8) Action points and main conclusions of SEAC-19

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-19, 5-6 June 2013
(SEAC-19 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 without modifications.	**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-18 action points, written procedures and other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-18. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/19/2013/01), including the oral report from the Commission on SEAC related developments in CARACAL. SEAC was informed about the calculation error in the SEAC opinion on Cr VI (which will be included in the minutes of SEAC-19). In addition, SEAC took note of the Chair's report from the teleinterviews conducted with SEAC stakeholder observers.	
5. Restrictions	
5.2 Restriction Annex XV dossiers	
a) Dichlorobenzene – 1st version of SEAC final opinion	
SEAC rapporteurs presented the first version of the SEAC final opinion. SEAC discussed the main changes made to the opinion of SEAC. SEAC adopted the SEAC final opinion by consensus. SEAC took note of the Background Document (BD) to this opinion.	**Rapporteurs** and **SECR** to make necessary editorial changes to the BD to make it in line with the adopted SEAC opinion. **SECR** to publish the final opinion of SEAC on DCB on the ECHA website and to forward the final opinions of SEAC and RAC and the BD to the Commission.
b) Lead in consumer articles – 1st version of SEAC draft opinion	
SEAC rapporteurs presented the first version of the SEAC draft opinion and the comments received from the members on	**Rapporteurs** to take comments into account in the next version of the SEAC draft opinion (due by mid-August 2013).

the Annex XV dossier.	**Rapporteurs** in cooperation with the Secretariat to submit a response to comments for distribution to SEAC members. **STOs** to encourage third parties to provide comments in the public consultation as soon as possible (public consultation closes 21 September 2013). **SECR** to consider the involvement of members in support of the (co-)rapporteurs.
c) 1-Methylpyrrolidin-2-one (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.	**Rapporteurs** to finalise the recommendations to the dossier submitter. **SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this 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 agreed on the Chair's recommendation to appoint the (co-)rapporteurs for the restriction dossier on nonylphenol (meeting document SEAC/19/2013/02 CONFIDENTIAL).	**SEAC members** to volunteer for (co-) rapporteurship on chrysotile in order to be included in the pool. **SECR** to launch the call for expression of interest in (co-)rapporteurship for bisphenol A restriction dossier shortly after SEAC-19.
6. Authorisations	
6.1 Capacity building	
SEAC was provided with the presentations on the tasks of SEAC in authorisation process.	
6.2 Recommendation of the review period in applications for authorisation (Joint RAC and SEAC Session)	
RAC and SEAC discussed the recommendation on setting the review period. RAC and SEAC agreed on the overall approach for setting the review period.	**SECR** to table the revised document for discussion and agreement at September plenary meetings.
6.3 Revised working procedure for appointment of (co-)rapporteurs for authorisation applications	
RAC and SEAC agreed on the revised	**SECR** to upload the revised working procedure

working procedure for appointment of (co-)rapporteurs for authorisation applications.	on ECHA website.
6.4 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 rapporteur for the first authorisation application.	**SEAC members** to volunteer to the pool of (co-)rapporteurs for applications for authorisation.
9. Action points and main conclusion of SEAC-19	
SEAC adopted the action points and main conclusions of SEAC-19.	**SECR** to upload the action points and main conclusions to CIRCABC IG.

III. List of Attendees
SEAC-19

SEAC members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
DALTON Marie
DANTINNE Catheline
FANKHAUSER Simone
FEYAERTS Jean-Pierre
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GRANDI Silvia
KIISKI Johanna
KNOFLACH Georg
LUTTIKHUIZEN Cees
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz Georg
SLEZAK Zbigniew
STOYANOVA-LAZAROVA Elina Velinova
THIELE Karen
THORS Åsa
VOIVONTAS Dimosthenis

ECHA staff
CALVO TOLEDO Juan Pablo
DUBOURG Richard
GIORDANO Serena
JACQUEMIN Katline
KIOKIAS Sotirios
KOSK-BIENKO Joanna
KIVELA Kalle
LOGTEMEIJER Christiaan
LUDBORZS Arnis
MAROSVOLGYI Nikoletta
MERKOURAKIS Spyridon
ORISPÄÄ Katja
ÖBERG Tomas
RODRIGUEZ IGLESIAS Pilar

Advisors, invited experts, dossier submitters (DS) & observers
BEEKMAN Martijn (advisor to C. Luttikhuizen and NMP DS representative)
CARLSSON Mattias (Lead and lead compounds DS representative, via Webex)
CASTELLI Stefano (invited expert, IT)
COGEN Simon (advisor to J-P. Fayaerts)
D'AMICO Flaviano (advisor to S. Grandi)
GOLOVACIOVA Llona (invited expert, LT)
HENNIG Philipp (advisor to K. Thiele)
KORHONEN Hanna (advisor to J. Kiiski)
LANGTVET Espen (observer, NO)
PALOTAI Zoltan (invited expert, HU)
PUES Jonathan (advisor to C. Dantinne, via Webex)
SLETTEN Thea Marcelia (invited expert, SE)
VASS Anne-Marie (Lead and lead compounds DS representative)
VERHOEVEN Julia (advisor to C. Luttikhuizen)

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)

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

SADAM Diana
SHUQOM Natasha
SOSNOWSKI Piotr
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
BARANSKI Boguslaw
BJORGE Christine
BORGES Teresa
CARVALHO João
Di PROSPERO FANGHELLA Paola
DUNAUSKIENE Lina
DUNGEY Stephen
GRUIZ Katalin
HAKKERT Betty
KADIKIS Normunds
KAPELARI Sonja
KORATI Safia
LEINONEN Riitta
PARIS Pietro
PASQUIER Elodie
PINA Benjamin
POLAKOVICOVA Helena
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SCHULTE Agnes
SMITH Andrew
SOERENSEN Peter
STOLZENBERG Hans-Christian
TADEO José Luis
TSITSIMPIKOU Christina
Van der HAGEN Marianne
VIVIER Stéphanie

Advisors (to the RAC members)
ALESSANDRELLI Laura (advisor to P. Di Prospero Fanghella)
KORHONEN Hanna (advisor to R. Leinonen)
NÚÑEZ Laura (advisor to J. L. Tadeo)
EKOKOSKI Elina (advisor to R. Leinonen)
PECZKOWSKA Beata (advisor to B. Baranski)
ROMOLI Debora (advisor to P. Paris)

EFSA observer
PARRA MORTE Juan

Stakeholder observers
ANNYS Erwin (CEFIC)
DOLORES Romano (EEB)
MUNARI Tomaso (EuCheMS)
VEROUGSTRAETE Violaine (Eurometaux)

Remote participants
RAC members
BRANISTEANU Radu
Advisors
SMITH Helen (advisor to RAC member A. Smith)

ECHA staff
BOWMER Tim
CSAK Viktoria
DVORAKOVA Dana
KOKKOLA Leila
RIVERO Debora

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*
Report from other ECHA bodies and activities (AP 4.a)	*SEAC/19/2013/01*
Appointment of (co-)rapporteurs for restriction dossiers (AP 5.3)	*SEAC/19/2013/02 CONFIDENTIAL*
Revised working procedures for appointment of (co-)rapporteurs for authorisation applications (AP 6.3)	*SEAC/19/2013/03*
Recommendation of the review period in applications for authorisations (AP 6.2)	*SEAC/19/2013/04*
Appointment of (co-)rapporteurs for authorisation applications (AP 6.4)	*SEAC/19/2013/05 CONFIDENTIAL*

ANNEX II

DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS

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

Name of participant	**Agenda item**	**Interest declared**
BEEKMAN Martijn	5.2c 1-Methylpyrrolidin-2-one (NMP)	Dossier submitter
LUTTIKHUIZEN Cees	5.2c 1-Methylpyrrolidin-2-one (NMP)	Dossier submitter
THORS Åsa	5.2d Lead and lead compounds	Dossier submitter
VASS Anne-Marie	5.2d Lead and lead compounds	Dossier submitter
VERHOEVEN Julia	5.2c 1-Methylpyrrolidin-2-one (NMP)	Dossier submitter

6 June 2013
SEAC/A/19/2013 Final

Final Draft Agenda

19th meeting of the Committee for Socio-economic Analysis

5-6 June 2013
ECHA Conference Centre (Annankatu 18, Helsinki)
5 June: starts at 14:00
6 June: ends at 17:00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/19/2013
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-18 action points, written procedures and other ECHA bodies
SEAC/19/2013/01
For information

Item 5 – Restrictions

5.1 General restriction issues

For information

5.2 Restriction Annex XV dossiers

a) Dichlorobenzene – 1st version of SEAC final opinion
For adoption

b) Lead in consumer articles – 1st version of SEAC draft opinion
For discussion

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

5.3 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/19/2013/02
(confidential)
For information and agreement

Item 6 – Authorisations

6.1 Capacity building

For information

6.2 Recommendation of the review period in applications for authorisation

SEAC/19/2013/04
For discussion/agreement

6.3 Revised working procedure for appointment of (co-)rapporteurs for authorisation applications

SEAC/19/2013/03
For discussion/agreement

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

SEAC/19/2013/05
(confidential room document)
For information/agreement

Item 7 – AOB

a) Update of the work plan
b) First meeting of the NeRSAP network – a short debrief and potential future of the network

For information

Item 8 – Action points and main conclusions of SEAC-19

Table with Conclusions and Action points from SEAC-19

For adoption