

16 May 2018

SEAC/M/38/2018 Final

Final

Minutes of the 38th meeting of the Committee for Socio-economic Analysis

13 - 15 March 2018

I. Summary Record of the Proceeding

1) Welcome and apologies

Tomas Öberg, Chairman of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the thirty-eight meeting of SEAC. The Chairman also informed SEAC that apologies have been received from four members, in addition one co-opted member had resigned from the Committee.

The Chairman informed the participants that the meeting would be recorded solely for the purpose of writing the minutes and the recordings would be destroyed once no longer needed.

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

2) Adoption of the Agenda

The Chairman introduced the final draft agenda of SEAC-38 (SEAC/A/38/2018 rev.1). The agenda was adopted with minor modifications under AOB. 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 Chairman requested members and their advisors participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Five members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.1.a.1, 5.1.a.4 and 5.1.a.5 and 6.2.a-3. These members did not participate in voting under those 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-37 action points, written procedures and update on other ECHA bodies

The Chairman informed the participants that all action points of SEAC-37 had been completed or would be followed up during the on-going SEAC-38 meeting. The Chairman also informed the Committee that the final minutes of SEAC-37 had been adopted by written procedure and had been uploaded to S-CIRCABC as well as on the ECHA website. The Chairman thanked members for providing comments on the draft SEAC-37 minutes.

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

b) General SEAC procedures

The Chairman informed the meeting that the three years term of the co-opted members in RAC and SEAC expires in September 2018. From ECHA's point of view, their contribution to the work of the Committee has been very valuable. The anticipated workload in the coming years justifies maintaining additional specialist capacity. In the interest of transparency, ECHA has chosen to use an open call to select candidates for all 10 co-opted places in RAC and SEAC. The Chairman invited the members to agree on the draft proposal for co-opting additional members in line with the meeting document (SEAC/28/2018/01), which confirms the selection procedure and the required competences. SEAC agreed on the selection procedure as proposed by the Secretariat and on the required competences. One member suggested to also add impact assessment and its methodologies to the list.

In addition, the Chairman informed the Committee that the Secretariat is changing the way in which members can express their interest to volunteer as (co-)rapporteurs, to an electronic form. SEAC took note of a short demonstration on the new online survey to be used.

5) Restrictions

5.1) Restriction Annex XV dossiers

a) Opinion Development

1) Diisocyanates – final SEAC opinion

The Chairman welcomed the dossier submitter's representatives from Germany, an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer. He reminded the participants that this restriction proposal (submitted by Germany) limits the use of diisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures as well as a minimum standardised training package have been implemented. Information on how to get access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of diisocyanates in the substance or mixture placed on the market or used would be less than 0.1% by weight, as well as for mixtures containing diisocyanates at higher levels than 0.1% by weight which fulfil criteria that show that the potential risks using such products are very low. The Chairman reminded the Committee that the public consultation on the agreed SEAC draft opinion ended on 20 February 2018 with 20 comments received. The (co-)rapporteurs updated the opinion based on the comments received and the draft of the SEAC final opinion was made available to the Committee on 6 March.

The (co-)rapporteurs were then invited to present the results of the public consultation and their impact on the SEAC opinion. They reminded the Committee that SEAC was concerned about potential extra costs due to technical and organisational measures required in the proposal and a specific question was posed on this in the public

consultation on the SEAC draft opinion. Several industry actors had commented that the measures described in the proposal are already implemented due to other legislation and it was claimed that cases where the measures are not implemented relate to non-compliance. The draft SEAC opinion was updated accordingly. The rapporteurs also reminded the participants that SEAC expressed concern about the RAC recommendation on MSs involvement in the approval of the training material – this concern was shared by several MSs and industry stakeholders in the public consultation and the draft SEAC opinion was amended in this regard. Furthermore, the rapporteurs informed SEAC that in relation to possible derogation for medical devices, no specific information on costs/benefits of derogating (or not) became available in the public consultation and the rapporteurs therefore have not included this derogation in the proposed restriction. The rapporteurs also reminded the Committee that a specific question was posed on the length of the transitional period, to which many parties proposed 5-6 years, however, with no specific justification. As time will be needed, first, for setting up the training programs, and then for training the workers, the rapporteurs proposed to SEAC to set 2 years transitional period for setting up the training programs and 4 years for taking the training.

One SEAC member noted that the proposed transitional period seems too long, considering that industry has been claiming they already have some training in place. The rapporteurs responded that the situation is different across different sectors and some are more advanced than others. Another member raised a question what expectations the rapporteurs had for the evidence to justify the derogation for medical devices – there was some quantitative information provided by at least one company. The rapporteurs explained that they had evaluated the information submitted in the public consultation thoroughly and did not find there enough evidence for justifying this derogation. They added that one should not forget that the proposed restriction is not a total ban.

The same member was also interested if and how the rapporteurs had taken into account the comments received on the question posed by SEAC regarding the affordability of the proposed restriction to SMEs. The rapporteurs noted that the responses to this question were of quite general nature and therefore not so useful for the opinion. Finally, this member criticised the process between the agreement on the SEAC draft opinion and adoption of SEAC final opinion, as the time is too short, most comments arrive quite late in the public consultation and there is very limited and clearly insufficient time for the rapporteurs to review all comments and update the opinion accordingly. Several members questioned the length of the transitional period, which was not very clear in the draft of SEAC final opinion and it was suggested to make it clearer.

A representative of the European Commission noted that it is important that the opinion indicates exactly which information is available, what comes from whom (e.g. dossier submitter, industry, NGOs) and what SEAC has been able to assess. Also, he asked that it should be very clearly stated in the opinion that it is not on SEAC's remit to assess the appropriateness of the conditions within the restriction proposal of use to ensure minimisation of exposure.

SEAC adopted the final opinion by simple majority (with editorial modifications agreed at SEAC-38). One member raised reservations regarding the evaluation of practicalities, which he considered to be unfounded. Five members took minority position and

considered the restriction not warranted due to insufficient justification that the action is the most appropriate measure.

The rapporteurs were asked, together with the Secretariat, to make final editorial changes to the opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC opinion. The Secretariat will forward the adopted opinion and its supportive documents to the Commission as well as publish on the ECHA website. The Chairman thanked the rapporteurs for their work on this dossier.

2) Lead and lead compounds in PVC – final SEAC opinion

The Chairman welcomed the dossier submitter's representatives from ECHA and an occasional stakeholder observer. He reminded the participants that this restriction dossier (submitted by ECHA) proposes a restriction of lead compounds in PVC articles in concentrations equal to or greater than 0.1% (w/w) with a 15 year derogation for certain building and construction articles produced from recycled PVC (with a higher restriction limit of 1% w/w) and a 10-year derogation for PVC silica separators in lead acid batteries. The Chairman reminded the Committee that the public consultation on the agreed SEAC draft opinion ended on 20 February 2018 with seven comments received. The (co-) rapporteurs updated the opinion based on the comments received and the draft of the SEAC final opinion was made available to the Committee on 5 March.

The rapporteur was then invited to present the results of the public consultation and their impact on the SEAC opinion. She reminded the participants about the open issues with specific questions in the public consultation on the SEAC draft opinion – on derogation of recycled PVC (possibility to encapsulate articles made of recycled soft PVC with higher leaching potential), use of lead pigments in PVC and concentration limit. The rapporteur specified that comments received in the public consultation indicated that encapsulation of articles made of recycled soft PVC might well be technically feasible. She added that encapsulation techniques do not seem to be applied in practice yet and it is reasonable to allow a longer transitional period than 24 months. Therefore, the opinion justification text has been amended, but no change to the restriction is proposed. Furthermore, the rapporteur noted that no information was received in the public consultation that other lead pigments are used in PVC and therefore no changes to the restriction are proposed. With regard to the concentration limit, comments were received indicating that a concentration limit of 0.01% could cause problems due to cross-contamination. Further information received confirmed that lead concentrations of 0.01% could still be detected by using cost-effective analytical methods like XRF. The rapporteurs had therefore amended the opinion justification text, but no change to the restriction was proposed.

One stakeholder observer criticised that allowing substances of high concern being used in recycled products is not the right direction to go. The rapporteur responded that they had looked at the risks of recycling and found that these are lower than the risks of non-recycling and this was the main argument for proposing the derogation. Another stakeholder observer shared a similar concern – that derogations only postpone the problem of now to the future. An occasional stakeholder observer highlighted that PVC can be recycled 7 to 10 times and that in the future, there might be better solutions available to deal with this problem.

SEAC adopted the final opinion by consensus. The rapporteurs were asked, together with the Secretariat, to make final editorial changes to the opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC opinion. The Secretariat will forward the adopted opinion and its supportive documents to the Commission as well as publish on the ECHA website. The Chairman thanked the rapporteurs for their work on this dossier.

3) Lead and lead compounds in shot – third draft opinion

The Chairman welcomed the dossier submitter's representatives from ECHA, an industry expert (FACE) accompanying a regular stakeholder observer and a representative from the UNEP-Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), accompanied by an expert. He reminded the participants that this restriction proposal had been submitted by ECHA in April 2017 and had been considered in conformity by SEAC in its May/June plenary. The dossier proposes a restriction on the use of lead shot in wetlands. The harmonisation of the conditions of use of lead in shot with respect to wetlands is a priority at EU level as national legislation has already been enacted by some Member States (or regions in some Member States). The phasing out of lead gunshot in wetlands is also required under the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA), under the auspices of the UN Environment Programme (UNEP), to which the EU and many member states are parties. The Chairman reminded the Committee that the public consultation on this restriction proposal ended on 21 December 2017 with 278¹ comments received. The third draft opinion was made available to the Committee on 7 February 2018 and comments by six SEAC members were received during the subsequent commenting round. The aim of the meeting was for the Committee to adopt its opinion on this dossier taking into account the comments received in the public consultation.

The Secretariat briefly reported to SEAC on the RAC third draft opinion on this dossier that was discussed and adopted at the RAC-44 plenary meeting. The rapporteurs then presented the third draft opinion. They explained to the Committee that the key issues proposed for discussion at this meeting are proportionality of the restriction proposal, uncertainties evaluated in the SEAC draft opinion, practicality, including enforceability of the restriction proposal, as well as its monitorability. The SEAC rapporteurs concluded that benefits of the restriction are higher than its costs. Benefits only partly covered in the monetised estimate of €105 million are an underestimate of the total benefit. They noted that the non-quantified benefits were likely to be substantial (non-use values not included). They explained that in their view the upper bound cost estimate represent an unlikely worst case situation. The SEAC rapporteurs clarified that price differences on alternatives are likely to be lower, and that the non-quantified costs are uncertain, but likely to be minor. They also concluded that the restriction proposal is a cost-effective action to avoid lead emissions (depending on the scenario, the cost-effectiveness ranged from €0.3 to €25 per kg of lead). These values are far below the cost-effectiveness values estimated for other REACH restrictions on lead and other substances (e.g. PBT-substances). The SEAC rapporteurs also concluded that affordability is in general reasonable for hunters, i.e. additional cost for purchasing non-lead shot ammunition will be in the range of €0 (best case) to €65 (worst case) per year that correspond to 0-2.2% of the average annual hunting budget of a hunter. This cost, however, does not

¹ Comments containing offensive language received during the public consultation are considered to be inappropriate and they are discounted from the total number of the received comments.

include the testing and replacing of shotguns, which would be an additional cost to the affected hunter.

During the discussion on the scope of the restriction proposal the Secretariat clarified that the targeted shooting in wetlands is included in the scope of the restriction. An industry expert from FACE expressed general support towards the initiative to phase-out lead over wetlands. However he disagreed with the conclusions of the SEAC rapporteurs, in particular, on the cost calculations to comply with the restriction and to enforce it; those, according to FACE, are higher than estimated by the dossier submitter and by SEAC. He also disagreed with a proposed transitional period of three years, noting that awareness and social campaigns would be needed and suggested a five year transitional period. Among these issues he also highlighted contamination of wetlands by plastics from the spent ammunition, stronger justification for inclusion of clay shooting, and difficulties with the Forestry sector. Finland was mentioned by the FACE expert as an example where shooting of steel gunshot in certain forest parks is not allowed. A representative of the European Commission noted that certain clarifications of the analysis of the risk management options were needed and highlighted that the opinion would benefit from making clearer what the differences between the options are. In addition, he requested the Committee to present in the opinion a comparative analysis of 'possession' vs 'use' of lead gunshot. It was also stressed that it is very important that the opinion clearly highlights what the uncertainties are and what weight they may have on the final conclusion on proportionality. A representative of the stakeholder organisation expressed her concern about a narrow scope of the restriction proposal due to enforcement difficulties. She noted the importance of clear communication of the restriction consequences to the hunting communities.

The Committee agreed the draft opinion on the restriction proposal on lead in shot (with modifications agreed at SEAC-38) by consensus. The rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the agreed SEAC draft opinion and to ensure that the supporting documentation (Background Document and Responses to comments from the public consultation) is in line with the agreed SEAC draft opinion. The Chairman informed that the public consultation of the SEAC draft opinion will be launched on 21 March 2018.

4) Substances used in tattoo inks and permanent make-up

The Chairman welcomed the SEAC rapporteurs, representatives present in person or via webex of the dossier submitter (from Denmark, Norway and ECHA) and dossier submitter experts from Germany. The restriction proposal was submitted by ECHA together with Denmark, Italy and Norway on 6 October 2017. In addition, Germany contributed significantly to the proposal. The proposal aims to restrict the intentional use of certain substances in tattoo inks or to impose concentration limits for selected substances (impurities). These substances include those with harmonised classifications as carcinogenic, mutagenic, reprotoxic, skin sensitising/corrosive/irritant, eye damaging/irritant as well as other substances prohibited in cosmetic products (under the Cosmetic Products Regulation, (EC) 1223/2009) and selected impurities. Two restriction options (RO1 and RO2) with the same scope are proposed. They differ in terms of the proposed concentration limits and how the links with the Cosmetic Products Regulation annexes are managed. The restriction is expected to provide benefits because of avoided cases of non-infectious inflammatory, systemic, reproductive, developmental, and

carcinogenic adverse effects. The report demonstrates that very few avoided cases are necessary (e.g. 320 – 1 050 avoided cases of tattoo removal due to non-infectious inflammatory complications) for the benefits to exceed the costs of the proposed restriction options. The public consultation was launched on 20 December 2017 (and will end on 20 June 2018). Early public consultation comments (six received) were requested by 16 February 2018. The first version of the draft opinion was provided to the Committee on 2 March 2018, and no commenting round was organised prior to the meeting in order to test a new practice that might be implemented for the opinion development on the restriction dossiers.

The Secretariat gave a short update from RAC-44 discussions, where RAC had agreed that chemicals in tattoo inks pose a health risk for human population, although incidence and prevalence of tattoo-related adverse health effects is difficult to assess at the present moment.

The SEAC rapporteurs then presented the first draft opinion. They outlined the main scope of the restriction proposal and concluded that restriction is an appropriate EU wide measure. According to the rapporteurs, action on union-wide basis is justified as tattoo inks are placed on the market in all member states in EU, however there are differences in legal situation in different member states, and common requirement is needed across all supply chains that place tattoo inks on the EU market. Furthermore, the other RMOs assessed are likely not to be as appropriate as a restriction. The rapporteurs concluded that their assessment of RO1 and RO2 is still under development and it will be further elaborated once more input from the public consultation and Forum advice is available.

While presented with substitution cost (e.g. price difference between compliant and non-compliant inks as a proxy for substitution cost) and enforcement cost, some members commented that final figures might change once the scope has been defined, but supported the overall approach taken by the rapporteurs.

The Chairman concluded that based on the feedback provided to the rapporteurs, SEAC considered that the restriction is an appropriate EU-wide measure, and endorsed the overall methodology and key assumptions used in the estimation of substitution and enforcement costs. The rapporteurs were then requested to develop the second draft opinion, taking into account the SEAC-38 discussions, by early May 2018. In order to collect the remaining comments from SEAC members, the Secretariat will launch a two week commenting round in S-CIRCABC on the first version of SEAC draft opinion (by 29 March).

5) C9-C14 PFCAs, their salts and related substances

The Chairman welcomed the dossier submitters' representatives from Germany and Sweden, the RAC (co-)rapporteurs and the Forum rapporteur, following via WebEx. He informed the participants that the restriction dossier had been submitted by Germany and Sweden in October 2017 and proposes to restrict the use, placing on the market and import of C9-C14 PFCAs, their salts and related substances as substances on their own or in a mixture or in an article or parts therein in a concentration equal to or above 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCAs related substances. Thus, articles and mixtures manufactured in Europe can comply with the proposed threshold. C9-C14 PFCAs, their salts and related substances are mainly unintended by-products occurring during the manufacturing of per- and polyfluorinated

substances containing a carbon chain of less than nine carbon atoms, such as perfluorooctanoic acid (PFOA, C8-PFCA) based substances and perfluorohexanoic acid (C6-PFCA) based substances.

The Secretariat provided a brief update from the RAC discussion on this dossier held within RAC-44. The SEAC (co-)rapporteurs then presented to the Committee the first draft opinion. They explained that C9-C14 PFCAs are PBT/vPvB substances, for which it is not possible to establish a safe level of exposure and their emissions are to be minimised. These substances are ubiquitous and have the potential for environmental long-range transport. There is no intentional manufacture and only one use (imported semiconductors) identified so far. However, imported articles and mixtures may contain C9-C14, their salts and related substances. The rapporteurs were therefore of the view that action on an EU-wide basis is justified in the case of this restriction. One SEAC member was interested in the legal basis for this restriction – as the risk is not present at the moment. The Secretariat promised to confirm the legal basis for this proposal.

The rapporteurs highlighted that alternative techniques and substances are easily available on the market and economically feasible. They outlined the expected costs and benefits of the restriction as well as their conclusion regarding the proportionality of the proposed measure. One SEAC member was questioning the reformulation costs for cosmetics, which the rapporteurs compared to D4/D5 restriction proposal, but in the view of this member had been of different order of magnitude. The rapporteurs responded that the costs used are not per reformulation as such, but taken on an annual basis – however, they promised to have a closer look at the calculations of the dossier submitter in the next version of the opinion. Another member was interested in the testing costs for textile industry (for enforcement), which in his view have also been underestimated, as for performing these tests, a lot of textiles need to be purchased. The rapporteurs responded that this information and figures are taken from the dossier and is in line with the Forum advice.

One SEAC member pointed out that derogating fire-fighting foams should be explained in the opinion with socio-economic arguments rather than with a need to be consistent with the previous PFOA restriction. Furthermore, he questioned why no derogation has been foreseen for recycled articles, which were derogated in the PFOA case. The Secretariat explained to the Committee that recycled articles do not degrade to PFOA and therefore this derogation is not needed.

The Committee supported the conclusions of the (co-)rapporteurs as presented. It was agreed that the Secretariat will launch a written commenting round for members to provide remaining comments on the first draft opinion. The rapporteurs were asked to prepare the second draft opinion, taking into account SEAC-38 discussion, by beginning of May 2018.

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

The Secretariat presented and the Committee agreed on the pool of (co-)rapporteurs (in line with restricted meeting document SEAC/38/2018/02) for two restriction proposals on plastic and rubber granulates containing PAHs above a set concentration limit for use on synthetic turf pitches (expected submission July 2018) and on leave on personal care products and other consumer/professional products containing D4/D5 and D6 (expected submission January 2019).

The Chairman informed the Committee regarding the upcoming restriction proposals that has been included in the Registry of Intentions (RoI). In January 2019, ECHA on request of the Commission, will be submitting four restriction proposals on calcium cyanamide as a fertiliser; formaldehyde and formaldehyde releases in mixtures and articles for consumer uses; intentional use of microplastic particles in consumer/professional use products and on oxo-degradable plastics in various products for consumer and professional use. In addition, France together with Sweden will submit a restriction proposal on substances meeting the classification criteria as skin sensitizers and skin irritants (expected submission January 2019).

The Chairman reminded that the calls for expression of interest for new dossiers will be launched late 2018.

6) Authorisations

6.1) General authorisation issues

a) Update on incoming/future applications

The Secretariat informed the Committee that no new applications for authorisation or review reports had been submitted during the February 2018 submission window. The Secretariat estimated that around 10 applications for authorisation and review reports might be submitted to ECHA during the second half of 2018.

b) Updated AfA opinion templates

The Secretariat presented a new template of AfA opinion. SEAC members and observers of the stakeholder organisations as well as the European Commission expressed general support to the proposed changes and agreed that from the administrative point of view the new structure of chapters is appropriate. They found idea of harmonised "AfA in a Nutshell" and "Justifications in a Nutshell" very useful. The new template should reduce the length of the opinion and should limit unnecessary repetitions between RAC and SEAC e.g. new section 1. "Short description of use". During the discussion the Secretariat gathered feedback and comments expressed by the SEAC members and the observers of the stakeholder organisations and the Commission. The secretariat will launch a consultation to collect written comments from the members.

6.2) Authorisation applications

a) Discussion on key issues

- 1. DBP_AVX**
- 2. Diglyme_Omnichem**
- 3. SD_Olwerke**

The Chairman introduced the applications for authorisation. At this plenary meeting the Secretariat presented the identified key issues in the three applications for authorisation.

The Secretariat in cooperation with the SEAC rapporteurs provided general information regarding these new applications. In the presentations of the cases, the Secretariat outlined the key issues identified by the rapporteurs and asked the Committee for comments and further suggestions.

The Committee noted those key issues. SEAC will request further clarifications from the applicants on the issues identified and discussed by the rapporteurs and the Secretariat. The SEAC rapporteurs will draft the opinions on the applications for authorisation for discussion and agreement at the next SEAC plenary meeting in June 2018.

b) Agreement on draft opinions

1. CT_Hapoc (1 use)

The SEAC Chairman informed the Committee that on 8 February 2018 ECHA received a letter from the applicant, in which the applicant informed ECHA that they had subsumed Uses 2 to 4 of their application for authorisation under one single Use. Furthermore, they had changed the Use title by removing the reference to a given risk level to read: "Use of chromium trioxide in solid form and in aqueous solution of any composition to modify the properties of surfaces made of metal or plastic, with or without current flow". The SEAC Chairman noted that the opinion making is simplified accordingly, as there is no need to make any distinction between Uses 2, 3 and 4. In practise, there is only one dataset which was evaluated by SEAC under Use 2 at the previous plenary meeting. Furthermore, there is no need to refer to the acceptability of any particular risk level (for a genotoxic carcinogen without threshold) as originally proposed by the applicant. Thus, RAC and SEAC now need to discuss and agree the draft opinion on Use 1 (formulation). The draft opinion on Use 2 had been agreed at the previous meeting. In line with the altered situation, the rapporteurs and the Secretariat have made appropriate changes to the draft opinion on Use 2. The SEAC Chairman also informed the Committee that the applicant suggested for practical reasons to change the language of communication between ECHA, its scientific committees and the applicant to English.

The SEAC rapporteurs presented the draft opinion on Use 1 (formulation). The Committee agreed on the draft opinion on Use 1 as proposed by the rapporteurs by consensus.

2. SC_Wesco (1 use)

3. DtC_Wesco (1 use)

4. PCO_Aviail (2 uses)

The Chairman introduced the applications for authorisation. At SEAC-36, the Committee discussed the key issues for these applications. At SEAC-37 the SEAC rapporteurs presented a status update concerning preparation of the draft opinions. At this plenary, the SEAC Members were asked to consider the agreement on the SEAC draft opinions.

The Chairman invited the Secretariat to inform SEAC about the status of the RAC draft opinions. Then the SEAC rapporteurs presented the four draft opinions on the three applications for authorisation.

SC_Wesco is an upstream single use application on the use of strontium chromate in primers applied by aerospace and defence companies and their associated supply chains.

DtC_Wesco is an upstream application on the use of dichromium tris(chromate) for chemical conversion coating applications by aerospace and defence companies and their associated supply chains.

PCO_Aviall is an upstream application on the following two uses of pentazinc chromate octahydroxide: Use 1: Formulation of mixtures, Use 2: Use of pentazinc chromate octahydroxide in wash primer, fuel tank primer and aluminized primer for the purpose of corrosion protection in aeronautic applications.

The rapporteurs proposed conclusions that there are no suitable alternatives available to implement by the sunset date and the benefits of continued use outweigh the risks. SEAC members and the observers from the European Commission discussed specific issues, such as scope of the uses and feasibility to substitute the SVHCs, internal corporate substitution requirements, successful substitution in aerospace sector and a length of the review period. The European Commission observers requested to better define the conclusion on the suitability of alternatives, as well as an appropriate framing of the scope through the use description.

SEAC agreed on the draft opinions as proposed by the rapporteurs by consensus.

5. PCO_IP (2 uses)

The Chairman introduced the application for authorisation. At SEAC-37, the Committee discussed the key issues for this application. At this plenary meeting the SEAC rapporteurs presented a status update concerning preparation of the draft opinions.

The Chairman invited the Secretariat to inform SEAC about the status of the RAC draft opinions, which were discussed at the RAC plenary meeting. The SEAC rapporteurs updated the Committee members about the opinions development progress. A brief discussion followed. The dialogue on the application for authorisation will take place later in March 2018.

The rapporteurs were asked to draft the opinions on the application for authorisation for the discussion and agreement at the next SEAC plenary meeting in June 2018.

6.3 Review reports

a) Agreement on draft opinions

1. RR1_DEHP_VINYLOOP (2 uses)

2. RR1_DEHP_PP (2 uses)

The Chairman introduced the review reports. At SEAC-37, the Committee discussed the key issues for these review reports. At this plenary meeting the SEAC rapporteurs presented a status update concerning preparation of the draft opinions.

The Chairman invited the Secretariat to inform SEAC about the status of the RAC draft opinions, which were discussed at the RAC plenary meeting. The SEAC rapporteurs updated the Committee members about the opinions development progress in light of the recent dialogue, which took place in February 2018. During the discussion the

Committee discussed non-use scenarios submitted by the authorisation holders, the analysis of alternatives and potential overlap between types of articles produced in Use 2 of the review reports and the recent restriction proposal on certain phthalates in consumer articles.

The rapporteurs were asked to draft the opinions on the both review reports for the discussion and agreement at the next SEAC plenary meeting in June 2018.

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

The pool of (co-)rapporteurs, as outlined in the amended restricted room document SEAC/38/2018/05 rev.1, was agreed by SEAC. The Committee also requested the Secretariat to review the process of appointment of (co-) rapporteurs for AfAs.

7) AOB

a) Update of the work plan

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

b) Coaching on presentation skills

As a capacity building for the Committee members, SEAC was provided a coaching session on presentation skills and a presentation on effective visuals.

c) Update from NeRSAP 7 and planning for NeRSAP 8

A stakeholder observer representative provided an update from the seventh meeting of Network of Reach Socio-economic and AoA practitioners (NeRSAP) held in Bilbao, Spain (February 2018). The agenda included issues related to authorisations and restrictions. SEAC was also presented planning for the next meeting, which will take place in Antwerp, Belgium, in November 2018.

d) How to better involve alternative providers in the authorisation process and assess the alternatives

Two stakeholder observer representatives from ChemSec and ClientEarth provided a joint presentation on how to find and analyse alternatives in the authorisation process. They recommended to make better use of existing tools as well as a call for developing new tools in order to boost information on existing alternatives. They also recommended to widen the scope of the analysis of alternatives.

e) Health and environment costs of recycling policies

This presentation was postponed until SEAC-39 due to time constraints.

8) Action points and main conclusions of SEAC-38

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

II. Main conclusions and action points

SEAC-38, 13 - 15 March 2018
(Adopted at SEAC-38 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 minor modifications under AOB.	SECR to upload the adopted agenda to SEAC S-CIRCABC IG as part of the meeting minutes.
3. Declarations of conflicts of interest to the Agenda	
Conflicts of interest have been declared and will be taken to the minutes.	
4. Report from other ECHA bodies and activities	
<i>a) Report on SEAC-37 action points, written procedures and update on other ECHA bodies</i>	
SEAC was informed on the status of the action points of SEAC-37. Furthermore, SEAC took note of the report from other ECHA bodies, including the oral report from the Commission on SEAC related developments in the REACH Committee and in the CARACAL.	
<i>b) General SEAC procedures</i>	
SEAC took note of and discussed the meeting document on co-opted members (SEAC/38/2017/01). SEAC agreed on proposals for the required competences and selection procedure for co-opting additional members.	SECR to take note of discussions on the call for expression of interest on the appointment of co-opted members.
5. Restrictions	
5.1 Restriction Annex XV dossiers	
a) Opinion development	
1. Diisocyanates - final SEAC opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the SEAC final opinion and the results of the public consultation on the SEAC	Rapporteurs together with SECR to do the final editing of the SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is

<p>draft opinion.</p> <p>SEAC adopted its final opinion on Diisocyanates dossier by simple majority (with editorial modifications agreed at SEAC-38). The minority views will be published together with the opinion.</p>	<p>in line with the adopted SEAC final opinion.</p> <p>SECR to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p> <p>Members taking minority opinions should send their scientific and technical reasons for their minority positions to SECR by 23 March 2018.</p>
<p>2. Lead and lead compounds in PVC – final SEAC opinion</p>	
<p>SEAC rapporteurs presented and SEAC discussed the draft of the SEAC final opinion and the results of the public consultation on the SEAC draft opinion.</p> <p>SEAC adopted its final opinion on Lead in PVC dossier by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC final opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.</p> <p>SECR to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</p>
<p>3. Lead and lead compounds in shot – third draft opinion</p>	
<p>SEAC rapporteurs presented and SEAC discussed the third draft opinion.</p> <p>SEAC agreed on the draft opinion on Lead in shot dossier by consensus.</p>	<p>Rapporteurs together with SECR to do the final editing of the SEAC draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion.</p> <p>SECR to launch a public consultation on the SEAC draft opinion in March 2018.</p>
<p>4. Substances used in tattoo inks and permanent make-up – first draft opinion</p>	
<p>SEAC rapporteurs presented and SEAC discussed the first draft opinion.</p>	<p>SECR to launch a written commenting round for members to provide remaining comments via the S-CIRCABC newsgroup (until 29 March 2018).</p> <p>Rapporteurs to prepare the second draft opinion, taking into account the SEAC-38 discussions, by the beginning of May 2018.</p>
<p>5. C9-C14 PFCAs, their salts and related substances – first draft opinion</p>	
<p>SEAC rapporteurs presented and SEAC discussed the first draft opinion.</p>	<p>SECR to launch a written commenting round for members to provide remaining comments via the S-CIRCABC newsgroup (until 29 March 2018).</p> <p>Rapporteurs to prepare the second draft opinion, taking into account the SEAC-38 discussions, by the beginning of May 2018.</p> <p>SECR to confirm the legal basis for this restriction.</p>

5.2 Appointment of (co-)rapporteurs for restriction dossiers	
SEAC agreed on the pool of (co-)rapporteurs for restriction proposal on rubber granulates as well as on D4/D5/D6 (in line with the restricted meeting document SEAC/2018/38/02).	SEAC members to volunteer to the pool of D4/D5/D6 restriction proposal.
6. Authorisation	
6.1 General authorisation issues	
a) Update on incoming/future applications	
SEAC took note of the update on the incoming/future applications.	
b) Updated AfA opinion templates	
SEAC took note of and discussed the room document (SEAC/38/2018/03) on updated AfA opinion templates.	SECR to update the document considering the SEAC-38 discussions. SECR to launch a written consultation on the updated Afa opinion templates.
6.2 Authorisation applications	
a) Discussion on key issues	
<ul style="list-style-type: none"> a) DBP_AVX b) Diglyme_Omnichem c) SD_Olwerke 	
SEAC discussed the key issues identified in the applications for authorisation.	Rapporteurs to prepare the first versions of the draft opinions, taking into account the SEAC-38 discussions.
b) Agreement on draft opinions	
<ul style="list-style-type: none"> 6. CT_Hapoc (1 use) 7. SC_Wesco (1 use) 8. DtC_Wesco (1 use) 9. PCO_Aviall (2 uses) 	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. <u>CT_Hapoc (use 1):</u> SEAC agreed on the draft opinion by consensus. <u>SC_Wesco (use 1), DtC_Wesco (use 1), PCO_Aviall (uses 1 and 2):</u> SEAC agreed on the draft opinions by consensus.	Rapporteurs together with SECR to do the final editing of the SEAC draft opinions. SECR to send the draft opinions to the applicants for commenting.

10. PCO_IP (2 uses)	
SEAC rapporteurs presented and SEAC took note of status update on the opinion development progress for the application for authorisation.	Rapporteurs to prepare the first versions of the draft opinions, taking into account the SEAC-38 discussions.
6.3 Review reports	
a) Agreement on draft opinions	
<ol style="list-style-type: none"> 1. RR1_DEHP_VINYLOOP (2 uses) 2. RR1_DEHP_PP (2 uses) 	
SEAC rapporteurs presented and SEAC took note of status update on the opinion development progress for the applications for authorisation.	Rapporteurs to prepare the first versions of the draft opinions, taking into account the SEAC-38 discussions.
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 in line with SEAC/37/2017/05 restricted room document).	<p>SEAC members to volunteer to the pool of (co-) rapporteurs for applications for authorisation.</p> <p>SECR to upload the updated document to confidential folder on S-CIRCABC IG.</p> <p>SECR to continue the revised process of appointment of (co-) rapporteurs for AfAs.</p>
8. Action points and main conclusions of SEAC-38	
SEAC adopted the action points and main conclusions of SEAC-38.	SECR to upload the action points and main conclusions to S-CIRCABC IG.

III. List of Attendees

SEAC-38

SEAC members
ALEXANDRE Joao
ANASTASIOU Christos
BERGS Ivars
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
CSERGÓ Robert (co-opted)
DELCOURT Benjamin
DOUGHERTY Gary
FANKHAUSER Simone
FIORE Karine
FOCK Lars
GEORGIOU Stavros
JANSSEN Martien
JONES Derrick (co-opted)
KIISKI Johanna
KRAJNC Karmen
LÜDEKE Andreas
LUIT Richard
NARROS SIERRA Adolfo
NICOLAIDES Leandros
NORING Maria
OLTEANU Maria
RUZGYS Karolis
SCHUCHTAR Endre
STOYANOVA-LAZAROVA Elina
THIELE Karen
URBAN Klaus
ZAIKOVA Ilona
ZAMFIR Adrian-Stefan
Commission observers
BENGYUZOV Manol (DG GROW)
GALLEGO Matteo (DG ENV)
Stakeholder observers & accompanying experts
HÖK Frida (ChemSec)
JÁNOSI Amaya (CEFIC)
MIKANDER Nina (AEWA – UNEP international observer for the discussion on Lead in shot)
PALMERSHEIM Jörg (ISOPA expert accompanying CEFIC for the discussion on Diisocyanates)

Advisors, invited experts, observers & dossier submitters (DS)
ANDERSSON Wiktor as advisor to Maria NORING via WebEx
AVERBECK Frauke as DS for Diisocyanates via WebEx
BERNHEIM Theresa as advisor to Karen THIELE
BIEGEL-ENGLER Annegret as DS for PFCAs via WebEx
BLOM Cecile as DS for tattoo inks via WebEx
BORG Daniel as DS for PFCAs via WebEx
De BLAEIJ Arianne as advisor to Martien JANSSEN via WebEx
FOSSNES Tone-Line as FORUM rapporteur for PFCAs and as DS for tattoo inks via WebEx
FURLAN Janez as invited expert via WebEx
HAUG Eva as DS for tattoo inks via WebEx
HELLER-HUTORAN Svetlana as DS for Diisocyanates via WebEx
HELMEDACH Achim as advisor to Karen THIELE
JONGENEEL Rob as advisor to Richard LUIT
LANGTVET Espen as DS for tattoo inks via WebEx
LERCHE Dorte as advisor to Lars FOCK
LINDQVIST Martin as DS for PFCAs via WebEx
NIEDERSTRASSE Bernd as DS for PFCAs and tattoo inks via WebEx
ØYSTEIN FOTLAND Tor as DS for tattoo inks via WebEx
REALE Priscilla as advisor to Luisa CAVALIERI via WebEx
ROTHER Dag as DS for Diisocyanates via WebEx
ROUW Aart as DS for Diisocyanates
STAUDE Claudia as DS for PFCAs via WebEx
TRUBIROHA Achim as a DS for PFCAs via WebEx

Stakeholder observers & accompanying experts (cont.)
ROGER Apolline (ClientEarth)
SCALLAN David (FACE – expert accompanying CEFIC for Lead in Shot)
SWIFT John (AEWA – expert accompanying UNEP for the discussion on Lead in shot)
TILLIEUX Geoffroy (EUPC = European Plastics Converters), for the discussion on Diisocyanates and Lead and its compounds in PVC
WAETERSCHOOT Hugo (EUROMETAUX)
RAC rapporteurs
LEINONEN Riitta (via Webex)

Advisors, invited experts, observers & dossier submitters (DS) (cont.)
VAN DER HAGEN Marianne as DS for tattoo inks via WebEx
VERHOEVEN Julia as advisor to Martien JANSSEN via Webex
WALENDZIK Gudrun as DS for Diisocyanates
ECHA STAFF
ANTONAKI Marianthi
BERGES Markus
BLAINEY Mark
FRANKE Greta
GHAZANFARI Sara
HANSEN Bjorn
HOLLINS Stephen
KIVELA Kalle
KOSK-BIENKO Joanna
KOULOUMPOS Vasileios
LOGTMEIJER Christiaan
LUDBORZS Arnis
MARQUEZ-CAMACHO Mercedes
MAZZOLINI Anna
MOTTET Denis
NICOT Thierry
ORISPÄÄ Katja
OTTATI Maria
PELTOLA Jukka
PILLET Monique
REGIL Pablo
RHEINBERGER Christoph
RODRIGUEZ-IGLESIAS Pilar (via WebEx)
ROGGEMAN Maarten
SADAM Diana (via WebEx)
SIMPSON Peter
SJOBORG Thomas
SOSNOWSKI Piotr
STOYANOVA Evgenia
VAINIO Matti
ÖBERG Tomas

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 Draft Agenda

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

Document	Number
Final Draft Agenda	<i>SEAC/A/38/2018_rev.1</i>
General SEAC procedures – Co-opted members	<i>SEAC/38/2017/01</i>
Appointment of (co-)rapporteurs for restriction dossiers	<i>SEAC/38/2018/02</i>
Updated AfA opinion templates	<i>SEAC/38/2018/03</i>
Authorisation applications: Agreement on draft opinions – CT_Hapoc	<i>SEAC/38/2018/04 (restricted room document)</i>
Appointment of (co-)rapporteurs for authorisation applications (closed session)	<i>SEAC/38/2018/05 (room document)</i>

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 Article 9(2) of the SEAC Rules of Procedure):

<u>Name of participant</u>	<u>Agenda item</u>	<u>Interest declared</u>
LUDEKE Andreas	5.1a-4 Substances used in tattoo inks and permanent make-up 5.1a-5 C9-14 PFCAs, their salts and related substances 5.1a-1 Diisocyanates	Participation in the preparation of the restriction dossiers
FOCK Lars	5.1a-4 Substances used in tattoo inks and permanent make-up	Participation in the preparation of the restriction dossier
NORING Maria	5.1a-5 C9-14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossier
THIELE Karen	5.1a-5 C9-14 PFCAs, their salts and related substances	Participation in the preparation of the restriction dossier
COGEN Simon	6.2.a-3 Diglyme_Omnichem	Personal interest

Final Draft Agenda

38th meeting of the Committee for Socio-economic Analysis

13 -15 March 2018

ECHA Conference Centre (Annankatu 18, Helsinki)

13 March starts at 10.00
15 March ends at 13.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/38/2018
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-37 action points, written procedures and update on other ECHA bodies
- b) General SEAC procedures

For information

SEAC/38/2018/01
For discussion/agreement

Item 5 – Restrictions

5.1 Restriction Annex XV dossiers

- a) Opinion development
 - 1) Diisocyanates – final SEAC opinion

- 2) Lead and lead compounds in PVC – final SEAC opinion
For adoption
- 3) Lead and lead compounds in shot – third draft opinion
For agreement
- 4) Substances used in tattoo inks and permanent make-up – first draft opinion
- 5) C9-C14 PFCAs, their salts and related substances – first draft opinion
For discussion

5.2 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/38/2018/02
(restricted meeting document)
For agreement

Item 6 – Authorisation

6.1 General authorisation issues

- a) Update on incoming/future applications
- b) Updated AfA opinion templates

SEAC/38/2018/03
For discussion

6.2 Authorisation applications

- a) Discussion on key issues
 - 1. DBP_AVX
 - 2. Diglyme_Omnichem
 - 3. SD_Olwerke
- c) Agreement on draft opinions
 - 1. CT_Hapoc (1 use)
 - 2. SC_Wesco (1 use)
 - 3. DtC_Wesco (1 use)
 - 4. PCO_Aviall (2 uses)

SEAC/38/2018/04
(restricted meeting document)
For discussion and agreement

- 5. PCO_IP (2 uses)

For discussion

6.3 Review reports

b) Agreement on draft opinions

3. RR1_DEHP_VINYLOOP (2 uses)

4. RR1_DEHP_PP (2 uses)

For discussion and agreement

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

SEAC/38/2018/05

(room document)

For agreement

Item 7 – AOB

a) Update of the work plan

b) Coaching on presentation skills

c) Update from NeRSAP 7 and planning for NeRSAP 8

d) How to better involve alternative providers in the authorisation process and assess the alternatives

e) Health and environment costs of recycling policies

For information

Item 8 – Action points and main conclusions of SEAC-38

Table with Conclusions and Action points from SEAC-38

For adoption