

27 August 2019 SEAC/M/43/2019 FINAL

# <u>Final</u>

Minutes of the 43<sup>nd</sup> meeting of the Committee for Socio-economic Analysis

11-14 June 2019

### 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 43<sup>rd</sup> meeting of SEAC. The Chairman also informed SEAC that apologies had been received from three members.

The Chairman informed the participants that the meeting would not be recorded.

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-43. The agenda was adopted without modifications (in line with SEAC/A/43/2019\_rev.1). 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. Six members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2a.2, 5.2b.4 and 5.2b.6. These members did not participate in voting under those Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

The Chairman declared the absence of conflict of interest for all items of SEAC-43 plenary meeting.

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-42 action points, written procedures and update on other ECHA bodies

The Chairman informed the participants that all action points of SEAC-42 had been completed or would be followed up during the on-going SEAC-43 meeting.

The Chairman also informed the Committee that the final minutes of SEAC-42 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-42 minutes.

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

### b) Update of SEAC accredited stakeholders list (closed session)

The Secretariat presented to SEAC an update of the SEAC accredited stakeholders list. The Committee agreed with the proposal by the Secretariat in line with the restricted meeting document SEAC/43/2019/01\_rev.1. The Chairman informed SEAC that the Secretariat will publish the updated list on the ECHA website.

# 5) Restrictions

### 5.1) General restriction issues

#### a) Report from the recent Restrictions Task Force activities

The Secretariat presented to the Committee the report from the last Restrictions Task Force (RTF) meeting that took place on 22 May 2019, as well as the issues planned to be tackled in the near future. It was agreed that the Secretariat will share the Action points of the last RTF meeting with RAC and SEAC via S-CIRCABC.

#### **5.2)** Restriction Annex XV dossiers

#### a) Conformity check and key issues discussion

# 1) Perfluorohexane-1-sulphonic acid (PFHxS), its salts and related substances

The Chairman welcomed the Dossier Submitter representatives from Norway. He informed the participants that the restriction dossier had been submitted in April 2019. The representative of the Dossier Submitter gave an introductory presentation on the dossier. They explained that the dossier outlined a proposal to restrict the manufacture, use and placing on the market of PFHxS, its salts and related substances as substances, constituents of other substances, mixtures and articles or parts thereof. The restriction proposal aims to reduce emissions of PFHxS, its salts and their related substances to the environment and, as a result, minimise human exposure (the main potential exposure pathways are intake via food and drinking water and through exposure to house dust). Even though PFHxS including its salts and PFHxS-related substances are not registered under REACH, there is an ongoing exposure of humans and the environment to PFHxS from diffuse and point sources. The continuous emissions of PFHxS combined with the very persistent nature of the substance is expected to lead to increasing exposure if the emissions are not reduced.

The Chairman then informed the Committee that RAC had discussed the conformity of this dossier within RAC-49 last week and that the proposal was considered in conformity from the RAC point of view.

The rapporteurs then presented the outcome of the conformity check and the recommendations to the Dossier Submitter; they considered the dossier to be in conformity. SEAC members asked some clarifying questions from the Dossier Submitter and the rapporteurs, especially in relation to the baseline. The rapporteurs and the Dossier Submitter responded to the questions raised. The Chairman observed that the issues raised are not seen as conformity issues, but they will be considered in the further

evaluation of the dossier within the opinion development. Furthermore, SEAC noted the similarities between the previous restriction proposals on PFOA and C9-C14 PFCAs.

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteurs presented their key issues of the restriction proposal. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 19 June 2019.

### 2) Skin sensitisers in textile

The Chairman welcomed the Dossier Submitter's representatives from France and Sweden (following in person and via WebEx). He informed the participants that the restriction dossier had been submitted in April 2019.

The Dossier Submitter's representative provided an introductory presentation on the dossier. They explained that the dossier proposes to restrict the skin sensitising substances in finished textile, leather, hide and fur articles, placed on the market for the first time. There is a growing concern at the EU level and worldwide about skin sensitisation of the general population from exposure to chemicals in textile and leather articles, such as clothes and footwear. The number of individuals sensitised to chemical substances in textile and leather in the EEA population is estimated by the Dossier Submitter to be between 4 and 5 million, which corresponds to 0.8-1% of the EEA population. The number of new (incident) cases of sensitisation to chemicals in textile and leather are estimated by the Dossier Submitter to be between 45 000 and 180 000 per year, which corresponds to 0.01-0.04% of the EU general population annually.

The rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter. They pointed out that they had made a few recommendations for improving the dossier (on the proposed restriction, information on alternatives and socio-economic assessment), most of which are of medium priority.

The Committee agreed that the dossier conforms to the Annex XV requirements. In addition, the rapporteurs presented their key issues of the restriction proposal. The Chairman informed the Committee that the public consultation on this restriction proposal will be launched on 19 June 2019.

#### b) Opinion development

#### 1) Siloxanes (D4, D5 and D6) – first draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the RAC rapporteur and an industry expert accompanying the regular stakeholder observer. He informed the participants that this restriction dossier had been submitted in January 2019 and had been considered in conformity in the previous SEAC-43 meeting. The dossier proposes to restrict the placing on the market of D4, D5 and D6 as substances, as constituents of other substances, or in mixtures in a concentration equal to or greater than 0.1% w/w of each substance. These substances are manufactured and used in a variety of sectors in the EEA. They are mainly used as intermediates for the production

of silicone polymers (which is outside of the scope of the proposed restriction) but are also used as substances on their own or in the formulation of various mixtures that are subsequently used by consumers and professionals. D4, D5 and D6 were identified by ECHA's MS Committee as SVHC substances with PBT/vPvB properties.

The RAC rapporteur provided a brief update from the RAC discussion on this dossier held within RAC-49. The SEAC rapporteurs then presented the first draft opinion. The rapporteurs explained to the Committee that from their perspective the scope of the restriction, including the proposed derogations, is clear. Furthermore, the rapporteurs were convinced that action is needed on an EU-wide basis and that the restriction is the most appropriate EU-wide measure to address the concern caused by emissions of D4, D5 and D6 to the environment. With regards to costs, the rapporteurs noted that the DS had included extensive data and relatively detailed calculations for the reformulation costs for affected cosmetics, but relatively limited information for estimating raw material costs and consumer surplus losses. In the view of the rapporteurs the cost assessment performed by the DS provides a good indication for order of magnitude. The rapporteurs also mentioned that enforcement and testing costs had not been elaborated in the Annex XV report and the DS had recently provided additional evaluation of the enforcement and testing costs, which the rapporteurs had not reviewed yet.

One member suggested that the justification for extending the scope compared to the previous (UK) restriction on the placing on the market of D4 and D5 in wash-off cosmetic products should be clear in the opinion and that the cost-effectiveness of the proposal should be compared to the 'wash off' restriction. Several members supported this view, but others stated that it would be difficult to perform such analysis, as the approaches taken in the two dossiers were different. The rapporteurs agreed to discuss this issue and consider it further in the second rapporteurs' dialogue. The same member was also interested why the rapporteurs are considering the consumer surplus losses to be low. The rapporteurs responded that as there are many products on the market available without D4, D5 and D6, they do not expect big losses in performance because of this restriction. The DS representative confirmed that two other sources of evidence had been considered on this topic. First, they had been in contact with an eco-label, which requires that certified products (which would not contain D4, D5 and D6) must pass consumer acceptability tests. Increasing or stable sales are also required to maintain the eco-label. Second, the DS has performed econometric analysis which found no evidence of a relationship between the presence of D4, D5 and D6 in a product and its price.

An industry expert pointed out that the scope of the restriction, in particular derogations, are not very clear and they are planning to submit comments on this within the ongoing public consultation. They also emphasised that costs for non-cosmetic applications have not been evaluated in the DS assessment and that they are also submitting some quantitative data on these within the public consultation.

The Committee members supported the view of the rapporteurs that the scope of the restriction is clear and that action is required on an EU-wide basis. The SEAC members also provisionally supported the view of the rapporteurs that the proposed restriction is the most appropriate EU-wide measure, on the costs assessment for cosmetics and that a qualitative assessment is sufficient for other uses than cosmetics. The Chairman informed the Committee that the Secretariat will launch a written consultation on the

first draft opinion after SEAC-43. The rapporteurs were asked to prepare the second draft opinion, taking into account the SEAC-43 discussion and the SEAC written consultation, by early August 2019.

#### 2) Formaldehyde – first draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA and an industry expert accompanying the regular stakeholder observer. He informed the participants that the restriction dossier had been submitted by ECHA in January 2019. The proposal aims to restrict the placing on the market or the use of articles that would release formaldehyde above a certain threshold (concentration  $\geq 0.124 \text{ mg/m}^3$  in the air of a test chamber used under the conditions prescribed in EN 717-1). Formaldehyde released from an article may come from formaldehyde and/or other substances that release formaldehyde (formaldehyde releasers) used in the production process of the article. Articles subject to the CMRs in textiles restriction as well as the use of formaldehyde and formaldehyde releasers as biocide are exempted from the proposed restriction.

The Secretariat provided an update from the RAC discussion on the dossier held within RAC-49. RAC took note of the DNEL of  $0.1 \text{ mg/m}^3$  as proposed by the DS, based on an existing WHO guideline, derived from human sensory irritation data. RAC highlighted several limitations of the underlying data and have agreed a chronic DNEL of  $0.05 \text{ mg/m}^3$  for the inhalation route

The SEAC rapporteurs then presented the first draft opinion. In their presentation the rapporteurs focused on the scope of the restriction proposal, the derogations proposed by the DS, the justification for a restriction as an EU-wide measure aspects relevant to the enforceability of the restriction (specifically the testing method mentioned in the proposal) as well as the socio-economic costs and benefits of the restriction proposalSEAC discussed issues relating to wording of the legal text (specifically the term "use"). Some SEAC members expressed a preference to remove the word "use" from the restriction wording as it could have consequences beyond the intention of the Dossier Submitter. In addition, a possible derogation for second-hand articles and recycled articles was discussed but it was also noted that it may be prudent to get RAC's view on possible risks from such articles before considering recommending a further derogation for these articles. With regard to testing, the SEAC rapporteurs invited the Committee to discuss a proposal to consider both EN 717-1 and the newer EN 16516 (both based on test chamber) as reference methods in the restriction proposal to allow for more flexibility. The SEAC members discussed the differences between the two testing standards, their limitations and whether other sector-specific test methods could be used to demonstrate compliance (e.g. by use of correlations between the reference methods and other test methods). The expert from EPF clarified that EN 717-1 has been successfully used in the panel sector and that industry has experience in correlating results from production control methods (based on different standards) to EN 717-1. The EPF expert also noted that EN 16516 is designed to assess releases of VOCs and may work well for articles other than wood-based panels, while EN 717-1 is specific for formaldehyde and should be the method allowed for testing of panels. The Committee also discussed whether it would be beneficial for testing-related issues to be elaborated in an appendix to the restriction proposal rather than in the draft legal text. While it was acknowledged that a discussion on proportionality may be premature, some SEAC

members expressed concerns on proportionality and the need to better understand the impact of the proposal on reducing risks for human health as well as the cost-benefit differences between RO3 and RO4. One SEAC member also suggested that the estimate of enforcement costs, as used by the DS in the Annex XV restriction dossier, is not representative, as these refer to average costs rather than incremental costs. A comment was made by a SEAC member on whether voluntary agreements to limit formaldehyde releases from articles do also apply to exported articles.

The Rapporteurs were requested to take the discussion of SEAC-43 and the results of the SEAC consultation into account in the second draft SEAC opinion. The Chairman concluded that the Committee will continue discussions on the parts of the draft SEAC opinion relating to costs, benefits, proportionality and derogations at the next Committee meeting (SEAC-44) in September 2019. He also encouraged industry to contribute actively to the ongoing public consultation by submitting available data ahead of the next SEAC plenary meeting in September.

### 3) Microplastics – first draft opinion

The Chairman welcomed the Dossier Submitter representatives from ECHA, supported by experts from Sweden (KemI) via WebEx, the occasional stakeholders and the industry experts accompanying regular stakeholder observers. He informed that the dossier was submitted by ECHA in January 2019. The proposal aims to restrict the use of intentionally added microplastics and is comprised of various measures including a ban on the placing on the market of uses of microplastics where they will inevitable be released to the environment alongside requirements for better information in the supply chain and mandatory reporting for uses where better risk management could further reduce releases. The restriction includes derogations for uses in certain sectors (e.g. medicinal products) and for naturally occurring and (bio)degradable polymers. The Dossier Submitter has estimated that approximately 36 000 tonnes per year of intentionally added microplastics are currently released to the environment per year. These are most likely to accumulate in terrestrial environments, although their presence in the aquatic environment has been under greater focus. The scope of the proposed restriction covers a wide range of uses in consumer and professional products, including detergents, cosmetics, paints and coatings, construction, medical and agricultural. The proposed restriction is estimated to result in an emission reduction of 85-95% after its progressive entry into effect.

The Secretariat informed the Committee that RAC had discussed the first version of this dossier during RAC-49 last week. RAC had provisionally agreed that there is sufficient evidence to conclude that intentionally added microplastics constitute a concern for the environment and human health that needs to be addressed. Furthermore, RAC had agreed that the non-threshold approach is an appropriate means to assess the risk and agreed that intentionally-added microplastics should be addressed as a group of polymer-based materials sharing similar physical properties and potential concern for the environment and human health.

The SEAC rapporteurs presented the first draft opinion. They supported the view of the Dossier Submitter that any necessary action to address risks associated with intentionally added microplastics should be implemented in all Member States. They also agreed with the scope of the restriction as proposed by the Dossier Submitter. Furthermore, the rapporteurs explained the definitions and derogations of the proposed restriction and noted the overlap with the rubber granulates restriction proposal. With regard to the costs of the proposed restriction, the rapporteurs noted that the approach taken by the Dossier Submitter is an appropriate and pragmatic way to assess the economic impacts of the proposed restriction. However, the SEAC rapporteurs highlighted that the presented cost estimates cannot be regarded as precise figures due to the lack of data to underpin the assessment, they rather illustrate the range of costs that may result from the ban proposed.

The scope was discussed in detail especially in relation to definitions. In response to a questions from an industry stakeholder, the Secretariat informed that ECHA is working on a Q&A document to assist with the interpretation of the definitions, which will be published on ECHA's website. With regard to costs, questions were raised by SEAC members whether suitable alternatives are available. The Dossier Submitter representatives stated that suitable alternatives have not been identified for all product groups; therefore, the transitional periods are proposed to allow sufficient time for their identification and for industry to transition to them. Some SEAC members noted the high costs of the proposed restriction as well as the link between the cost estimates in the current proposal and the one for siloxanes.

A Commission observer took the floor and emphasised that SEAC's opinion is expected to clarify many of the open issues based on thorough scientific scrutiny of the assumptions and generalisations in the dossier and the information provided in the public consultation. He also noted the need for analysis on all impacted sectors, with a focus on specific industry sectors and, in particular the impact on uses of public interest and uses with high-societal benefit, as well as sectors where alternatives are currently not available. Several industry stakeholder observer representatives raised their concerns for this restriction (e.g. uncertainties in cost estimates, challenges linked to definitions, reporting and labelling requirements), and the Chairman encouraged industry to contribute actively to the ongoing public consultation by submitting available data ahead of the next SEAC plenary meeting in September. In this regard, SEAC also noted the high interest received from the public consultation so far. A representative of the cosmetics industry, reiterated key points already submitted in the public consultation, and highlighted that 94% of SMEs are in a business-to-business relationship with larger companies and therefore, also tend to use microplastics.

The Committee members supported the conclusions of the rapporteurs. It was concluded that the proposed scope and costs will be further defined once all public consultation comments have been analysed. It was furthermore agreed that the Secretariat will launch a written commenting round for members to provide further comments on the first draft opinion. The rapporteurs were requested to prepare the second draft opinion, taking into account the discussions in SEAC-43, by beginning of August 2019.

#### 4) *N*,*N*-dimethylformamide (DMF) – second draft opinion

The Chairman welcomed the Dossier Submitter's representative from Italy and an industry expert accompanying a regular stakeholder observer. The restriction dossier was submitted by Italy in October 2018. The proposal aims to restrict the uses of the substance on its own or in mixtures in a concentration equal or greater than 0.3 %, unless exposure conditions described as DNEL values for inhalation (3.2 mg/m<sup>3</sup>) and dermal (0.79 mg/kg bw/day) exposure of workers are met. DMF is manufactured in the EU, and used in the production of fine chemicals, pharmaceuticals, polymers, textiles, non-metallic products, and perfumes/fragrances. It is also used in the petrochemical industry and as a laboratory reagent. There is no consumer use of DMF.

The RAC rapporteur gave a brief update of the RAC-49 discussions: RAC agreed on a systemic long term DNEL of 6 mg/m<sup>3</sup> for inhalation based on rabbit developmental toxicity data and human liver toxicity data (which is higher than 3.2 mg/m<sup>3</sup> suggested by the DS). RAC also agreed on a dermal DNEL of 1.1 mg/kg/day, which is greater than the dermal DNEL value proposed by the DS (0.79 mg/kg/bw). In addition, RAC concluded that risks exist for some uses, and that they need to be addressed.

The SEAC rapporteur then presented the second draft opinion. They outlined the restriction benefits and costs parts of the presentation. On benefits side, they mentioned that the proposed restriction provides clear benefits, although many of them can only be described qualitatively. The restriction proposal is estimated to provide quantifiable health benefits in a range between  $\in$  41 million and  $\in$  55 million. As a whole, based on the reported assessment, the SEAC rapporteur was of the opinion that the proposed restriction will provide clear benefits. The Committee members in general agreed with the conclusions on benefits, but to not consider potential carcinogenic effects of the substance, since RAC based their hazard assessment on rabbit developmental toxicity data and human liver toxicity data.

During the discussion on the costs of the restriction proposal, the SEAC rapporteur stated that he considered it unlikely that the whole man-made fibre and 50 % of the coating sector would close down in response to the proposed restriction. The rapporteur had no numerical estimate for job loss, but noted that the relevant industry have not convincingly demonstrated that it is impossible to adequately control risk by using PPE and administrative risk management measures in cases where the risk cannot be controlled by other measures. With regard to competitiveness, it was not possible for the rapporteur to perform a detailed analysis as it was not known what specific costs for risk reduction measures will be.

An industry expert indicated that the man-made fibres sector had already invested to reduce the exposure level from 30 mg/m<sup>3</sup> to 15 mg/m<sup>3</sup> (OEL). Currently, the industrial sector is mainly operating enclosed systems. However, maintenance, which is the main source of exposure to DMF, is still necessary, and use of PPE is mandatory for these tasks. According to them, the 90th-percentile measured values (not adjusted for use of RPE) are around 12 mg/m<sup>3</sup>, and reducing of the air concentration further (i.e. to the value of 6 mg/m<sup>3</sup>) would not be feasible.

The rapporteur was requested to prepare the third draft opinion, taking into account SEAC-43 discussions and the results of the public consultation, by the beginning of August 2019.

#### 5) Five cobalt salts – second draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA and one industry expert, accompanying the regular stakeholder observer. He informed the participants that the restriction dossier had been submitted in October 2018 and proposes to restrict the placing on the market, manufacture and use of five cobalt salts as substances on their own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications unless a reference exposure value of 0.01  $\mu$ g Co/m<sup>3</sup> is used in chemical safety assessment by registrants or downstream users. The five cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)) are manufactured and used in a variety of sectors within the EEA, including for the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. The (co-) rapporteurs had developed the second draft opinion on this dossier, which was made available to SEAC on 15 May 2019. The written consultation took place from 15 to 24 May, during which five SEAC members submitted comments.

The RAC rapporteur provided a brief update from the RAC discussion on this dossier held during RAC-49. The SEAC rapporteurs then presented the second draft opinion. They explained to the Committee that they agree that a REACH restriction could generally be an appropriate measure to manage the risks. However, based on the assessment performed, the rapporteurs question the conclusion of the DS that the proposed restriction is the most appropriate EU wide measure. With regards to the costs of the proposed restriction, the Rapporteurs noted that the approach taken by the DS can be used to derive the cost estimates for a restriction but a number of uncertainties exist. They added that within the ongoing public consultation, an extensive alternative cost assessment had been provided by industry. The rapporteurs concluded that both DS and industry approaches provide a valid way forward to assess the costs of the proposed restriction and that, based on information provided, they consider it likely that the costs of the proposed restriction have been underestimated by the DS. In relation to benefits, the rapporteurs consider it likely that the monetised benefits of the proposed restriction have been overestimated by the DS, but that other, qualitatively described benefits are also expected due to the proposed restriction. However, they emphasised to the Committee that their conclusions would need to be updated, when RAC forms its final conclusions on hazard and risk. As regards the proportionality of the proposal, the rapporteurs pointed out that the monetised benefits of the proposed restriction do not outweigh the costs. The rapporteurs also concluded that the proposed restriction is overall enforceable, based on the advice provided by the Forum, but that practicality and monitorability is challenging, based on information provided in the public consultation. Several SEAC members expressed support for the rapporteurs' current conclusions.

One stakeholder observer criticised the alternative cost-benefit assessment provided by industry in the public consultation and was surprised that the rapporteurs have taken it into consideration in their draft opinion. They also pointed out that often those workers who are exposed to cobalt salts, could also be exposed to other dangerous substances. In such case, the RMMs are already in place, which might help to comply with the proposed reference value of 0.01 Co/m<sup>3</sup>. They also expressed doubts in relation to possible closure and relocation of the EU companies – and did not consider it possible that a company would relocate just because of this restriction, but there should be many other reasons for this (cost of labour, etc). Therefore, the costs are overestimated and the benefits underestimated in the dossier in their view. An industry expert informed the Committee that they indeed had submitted an alternative cost-benefit assessment in the public consultation and that they followed a similar approach as the DS. The rapporteurs confirmed that they are considering and thoroughly assessing the information submitted within the public consultation.

The Chairman concluded that the Committee in general supported the conclusions of the rapporteurs as presented. The rapporteurs were requested to prepare the third draft opinion, taking into account the discussions in SEAC-43, the RAC conclusions and the results of the public consultation, by early August 2019.

# 6) PAHs in granules and mulches used as infill material – third draft opinion

The Chairman welcomed the Dossier Submitter representatives from the Netherlands (present both in person and via WebEx) and the RAC rapporteur. He informed the participants that the restriction dossier had been submitted by the Netherlands in July 2018, in cooperation with ECHA. The restriction dossier focusses on granules and mulches used as infill material in synthetic turf pitches and in loose form on playgrounds and in sport applications. The basis for this dossier is a concern for human health resulting from current concentration limits for polycyclic aromatic hydrocarbons (PAHs) in End-of-Life Tyres (ELT) derived rubber infill granules used in synthetic turf pitches.

The rapporteurs had developed the third draft opinion on this dossier, made available to SEAC for commenting round which finished on 24 May 2019. Following the SEAC written consultation round (with four comments received from SEAC members), the (co-)rapporteurs prepared the revised third draft opinion which was made available to SEAC on 29 May 2019. The public consultation on this dossier finished on 19 March 2019 with 31 comments received.

The RAC rapporteur provided a brief update from the RAC-49 where RAC had adopted its opinion on this dossier. RAC had agreed that action is required on an Union wide basis and had agreed that the proposed restriction is effective in reducing identified risks, noting, however, that in order that the restriction to be effective, the end of waste criteria needs to be harmonised across EU. In response to a question from a SEAC member, the RAC rapporteur explained the justification for their recommendation that a concentration limit of 20 mg/kg ought to be used rather than the 17 mg/kg proposed by the Dossier Submitter.

The SEAC rapporteurs then presented the third draft opinion. They outlined the updates made in the draft opinion following the SEAC consultation and the SEAC-42 plenary discussions, including small editorials in the sections on justification for Union-wide basis and the scope and practicality (incl. enforceability). The costs section had also been updated (with costs of recyclers), concluding that revenue loss represents overestimate of societal restriction costs, and the rapporteurs found it plausible that the restriction costs would approach zero if the limit value would be 20 mg/kg as proposed by RAC. The SEAC members supported the modifications introduced to the text in the draft opinion.

Regarding proportionality, the SEAC members also supported the rapporteurs' conclusion that the restriction is proportionate. The preventive nature of this restriction was also noted since excessive values of REACH-8 PAHs concentrations will be avoided. A Commission observer referred to the communication from January 2018 on the interface between chemicals, products and waste on which it is acknowledged that something needs to be done for the harmonisation of the end-of-waste criteria in the EU and informed about an ongoing Commission study aimed at gaining a better understanding of Member States' practices as regards the implementation and verification of provisions on end-of-waste as a basis for possible guidelines, where rubber granules is being developed as a case study.

SEAC agreed on its draft opinion on the restriction proposal on rubber granules by simple majority. The rapporteurs were requested, together with the Secretariat, to make final editorial changes to the 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 the Committee that the Secretariat will launch a public consultation on the SEAC draft opinion on 19 June and SEAC is expected to adopt its final opinion on this dossier at SEAC-44 in September 2019.

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

The Chairman presented the update on the upcoming restriction dossiers expected to be submitted in July 2019 by ECHA (calcium cyanamide as a fertiliser; and lead chromates).

In December 2019, Germany will also be submitting a restriction proposal on undecafluorohexanoid acid and its salts and related substances. The call for expression of interest for this dossier will be launched in autumn 2019.

# 6) Authorisations

# 6.1) General authorisation issues

#### a) Update on incoming/future applications

The Secretariat informed the Committee that 38 new applications for authorisation were received during the May 2019 submission window. One of them is on use of chromium trioxide for Electrolytic Chromium Coating of Steel. Another seven are applications for authorisation for the uses of coal tar pitch, high temperature (CTPHT) formulation of mixtures (five AfAs) and manufacture of clay targets (two AfAs). Four of these AfAs involve also use of anthracene oil in formulation of mixtures. The remaining 30 applications for authorisation are for the uses of octylphenol ethoxylates and nonylphenol ethoxylates in the life sciences sector, including production of pharmaceutical active ingredient, formulation of reagents further incorporated in in vitro devices, their production and their use by professionals, such as laboratories, hospitals etc. Key issues in the new applications for authorisation will be discussed at SEAC-44 plenary meeting in September 2019.

The Secretariat also informed about high numbers of applications for authorisation expected to be received during extraordinary submission window which is open until 4 July 2019 and during the regular August 2019 submission window.

### b) Model opinions and revised format

The Secretariat updated the Committee on the ongoing work in preparing model opinions on applications for authorisation. It has two aims, firstly enabling the Committees to deal with the peak situations with high number of applications for authorisation received. Secondly, the model opinions will allow smoother and more targeted discussions on the draft opinions in the Committees. The opinions will be more concise, harmonised and fitfor-purpose. Having said that the Secretariat stressed that same level of scrutiny of the opinions will be assured. At the moment the Secretariat together with the Committees' rapporteurs are developing model opinions on the applications for authorisation OPE\_Boehringer, OPE\_Ortho and OPE\_Sebia from the February 2019 submission window. These applications will be put on the agenda for discussion and agreement at the September 2019 plenary meetings of RAC and SEAC. The Secretariat also provided answers to the comments and questions received during the SEAC consultation on the model opinions in May 2019.

In addition, the Secretariat informed SEAC about the opinion format change. It was a consequence of the European Court of Justice ruling on the Court Case T-837/16 of 7 March 2019. The Secretariat in this work also had consulted the Advisory Group on Applications for Authorisation of the ECHA Management Board. At the moment the Secretariat is finalising work on the opinion format changes.

During the discussion SEAC members asked questions of clarifying nature and expressed cautious support towards the initiatives of the Secretariat.

# c) Update on General Court Cases

The Secretariat gave an update to the Committee about the judgment of the General Court in Case T-837/16 of 7 March 2019– Sweden v. Commission regarding a decision granting an authorisation for some uses of lead sulfochromate yellow and of lead chromate molybdate sulphate red, the pending appeal by the Commission against judgment in the Case C-389/19 P, and of the pending action of Client Earth against the Commission review decision in the Case T-436/17. In addition, the Secretariat also informed the Committee about the uses of DEHP in recycled DEHP. In this case action by Client Earth had been taken challenging review decision of the Commission. However, judgment in the Case T-108/17 was dismissing the action. It is known that the ClientEarth intends to appeal to the Court.

During the discussion the SEAC members asked questions of clarifying nature to the Secretariat.

# 6.2) Authorisation applications

#### a) Discussion on key issues

# 1) 11 applications for authorisation received during the February 2019 submission window (7 OPE/NPE, 3 Cr(VI), 1 CTPHT)

The Secretariat, in cooperation with the SEAC rapporteurs, provided general information regarding the new applications for authorisation listed below:

- CT\_TES (single use, downstream)
- SC\_Ariston (single use, downstream)
- SD\_Bussi (single use, downstream)
- CTPht\_Ariane (single use; downstream)
- OPE\_Boehringer (single use, downstream)
- OPE\_Ortho (two uses, downstream)
- OPE\_Stago (two uses, downstream)
- OPE\_BioMarin (two uses, downstream)
- OPE\_Sebia (three uses, downstream)
- NPE Sebia (single use, downstream)
- OPE\_bioMerieux (three uses; downstream)

#### b) Agreement on draft opinions

- 1) CT\_Aloys
- 2) CT\_Ideal
- 3) CT\_Keuco
- 4) CT\_Schell

The Chairman introduced the applications for authorisation. At SEAC-42, the Committee discussed the key issues for these applications. At this plenary, the SEAC members were asked to consider the agreement of the SEAC draft opinions.

The Chairman invited the Secretariat to inform SEAC on the outcome of the discussions and agreement of RAC draft opinions. The SEAC rapporteurs presented the six draft opinions on the four applications for authorisation.

CT\_Aloys is a downstream user's application for authorisation on one use of chromium trioxide. Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.

CT\_Ideal is a three downstream users' application for authorisation on the two uses of chromium trioxide. Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications. Use 2: Etching of plastics with chromium trioxide as pre-treatment step for electroplating processes.

CT\_Keuco is a downstream user's application for authorisation on the two uses of chromium trioxide. Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications. Use 2: Etching of plastics with chromium trioxide as pre-treatment step for electroplating processes.

CT\_Schell is a downstream user's application for authorisation on one use of chromium trioxide. Use 1: Electroplating of different types of substrates using chromium trioxide to achieve functional surfaces with high durability and a bright or matt silvery appearance for sanitary applications.

SEAC rapporteurs conclude that the analysis of alternatives is sufficiently detailed to conclude on the technical and economic feasibility of the alternatives, and that there is currently no economically and technically feasible alternative. Benefits of continued use outweigh the risks by a considerable margin. The applicant's analysis was considered by SEAC to provide robust conclusions in this respect. The discussion largely focused on the market and customers' requirements towards the specific articles produced by the applicant. The SEAC members also discussed a requested length of the review period.

The Committee agreed on the draft opinions by consensus, with some further postediting to be done by the rapporteurs together with the Secretariat.

#### 5) CT\_Thyssen

The Chairman introduced the application for authorisation. At SEAC-42, the Committee discussed the key issues for this application. At this plenary, the SEAC members were asked to consider the agreement of the SEAC draft opinions.

The Chairman invited the Secretariat to inform SEAC on the outcome of the discussions and agreement of RAC draft opinions. The SEAC rapporteurs presented the two draft opinions on the application for authorisation.

This is a downstream user's application for authorisation on the two uses of chromium trioxide. Use 1: Use of Chromium (VI) Trioxide for Passivation of tinplated steel (ETP). Use 2: Use of Chromium (VI) Trioxide for Electrolytic Chromium Coating of Steel (ECCS).

On both uses, the SEAC rapporteurs concluded that while the analysis of alternatives lack some detail with respect to the long listed alternatives, this is not sufficient to cast doubt on the applicant's conclusions that at present there are no suitable alternatives. The SEAC rapporteurs noted that the applicant is already engaged in a substitution programme. The SEAC rapporteurs also noted the limited human health impacts as well as the expected economic and social impacts from continued use. The information provided in the application is sufficient to demonstrate that the benefits of continued use exceed the risks to human health. The SEAC members discussed the requested review period in connection with the Analysis of Alternatives as submitted by the applicant.

The Committee agreed on the two draft opinions by consensus, with some further postediting to be done by the rapporteurs together with the Secretariat.

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/43/2019/02\_rev.1, was agreed by SEAC.

# 7) AOB

#### a) Update of the work plan

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

# b) Presentation on the Delphi study to identify and assess factors influencing potential impacts of PBT/vPvB substances

The SEAC member gave a presentation on her study to identify and assess factors influencing potential impacts of PBT/vPvB substances.

Other SEAC members welcomed the presentation and asked questions of clarifying nature.

### 8) Action points and main conclusions of SEAC-43

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

# II. Main conclusions and action points

# SEAC-43, 11 - 14 June 2019 (Adopted at SEAC-43 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 (SEAC/A/43/2019).	<b>SECR</b> to upload the adopted agenda to SEAC S CIRCABC IG as part of the meeting minutes.	
3. Declarations of conflicts of interest to the Age	enda	
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-42 action points, written proced	ures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-42. 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 CARACAL.		
b) Update of SEAC accredited stakeholders' list (close	sed session)	
SEAC agreed on the update of SEAC accredited stakeholders' list (restricted meeting document SEAC/43/2019/01_rev.1).	<b>SECR</b> to publish the updated list on the ECHA website.	
5. Restrictions		
5.1 General restriction issues		
a) Report from the recent Restrictions Task Force	activities	
SEAC took note of the report from the Restrictions Task Force meeting.		
5.3 Restriction Annex XV dossiers		
a) Conformity check and key issues discussion		

SEAC agreed that the dossier conforms to the Annex XV requirements. SEAC took note of the recommendations to the dossier submitter.	<ul><li>SECR to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG.</li><li>SECR to launch a public consultation on the restriction proposal on 19 June 2019.</li></ul>	
2) Skin sensitisers in textile		
SEAC agreed that the dossier conforms to the Annex XV requirements. SEAC took note of the recommendations to the dossier submitter.	<b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG. <b>SECR</b> to launch a public consultation on the restriction proposal on 19 June 2019.	
b) Opinion development		
1) Siloxanes (D4, D5 and D6) – first draft opinion		
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<b>SECR</b> to launch a written commenting round for members to provide comments on the first draft opinion via the S-CIRCABC newsgroup (until 28 June 2019).	
	<b>Rapporteurs</b> to prepare the second draft opinion, taking into account the SEAC-43 discussions and the results of the SEAC written consultation, by the beginning of August 2019.	
2) Formaldehyde – first draft opinion		
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<b>SECR</b> to launch a written commenting round for members to provide comments on the first draft opinion via the S-CIRCABC newsgroup (until 28 June 2019).	
	<b>Rapporteurs</b> to prepare the second draft opinion, taking into account the SEAC-43 discussions and the results of the SEAC written consultation, by the beginning of August 2019.	
3) Microplastics – first draft opinion		
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	<b>SECR</b> to launch a written commenting round for members to provide comments on the first draft opinion via the S-CIRCABC newsgroup (until 28 June 2019).	
	<b>Rapporteurs</b> to prepare the second draft opinion, taking into account the SEAC-43 discussions and the results of the SEAC written consultation, by the	

	beginning of August 2019.
4) <i>N,N</i> -dimethylformamide – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	<b>Rapporteurs</b> to prepare the third draft opinion, taking into account the SEAC-43 discussions and the results of the public consultation, by early August 2019.
5) Five cobalt salts – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	<b>Rapporteurs</b> to prepare the third draft opinion, taking into account the SEAC-43 discussions and the results of the public consultation, by early August 2019.
6) PAHs in granules and mulches used as infill ma	terial – third draft opinion
SEAC rapporteurs presented and SEAC discussed the revised third draft opinion. SEAC agreed on the draft opinion by a simple majority (with editorial modifications agreed at SEAC-43).	<ul> <li><b>Rapporteurs</b> together with <b>SECR</b> 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.</li> <li><b>SECR</b> to launch a public consultation on the SEAC draft opinion in June 2019.</li> </ul>
5.3 Appointment of (co-)rapporteurs for restri	ction dossiers
SEAC took note of the update on the upcoming restriction proposals. The call for expression of interest for (co-)rapporteurs for the restriction dossier arriving in the second half of 2019 will be launched in autumn 2019.	<b>SEAC Members</b> to volunteer for the pool of (co-)rapporteurs for the restriction dossier arriving to ECHA in the second half of 2019.
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) Model opinions and revised format	
SEAC took note of the planned revision of the opinion format and the latest developments of the model opinions.	
SEAC discussed the proposed changes in the	

format and the further development of the	
model opinions and their use for the incoming applications.	
applications.	
c) Update on General Court Cases	
SEAC took note of the update on General Court	
Cases on authorisation decisions as presented by	
the SECR.	
6.2 Authorisation applications	
a) Discussion on key issues	
<ol> <li>11 applications for authorisation received durin OPE/NPE, 3 Cr(VI), 1 CTPHT)</li> </ol>	ng the February 2019 submission window (7
SEAC discussed the key issues identified in the applications for authorisation.	<b>Rapporteurs</b> to prepare the first versions of the draft opinions, taking into account the SEAC-43 discussions.
b) Agreement on draft opinions	
1. CT_Aloys (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.
SEAC agreed on its draft opinion on this application for authorisation by consensus.	<b>SECR</b> to send the draft opinion to the applicant for commenting.
2. CT_Ideal (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.
SEAC agreed on its draft opinions for Uses 1 and 2 on this application for authorisation by consensus.	<b>SECR</b> to send the draft opinions to the applicant for commenting.
3. CT_Keuco (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.
SEAC agreed on its draft opinions for Uses 1 and 2 on this application for authorisation by consensus.	<b>SECR</b> to send the draft opinions to the applicant for commenting.
4. CT_Schell (1 use)	

SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion.	<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinion.	
SEAC agreed on its draft opinion on this application for authorisation by consensus.	<b>SECR</b> to send the draft opinion to the applicant for commenting.	
5. CT_Thyssen (2 uses)		
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions for uses 1 and 2 on this application for authorisation by consensus.	<ul><li><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC draft opinions.</li><li><b>SECR</b> to send the draft opinions to the applicant for commenting.</li></ul>	
6.3 Appointment of (co-)rapporteurs for auth	orisation applications (closed session)	
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with the restricted room document SEAC/43/2019/02).	<b>SEAC members</b> to volunteer to the pool of (co-) rapporteurs for applications for authorisation. <b>SECR</b> to upload the updated document to confidential folder on S-CIRCABC IG.	
8. Action points and main conclusions of SEAC-43		
SEAC adopted the action points and main conclusions of SEAC-43.	<b>SECR</b> to upload the action points and main conclusions to S-CIRCABC IG.	

# **III. List of Attendees**

#### SEAC-43

SEAC members	
ALEXANDRE Joao	
ANASTASIOU Christos	
BERGS Ivars	
BLAHA Karel	
BRIGNON Jean-Marc	
CASTELLI Stefano	
CAVALIERI Luisa	
COGEN Simon	
DELCOURT Benjamin	
DOMINIAK Dorota	
DOUGHERTY Gary	
FANKHAUSER Simone	
FIORE Karine	
FOCK Lars	
FORKMAN Mats	
GEORGIOU Stavros	
JANSSEN Martien	
JONES Derrick	
JOYCE John	
KAJIC Silva	
KIISKI Johanna	
KNOFLACH Georg	
KRAJNC Karmen	
LEAHY Eimear	
LUIT Richard	
LÜDEKE Andreas	
NARROS SIERRA Adolfo	
RONKAINEN Dora	
ROUW Aart	
SCHUCHTAR Endre	
SHAKHRAMANYAN Nikolinka	
THIELE Karen	
URBAN Klaus	
VASILIUNE Zieduna	
ZAMFIR Adrian-Stefan	
Commission observers	
BENGYUZOV Manol (DG GROW)	
BERTATO Silvia (DG GROW) via Webex	
GALLEGO Matteo (DG ENV)	
HUALDE-GRASA Patricia (DG GROW)	
via Webex	
SVARD Amie (DG GROW) via Webex	
Stakeholder observers & accompanying experts	
BALLACH Jochen (IVS =	
Industrievereinigung Chemiefaser),	
accompanying exert to CEFIC for N,N-	
Dimethylformamide	

observers & dossier submitters (DS)	
ASSMANN Mervi as advisor to Johanna KIISKI	
CARLSSON FENG Mattias as DS for skin sensitizers via WebEx	
CORRELL MYHRE Ingunn as DS for PFxHS	
DE BLAEIJ Arianne as advisor to Martien JANSSEN via webEx	
DORTH Helena as DS for skin sensitizers via WebEx	
DUBOIS Cecile as DS for skin sensitizer	
HELMEDACH Achim as advisor to Karen THIELE	
LANGTVET Espen as DS for PFxHS	
LERCHE Dorte as advisor to Lars FOCK	
LINDQVIST Martin as advisor DS for skin sensitizers via WebEx	
PETERS Oliver as advisor to Karen THIELE via WebEx	
REALE Priscilla as advisor to Luisa Cavalieri via WebEx	
THIERRY Morgane as advisor to Karine FIORE	
THORS Asa as DS for skin sensitizers via WebEx	

Advisors, invited experts,

Stakeholder observers & accompanying experts (cont.)	
BERNARD Alice (ClientEarth)	
COLACICCO Rudy (EPPA) ,	
accompanying expert to Cosmetics	
Europe for Microplastics restriction;	
EVANS Karl (DOW Europe) as	
accompanying expert to CEFIC for	
Siloxanes restriction;	
HARTMANN Rola Azzi (ROCHE),	
accompanying expert to Medtech	
Europe for Microplastics restriction	
HOLLAND Mike (EAERE = European	
Association for Environmental and	
Resource Economists)	
HöK Frida (Chemsec)	
JÁNOSI Amaya (CEFIC = European	
Chemical Industry Council)	
KARJOMAA Sari (Cosmetic Europe –	
Finnish Secretariat, Finnish Cosmetic	
and Detergent Association), occasional	
Stakeholder for Microplastics restriction	
MACAUDIERE Sylvie (ARKEMA),	
accompanying expert to CEFIC for	
Microplastics	
MEYEROVICH Kira (Medtech Europe),	
occasional Stakeholder for	
Microplastics restriction;	
McCARTHY Adam (ALBEMARLE),	
accompanying expert to CEFIC for	
Cobalt salts restriction	
MISTRY Rohit (EFTEC = Economics for	
the Environment), accompanying	
expert to EUROMETAUX for Cobalt salts	
restriction	
MUSU Tony (ETUC = European Trade	
Union Confederation)	
ROBINSON Nik (EOSCA = European	
Oilfield Speciality Chemical	
Association), accompanying expert to	
AISE for Microplastics restriction	
SCAZZOLA Roberto (AISE =	
International Association for Soaps,	
Detergents and Maintenance Products),	
occasional Stakeholder for	
Microplastics restriction;	
Ten BRICK Patrick (EEB = European	
Environmental Bureau)	
WAETERSCHOOT (EUROMETAUX =	
European Association of the Metals industry);	
WIJNENDAELE Kris (European Panel	
Federation), accompanying expert to	
CEFIC for Formaldehyde restriction	

ECHA STAFF
BLAINEY Mark
DI BASTIANO Augusto
GHAZANFARI Sara
GMEINDER Michael
HENRICHSON Sanna
HOLLINS Stephen
JACQUEMIN Katline
KIVELA Kalle
KOSK-BIENKO Joanna
LEFEVRE-BREVART Sandrine
LUDBORZS Arnis
MARQUEZ-CAMACHO Mercedes
NICOT Thierry
ORISPÄÄ Katja
OTTATI Maria
PELTOLA Jukka
PILLET Monique
REGIL Pablo
SADAM Diana
SIMPSON Peter
SOSNOWSKI Piotr
STOYANOVA Evgenia
ÖBERG Tomas
VAINIO Matti
VAN DER ZANDT Peter

RAC rapporteurs
DUNAUSKIENE Lina
LUND Bert-Ove
KAPELARI Sonja
MULLOOLY Yvonne
NEUMANN Michael
SANTONEN Tiina
SCHLUTER Urs

# **IV. List of Annexes**

- ANNEX I. List of documents submitted to the members of the Committee for Socioeconomic 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	SEAC/A/43/2019
Update of SEAC accredited stakeholders' list	SEAC/43/2019/01_rev.1 (restricted room document)
Appointment of (co-)rapporteurs for authorisation applications (closed session)	SEAC/43/2019/02 (restricted room document)

# 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):

Name of participant	Agenda item	Interest declared
CAVALIERI Luisa	5.2b.4 -N,N- dimethylformamide (DMF)	Contract with the MSCA submitting the dossier
CASTELLI Stefano	5.2b.4 -N,N- dimethylformamide (DMF)	Working for the MSCA submitting the dossier
FIORE Karine	5.2a.2 Skin sensitizers in textile	Participation in the preparation of the restriction dossiers
FORKMAN Mats	5.2a.2 Skin sensitizers in textile	Working for the MSCA submitting the dossier
JANSSEN Martien	5.2b.6 Plastic and rubber granulates containing PAHs	Working for the MSCA submitting the dossier
LUIT Richard	5.2b.6 Plastic and rubber granulates containing PAHs	Participation in the preparation of the restriction dossier



ANNEX III

11 June 2019 SEAC/A/43/2019

# **Final Agenda**

# 43<sup>nd</sup> meeting of the Committee for Socio-economic Analysis

# 11 – 14 June 2019 ECHA Conference Centre (Annankatu 18, Helsinki)

# 11 June starts at 14.00 14 June ends at 13.30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/43/2019 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-42 action points, written procedures and update on other ECHA bodies

For information

b) Update of SEAC accredited stakeholders' list (closed session)

SEAC/43/2019/01\_rev.1 (restricted room document) For agreement

#### Item 5 – Restrictions

#### 5.1 General restriction issues

a) Report from the recent Restrictions Task Force activities

#### For information

#### 5.2 Restriction Annex XV dossiers

- a) Conformity check and key issues discussion
  - 1. Perfluorohexane-1-sulphonic acid, its salts and related substances
  - 2. Skin sensitisers in textile

#### For discussion and agreement

- b) Opinion development
  - 1. Siloxanes (D4, D5 and D6) first draft opinion
  - 2. Formaldehyde first draft opinion
  - 3. Microplastics first draft opinion
  - 4. *N*,*N*-dimethylformamide second draft opinion
  - 5. Five cobalt salts second draft opinion

#### For discussion

6. PAHs in granules and mulches used as infill material – third draft opinion *For discussion and agreement* 

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

#### For information

#### Item 6 – Authorisation

#### 6.1 General authorisation issues

- a) Update on incoming/future applications
- b) Model opinions and revised format
- c) Update on General Court Cases

#### 6.2 Authorisation applications

- a) Discussion on key issues
  - 1. 11 applications for authorisation received during the February 2019 submission window (7 OPE/NPE, 3 Cr(VI), 1 CTPHT)

#### For discussion

For information

For discussion

For information

- b) Agreement on draft opinion
  - 1. CT\_Aloys (1 use)
  - 2. CT\_Ideal (2 uses)
  - 3. CT\_Keuco (2 uses)
  - 4. CT\_Schell (1 use)
  - 5. CT\_Thyssen (2 uses)

#### For discussion and agreement

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

SEAC/43/2019/02 (restricted room document) For agreement

# Item 7 – AOB

- a) Update of the work plan
- b) Presentation on the Delphi study to identify and assess factors influencing potential impacts of PBT/vPvB substances

#### For information

#### Item 8 – Action points and main conclusions of SEAC-43

Table with Conclusions and Action points from SEAC-43