22 November 2019

SEAC/M/44/2019 FINAL

Final

Minutes of the 44th meeting of the Committee for Socio-economic Analysis

16-20 September 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 44th meeting of SEAC. The Chairman also informed SEAC that apologies had been received from six 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-44. The agenda was adopted without modifications (in line with SEAC/A/44/2019). 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. Seven members declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.1b.1, 5.1b.2, 5.1b.7, and 5.1b.8. 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-44 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-43 action points, written procedures and update on other ECHA bodies

The Chairman informed the participants that all action points of SEAC-43 had been completed or would be followed up during the on-going SEAC-44 meeting.

The Chairman also informed the Committee that the final minutes of SEAC-43 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-43 minutes. The Chairman also explained that as an efficiency measure, the SEAC minutes will be shorter in the future.

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

5) Restrictions

5.1) Restriction Annex XV dossiers

a) Conformity check and key issues discussion

1) Calcium cyanamide in fertilisers

The Chairman welcomed the Dossier Submitter's representatives from ECHA and the RAC (co-)rapporteurs (following via WebEx). He informed the participants that the restriction dossier had been submitted in July 2019.

The Dossier Submitter's representative provided an introductory presentation on the dossier. He explained that the proposal concerns the placing on the market of calcium cyanamide used as a fertiliser. The use of calcium cyanamide as a fertiliser is regulated by (EU) 2019/1009. Circa 130 000 tonnes of calcium cyanamide are manufactured annually in the EU of which about 53 000 tonnes are for use as a fertiliser. This is supplied mainly to professional farmers and estimated to be used for fertilising over 230 000 hectares. The Dossier Submitter has found that the use of calcium cyanamide as a fertiliser leads to a risk that is not adequately controlled for both surface water adjacent to fertilised fields and to soil.

The rapporteurs presented the outcome of the conformity check and the recommendations to the Dossier Submitter. They noted that this was a clear and thorough report and that all aspects of the proposal are discussed comprehensively in their view. The rapporteurs also pointed out a few recommendations for improving the dossier (e.g. more details on why calcium cyanamide is not used more when it seems so profitable, more details on alternatives and on benefits, etc.).

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 25 September 2019.

b) Opinion development

1) Skin sensitisers in textile – first draft opinion

The Chairman welcomed the Dossier Submitter's representatives from France and Sweden, an occasional stakeholder observer and an expert accompanying the occasional stakeholder observer. He informed the participants that the restriction dossier had been submitted in April 2019 and proposes to restrict skin sensitising substances in finished textile, leather, hide and fur articles, placed on the market for the first time.

The Secretariat provided to the Committee the report from the RAC discussions on this dossier held within RAC-50. The rapporteurs then presented the first draft opinion to the

Committee. They recommended that in this plenary meeting, the Committee would agree on the need for EU-wide measure, discuss and agree on the scope of the proposal, preliminarily discuss conditions, discuss and agree costs as well as preliminarily discuss benefits, other impacts and practicality. Several members expressed support for the first draft opinion. The COM observer enquired if the proposal included a dynamic link with skin sensitisers included in the EU Cosmetic Products Regulation (CPR) as well as the CLP legislation. The Dossier Submitter noted that RAC had also made a similar suggestion during the RAC-50 discussions. An occasional stakeholder observer emphasised that they also support establishing a dynamic link between this restriction and CLP as well CPR legislation – for consistency and for easier enforcement. Furthermore, she informed the Committee that they had submitted additional information about alternatives in the ongoing public consultation. The (co-)rapporteurs confirmed that they would take this information into consideration later in the opinion development process, together with the other public consultation comments.

The Chairman concluded that the Committee in general supports the assessment carried out by the rapporteurs so far. He reminded SEAC that the Secretariat would be launching a two week written commenting round on the first draft opinion after SEAC-44. The (co-)rapporteurs were requested to prepare the second draft opinion, taking into account SEAC-44 discussions and the SEAC written consultation, by early November 2019.

2) Perfluorohexane-1-sulphhonic acid, its salts and related substances – first draft opinion

The Chairman welcomed the Dossier Submitter representatives from Norway. He informed the participants that the restriction dossier had been submitted in April 2019. The dossier proposes 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 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 RAC rapporteur provided a brief update from the RAC-50 where RAC had concluded on the main elements from the restriction (the proposed scope, justification and reasons for the grouping of PFHxS, concluding that targeting use and placing on the market will reduce current emissions and prevent substitution from PFOA in 2020). Furthermore, RAC had concluded on the hazard assessment with focus on minimising emissions. RAC had agreed that there is a risk that needs to be addressed, and emissions are used as a proxy for risks. Finally, RAC had agreed that action is required on an EU-wide basis, and that a restriction is the most appropriate EU wide measure.

The SEAC (co-)rapporteurs then presented the first draft opinion. Some SEAC members questioned the need for a transition period as the substance is reported to not be currently used, and questions were also raised with regard to derogations, concentration limits and recycling. A representative of the European Commission requested that the considerations on firefighting foams should be aligned with those in the Stockholm Convention for PFOA. The rapporteurs would elaborate these further based on the input

received via the public consultation. Further work would be also needed regarding costs (e.g. testing costs).

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. The Chairman informed the Committee that the Secretariat will launch a written consultation on the first draft opinion after SEAC-44. The rapporteurs were asked to prepare the second draft opinion, taking into account the SEAC-44 discussion and the SEAC written consultation, by early November 2019.

3) Siloxanes (D4, D5 and D6) – second draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the RAC rapporteur, an industry expert accompanying the regular stakeholder observer and an occasional stakeholder observer. He informed the participants that this restriction dossier had been submitted in January 2019 and 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 European Economic Area. They are mainly used as monomers for the production of silicone polymers 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 informed the Committee that RAC had been provided with a status update on this dossier only and no discussion had been carried out on the RAC second draft opinion. The SEAC (co-)rapporteurs then presented the second draft opinion. They reminded the Committee that at the previous SEAC-43 plenary meeting, the Committee had agreed that the scope of the proposed restriction is clear, that action is required on an EU-wide basis and also provisionally supported that the proposed restriction is the most appropriate EU-wide measure. At the current SEAC-44 plenary, they suggested to finalise the discussion that the restriction is the most appropriate EU-wide measure, to discuss the availability of alternatives, agree that performance loss/consumer surplus loss is not considered a major issue, that substitution costs for other uses are considered negligible, that enforcement costs are underestimated in the proposal, and discuss proportionality.

Several members welcomed the changes made in the second draft opinion. An industry expert questioned if emissions to air are relevant or not to be taken into consideration in the proportionality assessment performed by SEAC. The RAC rapporteur clarified that as these substances have been identified as PBT/vPvB substances by MSC, emissions to all compartments need to be minimised and D4, D5 and D6 should not be treated differently from other PBT/vPvB substances.

The Committee members confirmed that the proposed restriction is the most appropriate EU-wide measure. The Committee members also supported the proportionality assessment made by the (co-)rapporteurs, leaving derogations to be discussed and finalised at the next plenary meeting. The rapporteurs were asked to prepare the third

draft opinion on this dossier, taking into account SEAC-44 discussions and the results of the public consultation, by early November 2019. SEAC is expected to agree on its draft opinion on this dossier at SEAC-45 in November/December 2019.

4) Formaldehyde – second draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the industry expert accompanying the regular stakeholder observer, the occasional stakeholder observer, and the SEAC rapporteurs. He informed the participants that the restriction dossier had been submitted by ECHA in January 2019. The proposed restriction aims to restrict the placing on the market of articles releasing formaldehyde at rates resulting in concentrations greater than 0.124 mg/m^3 in a test chamber. The proposal covers articles where formaldehyde or formaldehyde-based substances (formaldehyde releasers) have been intentionally added in their production process (either as such or in mixtures) and where releases may occur as a result of off-gassing of residual formaldehyde present in the article or from degradation of substances used in the production process. Articles for outdoor use only are not within the scope of the restriction proposal. Articles subject to the existing restriction on CMRs in textiles, clothing and footwear (Annex XVII entry 72) as well as the use of formaldehyde and formaldehyde releasers as a biocide are exempted from the proposed restriction.

The RAC rapporteurs provided an update from the RAC-50 discussions. RAC had agreed to consider short-term exposure of formaldehyde arising from the use of mixtures and other temporary emission sources in the uncertainty analysis only. RAC agreed that there is a risk to be addressed. In addition, RAC made a preliminary agreement to recommend that road vehicles/cars, railway carriages, aeroplanes, boats and passenger ships should be retained in the scope of the proposed restriction for the time being, but to discuss this aspect further at the next meeting. The Committee also took note of the approach presented by the RAC rapporteurs to derive an emission limit for articles which is lower than the one proposed by the Dossier Submitter and on the proposal to use the DNEL derived by RAC as an air concentration limit for vehicle cabin interiors.

The SEAC rapporteurs then presented the second draft opinion. In their presentation the rapporteurs focused on the scope of the restriction proposal, the derogations proposed by the Dossier Submitter, testing methods, and comments received during the public consultation outlining potential overlaps with existing regulations. They also stated that the voluntary agreements, which are in place in major EU industry sectors, are not sufficient risk management options because not all EU manufacturers have subscribed to them, there are observed freeriding cases, and imports are not covered by such agreements. They added that national regulations on formaldehyde and formaldehyde releasers are in place in eight EU Member States.

During the discussion, SEAC members noted that the precision in the description of the scope of the restriction, based on revisions by the Dossier Submitter, had improved. One SEAC member suggested to include second-hand articles releasing formaldehyde in the scope of the restriction. Another SEAC member commented on the reliability of the testing methods. The industry expert contributed to the discussion on proportionality by outlining the impacts that would be expected should a restriction adopt more stringent emission limit value than that proposed by the Dossier Submitter.

The rapporteurs were requested to take the discussions of SEAC-44 and the results of the public consultation into account in the third draft SEAC opinion. The Chairman concluded that the Committee accepted the proposed scope of the restriction as it is in the second version of the draft opinion; the Committee will continue discussions on proportionality (considering that a lower emission limit value may be recommended by RAC) and derogations aiming to conclude the draft opinion at the next Committee meeting (SEAC-45) in November/December 2019.

5) Microplastics – second 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 the Committee that the dossier was submitted by ECHA in January 2019. The proposal aims to restrict the placing on the market and use of intentionally added microplastics and is comprised of various measures including a ban on the placing on the market of substances/mixtures containing microplastics where they will inevitably be released to the environment when used 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 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 products, medical diagnostics and agricultural uses. The proposed restriction is estimated to result in an emission reduction of 85-95% after its progressive entry into effect.

The Secretariat then informed the Committee that RAC had discussed the second version of the draft opinion in RAC-50. RAC had agreed that although there are uncertainties in the understanding of the hazard of microplastics they constitute an intrinsic hazard. Furthermore, RAC had agreed that all releases should be minimised. RAC had provisionally agreed on the assumptions regarding releases, emissions, exposure route and environmental fate of microplastics. Finally, RAC had agreed there is justification for action on a Union-wide basis.

The SEAC rapporteurs presented the second draft opinion outlining the updates made with regard to the scope, costs and benefits based on the earlier comments received from the SEAC members and the public consultation comments reviewed so far. SEAC members generally supported the rapporteurs' conclusions.

In addition, there were questions from the industry experts accompanying the regular stakeholder observers regarding the proposed transition period and the impact on enforceability of the restriction based on RAC's recommendation that there should be no lower size limit for microplastics (Dossier Submitter proposal was for a lower size limit of 1 nm). The Secretariat noted that enforceability issues will be further discussed with the Forum. A representative of the Commission enquired how impacts arising from uses covered by the restriction but not specifically assessed in the Annex XV dossier would be analysed by the committee, such as infill material used in artificial turf. She stressed that the committee should focus its evaluation on the scientific input provided by stakeholders through the public consultation rather than any policy considerations. She also questioned whether the adoption of the Fertilising Products Regulation would affect the baseline assumptions, as a substantial part of the market is covered by that Regulation. Different stakeholder representatives called for sector-specific elaborations in the draft opinion (i.e. lack of alternatives, costs of reformulation), and the rapporteurs reassured stakeholders that all input provided via public consultation (which finishes by 20 September 2019) will be assessed during the opinion development. In this context, the Chairman announced that due to the complexity of the dossier and the high volume of public consultation comments received, the RAC opinion deadline had been prolonged until March 2020, hence delaying also the SEAC opinion deadline.

The Committee members supported the proposed updates regarding the scope as presented by the rapporteurs. Furthermore, SEAC agreed that the proposed restriction is the most appropriate EU wide measure. Further assessment will be required regarding practicability and monitoribility as well as cost and benefit assessment based on the public consultation comments received. The rapporteurs were requested to prepare the third draft opinion, taking into account the discussions in SEAC-44 and the results of the public consultation, by the beginning of November 2019.

6) Five cobalt salts – third draft opinion

The Chairman welcomed the Dossier Submitter's representatives from ECHA, the RAC rapporteurs, two experts accompanying the regular stakeholder observers, as well as one occasional 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 (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate) as substances on their own or in mixtures in a concentration equal or above 0.01% by weight in industrial and professional applications. The salts are manufactured and used in the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. The rapporteurs had developed the third draft opinion on this dossier, on which a written consultation had been organised prior to SEAC-44. The Chairman also informed the Committee that due to the complexity of the discussion, RAC had not yet adopted its opinion on this dossier and therefore also the SEAC agreement on its draft opinion is postponed until November/December 2019 and the adoption of the final opinion to March 2020.

The RAC rapporteur provided a brief update from the RAC discussion on this dossier held within RAC-50. The SEAC co-rapporteur then presented the third draft opinion. He noted

that from the restriction options left for consideration (RO1a and RO1b[1]), the rapporteurs had concluded that option RO1b would not be proportionate from a CBA perspective and its appropriateness is questionable. For option RO1a, no definite conclusion on proportionality can be drawn, cost estimates available to SEAC differ substantially and both assessments contain uncertainties. Furthermore, this option provides a lower level of protection to workers compared to the other options assessed. The co-rapporteur emphasised that the SEAC third draft opinion is partly outdated due to the RAC-50 discussion and conclusions. He pointed out that the Dossier Submitter had concluded that even with the change of REV to 8h TWA (agreed at RAC-50), the assessment of RO1a and 1b is appropriate to be further used for the opinion making by SEAC and had agreed to provide a qualitative assessment on how costs and benefits are affected by this change. However, this change is not expected to influence the conclusion on proportionality, but positively influences the practicality of a restriction.

The Committee members generally supported the conclusions of the rapporteurs on option RO1b although one Member found that it can yet not be concluded whether or not this option is proportionate. For option RO1a, SEAC members were not yet ready to conclude on proportionality, especially because of remaining uncertainties on the costs side. The COM observers reminded the Committee to include in its draft opinion the SEAC view on the length of the transitional period as well as more information on the availability of alternatives.

The Chairman informed the Committee that the Secretariat would be launching an additional SEAC written consultation after SEAC-44 for any further comments on the third draft opinion. The rapporteurs were requested to prepare the fourth draft opinion, taking into account the discussions in SEAC-44, the SEAC written consultation and the RAC-50 conclusions, by early November 2019.

7) *N,N*-dimethylformamide – third draft opinion

The Chairman welcomed the Dossier Submitter's representative from Italy, the expert accompanying a representative of Cefic, occasional stakeholder observers and their experts and the SEAC rapporteur. 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 %. DMF is manufactured in the EU, and used in the production of fine chemicals, pharmaceuticals, polymers, textiles, non-metallic products, perfumes/fragrances as a laboratory reagent (professional use) and as an intermediate.

The RAC rapporteur gave a brief update of the RAC-50 discussions. The SEAC rapporteur then presented the third draft opinion. He specifically focused on benefits, costs and the practicalities of the restriction. The rapporteur noted that the cost estimate had uncertainties, because industry has not convincingly demonstrated their inability to adequately control the risk by use of personal protection equipment (PPE) and/or administrative measures (e.g. job rotation), where technical risk reduction measures are non-feasible. He also pointed out that there are significant uncertainties in the industry responses to the public consultation (e.g. will the companies really close down?).

[1] RO1a – reference exposure value (REV) 10 µg Co/m^3;
RO1b – reference exposure value 1 µg Co/m^3

According to the responses from the industry in the public consultation, cost would not significantly change as a consequence of the RAC DNEL value compared to the DS proposed values.

Subsequently the SEAC members discussed the length of the transitional period, uncertainties in cost calculations and the Forum advice. A representative of the European Commission stressed the need to very clearly indicate in the assessment of the proportionality what are the assumptions and the uncertainties that may hamper the conclusion. Two industry experts intervened during the discussion mainly to repeat some comments they had already made in the public consultation. The Chairman invited all interested stakeholders to participate in the 60 day public consultation on the SEAC opinion, and raise their specific concerns there.

SEAC agreed on its draft opinion on the restriction proposal on DMF by consensus. The rapporteur was requested, together with the Secretariat, to undertake the final editing of the 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 the Committee that the Secretariat will launch a public consultation on the SEAC draft opinion in September 2019.

8) PAHs in granules and mulches used as infill material – draft final opinion

The Chairman welcomed the Dossier Submitter's representatives from the Netherlands (via WebEx). He informed the participants that the restriction dossier was submitted by the Netherlands on 20 July 2018, in cooperation with ECHA. The proposed restriction 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 rubber infill granules used in synthetic turf pitches derived from end-of-life tyres (ELT). Recent evaluations by RIVM (2017) and ECHA (2017) have both concluded that exposure to PAHs via infill material on synthetic turf pitches results in a relatively low risk of cancer. However, the reports highlighted that the current concentration limits permitted in entry 28 of Annex XVII of REACH are insufficient for protecting those who come into contact with the granules and mulches while playing at sports facilities and playgrounds. The public consultation on the SEAC draft opinion finished on 19 August 2019 with nine comments received.

The SEAC rapporteurs presented the outcome of the public consultation on the SEAC draft opinion. As a result of the public consultation outcome, the SEAC rapporteurs did not propose any modifications to the agreed draft opinion.

SEAC adopted its opinion on the restriction proposal on rubber granules by simple majority. One SEAC member declared a minority position due to his view on the proportionality of the measure, and was requested to submit his minority position (outlining the scientific and technical reasons) to the Secretariat by 27 September. The written reasons for the minority view will be published on ECHA website together with the adopted opinion.

The rapporteurs were requested, together with the Secretariat, to make the final editorial changes to the adopted SEAC opinion and to ensure that the supporting documentation (Background Document and responses to comments from the public

consultation) is in line with the adopted SEAC opinion. The Chairman thanked the rapporteurs for their efficient and thorough handling of this restriction proposal, the Committee members and the stakeholder observers for their contributions.

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

The Secretariat presented and SEAC agreed on the updated pool of (co-)rapporteurs for the restriction dossier on lead chromates dossier (in line restricted meeting document SEAC/44/2019/01). 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 19 new applications for authorisation were received during the July and August 2019 submission window. All of them are applications for authorisation 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 45 plenary meeting in November/December 2019. The Secretariat also informed about high numbers of opinions to be processed under the November 2019 submission window timelines.

The Secretariat also informed the Committee about discussion in RAC concerning the applications for authorisation for the uses of 4-tert-OPnEO, in which applicants derived PNEC values for endocrine disruption effects. RAC concluded that the dataset and analysis provided in the report is not sufficient to derive PNEC for these effects for 4-tert-OPnEO.

In addition, the Secretariat presented a new opinion format for applications for authorisation. The new opinion format considers the recent European Court rulings on applications for authorisation, as well as the REACH Regulation Review issued by the European Commission. The aim of the new opinion format is to provide, in concise and consistent opinions, all relevant technical and scientific elements while leaving policy judgement to the European Commission.

The SEAC members briefly discussed the issues presented by the Secretariat. The representative of the European Commission placed a reservation on behalf of the Commission on the new AfA opinion format. He noted that certain changes to the format stem neither from the Court judgments nor the REACH Review, that those changes are not necessarily in line with the Commission's view and may result in deficient opinions, while recognising that at the moment there are different views within the Commission

services on how to phrase certain parts the opinion. He also noted that ECHA needs to ensure that the intended transfer of agreed draft opinions into the new format does not lead to any changes in substance.

b) Production and (re-)approval of medicinal products: presentation by an expert of a national authority

The invited expert from Paul-Ehrlich-Institut (Federal Institute for Vaccines and Biomedicines) presented the overview of the production and (re-)approval of medicinal products based on the example substituting Triton X-100. He clarified that procedures of approval are different for IVD kits, "chemical" medicinal products produced in purely chemical technology and biological medicinal products produced via biotechnology. For the approval of substitutes in IVD kits in most of the cases requirements will cover only information on quality of the substitutes and confirmation of function. In case of medicinal products produced in purely chemical technology any change of the production of ingredients requires a confirmation of purity of the final product by the (bio)chemical characterisation of the substance. Most complicated are changes in the production of medicinal products produced via biotechnology. Any changes in the production requires combination of physico-chemical-biological testing, together with the production process and its control and the full approval process even if the composition of the medicinal products will remain the same.
The expert presented regulatory time-lines which are in the worse-case scenario up to 6 months. A more critical time factor is the time required for the generation of data which could take up 10 years.

According to the expert Triton X-100 has been used in 3 main types of use: as detergent, in the preparation of SD-plasma (as virus inactivation) and as ingredient in flu vaccines (important for virus inactivation/splitting and solubilisation of virus proteins/aggregates).

During the discussion the invited expert pointed out several issues which should be considered by SEAC. The companies may use patents to limit competitors' access to alternatives. In some cases applicants may provide incomplete data for the approval process. That gives them extra time while the authorities consider their decision and then additional time to provide the missing information according to a new deadline. In some of the cases, i.e. vaccines, there is a limited number of producers and any disturbance of production may result in a shortage of vaccines for patients. There are some cases where the approval of medicinal products outside the EU takes longer than in the EU. That is due to the merits (well organised and secure) of the approval system in the EU.

Concerning the testing of several surfactants in parallel, the expert underlined that first physical and chemical tests are performed. Clinical tests are only performed for promising substitutes.

Answering questions the expert informed SEAC on possible timelines required for the substitution of Triton X-100. The expert highlighted that a generic timeline on how long the substitution process would last would not make sense as this duration differs from case to case and depends on the substitution progress already made in each case. It has to be noted that there are 4 paths to the medicinal product approval in EU:

1. Centralized process through the EMA
2. Application to the designated national body within the EU
3. Mutual recognition: after approval in single state, application for mutual recognition in all states via the EMA
4. Decentralized process: simultaneous application in multiple EU states.

There is a special category of drugs—so-called *orphan drugs—which* are developed to treat rare diseases. For these diseases production of treatment is typically not profitable without government subsidiaries. In such cases the manufacturer is receiving market exclusivity up to 10 years. Important points to add:

- For drugs a reasonable timeline seems to be a decade,
- For SD plasma, the expert highlighted that one may not even want to substitute due to patient safety and supply security,
- For IVD kits, there are changes all the time and for a particular test replacement could possibly achieved over a period of 5-7 years.

6.2) Authorisation applications

a) Discussion on key issues

1. 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI))

The Secretariat in cooperation with the SEAC rapporteurs provided general information regarding the new applications for authorisation and specified the identified key issues in the applications listed below:

- 146_CT_TataSteel (single use)
- 147_CTPht_AO_Bilbaina (single use)
- 148_CTPht_DEZA (single use)
- 149_CTPht_Nalon (single use)
- 150_CTPht_AO_Koppers (single use)
- 151_CTPht_AO_Rutgers (single use)
- 152_CTPht_AO_RainCarbon (single use)
- 153_CTPht_Bilbaina (single use)
- 155_OPE_Siemens_2 (five uses)
- 157_OPE_Kedrion (single use)
- 158_OPE_Sanofi (single use)
- 159_OPE_Merck (single use)
- 161_OPE_Swords (single use)
- 166_OPE_Ompi (single use)
- 167_OPE_Roche (single use)
- 168_OPE_Vetter (single use)
- 169_OPE_Nordisk (single use)
- 171_OPE_Wallac (two uses)
- 173_OPE_Sobi (single use)

- 174_OPE_Eli_Lilly (single use)
- 175_OPE_Rousselot (single use)
- 176_OPE_Abbott_1 (five uses)
- 177_OPE_Abbott_2 (single use)
- 178_OPE_Janssen (single use)
- 179_OPE_Octapharma (two uses)
- 181_OPE_NPE_Roche (three uses)
- 183_NPE_GEHC_Bio-Sciences (single use)

b) Agreement on draft opinion

1. CT_TES (1 use)

The Chairman introduced the application for authorisation. 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 draft opinion on the application for authorisation.

This is a downstream user's application for authorisation on the use of chromium trioxide as surface treatment for the manufacture of grain-oriented electrical steel used in magnetic circuits of electric devices, in particular magnetic cores of high-performance transformers.

The SEAC rapporteurs concluded that alternatives are currently not available or suitable. All promising alternatives are in an earlier stage of development, requiring further R&D investment and testing to assess whether they may become suitable in the future. They proposed to SEAC to conclude that the information provided in the application is sufficient to demonstrate that the benefits of continued use outweigh the risks to human health by several orders of magnitude.

The SEAC members asked the rapporteurs about the robustness of the AoA and the confidentiality claims concerning the AoA. The rapporteurs informed SEAC that information in the confidential part of the AoA and further clarifications provided by the applicant were sufficient to make conclusions. Then the SEAC discussed elements considered in the socio-economic analysis.

The Committee agreed on the draft opinion by consensus. The Secretariat together with the rapporteurs will adjust the opinion text to the new opinion format.

2. SC_Ariston (1 use)

The Chairman introduced the application for authorisation. At this plenary, the SEAC members were asked to consider the agreement of the SEAC draft opinion. The Chairman informed SEAC that the Ariston RAC opinion is scheduled for discussion at the RAC Working Group on AfAs in October and for agreement at the November/December 2019 RAC plenary meeting. The SEAC rapporteurs presented the SEAC draft opinion on the application for authorisation.

The Ariston case is a downstream user's application for authorisation on the use of sodium chromate as an anticorrosion agent of the carbon steel in sealed circuit of gas absorption appliances up to 0.70 % by weight (as Cr^{6+}) in the refrigerant solution.

The SEAC rapporteurs concluded that taking into account the information provided by the applicant in the AoA and in the responses to the SEAC questions, SEAC can concur with the applicant's conclusions that alternatives analysed are not suitable and not available at this point in time and that based on this the substitution is expected to take not less than 12 years. They proposed SEAC to conclude that benefits outweigh risks by several orders of magnitude. The SEAC rapporteurs pointed out that to support the request for the review period of 20 years the applicant offered only qualitative arguments.

The SEAC members asked whether the use of the Inhibitor 7 as an alternative has been challenged by the rapporteurs. The rapporteurs explained that this alternative has been discussed with the applicant and it is considered non-suitable due to decrease of effectiveness in temperatures above 200 ^{o}C. A representative of the European Commission noted that the opinion needs to indicate whether there have been inputs from the public consultation and indicated that the justification of the review period has also to take into account socio-economic considerations.

The Committee agreed on the draft opinion by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat. Since this draft opinion has not been agreed by RAC yet, SEAC may reopen the agreed SEAC draft opinion, in case the conclusions in the agreed RAC draft opinion have an impact on the SEAC opinion.

3. SD_Bussi (1 use)

The Chairman introduced the application for authorisation. At this plenary, the SEAC members were asked to consider the agreement of the SEAC draft opinion. The Chairman informed SEAC that the Bussi RAC opinion is scheduled for discussion at the AFA WG in October and for agreement at the December RAC plenary meeting. The SEAC rapporteurs presented the SEAC draft opinion on the application for authorisation.

The Bussi case is a downstream user's application for authorisation on the use of sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorite.

The SEAC were of the opinion that the Applicant has demonstrated sufficient effort in search of alternatives by performing literature review based research. Convincing information has been provided by the applicant, as well as the thorough assessment of the technical feasibility associated with substitution of SD with shortlisted alternatives. As a result, the rapporteurs recommended SEAC to conclude that none of the shortlisted alternatives can be seen as the suitable alternative at this point in time or implemented in a short or medium review period. Concerning the outcome of the SEA the rapporteurs were of the opinion that benefits outweigh risks by several orders of magnitude.

During the discussion one SEAC member questioned whether the information provided in the AoA can be considered as a proper substitution plan. The rapporteurs informed the Committee that the applicant is planning to provide the substitution plan at the latest when commenting the draft opinion. A representative of the European Commission noted that the opinion needs to indicate whether there have been inputs from the public consultation and indicated that the justification of the review period has also to take into account socio-economic considerations.

The Committee agreed on the draft opinion by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat. Since this draft opinion has

not been agreed by RAC yet, SEAC may reopen the agreed SEAC draft opinion, in case the conclusions in the agreed RAC draft opinion have an impact on the SEAC opinion.

4. CTPht_Ariane (1 use)

The Chairman introduced the application for authorisation. At SEAC-43, 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 opinion.

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

This is an application for authorisation for industrial use of pitch, coal tar, high temp. (CTPht) as precursor of carbon matrix in the manufacturing of thermally and thermo-mechanically highly loaded carbon/carbon parts including nozzle throats and other critical carbon-carbon composite parts, resistant to very harsh erosion conditions, and very high temperature ranges, dedicated to high-performance civilian and military aerospace launchers.

The SEAC rapporteurs concluded that the alternatives identified by the applicant (no additional information on alternatives was received during the public consultation) are not suitable by the sunset date. The SEAC rapporteurs also concluded that, drawing on the applicant's assessment, the socio-economic benefits appear much greater than the monetised additional risks from continued use. The applicant has quantified the benefits in terms of savings in lost profits, loss of investments and unemployment. The rapporteurs noted that even if the number of years of lost profits and loss of investment is cut significantly, the ratio of costs to benefits are orders of magnitude apart. In addition, they took note of the conclusion of RAC that the exposure as well as the releases to the environment appear adequately minimised. One SEAC member had a question for clarification related to the analysis of alternatives.

The Committee agreed on the draft opinion by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat.

5. OPE_Boehringer (1 use)

The Chairman introduced the application for authorisation. 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 draft opinion on the application for authorisation.

This is a downstream user's application for authorisation on the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) in a washing buffer to purify biological APIs (active pharmaceutical ingredients) during the production of Palivizumab and Moxetumomab pasudotox-tdfk.

The SEAC rapporteurs concluded that technically feasible alternatives could be developed during the requested RP of 12 years (Palivizumab, at least 10.5 years) and even during 7-year RP (Moxetumomab, at least 5.5 years). However, the costs related to R&D and for obtaining market approvals are prohibitively high so the rapporteurs proposed that SEAC considers the alternatives not to be economically feasible for the applicant.

Upon a question from a representative of the European Commission, SEAC discussed if it was justified to include in one use the use of the substance in two types of drugs. The rapporteurs were of the opinion that it is justified as the production process is very similar. Anyway the long process of approval of medicinal products has to be taken in to consideration. The same representative of the European Commission enquired whether alternative drugs had been considered in the analysis of alternatives. In further discussion on cost–benefit analysis the rapporteurs clarified that the cost to the environment will be very low (negligible) as the applicant collects all wastes for incineration which was considered more cost-effective measure to reduce risks.

The Committee agreed on the draft opinion by consensus. The Secretariat together with the rapporteurs will adjust the opinion text to the new opinion format. A Commission representative noted a reservation on the new format for this case and explained that certain general conclusions from the new format were not relevant for this case, whereas important elements were not captured.

6. OPE_Ortho (2 uses)

The Chairman introduced the application for authorisation. 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 draft opinion on the application for authorisation.

This is a downstream user's application for authorisation submitted by Ortho-Clinical Diagnostics for the following two uses of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO).

Use 1: Formulation of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) for use in the manufacture of in vitro diagnostic VITROS® products used for infectious disease screening, endocrinology, and oncology testing. The use involves the use of < 5 kg Triton X-100 and the applicants requested the 12-year long review period.

The SEAC rapporteurs informed SEAC that the use 1 only covers formulation. For this use, the AoA is not relevant and not discussed.

SEAC discussed if the cost of the reduction of the emission should be compared with other PBT substances or applications. Then SEAC members asked why the applicant asked for 12 years review period while one of the reagents may become available to the applicant already within 7 years. The rapporteurs explained that the applicant needs to replace two reagents and has no resources to conduct two substitution plans in parallel. A stakeholder observer intervened and stated that during the PC they provided the list of surfactants as proposal of alternatives and asked if those were considered by SEAC. The rapporteurs pointed that to qualify as the substitute a surfactant has to fulfil certain criteria and it has to be analysed case by case and not all surfactants are automatically sufficient for all processes.

The Committee agreed on the draft opinion by consensus. The Secretariat together with the rapporteurs will adjust the opinion text to the new opinion format.

Use 2: Use of 4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (as Triton X-100) in two in vitro diagnostic VITROS® products used by professional diagnostic laboratories to detect antibodies to human hepatitis A virus and IgG antibodies to rubella virus. The use

involves the use of 0.5 kg Triton X-100 and the applicant requested the 10-year long review period requested.

The SEAC rapporteurs informed SEAC that the in their opinion the alternatives will not be available before the Sunset Date.

A representative of the European Commission said that it would be useful that the opinion identifies the hazards of the most promising alternatives and pointed out that there should be information for use 2, likewise for use 1, on the timelines towards substitution. The other representative of the European Commission noted that it would be appreciated to know what the impact of not having the IVD kits available is.

The Committee agreed on the draft opinion by consensus. The Secretariat together with the rapporteurs will adjust the opinion text to the new opinion format.

7. OPE_Stago (2 uses)

The Chairman introduced the application for authorisation. At SEAC-43, 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.

RAC will discuss the draft opinions in the RAC Working Group meeting on applications for authorisation, which will take place in October 2019. The SEAC rapporteur presented the two draft opinions on the application for authorisation.

This is an application for authorisation for the following two uses of 4-tert-OPnEO:

- Use 1: Industrial use of 4-tert-OPnEO for its detergent properties in the process of cell lysing for the production of in-vitro diagnostic reagents.
- Use 2: Industrial use of 4-tert-OPnEO in view of controlling the amount of non-specific reactions in the production of in-vitro diagnostic reagents.

On both uses, the SEAC rapporteur concurred with the applicant that currently none of the identified alternatives to Triton X-100 is a technically feasible alternative for the use applied for as substantiated by the tests made by the applicant. Overall, the SEAC rapporteur found the substitution initiative credible, with well-described phases and timelines for completion assigned to each of them. On socio-economic analysis the SEAC rapporteur concluded that the information provided in the application is sufficient to demonstrate that the benefits of continued use exceed the risks to the environment. The subsequent discussion focussed on technical and economic feasibility of alternatives.

A representative of the European Commission asked SEAC to further elaborate why the alternatives are not technically feasible and to indicate whether there were any inputs from the public consultation on alternatives.

The Committee agreed on the two draft opinions by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat. Since these draft opinions have not been agreed by RAC yet, SEAC may reopen the agreed SEAC draft opinions, in case the conclusions in the agreed RAC draft opinions have an impact on the SEAC opinions.

8. OPE_BioMarin (2 uses)

The Chairman introduced the application for authorisation. At SEAC-43, 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.

RAC will discuss the draft opinions in the RAC Working Group meeting on applications for authorisation, which will take place in October 2019. The SEAC rapporteur presented the two draft opinions on the application for authorisation.

This is an application for authorisation for the following two uses of 4-tert-OPnEO:

- Use 1: Industrial use as a surfactant to perform viral inactivation of biological proteins in the manufacture of a biopharmaceutical Final Bulk Drug Substance (FBDS) for an Enzyme Replacement Therapy (BMN250) for the treatment of rare and orphan diseases in the human population.
- Use 2: Industrial use as a surfactant to perform viral inactivation of biological proteins in the manufacture of a biopharmaceutical Final Bulk Drug Substance (FBDS) for Gene Therapy products for the treatment of rare conditions in the human population.

On both uses, the SEAC rapporteur concurred with the applicant that there is currently no technically feasible alternative. The SEAC rapporteur also found credible the applicant's claim that even if an alternative was to become technically feasible, its successful implementation across the entire range of products would require the requested review period. Overall, the SEAC rapporteur found the substitution initiative credible, with well-described phases and timelines for completion assigned to each of them. On socio-economic analysis SEAC concluded that the information provided in the application, combined with the provision of subsequent additional information, is sufficient to demonstrate that the benefits of continued use exceed the risks to the environment. The SEAC members discussed qualifying descriptor for releases to the environment, availability of alternatives, and lack of a business plan in the application's documentation package.

The Committee agreed on the two draft opinions by consensus, with some further post-editing to be done by the rapporteurs together with the Secretariat. Since these draft opinions have not been agreed by RAC yet, SEAC may reopen the agreed SEAC draft opinions, in case the conclusions in the agreed RAC draft opinions have an impact on the SEAC opinions.

9. OPE_Sebia (3 uses)

10. NPE_Sebia (1 use)

The Chairman introduced the two applications for authorisation. At SEAC-43, 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.

RAC will discuss the draft opinions in the RAC Working Group meeting on applications for authorisation, which will take place in October 2019. The SEAC rapporteur presented the four draft opinions on the two applications for authorisation.

OPE_Sebia is an application for authorisation for the following three uses:

- Use 1: Industrial use of 4-ter[t]-OPnEO for its "wetting" detergent properties allowing the dissolution, the dilution and the good spreading of substrates and reagents, necessary to optimize the sensitivity of gel electrophoresis in vitro diagnostic tests.
- Use 2: Industrial use of 4-tert-OPnEO for its detergent properties in the production of electrophoresis gels in view of ensuring the positioning of specific proteins necessary for the interpretation of results of gel electrophoresis in vitro diagnostic tests.

- Use 3: Industrial use of 4-tert-OPnEO for its detergent properties resulting in cellular lysis and protein interactions rupture and required for the production of reagents involved in the determination of proteins of interest in gel and capillary electrophoresis IVD test.

NPE_Sebia is an application for authorisation for the industrial use of 4-NPnEO for its detergent properties in the production of buffers and reagents in view of ensuring the positioning of specific proteins necessary for the interpretation of gel electrophoresis in vitro diagnostic tests results based on the determination of isoenzymes.

In all the four draft opinions, the SEAC rapporteur was of the opinion that the applicant's analysis of alternatives was not comprehensive and, therefore, clarifications were required on several issues. Nevertheless, the SEAC rapporteur acknowledged that the applications, in conjunction with the additional information that was supplied, provided a sufficient level of detail to conclude on the current technical and economic feasibility of the alternatives and the review period requested by the applicant. She noted that the comment received during the public consultation presented alternatives that would require the same overall substitution steps as those shortlisted by the applicant. Regarding the socio-economic analysis, SEAC took into account the benefits of continued use to the applicant, the industries it supplies and the patients benefitting from the products associated with the uses applied for. The SEAC members discussed the analysis of alternatives, and parts of the socio-economic analysis covering calculations of unemployment number. A representative of the European Commission asked SEAC to reflect on whether the assessment of the alternatives from the public consultation by the applicant is credible. The other Commission representative inquired why the application was considered 'bridging' considering that the evidence did not seem to support such qualification.

The Committee agreed on the four draft opinions by consensus, with some further post-editing to be done by the rapporteur together with the Secretariat. Since these draft opinions have not been agreed by RAC yet, SEAC may reopen the agreed SEAC draft opinions, in case the conclusions in the agreed RAC draft opinions have an impact on the SEAC opinions.

11. OPE_bioMerieux (3 uses)

The Chairman introduced the application for authorisation. At SEAC-43, 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.

RAC will discuss the draft opinions in the RAC Working Group meeting on applications for authorisation, which will take place in October 2019. The SEAC rapporteur presented the three draft opinions on the application for authorisation.

This is an application for authorisation for the following three uses of 4-tert-OPnEO:

- Use 1: Industrial use of 4-tert-OPnEO for its non-ionic detergent properties in the formulation of reagents for molecular in vitro preparative and testing applications.
- Use 2: Industrial use of 4-tert-OPnEO for its non-ionic detergent properties to control the level of non-specific reactions in the formulation of in vitro reagents for clinical and industrial in vitro testing immunoassays.

- Use 3: Industrial use of 4-tert-OPnEO for its detergent properties, used for the extraction of biological material which is further formulated and intended for clinical and industrial in vitro testing applications.

On all the three uses, the SEAC rapporteur was of the opinion that the analysis of alternatives is sufficiently detailed to conclude on the technical and economic feasibility of the alternatives and the derived review period requested by the applicant. In the application for authorisation, the applicant presented a substitution initiative consisting of different phases. In addition, the applicant listed and described each phase in the substitution initiative and set specific timelines for completion as well as the expected outcome resulting from each phase. The SEAC rapporteur took into account the benefits of continued use to the applicant, the industries it supplies and patients, customers and consumers benefitting from products associated with the uses applied for. SEAC concluded that the information provided in the application is sufficient to demonstrate that the benefits of continued use exceed the risks to the environment. The SEAC members discussed the availability of alternatives and confidentiality issues regarding alternatives for Use 1.

The Committee agreed on the three draft opinions by consensus, with some further post-editing to be done by the rapporteur together with the Secretariat. Since these draft opinions have not been agreed by RAC yet, SEAC may reopen the agreed SEAC draft opinions, in case the conclusions in the agreed RAC draft opinions have an impact on the SEAC opinions.

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

The pool of (co-)rapporteurs, as outlined in the restricted room document SEAC/44/2019/02_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) Study for the development of an evidence-based approach as support to regulators when assessing how to manage the presence of substances of concern in recycled materials (presentation by RIVM of the final results)

The RIVM representative provided to the Committee a presentation of the final results of the study for the development of an evidence-based approach as support to regulators when assessing how to manage the presence of substances of concern in recycled materials. The aim of the presentation was to inform SEAC about the outcome of this project and a framework to underpin how to deal with recycling when considering to

restrict a substance of concern, as well as hear the reflections of SEAC on the applicability of this framework and the implementation of the framework in (near) future dossiers. The Restriction Taskforce is also preparing a draft note on recycling to reach a common approach on how to take into account recycling in a restriction proposal.

Several members expressed support for this framework and noted that it could be useful for the SEAC work.

8) Action points and main conclusions of SEAC-44

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

II. Main conclusions and action points

SEAC-44, 16 - 20 September 2019
(Adopted at SEAC-44 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/44/2019).	**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	
a) Report on SEAC-43 action points, written procedures and update on other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-43. 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.	
5. Restrictions	
5.1 Restriction Annex XV dossiers	
a) Conformity check and key issues discussion	
1) Calcium cyanamide in fertilisers	
SEAC agreed that the dossier conforms to the Annex XV requirements.	**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG. **SECR** to launch a public consultation on the restriction proposal on 25 September 2019.
b) Opinion development	
1) Skin sensitisers in textile – first draft opinion	

SEAC rapporteurs presented and SEAC discussed the first draft opinion.	**SECR** to launch a written commenting round for members to provide comments on the first draft opinion (until 4 October 2019). **Rapporteurs** to prepare the second draft opinion, taking into account the SEAC-44 discussions and the results of the SEAC written consultation, by the beginning of November 2019.
2) Perfluorohexane-1-sulphhonic acid, its salts and related substances – first draft opinion	
SEAC rapporteurs presented and SEAC discussed the first draft opinion.	**SECR** to launch a written commenting round for members to provide comments on the first draft opinion (until 4 October 2019). **Rapporteurs** to prepare the second draft opinion, taking into account the SEAC-44 discussions and the results of the SEAC written consultation, by the beginning of November 2019.
3) Siloxanes (D4, D5 and D6) – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	**Rapporteurs** to prepare the third draft opinion, taking into account the SEAC-44 discussions and the results of the public consultation, by the beginning of November 2019.
4) Formaldehyde – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	**Rapporteurs** to prepare the third draft opinion, taking into account the SEAC-44 discussions and the results of the public consultation, by the beginning of November 2019.
5) Microplastics – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	**Rapporteurs** to prepare the third draft opinion, taking into account the SEAC-44 discussions and the results of the public consultation, by early November 2019.
6) Five cobalt salts – third draft opinion	

SEAC rapporteurs presented and SEAC discussed the third draft opinion.	**SECR** to launch an additional commenting round in SEAC on the third draft opinion after SEAC-44. **Rapporteurs** to prepare the fourth draft opinion, taking into account the SEAC-44 discussions and the RAC-50 conclusions, by early November 2019.
7) N,N-dimethylformamide – third draft opinion	
SEAC rapporteurs presented and SEAC discussed the third draft opinion. SEAC agreed on the draft opinion by consensus (with modifications agreed at SEAC-44).	**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. **SECR** to launch a public consultation on the SEAC draft opinion in September 2019.
8) PAHs in granules and mulches used as infill material – draft final opinion	
SEAC rapporteurs presented and SEAC discussed the draft of the final opinion. SEAC adopted the final opinion by simple majority.	**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. **SEAC member** to submit the minority position (outlining the scientific and technical reasons) to SECR by 27 September 2019.
5.2 Appointment of (co-)rapporteurs for restriction dossiers	
SEAC agreed on the pool of (co-)rapporteurs for the Lead Chromate restriction proposal to be submitted in September 2019 (in line with the restricted meeting document SEAC/44/2019/01). 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 December 2019 will be launched shortly.	**SEAC members** to volunteer for the pool of (co-) rapporteurs for the restriction dossier arriving to ECHA in December 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, AfA horizontal issues and the new AfA opinion format.	
b) Production and (re-)approval of medicinal products: presentation by an expert of a national authority	
SEAC took note of the presentation by an expert.	
6.2 Authorisation applications	
a) Discussion on key issues	
1) 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI))	
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-44 discussions.
b) Agreement on draft opinions	
1. CT_TES (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
2. SC_Ariston (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.
3. SD_Bussi (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.

4. CTPht_Ariane (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
5. OPE_Boehringer (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinion. **SECR** to send the draft opinion to the applicant for commenting.
6. OPE_Ortho (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **SECR** to send the draft opinions to the applicant for commenting.
7. OPE_Stago (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
8. OPE_BioMarin (2 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
9. OPE_Sebia (3 uses)	

SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
10. NPE_Sebia (1 use)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinion. SEAC agreed on its draft opinion on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinion has been agreed by RAC.
11. OPE_bioMerieux (3 uses)	
SEAC rapporteurs presented and SEAC discussed the SEAC draft opinions. SEAC agreed on its draft opinions on this application for authorisation by consensus.	**Rapporteurs** together with **SECR** to do the final editing of the SEAC draft opinions. **Rapporteurs** and **SECR** to consider the need to come back to discussions in SEAC after the opinions have been agreed by RAC.
6.3 Appointment of (co-)rapporteurs for authorisation applications (closed session)	
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with the restricted room document SEAC/44/2019/02).	**SEAC members** to volunteer to the pool of (co-) rapporteurs for applications for authorisation. **SECR** to upload the updated document to confidential folder on S-CIRCABC IG.
7. AOB	
b) RIVM presentation of the final results of the CLEAR project	
SEAC took note of the presentation by an RIVM representative.	
8. Action points and main conclusions of SEAC-44	
SEAC adopted the action points and main conclusions of SEAC-44.	**SECR** to upload the action points and main conclusions to S-CIRCABC IG.

III. List of Attendees

SEAC-44

SEAC members
ALEXANDRE Joao
ANASTASIOU Christos
ANTONIADOU Sofia
BERGS Ivars
BLAHA Karel
BRIGNON Jean-Marc
CASTELLI Stefano
CAVALIERI Luisa
COGEN Simon
DOMINIAK Dorota
FIORE Karine
FOCK Lars
FORKMAN Mats
JANSSEN Martien
JONES Derrick
JOYCE John
KAJIC Silva
KIISKI Johanna
KNOFLACH Georg
LEAHY Eimear
LOČS Jãnis
LUIT Richard
LÜDEKE Andreas
MÅGE Marit
NIKOVA Julieta
RONKAINEN Dora
ROUW Aart
SCHUCHTAR Endre
SHAKHRAMANYAN Nikolinka
THIELE Karen
URBAN Klaus
VASILIUNE Zieduna
Commission observers
BENGYUZOV Manol (DG GROW)
BERTATO Valentina (DG ENV) via Webex
GALLEGO Matteo (DG ENV)
HUALDE-GRASA Patricia (DG GROW) via Webex
SVÄRD Amie (DG GROW) via Webex
Stakeholder observers & accompanying experts
ANGIULLI Francesca (AISE = International Association for Soaps, Detergents and Maintenance Products) as Occasional Stakeholder for Microplastics restriction

Advisors, invited experts, observers & dossier submitters (DS)
ASSMANN Mervi as advisor to Johanna KIISKI
BLUEMEL Johannes (Paul-Ehrlich-Institut) as an invited expert for AfA General issues
CARLSSON FENG Mattias acting as advisor to Mats FORKMAN and dossier submitter for Skin sensitizers restriction dossier
CASTELLI Stefano acting as dossier submitter for DMF restriction dossier
CORREL MYHRE Ingunn and LANGTVET Espen as dossier submitters for PFHxS restriction dossier
De BLAEIJ Arianne acting as advisor to Martien JANSSEN
DUBOIS Celine acting as advisor to Karine FIORE via WebEx
FIORE Karine acting as dossier submitter for Skin sensitizers restriction dossier
HELMEDACH Achim acting as advisors to Karen THIELE
PALUDAN Elisabeth acting as advisor to Lars FOCK
PETERS Oliver acting as advisor to Karen THIELE via WebEx
REALE Priscilla acting as advisor to Luisa CAVALIERI via WebEx
STEWART Alexandra, DORFH Helena and THORS Åsa, acting as dossier submitters for Skin sensitizers restriction dossier via WebEx

Stakeholder observers & accompanying experts (cont.)
BALLACH Jochen (IVS = Industrievereinigung Chemiefaser), accompanying exert to EUROMETAUX for Microplastics and DMF restrictions
BUIJS Nathalie (MedTech Europe) as Occasional Stakeholder for D4/D5/D6, Formaldehyde, Microplastics, DMF and Cobalt salts restrictions and some AfAs
COLLACICO Rudy (EPPA) as accompanying expert to Cosmetics Europe for Microplastics restriction
DOBE Chris (ECPA = European Crop Protection Association) as accompanying expert to AISE for Microplastics restriction
DRMAC Dunja (EURATEX = European Apparel and Textile Organisation) as Occasional Stakeholder for DMF and Skin sensitizers restriction
EGGERMONT Bruno (EURATEX = European Apparel and Textile Organisation) as accompanying expert to EURATEX for DMF and Skin sensitizers restrictions
INGISMARSDOTTIR Sigridur (Haldor Topsoe) as accompanying expert to CEFIC for Cobalt salts
VEROUGSTRAETE Violaine (EUROMETAUX = European Association of the Metals Industry)
HOLLAND Mike (EAERE = European Association for Environmental and Resource Economists)
HÖK Frida (Chemsec)
JÁNOSI Amaya (CEFIC = European Chemical Industry Council)
LANGEVELD Kees (Fertilizers Europe) as accompanying expert to EuPC for Microplastics restriction
LAROCHE Charles (IFRA = International Fragrance Association) as Occasional Stakeholder for Microplastics restriction
MACAUDIERE Sylvie (ARKEMA), accompanying expert to CEFIC for Microplastics restriction
MISTRY Rohit (EFTEC = Economics for the Environment), accompanying expert to EUROMETAUX for Cobalt salts restriction

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SOSNOWSKI Piotr

Stakeholder observers & accompanying experts (cont.)
ROGER Appoline (ClientEarth)
SANTOS Tatiana (EEB = European Environmental Bureau)
SHAEFER Dietmar (Evonik Nutrition & Care GmbH) as accompanying expert to CEFIC for D4/D5/D6 restriction
WATSON Diane (Cosmetics Europe) as Occasional Stakeholder
WIJNENDAELE Kris (European Panel Federation), accompanying expert to CEFIC for Formaldehyde restriction

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BRANISTEANU Radu
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NEUMANN Michael
PARIS Pietro
RUCKI Marian
SANTONEN Tiina
SCHULTE Agnes
SCHLÜTER Urs
SEBA Julie
SOGORB Miguel
STAHLMANN Ralf
VAN DER HAAR Rudolf

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

ANNEX I

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

Document	Number
Final Draft Agenda	SEAC/A/44/2019
Appointment of (co-)rapporteurs for authorisation applications (closed session)	SEAC/44/2019/02 (restricted room document)
Appointment of (co-)rapporteurs for restriction applications	SEAC/44/2019/01 (restricted room document)

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):

Name of participant	**Agenda item**	**Interest declared**
CAVALIERI Luisa	5.1b.7–N,N-dimethylformamide (DMF)	Contract with the MSCA submitting the dossier
CASTELLI Stefano	5.1b.7–N,N-dimethylformamide (DMF)	Working for the MSCA submitting the dossier
FIORE Karine	5.1b.1 Skin sensitizers in textile	Participation in the preparation of the restriction dossiers
FORKMAN Mats	5.1b.1 Skin sensitizers in textile	Working for the MSCA submitting the dossier
JANSSEN Martien	5.1b.8 Plastic and rubber granulates containing PAHs	Working for the MSCA submitting the dossier
LUIT Richard	5.1b.8 Plastic and rubber granulates containing PAHs	Participation in the preparation of the restriction dossier
MÅGE Marit	5.1b.2 Perfluorohexane-1-sulphhonic acid, its salts and related substances (PFHxS)	Working for the MSCA submitting the dossier

ANNEX III

5 September 2019
SEAC/A/44/2019

Final Draft Agenda

44th meeting of the Committee for Socio-economic Analysis

16 - 20 September 2019

ECHA Conference Centre (Annankatu 18, Helsinki)

Monday 16 September starts at 14.00
Friday 20 September ends at 12.00

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/44/2019
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-43 action points, written procedures and update on other ECHA bodies

For information

Item 5 – Restrictions

5.1 Restriction Annex XV dossiers

b) Conformity check and key issues discussion

1) Calcium cyanamide in fertilisers

For discussion and agreement

c) Opinion development

1) Skin sensitisers in textile – first draft opinion

2) Perfluorohexane-1-sulphhonic acid, its salts and related substances – first draft opinion

3) Siloxanes (D4, D5 and D6) – second draft opinion

4) Formaldehyde – second draft opinion

5) Microplastics – second draft opinion

6) Five cobalt salts – third draft opinion

For discussion

7) *N,N*-dimethylformamide – third draft opinion

For discussion and agreement

8) PAHs in granules and mulches used as infill material – draft final opinion

For discussion and adoption

5.2 Appointment of (co-)rapporteurs for restriction dossiers

SEAC/44/2019/01

(restricted document)

Item 6 – Authorisation

6.1 General authorisation issues

a) Update on incoming/future applications

b) Production and (re-)approval of medicinal products: presentation by an expert of a national authority

For information

6.2 Authorisation applications

c) Discussion on key issues

1. 27 applications for authorisation from May 2019 submission window (OPE/NPE, CTPht, Cr(VI))

For discussion

d) Agreement on draft opinion

1. CT_TES (1 use)
2. SC_Ariston (1 use)
3. SD_Bussi (1 use)
4. CTPht_Ariane (1 use)
5. OPE_Boehringer (1 use)
6. OPE_Ortho (2 uses)
7. OPE_Stago (2 uses)
8. OPE_BioMarin (2 uses)
9. OPE_Sebia (3 uses)
10. NPE_Sebia (1 use)
11. OPE_bioMerieux (3 uses)

For discussion and agreement

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

SEAC/44/2019/02
(restricted room document)

Item 7 – AOB

a) Update of the work plan

b) Study for the development of an evidence-based approach as support to regulators when assessing how to manage the presence of substances of concern in recycled materials (presentation by RIVM of the final results)

For information

Item 8 – Action points and main conclusions of SEAC-44

Table with Conclusions and Action points from SEAC-44

For adoption