

27 May 2014 SEAC/M/22/2014 FINAL

# <u>Final</u>

Minutes of the 22<sup>nd</sup> meeting of the Committee for Socio-economic Analysis

11 - 14 March 2014

# I. Summary Record of the Proceeding

# 1. Welcome and apologies

Tomas Öberg, Chair of the Committee for Socio-economic Analysis (SEAC), ECHA, welcomed the participants of the twenty second meeting of SEAC.

The Chair informed the Committee that apologies had been received from five members, one stakeholder observer, one invited expert and one international observer. One invited expert, eight advisors to members present at the meeting as well as two representatives of the European Commission, observers of stakeholder organisations were introduced. The Chair informed the participants that members' advisors, dossier submitter representatives and representatives of the European Commission were to follow the relevant parts of the meeting via WebEx.

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

# 2. Adoption of the Agenda

The Chair introduced the draft Agenda of SEAC-22. The Agenda was adopted with minor modifications. The final Agenda is attached to these minutes as Annex III. The list of all meeting documents is attached to these minutes as Annex I.

# 3. Declarations of conflicts of interest to the Agenda

The Chair requested members, their advisors and invited experts participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Five members and six advisors declared potential conflicts of interest, or had this declared for them by the Chair, to the substance-related discussions under the agenda items 6.2 and 7.1. These members did not participate in voting under the respective agenda items, as stated in Article 9.2 of the SEAC Rules of Procedure.

The list with declared conflicts of interest is given in Annex II of these minutes.

# 4. Report from other ECHA bodies and activities

# a) Report on SEAC-21 action points, written procedures and other ECHA bodies

The Chair reported that all action points of SEAC-21 had been completed or would be followed up during the on-going SEAC-22 meeting.

The Chair informed the Committee that the final minutes of SEAC-21 had been adopted by written procedure and had been uploaded to CIRCABC as well as on the ECHA website. The Chair informed about a comment received from the Commission (which was not included in the RCOM and not taken into the final minutes) on reasons why they think it is necessary to include the additional questions on the proposed exemptions in the public consultation on the SEAC draft opinion on lead. The Commission representative called for more information to be requested within the public consultation of the SEAC draft opinion regarding keys, locks and padlocks in order to understand if the proposed exemptions are justified or not, and finally to support the Commission's decision-making. In the view of the Commission, without the necessary information related to the proposed

exemptions, SEAC will not be in a position to provide an opinion on the proposed exemptions.

The Chair thanked members for providing comments on the draft SEAC-21 minutes. In this context, the Chair also informed that due to the increased workload of SEAC and the alignment with the RAC minutes, the Secretariat will draft the shorter and more concise minutes from the SEAC plenary from now on.

In addition, the Chair explained that a report covering the developments in the ECHA MB, RAC, MSC, the Forum and the BPC had been compiled and distributed to SEAC as a meeting document (SEAC/22/2014/01).

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

Furthermore, the Secretariat presented the results of the Annual Satisfaction Survey 2013, followed up by a report from the Chair on the telephone interviews conducted with the SEAC members.

## 6. Restrictions

## 6.1 General restriction issues

# a) Update on intended restriction dossier

The Committee was provided with an update on intended restriction dossiers and informed that the Registry of Intentions currently includes the following notifications:

- N,N-dimethylformamide; dimethyl formamide (to be submitted by Italy in January 2015).
- **Methanol** (to be submitted by Poland in August 2014).
- **Bis(pentabromophenyl) ether (DecaBDE)** (to be submitted by ECHA on request of the Commission in August 2014).
- **Perfluorooctanoic acid** (**PFOA**) and any other linear or branched perfluoroheptyl derivative with the formula C7F15-X and any linear or branched perfluorooctyl derivative with the formula C8F17-X (where X=any group, including salts, other than F, Cl, Br), except those derivatives with the formula C8F17-S02X', C8F17-C(=0)OH or C8F17-CF2-X' (where X'=any group, including salts) (to be submitted by Germany in October 2014). The compilation of the Annex XV dossier is carried out as a joint project between the German and the Norwegian MSCAs. The call for rapporteurs will be launched soon after SEAC-22.
- Cadmium and its compounds in plastics the dossier was supposed to be submitted by ECHA on request of the Commission, however, the intention has been withdrawn because of lack of information and uncertainties. ECHA will report their findings in Annex XV report and discuss the issue in the next CARACAL meeting.

# b) Revision of the restriction process

At SEAC-22, the Committee was informed about the measures proposed to be taken in order to improve the efficiency of the restriction process. The Secretariat provided an update on the results of the questionnaire carried out in December 2013 among RAC and SEAC members, MSCAs and accredited stakeholder observers of the two Committees, as well as on the work of the Restrictions Efficiency Task Force carried out so far (including their initial recommendations).

The Secretariat then presented to the Committee the revised opinion development procedure for the restriction process. SEAC agreed to the revised procedure (meeting document SEAC/22/2014/03\_rev.1). The Chair informed that the new procedure will be applied starting from the restriction dossiers that had passed the conformity check within this plenary meeting.

## 6.2 Restriction Annex XV dossiers

# a) Opinion development

# 1) Lead and its compounds intended for consumer use - final opinion

The Chair welcomed the SEAC rapporteurs and the DS representative from the Swedish MSCA. The restriction dossier on lead and lead compounds was submitted to ECHA by Sweden in December 2012. SEAC agreed its draft opinion at SEAC-21, the public consultation on the SEAC draft opinion was launched on 17 December 2013. The public consultation finished on 14 February 2014, and there were 21 comments received from different stakeholders, individuals and some Member State Competent Authorities. The 1st version of the SEAC final opinion, the updated Background document and the responses by the rapporteurs to the public consultation comments were uploaded to the Committee on 28 February 2014.

The Chair reminded the Committee that the aim of the meeting is to adopt the SEAC opinion at SEAC-22.

After the introduction, the Chair connected an invited expert via WebEx, Professor Alexander, the vice chair of the EFSA scientific committee who had agreed to answer the Committee members' questions on different interpretations by SEAC members of fractional IQ loss discussed in the 2013 EFSA opinion. It was noted by the Chair that the comments provided by Professor Alexander are made in his personal capacity, not as a representative of EFSA. Professor Alexander explained that in the EFSA opinion a dose response curve was made on effects of lead on IQ, which identified lowest change in IQ of 1 % or 1 IQ point. The selection of a reference point the lower confidence interval of 1 IQ point in the EFSA opinion was compared with current lead exposure in children from food. The margin of exposure was close to 1 or less, hence all reduction of lead exposure had a positive health impact. He concluded that one should not look at the reference point in isolation but to take into account the current exposure to lead. Furthermore, Professor Alexander stated that the impacts would not be seen in a single child but the impact would be at the population level.

After the clarifying questions to the EFSA expert, the rapporteurs presented the changes to the current opinion based on the public consultation on the SEAC draft opinion and changes to make the opinion more consistent. In the discussions following the presentation, the SEAC members supported the reintegration of the migration limit as

proposed by the rapporteurs. Furthermore, SEAC agreed that an exemption for the metallic nosecones of the writing instruments should not be granted, as there was no quantitative SEA information received from the public consultation. Discussions took place regarding the construction products which were proposed by the rapporteurs to be included in the 'out of scope' list in the Background document.

Furthermore, in the margins of SEAC-22, an ad hoc group was organised with the interested SEAC members to discuss the relevance of the neurological impacts of fractional IQ losses and the valuation of such small impacts in neurological development. SEAC was provided a report back from the discussions on the next day. The ad hoc group had discussed whether fractional IQ impacts are relevant for the analysis (and had confirmed that the EFSA dose-response curve showed a continuous relationship between changes in lead blood levels and IQ). Most agreed that, at population level, this small impact should be valued in the same manner as a larger impact.

After the presentation, further discussions took place on its relevance for the evaluation by SEAC. For transparency reasons, a stakeholder observer called for the reference to an alternative population burden approach in the opinion. The Chair concluded that based on the discussions at the ad hoc group as well as the follow-up discussions at SEAC-22 the rapporteurs would make further textual modifications in the opinion to reflect the views expressed by SEAC.

One member raised again the concern for derogation for enamels, and asked for this to be reflected in the justification of the opinion. This, however, was not supported by the SEAC members, as there were no scientific data provided to amend the relevant derogation or change the opinion text. Another member still considered the scope of the restriction unclear, and claimed that proposed restriction is not proportionate (e.g. the valuation of non-measurable effects and societal impacts from non-measurable effects). In addition, following a relevant recommendation from the Commission, the transition period of 12 months was also inserted in the wording of the proposal.

The Chair asked the Committee to adopt the opinion. The opinion was adopted by absolute majority (a majority of all members having the right to vote). One member took a minority position to the opinion based on reasons included in a separate document which has been published on the ECHA website.

The Chair informed that the Secretariat together with the rapporteurs will make the final editorial changes to the opinion and align the Background Document with the adopted SEAC final opinion. The Secretariat will forward the RAC and SEAC opinions and the BD to the Commission.

# 2) Nonylphenol – 2<sup>nd</sup> version of the draft opinion

The Chair welcomed the dossier submitter representatives (Sweden) and the RAC rapporteurs (one of whom was present in person and another followed via WebEx). He reminded the Committee that the restriction dossier on Nonylphenol (NP) and Nonylphenol ethoxylate (NPE) had been submitted to ECHA in August 2013 and that the 2nd version of the SEAC draft opinion and the related documents had been provided to the Committee on 20 February 2014.

The RAC rapporteur provided to the Committee an update from the RAC discussion on this dossier held within RAC-28, where the Committee had agreed that there is an EU-wide risk in need of control and that the restriction is a good risk reduction option, but will possibly still leave some sites at risk (please see the RAC-28 minutes for more details).

The SEAC rapporteurs then presented the 2nd version of the SEAC draft opinion. They informed that the proposed wording of the restriction had been revised to reflect the advice received by the Forum. Furthermore, NP is now proposed to be excluded from the scope as it is not used in textile manufacturing process and only traces of NP are detected in textiles. Several SEAC members supported the proposed new wording and the exclusion of NP from the scope of the restriction, although one member sought a clarification on what is meant by "traces" of NP.

The rapporteurs explained that two REACH restriction options were evaluated in the dossier and the option with the limit value of 100 mg/kg textile and the transitional period of 5 years had been considered as the most appropriate. The transitional period had been proposed based on information provided by STOs, which was difficult to verify. Several SEAC members expressed the view that the length of the proposed transitional period seems too long, as in these supply chains the articles change at least twice per year. One SEAC member questioned why a lower limit value was not considered further. The RAC rapporteurs explained that a lower limit value would not change much the risk reduction capacity of the proposal and the SEAC rapporteurs that the restriction would then be even less cost-effective.

The rapporteurs reminded the Committee that with regard to costs, both substitution and compliance control costs have been assessed in the dossier, however, the compliance control costs are considered very uncertain depending whether testing is required. With regard to benefits, the dossier submitter considers them "substantial" but has not quantified them. The rapporteurs have considered both a cost-benefit approach (semi-quantitative assessment only) and a cost-effectiveness approach (compared to previous measures on NP/NPE) for assessing proportionality. They have concluded that the restriction proposal is proportionate if only substitution costs are considered. One SEAC member noted that he did not see in the dossier any justification why benefits are considered substantial and suggested linking the risk reduction to changes in the status of EU water bodies. Another member highlighted that a firm comparison between costs and benefits is not needed in this case, as NP is a priority substance under the Water Framework Directive, and this should be sufficient for justification. Another member pointed out that comparison of the cost effectiveness of the previous restriction on NP/NPE can be misleading as often regulators first take the cheapest measure.

The Chair summarised the discussion and proposed to the Committee to skip the 3rd version of the draft opinion, which based on the working procedure is prepared at/shortly after this plenary meeting. SEAC agreed to this proposal and the (co-)rapporteurs were asked to take the plenary discussion into account in the next version of the draft opinion prepared by 2 May 2014.

# 3) 1-Methyl-2-pyrrolidone (NMP) - 2nd version of the draft opinion

The Chair welcomed the dossier submitter representatives (NL), who followed the discussion remotely via WebEx. He reminded the Committee that the restriction dossier on 1-Methyl-2-pyrrolidone (NMP) had been submitted to ECHA in August 2013 and that the 2nd version of the SEAC draft opinion and the related documents had been provided to the Committee on 20 February 2014.

The Secretariat provided to the Committee an update from the RAC discussion on this dossier held within RAC-28, where the Committee had accepted the DNEL values

developed by the rapporteurs for evaluation of exposures and calculation of RCRs and had discussed RMOs described in the dossier.

The SEAC rapporteurs then presented the 2nd version of the SEAC draft opinion. They emphasised that in their view, SEAC is not in a position to recommend the most appropriate RMO, but should, in its draft opinion, give the arguments for and against different RMOs. These arguments should present the best estimate of impacts (health and costs) for the proposed RMOs for the different sectors and for RMO1 (general ban of NMP), to conclude that this option is not proportionate. The rapporteurs were of the view that choosing the most appropriate legal framework is a political decision and should be left for the Commission. Some members and one stakeholder observer where of the opinion that it is the dossier submitter's task to demonstrate that the proposed restriction is the most appropriate RMO and if they have not managed to demonstrate this, it should be explained in the opinion. Another member added that SEAC should not try to find what the best RMO is, but should assess which of the presented RMOs would achieve the objective best. The comparison between the proposed RMO and other measures should be undertaken, but only for the assessment of the proposed measure and not for recommending any other option.

The Chair summarised the discussion and proposed to the Committee to skip the 3rd version of the draft opinion. SEAC agreed to this proposal and the (co-)rapporteurs were asked to take the plenary discussion into account in the next version of the draft opinion to be prepared by 2 May 2014.

# b) Conformity check

# 1) Cadmium and its compounds in artist paints - outcome of the conformity check

The Chair opened the agenda topic by giving a brief background for the restriction proposal, which was submitted to ECHA by Sweden on 17 January 2014. The conformity check procedure was launched on 13 February 2014, with the SEAC comments on the conformity of the restriction. On 13 February also the draft conformity check report by the rapporteurs was uploaded to the Committees, and the views of SEAC members were requested to be included by 24 February (there was one comment received). The revised conformity check report by the rapporteurs was uploaded on 27 February 2014.

Furthermore, a short update was provided to the Committee on the RAC-28 discussions where RAC had concluded that the dossier is in conformity.

After the introduction, the Chair asked the representatives of the dossier submitter (Sweden) to present the main elements of the proposed restriction to the Committee. The proposed restriction by Sweden concerns placing on the market and use of cadmium and its compounds in artists' paints, TARIC code [3213] and pigments TARIC code [3212] intended for the manufacture of artists' paints. In this restriction proposal Swedish dossier submitter has chosen a quantitative risk assessments using two different endpoints, i.e. bone fractures and postmenopausal breast cancer. The exposure to cadmium is via food, due to the fact that the cadmium compounds used in artists' paints will eventually dissolve in the soil and hence there is a potential crop uptake.

Following the introductory presentations, the SEAC rapporteur(s) presented the outcome of the SEAC conformity check and recommended that the dossier would be considered in conformity. Furthermore, they presented the recommendations to the dossier submitter.

SEAC agreed that the cadmium in artists' paints dossier conforms to the requirements of Annex XV. The Chair informed the Committee that following the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter and launch a public consultation on this dossier on 19 March 2014.

# 2) Chrysotile - outcome of the conformity check

The Chair opened the agenda topic by introducing the background on the amendment to an existing restriction. The conformity check procedure was launched on 13 February 2014, with the SEAC comments on the conformity of the restriction proposal. On 13 February also the draft conformity check report by the rapporteurs was uploaded to the Committees, and the views of SEAC members requested to be included by 24 February (one comment received). Based on the comments received, the revised conformity check report by the rapporteurs was uploaded to the Committee on 27 February 2014.

After the introduction, the Chair asked the representative of the dossier submitter (ECHA) to present the main elements of the proposed restriction to the Committee. In January 2013, the European Commission requested ECHA to prepare an Annex XV restriction report with a view of prohibiting the placing on the market and use of diaphragms containing chrysotile. Several clarifying questions were asked by the SEAC members on the justification and background of the proposed restriction. A stakeholder observer questioned why the restriction proposal covers the import of asbestos fibres which does not appear to be allowed in the context of the current Annex XVII entry.

Furthermore, the RAC rapporteurs reported back from the RAC-28 discussions, where RAC had concluded the dossier in conformity.

Following the introductory presentations, the SEAC rapporteurs presented the outcome of the SEAC conformity check and recommended that the dossier would be considered in conformity. They furthermore presented a recommendation to the dossier submitter.

SEAC agreed that the chrysotile dossier conforms to the requirements of Annex XV. The rapporteurs were asked to modify the recommendations to the dossier submitter based on the request by one member (e.g. to reflect the historical background of the proposal). The Chair informed the Committee that following the conclusion of SEAC on conformity, the Secretariat would communicate the results of the conformity check and recommendations to the dossier submitter and launch a public consultation on this dossier on 19 March 2014.

# 3) 4,4-Isopropylidenediphenol (bisphenol A) - outcome of the conformity check

The Chair welcomed the dossier submitter representative (France) and the RAC rapporteurs. He informed the participants that the restriction dossier on bisphenol A (BPA) had been submitted by France on 17 January 2014. The conformity check process in RAC and SEAC was launched on 13 February and the Committees were expected to reach a conclusion on conformity by 14 March 2014 at the latest.

The representative of the dossier submitter provided an introductory presentation on the proposal to restrict BPA in thermal paper. BPA is used as a developer in the thermal reactive coating of the paper.

The RAC rapporteurs informed the Committee of the RAC outcome of the conformity check, where the Committee had concluded at RAC-28 that the dossier is not in conformity with Annex XV requirements (please see RAC minutes for more details).

The SEAC rapporteurs then presented to the Committee the SEAC outcome of the conformity check. In their view, the dossier meets the requirements of Annex XV of REACH and is therefore in conformity. They also presented to the Committee their recommendations to the dossier submitter, e.g. to clarify whether and why exposure estimates are suitable for expected disease burden calculations, to include evidence of production and respective use volumes of alternatives, to improve justification for entry into force (3 years), etc.

SEAC agreed that the dossier on BPA conforms to the requirements of Annex XV.

# 4) Ammonium salts - outcome of the conformity check

The Chair welcomed the dossier submitter representatives (France) and the RAC rapporteur. He informed the participants that the restriction dossier on inorganic ammonium salts had been submitted by France on 15 January 2014 within Article 129 of REACH (safeguard clause) and was the first dossier of that kind to be processed by RAC and SEAC. This dossier follows the national measure adopted in France in June 2013 to protect the public from exposure to ammonia released from ammonium salts used as additives in cellulose wadding based insulation materials in buildings. The Commission authorised the French provisional measure in October 2013 and based on Article 129(3), France had to prepare an Annex XV restriction dossier within three months of the date of the entry into force of the implementing Commission decision. The conformity check process in RAC and SEAC was launched on 13 February and the rapporteurs' final draft conformity check outcome was made available to the Committee on 6 March 2014.

The representatives of the dossier submitter provided an introductory presentation of the proposal. Substances in the scope of the submitted Annex XV proposal are inorganic ammonium salts that are used in cellulose wadding insulation for their flame retardant properties. These salts can lead to emissions of ammonia, which can act as an irritant gas for mucous membranes and respiratory tract. The proposal restricts the use of inorganic ammonium salts unless the emission of ammonia is below 0.3 ppm conditions of the restriction are the following: inorganic ammonium salts may be used only if emission of ammonia is below 0.3 ppm, a threshold based on the DNEL for the general population (long-term, inhalation route) and with respect to specific testing parameters.

The RAC rapporteur informed the Committee of the RAC outcome of the conformity check, where the Committee had concluded at RAC-28 that the dossier is not in conformity with Annex XV requirements (please see the RAC minutes for more details).

The SEAC rapporteurs then presented to the Committee the SEAC outcome of the conformity check and recommended that the dossier should be considered not in conformity. They explained that in their view, the proposal does not specify the scope of the restriction in sufficient detail. Furthermore, the Annex XV report does not appear to present sufficient information on the uses of the substances and resulting exposure and to provide evidence that implemented risk management measures are not sufficient. The report also does not appear to allow an evaluation of the assessment of the proposed restriction and other identified RMOs against their effectiveness, practicality and monitorability.

The representative of the Commission presented to the Committee a letter that they had written to ECHA and which had been distributed to RAC and SEAC prior to SEAC-22, providing the Commission interpretation of the REACH provisions applicable to the Annex XV dossier at stake. In the view of the Commission: i) the Annex XV requirement, that justification shall be provided that action is required on a Union-wide basis, shall be considered as fulfilled, and ii), unless the dossier is manifestly not in conformity with Annex XV, additional clarifications with regards to remaining questions should be sought during the opinion-making process.

Three SEAC members emphasised that in their view, SEAC should conclude that this dossier is conforming. One Member found that the scope is clearly defined as it is possible to judge whether an article is covered by the restriction or not. On the possibility to assess the resulting exposure he argued that SEAC could develop an opinion without the information suggested should be requested by the rapporteurs. Much of the rapporteur's justification for proposing non conformity was related to the exposure limit and the proposed test method. The member argued that if these elements were not sufficiently clarified, the proposal could be assessed by considering it as a ban on the use of ammonium salts in the covered isolation materials. He found that all justification presented in the draft CC belonged to the evaluation phase and that it could be included in the recommendations. Many other members, however, supported the rapporteurs.

SEAC agreed that the dossier on inorganic ammonium salts does not conform to the requirements of Annex XV.

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

The Secretariat presented the recommendation of the Chair for the pools of (co-) rapporteurs for the restriction dossiers **methanol** (to be submitted by Poland), and **N,N-dimethylformamide**; **dimethyl formamide** (to be submitted by Italy) as outlined in the meeting document SEAC/22/2014/04 RESTRICTED. SEAC took note on the pools for co-rapporteurs as proposed in the recommendation.

The Secretariat encouraged interested members to volunteer to be included in the pool of (co-)rapporteurs for these dossiers.

## 7. Authorisations

# 7.1 Authorisation applications

# a) Authorisation applications on phthalates – $\mathbf{1}^{\text{st}}$ outline/version of the draft opinion

# 1) Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a)

The Secretariat informed the Committee about the discussions at the RAC-28A plenary. RAC's preliminary conclusion is that the applicant demonstrated an adequate control of the risks to consumers and the general population. However, the Committee concluded that there is no adequate control for workers, based on the higher end occupational exposure data available to RAC.

The SEAC rapporteur informed that following the outcome of the trialogue meeting held for DEZA's uses of DEHP and DBP in ceramic sheets and printing pastes for production of

capacitors and lambda sensor elements (use 3), the use would not be discussed in this plenary meeting.

The SEAC rapporteur informed the Committee on some shortcomings in the Analysis of Alternatives (AoA) of the three applicants. Applicants adopted their point of view as a manufacturer of DEHP in assessing the suitability of alternatives. Alternative substances were considered not economically feasible based on plant conversion costs and issues related to the accessibility and price of feedstock. Taking this approach, alternative materials were not considered.

According to the SEAC rapporteur, alternative substances seem overall technically feasible for DUs in a wide range of applications. Moreover, the rapporteur stressed that several compounders had reported that they would shift some of their production to other materials in the non-use scenario. In addition, alternatives seem overall available for DUs. Regarding the economic feasibility for DUs, a higher price for alternatives and increased production costs were noted. The rapporteur however noted that these costs appear to be affordable for a majority of situations.

The Chair summarised and concluded that the rapporteur should challenge the manufacturer's point of view in the assessment of the suitability and availability of alternatives. Furthermore, considering the legal provisions, the assessment should focus on the function of DEHP that needs to be replaced, i.e. an alternative should be assessed at the level of the downstream user.

It was discussed whether the AoA demonstrated that no alternatives were suitable and whether SEAC would need to provide evidence to demonstrate that alternatives are suitable for all DUs in this broad application. On the latter (methodological) question, several members were of the view that the Committee does not need to have evidence for all DUs, however, were to draw the line remains to be clarified.

The rapporteur explained that the socio-economic impacts to the applicant were described in terms of closure of facilities as well as loss of production and raw materials. Impacts to DUs are essentially substitution costs. In the following discussion, the SEAC members questioned whether it is appropriate to attribute plant closure costs claimed by one of the applicants fully to the non-use scenario in the REACH authorisation process.

The rapporteur briefly presented the health impact assessment methodology. It was discussed if SEAC could use the hypothetical scenario described by the applicants. Several members considered that the assessment might be helpful and that SEAC should evaluate the assessment.

The Chair listed the actions to be taken following the SEAC-22 meeting discussions and in view of the next SEAC plenary as follows: the rapporteur will take into consideration the discussions and prepare accordingly the 1<sup>st</sup> version of the SEAC draft opinion. This version will be subsequently consulted with SEAC members via a written consultation. The rapporteur will then modify the draft if needed according to the possible comments made by members, in order to discuss the document at the forthcoming SEAC plenary in June.

# 2) Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b)

Due to the similarities of the dossiers, the uses 1 and 2 for this application were discussed together with the application from ARKEMA FRANCE (DEHP2a, see point 7.1a1 above).

# 3) Three uses of DEHP submitted by DEZA a.s. (DEHP 2c)

Due to the similarities of the dossiers, the uses 1 and 2 for this application were discussed together with the application from ARKEMA FRANCE (DEHP2a, see point 7.1a1 above). The discussion on the use 3 was postponed for the SEAC-23 plenary meeting.

# 4) Three uses of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3)

## Uses 1 (DEHP) and 2 (DBP)

The rapporteur informed about the outcome of the rapporteurs dialogue and the trialogue with the applicant, and presented the first preliminary conclusions for the application for authorisation for industrial use of DEHP and DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles. The rapporteur informed SEAC that RAC had adopted its opinions on these uses with the conclusion that the risk is adequately controlled without further recommendation for additional monitoring conditions neither recommendation for the review period.

Concerning the analysis of alternatives the rapporteur proposed the conclusion that the alternatives for the moment are not technically feasible due to the need to wait for the requalification programme. Therefore, there is no need to further investigate the economic feasibility in the light of the conclusion on technical feasibility. After a brief discussion the Chair summarised that there seems to be support for this preliminary conclusion.

The rapporteur then asked the Committee if a review period of 4 or 7 years should be recommended for these two opinions. The majority of members expressing a view proposed a normal 7 years review period. In addition, some members proposed to request a midterm report on the R&D progress but this proposal was not generally supported. The Chair concluded that there was support among the members for a normal review period, but scepticism with regard to any additional reporting requirements.

The rapporteur informed that in the next step of the procedure she will prepare the 1<sup>st</sup> version of the SEAC draft opinion which will reflect the discussion. The Secretariat will launch the SEAC consultation.

# Use 3 (DPB)

The Secretariat informed SEAC that RAC had not concluded on risk assessment and had decided to ask the applicant for clarifications as combined RCR for this use is 0,924.

The rapporteur informed about the outcome of the rapporteurs dialogue and the trialogue with the applicant and presented the first preliminary conclusions for the application for authorisation for industrial use of DBP within specialty paint in manufacture of motors for rockets and tactical missiles. The preliminary conclusion on the analysis of the alternatives is that for the moment alternatives are not technically and economically feasible due to the need to perform the remaining tests and requalification of the alternative.

The Chair summarised the discussion and informed the Committee about the further steps. The rapporteur will prepare the  $\mathbf{1}^{\text{st}}$  version of the SEAC draft opinion for this use reflecting the discussions and the Secretariat will launch the SEAC consultation.

# 5) The use of DBP submitted by Sasol-Huntsman GmbH & Co. KG (DBP 1)

The rapporteur presented briefly the application, informed about the outcome of the rapporteurs dialogue and the written consultations with the applicant, and presented the first version of the draft opinion for the application for authorisation for use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride (MA).

The rapporteur informed SEAC that RAC had adopted its opinion on this application. RAC agreed that adequate control had been demonstrated by the applicant. RAC did not assess the risks of alternatives and decided not to recommend specific conditions or monitoring arrangements over and above the RMMs and OCs that have already been included in the application. RAC saw no reason to make any recommendation for a shorter review period.

The rapporteur presented the analysis of alternatives with the special focus on two commercially proven technologies for the MA production: ALMA technology (DIBE) and Water-based technology. In both cases the rapporteur proposed to SEAC the conclusions that alternatives are technically feasible but not suitable on the basis of not meeting the economic feasibility criteria. The rapporteur also presented the efforts made by the applicant to identify possible alternatives, included alternative solvents to replace DBP in the applicants MA recovery technology. One SEAC member noted that in his opinion the costs for the transition to the ALMA technology are overestimated nevertheless, he agreed with the conclusion. The rapporteur confirmed that, also according to public sources, the ALMA technology is licensed by a competitor of the applicant. The Chair concluded that SEAC agreed with the proposed conclusions concerning both alternatives.

The rapporteur discussed her conclusions of the potential socio-economic impacts expected in the event of no authorisation. Due to adequate control and small population potentially exposed to DBP, the risks associated with the use are minimal. The socio-economic implications to the applicant and its immediate supply chain, as well as MA downstream users (due to anticipated price increase due to likely supply shortage) are expected to be considerably higher than the benefits in the events of no authorisation.

Concerning the review period the rapporteur considered the RAC decision on the adequate control, large socio-economic implications if no authorisation is granted, long investment cycle (more than 20 years) and time necessary to find another solvent (more than 12 years). Based on above considerations the rapporteur proposed a long review period of 12 years.

The SEAC members asked for clarification how information about previous plant expansions by the applicant was used by the rapporteur in the argumentation for a long review period. The rapporteur explained that since the start of operations in 1963, the applicant transitioned from the water recover technology in 1999 while other investments related to a change of feedstock (driven by market changes) and expansions of production lines. The rapporteur proposed that an argumentation for a long review period on the basis of a demonstrably long investment cycle is added to the draft opinion.

The Chair reminded the Committee that SEAC had previously discussed and agreed on criteria for setting the review period. Out of 5 criteria 3 are fulfilled in this case. After some other supporting comments of the SEAC members, the Chair concluded that there seemed to be agreement to recommend a review period of 12 years.

The rapporteur subsequently asked if the Committee sees a need for any additional conditions and monitoring arrangements or reporting on the R&D accomplishments. Some members proposed that due to the recommended long review period the applicant should provide midterm report on progress of the R&D program. Some other members questioned the legal status and usefulness of such report. The Secretariat reminded that according to the REACH legal text authorisations may be reviewed at any time if the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact or new information on possible substitutes becomes available. The Chair concluded that there does not seem to be support for SEAC to propose any additional conditions and monitoring arrangements or reporting on the R&D accomplishments.

SEAC agreed by consensus on the draft opinion with the addition of a short text on the applicant's long investment cycle. SEAC recommends the Commission to grant the authorisation for a period of 12 years. The Chair informed about further steps of the procedure and thanked the rapporteur and the AfA team for their work.

# 6) Three uses of DBP submitted by DEZA a.s. (DBP 2)

## <u>Use 1</u>

The rapporteur presented the application, informed about the outcome of the rapporteurs' dialogue and the written consultations with the applicant. She presented the first version of the draft opinion of the application for authorisation for use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride (MA). The rapporteur informed SEAC that RAC had adopted its opinion on this application. She informed also that after discussion with the Secretariat it was decided to assess the suitability of the alternatives also from the perspective of the DU.

The rapporteur informed SEAC that both applications by Sasol-Huntsman GmbH and by DEZA are very similar. DEZA as manufacturer added supplementary information from the manufacturer perspective to the assessment done by the DU. Information that Deza cannot manufacture the alternatives to DBP is taken into account in the socio-economic assessment.

The rapporteur argued that the cases presented by Sasol-Huntsman GmbH and DEZA are the same due to similarities in the information presented in the applications, the public consultation comments, and the approach to take the perspective of the DU in the assessment of the suitability of the potential alternatives. The rapporteur proposed the same opinion and the same conclusions with additions concerning the manufacturer perspective. She recommended the same review period of 12 years.

SEAC agreed on the draft opinion by consensus, recommending the Commission to grant the authorisation for a period of 12 years. The Chair informed that the same editorial changes will be made to this opinion as agreed for the Sasol-Huntsman opinion (inclusion of wording regarding a long investment cycle). The Chair communicated further steps of the procedure and thanked the rapporteur and the AfA team for their work.

# Use 2 and Use 3

The Chair invited the rapporteur to present current progress in the opinion development for the use 2 (Use in propellants) and use 3 (Industrial use of DBP in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements).

The rapporteur informed that for use 2 a new set of RAC questions will be sent to the applicant. For use 3 she informed SEAC that several problems were identified during the trialogue and RAC is waiting for further clarifications. The Chair informed that further discussion on these uses will be postponed until SEAC-23. The rapporteur will now prepare the 1<sup>st</sup> versions of the SEAC draft opinions and the Secretariat will launch the SEAC consultation.

# 7) Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl (DEHP 4)

The rapporteur presented his general views on the application for authorisation submitted by Vinyloop Ferrara S.p.A., Stena Recycling AB and Plastic Planet srl for the following uses: Use 1: Formulation of recycled soft PVC containing DEHP in compounds and dryblends; Use 2: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles. The rapporteur briefly introduced comments received during the public consultation on the application.

The rapporteur also informed the Committee that two SEAC members commented on the application during the SEAC consultation. One comment received was regarding RAC's determination that adequate control is demonstrated. Another comment was criticising that the scope and uses are unclear.

The rapporteur reported that during the trialogue the applicants answered all the rapporteur's questions.

The rapporteur informed the Committee about the content of DEHP in collected PVC by the applicants. Concentration of DEHP ranges from 1% up to 20% with typical concentration of DEHP below ten per cent. Currently operations could be considered EUwide. However, due to the fact that DEHP is apparently used in lower amounts than before and the use may further decrease in the future, it is anticipated that the content of the substance in the recyclate will decrease over time. Applicants also perform certain monitoring of the substance in the PVC waste. The rapporteur informed SEAC that according to first considerations after the RAC-28 meeting the claim of adequate control may be challenged. The rapporteur in his presentation touched upon the scope of the application regarding its borderline case with the Waste Framework Directive 2006/12/EC, but no discussion followed in the Committee. Representative of the European Commission stated that currently there are internal discussionsat the Commission on the matter between the relevant Commission services. The Commission's intention is to issue its position before ECHA provides the Committees' opinions. One SEAC member suggested exporting waste as an alternative. The rapporteur explained that the applicants' recycling scheme is developed to recycle copper wires by-waste, which is PVC wires shell. One member requested the rapporteur to provide non-use scenario figures from the application for authorisation. The rapporteur explained that in the case of non-use scenario there would be 150 to 200 job-losses, which would give some increase for waste collectors and incinerators. It would also give increase of market for virgin PVC products of around 210-275 million EUR in five years.

With regard to the <u>analysis of alternatives</u>, three alternatives were suggested during the public consultation: waste segregation, DEHP elimination, e.g. through extraction, and replacement of post-consumer PVC waste by post-industrial PVC waste. During the trialogue the applicants commented that waste segregation is technically unjustified and is not economically feasible; DEHP elimination is technically challenging and economically unrealistic; switching to the post-industrial PVC waste stream is treated by the applicants

as very unfavourable in terms of economics, and post-industrial PVC waste has poor availability.

Concerning the <u>review period</u> the rapporteur indicated that socio-economic analysis prepared by the applicant, remains brief on the subject, i.e. only mentioning average lifetimes of different PVC applications. When asked by the rapporteur about economic underpinning information, e.g. investment cycles data, the applicants delivered the confidential information on financial and technical lifetimes. All three applicants have quite long investment cycles; moreover all three applicants started their activities in the field in different years (2002, 2008, 2010). One member noted that the whole approach chosen by the applicants reminds the choice in favour of the self-eliminating problem, when concentration of DEHP in the post-consumer waste will decrease. Another member of SEAC noted that recycling should be encouraged and that long review period has to be granted.

The Chair summarised the discussion and informed the Committee about the further steps. SEAC agreed that the rapporteur will take the SEAC plenary discussion into account in the  $1^{\rm st}$  version of the SEAC draft opinion (by 24 March 2014). The Secretariat will open a written commenting round on this version.

# b) Authorisation applications – outcome of the conformity check

The rapporteurs briefly presented the following applications for authorisation received by ECHA:

- 1) Application for authorisation submitted by Boliden Kokkola Oy on the following use of diarsenic trioxide: Use of diarsenic trioxide in the purification of metal impurities from the leaching solution in the zinc electrowinning process.
- 2) Application for authorisation submitted by Nordenhamer Zinkhütte GmbH on the following use of diarsenic trioxide: Industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electrowinning process.
- 3) Application for authorisation submitted by Linxens France on the following uses of diarsenic trioxide: Use 1: Formulation of diarsenic trioxide into a mixture. Use 2: Industrial use of diarsenic trioxide as processing aid in gold electroplating.
- 4) Application for authorisation submitted by DCC Maastricht B.V. OR C.I. on the following uses of Pigment Yellow 34 and C.I. Pigment Red 104:

Use 1: Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use. Use 2: Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.). Use 3: Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc or as road marking. Use 4: Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use. Use 5: Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use. Use 6: Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking.

SEAC agreed with the rapporteurs that all above listed applications for authorisation are in conformity. The Secretariat will upload the conformity reports to the non-confidential part of CIRCABC and will send them to the applicants.

The teams of rapporteurs also reported on some issues which could be relevant to the evaluation of the applications. They will formulate their questions to the applicants for

further clarification. The Chair thanked the rapporteurs for their presentations and the Committee for their participation in the discussions.

# **8. AOB**

# a) Update on the workplan

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

# b) Report from the Working group on PBT evaluation

The representative of the SEAC working group on PBT evaluation presented the general outcome of the first meeting of this working group held on 11 February 2014 as well as the next steps. The objective of the working group is to develop a proposal for a framework with which SEAC can assess restriction reports and authorisation applications for PBT and vPvB substances. Intermediate report together with the initial proposal for a framework is expected in June 2014.

# c) Update on NeRSAP 2

SEAC was provided an update by the representative of the stakeholder observer regarding the NeRSAP activities.

# 9. Action points and main conclusions of SEAC-22

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

# II. Main conclusions and action points

# MAIN CONCLUSIONS & ACTION POINTS SEAC-22, 11-14 March 2014

(SEAC-22 meeting)

Agenda point		
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)	
2. Adoption of the agenda		
The agenda was adopted with minor modifications.	<b>SECR</b> to upload the adopted agenda to SEAC CIRCABC IG as part of the meeting minutes.	
3. Declarations of conflicts of interest to the	Agenda	
Conflicts of interest have been declared and will be taken to the minutes.		
4. Report from other ECHA bodies and activit	ies	
a) Report on SEAC-21 action points, written pro	cedures and other ECHA bodies	
SEAC was informed on the status of the action points of SEAC-21. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/22/2014/01), including the oral report from the Commission on SEAC related developments in the REACH Committee and in the CARACAL.		
SEAC took note of a presentation on the results of the Satisfaction Survey 2013.	<b>SECR</b> to analyse the results of the survey further and come up with possible follow-up actions, if necessary.	
5. Update of stakeholder participation in th	ne work of SEAC (closed session)	
SEAC agreed with the proposed amendments to the list of stakeholders as presented in the meeting document SEAC/22/2014/02 (restricted) with minor modifications.	<b>SECR</b> to update the list of SEAC stakeholders and publish on the ECHA website.	
6. Restrictions		
6.1 General restriction issues		
b) Revision of the restriction process		
SEAC agreed on the revised working procedure on developing opinions on Annex XV restriction dossiers (SEAC/22//2014/03_rev.1).	J	
SEAC took note of the report of the Restrictions Efficiency Task Force.		
6.2 Restriction Annex XV dossiers	1	
a) Opinion development		
1) Lead in consumer articles – final opinion		

Rapporteurs presented and SEAC discussed the 1<sup>st</sup> version of the SEAC final opinion.

SEAC adopted the final opinion on the restriction proposal on lead and its compounds by simple majority. The minority views will be reflected in the minutes.

**Rapporteurs** and **SECR** to make final editorial changes to the opinion and ensure that the BD is in line with the adopted SEAC opinion.

**SECR** to publish the final opinion of SEAC on the ECHA website and to forward the final opinions of SEAC and RAC and the BD to the Commission.

# 2) Nonylphenol – 2nd version of the draft opinion

Rapporteurs presented and SEAC discussed the 2<sup>nd</sup> version of the SEAC draft opinion.

**Rapporteurs** to take the SEAC discussion into account in the next version of the draft opinion (by 2 May).

**SEAC members** to provide comments on this version within the written commenting round prior to SEAC-23.

# 3) 1-Methyl-2-pyrrolidone (NMP) – 2nd version of the draft opinion

Rapporteurs presented and SEAC discussed the 2<sup>nd</sup> version of the SEAC draft opinion.

**Rapporteurs** to take the SEAC discussion into account in the next version of the draft opinion (by 2 May).

**SEAC members** to provide comments on this version within the written commenting round prior to SEAC-23.

# b) Conformity check

# 1) Cadmium and its compounds in artist paints - outcome of the conformity check

SEAC agreed that the dossier conforms to the Annex XV requirements.

SEAC took note of the recommendations to the dossier submitter.

**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC.

**SECR** to inform the dossier submitter on the outcome of the conformity check.

## 2) Chrysotile - outcome of the conformity check

SEAC agreed that the dossier conforms to the Annex XV requirements.

SEAC took note of the recommendations to the dossier submitter.

**Rapporteurs,** together with **SECR,** to finalise the recommendations to the dossier submitter.

**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC.

**SECR** to inform the dossier submitter on the outcome of the conformity check.

## 3) 4,4-Isopropylidenediphenol (bisphenol A) - outcome of the conformity check

SEAC agreed that the dossier conforms to the Annex XV requirements.

SEAC took note of the recommendations to the dossier submitter.

**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC.

**SECR** to inform the dossier submitter on the outcome of the conformity check.

# 4) Ammonium salts - outcome of the conformity check

SEAC agreed that the dossier does not conform to the Annex XV requirements.

SEAC took note of the recommendations to the dossier submitter.

**SECR** to compile the RAC and SEAC final outcomes of the conformity check and upload this to CIRCABC.

**SECR** to inform the dossier submitter on the outcome of the conformity check.

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

SEAC took note of the pool of (co-) rapporteurs for methanol, and dimethyl formamide (as presented in the restricted room document SEAC/22/2014/04).

**SEAC** members to send their expressions of interest for the (co-)rapporteurs for the upcoming dossiers.

## 7. Authorisations

- a) Authorisation applications on phthalates 1st outline/version of the draft opinion
- 1) Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a)

Rapporteur presented and SEAC discussed the  $\mathbf{1}^{\text{st}}$  outline of the SEAC draft opinion.

**Rapporteur** to take the SEAC plenary discussion into account in the 1<sup>st</sup> version of the SEAC draft opinion (by 24 March 2014).

**SECR** to open a written commenting round on this version.

2) Two uses of DEHP submitted by Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna (DEHP 2b)

Rapporteur presented and SEAC discussed the 1<sup>st</sup> outline of the SEAC draft opinion.

**Rapporteur** to take the SEAC plenary discussion into account in the  $1^{st}$  version of the SEAC draft opinion (by 24 March 2014).

**SECR** to open a written commenting round on this version.

3) Three uses of DEHP submitted by DEZA a.s. (DEHP 2c)

Rapporteur presented and SEAC discussed the 1<sup>st</sup> outline of the SEAC draft opinion.

**Rapporteur** to take the SEAC plenary discussion into account in the 1<sup>st</sup> version of the SEAC draft opinion (by 24 March 2014).

**SECR** to open a written commenting round on this version.

4) Three uses of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3)

Uses 1-2, 3:

Rapporteur presented and SEAC discussed the 1 <sup>st</sup> outline of the SEAC draft opinion.	Rapporteur to take the SEAC plenary discussion into account in the 1 <sup>st</sup> version of the SEAC draft opinion (by 1 April 2014).  SECR to open a written commenting round on this version.		
5) The use of DBP submitted by Sasol-Huntsman GmbH & Co. KG (DBP 1)			
Rapporteur presented and SEAC discussed the 1 <sup>st</sup> version of the SEAC draft opinion.  SEAC agreed on the draft opinion by consensus.	<b>SECR</b> to send to the applicant the draft opinion with a request to indicate his intention to submit comments on the draft opinion.		
6) Three uses of DBP submitted by DEZA a.s. (L	OBP 2)		
Use 1: Rapporteur presented and SEAC discussed the 1st version of the SEAC draft opinion.  SEAC agreed on the draft opinion by consensus.	<b>SECR</b> to send to the applicant the draft opinion with a request to indicate his intention to submit comments on the draft opinion (after draft opinions on other uses also concluded).		
Use 2:  Discussion on the use 2 has been postponed until SEAC-23.			
Use 3:  Discussion on the use 3 has been postponed until SEAC-23.			
7) Two uses of DEHP submitted by VINYLOOP I Planet srl (DEHP 4)	FERRARA S.p.A.; Stena Recycling AB and Plastic		
Uses 1 and 2:  Rapporteur presented and SEAC discussed the rapporteur's general views on the application.	Rapporteur to take the SEAC plenary discussion into account in the 1 <sup>st</sup> version of the SEAC draft opinion (by 24 March 2014).  SECR to open a written commenting round on this version.		
b) Authorisation applications – outcome of the conformity check 1) Diarsenic trioxide 1 submitted by Boliden Kokkola Oy			
SEAC agreed on the conformity of the application for authorisation.	SECR to upload the final outcome of the conformity check to CIRCABC.		
	<b>SECR</b> to inform the applicant on the outcome of the conformity check.		
2) Diarsenic trioxide 2 submitted by Nordenham	er Zinkhütte GmbH		
SEAC agreed on the conformity of the application for authorisation.	<b>SECR</b> to upload the final outcome of the conformity check to CIRCABC.		
	SECR to inform the applicant on the outcome		

of the conformity check.		
nnce		
<b>SECR</b> to upload the final outcome of the conformity check to CIRCABC.		
<b>SECR</b> to inform the applicant on the outcome of the conformity check.		
104 submitted by DCC Maastricht B. V. OR		
SECR to upload the final outcome of the conformity check to CIRCABC.  SECR to inform the applicant on the outcome of the conformity check.		
SEAC members to volunteer to the pool of (co-)rapporteurs for applications for authorisation.  SECR to upload the updated document to confidential folder on CIRCABC.		
9. Action points and main conclusion of SEAC-22		
<b>SECR</b> to upload the action points and main conclusions to CIRCABC IG.		

#### **III. List of Attendees**

#### SEAC-22

SEAC members
ALEXANDRE João
BENDL Jiri
BOUSTRAS Georgios
BRIGNON Jean-Marc
COGEN Simon
CSERGŐ Robert
D'AMICO Flaviano
DANTINNE Catheline
FANKHAUSER Simone
FIORE-TARDIEU Karine
FOCK Lars
FURLAN Janez
GEORGIOU Stavros
GRANDI Silvia
KIISKI Johanna
KNOFLACH Georg
KRAJNC Karmen
LADOPOULOU Angela
LUTTIKHUIZEN Cees
PALOTAI Zoltán
RODRIGUEZ DE SANCHO Maria Jesus
SCHUCHTAR Endre
SIMON Franz-Georg
SLETTEN Thea Marcelia
SLEZAK Zbigniew Tomasz
SMILGIUS Tomas
THIELE Karen
THORS Åsa

# Advisors, invited experts, dossier submitters (DS) & observers

ALEXANDROPOLOU Ionna, invited expert (GR)
BEEKMAN Martijn and VERHOEVEN Julia (NMP DS representatives, via WEBEX)

BERNHEIM Teresa (advisor to K. Thiele)

BIRKELI Kenneth (advisor to Thea M. Sletten)

CARLSSON Mattias, CEDERBERG Inger, IVARSSON Jenny, PARKMAN Helena, VIRDARSON Jenny and WARHOLM Margareta (Cadmium in artist paints DS representatives via WEBEX)

CASTELLI Stefano (advisor to Flaviano D'Amico)

CAVALIERI Luisa (advisor to Karine Fiore-T., and Ammonium salts DS representative)

FAYAERTS Jean-Pierre (advisor to Simon Cogen via WEBEX)

IVARSSON Jenny (NP DS representative via WEBEX)

JOENGEEL Rob and LUIT Richard (advisors to Cees Luttikhuizen)

LE COQ Pierre (Ammonium salts DS representative)

LESTANDER Dag (advisor to A. Thors and NP DS representative via WEBEX)

NIEMELÄ Helena (advisor to Johanna Kiiski)

TER BURG Wouter (advisor to Cees Luttikhuizen via WEBEX)

VASS Anne-Marie (advisor to Åsa Thors, and Lead and lead compounds DS representative)

# Stakeholder observers

ANNYS Erwin (CEFIC)

BUONSANTE Vito (EEB/Client Earth)

BINKS Steve (ILZRO, expert accompanying the EUROMETAUX observer - Lead and lead compounds)

EICHLER Jean-Olaf (BASF, the Chemical Company accompanying the CEFIC observer – NMP)

HOLLAND Mike (EAERE)

MOUCHEBOEUF Jean (UEAPME)

MUSU Tony (ETUC)

SANTOS OTERO Tatiana (EEB – Authorisation applications)

WATERSCHOOT Hugo (EUROMETAUX)

# RAC (co-)rapporteurs DUNAUSKIENE Lina DUNGEY Steve (via WEBEX) JENSEN Frank (via WEBEX) KADIĶIS Normunds

Representative of the European Commission			
BENGYUZOV Manol (DG ENTR)			
BERTATO Valentina (DG ENTR, via			
BORRAS-HERRERO Anna (DG ENTR, via WEBEX)			
FERNANDES DE BARROS Mariana (DO ENTR, via WEBEX)			
GALLEGO Mateo (DG ENV)			
GARCIA-JOHN Enrique (DG ENTR, via WEBEX)			
LUVARA` Giuseppina (DG ENTR, via WEBEX)			
ROZWADOWSKI Jacek (DG ENTR, via WEBEX)			
STRECK Georg (DG ENTR, via WEBEX)			

SCHLÜTER Urs (via WEBEX)
SCHULTE Agnes
STOLZENBERG Hans-Christian
SØRENSEN Peter Hammer
VAN DER HAGEN Marianne

ECHA staff
BERGES Markus
BLAINEY Mark
GIORDANO Serena
HENNIG Philipp
JACQUEMIN Katline
KIOKIAS Sotirios
KOSK-BIENKO Joanna
KIVELA Kalle
LIOPA Elina
LOGTEMEIJER Christiaan
LUDBORZS Arnis
MARQUEZ-CAMACHO Mercedes
MAZZOLINI Anna
MOTTET Denis
NICOT Thierry
ORISPÄÄ Katja
ÖBERG Tomas
RODRIGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
PELTOLA Jukka
SADAM Diana
SHUQOM Natasha
SOSNOWSKI Piotr
STOYANOVA Evgenia
THUVANDER Ann
VAINIO Matti
VAN HAELST Anniek
ZBIHLEJ Tomáš

# **IV. List of Annexes**

ANNEX I. List of documents submitted to the members of the Committee for Socio-economic Analysis

ANNEX II. Declared conflicts of interest

ANNEX III. Final Agenda

ANNEX IV. Outcome of written procedures and other consultations

# **ANNEX I**

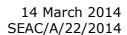
# Documents submitted to the members of the Committee for Socio-economic Analysis

Final Draft Agenda	SEAC/A/22/2014		
Report on SEAC-21 action points, written	SEAC/22/2014/01		
procedures and other ECHA bodies (AP 4.a)			
Update of stakeholder participation in the work of	SEAC/22/2014/02		
SEAC (AP 05)			
Revision of the restriction process (AP 6.1a)	SEAC/22/2014/03		
Appointment of (co-)rapporteurs for restriction	SEAC/22/2014/04		
dossiers (AP 6.3)	RESTRICTED		
Appointment of (co-)rapporteurs for authorisation	SEAC/22/2014/05		
applications (AP 7.2)	RESTRICTED		

# DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS

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

Name of participant	Agenda item	Interest declared
BRIGNON Jean-Marc	6.2b-3 Bisphenol A	Working for the MS submitting the restriction dossier
	6.2b-4 Ammonium salts	Working for the MSCA submitting the restriction dossier
CAVALIERI Luisa	6.2b-3 Bisphenol A 6.2b-4 Ammonium salts	Working for the MSCA submitting the restriction dossier
FIORE Karine	6.2b-3 Bisphenol A 6.2b-4 Ammonium salts	Working for the MSCA submitting the restriction dossier
LESTANDER Dag	6.2a-1 Lead and lead compounds 6.2a-2 Nonylphenol 6.2b-1 Cadmium in artists' paints	Working for the MSCA submitting the restriction dossier
JONGENEEL Rob	6.2a-3 Methylpyrrolidin- 2-one (NMP)	Working for the organisation preparing the restriction dossier
LUIT Richard	6.2a-3 Methylpyrrolidin- 2-one (NMP)	Working for the organisation preparing the restriction dossier
LUTTIKHUIZEN Cees	6.2a-3 Methylpyrrolidin- 2-one (NMP)	Working for the MSCA submitting the restriction dossier
NIEMELÄ Helena	7.1b Applications for Authorisation on Diarsenic trioxide	Previous involvement
SLEZAK Zbigniew	Applications for Authorisation on DEHP	Previous involvement
THORS Åsa	6.2a-1 Lead and lead compounds 6.2a-2 Nonylphenol 6.2b-1 Cadmium in artists' paints	Working for the MSCA submitting the restriction dossier
VASS Anne-Marie	6.2a-1 Lead and lead compounds 6.2a-2 Nonylphenol 6.2b-1 Cadmium in artists' paints	Working for the MSCA submitting the restriction dossier





# Final Agenda

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

# 11-14 March 2014 ECHA Conference Centre (Annankatu 18, Helsinki) 11 March: starts at 10:00

14 March: ends at 13:00

Item 1 - Welcome and Apologies

Item 2 - Adoption of the Agenda

SEAC/A/22/2014 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-21 action points, written procedures and other ECHA bodies SEAC/22/2014/01

For information

Item 5 – Update of stakeholder participation in the work of SEAC (closed session)

SEAC/22/2014/02 (restricted) For information and agreement

# **Item 6 - Restrictions**

#### 6.1 General restriction issues

a) Update on intended restriction dossiers

For information

### 6.2 Restriction Annex XV dossiers

- a) Opinion development
  - 1) Lead and its compounds intended for consumer use final opinion

For discussion/adoption

2) Nonylphenol – 2<sup>nd</sup> version of the draft opinion

For discussion

3) 1-Methyl-2-pyrrolidone (NMP) – 2<sup>nd</sup> version of the draft opinion

For discussion

- b) Conformity check
  - 1) Cadmium and its compounds in artist paints outcome of the conformity check

For agreement

2) Chrysotile - outcome of the conformity check

For agreement

3) 4,4-Isopropylidenediphenol (bisphenol A) - outcome of the conformity check

For agreement

4) Ammonium salts - outcome of the conformity check

For agreement

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

SEAC/22/2014/04

(restricted room document)

For information

## Item 7 - Authorisations

# 7.1 Authorisation applications

- a) Authorisation applications on phthalates 1<sup>st</sup> outline/version of the draft opinion
  - 1) Two uses of DEHP submitted by ARKEMA FRANCE (DEHP 2a):

<u>Use 1</u>: Formulation of DEHP in compounds, dry-blends and Plastisol formulations

<u>Use 2</u>: Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

For discussion

2) Two uses of DEHP submitted by *Grupa Azoty Zakłady Azotowe Kędzierzyn Spółka Akcyjna* (DEHP 2b):

<u>Use 1</u>: Formulation of DEHP in compounds, dry-blends and Plastisol formulations

<u>Use 2</u>: Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

For discussion

3) Three uses of DEHP submitted by DEZA a.s. (DEHP 2c):

<u>Use 1</u>: Formulation of DEHP in compounds, dry-blends and Plastisol formulations

<u>Use 2</u>: Industrial use in polymer processing by calendering, spread coating, extrusion, injection moulding to produce PVC articles

<u>Use 3</u>: Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

For discussion

4) Three uses of DBP and DEHP submitted by Roxel (UK Rocket Motors) Ltd (DEHP 3):

<u>Use 1</u>: Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles

 $\underline{\sf Use~2}$ : Industrial use of DEHP in manufacture of solid propellants and motor charges for rockets and tactical missiles

<u>Use 3</u>: Industrial use of DBP within a specialty paint in manufacture of motors for rockets and tactical missiles

## For discussion/agreement

5) The use of DBP submitted by Sasol-Huntsman GmbH & Co. KG (DBP 1):

<u>Use 1</u>: Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride

### For discussion/agreement

6) Three uses of DBP submitted by DEZA a.s. (DBP 2):

<u>Use 1</u>: Use as an absorption solvent in a closed system in the manufacture of Maleic Anhydride

Use 2: Use in propellants

<u>Use 3</u>: Use in ceramic sheets and printing pastes for production of capacitors and lambda sensor elements

## For discussion/agreement

7) Two uses of DEHP submitted by VINYLOOP FERRARA S.p.A., Stena Recycling AB and Plastic Planet srl (DEHP 4):

<u>Use1</u>: Formulation of recycled soft PVC containing DEHP in compounds and dryblends

<u>Use 2</u>: Industrial use of recycled soft PVC containing DEHP in polymer processing by calendering, extrusion, compression and injection moulding to produce PVC articles

For discussion

- **b)** Authorisation applications outcome of the conformity check
  - 1) Diarsenic trioxide 1 submitted by Boliden Kokkola Oy
  - 2) Diarsenic trioxide 2 submitted by Nordenhamer Zinkhütte GmbH
  - 3) Diarsenic trioxide 3 submitted by Linxens France
  - 4) C.I. Pigment Yellow 34 and C.I Pigment Red 104 submitted by *DCC Maastricht B. V. OR*

For agreement

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

SEAC/22/2014/05 (restricted room document) For agreement

# Item 8 - AOB

- a) Update of the work plan
- b) Report from the Working group on PBT evaluation
- c) Update on NeRSAP 2

For information

## Item 9 - Action points and main conclusions of SEAC-22

Table with Conclusions and Action points from SEAC-22

For adoption

# **ANNEX IV**

# Outcome of written procedures and other consultations

Subject		Timeline	Outcome
Adoption of SEAC-	Procedure launched:	14 February 2014	SEAC-21 minutes were adopted by consensus
21 final minutes	Response deadline:	24 February 2014	