

17 February 2016 SEAC/M/29/2015 Final

# <u>Final</u>

Minutes of the 29<sup>th</sup> meeting of the Committee for Socio-economic Analysis

1-4 December 2015

### 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 twenty ninth meeting of SEAC.

The Chairman briefly introduced the three newly appointed co-opted members. He then informed the Committee that apologies had been received from five members. Five advisors to the members, three invited experts, two representatives of the European Commission, observers of seven regular stakeholder organisations, three accompanying experts and one expert nominated by an occasional stakeholder organisation present at the meeting were introduced. The Chairman informed the participants that two members, two members' advisors and representatives of the European Commission were to follow the relevant parts of the meeting via WebEx, and that the RAC rapporteurs, the dossier submitter representatives and the experts following specific agenda items would be presented at the beginning of the relevant discussions.

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

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

### 2) Adoption of the Agenda

The Chairman introduced the final draft agenda of SEAC-29. The agenda was adopted with minor modifications (under Agenda Item 9, AOB). The final agenda is attached to these minutes as Annex III. The list of all meeting documents is attached to these minutes as Annex I.

#### 3) Declarations of conflicts of interest to the Agenda

The Chairman requested members and their advisors participating in the meeting to declare any conflicts of interest to any of the specific agenda items. Seven members and three advisors declared potential conflicts of interest to the substance-related discussions under the Agenda Items 5.2 and 6.2. These members did not participate in voting under the respective Agenda Items, as stated in Article 9(2) of the SEAC Rules of Procedure.

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-28 action points, written procedures and other ECHA bodies

The Chairman informed the participants that all action points of SEAC-28 had been completed or would be followed up during the on-going SEAC-29 meeting. The

Chairman also informed the Committee that the final minutes of SEAC-28 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-28 minutes. The Chairman explained that a report covering the developments in the ECHA MB, RAC, MSC, the Forum and BPC had been compiled and distributed to SEAC as a meeting document (SEAC/29/2015/01).

The representative of the Commission was then invited to update the Committee on SEAC related developments in the REACH Committee, in the CARACAL and in the European Parliament (i.e. in relation to an application for authorisation). The representative of the Commission also provided a general feedback on the work of Committee. The members shared their initial reactions on the resolution by the European Parliament, some agreeing there might be a need to reflect on the issue of proportionality and how it is communicated in the opinions, while others were asking questions about the background to the statement by the Parliament. The Chairman concluded that SEAC would have to return to and discuss this issue more in detail in the near future, and also consider if the wording of the opinions should be changed.

In addition, the Chairman reported from tele-interviews conducted with SEAC members in the second half of 2015.

### b) General SEAC procedures

The Chair of the Conflict of Interest Advisory Committee (COIAC), established by the Management Board in 2011, presented the role of the COIAC and the recommendations and clarifications provided on request to the Management Board and the Executive Director related to potential Conflict of Interest. The external expert member of the COIAC gave a presentation on ethics and conflict of interest for holders of public office.

# 5) Restrictions

#### 5.1) General restriction issues

#### a) Revision of the restriction process

The Secretariat presented to SEAC the revised draft working procedures for conformity check and opinion development on Annex XV restriction dossiers (meeting documents SEAC/29/2015/02 and SEAC/29/2015/03). The Secretariat explained to the Committee that this revision is based on the recommendations made by the Restrictions Efficiency Task Force (RETF) and the experience gained from processing various restriction dossiers and is in line with the Framework for RAC and SEAC in checking conformity and developing opinions on restriction proposals, which was agreed by the Committee in September 2015.

One member questioned whether the rapporteurs are supposed to update the draft opinion after the written commenting round and before the plenary discussion. The Secretariat responded that if the comments are substantial, there might be a need for an updated version, especially before the last plenary discussion and agreement on the SEAC draft opinion. Another member emphasised the importance of the dossier submitter's introductory presentation before the conformity check discussion and recommended that even if the decision on conformity is taken by written procedure, the dossier submitter would be offered a possibility to provide this presentation. One SEAC member pointed out that when the Secretariat publishes the final opinion on the ECHA website and sends the opinion package to the Commission, the rapporteurs and the dossier submitter would be informed about that – he suggested and the Committee agreed to make this addition in the last step of the working procedure on opinion development. The Committee agreed the two working procedures with editorial modifications introduced at SEAC-29.

The Secretariat then presented to SEAC the new opinion template for restriction dossiers (meeting document SEAC/29/2015/04), which had been revised based on the recommendations by the RETF as well as the experience gained from past restriction dossiers and linked to the new Annex XV reporting template. The new template had been provided to SEAC, RAC and to the Commission for written commenting prior to SEAC-29 and the updated version takes into account the comments received from these parties. Several SEAC members welcomed the proposed template and made further comments and suggestions on the template that the Secretariat took note of. The Chairman reminded the Committee that the template is considered as a living document and will be continuously updated.

# 5.2) Restriction Annex XV dossiers

### a) Opinion development

# 1) 4,4-Isopropylidenediphenol (bisphenol A) – draft final opinion

The Chairman welcomed the dossier submitter representative (France) and the RAC rapporteurs and then introduced the state of play regarding the restriction dossier on the placing on the market of thermal paper containing BPA. The Chairman explained that the public consultation on the SEAC draft opinion ended on 16 September with 8 comments received. The draft final opinion, taking into account the comments of the public consultation, was made available to SEAC on 24 November.

The (co-)rapporteurs presented the results of the public consultation and explained the revisions made in the draft final opinion. The main assessment had been updated with a more accurate assessment that was previously annexed. Moreover, the comments from public consultation had led to further clarifications to the methodology and to other improvements such as an adjustment to the valuation factor for immunotoxicity. A Commission observer asked why the valuation factors for disease appeared to be rather low. The rapporteurs explained that the valuation factors presented (in  $\in$  per case of disease) were already discounted values, i.e., they accounted for the time between exposure and the onset of disease. The rapporteurs also clarified that the revisions made by SEAC resulted in higher valuation factors (i.e. higher benefits of a restriction) compared to the ones provided by the Dossier Submitter.

A SEAC member referred to publications by Trasande et al. (2015) and Legler et al. (2015) and was of the view that the disease burden approach in these studies should be considered as a relevant alternative assessment of the benefits of a restriction on BPA in thermal paper. The SEAC (co-)rapporteurs replied that RAC is of the view that the available data on these effects does not allow a quantification of the dose-response relationships. Therefore, the disease burden approach in these publications appears not consistent with the view of RAC and thus seemed not to be appropriate to be used in the justification to SEAC's opinion.

SEAC agreed with the rapporteur's proposal that comparing the socio-economic benefits to the socio-economic costs, the proposed restriction is considered unlikely to be proportionate. Furthermore, SEAC confirmed its view that other elements to proportionality of the restriction are important and that there may be favourable distributional and affordability considerations.

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

### 2) Perfluorooctanoic acid (PFOA) – draft final opinion

The Chairman welcomed the dossier submitters' representatives (Germany and Norway), the RAC (co-)rapporteurs and an industry expert accompanying a stakeholder observer. The Chairman reminded the Committee that this dossier had been submitted by Germany and Norway in October 2014. The dossier submitters propose a restriction on the manufacture, marketing and use of PFOA, its salts and PFOA-related substances, as well as of articles and mixtures containing these substances. The public consultation on the SEAC draft opinion agreed at SEAC-28 was launched on 16 September and finished on 16 November 2015 with more than 60 comments received. The (co-)rapporteurs updated the SEAC opinion based on the public consultation comments and the draft of the SEAC final opinion was made available to SEAC on 24 November.

In presenting the draft of the SEAC final opinion to SEAC, the (co-)rapporteurs proposed that the Committee should focus its discussion on proportionality (whether members agree with the rapporteurs' conclusion on proportionality) and on derogations (should the derogation for spare parts be limited to sectors that requested derogations or cover all spare parts; is the derogation for placing on the market of semiconductor manufacturing equipment for 5 years justified and would additional derogation for nano-coatings for 6 years be justified).

One member explained that he could potentially agree with the rapporteurs' conclusions on proportionality, but there are in his view some weaknesses in the proportionality arguments, partly because of the nature of this restriction proposal (very wide scope that was not supported by a comprehensive assessment). One member was interested to hear from industry how they have estimated their transition costs. An industry expert clarified that the costs related to switching to alternatives have mostly already incurred, as industry has made a lot of investments within the last years to develop alternatives. Several members were concerned that as the scope of the restriction is so wide, there might be some information gaps in the SEAC assessment. The rapporteurs agreed, but highlighted that they have assessed the data submitted and SEAC needs to base its opinion on the data that is available.

A Commission observer requested more robust argumentation on the proposed derogations in particular for the recycling and the firefighting foam. He questioned why a 20 years transitional period has been given for new firefighting foams, while it seems from the opinion that suitable alternative is actually available and wondered why it was not possible to narrow the scope of this derogation as the opinion indicates that fluorine-free foam cannot be used in all situations. For the

derogation on recycling, the Commission observer indicated that as the main reason provided in the SEAC opinion for this derogation is related to difficulties for enforcements, risk management option (e.g., labelling of textiles) to overcome the implementation problem should be discussed by SEAC. The rapporteurs responded that just recently PFOS foams have been replaced with PFOA foams and the actors in the field have therefore requested longer transitional period, so that they would not need to destroy this recently acquired material. In addition, it is not clear if alternatives are suitable in all circumstances. With regard to the derogation on recycling, the rapporteurs and the Secretariat clarified that as this derogation was included in the original proposal and no information on this was received in the public consultation, there was not enough evidence to exclude this derogation. Several members and another Commission observer were questioning why the derogation for spare parts covers only certain sectors. The rapporteurs explained to SEAC that the list includes those sectors that had provided information in the public consultation, but they agreed that the derogation could also be justified for other sectors. The rapporteurs proposed and the Committee agreed to cover all spare parts with this derogation. One SEAC member expressed concerns regarding very long list of derogations in the restriction proposed by SEAC, which in his view is confusing and will also create difficulties for enforcement.

SEAC adopted its final opinion on the dossier on PFOA, its salts and PFOA-related substances by consensus (with modifications introduced at the meeting). The rapporteurs were asked, together with the Secretariat, to do the final editing of the SEAC opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC opinion. The Secretariat will forward the adopted opinion and its annexes to the Commission and publish it on the ECHA website. The Chairman thanked the (co-)rapporteurs for their work on this dossier.

#### 3) Methanol – revised draft opinion

The Chairman welcomed the dossier submitter from Poland, who followed the meeting remotely via WebEx, the RAC rapporteurs and an industry expert accompanying a stakeholder observer. The restriction proposal is aimed to prevent misuse of some mixtures containing high concentrations of methanol. The scope of the restriction proposal is targeted at windshield washing fluids and denaturated alcohol supplied to the general public. The Committee was informed that the public consultation ended on 18 September with 10 comments received. The revised draft opinion was made available on 6 November and the SEAC commenting round finished on 20 November, with comments received from four SEAC members. Based on the comments received and based on the conclusions in RAC-35, the rapporteurs updated the revised draft opinion, which was made available to the Committee on 3 December.

The RAC (co-)rapporteurs updated SEAC on the discussions on the dossier held within RAC-35, where RAC adopted its opinion on this restriction proposal by consensus. In presenting their revised draft opinion to SEAC, the (co-)rapporteurs focussed on the cost-benefit analysis and the proportionality assessment.

The SEAC (co-)rapporteurs clarified that the new concentration limit of 0.6% by weight in windshield washing fluid products and denaturated alcohol to be protective against methanol-induced blindness and death, as agreed in RAC-35, has no expected impact on the socio-economic analysis.

Several members recommended to calculate the monetary impact of the

substitution cost based on the assumption, that methanol would be replaced by the cheapest available alternative, ethanol. It is acknowledged, that some actors may also move to use of isopropanol. In addition, several members proposed to use the VSL estimates to monetise the benefits as a principle.

Members recommended a transitional period of 12 months to allow time for the supply chain to adapt to new operational conditions. Additional information whether this transition period would be enough for the producers/importers/suppliers to adapt to the proposed restriction would be gathered via the public consultation on the SEAC draft opinion.

The Committee agreed on the SEAC draft opinion by simple majority (with modifications introduced at the meeting) noting that the estimated benefits cover the costs and that, based on the described analysis, the proposed restriction is proportional. Six members expressed concern on whether the proposed restriction is the most appropriate measure available. The (co-)rapporteurs were tasked, together with the Secretariat, to make the final editorial changes to the agreed SEAC draft opinion and to ensure that the supporting documentation (BD and responses to comments from the public consultation) is in line with the SEAC draft opinion. The Secretariat will launch a public consultation on the SEAC draft opinion on this dossier at SEAC-30 in March 2016.

### 4) D4/D5 – second draft opinion

The Chairman welcomed the dossier submitter representatives from UK, the RAC (co-) rapporteurs, an industry expert accompanying a regular stakeholder observer and an occasional stakeholder observer. He reminded the participants that the restriction dossier on D4/D5 had been submitted by UK in April 2015. The dossier proposes that D4 and D5 shall not be placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products that are washed off in normal use conditions. MSC has recently provided an opinion that both substances are vPvB and the restriction proposal is aimed specifically at reducing emissions to the aquatic environment and is targeted at uses that lead to the greatest waste water emissions according to the registration CSRs. The Chairman informed the Committee that the (co-)rapporteurs had developed the second draft opinion on this dossier, which was made available to SEAC on 4 November 2015 and comments were received from five SEAC members in the following written commenting round.

The RAC (co-)rapporteurs were invited to briefly update SEAC on the discussions on the dossier held within RAC-35. The (co-)rapporteurs then presented to the Committee their second draft opinion. With regard to benefits of the proposal, they were interested whether other members have reservations regarding the willingness-to-pay (WTP) study used to estimate the benefits of the restriction and could agree with their proposal to use the results of the study as supporting qualitative data, rather than as definitive quantitative estimates of benefits. They also asked members if they agreed with the proposed conclusion that the restriction is proportionate and, if so, what compliance period the Committee would prefer based on the current information.

Several members agreed with the rapporteurs on their views regarding benefits and proportionality. In relation to the WTP study, and the concerns raised in terms of the methodology, they agreed with the proposal to use the results of the study in a qualitative way. In terms of the compliance period, several members recommended having a shorter compliance period, as industry is already aware that this restriction proposal was being developed by the UK and should be able to transfer to alternatives in 2 years. Other members considered that the compliance period should be assessed based on the socio-economic information to hand and not influenced by industry's awareness of the restriction proposal. The rapporteurs responded that they would like to see all public consultation comments before firming up their view on the length of the compliance period. A representative of the occasional stakeholder observer informed the participants that they have submitted a lot of information in the public consultation. They emphasised that the substitution process in this case is not easy and requires a fundamental change of architecture of the formulation – this is the reason why they have asked for 5 years transitional period.

The Chairman concluded that the Committee supports the (co-)rapporteurs' views on benefits and proportionality. It was agreed to decide on the length of the compliance period at the next SEAC plenary meeting, when all public consultation comments are available. The Chairman informed SEAC that the public consultation on this proposal finishes on 18 December 2015. The (co-)rapporteurs were asked to take the SEAC discussion and the public consultation comments into account in the third draft opinion.

# b) Conformity check (and key issues presentation)

# 1) TDFAs

The Chairman welcomed the RAC rapporteurs and the dossier submitter representatives from Denmark. He informed the participants that the restriction dossier on TDFAs had been submitted by Denmark on 2 October 2015. The conformity check process was launched on 5 November and the SEAC commenting round finished on 16 November (there were no comments received from SEAC members).

The dossier submitter's representative provided a brief introductory presentation on the dossier. The restriction proposal proposes a restriction on the use of (3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silanetriol and any of its mono-, di- or tri-O-(alkyl) derivatives in mixtures containing organic solvents placed on the market or used in spray products for consumers (aerosol dispensers, hand pump and trigger sprays and mixtures marketed for spray application). The restriction is targeted at mixtures with organic solvents in spray products for supply to the general public. TDFAs have been shown to cause serious acute lung injury in mice exposed to aerosolised mixtures containing TDFAs and organic solvent at certain concentration levels.

The RAC rapporteurs gave a short update from RAC-35 discussions, where RAC had concluded that the dossier is not in conformity due to certain gaps in both hazard and exposure assessment. The SEAC rapporteurs presented the outcome of the conformity check and the recommendations to the dossier submitter and proposed to the Committee that the dossier cannot be considered in conformity from the SEAC point of view due to the shortcomings in costs (e.g. lack of any estimates in substitution costs) and benefits estimates as well as due tos a scope

that hasn't been specified in sufficient detail in relation to the risk assessment that has been carried out. After the short discussion, the Committee agreed that the dossier does not conform to the Annex XV requirements. In addition, the rapporteurs presented their recommendations to the dossier submitter and these were supported by SEAC members. As the dossier has been considered not to be in conformity by both Committees, the Secretariat will inform the dossier submitter about the reasons of non-conformity.

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

The Secretariat informed the Committee that the meeting document on the pool of SEAC (co-)rapporteurships for the restriction proposal on BPA in tap water pipes (SEAC/2015/29/05.rev1) was withdrawn from the agenda due to notification from Sweden it will not submit a dossier. The Registry of Intentions will be updated shortly.

# 5) Authorisations

# 6.1) General authorisation issues

# a) Continuing review of RAC and SEAC recommendations (opinion trees)

The Secretariat presented to the Committee the new version of the opinion trees and the related guidance paper which had been updated taking into account the discussion at the previous RAC and SEAC plenaries. Several members and observers found the updated decision tree more transparent and clearer.

The issue of the decision on the non-conformity was raised. Some of the comments pointed that AoA should be reflected in the opinion tree e.g. by indicating that cases where suitable alternatives are available should lead to the recommendation not grant an authorisation. SEAC members made additional proposals on how to clarify the criteria for setting the review period as well as several editorial comments. The representative of the Commission noted the guiding nature of the document that need to be applied with the proper attention and made suggestions for improving the document.

SEAC agreed in principle on the document but recognised the need for further edits as suggested by many members. It was agreed that the Secretariat would revise the document in accordance with the plenary discussion and would launch a short written consultation on the final draft of the document.

#### b) Update on incoming/future applications for authorisation and on the Workshop on streamlining applications for authorisation

The Secretariat informed SEAC members on the main issues discussed at the Workshop on streamlining applications for authorisation held in Brussels in November 2015. The Secretariat also updated SEAC members on the forthcoming applications for authorisation. In the November 2015 submission window ECHA received 26 AfAs containing 38 uses. In February 2016 submission window ECHA expects around 30 further AfAs and another 3 in the May submission window. As foreseen before, this will result in a peak of the workload of the Committee in 2016. The Secretariat will contact members concerning the allocation of rapporteurships as soon as possible.

#### 6.2) Authorisation applications

# a) Outcome of the conformity check and presentation of key issues

1. One use of chromium trioxide submitted by *Kromatek Oy* on behalf of a group of companies (**Chromium trioxide - Kromatek**):

Use 1: Use of chromium trioxide in Cr(VI) based functional plating

The SEAC (co-)rapporteurs provided brief information on the application for authorisation and presented the draft outcome of the conformity check. The (co-) rapporteurs also presented their first impression of the application, highlighting some key issues for the attention of the Committee some of which would require further clarification by the applicant.

SEAC agreed that the application is in conformity and on the (co-)rapporteurs' proposals with regard to the key issues in the application. The Secretariat will inform the applicant about the outcome of the conformity check and ask them for further clarifications on the issues requested by the Committee. These included among others more clarifications about the SEA methodology used, as well as more details about the submitted non-use scenario.

2. Two uses of chromium trioxide submitted by *Grohe AG* (**Chromium trioxide - Grohe**):

<u>Use 1:</u> The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also called 'functional plating with decorative character')

<u>Use 2:</u> The use of Chromium Trioxide for pre-treatment step in the electroplating process

The SEAC (co-)rapporteurs provided brief information on the application for authorisation and presented the draft outcome of the conformity check. The (co-) rapporteurs also presented their first impression of the application, highlighting some key issues for the attention of the Committee some of which would require further clarification by the applicant.

SEAC agreed that the application is in conformity and on the (co-)rapporteurs' proposals with regard to the key issues in the application. The Secretariat will inform the applicant about the outcome of the conformity check and ask them for further clarifications on the issues requested by the Committee.

# b) First version of the draft opinion:

1. One use of sodium chromate submitted by *Dometic GMBH and Dometic Htgépgyártó és Kereskedelmi Zrt.* (Sodium chromate 1): <u>Use 1</u>: The use of sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight (Cr 6+) in the cooling solution.

The Chairman introduced the application for authorisation. At the previous meeting, SEAC agreed on the conformity of the application and discussed the key issues, as presented by the rapporteurs. The SEAC members were asked to consider the agreement on the SEAC draft opinion at this plenary.

The SEAC rapporteurs presented the first version of the SEAC draft opinion. The Committee discussion mainly focused on the difference between two types of endproducts manufactured by the applicant. SEAC noted that for one product type (low temperature boiler) the substitution project is well advanced while for the other one (high temperature boiler) the substitution will take more time. Therefore, SEAC agreed to propose additional conditions for the authorisation based on the substitution activities described in the application.

The Committee discussed the length of the review period and then, given the aforementioned condition, agreed on the draft opinion by consensus. The Chairman thanked the (co-)rapporteurs for their work on this dossier.

# One use of sodium dichromate submitted by *Boliden Mineral AB* (Sodium dichromate 1):

<u>Use 1</u>: The use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores.

The Chairman introduced the application for authorisation. At the previous meeting, SEAC agreed on the conformity of the application and discussed the key issues, as presented by the rapporteurs. The SEAC members were asked to consider the agreement on the SEAC draft opinion at this plenary.

The SEAC rapporteurs presented the first version of the SEAC draft opinion. The rapporteurs proposed the conclusions that SEAC agrees with the applicant stating that substitution is technically but not economically possible. The Committee discussed the criteria for establishing the review period i.e. applicants investment cycle, profit margin, applicant's R&D efforts.

The Committee agreed on the length of the review period and then on the draft opinion by consensus. The Chairman thanked the (co-)rapporteurs for their work on this dossier.

# 3. One use of 1,2-dichloroethane submitted by *Laboratoires Expanscience* (**EDC 1**):

<u>Use 1</u>: process and extracting solvent in fine chemical processes

The Chairman introduced the application for authorisation. At the previous meeting, SEAC agreed on the conformity of the application and discussed the key

issues, as presented by the (co-)rapporteurs. The SEAC members were asked to consider the agreement on the SEAC draft opinion at this plenary.

The RAC rapporteurs updated members on the deliberations at RAC-35. The SEAC (co-)rapporteurs then presented the first version of the SEAC draft opinion to the Committee. SEAC agreed with the conclusions of the (co-)rapporteurs that there was no alternative substance or technology which fulfilled all the needed characteristics and which would be available and suitable at the sunset date.

The Committee agreed on the length of the review period and then on the draft opinion by consensus. The Chairman thanked the (co-)rapporteurs for their work on this dossier.

#### c) Update on the developments in the draft opinions:

1. Six uses of chromium trioxide submitted by *LANXESS Deutschland GmbH* on behalf of a group of companies (**Chromium trioxide 1**):

<u>Use 1</u>: Formulation of mixtures <u>Use 2</u>: Functional chrome plating <u>Use 3</u>: Functional chrome plating with decorative character <u>Use 4</u>: Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character <u>Use 5</u>: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering Use 6: Passivation of tin-plated steel (ETP)

The Chairman introduced the application for authorisation. At the previous meeting, SEAC agreed on the conformity of the application and discussed the key issues, as presented by the rapporteurs.

The Chairman invited the RAC rapporteurs to inform SEAC about the discussion held at RAC-35. The RAC rapporteurs briefly presented the main points of the discussion and their concerns on exposure data and exposure assessment.

Following that, the SEAC rapporteurs presented their view on the key issues and presented new information received on the application for authorisation. The rapporteurs asked SEAC for advice how to develop the draft opinions on this complex application.

The Chairman opened the floor for discussion and SEAC members expressed their concerns on generally high uncertainties in this application. SEAC discussed the robustness of the human health impact analysis and assessment of potential job losses in the non-use scenario. SEAC members agreed that aesthetic criteria should be considered as economical not as technical in the AoA. Furthermore, they pointed that the AoA should have better justified why some of the well-known alternative technologies cannot be used. In addition, the applicants should have clarified niche uses where suitable alternatives already exist. SEAC members supported the rapporteurs' proposal to make one more effort to clarify these remaining issues and to prepare for this a third set of questions to the applicants.

The rapporteurs will take the discussion into account in the preparation of the first version of the SEAC draft opinion by early January.

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

The pool of (co-)rapporteurs, as outlined in the amended restricted room document SEAC/29/2015/07 rev 1, was agreed by SEAC.

# 8) AOB

### a) Update of the workplan

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

### b) Extension of the mandate of the PBT working group

The Secretariat proposed to extend the mandate of the SEAC working group on PBT evaluation until July 2016. After SEAC-29 the working group could evaluate the need to amend the framework based on the results of the Dutch benchmarking project, and experiences on how the framework has worked for recently agreed and ongoing restriction dossiers and applications for authorisation on PBT substances. The working group could review the initial framework and the framework as a final report could be agreed at the plenary meeting in June 2016. The Committee agreed with the extension of the mandate.

#### c) Workshop on valuing health impacts of chemicals

The Secretariat informed the Committee about the workshop on valuing health impacts of chemicals that will take place at ECHA on 11-12 January 2016.

# d) Information about the master thesis on the current practice of socio-economic analysis used in restriction proposals

A SEAC member informed about a master thesis of on the current practice of socio-economic analysis used in restriction proposals. The member suggested to the Secretariat to consider if this study needs to be made available and discussed in the Committee.

# 9) Action points and main conclusions of SEAC-29

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

# MAIN CONCLUSIONS & ACTION POINTS

SEAC-29, 1-4 December 2015

(Adopted at SEAC-29 meeting)

Agenda point	
Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the agenda	T
The agenda was adopted with minor modifications.	<b>SECR</b> to upload the adopted agenda to SEAC S-CIRCABC IG as part of the meeting minutes.
3. Declarations of conflicts of interest to the Age	nda
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-28 action points, written procedu	ures and other ECHA bodies
SEAC was informed on the status of the action points of SEAC-28. Furthermore, SEAC took note of the report from other ECHA bodies (SEAC/29/2015/01), including the oral report from the Commission on SEAC related developments in CARACAL, in the REACH Committee as well as in the European Parliament. Furthermore, SEAC was reported back from the Chairman's interviews with the SEAC members in 2015.	
b) General SEAC procedures	
SEAC took note of the presentation from the Conflict of Interest Advisory Committee (CoIAC).	
5. Restrictions	
5.1 General restriction issues	
SEAC agreed on the revised working procedures for conformity check and opinion development of Annex XV restriction dossiers (SEAC/29/2015/02, SEAC/29/2015/03) with editorial modifications introduced at SEAC-29.	SECR to upload the agreed working procedures to S-CIRCABC and ECHA website.
Furthermore, SEAC discussed the revised opinion template (SEAC/29/2015/04).	<b>SECR</b> to continue updating the opinior template as a living document.
5.2 Restriction Annex XV dossiers	
a) Opinion development	

1) Isopropylidenediphenol (Bisphenol A) – draf	t final opinion
SEAC rapporteurs presented the draft of the SEAC final opinion and the results of the public consultation on the SEAC draft opinion. SEAC adopted its final opinion on BPA by consensus (with modifications introduced at SEAC-29).	<ul> <li><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.</li> <li><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</li> </ul>
2) Perfluorooctanic acid (PFOA) – draft final op	inion
SEAC rapporteurs presented the draft of the SEAC final opinion and the results of the public consultation on the SEAC draft opinion. SEAC adopted its final opinion on PFOA by consensus (with modifications introduced at SEAC- 29).	<ul> <li><b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the SEAC opinion and to ensure that the supporting documentation (BD and ORCOM) is in line with the adopted SEAC final opinion.</li> <li><b>SECR</b> to forward the adopted opinion and its annexes to COM and publish it on the ECHA website.</li> </ul>
3) Methanol – revised draft opinion	
SEAC rapporteurs presented and SEAC discussed the updated revised SEAC draft opinion. SEAC agreed on the draft opinion on methanol by simple majority (with modifications introduced at SEAC-29). Dissenting views will be reflected in the minutes.	<b>Rapporteurs</b> , together with SECR, to do the final editing of the draft opinion and to ensure that the supporting documentation (BD and RCOM) is in line with the agreed SEAC draft opinion. <b>SECR</b> to launch a public consultation on the SEAC draft opinion in December 2015.
4) D4/D5 – second draft opinion	
SEAC rapporteurs presented and SEAC discussed the second draft opinion.	<b>Rapporteurs</b> to prepare the third SEAC draft opinion, taking into account the SEAC-29 discussions and the results of the public consultation, by end of January 2016.
b) Conformity check (and key issues presenta	tion)
1) TDFAs	
SEAC agreed that the dossier does not conform to the Annex XV requirements. SEAC took note of the recommendations to the dossier submitter.	<ul> <li><b>Rapporteurs</b> to include final editorials to the outcome of the conformity check and recommendations.</li> <li><b>SECR</b> to compile the RAC and SEAC final outcomes of the conformity check and upload this to S-CIRCABC IG.</li> <li><b>SECR</b> to inform the dossier submitter on the</li> </ul>

	outcome of the conformity check.
5.3 Appointment of (co-)rapporteurs for res	striction dossiers
The pool of (co-)rapporteurs for the Bisphenol A,4,4'-isopropylidenediphenol restriction proposal (as presented in the restricted meeting document SEAC/29/2015/05rev1) was withdrawn from the SEAC-29 agenda due to information received from the dossier submitter that the dossier will not be submitted.	
6. Authorisations	
6.1 General authorisation issues	
SEAC discussed and agreed in principle on the opinion trees (as presented in the meeting document SEAC/29/2015/06).	<b>SECR</b> to revise the document in accordance with the plenary discussion and to launch a consultation on the final draft of the document.
	<b>SECR</b> to upload the document to S-CIRCA and to the ECHA website.
Furthermore, SEAC took note of the update on the incoming/future applications for authorisation and on the Workshop on streamlining applications for authorisation.	
6.2 Authorisation applications	
a) Outcome of the conformity check and pres	entation of key issues
<ol> <li>One use of chromium trioxide submitted by Kromatek Oy on behalf of a group of companies (Chromium trioxide - Kromatek):</li> </ol>	
Use 1: Use of chromium trioxide in Cr(VI) based functional plating	
SEAC agreed that the application is in conformity and discussed the key issues identified in this application.	<b>SECR</b> to inform the applicant about the conformity of the application for authorisation.
	<b>Rapporteurs</b> to take the discussion into account in the preparation of the first version of the draft opinion.
2. Two uses of chromium trioxide submitted	
by Grohe AG (Chromium trioxide - Grohe):	
Use 1: The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also called 'functional plating with decorative character')	
Use 2: The use of Chromium Trioxide for pre- treatment step in the electroplating process	

<ul><li>SECR to inform the applicant about the conformity of the application for authorisation.</li><li>Rapporteurs to take the discussion into account in the preparation of the first version of the draft opinion.</li></ul>
<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion.
<b>SECR</b> to send the draft opinion to the applicant for commenting.
<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion.
<b>SECR</b> to send the draft opinion to the applicant for commenting.
<b>Rapporteurs</b> together with <b>SECR</b> to do the final editing of the draft opinion.
<b>SECR</b> to send the draft opinion to the applicant for commenting.
inion

Use 4: Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character	
Use 5: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering	
Use 6: Passivation of tin-plated steel (ETP)	
SEAC rapporteurs presented and SEAC discussed the key issues of the application. SEAC advised rapporteurs on drafting the first version of the SEAC draft opinion.	<b>Rapporteurs</b> to take the discussion into account in the preparation of the first version of the SEAC draft opinion by early January 2016.
6.3 Appointment of (co-)rapporteurs for autho	risation applications (closed session)
SEAC agreed on the updated pool of (co-) rapporteurs for applications for authorisation (considered as agreement on appointment in line with SEAC/29/2015/07 RESTRICTED room document).	<ul> <li>SEAC members to volunteer to the pool of (co-)rapporteurs for applications for authorisation.</li> <li>SECR to upload the updated document to confidential folder on S-CIRCABC IG.</li> </ul>
8. AOB	
b) Extension of the mandate of the PBT worki	ng group
SEAC agreed to extend the mandate of the PBT working group until July 2016.	
9. Action points and main conclusions of SEAC-29	)
SEAC adopted the action points and main conclusions of SEAC-29.	SECR to upload the action points and main conclusions to S-CIRCABC IG.

# III. List of Attendees

#### SEAC-29

SEAC members	Advisors, invited experts, observers & dossier submitters (DS)
ALEXANDRE Joao	BERNHEIM Theresa (advisor to K. Thiele, via WEBEX)
ALEXANDROPOULOU Ioanna	BLOM Cécile, CORRELL MYHRE Ingunn, KOPANGEN Marit [Norway], BIEGEL-ENGLER Annegret and STAUDE Claudia [Germany] (DS representatives for PFOA restriction dossier, via WEBEX)
BENDL Jiri	CASTELLI Stefano (invited expert, IT SEAC nominee)
BERGS Ivars	DELCOURT Benjamin (advisor to C. Dantinne)
BOUSTRAS Georgiou	DOMINIAK Dorota (advisor to I. Rydlewska-L.)
BRIGNON Jean-Marc	HEKRLE Marek (invited expert, CZ SEAC nominee)
COGEN Simon	HENÖKL Thomas (COIAC expert) for General SEAC procedures agenda item
CSERGŐ Robert	JENSEN BAAD Louise (adviso to L. Fock)
DANTINNE Catheline	MARTIN Sara (DS representative for D4/D5 restriction dossier, via WEBEX)
DOUGHERTY Gary	MARTINUSSEN SNEVE Marie (advisor to T.M. Sletten)
DRAKE Lars (co-opted)	NORING Maria (invited expert, SV SEAC nominee)
FANKHAUSER Simone	VIERKE Lena (DS representatives for PFOA restriction dossier)
FIORE Karine (DS representative for BPA	
restriction dossier)	
FOCK Lars	RAC (co-)rapporteurs
FURLAN Janez	BJØRGE Christine
GEORGIOU Stavros (DS representative for D4/D5 restriction dossier)	DUNAUSKIENE Lina
GRANDI Silvia (via WEBEX)	LUND Bert-Ove
HENNIG Philipp (co-opted)	NEUMANN Michael
JONES Derrick (co-opted)	RUCKI Marian
KAJIĆ Silva	SANTONEN Tiina STAŠKO Jolanta
KIISKI Johanna	
KNOFLACH Georg KRAJNC Karmen	SØRENSEN Peter Hammer
м. Мартика (1997)	VARNAI Veda
LOČS Jãnis LUIT Richard	Stakeholder observers & assembarying
	Stakeholder observers & accompanying experts
LUTTIKHUIZEN Cees	BUONSANTE Vito (ClientEarth)
LÜDEKE Andreas	JANOSI Amaya (CEFIC)
NARROS SIERRA Adolfo	HAIDER Sonja (ChemSec)
NICOLAIDES Leandros	HOLLAND Michael (EAERE)
OLTEANU Maria	HOWARD Gregory (EEB)
RYDLEWSKA-LISZKOWSKA Izabela	MUSU Tony (ETUC)
SCHUCHTAR Endre	WAETERSCHOOT Hugo (EUROMETAUX)
SLETTEN Thea Marcelia	BOCK Ronald (Chemours (DuPont), FluoroCouncil
	representative), accompanying CEFIC observer – PFOA restriction dossier
SMILGIUS Tomas	BLOOR Pamela (Unilever), nominated by occasional STO EFfCI – D4/D5 restriction dossier

STOYANOVA-LAZAROVA Elina Velinova

THIELE Karen (DS representative for PFOA restriction dossier) (via WEBEX) THORS Åsa

#### **Commission observers**

BENGYUZOV Manol (DG GROW) BINTEIN Sylvain (DG ENV) BERTATO Valentina (DG GROW, via WEBEX) LUVARA` Giuseppina (DG GROW, via WEBEX) PROKES Pavel (DG GROW, via WEBEX) ROZWADOWSKI Jacek (DG GROW, via WEBEX) ERLER Steffen (Saudi Arabian Industries Corporation (SABIC), accompanying CEFIC observer – Methanol restriction dossier VERBIESE Nicole (Reconsile), accompanying CEFIC observer – D4/D5 restriction dossier

ECHA	staff

BERGES Markus

BLAINEY Mark HEIKKILA Minna

HENRICHSON Sanna

JACQUEMIN Katline

KANELLOPOULOU Athanasia

KIOKIAS Sotirios

KIVELÄ Kalle

MARQUEZ-CAMACHO Mercedes

MAZZOLINI Anna

MERKOURAKIS Spyridon

MOTTET Denis

NICOT Thierry

ORISPÄÄ Katja

ÖBERG Tomas

PELTOLA Jukka

PILLET Monique

RHEINBERGER Christoph

ROGGEMAN Maarten

SADAM Diana

SHUQOM Natasha SIMPSON Peter

SOSNOWSKI Piotr

VAINIO Matti

VAN HAELST Anniek

#### **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

#### Documents submitted to the members of the Committee for Socioeconomic Analysis

Final Draft Agenda	SEAC/A/29/2015	
Report on SEAC-28 action points, written	SEAC/29/2015/01	
procedures and other ECHA bodies (AP 4a)		
General restriction issues:	SEAC/29/2015/02	
Revision of the restriction process (AP 5.1a)	SEAC/29/2015/03	
	SEAC/29/2015/04	
Appointment of (co-)rapporteurs for restriction	SEAC/29/2015/05	
dossiers (AP 5.3)	RESTRICTED	
General authorisation issues:	SEAC/29/2015/06	
Continuing review of RAC and SEAC		
recommendations (opinion trees) (AP 6.1a)		
Appointment of (co-)rapporteurs for	SEAC/29/2015/07	
authorisation applications (AP 6.3)	RESTRICTED ROOM DOCUMENT	

# DECLARATIONS OF CONFLICTS OF INTEREST TO THE RESPECTIVE AGENDA ITEMS

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

Name of participant	Agenda item	Interest declared
BERNHEIM Teresa	5.2a-2 PFOA	Working for the MSCA
		submitting the
		restriction dossier
BRIGNON Jean-Marc	5.2a-1 Bisphenol A	Participation in the
		preparation of the
		restriction dossier
DOMINIAK Dorota	5.2a-3 Methanol	Participation in the
		preparation of the
		restriction dossier
DOUGHERTY Gary	5.2a-4 D4/D5	Working for the MSCA
		submitting the
		restriction dossier
FIORE-TARDIEU Karine	5.2a-1 Bisphenol A	Participation in the
		preparation of the
		restriction dossier
FOCK Lars	5.2b-1 TDFAs	Participation in the
		preparation of the
		restriction dossier
GEORGIOU Stavros	5.2a-4 D4/D5	Participation in the
		preparation of the
		restriction dossier
HENNIG Philipp	5.2a-2 PFOA	Working for the
		MSCA submitting the
		restriction dossier
JENSEN Louise Baad	5.2b-1 TDFAs	Working for the
		MSCA submitting the
		restriction dossier
KIISKI Johanna	5.2a-3 Methanol	Participation in the
		preparation of the
		restriction dossier
MARTINUSSEN SNEVE Marie	5.2a-2 PFOA	Working for the
		MSCA submitting the
		restriction dossier
SLETTEN Thea Marcelia	5.2a-2 PFOA	Working for the
		MSCA submitting the
		restriction dossier
THIELE Karen	5.2a-2 PFOA	Participation in the
		preparation of the
		restriction dossier



4 December 2015 SEAC/A/29/2015

# Final Draft Agenda 29<sup>th</sup> meeting of the Committee for Socio-economic Analysis

# 1 – 4 December 2015 ECHA Conference Centre (Annankatu 18, Helsinki) 1 December: starts at 9:00 4 December: ends at 13:30

Item 1 – Welcome and Apologies

Item 2 – Adoption of the Agenda

SEAC/A/29/2015 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-28 action points, written procedures and other ECHA bodies

SEAC/29/2015/01 For information

b) General SEAC procedures

For information

#### Item 5 – Restrictions

#### 5.1 General restriction issues

a) Revision of the restriction process

SEAC/29/2015/02 SEAC/29/2015/03 For discussion and agreement SEAC/29/2015/04 For information and discussion

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

- a) Opinion development
  - 1) Isopropylidenediphenol (Bisphenol A) draft final opinion

2)	Perfluorooctanoic acid (PFOA) - draft final opinion	
		For adoption
3)	Methanol – revised draft opinion	
	F	or agreement
4)	D4/D5 - second draft opinion	
	1	For discussion
Conform	ity check (and key issues presentation)	
1) TDFA	As	

For agreement and discussion

5.3 Appointment of (co-)rapp	porteurs for restriction dossiers
	SEAC/29/2015/05
	(restricted document)
	For agreement

#### Item 6 – Authorisations

b)

#### 6.1 General authorisation issues

a) Continuing review of RAC and SEAC recommendations (opinion trees)

#### SEAC/29/2015/06

For discussion/agreement

b) Update on incoming/future applications for authorisation and on the Workshop on streamlining applications for authorisation

For information

#### 6.2 Authorisation applications

a) Outcome of the conformity check and presentation of the key issues

3. One use of chromium trioxide submitted by *Kromatek Oy* on behalf of a group of companies (**Chromium trioxide - Kromatek**):

<u>Use 1:</u> Use of chromium trioxide in Cr(VI) based functional plating

4. Two uses of chromium trioxide submitted by *Grohe AG* (**Chromium trioxide - Grohe**):

<u>Use 1:</u> The use of chromium trioxide for electroplating of different types of substrates with the purpose of creating a long-lasting, high durability surface with a shiny or matte look (also called `functional plating with decorative character')

<u>Use 2:</u> The use of Chromium Trioxide for pre-treatment step in the electroplating process

#### For discussion/agreement

- b) First version of the draft opinion:
  - 4. One use of sodium chromate submitted by *Dometic GMBH and Dometic Htgépgyártó és Kereskedelmi Zrt.* (**Sodium chromate 1**):

<u>Use 1</u>: The use of sodium chromate as an anticorrosion agent of the carbon steel cooling system in absorption refrigerators up to 0.75% by weight (Cr 6+) in the cooling solution.

5. One use of sodium dichromate submitted by *Boliden Mineral AB* (**Sodium dichromate 1**):

<u>Use 1</u>: The use of sodium dichromate in copper/lead separation in concentrators handling complex sulphide ores.

6. One use of 1,2-dichloroethane submitted by *Laboratoires Expanscience* (**EDC 1**):

<u>Use 1</u>: process and extracting solvent in fine chemical processes

#### For discussion/agreement

- c) Update on the developments in the draft opinions:
  - 2. Six uses of chromium trioxide submitted by *LANXESS Deutschland GmbH* on behalf of a group of companies (**Chromium trioxide 1**):

<u>Use 1</u>: Formulation of mixtures

Use 2: Functional chrome plating

<u>Use 3</u>: Functional chrome plating with decorative character

<u>Use 4</u>: Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional plating with decorative character

<u>Use 5</u>: Surface treatment (except ETP) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering

Use 6: Passivation of tin-plated steel (ETP)

#### For information and discussion

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

SEAC/29/2015/07 (restricted room document) For agreement

#### Item 7 – Capacity building

#### Item 8 – AOB

a) Update of the work plan

#### For information

b)	Extension of the mandate of the PBT working group		
c)	Workshop on valuing health impacts of chemicals	For agreeme	nt
		For information	<b>n</b>
d)	Information about the master thesis on the current economic analysis used in restriction proposals	practice of soci	0-

For information

### Item 9 – Action points and main conclusions of SEAC-29

Table with Conclusions and Action points from SEAC-29

#### For adoption