

## **Note for the attention of Maria Ottati, Chair of the Committee for Socio-economic Analysis**

### **Ref: Request to the Committee for Socio-economic Analysis to prepare an assessment of further information to be submitted by the applicants as regards certain applications for authorisation and integration into the relevant opinions**

In accordance with Article 77(3)(c) of the REACH Regulation, the Committee for Socio-economic Analysis (SEAC) is requested to assess and provide its opinion on the following:

- A. Credibility and completeness of the substitution plan, where submitted; and
- B. Technical evaluation of the justification that there are no suitable alternatives available in general, where submitted.

This additional assessment and resulting conclusions by SEAC, limited to the above mentioned points A. and B., should be included in an *ad hoc* addendum to the concerned opinion and provided to the Commission as soon as practically possible, reasonably within a shorter time frame than the one set out in Article 64(1).

If necessary, the respective Rapporteurs of the original opinions of the Committee for Risk Assessment may be requested to provide technical and scientific advice to the Rapporteurs of SEAC in terms of the risks of alternatives.

### **1. Background**

On 14 July 2020 ECHA received a note (Annex 1) from the European Commission, in which they request ECHA Committees to a) assess and provide their opinion on the credibility and completeness of the substitution plan, where submitted; b) carry out a technical evaluation of the justification that there are no suitable alternatives available in general, where submitted. The request covers 12 applications mentioned in the note.

In the EU General Court judgment of 7 March 2019, Case T-837/16, Sweden v. Commission<sup>1</sup>, the Court has given its interpretation, among others, of the condition set out in Article 60(4) and (5) and Article 62(4)(e) and (f) of REACH as regards suitability of alternatives and the requirement of a substitution plan, which differs from the previous interpretation and practice adopted by the Commission and reflected in the ECHA guidance on applications for authorisation ('the Guidance')<sup>2</sup>.

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<http://curia.europa.eu/juris/document/document.jsf?text=&docid=211428&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=1351718>

<sup>2</sup>[https://echa.europa.eu/documents/10162/23036412/authorisation\\_application\\_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9](https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9)

In fact, the General Court clarified that if suitable alternatives are available in general<sup>3</sup> but those alternatives are not technically or economically feasible for the applicant, and if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, an authorisation may be granted if the applicant submits a substitution plan. In other words, if there are suitable alternatives available in general for the use applied for but the applicant has demonstrated that these alternatives are not feasible for it or its downstream users, the applicant also has to submit a substitution plan.

In the light of this new interpretation, the Commission has re-assessed the ECHA opinions on pending applications for authorisation ('AfAs'), concluding that for certain AfAs it was necessary to request the applicants to submit additional information on the suitability of alternatives and, where relevant, substitution plans. The Commission therefore notified the concerned applicants of the request to provide such additional documentation and submit it to ECHA, within a 6-month deadline<sup>4</sup>. The requests include the following situations:

1. With regard to the AfAs for which the available information did not allow the Commission to draw a definitive conclusion on the lack or existence of suitable alternatives in general, the applicants have been requested to submit relevant information on the availability of suitable alternatives in general for the use applied for or for the utilisations or group of utilisations falling within the scope of that use, as well as a substitution plan where relevant:

a) where the applicant concludes that there are suitable alternatives available in general, it is expected that a substitution plan should be submitted for the use, utilisation or group of utilisations within the use;

b) where the applicant concludes that there are no suitable alternatives available in general, a justification for reaching that conclusion should be submitted.

2. With regard to the AfAs for which the available information allowed the Commission to draw a conclusion on the existence of suitable alternatives in general, the applicants have been requested to submit a substitution plan for the use applied for, utilisations or group of utilisations falling within that use.

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<sup>3</sup> In paragraphs 72 and 73 of the judgment, the General Court has provided key criteria to identify what a 'suitable alternative in general' is. Such an alternative should be safer (entailing a lower risk for human health and/or the environment) and suitable in the EU (this 'suitability' is not limited to the existence of an alternative in abstracto or in laboratory or exceptional conditions, but relates to the availability of alternatives technically and economically feasible in the EU). Therefore, the analysis concerning the suitable alternatives in general should be carried out from the perspective of the production capacities (for someone in the market) for those alternative substances and of the feasibility of those alternative substances or technologies, as well as in the light of the legal and factual requirements for placing them on the market.

<sup>4</sup> The relevant submission deadlines (referred to with the name of the leading applicant) are the following:

CT Hapoc GmbH & Co KG ('Hapoc 1') – 10 September 2020

CT Chemservice GmbH – The original deadline of 24 August 2020 was extended to 24 September 2020

CT REACHLaw Ltd – The original deadline of 10 September 2020 was extended to 24 September 2020

MOCA REACHLaw Ltd – The original deadline of 10 September 2020 was extended to 10 October 2020

CT Hapoc GmbH & Co KG ('Hapoc 2') – 10 September 2020

DEHP Deza – 6 November 2020

SD Ormezzano – The original deadline of 10 September 2020 was extended to 10 November 2020.

CT Gerhardt Kunststofftechnik GmbH – 6 November 2020

CT Schell GmbH – 8 December 2020

CT Aloys F. Dornbracht GmbH & Co.KG – 8 December 2020

CT Ideal Standard - Vidima AD – 8 December 2020

CT KEUCO GmbH & Co KG – 8 December 2020

Legend: CT= Chromium Trioxide; SD=Sodium Dichromate

Due to the technical nature of the requested information, the Commission requires ECHA's scientific and technical expertise and advice for completing its decision-making process, in accordance with the REACH Regulation. In this context, the Commission has requested ECHA to prepare an assessment of the further information to be submitted by the applicants as described above, and to integrate this assessment into the relevant opinions.

## **2. Terms of Reference**

SEAC is requested to prepare an assessment of the substitution plans and possible additional information to be submitted by the applicants as regards the above mentioned applications for authorisation and to integrate this assessment into the relevant opinions. SEAC needs to take into account comments from third parties from the consultation of substitution plans and the responses of the applicants.

This additional assessment and resulting conclusions by SEAC, limited to this mandate, should be included in *ad hoc* addenda to the concerned opinions and provided to the Commission as soon as practically possible, reasonably within a shorter timeframe than the one set out in Article 64(1).

If necessary, the Rapporteurs of the original applications of the Committee for Risk Assessment may provide technical and scientific advice to the Rapporteurs of the SEAC in terms of the risks of alternatives.

## **3. Timescale**

Considering the submission dates given to the concerned applicants it is appropriate for SEAC to organise the evaluation of the Substitution Plans in two batches. SEAC should aim to have the first discussion and agreement on the draft *ad hoc* addenda in the March and June 2021 SEAC meetings. The draft *ad hoc* addenda should be sent to the applicants for commenting, and SEAC should aim to adopt the final *ad hoc* addenda in the June and September 2021 SEAC meetings.

Given the limited scope of the request, it is considered realistic that each draft and final *ad hoc* addendum to the concerned opinions will be discussed and adopted by SEAC in one plenary meeting.

The *ad hoc* addenda to the concerned opinions by SEAC should be submitted to the Commission by 15 July 2021 and 15 October 2021 at the latest.

#### 4. Remuneration

The task for SEAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.

*(e-signed)*<sup>5</sup>

Bjorn Hansen  
Executive Director

Cc: Peter van der Zandt Director of Risk Management  
Tim Bowmer, Chair of the Committee for Risk Assessment

Annex 1: Note of the Commission dated 14 July 2020 concerning assessment of further information to be submitted by the applicants as regards certain applications for authorisation and integration into the relevant opinions

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<sup>5</sup> As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.