EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Chemicals and Consumer Industries
REACH

DIRECTORATE-GENERAL FOR ENVIRONMENT
Circular Economy and Green Growth
Sustainable Chemicals

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**NOTE FOR THE ATTENTION OF**
**MR P. VAN DER ZANDT, EUROPEAN CHEMICALS AGENCY**

**Subject:** **Assessment of further information to be submitted by the applicants as regards certain applications for authorisation and integration into the relevant opinions**

Dear Peter,

As you are aware, in the EU General Court judgment of 7 March 2019, Case T-837/16, *Sweden v. Commission*[1], 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*')[2].

In fact, the General Court clarified that if suitable alternatives are available *in general*[3] 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

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

[2] https://echa.europa.eu/documents/10162/23036412/authorisation_application_en.pdf/6571a0df-9480-4508-98e1-ff807a80e3a9

[3] 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.

alternatives are not feasible for him or his downstream users, he also has to submit a substitution plan.

In the light of this new interpretation, the Commission has re-assessed the ECHA opinions on the 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 the request to provide such additional documentation and submit it to ECHA, Unit Risk Management II, within a 6-month deadline[4]. The requests include the following situations:

1. With regard to the AfAs for which the available information did not allow 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 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.

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. Therefore, we would require ECHA Committees to **assess and provide their 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.

[4] The AfAs at stake (referred to with the name of the leading applicant) and relevant submission deadlines are the following:
CT Chemservice GmbH – 24 August 2020
CT REACHLaw Ltd – 10 September 2020
CT Hapoc GmbH & Co KG ('Hapoc 1') – 10 September 2020
CT Hapoc GmbH & Co KG ('Hapoc 2') – 10 September 2020
SD Ormezzano – The original deadline of 10 September 2020 was extended to 10 November 2020, following the applicant's request due to Covid-19 crisis.
MOCA REACHLaw Ltd – 10 September 2020
CT Gerhardi Kunststofftechnik GmbH– 6 November 2020
DEHP Deza – 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

This additional assessment and resulting conclusions by the scientific Committees, limited to the above mentioned points a) and b), should be included in an *ad hoc* addendum 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).

In addition, we would also request ECHA to **notify** the Commission whether the applicant submitted any information at the expiration of the relevant deadline.

As last point, in the light of this change of interpretation, all applicants should have equal opportunities to get a publically available guidance on the new interpretation of the rules. We therefore expect ECHA to **update the guidance as soon as possible** to align it with the case law, also considering the recently updated format for substitution plans.

Yours sincerely,

*(e-sign)*
Michael Flueh
Head of Unit
DG GROW

*(e-sign)*
Cristina de Avila
Head of Unit
DG ENV