A FRESH COAT OF PAINT ON THE ANALYSIS OF ALTERNATIVES

– translating the judgment on lead chromate authorisation into action

On 7 March 2019, the General Court annulled[1] an authorisation decision adopted under the REACH Regulation.[2] The Court, for the first time,[3] looked at the legality of an authorisation, and more specifically at the question of availability of safer alternatives. The judgment does not solve all questions, but it provides a useful reminder to public authorities and companies about how the authorisation system is supposed to work, and more specifically, who is supposed to bear the burden of proving the absence of suitable alternatives.

When translating the ruling into action, the key takeaway is that the companies that apply for authorisation (applicants) bear the burden of proving the conditions for authorisation are met, and in particular that no suitable alternatives are available. The public authorities involved have to analyse the analysis of alternatives provided by the applicants, take into account the information for third parties and reach a conclusion on the basis of full, consistent and relevant reasoning. If this is not possible based on the information provided by the applicant, it is the applicant who has to go "back to the drawing board", and in the meantime cannot be awarded an authorisation and a pat on the back.

ECHA, the Secretariat and the socioeconomic assessment committee (SEAC), are the first link in the long chain of public authorities entrusted with this process, and as such have a special role to play. They are the first point of contact for applying companies. They set the framework for the analysis, and the scientific opinion of SEAC has a unique influence on the final decision to grant or refuse authorisations. ECHA secretariat in their intitial contacts with the applicant and at their pre-submission meetings with the applicant as well as SEAC in their evaluation process needs to ask the right questions to the applicants and themselves, and remind applicants that it is up to them to make a compelling case and provide convincing answers to third-party comments in the public consultation. SEAC, the Commission or national governments are not there to rescue their case.

This report aims to support the necessary changes in working procedure by providing practical recommendations based on a translation of the judgment's findings.

1. Judgment of the General Court (Fifth Chamber) of 7 March 2019, Kingdom of Sweden v European Commission, Case T-837/16 available on the curia website.
2. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396 30.12.2006, p. 1)
3. A month later, the same Court ruled in another case relating to authorisation (case T-108/17, ClientEarth v. European Commission). This case touches upon different questions and will therefore not be covered in this analysis.

1. Core findings from the judgment

a) The Commission cannot hide behind ECHA's opinions

The Court insisted on the responsibility of the Commission to take authorisations decisions, and its right to depart from SEAC's scientific opinion (§66-68). However, that does not mean SEAC is free from all responsibility.

Indeed, the Court made very clear that:

- If the reasoning of SEAC's opinion is not "full, consistent and relevant", the Commission needs to "address questions to the committee aiming at remedying the potential deficiencies identified" (§68).
- SEAC cannot simply enumerate the considerations of the applicant on the absence of suitable alternatives, and/or the considerations from third parties heard during the public consultation (§93) without drawing any precise conclusions from them, especially when these are contradictory. If the applicant fails to provide convincing answers to the comments made in the public consultation, SEAC needs to say so, and conclude that the applicant failed to prove the absence of suitable alternatives.

The Commission needs to ask SEAC clarifying questions or perform their own analysis if SEACs opinions do not have a "full, consistent and relevant" reasoning.

b) SEAC needs the right expertise to fulfil its task

The Court described SEAC as a scientific committee who has thus to rely on a reasoning of a certain "scientific level" (§66–69). It refers, by analogy, to the *Pfizer case*, in which the Court, specified: "the competent public authority must be given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts." (§162 of Pfizer judgment in case T-13/99).

SEAC's members must have the relevant scientific expertise to be able to deliver the required reasoning.

c) The substitution plan is not an option

The Court, unfortunately, did not go into the details of what "economically and technically feasible" means. But it did provide some useful guiding principles:

- As explained in ECHA's guide, an alternative should perform the 'function' performed by the SVHC. It can be another substance, or a technique (such as a change in the final product) or a combination of both. It could also be a modification of the end-product that makes the very function of the substance unnecessary. (§71)
- It is not enough for an alternative to be suitable, to exist "in abstracto or in laboratory conditions or in conditions that only have an exceptional character" (§73).
- "Suitable" implies notably that the analysis be carried out "in terms of production capacity of these substances, the feasibility of these technologies as well as in terms of legal and factual conditions of their placing on the market" (§73).

- If an alternative is available "in general" but the solutions are not technically and economically feasible for the applicant, this does not *necessarily* mean that the authorisation must be rejected (§75); in that case the applicant however must still provide a substitution plan (§76).
- This "subjective" criteria is *only* one of the elements that must be taken into account to define the substitution plan. The substitution plan must include a calendar of actions proposed by the applicant including R&D information which the applicant is undertaking or plans to undertake to replace the SVHC (§76).

When an alternative is available but it can be concluded that it is not suitable for the applicant, SEAC must not stop its assessment there, but must also review the applicant's substitution plan. This substitution plan must include a calendar of actions and cannot be based solely on the applicant's own (subjective) perspective.

d) The burden of proof is on the applicant, not on SEAC, nor on third parties

The Court underlined that the burden to prove the absence of suitable alternatives is on the applicant. It also clarified that it means that the applicant "bears the risk" of the potential impossibility to conclude on the absence of available alternatives (§79). The Court also made explicit that ECHA or the Commission or other actors involved do not have to prove the opposite, i.e. that suitable alternatives are available (§79 and §89), for the authorisation to be legally rejected.

When the evidence put forward by the applicant leaves too much uncertainty as to the lack of suitable alternatives, SEAC must conclude that the applicant failed to show the absence of suitable alternatives. SEAC, itself (or third parties), does not have to prove that the alternatives are available and suitable. SEAC may simply state: the applicant failed to provide sufficient evidence that the alternatives do not exist or are not suitable.

e) The evidence on absence of alternatives must be "cogent", "reliable" and cover all the "uses" applied for

The Court gave some guidance on how much evidence would be sufficient, or not, to be able to conclude on whether the condition of absence of alternatives is fulfilled.

- "Mere hypothesis" on the absence of available alternatives are not sufficient for an authorisation to be granted (§81).
- If elements given by the applicant for authorisation are contradicted by elements presented by third parties, the question of the availability of alternatives must be analysed in more depth (§84), first by SEAC asking questions to the applicant.
- It is for the applicant to clarify any remaining (non-negligible) uncertainties on the question of availability of alternatives (§85–86); it needs to explain and properly justify in particular why the alternatives identified by third parties could not be used as alternatives to the SVHC for any of the uses covered in its application (§101).
- For the information on the absence of alternative to be sufficient, it must be "substantial" and "reliable" and cover all the "uses" applied for (§86)

- When the applicant for authorisation does not define the uses "restrictively", it exposes itself to the risk that uncertainties about the absence of alternatives for one specific use, calls into question the conclusion of absence of alternatives for all the other uses covered in the application (§94).
- When the uses applied for include preliminary steps where the substance has no function yet (such as the formulation of a paint) it is only in relation to the later stage, when the function of the substance manifests itself (e.g. when the metallic surfaces are manufactured for a specific purpose) that the analysis of alternative is to be performed (§95).

SEAC's opinions must highlight the remaining uncertainties, as well as an analysis of how important these uncertainties are, how the applicant answered to the comments in the third party consultation, and whether all uses applied for are covered by the analysis of alternatives. This analysis has to be done in relation to the function that the substance performs, which may manifest itself further down the supply chain, when the end-product is manufactured.

f) No putting off until tomorrow

The Court clearly stated that it is not legal to grant an authorisation while leaving the question of whether suitable alternatives are available open, nor attempt to remedy the uncertainties by requiring the applicant to provide necessary clarifications in the review report later on (§82–83; §97).

SEAC's opinion must not invite the Commission to, and the Commission, in turn, must not:

- **ask the applicant to dissipate the uncertainties as to the absence of alternatives in the review report**
- **leave it to the applicant, its downstream users or the national authorities, to define the exact scope of the uses covered by the authorisation**

2. Translating the core findings into tools

ECHA, SEAC and the applicants for authorisation have currently several tools at their disposal for their work on authorisation and in particular the analysis of alternatives:

- **A template opinion format (December 2018 version),** [4]
- **Instructions and format for applicants for the analysis of alternatives (February 2019 version),** [5] **and substitution plan (May 2017 version),** [6]
- **Instructions and format for third parties contributions (November 2015, March 2013 version),** [7]

In light of the findings from the Court on the 7 March, these tools need to be updated. The only documents that do not need immediate changes is the instruction/format for the applicant's analysis of alternatives. This is because it has been very recently improved and the judgment only confirms that the changes made were adequate and timely.

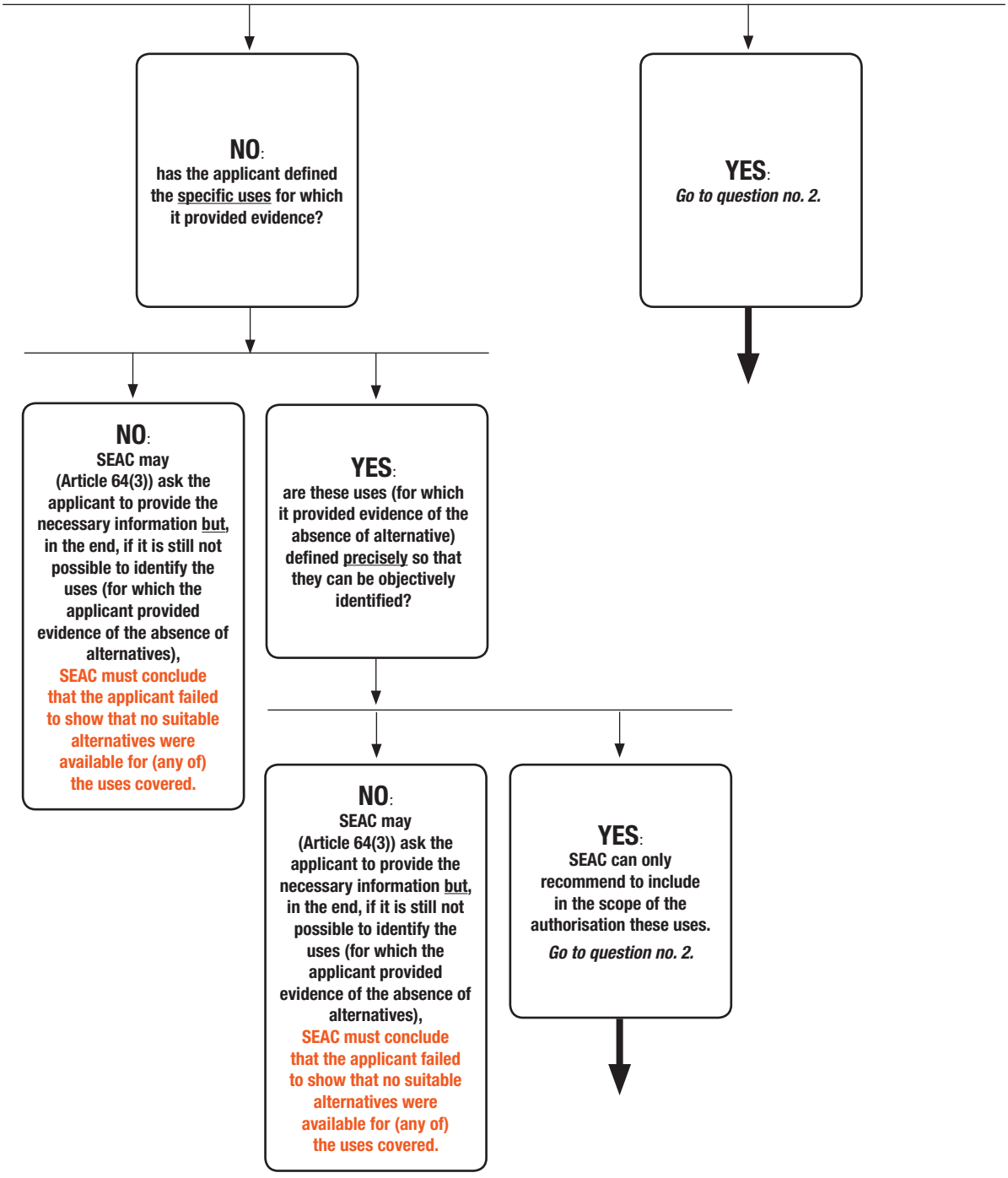
However, the template opinion format, even though it was updated at the end of 2018, needs, as a priority, to be updated as it sets out the wrong questions for SEAC regarding the analysis of alternatives. As a first step, we propose a "checklist" for SEAC (A), which should guide the adaptation of the opinion template (B). The third party contributions instruction and format would also need to reflect the Court's findings (C).

4. https://echa.europa.eu/documents/10162/13555/format_rac_seac_opinions_en.pdf/bd186fd3-2ee2-4557-8fa0-64dd559e1006
5. https://echa.europa.eu/sv/applying-for-authorisation/preparing-applications-for-authorisation
6. https://echa.europa.eu/documents/10162/13637/sub_plan_template_en.pdf/bbc85402-4610-4102-af74-4c5b8637ec3f
7. https://echa.europa.eu/documents/10162/13555/instructions_third_parties_afa_en.pdf/7bcfcfc7-e189-4e65-8e95-3c93520344c3

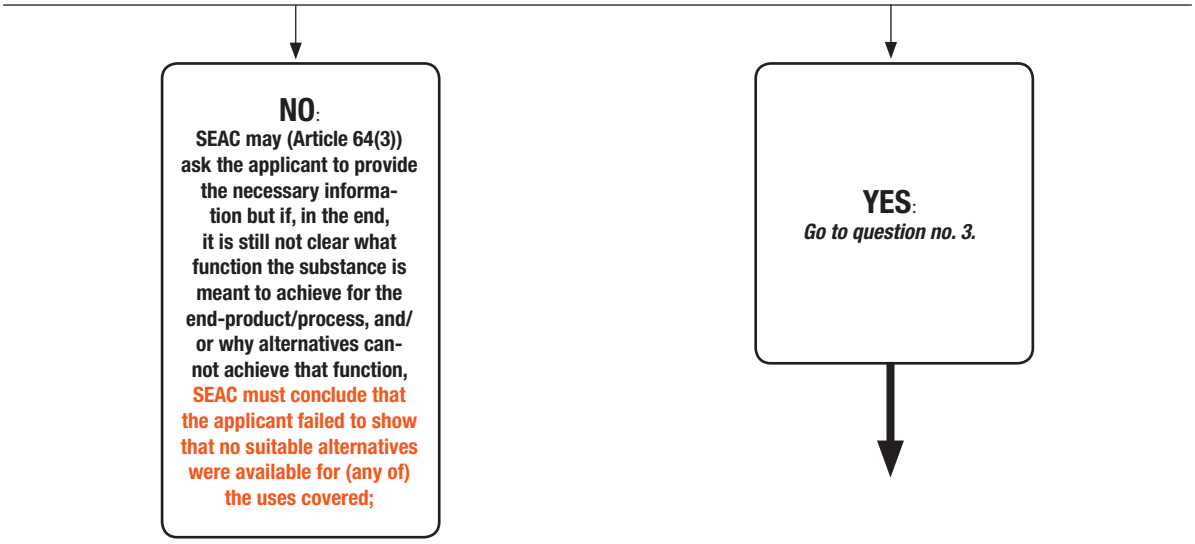
A. Suggestion for a check list for SEAC to assess the information provided on alternatives

Building on the judgment and the key principles detailed above we propose following check-list to be used by SEAC in their assessment of information provided by the applicant on alternatives.

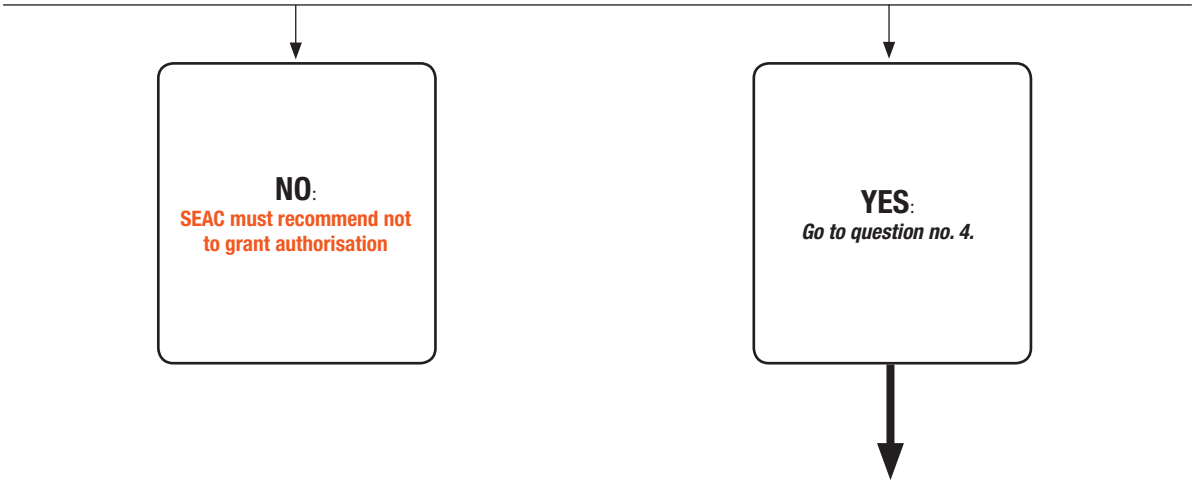
1. Did the Applicant provide information on alternatives covering all the uses covered in the application?



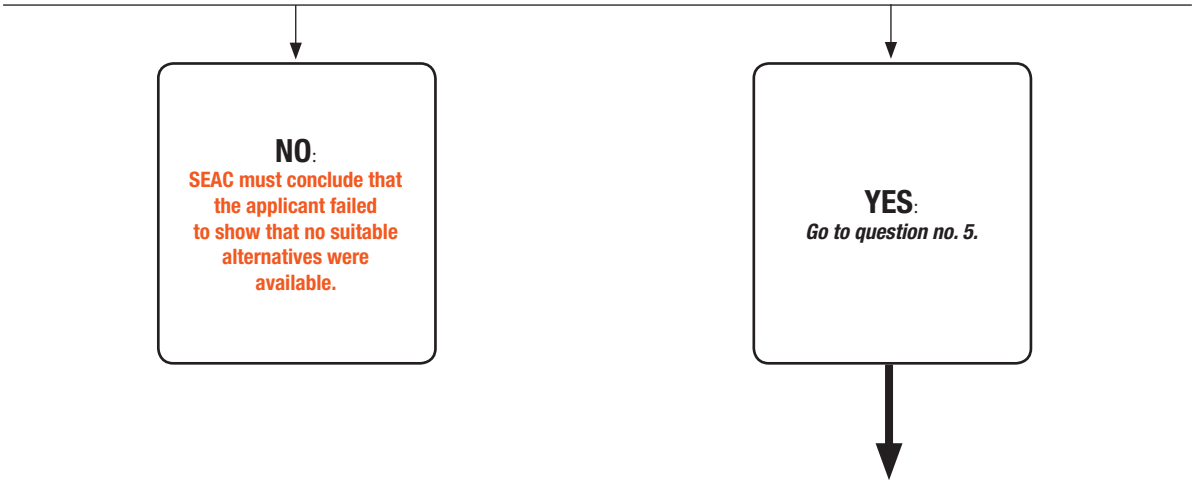
2. Did the Applicant provide information on alternatives to the substance, by reference to the function that the substance is meant to perform, at the relevant steps of the supply chain (i.e. when this function manifests itself)?



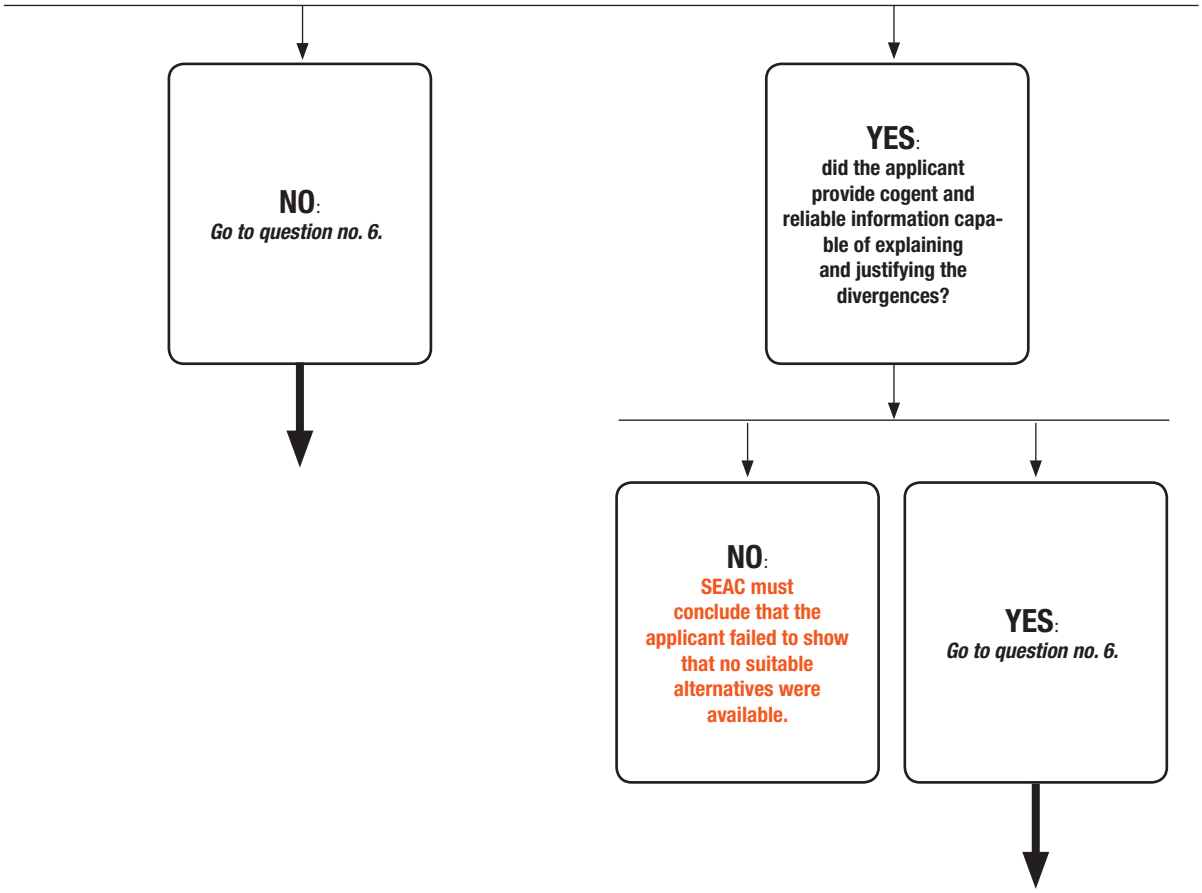
3. Did the Applicant provide a substitution plan for all the uses covered?



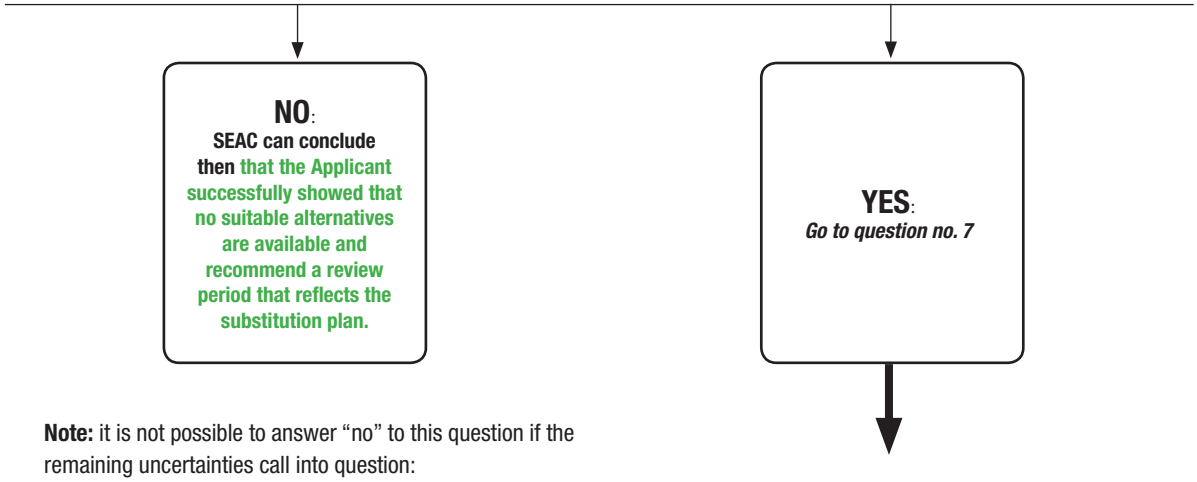
4. According to SEAC's assessment, is the information provided by the Applicant regarding alternatives reliable and cogent?



5. Was there information in the public consultation raising serious doubts regarding the Applicant's analysis of alternative (e.g. completeness) or substitution plan (e.g. time needed to adapt their facilities)?



6. Are there remaining non-negligible uncertainties as to the absence of suitable alternatives?



Note: it is not possible to answer "no" to this question if the remaining uncertainties call into question:

- The reliability of the information provided by the Applicant.
- The coherence between the information provided by the Applicant and information provided by third parties.

7. Are the remaining uncertainties as to the absence of alternatives due to the applicant's failure to provide relevant or precise enough information?

Note: it is not possible to answer "no" to this question if the uncertainties relate to:

- the definition of the use – a company is supposed to know what the SVHC is used for, even if the supply chain is "complex".
- the customers' needs – an efficient economic operator is supposed to know the needs and preferences of its customers, even if the supply chain is "complex".

B. Update to the opinion template

The main issue with the current opinion template is that it sets out the wrong questions for SEAC to answer.

Point 5 of the template asks: "Are suitable alternatives available [before the Sunset Date]?"

In light of the judgment, which insisted on the principle that the burden of proof is on the applicant (see 1d, p. 3) the relevant question should instead be: "Has the applicant provided full, relevant, consistent, cogent, and reliable information showing that no suitable alternatives are available yet for each and every use covered in the application?"

The template opens the door to "Recommendations to the [applicant] related to the content of the potential Review Report" under this section on alternatives.

In light of the judgement that deemed it illegal to request data on alternatives, that should have been provided at the time, to be provided later on in the review report (see 1f p. 4) the template should specify what type of recommendations can be included in the review report on alternatives. It must specify that it cannot include information that was supposed to be provided (and should have been available) at the time of the application.

In the more detailed questions set out in the template regarding the analysis of alternative (see p. 30), again it is not clear that the burden of proof is on the applicant, that the substitution plan is not an option, and the uncertainties must be set out.

In light of the judgment, we recommend using instead the questions set out in the above checklist (see part A p. 6–9).

The opinion template also fails to guide SEAC to focus on what matters.

For example in point 5.1, the template invites SEAC to repeat what the applicant has said, and what third parties have said without focusing on the key issues, nor on setting out a reasoning of its own an assessment of the data provided.

In light of the judgment, to ensure the opinion sets out a "full, consistent and relevant" reasoning (see 1a p. 2 and 1e p. 3) we recommend the addition of sections in the template that would focus on highlighting:

- **Whether the Applicant provided all the relevant information, e.g. information, for each use, of the function that the substance performs, and in which step of the supply chain or process this function manifests itself;**
- **Whether and why, SEAC considers cogent the information from the applicant justifying why the alternatives identified are unsuitable for each use;**
- **Whether and why SEAC considers that the information provided by the Applicant is reliable;**
- **Whether in case of third party contributions in the public consultation, the Applicant answered fully to the comments, and in a convincing manner;**
- **Whether and why, in particular, the Applicant's substitution plan is consistent with third party's comments and SEAC's knowledge and expertise on substitution.**

The pre-drafted conclusion in the template – "SEAC concluded that there appear to be [no] suitable alternatives in terms of their technical and economic feasibility that are available [by the Sunset Date] [by the end of the review period of the granted Authorisation]" – again not only forgets that the burden of proof is on the applicant, but also invites SEAC to make vague conclusions based on a vague reasoning or even no reasoning.

In light of the judgment, it should be replaced by the following possible conclusions:

A. SEAC concluded that the Applicant showed on the basis of cogent and reliable evidence that either

- **no alternative substances or technologies are available yet for any of the uses covered;**

or

- **the available alternatives are not (economically or technically) suitable for [use defined precisely] but failed to show this for [use defined precisely]."**

or

B. SEAC concluded that the Applicant failed to show on the basis of cogent and reliable evidence that the available alternatives are not (economically or technically) suitable for any of the uses applied for."

C.

Update to the third party consultation template

In order to receive relevant information from third parties about alternatives the public consultation mechanism in the context of REACH authorisation needs to be improved. While ECHA has significantly improved the instructions and format for applicants for the analysis of alternatives, there is still a need for action to make the public consultation more effective. In that regard, we refer back to our recommendations published in March 2018. [8]

In light of the judgment, an important issue needs to be clarified: third parties are not required to provide a full analysis of alternative or prove that alternatives do exist or are suitable for their comments to be taken into account, and for these comments to raise sufficient serious doubts as to the applicant's analysis and substitution plan (see part 1).

The current third party consultation template and instructions suggests that third parties have to provide a full analysis of alternative themselves, in order to rebut the Applicants claims. Indeed, the instructions refers to *Guidance on the preparation of an application for authorisation* (see p. 25). This is not in line with Article 64(2).

The instructions must make clear that a third party is not expected to do the work of the applicant and provide a full analysis of alternatives or prove itself that suitable alternatives are available.

8. https://chemsec.org/publication/authorisation-process,reach/how-to-find-and-analyse-alternatives-in-the-authorisation-process/

clientearth.org

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ClientEarth /ChemSec, May 2019