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ClientEarth

# Lead chromate case & SEAC

## The changes required

Following the first instance judgment in the Lead Chromate case (T-837/16), the Commission and SEAC implemented some changes in the authorisation process. The definition of what is an alternative available in general, and the systematic request for a substitution plan when there is one, were positive steps towards correctly implementing REACH. The other changes required by the judgement were delayed, in the hope that the Court will adopt a different position in appeal.

When hope turned to disappointment considering the Advocate General's opinion and the Judges' Decision in appeal (C-389/19P), the Commission decided nonetheless to stand its ground and consider the current practice as compliant with REACH.

This is however not the case; changes are required. SEAC secretariat and members have a particular responsibility in bringing the practice in compliance with EU law. SEAC is the first line of analysis of the application. The Commission and the Member States have the right to depart from its opinion, but not without difficulties. What the opinion contains, and its final conclusion, therefore weigh heavily on the final decision – and its legality.

The decision-making documents that frame applications for authorisation and SEAC opinions still reflecting the interpretation of REACH rejected by the Court must be amended. Members must bring the practice in compliance with the Court's judgement in the Lead chromate case.

# 1. Change the consequences of remaining uncertainties

## The rules set by the judgment

The Court set specific rules on the regulatory consequences the Commission must give to uncertainties on the availability of suitable alternative (para. 35).

| | |
|---|---|
| **Negligible uncertainties** | The Commission may grant the authorisation after a detailed examination and verification of sufficient amount of material and reliable information |
| **Non – Negligible uncertainties** | The Commission is obligated to reject the authorisation<br><br>Reducing the review period or setting conditions are not acceptable consequences |

The Court also said that the information used to reach a conclusion on the availability of alternatives must be significant and reliable.[1]

**The implications for SEAC are the following:**

SEAC role under REACH is to indicate to the Commission as objectively and explicitly as possible the quality and robustness of applications for authorisations, to support the final decision. The assessment of uncertainties in the analysis of alternative was rightly identified by the Court as a crucial part of the decision under the socio-economic route, SEAC must therefore:

- **Systematically identify** remaining uncertainties and qualify them as negligible or not;
- **Consider unconfirmed or overturned** – by other available information - assumptions as non-negligible uncertainties (para. 34);
- **Conclude** that the applicant has not discharged its burden of proving that no alternative is available in case of non-negligible uncertainties.

## The practice still does not fully comply with the judgement

- SEAC still does not systematically identify and qualify uncertainties.

  For instance: in the context of the MOCA Luc application (Use 1)[2], SEAC has identified uncertainties concerning if and when a successful candidate will be identified. In other words, it is unclear from the substitution plan whether an alternative will ever be successfully implemented.

[1] Judgment of the General Court (Fifth Chamber) of 7 March 2019, Case T-637/16, *Sweden v. Commission*, para 86.

[2] See Compiled RAC and SEAC opinions on application for authorisation by Limburgse Urethane Castings NV (MOCA).

While mentioning it, SEAC however did not qualify the significance of this uncertainty for the rest of the plan, and the extent to which it may affect its conclusions on the overall robustness of the application. [3]

- SEAC does not conclude that the companies failed to discharge its burden of proving no alternative is available when non-negligible uncertainties remain.

  This is noticeable in the opinion on some review reports that are still confidential. In a similar vein, SEAC notes with regard to the Hapoc's application that the applicant "might have taken a precautionary approach and overestimated the duration of some of the steps"[4], which should be considered as significantly impairing the completeness and credibility of the plan. The amount and quality of information provided by the applicant is considered "of correct quality" by SEAC, without further explanation of what this qualification means and entails. Nonetheless, SEAC concludes that the plan is credible.[5]

SEAC members:

- ☞ Must systematically identify and qualify (as negligible or not) uncertainties remaining in applications, as well as whether it is grounded on reliable and significant information
- ☞ Must conclude that the burden of proof has not been discharged in case of non-negligible uncertainties coming from data gaps, unreliable, insufficient or contradicted information.

## The decision-making documents need to comply with the judgement

A non-exhaustive review of the existing guidance documents on applications and opinions revealed endorsement of the interpretation of REACH sanctioned by the Court. For example:

- **Opinion template (September 2021[6])**

  The template was improved in the last update, which is very welcome. It is however missing a definition of uncertainties that would help to categorise them in line with the classification endorsed by the court (negligible/not negligible). Such definition as well as a consistent terminology in the description of uncertainties would help ensure a consistent approach. Different types of uncertainties (data not provided, data not verifiable, contradictory data etc) should be clearly distinguished and defined, with the relevant consequences attached to it.

- **SEAC/20/2013/03 Review period paper[7]:**

  The correct consequence for uncertainties related to the availability or suitability of alternatives is a negative opinion, not a short review period as currently stated.

[3] Compiled RAC and SEAC opinions on application for authorisation by Limburgse Urethane Castings NV (MOCA, Use 1), p. 39.
[4] Compiled RAC and SEAC opinions on application for authorisation by Hapoc (Chromium trioxide), p. 26.
[5] Compiled RAC and SEAC opinions on Hapoc Substitution Plan.
[6] Template for RAC and SEAC Opinion on an Application for Authorisation, Version 4.0.
[7] SEAC-20_AP 06.2, "Setting the review period when RAC and SEAC give opinions on an application for authorisation", September 2013.

- **RAC/35/2015/08 - SEAC/29/2015/06 - Opinion trees for non-threshold substances[8]**:

  The decision tree must consider the possibility of non-negligible uncertainties on the Analysis of Alternative. It should integrate the possibility to include the compulsory consequence to non-negligible uncertainties.

- **RAC/20/2012/06 - SEAC/14/2012/05 (2014) – common approach in opinion development on applications for authorisation[9]:**

  Incomplete or missing information and weak evidence should lead RAC and SEAC to give a negative opinion – not "advice on more stringent conditions or short review periods" (section 3). Section 6 on the analysis of alternative must be particularly amended on missing information.

  The identification and qualification of remaining uncertainties must be flagged as a key part of the evaluation. It should also be included in the **Working procedure for developing opinions on the applications for authorisation RAC/31/2014/07 rev2 SEAC/25/2014/05 rev2.**

- **RAC/57/2021 & SEAC/51/2021 - proposed common approach to assessing review reports:**

  The consequences for lack of reliability are additional conditions, monitoring arrangements or reduced review period – SEAC must clear on the fact that reliability issues caused by non-negligible uncertainties must lead to a negative opinion. This is also the only consequence which should be attached to lack of robust justification of delay in substitution activities

SEAC secretariat:

- ☞ Review existing application and opinion supporting documents to purge them of the interpretation of REACH invalidated by the Court;
- ☞ In the new opinion template, add a definition of the various types of uncertainties and the consequences attached to it;
- ☞ Adopt a common approach on how to deal with uncertainties in authorisation, including a distinction between data gap, data limitation (due to limits of available method/models) and contentious data/interpretation of data in order to get to the second step of qualifying uncertainty as negligible, non-negligible or high.

# 2. Change the assessment of technical feasibility

## The current practice

SEAC still accepts analysis of alternative that assess the technical feasibility against the performance of the SVHC rather than function to be performed,[10] contrary to what is called for by the guidance documents.[11]

[8] Guidance Paper on Opinion Trees for Non-Threshold Substances in Applications for Authorisations (AfA), January 2016, Version 1.1.
[9] Common approach of RAC and SEAC in opinion development on applications for authorisation, March 2012.

The evidence accepted to justify the need for a specific performance is sometimes weak and not sufficiently specified by the guidance documents.[12] This is particularly the case when the main justification for not switching to available alternatives are undocumented customer preferences.[13] Even SEAC members have opposed this approach, e.g. in one application, a member issued a minority position highlighting that the applicant "did not demonstrate convincingly that detailed aesthetics performance of some metal-plated can drive customer demand for the whole car".[14]

In 2019[15], we already called for the definition of technical requirements to be based on verifiable evidence, such as:

- Legal requirement for technical acceptability (safety, etc.);
- Critical performance related to the desired function objectively documented by performance certification requirements, including tolerances of these requirements (i.e. an acceptable range);
- Process constraints, for example documented by certification requirements, including tolerances of these requirements (i.e. an acceptable range);
- Customer requirement, but only if 1) duly documented 2) representing all or a representative majority of customers 3) with proof that the requirements were based on the customers' knowledge of the potential impact of SVHC use with no adequate control and of the performance of the relevant alternative;
- Standardised performance test;
- Tests by applicant but audited by independent third party

The result of this practice is a narrow assessment of what is an acceptable loss of performance,[16] often embracing the applicant's arguments at face value.

## Why it needs to change

[10] See for example compiled RAC and SEAC opinions on Limburgse Urethane Castings NV (MOCA, Use 1): SEAC notes that "in order to be acceptable to the customers, an alternative formulation has to reach **the same performance** level in all aspects (…) the customer requirements and market situation do require alternatives **that perform as well as the MOCA based systems and a less performing system would not be acceptable**" (pp. 35-37).

[11] See the detailed analysis in "How to find and assess alternatives" ChemSec, ClientEarth (2018) and Guidance on the preparation of an application for authorisation, p. 81.

[12] See notably the Format for Analysis of Alternatives and Socio-Economic Analysis, Version 3.0.

[13] See for example compiled RAC and SEAC opinions on application for authorisation by Ilario Ormezzano Sai srl (sodium dichromate) and Compiled RAC and SEAC opinions on review report by Blue Cube (TCE): "SEAC asked if consumer surveys were available to confirm the welfare loss if performance requirements were not met, but it was not possible for the downstream user of the authorisation holder to provide such information" (p. 37). See also Compiled RAC and SEAC opinions in application by Hapoc (chromium trioxide): "Whilst the uncertainties over technical feasibility still exist, the conclusion on suitability of alternative ultimately relies on arguments concerning the aesthetic preferences of final customers" (p. 48).

[14] See Jean-Marc Brignon minority position in application by Hapoc for chromium trioxide (Use 2).

[15] See report op. cit. note 12.

[16] See compiled RAC and SEAC opinions on Blue Cube review report, pp. 37-38. See also compiled RAC and SEAC opinions on application for authorisation by Doureca (chromium trioxide): "Doureca has tested drum coating on some parts of an OEM. The obtained results do not fulfil the required functionalities. Besides, this alternative only provides mat aspect and it is only suitable for small parts (this means the aesthetics requirement of having a bright/satin finishing is not met by this alternative). Due to these reasons it cannot be considered to be a technically feasible alternative" (p. 42).

The Court stated that the acceptability of technical performance loss must be assessed in a way that ensures the effectiveness of the substitution objective.[17] Performance can be inferior but still sufficient to maintain the function of the end-use. In other words, the reason why a performance loss cannot be tolerated must be thoroughly justified by verifiable information, and a refusal of any loss would defeat the very purpose of REACH. The fact that applications with a similar function but not using the SVHC exist, as well as contribution from third parties on the feasibility of alternatives raise non-negligible uncertainties on the absence of technical feasibility.[18]

ECHA secretariat:

- **Opinion template (September 2021)**

  The template must make clear that the decision needs to be made against the range of performance indispensable for the end-use. See also the checklist proposed for SEAC in the report we made with ChemSec after the first lead Chromate judgment.[19]

- **Application format (September 2021)**[20]

  The application format should require the applicant to provide a detailed description of the end uses, as well as of the range of acceptable technical performance necessary for the end-use, with a thorough justification of why this is needed.

- Provide guidance on what is acceptable customer requirement in order to set a shared understanding ad common expectations on what evidence is sufficient, which will help applicants and SEAC both. It should be clear that the definition of technical requirements must be duly documented by the applicant – and not merely based on alleged customers' preferences. The criticality of the use will be taken into account by SEAC, i.e. a heavier burden of evidence will apply each time it is unclear why the continued use of an SVHC is necessary (e.g. in the context of decorative uses).

SEAC members

- Exercise a more critical eye on the applicant's definition of technical feasibility, require a detailed description of the range of performance needed to maintain the function of the end-use.

[17] Judgment of the Court (First Chamber) of 25 February 2021, Case C-389/19P, *Commission v Sweden*, para. 56.
[18] As noted by the General Court in the Lead Chromate first instance decision, Case T-637/16, para. 89 et s.
[19] Report by ChemSec and ClientEarth "A fresh coat of paint" (2019).
[20] Format for Analysis of Alternatives and Socio-Economic Analysis, Version 3.0.

Apolline Roger

Chemicals Project Lead

aroger@clientearth.org

Hélène Duguy

Lawyer/Juriste

hduguy@clientearth.org