ClientEarth

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Contribution to the consultation on EURENCO- Review Report

The requirements to fulfil by Review Reports

Authorisations granted using the socio-economic route are meant to provide **a transitional period** to the companies which prove they legitimately need extra time to **develop or switch to safer alternatives.**

If suitable alternatives are available in general, i.e. they have been developed and are even being used by companies providing the same service/product, the burden of proof to justify a continuous authorisation is very high. The Review Report must contain verifiable and precise evidence that an exceptional, legitimate circumstance justifies giving even more time to the applicant in order to do what others have already done.

If there are no suitable alternative available in general, the applicant is still required to research and/or develop alternatives. The Review Report should contain precise and verifiable evidence that the applicant has investigated suitable alternatives- and how it plans to investigate further in the future.

In both situations, a Review Report should showcase **precisely and convincingly** the activities and efforts that the company benefitting from the authorisation has put into place to achieve substitution. Compared to an initial Application for Authorisation (AfA), the company undergoing review logically bears an even **heavier burden of proving** that more time is needed.

It is also important to remember that the Court clearly affirmed that "*the applicant for authorisation bears the risk of any impossibility of establishing whether it must be concluded that alternatives are unavailable*"[1]: any doubt remaining on the absence or infeasibility of an alternative must lead to **rejecting the authorisation request – which means, in the context of a Review Report, to withdraw the authorisation.**

Providing precise and detailed updated information, in particular within the substitution plan, is of utmost importance to support the Commission's decision to amend or withdraw the authorisation.

[1] General Court, T-837/16, Sweden v. Commission, 7 March 2019, EU:T:2017:740, para 79.

In the context of ECHA's assessment of the substitution plans submitted as part of ongoing AfA processes, the General Court of the EU has set several requirements which could serve as guiding principles to analyse the credibility of the substitution plans submitted in the context of review reports. In particular, the Court stated that a substitution plan must contain "a **timetable for proposed actions** by the applicant for authorisation pursuant to Article 62(4)(f) of the regulation (…) **to support the aim of eventual replacement of substances of very high concern** by suitable alternative substances or technologies (…)". [2] Following that Court's judgment, the Commission added that **precise information and justification for each action and timing** proposed should be provided, even in the context of longer-term plans.[3]

The Review Report submitted by Eurenco fails to meet these requirements.

In 2017, Eurenco was granted authorisation for the continued use of dichloroethane in the synthesis of Polyepichlorohydrin (PECH), which is used in the production of Glycidyl Azide Polymer (GAP) and plays a role in increasing the performance of military explosives. The company had committed to implement one of the shortlisted alternatives by the end of the review period.[4] This, however, did not happen and the company has asked for a 7-year extension of the review period to allow for the development of recently found alternatives.

Eurenco insists that GAP applications are critical to functioning of the defence sector.[5] Yet, this criticality cannot serve as a standalone argument to justify the continued use of dichloroethane, a classified EDC, when alternatives are known to exist and when a commitment was made as to their implementation before the end of the review period

As explained above, Eurenco must provide verifiable and detailed evidence of legitimate reasons to justify an extension of the review report. This is not the case here.

First, the company does not explain clearly or precisely what activities were undertaken in the past review period, in accordance with its commitment to substitute. The updated Analysis of Alternative (AoA) contains high-level/general information on those activities, e.g. mentioning that the company "engaged in research projects aiming at a complete reengineering of GAP's synthesis process with human health as main criterion" without providing details on the exact projects referred to or where they are at.[6]

Second, Eurenco does not bring forward new information on the alternatives that were, in 2017, considered available and suitable, at least on the short term, despite suspected carcinogenic properties. Eurenco repeats the conclusions presented to SEAC and RAC in the initial AfA, i.e. first R&D results from lab scale investigation are very promising; however, the alternatives cannot constitute a long-term solution due to their suspected impact on human health. This is not new[7] and Eurenco does not sufficiently substantiate

[2] See T-837/16, op. cit. above Para. 76.
European Commission Letter to applicants, sent on behalf of DG GROW and DG ENV: "Where it is clear that a suitable alternative in general cannot become economically and technically feasible for you in a short or medium term, you should still submit a substitution plan, explaining that substitution can only take place in a long term (e.g. when building a new plant or after the end of lifetime of the product)".
[4] SEAC and RAC Opinions on Eurenco AfA (2017), p. 32. https://echa.europa.eu/documents/10162/3c348d2f-a4c5-3e48-2220-d292631a898f
[5] See Appendixes to AoA and SEA, pp. 75-84.
[6] Updated AoA and SEA, p.8.
[7] SEAC and RAC Opinions, p. 31, read: "taking into account the intrinsic carcinogenic properties of these substances, this substitution step does not qualify as an acceptable long-term option. It is therefore considered as a temporary solution allowing pursuing the production of GAP and satisfying the customer requirements during the period of time needed for the development of a sustainable alternative."

why the company changed its position and decided to not implement the initially shortlisted alternatives deemed suitable for temporary substitution.

Third, Eurenco argues that new, safer alternatives have been found to replace the SVHC. But these alternatives are only "potentially" suitable, according to the company, due to uncertainties with regard to their economic and technical feasibility. However, Eurenco fails to properly document the alleged lack of technical feasibility. Merely stating that "technical obstacles" and "the qualification needed" make an alternative "unlikely technically feasible" unless more time is provided is not an acceptable argumentation.[8] It is not sufficient to mention that "the first experiments are for now not satisfactory" without describing *why* this is not satisfactory. Understanding what technical obstacles impede the implementation of an alternative is absolutely key for the policy maker to decide whether or not the granting of a renewed authorisation is needed.

Fourth, it was reminded above that a substitution plan should be as detailed and clear as possible, so that SEAC can effectively assess its completeness and credibility. Eurenco's substitution plan clearly defines the main phases the company will go through to eventually substitute the SVHC with Alternative 4. However, it is not fully clear why the company chose to design a substitution plan for Alternative 4 and not for other alternatives like Alternative 5, deemed by the applicant as the "most suitable alternative". According to the substitution plan, the Alternative 4 "*could* be the best compromise for a long-term alternative for the replacement of EDC", so it is, in fact, not certain. Moreover, "significant optimization work" would be required before that alternative is effectively implemented, that is not before 2028 – which is a long transition time.[9] This leaves the risk assessor, manager and third parties with little clarity as to the credibility of the plan proposed by Eurenco. The general lack of justification for the extended review period constitutes a significant impediment to the credibility of Eurenco's review report. The information that is currently provided should not be deemed sufficient to justify a renewed authorisation.

A review report without the adequate information should be rejected leading to the withdrawal of the authorisation.

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[8] Updated AoA and SEA, pp. 49-50
[9] Substitution plan, p. 5

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