REACH & CLP Hub: Why applicants for use authorisation under REACH may need to submit substitution plans

The European Commission has refined its understanding of 'availability of alternatives in general' when considering authorisation of the use of an SVHC under REACH. Bernadette Quinn from REACHLaw outlines the changes

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At the beginning of 2019, things were looking up for the Chromium Trioxide Authorisation Submission Consortium (CTACSub) – a consortium formed to submit an application to Echa covering six broad use descriptions for chromium trioxide. On 15 February 2019 the REACH Committee voted to adopt the submission consortium's application for certain uses of chromium trioxide.

The vote signalled that decision-making on all other pending upstream applications would also move forward. Many had been pending a decision for more than two years at that stage. However, almost immediately after the vote, a ruling of the General Court to annul the two lead chromate applications put the spotlight on how "availability of alternatives in general" is assessed in applications for authorisation.

The ruling said the Commission could not grant authorisation when there is uncertainty as to the availability of alternatives in general for the use applied for. This exact concern had been raised by Echa's committees during their assessment of the CTACSub application and many of the other pending upstream applications including chromium trioxide applications submitted by REACHLaw and Hapoc, Chromium VI Compounds for Surface Treatment REACH Authorisation Consortium (CCST), Global Chromates Consortium for Aerospace (GCCA) and the MOCA (2,2'-dichloro-4,4'-methylenedianiline) application.

Substitution plans

The General Court stated that where it is considered that suitable alternatives in general are available, the application must include a "substitution plan". However, none of the pending applications included substitution plans as these were not required following the Echa guidance. This meant that the Commission now had a dilemma over how to proceed with these pending upstream applications.

The approved decision for CTACSub was suspended while Echa and the Commission considered how to respond to the ruling. In May, the Commission submitted an appeal against certain aspects of the ruling. However the appeal did not challenge the ruling on substitution plans. This in effect means that substitution plans are now a

requirement when suitable alternatives in general are available for the use applied for.

New application process

In summer 2019 Echa adapted the application process for current and future applicants. From July onwards, the agency gave all applicants for uses of nonylphenol ethoxylates (NPE) and octylphenol ethoxylates (OPE) the opportunity to submit substitution plans retrospectively with their applications.

Then in September Echa announced that it had made changes to the template used by the scientific committees for risk assessment (Rac) and socio-economic analysis (Seac) in their opinions on applications for authorisation, specifically to address the court ruling.

The revised template states that the applicant has to submit a substitution plan if alternatives are available in general. It makes it clear that "suitable alternative" means an alternative which is both "safer" and "suitable". Meanwhile suitable means neither in abstracto nor "in laboratory or exceptional conditions" but:

technically and economically feasible in the EU; and available from the point of view of production capacities of the substance or feasibility of the technology, and legal and factual conditions for placing on the market.
These concrete actions clarified how the General Court ruling would be addressed by Echa committees with regard to applications where the committees had yet to issue their opinion to the Commission for decision-making.

How the General Court ruling would be addressed with regard to pending applications already with the Commission for decision-making - such as that of CTACSub - remained to be clarified.

Decorative chrome plating

By September it was clear that decorative chrome plating uses in the CTACSub upstream application, and in another upstream application by REACHLaw, would be processed separately from other uses covered, and that the Commission would request applicants to submit substitution plans.

The Commission indicated it would also issue similar requests for other pending applications where the Commission considered that suitable alternatives in general were available. It is not known why the Commission singled out decorative chrome plating. Neither is it immediately apparent from the Echa committee opinions. However decorative chrome plating is cited by some NGOs as a use that should not get an approved authorisation on the grounds that aesthetic properties are not an appropriate justification to allow the use of a banned chemical.

Retrospective submission

In February this year, the Commission began sending letters to the applicants concerned, requesting the submission of substitution plans. CTACSub applicants received their letters in February and others in March. The letters were addressed to upstream applicants covering decorative chrome plating uses apart from in two cases:

- MOCA as a curative for the manufacture of polyurethanes; and
- sodium dichromate as a mordant for wool dyeing.

In 2018 the Ilario Ormezzano application (for the use of sodium dichromate as a mordant for wool dyeing) got stuck at the decision-making stage due to information on the availability of alternatives that only came to light in an application submitted later by a competitor (Gruppo Colle).

Prior to the General Court ruling, the European Parliament had passed a resolution calling on the Commission to reject the application due to availability of alternatives. After the ruling, it was clear that the Commission would need to request a substitution plan before making a decision. A further complication was that the Commission had already adopted the Gruppo Colle application, making it difficult to reject that of Ilario Ormezzano.

The Commission has given the applicants six months to submit the requested substitution plans to Echa. If applicants do not submit the plans, their application will be refused. Once submitted, the committee for socio-economic analysis will give its opinion which will be issued to the Commission and taken into account in decision-making on the applications.

The letters include details on the criteria the applicant should apply regarding the concept of suitable alternatives in general. They are similar to those given in the updated template for the opinion of the Echa scientific committees published in September 2019. The annex also gives details of the content the Commission expects to see in substitution plans. These should give a clear and credible roadmap of the actions users are taking to phase out their use of the substance.

Broad use descriptions

As the use descriptions for the chromate and MOCA applications cover a wide variety of sectors, determining whether "suitable alternatives in general" are available may depend on how and where the product/component/part is used. The Commission's letters acknowledge this breadth and say applicants may determine that there are utilisations covered by the use description where suitable

alternatives in general are available, and others where they are not. For utilisations where the applicant concludes there are no suitable alternatives in general available, the Commission asks that the rationale is documented and included as an addendum to the analysis of alternatives report.

Implications for downstream users

Downstream users are now being informed by their upstream applicants of the Commission's request and the urgent need to contribute to information gathering. Downstream users' input is critical for upstream applicants to be able to prepare a downstream user-driven substitution plan.

For the CTACSub and REACHLaw applications, information gathering is particularly complex since there are two different chromium trioxide supply chains potentially supplying to the same downstream users (CTACSub supply chain and the Novotroitsk Plant of Chromium Compounds supply chain). Some downstream users may also no longer be relying on either upstream application. Numerous individual and joint applications have been submitted by downstream users in the sanitary sector since the latest application deadline and many already have a Commission decision.

The sheer number of downstream users that may be covered by the CTACSub and REACHLaw applications brings challenges of its own. At the time of submission of the CTACSub application, it was estimated there were approximately 1,500 sites using chromium trioxide for decorative chrome plating. Some will be small and some large. Some will be specialist platers, some generalists and some both. The time available to collect information from potentially hundreds of diverse users and compile a meaningful, credible, substitution plan that satisfies the Echa committee and Commission is very short. Applicants will be learning by doing, as there is no guidance available on how to prepare a substitution plan for an upstream application that has a broad use description.

The Echa committee and Commission will be on a similar learning curve as these will be the first upstream substitution plans submitted for assessment. Future applicants intending to prepare upstream applications will be following these closely.

Pending upstream applications

Some of the pending chromate upstream applications have already been adopted by the Commission (eg the GCCA and CCST consortia applications) and it is likely the rest will be voted on in forthcoming REACH Committee meetings.

A draft implementing decision for the five other CTACSub uses is already available on the Comitology website for discussion at the REACH committee webex meeting to be held on 13 May 2020. The agenda for the meeting indicates that if the discussion will be conclusive, the draft Decision may be submitted to a vote by written procedure following the Webex meeting.

The text of Commission decisions has been updated in light of the General Court ruling. Paragraph 8 of a current draft implementing decision available on the comitology website outlines that as a starting point, the Commission should not consider a potential alternative technically viable where losses to performance or technical compromises are not minor. However, it adds a caveat that the Commission considers it must be possible to depart from this approach "where justified by particular circumstances, including the specific function of the substance for the use applied for, the public interests at stake". This may mean that in future, considerations on the technical function of the substance for the use applied for will influence the decision-making on the suitability of alternatives, for example if the function is related to aesthetics.