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DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

DIRECTORATE-GENERAL FOR ENVIRONMENT

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Questions & Answers

EUROPEAN COURT OF JUSTICE JUDGMENT IN CASE C-144/21 (EUROPEAN PARLIAMENT VS. COMMISSION) AND ITS IMPACT ON CURRENT PRACTICE FOR AUTHORISATIONS UNDER REACH

1. What is the judgment about?

In Case C-144/21, the Court partially annulled Commission Decision ([1]) C(2020)8797 (so-called 'Chemservice decision'), namely the parts granting an authorisation for uses 2, 4, and 5 as well as the part granting authorisation for use 1 as far as it relates to the formulation of chromium trioxide into mixtures for uses 2, 4 and 5 of chromium trioxide under the REACH Regulation.

The Court maintained the effects of the annulled decision for a maximum of one year from the date of delivery of the judgment, until 20 April 2024.

2. What were the main findings of the judgment? What is the impact on current practice and on the discharge of burden of proof for the analysis of alternatives?

The ruling of the ECJ in the Case C-144/21 introduced several main clarifications in that regard, as follows:

i) the use applied for needs to be described with a **level of granularity** that allows a meaningful analysis of alternatives and ensures that the uncertainties on the availability of suitable alternatives, if any, are negligible;

ii) where relevant, applicants need to properly justify the **need for both the specific functionality (or functionalities) provided by the substance of very high concern and, for each functionality, the specific level of**

([1]) **Use 1** formulation of mixtures; **Use 2** functional chrome plating; **Use 4** surface treatment for applications in the aeronautics and aerospace industries (unrelated to functional chrome plating or functional chrome plating with decorative character); **Use 5** surface treatment for applications in various industry sectors, namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to functional chrome plating or functional chrome plating with decorative character).

performance. That justification could be of quantitative and/or qualitative nature, and it should be substantive;

iii) the **exposure data included in the risk assessment need to be representative and based on adequate measurements**. The Commission needs to consider the representativeness of the data provided, especially in the case of applications covering multiple sites. Data should be representative for all sites covered by the application for authorisation. For sites for which no data are available or used, it must be clear in the application that those sites' operational conditions and risk management measures are sufficiently similar to those at the sites from which data were used.

The Commission is applying such scrutiny in assessing pending files (and will apply it in the upcoming ones), in particular concerning the burden of proof required to the applicants on the analysis of alternatives. The Commission is also considering whether there is a need to amend any guidance document (ECHA guidelines, Q&A) to underline or clarify the revised requirements for applicants.

3. What is an appropriate level of granularity of the assessment and of the use description?

It is difficult to define in abstract or general terms the appropriate level of granularity of the assessment, since this level needs to be determined considering the specificities of the use applied for. However, for the purpose of discharging the burden of proof as indicated under question 2, applicants would not necessarily be required to provide an assessment for each piece or each end product. Instead, it could be sufficient if they **group those products in homogeneous categories based on functionalities/level of technical performance required**, as long as properly justified. However, the definition of the groups should allow enforcement authorities to identify to which group each product belongs. Defining the groups only by reference to key functionalities or mentioning one typical product belonging to the group would not meet this requirement.

Similar considerations apply to the use description. While it is in most cases not necessary to list each product, the use description should be sufficiently precise to understand which product categories are in the scope of the application. Broad references, such as "various items" or "for demanding sectors", and reference to key functionalities should be avoided.

4. What about the evidence regarding customers' acceptance?

Where applicants claim **customer's acceptance** as an argument to justify the need for the substance, it is essential that they substantiate it with robust and substantial evidence. **Applicants need to demonstrate that they are not able to accommodate losses of performance or technical compromises** linked to the alternative substance or technology, compared with the SVHC applied for, **despite efforts made** towards explaining to their customers the reasons for substitution and the need to find an alternative.

For more details on this exercise, you may consult ECHA's Q&A on customers' requirements ([2]).

5. What are the next steps by the Commission for the Chemservice decision?

The Commission will need to prepare a new draft decision on the original application submitted by Chemservice as regards uses 2, 4 and 5, as well as use 1 in relation to the formulation of chromium trioxide into mixtures for uses 2, 4 and 5. The re-assessment will be carried out in the light of the findings of the Court and the new draft decision will concern that application only. In this process, first the Commission will have to submit a draft decision for discussion with the Member States in the REACH Committee. The Commission can adopt the decision with the support of a qualified majority of the Member States.

6. The deadline of 20 April 2024 has elapsed and the Commission has not yet taken a decision on the original authorisation decision. What is the current state of play?

The Court maintained the effects of the annulled decision for a maximum of one year from the date of delivery of the judgment, i.e., until 20 April 2024.

After 20 April 2024, there has been a reversion to the legal situation where an application is submitted before the *latest application date* and a decision has not yet been taken on that application. This means that the transitional rules set out in Article 56(1)(d) of REACH apply since 20 April 2024 and that operators covered by the application that led to the annulled decision can use the substance, until a new decision on the initial application is taken.

The obligations linked to the granted authorisation now annulled, e.g., the conditions and monitoring arrangements set out in the annulled decision, or the notification requirements under Article 66, no longer apply since 20 April 2024. It is noted, however, that also in a previous similar case where the Court annulled an authorisation, the authorisation holder continued to uphold at least part of the conditions and monitoring arrangements, in order to continue to provide and demonstrate protection to their workers, citizens living around the site of use, and the environment.

In view of the above, if a company is a downstream user currently covered by the annulled decision on the original Chemservice application, they are still allowed to continue the use of chromium trioxide. They may do so at least until the Commission has taken a new decision on the original authorisation application.

Should a company, as a downstream user, consider making their own application, it needs to be taken into account that the authorisation process is currently experiencing considerable delays due to the high number of applications received, which go well beyond the current capacities. Moreover, it needs to be recalled that such an application will be submitted *after* the latest application date and is therefore not covered by any transitional arrangements allowing continued use as set out in Article 56(1)(d) of REACH. Therefore, should the Commission adopt a

([2]) https://qnapublic.echa.europa.eu/QnA/QnA?id=7185

refusal on the Chemservice application, the company cannot continue using chromium trioxide until there is a decision on their own application.

If, nevertheless, a decision is taken to prepare and submit a new application, downstream users are encouraged to prepare joint applications with other downstream users provided that their use is the same, and their approach as regards the risk management measures and the resulting performance in terms of exposure and emission values, is homogeneous. In other words, the joint application should not undermine the level of granularity required for a meaningful assessment.

7. Are other pending applications for authorisation affected by the judgment?

The Commission has concluded its assessment of the pending applications for authorisation to analyse whether any of them is affected by the judgment. The result of such assessment is that 12 applications are considered non-compliant, due to the incompleteness of the analysis of alternatives (mostly concerning the justification of functionality and level of performance). Therefore, the Commission requested those applicants to submit the relevant information to ECHA, for subsequent SEAC assessment.

Following that assessment, SEAC will issue an addendum to the original opinions, scheduled to be sent to the Commission by Q3 2025, for resuming the decision-making on the relevant files. Discussion on those files is now tentatively scheduled for the REACH Committee of October 2025).

8. Does the judgment affect granted authorisations where the same or similar approach was implemented as in the Chemservice decision?

Authorisations that were already granted benefit from the presumption of legality given that they were not challenged within the two months deadline after adoption. Yet, the Commission still has the possibility to review them. However, as of October 2023, the relevant authorisations have either already expired or will expire (since no review report was submitted by the applicable deadline), or a review report has already been submitted or such a review report is expected within less than one year.

For the authorisations for which a review report has been submitted or is expected, the Commission considers that it is appropriate not to trigger on its own initiative a review, but rather to continue the current process of assessment of the review reports. The Commission will make sure that those reviews take into account the clarifications of the judgment in its future decisions.

9. The two consortia including most of the operators covered by the annulled decision, CTACsub2 and ADCR, had submitted review reports. In light of the annulment of the original authorisation decision, what happens with those review reports?

On 20 April 2024, the review reports submitted became void, in as far as they refer to the annulled decision. In view of this, those review reports (or the relevant parts

thereof) are now treated as new applications for authorisation, submitted after the latest application date.

The ECHA opinion-making process is about to be finalised for CTACsub2 application (submitted in February 2024 as new application, but initially in February 2023 as review report) and, depending on whether the applicant decides to comment, the draft decision may be discussed in the REACH Committee of October or December 2025. The Commission will need to issue several decisions: one relating to the original (annulled) authorisation, and several ones relating to the new applications.

10. What is happening with use 6 of the original authorisation decision for the use of chromium trioxide in passivation of tin-plated steel - authorisation numbers REACH/20/18/28-34?

This decision was not challenged in court by the European Parliament. The judgment has therefore no effect for this particular use and the related authorisation remains valid until its expiration (21 September 2024). No review report was submitted ahead of the deadline (21 March 2022). Instead, authorisations for the same use were granted to individual companies, which previously were relying on the Chemservice Use 6 authorisation, and which submitted individual applications.