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Questions & Answers

REACH and Chromium(VI) substances

This Q&A document intends to address the most frequently asked questions concerning the Commission's risk management of Cr(VI) substances under REACH.

If you have any additional questions, not covered by the current version of this document, you are invited to contact DG GROW Unit F.1 REACH: GROW-F1@ec.europa.eu

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EUROPEAN COURT OF JUSTICE JUDGMENT IN CASE C-144/21 (*EUROPEAN PARLIAMENT VS. COMMISSION*)

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.

[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).

2. What were the main findings of the judgment that will have to be taken into account in future opinion- and decision-making?

First, 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.

Second, 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 performance. The Commission is to thoroughly verify that this burden of proof is discharged.

Third, 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.

3. 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.

4. What happens if the deadline of 20 April 2024 is reached and the Commission has not yet taken a decision on the original authorisation decision?

The Court maintained the effects of the annulled decision for a maximum of one year from the date of delivery of the judgment. After 20 April 2024, operators covered by the annulled decision would benefit from the transitional rules set out in Article 56(1)(d) of REACH, since there would be 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 these operators would be able to use the substance also after that date, until a new decision on the initial application is taken.

The obligations linked to the granted authorisation e.g. the conditions and monitoring arrangements set out in the annulled decision will no longer apply. 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 you are a downstream user currently covered by the annulled decision on the original Chemservice application, you are still allowed to continue the use

of chromium trioxide if you adhere to the use descriptions and operating conditions set out in the application. You may do so at least until the Commission has taken a new decision on the original authorisation application.

Should you, as a downstream user, consider making your own application, please take 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, be advised that such an application will be submitted *after* the latest application date and is therefore not covered by any transitional arrangements allowing continued use set out in Article 56(1)(d) of REACH. Therefore, should the Commission adopt a refusal on the Chemservice application, you cannot continue using chromium trioxide until there is a decision on your 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.

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

The Commission is assessing the pending applications for authorisation to analyse whether any of them is affected by the judgment and is identifying the way forward for those considered affected.

6. 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 not appropriate 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.

7. In February 2023, Chemservice submitted a review report. In light of the annulment of the original authorisation decision, what happens with that review report?

After 20 April 2024, or in case the Commission takes a decision on the original authorisation application before that date, the review report submitted will become void. In view of this, and considering that submitter requested it, the review report will be treated as a new application for authorisation, submitted after the latest application date. This implies that the applicants and companies covered by the new application will not benefit from the transitional arrangements. As a consequence, if the Commission adopts a refusal of the initial application, the applicants need to wait until the adoption of a new authorisation decision to be allowed to use the substance again.

The ECHA opinion-making process is expected to start as of February 2024 submission window, which means that the process timeline would start in April 2024. The Commission will need to issue two separate decisions: one relating to the original (annulled) authorisation, and one relating to the new application.

8. What is happening with the Chemservice application for chromium trioxide in functional chrome plating with decorative character (use 3)?

The Commission has not yet taken a decision on the application for use 3 and use 1 as regards the formulation of mixtures for use 3. Following the judgment of the General Court in Case T-837/16, the Commission invited Chemservice to submit a substitution plan because there were indications that suitable alternatives are available in the Union. Chemservice submitted this substitution plan, which was assessed by SEAC that concluded it was not credible. The Commission received the related addendum to the opinion in July 2021.

Until a decision is taken on that application, all downstream users covered by the Chemservice use 3 application can continue to use chromium trioxide as the application is covered by the transitional arrangements as set out in Article 56(1)(d) of REACH.

9. 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).

RESTRICTION OF CR(VI) SUBSTANCES UNDER REACH

10. Will the Commission restrict Cr(VI) substances under REACH?

On 27 September 2023, the Commission sent a mandate ([2]) to ECHA, requesting the development of an Annex XV dossier with a view to restrict Cr(VI) substances under REACH. This is the first step in a multi-year process, aiming to improve the effectiveness and efficiency in regulating Cr(VI) substances in the EU.

11. Why does the Commission want a restriction on Cr(VI) substances?

Chromium trioxide (which contains Cr(VI)) and ten other Cr(VI) containing substances were added to the REACH authorisation list in 2013 and 2014 with a sunset date of 21 September 2017 or 22 January 2019. The number of applications for authorisation for the use of these substances has far exceeded the Commission's and ECHA's predictions. The current workload related to these applications goes significantly beyond the annual

([2]) https://echa.europa.eu/current-activities-on-restrictions

capacity of ECHA's two scientific committees, i.e. the Risk Assessment Committee (RAC), and the Socio-Economic Assessment Committee (SEAC), as well as the capacity of the Commission and the REACH Committee. The result is severe delays in the opinion-making by the ECHA's scientific committees and in the decision-making by the Commission.

Considering that authorisation decisions often impose additional risk management measures for the authorisation holders, and that in some cases a lack of suitable alternatives are not demonstrated, the delay in deciding on authorisations undermines one of the objectives of the REACH Regulation, i.e. the protection of human health and the environment. The situation also undermines one of the aims of the authorisation provisions, namely that substances of very high concern should be progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

Moreover, as regards the management of risk in a broader perspective, ECHA and the Commission are employing a significant share of their resources to process applications for authorisations for Cr(VI) substances, to the detriment of addressing risks from other hazardous substances in the EU. Furthermore, this situation negatively affects applicants who are waiting for decisions on their applications, affecting the level playing field.

The Commission services therefore considers that the current approach envisaged for regulating Cr(VI) substances through authorisations is no longer appropriate to control the risk to human health posed by these substances.

12. What is the timeline foreseen for the introduction of the restriction?

The Commission sent a mandate to ECHA on 27 September 2023, published in the Registry of Intention on 11 October 2023, giving ECHA 12 months to finalise the Annex XV dossier, in accordance with Article 69(4) of REACH. Once the conformity check on the dossier is done by RAC and SEAC, the committees have 9 and 12 months, respectively, to finalise their opinions. The final opinion will then be sent to the Commission, who will draft the amending regulation and present it to the Member States' representatives in the REACH Committee. After an opinion by the REACH Committee, the European Parliament and the Council have a three-month scrutiny period before the restriction can be finally adopted by the Commission.

In a **best-case scenario**, the Commission expects that a restriction could be adopted in approximately 3 years from the receipt of the mandate by ECHA.

13. What will be the scope of the restriction?

In the Commission's mandate, ECHA is requested to prepare an Annex XV dossier with a view to restrict at least two Cr(VI) substances, namely chromium trioxide and chromic acid (entries 16 and 17 in Annex XIV). As part of the restriction dossier preparation, ECHA is requested to assess whether limiting the scope to those two substances only could lead to regrettable substitution with other Cr(VI) substances that would not be subject to the restriction. The scope of the Annex XV dossier may be extended to other Cr(VI) substances if ECHA concludes that this is necessary to prevent regrettable substitution.

The scope of the assessment will cover all uses of the substances, in analogy with the uses covered by the authorisation obligation when substances are listed in Annex XIV.

ECHA has been requested to develop several restriction options in the Annex XV dossier with a view to finding the most appropriate one to control the risk from those substances, while encouraging substitution with alternatives.

14. How will the restriction take into consideration already granted authorisations?

As part of the mandate to ECHA, the Commission has requested a careful analysis of the existing authorisations, in particular the appropriateness and effectiveness of the risk management measures implemented to control the risk of the substances, including the corresponding available exposure and emissions data.

The restriction may include derogations with differentiated transitional periods for different uses depending on, e.g. the risk, socio-economic considerations, and availability of alternatives. However, those derogations may not necessarily reflect granted authorisations in terms of timing and/or scope.

15. How will this exercise be carried out from a procedural perspective?

If a restriction will be the chosen way forward, the Commission would adopt two acts: the first amending Annex XIV in order to *'de-list'* the substances at stake (no uses of the substances will remain covered by the authorisation requirement); and the second amending Annex XVII, to introduce a restriction.

The two acts will need to enter into force simultaneously to avoid having a gap where the substances are not included in Annex XIV nor restricted under REACH.

16. How do the Commission and ECHA intend to manage authorisations and applications for authorisation of chromium trioxide, chromic acid (and other substances potentially in scope of the future restriction) in the period where the restriction is not yet adopted?

The current regulatory framework, i.e. REACH authorisation obligation, remains in place as long as the relevant substances are listed in Annex XIV. The submitted applications will continue to be evaluated by RAC and SEAC, who will issue opinions on those applications. The Commission will continue to prepare and present draft decisions to the Member States in the REACH committee and to adopt decisions on applications for authorisation.

The existing authorisation decisions and the relevant measures set out therein (e.g. conditions, deadlines for submitting review reports, etc.) will remain valid until the substances at stake are removed from Annex XIV, unless the expiry date of these authorisations falls before the 'de-listing'. Afterwards, the authorisation requirement will no longer apply to those substances, which will be regulated under the Restrictions Title (VIII) of REACH instead.

17. Is this exercise affecting actions under other pieces of EU legislation such as the Industrial Emissions Directive (IED) and Occupational Safety and Health (OSH)?

This exercise is without prejudice to ongoing actions under other pieces of EU legislation applicable to the uses of Cr(VI) substances at stake, such as IED or OSH. For instance, discussions are ongoing on the possibility to lower the binding occupational exposure limit for Cr(VI).