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

DIRECTORATE-GENERAL FOR ENVIRONMENT

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Questions & Answers

TOWARDS A RESTRICTION OF CR(VI) SUBSTANCES UNDER REACH

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

On 27 September 2023, the Commission sent a mandate ([1]) 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.

2. 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 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 is 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.

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

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 consider 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.

3. 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. The initial mandate was revised on 29 April 2024 ([2]) to extend the scope and adapt the relevant timing (from 12 to 18 months due to the additional work required). 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 a positive 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, i.e., by the end of 2026.

4. What will be the scope of the restriction?

In its mandate, the Commission initially requested ECHA 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 was requested to assess whether limiting the scope to only those two substances could lead to regrettable substitution with other Cr(VI) substances that would not be subject to the restriction.

The preliminary work so far by ECHA already confirmed such risk of regrettable substitution, and also pointed to enforceability considerations (in case of a restriction limited to entries 16 and 17). The Commission has therefore amended the initial mandate (see question 3) and extended the scope of the restriction dossier to all Cr(VI) substances listed in Annex XIV, except the lead chromates (entries 10 to 12), as the latter are not likely to be used as alternatives for chromium trioxide and chromic acid.

([2]) https://echa.europa.eu/fr/-/restriction-proposal-on-chromium-vi-to-cover-more-substances

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.

5. 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.

6. 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.

7. How do the Commission and ECHA intend to manage authorisations and applications for authorisation of the chromium(VI) 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.

8. 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).