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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])

1. 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 several 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.

Such delays do not further the objectives of the REACH Regulation, i.e. the protection of human health and the environment, and also may impede one of the aims of the authorisation provisions, namely that substances of very high concern

([1]) This document is prepared by the Commission services, in the interests of transparency, in relation to policy proposals or initiatives that are still under discussion and consideration within the Commission. The understandings, intentions, initiatives and ideas described herein may hence change, even entirely, over the course of the decision-making process. This document, prepared at technical level, has not been adopted or endorsed by the European Commission, and views expressed herein therefore do not necessarily reflect its views. This document does not seek or intend to interpret Union law, and it is not legally binding; only the Court of Justice of the European Union may provide authoritative interpretations of Union law.

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

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, it is sub-optimal for ECHA and the Commission to employ 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 may also negatively affect applicants that are waiting for decisions on their applications.

For those reasons, the Commission services are considering a different approach to appropriately 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 ([3]) to extend the scope and adapt the relevant timing (from 12 to 18 months due to the additional work required). Accordingly, ECHA has developed an Annex XV dossier, including organising two Calls for Evidence, and has published that dossier on 30 April 2025.

The Annex XV dossier can be found at the following link: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18971243a

As the conformity check on the dossier was done by RAC and SEAC (in June 2025), the committees have 9 and 12 months, respectively, to finalise their opinions on the Annex XV dossier.

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 by end-2027/beginning 2028.

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 of a possible restriction of 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

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

substitution with other Cr(VI) substances that would not be subject to the restriction.

The preliminary work that was done by ECHA had confirmed such risk of regrettable substitution and also pointed to enforceability considerations (in case of a restriction limited to the substances in entries 16 and 17 of Annex XIV). The Commission has therefore amended the initial mandate (see question 3) and extended the scope of the mandate 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. In addition, ECHA identified one Cr(VI) substance (barium chromate) that is not listed in REACH Annex XIV, but that could be used as a regrettable substitute.

The scope of the assessment now covers entries 16-22 and 28-31 in Annex XIV and barium chromate, including all their uses covered by the authorisation obligation when substances are listed in Annex XIV.

ECHA developed 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.

Restrictions, in principle, may include derogations depending on different factors and those derogations may also have differentiated transitional periods depending on e.g., the risk and socio-economic considerations, including availability of alternatives. Nevertheless, overall, the Commission needs to consider the RAC and SEAC opinions. Should there be derogations in this case, they may not necessarily reflect granted authorisations in terms of timing and/or scope.

Without prejudice to the outcome of the opinion-making process, substitution elements will need to be considered for the potential restriction.

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 application simultaneously to avoid having a gap where the substances are neither included in Annex XIV nor restricted under REACH. The entry into application date is the moment where the acts will deploy their effects, i.e. i) removal from Annex XIV and ii) inclusion in Annex XVII, i.e. restriction.

The current regulatory framework remains unchanged until the restriction enters into application, i.e. the existing authorisation decisions and the measures set out therein (e.g. conditions, deadlines for submitting review reports, etc.) will remain valid until that date.

It is likely that the date of the entry into application of the acts may be deferred as compared with their date of entry into force, to allow the necessary time to comply with the conditions included in the restriction; e.g. ECHA's proposal foresees 18 months for such transition.

7. How do the Commission and ECHA intend to manage applications for authorisation and review reports for chromium(VI) substances that are pending or that are submitted in the period until the restriction is adopted (estimated best scenario: end 2027/beginning 2028)?

When it comes to pending applications/review reports and future applications/review reports to be submitted in the period until the date of entry into force of the restriction, it is very unlikely that these can be fully processed before that date. This is because it takes approximately two years in total, for ECHA's scientific committees to develop their opinions and for the Commission to complete their decision-making process. Even if some decisions were to be adopted by the Commission in 2027, they would have very short period of validity (see considerations under question 9).

Against this background, to avoid inefficient and ineffective allocation of resources and taking into account the principles of good administration, the following actions will be taken during the upcoming period prior to the entry into force of the restriction:

a) all applications for authorisations/review reports for which the opinion-making of the ECHA scientific committees has started will be continued and the related opinions issued.
   ECHA will prioritise i) applications for authorisation/review reports for substances other than Cr(VI), as well as ii) applications for authorisation for new uses or new users of Cr(VI) substances which are not covered by any existing authorisation decision or any existing authorisation applications or review reports benefiting from the transitional arrangements set out in Article 58(1)(c) of REACH; this is to avoid any risk of market access disruption.
   This prioritisation implies that, until the outcome of the restriction procedure is known, i) new Cr(VI) applications for authorisation, as well as ii) Cr(VI) applications/review reports that have already been submitted but not yet been processed (i.e. for which no invoice has yet been sent by ECHA), **will most likely not be processed anymore by ECHA** before the entry into force of the restriction. ECHA will individually contact the operators concerned to inform them of the status of their pending application or review report.
   Therefore, operators submitting new applications for authorisation for Cr(VI) substances need to be mindful that it is very unlikely that the

processing of such applications will be initiated by ECHA and finalised by the Commission before the entry into force of the restriction.

b) The Commission will adopt by Q1 2026 a Decision **extending the deadlines for submission of all review reports ([4])** falling during the upcoming 3-year period, by amending all relevant authorisations in force. Such extension will be granted until a date (1 January 2029) beyond a more conservative estimate of the date of the entry into force of the restriction (Q4 2028, accounting for around one-year delay as compared with the optimistic scenario, see question 3).
This would avoid the submission of review reports that are very unlikely to be processed or the processing of which will not even be started before the restriction enters into force.
Obviously, that extension will also be reflected in all future authorisation decisions to be adopted after the entry into force of the amending decision (the extension act).
The Commission will closely follow the timing of the restriction process and, if justified, will propose a further extension of authorisations' review periods according to the revised timelines by means of a new act amending the relevant decisions.

8. Does this exercise affect actions under other pieces of EU legislation such as the Industrial Emissions Directive (IED) and Occupational Safety and Health (OSH) acts?

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 already ongoing in the OSH regulatory area on the possibility to lower the binding occupational exposure limit for Cr(VI). To prevent unnecessary administrative burden and facilitate enforcement, the Commission, as a starting point, will aim to align limit values in the REACH restriction with the OEL under OSH legislation but may propose deviations in well-defined and well-justified cases. This is without prejudice to the outcome of the ongoing opinion-making process and the future discussion at the REACH Committee.

9. What will be the fate of authorisation decisions that are still valid at the time of entry into force of the restriction?

While the ECHA opinion-making on the restriction is still ongoing, and without prejudice to its outcome, the Commission services can already share several early considerations on this matter, still at an early stage.

As explained, among others, in question 6, after the delisting of Cr(VI) substances from Annex XIV, the authorisation requirement (and hence the decisions) will no

([4]) This decision is undergoing the adoption phase and can be found in the relevant page of the comitology register: D110533/02 - Comitology Register

longer apply to those substances, that will be regulated under the Title VIII (restrictions) instead.

In this view, one possibility under consideration is for holders of an authorisation valid at the time of entry into force of the restriction, to benefit from an elective system giving them the choice to be covered by the provisions set out in their authorisation, or, alternatively, to be subject to those under the new restriction. That system, whose details are still under discussion, can only apply temporarily (with a time-limited validity of e.g. 18 months – to be determined) and it would not be conceived to cover review periods whose duration goes beyond that time-limited transition.

10. Will there be any reimbursement of the application fees already paid?

The Commission services and ECHA are discussing this question, hence the considerations expressed below are only initial. As general principle, fees are allotted to an activity carried out by the Agency under a given regulatory framework and they are not linked to an application being successful or rejected, or to a decision adopted on it. The underlying concept is that a fee is linked to and compensates for performing a concrete task.

Therefore, assuming that the fee has been paid, there may be different scenarios at the date of entry into force of the restriction, depending, in particular, on the stage of RAC and SEAC opinion making i.e. whether such process has started, and if not, which stage has been reached. In other words, a full fee refund may be envisaged if the opinion-making process has not been initiated at all.