



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

Brussels
 GROW.F.1/AS/nt
 grow.f.1(2023)9570727

**NOTE FOR THE ATTENTION OF
 DR S. MCGUINNESS, EXECUTIVE DIRECTOR ECHA**

Subject: Request to the European Chemicals Agency to prepare an Annex XV restriction dossier on certain chromium (VI) substances

1. BACKGROUND

Eleven Cr(VI) substances were added to Annex XIV ⁽¹⁾ in 2013 and 2014 with a sunset date of 21 September 2017 or 22 January 2019. Those substances are ‘*non-threshold substances*’ with harmonised classification as carcinogenic (1A or 1B) and exposure to them constitutes a risk to workers as well as, when exposed via the environment, to the general population.

The number of applications for authorisation for the use of these Cr(VI) substances has far exceeded the predictions at the time of inclusion of the substances in Annex XIV, and the current workload related to these applications goes significantly beyond the annual capacity of RAC and SEAC. This is causing severe delays in the opinion-making by those committees and in the decision-making by the Commission.

This situation undermines one of the objectives of the REACH Regulation, i.e. protection of human health and the environment, due to, among others, the delays in the implementation of additional risk management measures recommended by RAC for authorisations to be granted, improving the protection of workers and members of the general population exposed to Cr(VI) substances, or in setting specific limitations to the authorised uses (e.g. in terms of tonnage, scope of the use). The situation also undermines one of the aims of the authorisation provisions, namely that such substances 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

⁽¹⁾ Substances covered by entries 16-22 and 28-31 of Annex XIV.

hazardous substances in the Union. Furthermore, this situation negatively affects applicants who are waiting for decisions on their applications, affecting the level playing field.

We therefore consider that the approach envisaged for regulating Cr(VI) substances is no longer appropriate to control the risk to human health posed by these substances.

2. MANDATE

In view of the above, and in accordance with Article 69(1) of REACH, we would like to request ECHA to prepare a dossier in line with the requirements of Annex XV in view of a possible restriction of at least two Cr(VI) substances:

- **Chromium trioxide** (entry 16 in Annex XIV) is the Cr(VI) substance that generates the vast majority of applications for authorisation and must be included in the scope of the restriction.
- **Chromic acid** (entry 17 in Annex XIV) is a group of acids generated from chromium trioxide and substitution from chromium trioxide to chromic acid is therefore relatively easy. To avoid regrettable substitution, entry 17 needs to be included in the scope of the restriction proposal as well.

As part of the restriction dossier preparation, ECHA is requested to carry out a short analysis of the availability of alternatives, and assess whether the scope should be limited to chromium trioxide and chromic acid only by analysing the potential risk of regrettable substitution to other Cr(VI) substances that would not be subject to the restriction. Once the analysis is finalised, the final scope of the Annex XV dossier may be extended to other Cr(VI) substances.

The potential restriction of those substances would enter into force at the same time of their *de-listing* from Annex XIV, replacing the current authorisation requirements.

ECHA is further requested to include and assess several restriction options in the Annex XV dossier, with a view of finding the most appropriate one to adequately control the risk from those substances, while encouraging substitution to alternatives.

During the preparation of the Annex XV dossier, information should be gathered on the risk to workers as well as members of the general population via the environment. This includes, but is not limited to, carrying out a careful analysis of granted authorisations as well as processed and pending applications for 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 potential role and limitations of human biomonitoring as well as the interplay with risk management measures from other pieces of legislation, e.g. Occupational Safety and Health (OSH) (limit values) and Industrial Emissions Directive (IED) (best practices), including the on-going review of the Best Available Technique Reference Document (BREF) for plastic and metal surface treatment.

Socio-economic considerations, such as the availability of alternative substances and technologies and their technical performance, potential risks, costs, EU competitiveness, as well as the impacts of a potential restriction on sustainability and waste streams should also be part of the Annex XV dossier.

3. TIMING

The relevant intention into the Registry of Intentions should be entered no later than one month after receiving this letter. Moreover, we invite ECHA to complete the Annex XV dossier within 12 months from entering the relevant intention and initiate the restriction process, should the dossier demonstrate that the restriction is the most appropriate EU-wide measure in the light of the considerations made above.

Furthermore, we would request ECHA to keep the Commission regularly informed on the progress of the development of the restriction dossier. We would appreciate receiving a confirmatory letter that our request has been accepted.

(e-signed)
Kristin SCHREIBER
DG Internal Market, Industry,
Entrepreneurship and SMEs

(e-signed)
Aurel CIOBANU-DORDEA
DG Environment