chemical watch news & insight

by enhesa.

Hexavalent chromium compounds: What have we learned from ten years of the EU's authorisation requirement?

With a restriction proposal under development, Bernadette Quinn, head of REACHLaw's authorisation practice, unpicks key challenges facing authorisation, including duplication of existing OSH law and a need for a more holistic approach to substitution

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It is now more than ten years since entries for certain hexavalent chromium compounds were included on the REACH authorisation list. The listing meant that only authorised uses of these chemicals would be allowed after the 'sunset date' given in the entry, unless otherwise exempted. Most entries had sunset dates in 2017.

The first wave of authorisation applications was submitted between 2015 and 2016. However, the type and volume of authorisation applications received tested, and ultimately broke, the authorisation application process. The long delay in processing the flagship upstream application submitted for certain uses of chromium trioxide, and the annulment of the authorisation decision when it was finally adopted, triggered the submission of hundreds of individual applications that have overwhelmed the process. Last year, the European Commission issued a mandate to ECHA to prepare a restriction proposal for these chemicals. The Commission has stated that it intends to remove all entries for hexavalent chromium (Cr6) compounds from the authorisation list once the restriction is adopted.

The restriction proposal is currently under development and a public consultation on the proposal will be launched in April 2025. The scope of the restriction is not yet known, but

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indications at the moment are that it may include an OELV – the term used by ECHA is 'scientific limit value'. The limit value proposed may be very low. ECHA's call for evidence requested information from users on the costs associated with compliance with values ranging from 5 to 0.01µg/m^3 (8h TWA). In terms of timing, the ECHA committees' opinion on the proposal should be issued to the Commission in late 2026 and the Commission should adopt a decision between 2027-2028. Entry into force will depend on the specifics of the adopted restriction (scope, exemptions, derogations, etc).

Until the adoption of the restriction we will be in a 'twilight zone' situation where authorisation is still a legal requirement and users must continue to apply for authorisation, submitted applications must be assessed, and authorisations granted or refused. However, once the restriction is adopted and the entries removed from the authorisation list, the status of pending applications and granted authorisations is in principle void unless provisions are made for these parties.

It is an extraordinary, and unsatisfying, situation for all parties involved in the process.

Authorisation has evolved into a tool to protect human health and the environment

The Commission Q&A on its mandate to ECHA states that one of the motivators for the planned change in regulatory risk management measures was that delays in decision making on pending authorisation applications were undermining the objective of REACH to protect human health and the environment.

[...] Considering that authorisation decisions often impose additional risk management measures for the authorisation holders, [...], the delay in deciding on authorisations undermines one of the objectives of the REACH Regulation, ie the protection of human health and the environment. [...]

The authorisation requirement was intended to stimulate substitution of these chemicals to alternatives that are safer, leading to an eventual phase out. However, it is now apparent that authorisation is also being used as a means to improve risk management measures and minimise occupational exposure.

Looking across committee opinions and Commission decisions on the submitted applications, we see statements that the risk management measures and operational conditions described in applications are not appropriate or effective in limiting the health risk to workers. A long list of additional conditions and monitoring arrangements are imposed in authorisation decisions with the aim of contributing to the improvement of the risk management measures in order to minimise occupational exposure to hexavalent chromium.

In the recitals of Commission authorisation decisions, there is standard text that states that the conditions and monitoring arrangements imposed do not affect the obligation on use sites to comply with the provisions of the existing occupational safety and health (OSH) legislation. However, rather than affecting obligations, the issue is more that they duplicate them.

Duplication of existing OSH legislation for hexavalent chromium compounds

There is already extensive, and stringent, national OSH legislation in place across the EU, coming from the national transposition of EU directives.

Hexavalent chromium compounds are listed in the carcinogens, mutagens or reprotoxic substances directive 2004/37/EC (CMRD)) as substances with specific binding OELVs to minimise workers' exposure. As of the first amendment to the CMRD in 2017, the binding OELV is 0.005mg/m^3 (5µg/m^3) in air. There is a transitional period to 2025 where the binding OELV is temporarily set at 0.01mg/m^3 (0.025mg/m^3 for certain industries like welding and plasma cutting), but by 17 January 2025, all sectors must comply with the stricter limit of 0.005mg/m^3.

The CMRD sets stringent requirements for the risk management measures that must be in place at sites where hexavalent chromium compounds are used. These are summarised below:

- risk assessment – employers have a duty to perform a risk assessment for any task that may involve exposure to Cr6;
- substitution – employers are required to investigate alternatives to hexavalent chromium wherever technically feasible;
- engineering controls – where substitution is not possible, employers must implement technical measures, such as local exhaust ventilation to capture fumes and dust, and closed systems for processes like electroplating;
- personal protective equipment (PPE) – when exposure cannot be entirely controlled by other means, workers must be provided with adequate PPE, such as respirators or protective clothing;
- health surveillance – workers exposed to Cr6 must undergo regular health surveillance, including periodic medical examinations, to detect early signs of respiratory issues or other health effects related to Cr6 exposure. Workers with health conditions linked to Cr6 exposure, such as chronic respiratory diseases, should be removed from further exposure and provided with suitable alternative work; and
- monitoring and control – employers are required to monitor Cr6 levels in workplace air and ensure they stay below the set OEL. This includes regular air sampling and ensuring that workplace ventilation systems function properly. Records of exposure levels and health surveillance must be maintained over a long period due to the latency of cancer associated with Cr6.

Each EU member state is responsible for implementing the CMRD into national laws, and ensuring enforcement through labour inspections and non-compliance penalties. Once the CMRD is part of national legislation, employers in each member state must comply with the rules.

From the above list of CMRD provisions, it is evident that the conditions and monitoring arrangements imposed in Commission authorisation decisions are generally the same as existing requirements under national OSH legislation in each member state. It is evident that the assessment of operating conditions and risk management measures in authorisation applications was done without reference to the existing very stringent requirements under national legislation for workplaces where carcinogens are used.

The duplication between OSH legislation and REACH will continue if the alternative risk management measure now being proposed (restriction) includes an occupational exposure limit value. In June this year, hexavalent chromium compounds were included on the list of 'immediate priority substances under CMRD' for an update to the current binding OELV in the opinion of the Advisory Committee on Safety and Health at Work (ACSH). The ASCSH recommends that the Commission assesses the feasibility of adopting a limit value of 1µg/m^3. Given that there is a binding OELV in place and a recommendation that it be updated via the processes in place under the CMRD, it is not clear why the restriction would need to include an OELV.

A REACH restriction that includes a scientific limit value (an OELV by a different name) will duplicate the existing binding OELV in place for hexavalent chromium compounds in annex III of the CMRD.

Authorisation as a tool to stimulate substitution to (safer) alternatives

The other motivator given in the Commission Q&A for their change in risk management measures from authorisation to restriction refers to 'suitable' alternatives:

Considering [...] that in some cases a lack of suitable alternatives is not demonstrated [...] 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.

In its ruling on the appeal against the lead chromate authorisation (Case T-837/16), the General Court clarified that a suitable alternative should be safer, ie its use should represent a lower risk to human health and/or the environment as compared to the risk of using authorisation listed chemicals.

The aim of the authorisation requirement is, ultimately, to phase out use of these chemicals to safer alternatives. However, the current application process does not include an assessment of the safety of alternatives. Applicants typically demonstrate that potential alternatives are not technically and/or economically feasible, meaning there is no requirement to assess availability or safety of potential alternatives. If information on safety is provided in an application, it is not assessed by the ECHA committees with the rationale that the assessment is not necessary, as the alternatives were not technically or economically feasible for the applicant.

This is logical as the purpose of the application is to request permission to continue use of hexavalent chromium compounds, so the focus is, correctly, on the safety assessment of the use of these chemicals.

"There is no safety assessment available that would demonstrate that trivalent chrome plating systems are 'safer' alternatives to hexavalent chrome plating systems"

The Commission introduced the concept of 'suitable alternatives generally available' (SAGA) following the 2019 annulment of the lead chromate authorisation by the General Court in Case T-837/16. Since 2020, applicants are required to submit a substitution plan when it is considered that suitable alternatives are generally available. However the implementation has been challenging as one of the requirements of a SAGA is that it is 'safer', consistent with the aim of the authorisation requirement. However, no assessment of the 'safety' of alternatives that are considered to be 'generally available' is done by applicants, by alternatives providers, by the ECHA committees or by the Commission. This means it is not possible to conclude that an alternative is safer.

A good example of this challenge is trivalent chrome plating systems. The ECHA committees, the Commission and, in some cases, the applicants themselves have concluded this is a SAGA for decorative chrome plating. However, there is no safety assessment available that would demonstrate that trivalent chrome plating systems are 'safer' alternatives to hexavalent chrome plating systems. It is also not clear

what should be taken into account in the safety assessment. Should it be solely the intrinsic properties or the risk coming from the use? If the safety assessment is solely the intrinsic properties, then an alternative that requires the use of chemicals with SVHC status could not be considered safer. If the safety assessment is based on risk considerations, then provided it can be demonstrated that exposure is minimised, the alternative may be safer irrespective of the intrinsic properties. In the former case, this would rule out trivalent plating systems that include boric acid. While in the latter, these systems could be deemed to be safer provided operating conditions and risk management measures are in place to minimise exposure. The challenge with the latter is that the same case can be built for the continued use of hexavalent chromium compounds.

An open question is whether the authorisation requirement is simply stimulating substitution to alternatives that are technically, and economically, feasible without a critical assessment of their 'safety'.

The Commission's Chemical Strategy for Sustainability introduced the 'safe and sustainable by design' (SsbD) concept. It sets out the vision for chemicals that are safe for humans and the environment across their entire life cycle. The Commission's Joint Research Center (JRC) has published a framework for SSbD that outlines the methodology for identifying and assessing chemicals and products based on safety, sustainability, and life cycle considerations. The SSbD concept is being actively promoted through EU research and innovation programmes, such as Horizon Europe. There are ongoing funded projects that aim to develop new materials, chemicals and technologies based on SSbD principles.

At the moment, there is no cross-talk between the substitution requirement under REACH authorisation and the SSbD framework. Note that based on the current framework in testing by the JRC, chemicals classified as reproductive toxins (like boric acid Repr. 1B) would not be considered 'safer' and it would be screened out from the start.

A decade of REACH authorisation has shown that substitution of hexavalent chromium compounds to alternatives that are 'safer' will require a more holistic approach than simply an authorisation requirement or ban on use in a restriction.

FURTHER INFORMATION

Restriction proposal for certain CrVI compounds - Commission Q&A →

CMRD →

ACSH Opinion on priority chemicals for new or revised OELVs under EU OSH legislation →

Commission note on 'Suitable alternatives generally available' →

General Court judgment in Case T-837/16 Kingdom of Sweden v European Commission →

Restriction proposal →

Safe and sustainable by design Commission recommendation →

Designing safer chemicals - methodological guidance →