



## How EU and UK REACH authorisation is diverging in implementation

The first UK agency opinions for applications submitted under the UK REACH authorisation process show marked divergence from comparable applications processed under EU REACH says Bernadette Quinn of REACHLaw

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The EU REACH authorisation process has been running now for ten years and its implementation has been shaped by both the applications received and court rulings on specific applications, in particular the annulment of authorisations granted for [uses of lead chromate in paints](#) and [uses of chromium trioxide for surface treatment](#). The high numbers of applications received for two groups of chemicals, chromium trioxide (entry 16) and the detergents octyl- and nonyl-phenol ethoxylates (OPnEO and NPnEO - entries 42 and 43), has led to very standardised assessment approaches, in particular relating to conditions imposed on users covered by granted authorisations.

Many readers may have expected the new UK REACH process to follow the lines taken, and the practice developed, under EU REACH - particularly since the UK Health and Safety Executive (HSE), the agency responsible for the process, has yet to issue its own guidance and advises applicants to follow EU guidance and templates. However, this has proved not to be the case. Already in its first opinions, the UK agency has diverged significantly from the approach taken for comparable applications already processed under the EU approach.

### Professional uses of OPnEO and NPnEO in end use of IVD devices

When UK REACH came into force on 1 January 2021, existing

authorisations granted under EU REACH were grandfathered into UK REACH and transitional arrangements were put in place for "in-flight" applications (those still under assessment in the EU process on the exit day). This meant the first set of applications assessed under the UK process included some already assessed under the EU process.

These included applications for professional uses of the detergents OPnEO and NPnEO in the end use of in vitro diagnostic (IVD) devices. At this point, applications for more than 100 similar IVD uses had already been assessed, under EU REACH, by ECHA's committees. In its assessment of the risk coming from releases of waste containing these detergents, the ECHA risk assessment committee said there is no acceptable safe amount that can be released to the environment. ECHA committee opinions recommended that conditions be imposed on all authorised users to collect all waste containing these detergents for treatment. The opinions stated that this treatment must minimise releases to environmental compartments as far as technically and practically feasible. Releases into the sewer system or to surface waters were specifically forbidden. European Commission decisions granting authorisation followed these recommendations.

In contrast, the UK agency, in its assessment of comparable

applications submitted under UK REACH, compared predicted environmental concentrations (PECs) resulting from the use with the environmental quality standards (EQSs) proposed for ethinylestradiol (EE2), an endocrine disruptor with the same estrogenic mode of action. As the PECs were below the EQS values, the agency opinions concluded that the residual emissions from the use would not result in discernible environmental impacts on wildlife in the receiving surface waters. No conditions to collect all waste for treatment were imposed on the authorised users in the decisions issued by the UK Secretary of State for Environment, Food and Rural Affairs.

It is hard to overstate the divergence between the approaches taken for the same uses. The requirement to [collect all wastewater containing the detergents](#), even at very low concentrations, was challenged by applicants under the EU process without success, and its implementation has meant that large volumes of wastewater containing trace amounts of the detergents are collected for incineration. Under the UK process, there is no such requirement on users covered by the authorisation.

### Chrome plating uses of chromium trioxide - the applications that broke the EU process

UK agency opinions are now also available for the first applications submitted under UK REACH for chrome plating uses of chromium trioxide. UK users were covered by existing EU authorisations grandfathered into UK REACH (functional chrome plating) or "in flight" at the time of the UK's exit from the EU (decorative chrome plating).

Applications for uses of chromium trioxide under EU REACH have broken the process, with successful appeals against granted authorisations for upstream applications triggering a wave of downstream applications that could, in principle, run to more than 1,000. These numbers far exceed the capacity of the current process and could generate a processing backlog running into years.

In response, in October 2023, the European Commission took the [one-off decision](#) to ask ECHA to prepare a restriction dossier with options to adequately control the risks of chromium trioxide and chromic acid to human health. The Commission has stated its intention to delist the two entries from the authorisation list once the restriction comes into force (estimated as 2028). In the meantime, in principle the EU process continues as normal.

The ECHA committees have, to date, processed more than 100 applications, with the majority submitted in the past two to three years. The approach taken in their assessment of these applications has developed over time to a standard set of conditions of use and monitoring arrangements that the

committees recommended be imposed on the sites of use to minimise the risk to human health (exposure to workers and the local population via emissions to environment).

The duration of the authorisation (the so-called "review period") recommended in ECHA committee opinions has also been decreasing as the committee view has evolved to the position that "technically and economically feasible alternatives are generally available" and that substitution can be achieved in a standard review period (seven years). Authorisations granted for decorative chrome plating uses for the sanitary sector generally expire at the end of 2028. Looking at recent ECHA committee opinions for functional chrome plating, the same trend is now evident for these applications.

### UK agency assessment of chrome plating applications

So how has the UK agency approached the assessment of these applications? We can see from the recent agency opinions that there is considerable divergence in the starting point for the assessment of the operating conditions and risk management measures in place at the sites of use.

In contrast to the assessment done under EU REACH, the assessment by the UK agency has explicitly taken into account existing national obligations under earlier transpositions of EU directives - that is, the Control of Substances Hazardous to Health (COSHH). The agency took these existing obligations as benchmarks in its assessment of the information submitted on the conditions of use and risk management measures in place at the sites of use. As chromium trioxide has an assigned workplace exposure level (WEL), its use is subject to the requirements of COSHH, meaning employers are required to prevent or control exposure. Control is defined as adequate only if (a) the principles of good control practice are applied, (b) the WEL is not exceeded and (c) exposure to CrO<sub>3</sub> is reduced to as low as is reasonably practicable.

In its assessment, the agency used a detailed checklist of the operating conditions and risk management measures it considers to be the minimum requirements that are capable of controlling Cr(VI) exposures from chrome plating operations to as low a level as is technically and practically possible. It said the checklist was based on:

- HSE guidance on controlling the risks from chrome plating operations with a note added that there have been regulations covering such operations since the 1930s;
- HSE Research Reports on plating operations;
- industry guidance on controlling the risks from chrome plating operations, in particular that from the Surface Engineering Association;

- the 45 years of professional experience of occupational hygiene practice in diverse industry sectors (including electroplating) of a member of the UK REACH team; and
- discussions with colleagues in other divisions within the HSE.

It gave traffic light ratings (red, amber, green) for the compliance of the site with these minimum requirements.

In both available opinions, the agency concluded that the applicant has in place the necessary operating conditions and risk management measures to minimise the exposures of employees to Cr(VI) to as low a level as is technically and practically possible, provided that each measure is used correctly, and that where appropriate it is maintained in full working order.

For the exposure assessment, the agency explicitly referred to the WEL value and used it as reference for the values reported by the applicants. This has not been done to date in the EU assessment by the ECHA committee.

For both applications, the agency did not recommend conditions of use or additional monitoring arrangements be imposed in the decision. The agency instead recommended that the applicant continue with its current monitoring arrangements with reference to existing obligations. This would be absolutely unprecedented for a comparable application submitted under the EU process where conditions of use and monitoring arrangements are recommended by default.

For the chrome plating use, the agency recommended the requested ten-year review period be granted. At the moment, the review period recommended in ECHA committee opinions in comparable applications under EU REACH is typically “to the end of 2028”.

### A sign of more divergence to come?

There are only two agency opinions for uses of chromium trioxide available on the UK HSE website so far. There are a number of joint downstream user applications under assessment and several upstream applications submitted by the aerospace and defence sector. The latter applications are ones to watch as identical applications have been submitted under EU and UK REACH. Based on the two opinions available to date, it is likely that the assessments of the same information will take different starting points - the UK will start with existing obligations under national legislation while the EU process will assess the applications without this benchmark.

Regarding the ongoing restriction proposal under EU REACH,

there is no indication so far that the UK executive will follow the approach taken by the European Commission. This may ultimately mean that post 2028, chromium trioxide and chromic acid uses will be subject to restriction and remain under the authorisation requirement in the UK.

### Some learnings from the UK agency assessment approach

The agency started from existing obligations under its own national legislation when assessing the risk from continued use. National legislation came from national transpositions of EU directives. This is more challenging for the EU process as national transpositions may be different from member state to member state. In addition, as the assessment is carried out by committee members nominated by each member state, a rapporteur from one member state may not be familiar with the implementation in another member state. It can also be that the standard default recommendations reflect the differing implementations of national legislation.

The UK agency approach demonstrates that there is already existing national legislation in place that should ensure that the risks to human health and the environment are adequately controlled. It is then an open question if REACH authorisation or restriction should be used as a tool to manage risks that are, in principle, already addressed under existing national legislation.

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### FURTHER INFORMATION

[EU REACH authorisation process →](#)

[UK REACH authorisation process →](#)

[European Commission mandate to Echa to prepare a restriction dossier for chromium trioxide and chromic acid →](#)

[Decisions on IVD uses of OPnEO and NPnEO under UK REACH →](#)

[Decisions on IVD uses of OPnEO and NPnEO under UK REACH →](#)

[UK Agency opinions on decorative chrome plating uses of chromium trioxide →](#)

[UK Agency opinions on decorative chrome plating uses of chromium trioxide →](#)

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