

ZVO Position Paper

Review periods for chromium trioxide approval applications, in particular so-called “upstream” applications (16.10.2018)

The use of chromium trioxide became subject to authorisation by inclusion in Annex XIV of REACH. The widespread use of a wide variety of applications in electroplating initially led to seeking higher-level so-called “upstream” applications for effective processing by the European Chemicals Agency ECHA (in accordance with Regulation (EC) No. 1907/2006 (REACH), Articles 62 (2) and 62 (3)) in dialogue with the European authorities. Well over one hundred individual applications would have presented barely surmountable challenges for the competent EU authorities.

In the meantime, the REACH committees have reversed their view of this. Despite this and in the best of faith, numerous collective applications that clearly describe actual real existing risks have been filed to date, involving immense time and effort, but which have been repeatedly complicated by enquiries and doubts lodged by the committee. Similarly, the limited options for substitution have been made abundantly clear for the technically informed reader. The lack of alternatives for the various uses of chromium trioxide was not refuted either in public consultations or in field tests.

In the meantime, the EU Commission has identified differences in the generalised application structure for individual applications initially favoured by the ECHA. As a result of the implementation of this application format, which was initially favoured by the opinion-forming authorities, the upstream consortia concerned can now expect to be given either an insufficiently short four-year review period, or no authorisation at all.

The companies are subject to intensive continuous monitoring, especially in Germany. Accident inspections, various IED inspections (pollution control, sewage, waste, etc.), exposure measurements by the employers' liability insurance associations, audits, etc. according to 9001:2015 or ISO 14000, external monitoring of safety management, self-monitoring by means of waste water and exhaust air measurements and company medical monitoring are just a few of the mechanisms that have reduced the risk of hazardous substances to almost zero for years. This has allowed authorities and companies to achieve the usual standard of living in industrialised countries without endangering people and the environment at excessive cost.

The ZVO complains that ECHA's learning processes obviously result in the preferential treatment of certain individual applications, whereas upstream and/or collective applications are generally granted short review periods. For companies, this means that the initial assessments and statements of the European authorities no longer apply and that in the future increasingly expensive individual applications will have to be lodged, which is something many medium-sized companies can hardly afford.

A blanket refusal of approval would be disproportionate, as it would incomprehensibly ban an entire industrial sector from the technical supply chains – and all because the initial recommendations of the European technical authority would have been respected and implemented.

The same applies for review periods shorter than seven years. Here it should be noted that the upcoming decision will be issued more than one year after the sunset date for chromium trioxide (September 2017), at which time it should have already become available. As a result, the companies will have much less lead time to submit a new application, as the deadline will no longer be extended after the review period. This is unacceptable given the fact that it will no longer be possible to make use of the previous application structure and a completely new authorisation application will have to be submitted. For small and medium-sized enterprises (SMEs) in particular, it will be virtually impossible to draft new applications within the time limit and in the prescribed manner.

It would not be possible or safe to substitute chromium trioxide in the areas for which approval has been requested; above all, its substitution has not been tested with regard to any other possible consequences (safety issues, resource use, long-term experience and guarantee commitments to customer industries, etc.). Experts in the sector could easily foresee this outcome. However, the opinion-forming committees sadly revealed no insight with regard to this matter, even when this was repeatedly clarified to them and refinements were made to applications following their numerous enquiries.

The ZVO feels that the current opinions of the committees (EU Commission and REACH Committee) would be more objective with greater insight (expertise) into the technical situation and the risk scenario. Lacking knowledge or understanding of regulatory authorities should not form the basis for decision making or tightening decrees. For clearly understandable and logical reasons, this is also laid down in the EU precautionary principle. Thus, *“the precautionary principle can be invoked when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective valuation, if this evaluation does not allow the risk to be determined with sufficient certainty”*.

ZVO urges the return to this rational, comprehensible justification of decisions or opinions based on facts and clear criteria and the opening of a dialogue with the concerned industry.

ZVO therefore explicitly requests that the German Federal Government protects German industry. In this context, the existing (above-mentioned) protective measures in chemicals regulation should be taken into account in the vote on collective applications for the use of chromium trioxide.

In particular, the Federal Government must prevent any changes in the European assessment criteria which will result in disadvantages for German industry and which may ultimately culminate in the loss of medium-sized enterprises.