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Subject: REACH authorisation and innovation, Follow-up of meeting Commission CHEMTrust 4th of June on chemicals strategy

Dear [REDACTED]

thank you again for the meeting on 4th of June and for your questions. Concerning the issues with the REACH authorisation procedure and its impacts on innovation, we would like to follow-up involving our colleagues from ChemSec, [REDACTED], who are in copy to this email. ChemSec is supporting REACH implementation since two decades and working closely with companies to foster the substitution of hazardous chemicals with safer alternatives.

Authorisation, a driver for innovation towards safer substances and technologies

The authorisation procedure is a new and modern instrument introduced by REACH. Its aim is to identify Substances of Very High Concern (SVHCs) and to progressively replace them by suitable alternative substances or technologies. SVHCs include substances that are carcinogenic, mutagenic and reprotoxic, or persistent, bioaccumulate and toxic as well as substances of equivalent levels of concerns like endocrine disruptors. SVHCs on Annex XIV of REACH are banned unless the Commission authorised a specific use, either because i) the risks are managed or ii) no suitable alternatives are available and the socioeconomic benefits outweigh the risk of use. The applicant for an authorisation has to provide the proof that above conditions, in particular that no safer alternatives are available, are met. If applied correctly, this approach

would give a clear direction and planning certainty for all parties and promote substitution and innovation towards safer alternatives. ChemSec is working with companies and experts to promote safer alternatives([How to find and analyse alternatives in the Authorisation Process](#)).

Implementation has gone wrong, protecting incumbents and frustrating alternative providers

So far the Commission has always granted authorisations to all applicants. It has done so systematically based on insufficient evidence provided by the applicants and a very narrow interpretation of what constitutes an “available alternative”, reducing it to substances which deliver identical performance like for example the shade of a colour. This systematic misapplication of the authorisation procedure has been exposed by the General Court judgment from 7th of March 2019 which annulled the Commission's decision to authorise a use of lead chromate in paints. Also the European Parliament issued several resolutions highlighting the same or similar problems, for example in the case of sodium dichromate 2018, chromium trioxide 2019 and DEHP 2019.

The current implementation of the authorisation procedure has damaged the market for alternative providers. Many of them are left disappointed after having planned to expand their operations anticipating a substitution, which then did not materialise.

The Commission can fix the problem and boost innovation

We believe the European Commission should change its approach to authorisation to deliver protection in line with the REACH requirements and to boost innovation for safer alternatives. The General Court's judgement provides guidance for necessary changes in the process: 1) the applicant for authorisation bears the risk of a possible impossibility to determine whether to conclude on the unavailability of alternatives and in case of remaining uncertainties the applicant has not met the burden of proof and cannot be granted an authorisation; and 2) the Commission cannot rely on conditions attached to the authorisation, like shorter review periods, to remedy deficiencies of the assessment.

In most cases this means that the Commissions will have to judge whether a safer alternative, which usually will have different performance characteristics, i.e. different shade of colour, is acceptable considering the economic (change in products and trade) and health and environmental impacts (deaths per year etc..). In case it is, the authorisation would not be granted and the innovation towards safer alternatives would effectively be rewarded.

Please do not hesitate to get back to us for any questions you may have.

Kind regards,



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