



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Consumer, Environmental and Health Technologies
Directorate-General for Environment
Circular Economy and Green Growth

Directors

Brussels,
GROW/D1/VB/nt
grow.ddg1.d.1(2017) 2087107

**NOTE FOR THE ATTENTION OF
MR G. DANCET, EXECUTIVE DIRECTOR, ECHA**

Subject: Request to the European Chemicals Agency to prepare a restriction proposal conforming to the requirements of Annex XV to REACH

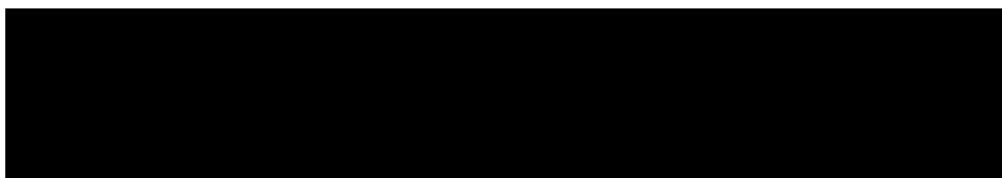
In accordance with Article 69 (1) of the REACH Regulation, we would like to request ECHA to prepare an Annex XV dossier in view of a possible restriction on five cobalt salts: cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate.

Background and justification for the request

The substances are classified as carcinogens (category 1B) and toxic for reproduction (category 1B) and have been identified as substances of very high concern and included in the candidate list. ECHA recommended the five cobalt salts for inclusion in Annex XIV to REACH in December 2011. In December 2012, the Commission requested ECHA to conduct an investigation on the uses of the five cobalt salts, considering that at least one of the uses (surface treatment) could pose a risk to human health that was not adequately controlled and might need to be addressed. When there are indications of uses that have a demonstrated risk according to Articles 69 (1) and 69 (4) of REACH, the Commission considers to initiate the restriction process as stated in the Roadmap for SVHC identification.

Therefore, the Commission did not propose the inclusion of the five cobalt salts in Annex XIV and asked ECHA to collect additional information on all their uses.

The Commission received a report from ECHA in July 2013, which identified uncertainties, in particular on the mode of action for the carcinogenicity effect of the five cobalt salts. In order to solve these uncertainties, ECHA commissioned an expert assessment on this specific endpoint, which was assessed by RAC, concluding that the five cobalt salts are genotoxic carcinogens via inhalation with a non-threshold mode of action.



In addition to the toxicological evaluation, ECHA sent in December 2016 an updated report to the Commission, including also information from the most recent update of the registration dossiers, specifically on uses and exposure. On the basis of the dose-response curve for the carcinogenicity effects and of the exposure data in the registration dossiers, ECHA concluded that exposure to the five cobalt salts in powder form (including granulate and dust) results in an excess lung cancer risk in the range of 10^{-3} to 10^{-2} (conservative approach).

On the basis of these conclusions, the first considerations of the Commission on the risk of the use of the five cobalt salts are confirmed and the Commission requests ECHA to start preparing an Annex XV dossier for all the uses of the five cobalt salts.

In considering all uses of the five cobalt salts, ECHA should identify those forms and uses for which the risk is not adequately controlled and address the identified risks through appropriate risk management measures which minimise the exposure to workers and professional users.

Timing

ECHA shall make the above conclusions public in the Public Activities Coordination Tool (PACT) by the end of April 2017 and shall enter the relevant intention for the five cobalt salts into the Registry of Intentions (RoI) by July 2017.

Within 12 months after the entry into the RoI, ECHA should communicate its conclusions to the Commission and initiate the restriction process, should the Annex XV dossier demonstrate that action on all or certain uses of the five cobalt salts is necessary on a Union-wide basis.

(e-signed)
Carlo Pettinelli
DG GROW

(e-signed)
Kestutis Sadauskas
DG ENV