

# ECHA PROPOSES A RESTRICTION ON FIVE COBALT SALTS<sup>1</sup>

## Summary

ECHA is proposing a restriction on the manufacturing, placing on the market and use of five cobalt salts: cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate), as substances on their own or in mixtures, in industrial and professional applications.

The public consultation on this proposed restriction will start on 19/12/2018 and ends on 19/06/2019. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome early comments, by 01/03/2019, to assist them in their opinion development.

## SUGGESTED RESTRICTION

### Scope

The proposal applies to the manufacture, placing on the market and use of the five cobalt salts as substances on their own or in mixtures in a concentration equal to or above 0.01% by weight in industrial and professional applications. According to the proposed restriction the cobalt salts cannot be manufactured, placed on the market or used unless a reference exposure value of 0.01 µg Co/m<sup>3</sup> is used in the registrations and downstream users' Chemical Safety Assessment and communicated through the Safety Data Sheet. Manufacturers and downstream users are required to implement a monitoring programme to demonstrate that all occupational exposures to the cobalt salts are below the reference exposure value of 0.01 µg Co/m<sup>3</sup>.

The use of the five cobalt salts as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003 on additives for use in animal nutrition is exempted from the restriction proposal.

### Reasons for action

The risk of developing cancer following occupational exposure to the cobalt salts is the main driver of the restriction. Workers are exposed to cobalt during the manufacture and use of the cobalt salts. Excess lifetime cancer risks levels above 10<sup>-5</sup> are encountered in all industrial sectors and activities related to the manufacture and use of the substances. Additionally, the exposure scenarios in the REACH registration dossiers do not take into account the non-threshold mode of action of the carcinogenic effect of the cobalt salts, as identified by RAC<sup>2</sup> in 2016, and as a result do not control or minimise the risks posed by the substances.

### Consequences of the action

The proposed restriction will result in a reduction in worker exposure levels and in the cancer risk and number of cancer cases resulting from occupational exposure to the cobalt

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<sup>1</sup> The information note has been prepared based on the Annex XV report prepared by ECHA.

<sup>2</sup> [https://echa.europa.eu/documents/10162/13563/rac\\_agreement\\_cobalt\\_salt\\_en.pdf/43762b12-5e8f-457a-9858-f5a4737c2e00](https://echa.europa.eu/documents/10162/13563/rac_agreement_cobalt_salt_en.pdf/43762b12-5e8f-457a-9858-f5a4737c2e00)

salts. It will lead to the implementation of adequate measures to control the risks from manufacture and use. It is estimated that around 35 000 workers at around 20 000 industrial sites are presently exposed to the cobalt salts. The reduction of risk in the EEA as a result of the proposed restriction is estimated to avoid around one occupational cancer case per year. Benefits of avoided cancer cases have been estimated to be in a range of € 3.8 million with an estimated cost to industry of € 370 million per year.

Although the cost related to the implementation of the restriction exceeds the benefits expected, the level of individual cancer risk encountered at the different sectors of manufacture and use of the cobalt salts require that adequate measures are implemented to decrease it.

### SPECIFIC INFORMATION REQUESTED

A few specific elements have been addressed in the Public Consultation to gather relevant information, if available, from stakeholders:

1. Do you have information regarding exposure at workplaces to the five cobalt salts in question?
  - a. What are workplace exposure levels, measured under the current conditions at your workplace / within your sector? If available, please provide us also with contextual information or study reports of the workplace measurements.
  - b. What risk management measures, including technical means (e.g. containment, LEV, technical general ventilation), workplace organisation (e.g. training of workers, certification systems) and personal measures (e.g. PPE, RPE), aiming at reduction of workplace exposure to cobalt salts, are already implemented at your workplace / within your sector?
  - c. Can you characterise the particle size distribution of the cobalt salts that are used at your workplace / within your sector? What is the ratio of the inhalable to the respirable fraction of the air-borne cobalt salts? Was this ratio derived by measurements? Can you describe these measurements?
2. Implementation of the restriction at workplaces:
  - a. What risk management measures aiming at reduction of workplace exposure to cobalt-salts are needed to achieve compliance with the proposed restriction, within the suggested time (24 months) at your workplace / within your sector? For answering this question, please keep in mind the hierarchy of controls. Is it possible at your workplace / within your sector to reduce the inhalation exposure to the foreseen reference level of  $0.01 \mu\text{g Co}/\text{m}^3$  by technical means (e.g. containment, LEV, technical general ventilation)?
  - b. Can you provide data on the measurability and monitorability of the proposed reference limit of  $0.01 \mu\text{g Co}/\text{m}^3$ ?
  - c. Do you foresee any challenges in the monitorability or enforceability of the proposed reference limit of  $0.01 \mu\text{g}/\text{m}^3$  at workplaces?
3. Do you have any further information on health hazards of cobalt salts?

- a. Do you know any new studies or assessments (not taken into account in the current restriction proposal) which might be important for the assessment of cancer risk caused by cobalt salts?
  - b. Do you have information on occupational asthmas or contact allergies caused by cobalt compounds? How many of these are caused specifically by the 5 cobalt salts covered in this restriction proposal (versus those caused by cobalt metal or other compounds)? Do you have information on the exposure levels that have resulted in asthma cases?
4. For the assessment of the restriction proposal, information is needed on how much exposure to these five cobalt salts account for the total exposure to cobalt (metal and compounds) in the EU.
  - a. Do you have information on how many workers in your country/sector are exposed to cobalt metal and compounds not covered by this restriction of five cobalt salts?
  - b. Is it possible to cover all the relevant (major) cobalt exposures under REACH or are there sources of cobalt exposures that cannot be covered under REACH but would possibly need to be covered under OSH legislation (e.g. by a BOELV set under CMD)?
5. The dossier gives an overview of the expected costs of the suggested restriction, i.e. of implementing the suggested reference exposure limit value of  $0.01 \mu\text{g Co}/\text{m}^3$  (Restriction option RO1d). However, the information is said to be from limited sources and difficult to verify. Do you consider the assessment of potential costs to industry as representative for companies affected? If not, what is, in your view, a representative cost estimate for your company/sector? Please provide information also on the cost estimates for the other restriction scenarios (such as RO1b, RO1c, etc.). Please provide sufficient evidence for your claim.
6. The suggested restriction is not a ban on using the substances, as they are understood to not have suitable alternatives for their respective uses, i.e. the substances are further allowed to be placed on the market and used. However, there are costs associated with the suggested restriction through implementing risk management measures in order to comply with the suggested reference exposure limit value of  $0.01 \mu\text{g Co}/\text{m}^3$ . Beside those costs, are there any other consequences for your business/sector? If yes, which ones? Please provide sufficient evidence for your claim.
7. The dossier states that currently, around 30 000 tonnes of the cobalt salts are used per year in the EU. Can you provide quantitative information on expected future changes in the consumption of cobalt salts? Please provide sufficient evidence for your claim.

### Comments preferably by 01/03/2019

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 19/12/2018. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 19/06/2019, the rapporteurs of

## PUBLIC CONSULTATION

RAC and SEAC would appreciate receiving comments by 01/03/2019 to assist them in the early stages of the opinion development process.

The final opinions of both Committees are scheduled to be available by December 2019. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

**Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance**

**[http://echa.europa.eu/documents/10162/13641/public\\_consultation\\_guidance\\_en.pdf](http://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf)**