



## EUROPEAN COMMISSION

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Resources based, manufacturing and Consumer goods Industries  
The Director

ENVIRONMENT DIRECTORATE-GENERAL  
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The Director

<b>ECHA</b>	<b>A/0433</b>
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Brussels, **21 DEC. 2012**  
ENTR/F1/VB/nt ARES(2012)

Mr Jack De Bruijn  
European Chemicals Agency  
Annankatu 18  
P.O. Box 400  
FI - 00121 Helsinki

**Subject:** Upcoming request to ECHA to prepare an Annex XV dossier on certain uses of cobalt salts under Regulation (EC) No 1907/2006 (REACH)

Dear Mr De Bruijn,

On 20 December 2011, ECHA recommended the following five cobalt salts for inclusion in Annex XIV:

- Cobalt sulphate
- Cobalt dichloride
- Cobalt dinitrate
- Cobalt carbonate
- Cobalt diacetate

The Commission, taking into consideration the ECHA recommendation, presented on the 21 November 2012 at the REACH Committee the draft Commission regulation amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH'). In recitals 11 and 12 of this draft Regulation, the Commission indicates that *"at least one of the uses of those substances (i.e. surface treatment) poses a risk to human health that is not adequately controlled and needs to be addressed. Therefore, in accordance with Article 69(1) of Regulation (EC) No 1907/2006, the Commission should ask the Agency to prepare a dossier in accordance with the requirements of Annex XV to that Regulation."* Indeed, according to ECHA's background documents for the cobalt salts, *"the main route of occupational exposure is via the respiratory track by inhalation of dusts, fumes and mists containing the substance. Workers exposure in industrial applications may be controlled in most instances, but there are uses, e.g. in surface*

*treatment, which include process steps with significant potential for exposure to dust, fumes and aerosols containing the substance".*

These elements lead the Commission to consider that the use of these cobalt salts in surface treatment poses a risk to workers' health that is not adequately controlled and might need to be addressed.

However, based on the information provided in ECHA's recommendation and its background document, as well as following an informal discussion between the Commission and ECHA services, it also appears that there might be additional uses which pose risks to human health that are not adequately controlled in the sense of Article 69(1), and therefore there is a need to investigate such uses before the Commission can decide whether to ask ECHA to include them within the scope of the Annex XV dossier.


Appendix I outlines a (non-exhaustive) list of uses which might be covered by the Annex XV dossier (section B) as well as some uses which, at a first evaluation by the Commission, are not expected to be included in the Annex XV dossier (section C). Appendices I – section A and II indicate which uses of the cobalt salts have to be covered by the Annex XV dossier.

Therefore, in order to facilitate and focus the work of ECHA for the development of the scope of an Annex XV dossier and to confirm the Commission's first considerations as described above, it was informally agreed between the Commission and ECHA services that ECHA will conduct a preliminary investigation using internal expertise to collect and evaluate all relevant information which is already available from the registration dossiers for the five cobalt salts. In parallel, ECHA should consider the launching of a targeted consultation with the main sectors of industry manufacturing or using cobalt salts for any of the additional specific uses, as listed in Appendix I to this letter. While collecting this additional information, ECHA should also assess if the scope of the Annex XV dossier should be extended to consider other cobalt salts.


We would welcome receiving your report of these preliminary investigations by mid-2013, whereupon, depending on the findings, the Commission will officially request ECHA to prepare an Annex XV dossier in accordance with Article 69(1) of REACH.

Wishing to continue our fruitful collaboration, our services will be available for any further clarification and discussion.

Yours sincerely,



Gwenole Cozigou  
DG Enterprise and Industry



Gustaaf Borchardt  
DG Environment

## Appendix I

### General description of the uses of cobalt salts

Information on volumes, as provided by the cobalt industry:

- Total production volume of **10.000** tons/year for the five salts
- **8.600** tons (**86%**) is used as intermediate

The Commission currently considers that intermediate uses do not pose a risk which is not adequately controlled and therefore there is no need to act according to Article 69(1) REACH.

Information on non-intermediate uses (~ 14%), as provided by the cobalt industry<sup>1</sup>:

Cobalt salt	Tonnage (tons/year)	Uses (tons/year)
Cobalt carbonate	~130 (2% of total)	Surface treatment: ~3 Animal feed: ~120
Cobalt dinitrate	~ 100 (10% of total)	Surface treatment: ~100 Corrosion prevention: ~1
Cobalt dichloride	~ 65 (2% of total)	Surface treatment: ~40 Medicinal products/biotechnologies/in vitro diagnostic: ~15 Corrosion prevention: ~5 Biogas/fertiliser: ~5 Animal feed: ~ 1 Humidity indicator card: ~0.5
Cobalt sulphate	~150 (5% of the total)	Surface treatment: ~115 Animal feed: ~25 Corrosion prevention: ~3
Cobalt diacetate	~ 700 (90% of the total)	Catalyst: ~600 Pigment in PET <sup>2</sup> : ~40 Surface treatment: ~30 Animal feed: ~ 7

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<sup>1</sup> Please notice that this information has not been independently verified

<sup>2</sup> Use being phased out, according to industry communication

## **Analysis of uses with regard to the possible inclusion in the scope of the Annex XV dossier:**

### **A - Uses that should be included in the Annex XV dossier (see Appendix 2 for more details):**

- Surface treatment
- Use of cobalt diacetate (mainly) as pigment for PET

### **B - Uses which might be included in the Annex XV dossier:**

The main objective should be to investigate if the following uses have a potential for workers' exposure to powders, fumes and aerosols of cobalt salts.

1. Use as a catalyst for the production of PTA/IPA/DMT (*mainly cobalt diacetate*):  
Cobalt diacetate has been reported to be used under the equivalent of strictly controlled conditions. It is apparently used only in liquid form.  
Since this use is limited to fewer than 10 sites within the EU, ECHA could investigate if only cobalt salts-containing solutions are used and if the use conditions show a potential for exposure of workers to fumes and aerosols. Additionally, ECHA should investigate the potential environmental releases of cobalt diacetate during this use.
2. Use in corrosion prevention/as an oxygen scavenger/in water treatment (*cobalt chloride, cobalt sulphate, cobalt nitrate*):  
Cobalt salts are used as oxidation catalysts to increase the speed of the oxygen scavenging reaction. Very low tonnages are reported for this use. Cobalt appears to be used in solution, under the specific concentration limit of 0.01%, in closed water systems.  
ECHA should seek to confirm whether this use only involves solutions with very low concentrations of cobalt, and whether the use conditions show a potential for exposure of workers to fumes and aerosols containing cobalt.
3. Use for animal feed and as fertiliser (*cobalt carbonate, cobalt dichloride, cobalt sulphate, cobalt diacetate*):  
Cobalt salts are added to soils and animal feed to correct deficiencies in vitamin B12. When added to the soil, cobalt is assimilated into plants and then made available to livestock.  
The Commission services will investigate whether and how sector specific legislation applies to these uses, and will transmit its findings to ECHA.  
ECHA should investigate in which forms (powder *or*. solution) cobalt salts are supplied to farms, and whether agricultural workers are exposed during normal conditions of use.
4. Use for biogas production (*cobalt sulphate, cobalt dichloride, cobalt acetate and cobalt carbonate*):  
Cobalt is an essential element in culture media for growing micro-organisms. Small amounts (in the order of grams) of cobalt salts are placed in sealed biodegradable bags directly into a substrate dosing unit of the biogas reactor in a

closed system. They can also be dosed in liquid form. Operators are reported to be trained to handle cobalt salts.

ECHA should investigate whether the use conditions show a potential for exposure of workers to cobalt-containing powders.

**C - Uses which, on first evaluation by the Commission, are not expected to be included within the scope of the Annex XV dossier, but for which Commission services are seeking ECHA's confirmation of its assumptions:**

1. Use in the biotechnology industry (cobalt dichloride)

Cobalt dichloride is used as a trace element in culture media to activate fermentation and enzyme processes. Very low tonnages are reported for this use, which occurs in laboratory settings, which are normally regarded as adequately controlled conditions. In light of this, it should be evaluated whether this use presents a risk that would require the Commission to act under Article 69(1).

2. Use in the pharmaceutical industry/in vitro diagnostic (mainly cobalt dichloride, but other salts can be used)

Cobalt is needed as an essential micronutrient for cell cultures in fermentation processes for industrial biomedical and laboratory operations. Very low tonnages are reported for this use, which occurs in laboratory settings, which are normally seen as adequately controlled conditions. In light of this, it should be evaluated whether this use presents a risk that would require the Commission to act under Article 69(1).

3. Humidity indicator cards (cobalt dichloride)

Cobalt dichloride is used in very low quantities in humidity indicators cards, which are used to indicate the presence of moisture in the military, aerospace and electronic/semiconductor industries. According to available information, a single company provides 90% of global production. Very low tonnages are reported for this use, which occurs in laboratory settings, which are normally seen as adequately controlled conditions. In light of this, it should be evaluated whether this use presents a risk that would require the Commission to act under Article 69(1).

## **Appendix II: Uses to be included in an Annex XV dossier for restriction**

### Use in surface treatment (all five substances)

The information on surface treatment use (~ 300 tons, 3%) as provided by the cobalt industry<sup>3</sup> is the following.

- Use of the different salts for surface treatment:
  - Metal/alloy plating: the most used salt is cobalt sulphate, with cobalt dichloride and cobalt diacetate use also reported; the reported use is 0.1-1 tonne/site/year; the salts are used both in solid form and in ready-to-use solution
  - Passivation: the most used salt is cobalt dinitrate (1-100 tonne/site/year), followed by cobalt sulphate (0.01-100 tonne/site/year) and cobalt dichloride (0.01-10 tonne/site/year); the salts are used in ready-to-use solutions

According to data collected by ECHA during the prioritisation process, use in surface treatment appears to lead to potential exposure to a significant number of workers and takes place at a large number of sites. The Commission therefore concludes that this use should be within the scope of the Annex XV dossier for restriction.

However, the following points could be investigated in view of the preparation of the Annex XV dossier:

- Should cobalt carbonate be excluded? There appears to be a very low tonnage used for surface treatment, probably because of the very low solubility.
- Are specific cobalt salts used for specific surface treatment processes?
- Are other cobalt salts used for surface treatment processes?
- In which forms are the cobalt salts used in the two main types of surface treatment: powder or solution form?
- Is the solution prepared in dedicated sites? At the cobalt manufacturers' sites?
- Is the risk limited to the powder form? Is there a possibility for exposure also with use in solution, because of the presence of aerosols?
- What is the degree of automatism of the two main types of surface treatment? Are there steps where manual handling is needed/more frequent?
- What is the status of the search for alternatives, especially in the passivation sector?
- Are individual Risk Management Measures (LEV, PPEs, etc) routinely used at the workplace? Are there sector-specific recommendations? Are RMMs indicated in the exposure scenarios applied? Would there be a need for harmonised RMMs at the EU level?
- Is the DNEL recommended by registrants implemented in surface treatment sites?

### Use as a pigment in PET (mainly cobalt diacetate)

According to industry, this use is currently being phased out. This use is therefore expected to be included in the Annex XV dossier for restriction for a total ban.

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<sup>3</sup> Results of a survey conducted by the Cobalt Development Institute among users of cobalt salts for surface treatment (March 2012). Please note that this information has not been independently verified.