Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on
cobalt sulphate; cobalt dinitrate; cobalt dichloride; cobalt carbonate; cobalt di(acetate)

IUPAC Name	EC/List number	CAS number
cobalt sulphate	233-334-2	10124-43-3
cobalt dichloride	231-589-4	7646-79-9
cobalt dinitrate	233-402-1	10141-05-6
cobalt carbonate	208-169-4	513-79-1
cobalt di(acetate)	200-755-8	71-48-7

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Preface

The preparation of this restriction dossier on five cobalt salts was initiated on the basis of Article 69(1) of the REACH Regulation on request of the Commission[1].

The proposal has been prepared using version 2 of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of annexes and appendices with more detailed information, analysis and detailed references that underpins the report.

This version of the report has been reviewed for confidential information and any such information has been redacted.

A number of editorials were made before the consultation to ensure the process was as efficient as possible.

[1] https://echa.europa.eu/documents/10162/13641/commissions_request_cobalt_salt_en.pdf/d21c5c69-9640-47c5-9b36-40060590c17a

Summary

The five cobalt salts (henceforth "the cobalt salts"): cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) are manufactured and used in a variety of sectors within the European Economic Area, including the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. Currently, around 30 000 tonnes of the cobalt salts are used per year in the EU with the highest amounts used as transported isolated intermediates for the manufacture of other chemicals.

The volumes placed on the EU market have doubled in the last ten years and the rise in demand is expected to continue at the same speed in the near future due to increasing demand of rechargeable batteries and biotechnology-health applications. At present, it is estimated that around 35 000 workers at around 20 000 industrial sites are exposed to the cobalt salts.

The cobalt salts are classified as Carc. 1B (inhalation), Muta. 2, Repr. 1B and skin and respiratory sensitisers. In 2016, RAC agreed that the cobalt salts should be considered as genotoxic carcinogens with a non-threshold mode of action and endorsed a dose-response relationship for these substances. However, in their REACH registration dossiers industry identifies the cobalt salts as non-genotoxic carcinogens with a threshold mode of action. A DNEL value of 40 µg Co/m^3 is used by the registrants in their Chemical Safety Assessments. According to the dose-response relationship derived by RAC, worklife exposure to this DNEL value corresponds to an excess lifetime cancer risk of 4 x 10^{-2}.

The Dossier Submitter has examined the occupational risks related to the manufacture and use of the cobalt salts and identified two reasons for concern:

1. The registration dossiers do not reflect the non-threshold carcinogenic nature of the cobalt salts. The current DNEL value used by the registrants in their exposure scenarios leads to the registrants significantly underestimating the risks at the workplaces.

2. The individual excess lifetime cancer risk levels for workers are above 10^{-5} in all industrial sectors and activities. The exposure data show that worker exposure is generally highest in activities involving the use of solid forms (powder, granules, etc.) of the cobalt salts and in activities such as electroplating where the use of electrical currents may generate aerosols.

Based on these findings, the Dossier Submitter has concluded that the risks arising from the manufacture and use of the cobalt salts are not adequately controlled in opposition to the registrants' Chemical Safety Assessments, and this issue needs to be addressed at the Union level.

The Dossier Submitter has identified the implementation of a reference exposure value to be used in the registrants' and downstream users' Chemical Safety Assessments (CSA) as the most appropriate measure to address the identified risks. This reference exposure value would have to be communicated to all actors in the supply chain through the extended Safety Data Sheet. Manufacturers and downstream users are required to demonstrate compliance with the reference exposure values to ensure an effective implementation of the restriction. Reference exposure values provide some flexibility to industry to identify and implement adequate measures to control the risks and will require monitoring arrangements to ensure that the implementation is effective in reducing the risks to a required level.

Four reference exposure values were assessed: 10 µg Co/m^3 (RO1a), 1 µg Co/m^3 (RO1b), 0.1 µg Co/m^3 (RO1c) and 0.01 µg Co/m^3 (RO1d). All options include a possible derogation for the

use of the cobalt salts as an additive in feedingstuffs within the scope of the Regulation (EC) No 1831/2003 on additives for use in animal nutrition. Table 1 gives a concise summary of the results of the assessment of these four restriction options.

Table 1: Results of the assessment of four restriction options

Option	Ambition level of risk control	Individual excess lifetime cancer risk (ELR)	Estimated number of affected workers (`000)	Estimated avoided cancer cases per year	Estimated annual benefits (€m)	Estimated annual costs (€m)
Reference exposure level						
RO1a	10 µg/m^3	10^{-2}	0.3	0.05	0.2	0.003
RO1b	1 µg/m^3	10^{-3}	8.4	0.48	1.8	2.8
RO1c	0.1 µg/m^3	10^{-4}	15.2	1.02	3.8	260
RO1d	0.01 µg/m^3	10^{-5}	18.9	1.04	3.8	370

Notes: €m= million euros

The effectiveness, practicality and monitorability of each restriction option is assessed and presented in the dossier. Other restriction options based on the implementation of technical measures to control exposure (RO2a, RO2b, RO2c, RO2d) have also been assessed by the Dossier Submitter but were discarded.

The aim of this restriction is to decrease the individual excess cancer risk levels and resulting cancer cases arising from occupational exposure to the cobalt salts via inhalation. According to the ECHA Guidance[2], "the decision point for 'acceptable' lifetime (i.e., a working life of 40 years) cancer risk levels used for workers are generally around 10^{-5} but higher or lower levels have been considered to be tolerable under certain circumstances". Based on this guidance and the assessment performed, the Dossier Submitter concludes that a reference exposure value of 0.01 µg/m^3 is the most appropriate Union-wide measure to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts.

[2] ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (ECHA, 2012)

Proposed restriction

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Cobalt sulphate CAS no 10124-43-3 EC no 233-334-2 Cobalt dichloride CAS no 7646-79-9 EC no 231-589-4 Cobalt dinitrate CAS no 10141-05-6 EC no 233-402-1 Cobalt carbonate CAS no 513-79-1 EC no 208-169-4 Cobalt di(acetate) CAS no 71-48-7 EC no 200-755-8	1) Shall not be manufactured, placed on the market or used as substances on their own or in mixtures in a concentration equal to or above 0.01% by weight, unless: a) if required by article 14 of REACH, registrants have carried out in their Chemical Safety Assessment an assessment according to paragraph 6.5 of Annex I of REACH and have used a reference exposure value of 0.01 µg Co/m^3 to demonstrate that all occupational exposures to the cobalt salts are below this reference level, and b) if required by article 37(4) of REACH, downstream users have carried out in their Downstream users Chemical Safety Assessment an assessment according to paragraph 6.5 of Annex I of REACH and have used a reference exposure value of 0.01 µg Co/m^3 to demonstrate all occupational exposures to the cobalt salts are below this reference level, and c) the supplier has provided the recipient of the substance on their own or in mixtures in a concentration equal to or above 0.01% by weight with a Safety Data Sheet and exposure scenarios (where relevant) according to article 31 of REACH that includes the operational conditions and risk management measures to control occupational exposure to the cobalt salts below a reference exposure value of 0.01 µg Co/m^3. The Safety Data Sheet shall state the reference exposure value under Section 8.1 Control parameters. d) the manufacturers and downstream users have implemented a monitoring programme to ensure that all occupational exposures to the cobalt salts are below a reference exposure value of 0.01 µg Co/m^3 .[3] 2) Paragraph 1 above shall not apply to the extent that the cobalt salts specified in column 1 are used as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003 on additives for use in animal nutrition.

RAC did not support the Dossier Submitter's proposal for the reference value of 0.01 µg Co/m3, and instead proposed an 8 h TWA limit value of 1 µg Co/m3 (as inhalable fraction) and 0.5 µg Co/m3 (respirable fraction). Additionally, RAC considers it necessary, and proposes to the European Commission, to derive a binding occupational exposure limit value (BOELV) for cobalt and its compounds according to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD). RAC

[3] See appendix 1 for the calculation of exposure levels.

recommends that this value should be identical to the limit values given in this restriction.
In addition, RAC does not support derogation for cobalt use as an additive in feeding stuff.
See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

Report

1. The problem identified

1.1. Scope and general information

1.1.1. Introduction

This restriction concerns the placing on the market, manufacture and use of five cobalt salts (henceforth "the cobalt salts"): cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) where the Dossier Submitter has identified that risks are not adequately controlled and that risk management is required at the Union level.

The cobalt salts were prioritised for inclusion in Annex XIV to the REACH Regulation by the ECHA recommendation of 20 December 2011 (3rd recommendation[4]). These substances meet the criteria for classification as carcinogenic (category 1 B) and toxic for reproduction (category 1 B), in accordance with Regulation (EC) No 1272/2008, had been identified as substances of very high concern and were included in the candidate list in accordance with Article 59 of Regulation (EC) No 1907/2006 (REACH).

In December 2012, the Commission requested ECHA to conduct an investigation on the uses of the cobalt salts, as they indicated that at least one of the uses of the cobalt salts (e.g. surface treatment) poses a risk to human health that is not adequately controlled that might need to be addressed. The inclusion into Annex XIV of REACH was postponed until the investigation was completed[5].

The investigation was carried out to determine whether the uses of the five cobalt salts may pose a risk to human health which is not adequately controlled and should therefore be addressed within the scope of an Annex XV restriction dossier. As a result of this request, a detailed study report was submitted to the Commission in July 2013[6]. Overall, the 2013 report concluded that the existence of a significant potential for exposure to the cobalt salts had not been demonstrated in the uses covered by the study. However, a number of uncertainties were identified that could have a major impact on this conclusion, in particular whether the cobalt salts exhibit a threshold mode of action regarding their carcinogenicity effects - as claimed in the registration dossiers - or that they should be considered as non-threshold carcinogens. Additionally, the report highlighted several deficiencies in the registration dossiers - mainly related to the absence of relevant exposure scenarios for some uses - that were an issue of concern. Following the conclusion of the 2013 report, ECHA commissioned an assessment of the mode of action of the cobalt salts, which has concluded that the cobalt

[4] https://echa.europa.eu/documents/10162/13640/3rd_a_xiv_recommendation_20dec2011_en.pdf/22d19030-4756-4c95-b120-7c582e1335c6

[5] See recitals 11 and 12 of Commission Regulation (EU) No 348/2013 of 17 April 2013 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): http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0348&qid=1493704087781&from=en

[6] A preliminary investigation into the conditions of use of five cobalt salts" Final report; ECHA, July 2013 (unpublished).

salts are genotoxic carcinogens by inhalation with a non-threshold mode of action; in 2016 RAC[7] supported this conclusion.

As a follow-up, ECHA prepared a report on 2017 based on new data available, i.e. the registration dossiers updated by the registrants and the dose-response relationship for the carcinogenicity effect agreed by RAC as part of the assessment of the mode of action of the cobalt salts. According to the ECHA report, excess cancer risk values in the range of 10^{-3} to 10^{-2} were found in all sectors for activities which give rise to exposure to cobalt salts in solid forms (powder, granulates, etc.) while lower excess cancer risk values, in the range of 10^{-5} to 10^{-3} resulted from activities involving exposure to aqueous solutions. Based on these findings, the Commission requested ECHA to prepare an Annex XV restriction dossier on the five cobalt salts.

1.1.2. Commission request

The Commission requested ECHA to assess the human health risk, the relevant socio-economic impacts and the need for European Union-wide action beyond any national measures already in place by preparing an Annex XV dossier for all the uses of the cobalt salts.

In their request, the Commission requested ECHA to identify those forms and uses for which the risk is not adequately controlled and to address the identified risks through appropriate risk management measures which minimise the exposure to workers and professional users.

By July 2018, 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.

1.1.3. Scope of the restriction

The restriction proposal applies to the placing on the market, manufacture and use of the 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.

The Dossier Submitter has not identified any consumer uses of the cobalt salts and they are therefore outside the scope of the restriction.

The concentration limit of 0.01% by weight is the specific concentration limit for carcinogenicity 1B (H350i) according to the harmonised classification and labelling of the cobalt salts (section 1.2.2).

1.2. Hazard, exposure and risk

1.2.1. Identity of the substances and physical and chemical properties

Table 2 below identifies the five cobalt salts within the scope of the proposed restriction**.**

Table 2: Cobalt salts within the scope of the restriction

EC/List number	CAS number	Name
233-334-2	10124-43-3	Cobalt sulphate
231-589-4	7646-79-9	Cobalt dichloride

[7] ECHA (2016) RAC agreement: Establishing a reference dose response relationship for carcinogenicity of five cobalt salts: http://echa.europa.eu/documents/10162/13563/echa_sr23_project_en.pdf

233-402-1	10141-05-6	Cobalt dinitrate
208-169-4	513-79-1	Cobalt carbonate
200-755-8	71-48-7	Cobalt di(acetate)

The restriction report also covers the hydrated forms of the substances.

The five cobalt salts are considered as water soluble compounds and often referred to as "soluble cobalt salts". Nevertheless, although the solubility of cobalt sulphate, cobalt dichloride, cobalt dinitrate and cobalt di(acetate) is high (above 300 g/L at 20°), cobalt carbonate is almost insoluble in water with a solubility well below 0.1 g/L.

The physical and chemical properties of the cobalt salts are presented in section B.1.

1.2.2. Classification and Labelling

The cobalt salts have the following harmonised classification: Skin Sens. 1 (H317); Resp. Sens. 1 (H334); Carc. 1B (H350i); Muta. 2 (H341); Repr. 1B (H360F), Aquatic Acute 1 (H400) and Aquatic Chronic (H410). The specific concentration limit for Carc. 1B (H350i) is C≥0.01%. Cobalt sulphate and cobalt dichloride are also classified as Acute Tox 4 (H302).

It is to be noted that the harmonised classification for other less soluble cobalt compounds such as cobalt sulphide and cobalt metal does not include at present the hazard classes of Carc. 1B (H350i); Muta. 2 (H341) and Repr. 1B (H360F). Nevertheless, at the time of developing this report, RAC has proposed to update the harmonised classification of cobalt metal, including Carc. 1B for all routes of exposure, Muta 2 and Repr 1B. Further work on the harmonisation of the classication and labelling of cobalt compounds is expected in the near future.

1.2.3. Grouping of the substances

The five cobalt salts under the scope of the restriction have been selected and grouped as they all have a harmonised classification as Carc 1B and Muta 2. The divalent cobalt (II) ion is the common critical entity of the salts in relation to the carcinogenic and mutagenic potential. Upon dissolution of the cobalt salts, the cobalt (II) ion is considered the moiety responsible for systemic toxicity (NICNAS 2016). Local toxicity is expected to result from the combination of released ions (i.e. both the cobalt (II) ion and the anion) on exposure to lungs or skin (ATSDR, 2014).

All five cobalt salts are considered to have similar bioaccessibility and bioavailability; that is, they all release the cobalt (II) ion into biological fluids at similar rates (NTP 2016). Therefore data available from one cobalt salt can be read across to other cobalt salt when data are lacking for a specific substance in the group (ECHA, 2017c).

In fact, cobalt metal and several other poorly water-soluble compounds (e.g. cobalt oxide) have been found to be soluble in biological fluids, suggesting that they release cobalt (II) ions *in vivo* (NTP, 2016). Since it is assumed that the carcinogenicity and mutagenicity of the cobalt compounds is driven by the cobalt (II) ion, these cobalt compounds could be theoretically in the scope of this restriction. However, due to the request of the Commission, this restriction has been limited to the five named cobalt salts. The Commission could at a later date consider if any further work is needed to extend the scope of the assessment.

RAC considers that limiting the restriction to five salts has consequences for worker protection and makes it difficult to monitor exposure in the case of co-

exposures. Therefore, RAC recommends additionally to the European Commission to derive a binding occupational exposure limit value (BOELV) for cobalt and its compounds according to directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD).

In addition, RAC considers that non-cancer hazards, which may be related to the short-term exposures or infrequent peak exposures should be also taken account and the limit value should be protective also for these effects. It is also important to protect workers from the risk of skin sensitisation caused by dermal exposure. See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.2.4. Hazard assessment

1.2.4.1. Scope

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 as high as 10^{-2} can be encountered in several sectors 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 (ECHA, 2016), and as a result do not control or minimise the risks posed by the substances.

The hazard assessment presented in this restriction proposal is therefore focused on the carcinogenic effect of the cobalt salts. In addition, the skin and respiratory sensitisation properties of the cobalt salts have been reviewed and the major findings are presented here. Although this is not quantified, it is understood by the Dossier Submitter that the conditions of the proposed restriction will lead to a reduction in occupational exposure that will result not only in a reduction of cancer cases but also in the prevention of new cases of skin and respiratory sensitisation among the exposed workers.

1.2.4.2. Carcinogenicity

The carcinogenic properties of the cobalt salts have been recognised in a number of expert assessements (ATSDR (2004), SWH (2005), IARC (2006), WHO/CICAD (2006), MAK (2007, 2009), EFSA (2009, 2012), ECHC (2011), Danish EPA (2013), OECD (2014), ANSES (2014), NTP (2014, 2016)). The five cobalt salts under this restriction proposal have a harmonised classification as Carc. 1B (inhalation).

According to IARC (2006) cobalt sulphate and other soluble cobalt (II) salts are possibly carcinogenic to humans (Group 2B). Also metallic cobalt metal (without tungsten carbide) was concluded as possibly carcinogenic to humans (Group 2B), due to sufficient evidence in animals.

In 2016 RAC concluded that the cobalt salts should be considered as genotoxic carcinogens via the inhalation route with a non-threshold mode of action (ECHA, 2016). RAC agreed on a dose-response relationship for the carcinogenicity effect of the cobalt salts based on the assessment commissioned by ECHA in 2015 (ECHA Project SR 23, Larsen *et al,* 2015). A further review of the literature conducted for the purpose of the development of this restriction dossier has not revealed any relevant new data related to the carcinogenicity and mutagenicity of the cobalt salts. The latest NTP review (NTP, 2016) concluded that "cobalt and cobalt compounds that release cobalt ions *in vivo* are reasonably anticipated to be human

carcinogens based on sufficient evidence from studies in experimental animals and supporting mechanistic data. Cobalt metal and cobalt compounds that release cobalt ions *in vivo* (regardless of their solubility in water) act via similar modes of action and induce similar cytotoxic, genotoxic, and carcinogenic effects." The findings of two epidemiology reports recently published did not provide any further evidence related to the carcinogenicity effect of the cobalt salts.

The REACH registration dossiers (CoRC, 2018) present the cobalt salts as non-genotoxic carcinogens with a threshold mode of action. The registration dossiers have not been updated to take into account the RAC agreement in 2016.

The carcinogenic and mutagenic properties of the cobalt salts are presented in the corresponding sections below. Since most of the available data have been already reviewed in the context of the study commissioned by ECHA (ECHA Project SR 23, Larsen *et al*, 2015) and the agreement by RAC on the mode of action of the cobalt salts (ECHA, 2016), only the main conclusions are discussed here. Sections B.4.3 and B.4.4 of the restriction dossier present a more detailed description of the data together with a assessment of the relevance of the latest epidemiology studies published on the carcinocenicity of the cobalt salts (Sauni *et al*, 2017; Marsh *et al*, 2017).

Experimental data

Significant dose-related increases were seen for alveolar/bronchiolar neoplasms in all dose groups in male and female mice and rats exposed to cobalt metal by inhalation. Tumours were also induced at sites distant from the lung in rats, including tumours of the pancreas in males and of the hematopoietic system (mononuclear-cell leukaemia) in females, indicating a systemic effect. Increased incidence of neoplasms in the kidney in male rats and pancreas in female rats may have been related to cobalt metal inhalation. Exposure to cobalt metal also induced adrenal gland tumours (benign and malignant pheochromocytomas) in male and female rats which could be caused by direct or indirect mechanisms. Adrenal gland neoplasms can develop because of damage to the lungs that causes systemic hypoxemia leading to chronic inflammation and subsequent neoplasm developments (NTP 2014). It is possible that the adrenal glands neoplasms observed may not be directly caused by systemic exposure to cobalt but could be a secondary response to lung damage. However, this mechanism does not explain the neoplasms in the kidney and pancreas after inhalation exposure.

Two 2-year carcinogenicity studies with inhalational exposure to cobalt sulphate in rats and mice are available (NTP 1998, Bucher 1999). In these studies, increased incidences of alveolar/bronchiolar neoplasms in both sexes of both species were seen. Furthermore, adrenal pheochromocytomas were increased in female rats, and to some extent in male rats (NTP 1998, Bucher 1999).

No experimental studies are available for the cobalt salts (neither for cobalt metal or other cobalt compounds) via the dermal and the oral route.

Based on the experimental studies of inhalation exposure to cobalt sulphate, it has been previously considered that the local induction of alveolar/bronchiolar tumours in the lungs is the only carcinogenic relevant response from inhalation exposure to the cobalt salts (ECHA Project SR 23, Larsen *et al*, 2015). However, experimental findings in cobalt metal studies support the evidence of systemic exposure of rats and mice to cobalt. Cobalt concentrations and burdens increased with increasing exposure concentrations in all studies in all tissues examined. In addition neoplasms were observed at several organ sites (pancreas, hematopoietic system and kidney) distal to the route of administration. Therefore the induction of systemic carcinogenicity effects via the inhalation route is also considered relevant. Potential local and systemic effects via other routes of exposure (dermal, oral)

cannot be discarded (ECHA, 2017b). Based on the evidence available, RAC proposed the classification of cobalt as Carc. Cat. 1B (H350) without specifying the route of exposure.

The relevance of systemic effects via inhalation and other routes of exposure has been questioned by industry in several comments submitted in the consultation. However no new evidence has been submitted that put into question RAC's conclusions from 2017 (ECHA, 2017b).

Human data

Very limited human data are available with regard to carcinogenicity of cobalt and cobalt compounds. Thus, only two epidemiological studies concerning occupational exposure to cobalt (without tungsten) were identified in OECD (2014) as well as IARC (2006) reviews (Mur *et al*, 1987; Moulin *et al*, 1993). Based on these studies, it was concluded that the human data were too limited to draw any conclusions regarding the carcinogenicity of the cobalt salts (ECHA Project SR 23, Larsen *et al,* 2015).

According to NTP (2016), there is inadequate evidence from studies in humans to evaluate the association between exposure to cobalt and cobalt compounds that release cobalt ions *in vivo* and cancer. Although almost all the cohort studies assessed reported approximately a doubling of the risk of lung cancer from exposure to various cobalt compounds, NTP concluded it was unclear that the excess risks were due to exposure specifically to cobalt because of potential confounding from exposure to known lung carcinogens or other limitations. In addition, the studies were found to have limited sensitivity to detect a true risk because of small number of cases, crude exposure assessment, or concern about healthy worker related effects (NTP, 2016).

Several epidemiology studies have shown statistically significant increased cancer risk for lung (Lasfargues et al, 1994; Wild et al, 2000), trachea (Lasfargues et al, 1994), bronchus (Lasfargues et al, 1994), and tongue (Sauni et al, 2017) in workers occupationally exposed to cobalt in hardmetal production and in cobalt manufacturing. In spite of the positive associations between exposure to cobalt and occupational cancer risks found, the available studies present a number of limitations (small number of study subjects, limited information on exposures, confounding exposure to other carcinogens including smoking) that prevent to draw a definite conclusion on the excess cancer risk related to occupational exposure to cobalt. RAC (ECHA, 2017b) in the context of the development of the opinion on the classification and labelling of cobalt metal concluded that the available epidemiological studies were not useful to conclude whether cobalt metal is carcinogenic in humans due to co-exposure to other carcinogens. In their evaluation RAC considered two epidemiological studies recently published (Sauni *et al*, 2017; Marsh *et al*, 2017) not included in previous assessments. The Sauni study evaluated the cancer incidence among workers (995 males) employed in a Finnish cobalt plant for at least a year between 1968 and 2004. In this study, the only cancer type with increased incidence was tongue cancer. However, because of the small size of the study, RAC concluded that the results must be interpreted with caution. The second study is a large international occupational epidemiologic investigation of hard metal[8] workers (Marsh *et al*, 2017) which involved 32 354 workers from three companies and 17 manufacturing sites. According to RAC, the study showed no consistent evidence of elevated lung cancer mortality risk among cobalt exposed hard metal workers (ECHA, 2017b). The Marsh *et al* study is discussed in more detail in Section B.4.4.2.

Genotoxicity

[8] Hard metal is an alloy of tungsten carbide and cobalt.

Only very limited and non-conclusive human data are available with respect to the assessment of genotoxic effects from cobalt/cobalt salt exposure. Most consistently the cobalt (II)-ion is considered genotoxic *in vitro* due to the induction of chromosome damage in mammalian cells.

In addition:

- Several i.p. studies on water soluble cobalt salts have been positive for genotoxic effects after systemic uptake[9].
- Oral studies are non-conclusive i.e. there is no clear evidence on systemic genotoxicity after oral exposure.
- There may be local genotoxic effects, but these have not been really studied in appropriate studies (e.g. by *in vivo* comet assay in respiratory epithelial cells). NTP results on k-*ras* mutations in lung tumours suggest oxidative damage in lung tissue. In addition, i.p. data indicate oxidative damage on DNA.

Based on this, it is concluded that genotoxicity as a mode of action behind lung tumours cannot be ruled out.

Mode of action

At present thresholds have not been identified in relation to the carcinogenicity and genotoxicity effects of the cobalt salts. Due to lack of identified thresholds and to remaining uncertainties regarding the mechanisms involved, the cobalt salts are considered as genotoxic carcinogens and are assessed in this dossier using a non-threshold approach. This is in line with the approach agreed by RAC in 2016 in the context of the development of a dose response relationship for the carcinogenicity of the cobalt salts (ECHA, 2016).

In contrast to this approach, the REACH registration dossiers of the cobalt salts state that the cobalt substances are not directly mutagenic, and genotoxicity is not the predominant mode of action of cancer, concluding that "a non-threshold mode of action for the carcinogenicity could be excluded" (CoRC, 2018).

According to the comments provided by the cobalt industry in the consultation of this restriction proposal, the cobalt salts are non-genotoxic (or non-direct genotoxic) and exhibit a threshold in the dose-response. A value of 5 $\mu g/m^3$ for the respirable fraction is proposed for the threshold. In their comments, the cobalt industry states that new data is available that support this view and that was not taken into account by RAC in their previous assessment of cobalt compounds (ECHA, 2016; ECHA 2017b).

The Dossier Submitter has reviewed the information provided in the consultation, including two ToxTracker reports (Hendriks *et al*, 2019 (unpublished, confidential) and Cappellini et al, 2018) and articles by Smith and Perfetti, 2018 and Lison e*t al*, 2018) (see section B.4.4.3). It is to be noted that Toxtracker is an *in vitro* screening tool which has not been validated yet. Other articles claimed as new by the cobalt industry (Marsh *et al* 2017 and Sauni *et al* 2017) have been already taken into consideration in this restriction dossier.

The new information made available by the cobalt industry supports the assumption that cobalt salts induce oxidative DNA damage which was already recognised by RAC (ECHA, 2016; ECHA 2017b). However, the data do not demonstrate that the DNA damage is induced

[9] These studies, whilst individually being reliable with restrictions, taken as a weight of evidence demonstrate there is a concern for genotoxicity.

exclusively via oxidative stress and thus non-linear /threshold mechanisms. Other non-threshold mechanisms cannot be discarded.The mode of action of the cobalt salts is further discussed in section B.4.4.3.

Dose-response relationship

In 2016, RAC agreed on a dose-response relationship for the carcinogenicity of the cobalt salts (ECHA, 2016). Following a linearised approach, the following dose-response relationship was derived for the respirable fraction:

Excess risk (lung cancer, workers) = 1.05(mg Co/m^3)$^{-1}$ x exposure level (respirable fraction)

RAC recognised that excess risks could be overestimated following this approach, especially at very low exposure levels (ECHA, 2016). The methodology used by RAC for the derivation of the dose-response relationship is further discussed in section B.4.5.

Although, according to RAC, the non-respirable fraction should also be considered as carcinogenic, the dose–response relationship related to this metric was not derived since not enough data were available. The non-respirable fraction will deposit in the upper part of the respiratory tract where it can be absorbed directly into the blood or moved into the gastrointestinal tract by mucociliary action. Once absorbed, it may result in systemic and local carcinogenicity effects as discussed in the previous section. Taken this into account and as a precautionary approach, the Dossier Submitter will apply the dose–response relationship derived by RAC for the lung cancer effect of the respiratory fraction to characterise all cancer effects (local and systemic) resulting from inhalation exposure to the cobalt salts.

Using this approach, the following levels of excess cancer risks can be calculated in relation to lifetime worker inhalation exposure (8h/day, 240 days/year, 40 years):

Exposure levels (µg Co/m^3)	**Excess lifetime cancer risk in workers**
100	1.05×10^{-1}
10	1.05×10^{-2}
1	1.05×10^{-3}
0.1	1.05×10^{-4}
0.01	1.05×10^{-5}

The registration dossiers define the cobalt salts as non-genotoxic carcinogens with a DNEL value of 100 µg Co/m^3 for the carcinogenicity effect. The point of departure for the derivation of the DNEL value is the same as the one selected by RAC for the derivation of the dose-response. However, according to the registrants, a DNEL value of 40 µg Co/m^3 should be used for risk characterisation. The aim of the DNEL is to prevent respiratory inflammation, based on lung function measurements in cobalt-exposed workers (Sauni, 2010). The DNEL is based on the study NOAEC, at which no respiratory inflammation and no lung function impairment were observed.

In the consultation the cobalt industry identified the study by Suh *et al* (2016) which had not been previously considered by the Dossier Submitter. The study focuses on the derivation of a dose-response metric for cobalt metal. According to the authors "the mechanistic data support that the carcinogenic mode of action (MoA) is likely to involve oxidative stress and

thus non-linear /threshold mechanisms. However the lack of a detailed MoA and the use of high toxic exposure concentrations in the bioassay preclude derivation of a reference concentration protective of cancer. Several analysis resulted in an IUR [inhalation unit risk] of 3.4 x 10^{-3} per µg/m^3 for cobalt metal". The Dossier Submitter would like to stress that this is in line with the RAC agreement in 2016 and the restriction report. It is also worthy to note that the Dossier Submitter has estimated an inhalation unit risk of 1.05 x 10^{-3} per µg/m^3 for the cobalt salts which is in a similar order of magnitude to the value calculated for cobalt metal by Suh *et al*.

Conclusions on carcinogenicity

There is inadequate evidence from studies in humans to evaluate the association between exposure to cobalt and cobalt compounds and cancer. Based on experimental findings, the cobalt salts are considered as genotoxic carcinogens via the inhalation route and are assessed in this dossier using a non-threshold approach. By taking into account the systemic effects from the experimental studies on cobalt metal and the toxicokinetics and cancer mechanisms involved, it cannot be excluded that exposure to the cobalt salts may lead to local and systemic effects via different routes of exposure.

Since carcinogenicity data are only available for local tumours in the respiratory tract in relation to inhalation exposure to respirable particles, the dose-response estimation can only be derived for this fraction. As a precautionary approach, the Dossier Submitter has decided to apply the dose-response relationship thus derived to the inhalable fraction to take the carcinogenicity effect of the non-respirable particles into consideration.

In the consultation, the cobalt industry has provided new evidence that according to their view put into question the use of a non-threshold approach to derive the dose-response of the cobalt salts. However, the information provided does not support a change in the dose-response of the carcinogenicity of the cobalt salts agreed by RAC in 2016. In fact, the new study by Suh *et al* (2016) supports a similar approach for the calculation of the risk levels for cobalt metal.

RAC re-evaluated the data available on the carcinogenicity and mutagenicity of cobalt salts. RAC assessed whether a mode of action-based threshold for cancer effects could be derived for cobalt following the methodology of the ECHA/RAC – SCOEL Joint Task Force (ECHA, 2017, added later on as Appendix 17 to ECHA guidance Chapter R-8: Characterisation of dose [concentration]-response for human health, ECHA, 2019). However, it was concluded that the data was insufficient to derive such a health-based threshold (see further RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts and appendix 8 of the Annexes to this restriction providing a comparison between Nickel and Cobalt carcinogenicity).

However, in contrast to the Dossier Submitter, RAC acknowledges that chronic inflammation is likely to play a role in the mode of action of cobalt-caused genotoxicity and cancer. RAC derived an estimated threshold level for chronic pulmonary inflammation of 0.5 µg Co/m³ (respirable fraction) using animal data. This was considered to present a breakpoint in the dose-response of cobalt carcinogenicity. Below this level, the cancer risk was considered to be reduced significantly compared to the risk estimated on the basis of linear extrapolation. Additionally, since inflammation and secondary genotoxicity at levels >0.5 µg/m³ may enhance the cancer risk, the levels should be controlled below the breakpoint as an 8 h time weighted average (TWA) rather than a frequency and duration-adjusted reference exposure value. See further final RAC Opinion on an Annex XV

dossier proposing restrictions on Soluble Cobalt Salts.

RAC did not support the Dossier Submitter's proposal to use the same dose-response to characterise also the upper respiratory tract and systemic cancer risk. Neither epidemiological nor animal studies have provided evidence of upper respiratory tract tumours. In animal studies > 40% of the respirable particles are expected to deposit in the head region whereas about 4 % ends up to alveolar region. When taking into account the absence of tumours in the upper respiratory tract at the highest concentration tested (3.0 mg/m^3 cobalt sulphate hexahydrate) whereas already 0.3 mg/m^3 concentration resulted in increased incidence of pulmonary tumours, the risk of upper respiratory tract cancers is more than one order of magnitude lower than that of lung cancer. Even though in animal studies pheochromocytomas and pancreatic cancers were observed after the inhalation exposure to cobalt metal, the relevance of these systemic cancers to low level human exposures is unclear since the mechanisms of these cancers may be related to the high doses used in animal studies and may exert a threshold (RAC, 2017). Because of the clear potency difference (1-2 orders of magnitude), RAC considers that the use of dose response for respirable particles covers also possible cancer risk caused by the non-respirable particles. See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.2.4.3. Respiratory and skin sensitisation

The results from epidemiological and experimental studies show that the cobalt salts are skin and respiratory sensitisers. Evidence of occupational asthma has been found among workers exposed to cobalt and cobalt compounds.

Information received in the stakeholder consultation from three Member States suggests an incidence of 1 to 3 cases of skin diseases and 0 to 1 asthma cases per year related to exposure to cobalt compounds. However the information is too scarce to draw any firm conclusion on the prevalence of occupational skin diseases and asthma related to cobalt exposure in the EU. Moreover, there is no specific information on the number of cases that may result as a consequence of exposure to the five cobalt salts within the scope of the restriction dossier.

The number of sensitisation cases reported by the Cobalt REACH Consortium in the consultation seems to follow the same pattern. According to the information provided, the number of asthma cases reported in the last 10 years by the companies participating in a survey is zero while the number of skin sensitisation cases has been reported as less than 0.5 cases per year. The number of cases reported result from exposure to cobalt and cobalt compounds and cannot be related to the specific cobalt compounds covered by the restriction proposal.

In general terms the Dossier Submitter considers that the information available does not allow for the quantification of the incidence of sensitisation cases at the EU level.

Further discussion on the respiratory and skin sensitisation effects of the cobalt salts is presented in section B.4.2.

The Dossier Submitter did not perform a quantitative hazard assessment for the other toxicological effects of cobalt, including respiratory sensitisation and other non-cancer lung effects as they were considered to be covered by the proposed reference exposure value. RAC considered it important to adequately assess also these risks. According to the RAC assessment, the data by Nemery et al., 1992

gives a NOAEC of 5 µg Co/m³ for the effects on lung function. Based on this, a limit value of 1 µg Co/m³ for the inhalable fraction was set by using an assessment factor (AF) of 5 for inter-individual differences. RAC agrees with the Dossier Submitter that the current data do not allow the setting of a NOEC for asthma. However, based on the data available from three Member States and from an industry survey, asthma caused by cobalt seems to be uncommon nowadays. RAC concluded that the limit value given above is likely to reduce the risk of respiratory sensitisation as well. Since cobalt sensitisation may be more related to daily exposure levels rather than cumulative exposure, this value should be used as an 8 h TWA value rather than a frequency- and duration-adjusted reference exposure value.

RAC also notes that an air limit value alone cannot protect from skin sensitisation. Therefore, a careful control of skin exposure at workplaces is also needed. See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.2.5. Exposure

1.2.5.1. Manufacture and uses

The cobalt salts are manufactured and imported into the EU and used in a wide range of sectors and applications. The total volume manufactured and imported is estimated at 37 400 tonnes/year, of which 30 000 tonnes/year are used in the EU and 7 400 are exported. Approximately 85 % of the cobalt salts are used as intermediates in the EU; 70% of the total volume are used as transported isolated intermediates (CoRC, 2017). Table x below shows the sectors of use of the cobalt salts and the corresponding volumes for each sector.

Table 3: Estimated annual volume of cobalt salts by sector of use

Sector/Uses	**Volume used in EU (tonnes 2011-2013)**
Intermediate uses	
Manufacture of chemicals	26 600
Manufacture of batteries	n/a [1]
Manufacture of catalysts	1 700
Manufacture of pigments and dyes	<<100
Non-intermediate uses	
Use as catalyst	700
Use in surface treatment (incl.: formulation, passivation and plating)	500
Use as colorant in the production of PET[2]	0
Use in biotechnology (incl. biogas, fermentation, health sector, animal feed and fertilizers[2])	400

Sector/Uses	Volume used in EU (tonnes 2011-2013)
Bespoke uses (incl. humidity indicators card, water treatment chemicals, laboratory reference standards)	<<100
Total	30 000

Source: Data extracted from information provided by the Cobalt Institute in the call for evidence for the preparation of this restriction dossier (CoRC, 2017)
1 The volume used in the manufacture of batteries is included in the manufacture of chemicals
2 These uses are understood not to be taking place in the EU at present.

The processes involved in the manufacture and use of the cobalt salts are discussed in detail in annex A. Some of the uses of the cobalt salts, i.e. the use as a colorant in the production of PET, the use as fertilisers, and some uses within the pigment sector, are considered not to take place any more. These uses will not be furthered considered by the Dossier Submitter in the risk assessment.

1.2.5.2. Worker exposure

Workers may be exposed to the cobalt salts in the manufacture and use of the substances via the inhalation and the dermal route. Oral exposure may also be possible if adequate hygiene practices are not in place. The focus of the restriction dossier is on the worker inhalation exposure and this will be covered in more detail in the following sections. The dermal exposure (and potential oral exposure) will only be briefly discussed.

According to the exposure scenarios in the registration dossiers, the five cobalt salts are prepared and used as solids in powder form with a medium dustiness, i.e. a moderate potential to become airborne (CoRC, 2018). Some of the processes, (e.g. in animal feed, manufacture of catalysts, etc.) result in the transformation of the cobalt salts into different solid formats (cakes, granules, pellets, etc.) with a lower potential for dust emission.

The cobalt salts (except for cobalt carbonate) are also produced and used in liquid form, mainly as aqueous solutions. Although the use of aqueous solutions is generally assumed to result in a lower emission potential, it may lead to the generation of mists and fumes in high energy activities such as electroplating and hot metallurgical processes.

The particle size of the aerosols (dust, fumes and mists) generated as a result of the manufacture and use of the substances is a key parameter in the occupational exposure to the cobalt salts. Large particles, generally greater than 100 µm in diameter, will settle out quickly, often close to the contaminant source and may result in exposure via the dermal and the oral route, if adequate risk management and hygiene measures are not in place. However, smaller particles have no independent motion but travel with the air in which they are suspended and are therefore capable of pervading the whole workplace if they are not controlled at source (Vincent, 2005).

The particle size of the airborne contaminants plays a significant role in the uptake of the substance and the health effects resulting from the exposure to the cobalt salts (section 1.2.4.2). Cobalt salt particles greater than 10 µm in diameter are more likely to deposit in the upper airways of the respiratory tract, while the smaller particles (termed as "respirable fraction") will penetrate to the lower gas exchange region of the lung. It is to be noted that the dose-response relationship for the cobalt salts has been derived only for the respirable fraction.

The exposure values of the cobalt salts presented in the registration dossiers (CoRC, 2018) and available in literature correspond in general to the inhalable fraction (particles smaller than 100 µm). According to industry (CoRC, 2017), the ratio of the inhalable to respirable fraction for the cobalt salts can be estimated at 10 as a reasonable worst case, based on a report containing detailed particle size information from three workplaces generated by Vetter *et al* (2016). The Dossier Submitter considers that a ratio of 10 does not take into account the different scenarios where exposure to the cobalt salts may take place. Instead, based on the study conducted by Okamoto (1998), the dossier submitter proposes a ratio of 2 as the reasonable worst case for the estimation of the respirable fraction for the cobalt salts. Further discussion on the extrapolation from inhalable to respirable fraction is presented in appendix 2.

Nevertheless, as discussed in section 1.2.4.2, the Dossier Submitter proposes to apply the dose-response (derived for the respirable fraction) to the inhalable fraction as a preventive approach to take into account the carcinogenicity effect of the non-respirable fraction. The approach is further explained in the risk characterisation section.

Inhalation exposure

Air monitoring data, as presented in the registration dossiers (CoRC, 2018), are the basis for the exposure assessment. The data were obtained from a number of workplaces where cobalt and /or cobalt substances are manufactured and handled. Thus measured cobalt levels are in most cases reflective of parallel exposure to a variety of cobalt substances and not only relevant for the cobalt salts. The measured values are based on personal sampling. For some of the exposure scenarios for which specific monitoring data were not available, analogous data from other cobalt compounds and or activities have been used to estimate exposure (CoRC, 2018). It is to be noted that for some exposure scenarios the number of measurements available is very low which introduces a significant level of uncertainty to the analysis. This is especially relevant for the surface treatment sector, where the number of measurements provided is one for the raw material handling step, one for passivation and two for plating. Additionally, a number of exposure values are derived from modelling (MEASE (1.02.01)) by the registrants. The exposure values for each exposure scenario and each sector of use as reported in the registration dossiers are presented in appendix 3. All exposure data correspond to the inhalable fraction.

The air monitoring data present a high variability in the results for most of the activities: the difference between the median and the RWC (Reasonable Worst Case)[10] is in the range of 2 to 5 times but higher than 10 times for some tasks (e.g. packaging activities). This high variability may be explained by the fact that the database is composed from data from different workplaces and compiled over a number of years. It nevertheless reflects a high variability in operating conditions and risk management measures of the different workplaces.

It is important to highlight that the manufacture and use of the cobalt salts do not seem to take place on a continuous basis in most of the sectors and this has a significant impact on the time weighted exposure levels resulting from the different tasks. The registration dossiers (CoRC, 2018) identify the frequency and duration of each exposure scenario for which the exposure levels are calculated. It is understood that these parameters are representative of

[10] The registrants have used the 90th percentile value to define the reasonable worst case exposure (RWC) for those dataset where the number of measurements is at least 6 points. For lower number of data, either the 95th percentile value or the maximum value are taken forward as the RWC. The Dossier Submitter agrees with this approach which is in line with the recommendation of the ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R.14: Occupational exposure assessment (Version 3.0, 2016)

the activities taking place in each sector. However, the data on frequency and duration of the activities are based on a very small number of companies (CoRC, 2017).

An overview of exposure values representative for each sector of use is shown in Table 4. The values are compiled from the exposure scenarios of the registration dossiers.

Table 4: Exposure data from the registration dossiers for the different sectors of manufacture and use (CoRC, 2018)

Sector/use/Activity	**Air concentration [a] µg Co/m³ (Median-RWC)**	**Exposure level [b] µg Co/m³ (RWC 8h TWA)**
Manufacture	54-808	8
Manufacture of chemicals	31-206	10
Manufacture of batteries	16-153	1
Manufacture of catalysts	12-21[c]	3
Manufacture of pigments and dyes	4-29	3
Use as catalysts	0.8-3[c]	3
Use in surface treatment		
- Formulation - Passivation - Plating	2-4[c] 2-4[c] 9-14[c]	0.7 4 7
Use in biotechnology		
- Biogas production - Fermentation and biotech processes - Animal feed	- 1 -	5[d] 0.3 2[d]
Bespoke uses		
- Humidity indicators - Water treatment chemicals - Laboratory reference standards	0.2[c] 19-168 1	0.1 17 0.3

a. Air monitoring measurements based on personal samplers (except where otherwise stated). The median value is reported for those sectors where it is available. The Reasonable Worst Case (RWC) is based on the 90th percentile unless otherwise stated. The values shown correspond to the activities within the sector showing the highest exposure levels in the exposure scenarios, excluding cleaning and maintenance. For intermediate uses, only activities where the cobalt salts are present are considered, i.e. before they are transformed into another substances.
b. Exposure levels based on RWC air concentration, taking the use of RPE (if applicable) and the duration of the activity into account.
c. RWC based on the 95th percentile or the maximum value.
d. Modelled value (MEASE (1.02.01))

In general terms, it can be said that exposure levels (RWC 8h TWA) range from 1 to 10 µg Co/m^3 for the majority of the uses of the cobalt salts. The manufacture of the cobalt salts and the manufacture of chemicals presents exposure values in the range of 8 to 10 µg Co/m^3. One sector of use which shows higher values is the formulation of water treatment chemicals (17 µg Co/m^3), while fermentation and biotechnology processes and the manufacture of humidity indicators show levels of exposure well below 1 µg Co/m^3. For the surface treatment

sector, exposure values range from 0.7 µg Co/m^3 to 4 µg Co/m^3 for formulation and passivation, up to 7 µg Co/m^3 for plating operations.

On the other hand, the exposure levels reported in the registration dossiers for the animal feed sector (and shown in Table 4 above) correspond exclusively to the formulation of mixtures to be used as additives in animal feed. The use of these mixtures by professional users, i.e. farmers, is not reported and the resulting exposure levels are therefore not known. However, the use of the cobalt salts as additives in feedingstuffs is subject to Regulation (EC) no 1831/2003 on additives for use in animal nutrition, which establishes the requirement of an authorisation for this use. The authorisation of the cobalt salts as food additives[11] issued in 2014 ensures that the concentration of cobalt is below 0.0001% in the animal feed used by farmers and therefore well below the classification limit. Other cobalt-containing mixtures (complementary and dietetic feed with a cobalt concentration below 0.01% and 0.1% respectively) require the use of personal protective equipment, including RPE and gloves. It is understood that, under the requirements of the authorisation of the cobalt salts as feed additives, the exposure levels arising from the use of cobalt salts as feed additive will be significantly low.

The Dossier Submitter has not been able to verify the exposure values reported in the registration dossiers independently. Although exposure levels to cobalt substances are available in the literature, they are generally related to the manufacture of cobalt metal and hard metal and not to the manufacture and use of the cobalt salts. A recent epidemiology study (Sauni *et al*, 2014) performed in a cobalt manufacturing plant in Finland reports exposure values below 20 µg Co/m^3 in the manufacture of cobalt sulphate and cobalt carbonate (among other cobalt compounds). According to this study the highest exposure levels in the plant are related to the manufacture of cobalt metal with exposure levels in the range of 60 µg Co/m^3.

Several member states have also submitted data on cobalt exposure as part of the stakeholder consultation (see annex G). Exposure levels relate to cobalt in general and are not specifically related to the use of the cobalt salts within the scope of the restriction. The most comprehensive database is submitted by France where cobalt exposure data from 2007 to 2017 are compiled. Surface treatment activities are included in the report as well as feed grade materials. For those uses, the median exposure levels reported, based on personal sampling, are 2.0 µg Co/m^3 and 1.0 µg Co/m^3 respectively, while the RWC (90th percentile) values are 75.5 µg Co/m^3 and 32.1 µg Co/m^3. Slovakia reports the measurement of cobalt exposure by personal sampling in passivation to be below 4 µg Co/m^3. Additionally, according to the German Technical rules (TRGS 561, 2017), cobalt exposure during passivation is below 1 µg Co/m^3. In general, these values are in line with those reported by the registrants. Nevertheless the RWC (90th percentile) exposure values provided by France are significantly higher than those reported in the registration dossiers and shown in Table 4 above. The reason for the discrepancies are not known. It can be pointed out that the French database can be considered robust with a number of measurement values above 50 for both uses, but with a significant variability within each of them. If the 75th percentile values are considered instead of the 90th percentile, the exposure levels are 10 µg Co/m^3 for surface treatment and 3 µg Co/m^3 for feed grade materials, fully in line with the values reported by the registrants.

In conclusion, the Dossier Submitter considers that the exposure levels reported in the registration dossiers can be used for risk assessment, in spite of the uncertainties related to the low number of measurement data and the use of modelled data for some activities. The scarce data on exposure related to similar activities gathered from the literature and other sources do not significantly contradict the values presented by the registrants. The exposure

[11] Commission implementing regulation (EU) No 131/2014

values corresponding to each of the exposure scenarios from the registration dossiers are presented in tabular form in appendix 3 and further discussed in section B.9. These exposure values are used for the calculation of the excess cancer risk levels reported in the risk characterisation section below.

As previously discussed, the potential for inhalation exposure is determined by factors such as the physical form of the substance as well as the process or activity that takes place. Within each sector of activity, the tasks where the cobalt salts are used in solid form (mainly as powder) gives rise to the highest exposure values. This can be seen in appendix 3 where all the different tasks are described for each of the sectors of use, together with the exposure values and the operational conditions. Since the duration of the activities have a significant impact in the resulting exposure levels (RWC 8h TWA), this effect is better reflected in the air concentration levels of cobalt resulting from each of the activities. The tasks involving the handling of cobalt salts in powder form, e.g. loading, unloading, packaging, etc. result in air concentration values in the level of 200 µg Co/m^3. Similar air concentration levels are measured for hot metallurgical process (e.g. calcination) where the high temperatures increase the potential to generate airborne particles. On the other hand the use of cobalt salts in aqueous solutions result in significantly lower air concentration values, ranging from around 0.5 to 5 µg Co/m^3. Electroplating, involving the use of electrical currents, produces air concentration levels in the range of 14 µg Co/m^3 while passivation (without electrical current) results in air concentration levels of 1 µg Co/m^3.

In general terms, it can be concluded that the potential for exposure in all sectors of use is driven by activities where the cobalt salts are used in solid form (including cleaning and maintenance) and by activities where high energy is applied (either temperature or electrical currents). Depending on the operational conditions and the risk management measures in place, exposure levels (RWC 8h TWA) in the range of 5 to 17 µg Co/m^3 are reported for these activities. Combined exposure is expected to be higher for workers involved in several daily activities resulting in exposure to the cobalt salts. However, the calculation of the combined exposure is not straightforward since the frequency of the activities varies significantly depending on the sector of use, ranging from 4 to 240 days/year. Therefore, instead of calculating the combined daily exposure, the Dossier Submitter has taken the approach to estimate the excess cancer risk for each of the activities, and based on this, to calculate the individual excess cancer risk for each sector of use. This is further discussed in the risk characterisation section (section 1.2.6).

Regarding workplace exposure RAC did not support the Dossier Submitter on a number of points and took into account information provided in the consultation.

RAC concluded that a ratio of two (50% respirable dust) is still a reasonable worst case for the ratio of the respirable to the inhalable dust fraction. RAC agreed to take forward different values (50% and 100% fraction of respirable dust) for risk assessment in order to simplify comparisons.

The available data set for inhalation exposure has a number of significant limitations, which introduces a substantial level of uncertainty.

As the use of cobalt salts takes place on a non-continuous basis in most sectors, the Dossier Submitter has considered the frequency and duration of each single task for the calculation of the excess cancer risks. It is unclear if the frequency and duration considerations are representative for the tasks in question, as the data on frequency and duration of the activities – as reported by industry – are based on a very limited number of companies.

For some uses / activities the Dossier Submitter used modelled or analogous data,

which is neither justified and explained in the Background Document nor is the modelling transparent (input parameters, model outputs). The clarifications provided in the consultation reduces the uncertainty of the analogous data to some extent. The modelled data are still uncertain.

Despite of the limitations as described above, the level of exposure as used for risk assessment is in a reasonable order of magnitude given that information provided during the consultation by different contributors in principal confirms the order of magnitude of the exposure levels.

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

Dermal exposure

No data on dermal exposure are available to the Dossier Submitter. The registration dossiers assess dermal exposure in a qualitative way and require the use of gloves and protective equipment to prevent potential dermal exposure to the cobalt salts. Good occupational hygiene practices are also recommended to prevent potential oral exposure to workers. Quantitative data regarding dermal exposure to the cobalt salts have not been found either in literature or from other sources. Three Member States (Ireland, Finland, Slovakia) report cases of skin sensitisation related to cobalt exposure for workers (from one to three per year depending on the country) but the data do not allow to make any connection with the cobalt-containing substances involved, or the sector of use where the case has taken place.

Due to the lack of data, the Dossier Submitter does not consider feasible to make any qualitative or quantitative assessment of the dermal exposure arising from the manufacture and use of the cobalt salts.

The lacking information on dermal exposure adds an additional uncertainty to RAC's assessment because a full risk characterisation would include also dermal aspects. This is especially relevant for these five cobalt salts as they are skin sensitizers.

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.2.5.3. Risk Management Measures

The exposure scenarios in the registration dossiers (CoRC, 2018) identify the operational conditions and the risk management measures required to control exposure to the cobalt salts. This information is presented in appendix 3 and discussed further in section B.9.

According to the exposure scenarios:

- Reaction processes (including hot and wet metallurgical processes) take place in closed systems while transfer operations, formulation and packaging take place either in closed, semi-closed or open systems, depending on the sector of use.
- Local exhaust ventilation (LEV) with a minimum effectiveness between 78% and 90% is specified for certain activities.

- Surface treatment processes take place either in closed systems (electroplating) or in open systems (passivation, manual brush plating) with LEV.
- The use of respiratory protective equipment (RPE) is recommended for specific tasks, with an APF[12] ranging between 10 and 40.
- A set of organisational measures are required for all uses, including the use of gloves, regular training and good occupational hygiene practices to ensure the effectiveness of the implemented measures.

In a specific survey conducted for the development of this restriction dossier (see section G) the respondents provided specific information regarding the risk management measures in place. The survey focused on the technical measures in place to control exposure in those activities with the highest potential for exposure to the cobalt salts, i.e. the handling of cobalt salts in solid form, reaction processes (including metallurgical processes), and electroplating. Out of a total of 36 respondents from eight sectors of use, all of them except for the companies in the surface treatment sector identified the use of closed systems, or partially enclosed systems and LEV, as representative risk management measures to control exposure to the cobalt salts. All respondents from the surface treatment sector (16) identified the use of open baths with LEV as a standard practice for electroplating. The use of closed systems with LEV in electroplating (specified in the exposure scenarios as stated above) was identified as "not practicable" by the respondents. One formulator of surface treatment formulations responded that no technical measures were in place but the use of RPE (APF 20) was required in all activities involving the use of cobalt salts. One respondent manufacturing humidity indicators, reports the use of cobalt salts in powder form, while the exposure scenarios of the registration dossiers specify exclusively the use of aqueous solutions for this use.

Additional information regarding the risk management measures in place was compiled through different contacts with sector associations and individual companies, as part of the stakeholder consultation (section G). The information provided is further described in section B.9 for each sector of use. In general terms, the information is in line with the survey results. One sector that provided further clarifications (meeting at ECHA, 23/03/2018) is the catalyst sector, which uses cobalt dinitrate and cobalt carbonate as transported isolated intermediates for the manufacture of catalysts. According to this sector organisation, the cobalt salts are handled in closed systems and/or partially closed system with LEV, although it is recognised that these engineering measures may not be in place in all manufacturing sites.

In general terms, the Dossier Submitter considers that risk management measures, including the use of closed systems and /or LEV systems, are implemented to control exposure to the cobalt salts in a significant number of workplaces. However, sufficient risk management measures do not seem to be in place for all activities and in all sites. It is understood that downstream users may deviate from the exposure scenarios as far as they can demonstrate that the risks are under control. This is the case for example in the surface treatment sector where the technical measures implemented at worksites significantly differ from those recommended in the exposure scenarios, as discussed above.

The Dossier Submitter notes that the exposure scenarios are developed to ensure the safe use of the cobalt salts with a **DNEL** of 40 mg Co/m^3. In this context, downstream users may implement their own risk management measures and operational conditions as far as they can ensure that exposure levels are below the DNEL value. This may result in significantly different levels of control of exposure to the cobalt salts. This is further reflected in the high

[12] Assigned protection factor according to EN 529.

variability in exposure levels, illustrated by the median and RWC values, reported in the registration dossiers and by other sources.

It was not possible for RAC to identify a limited number of activities that are especially relevant for high exposure levels, that are relevant for all of the sectors and that could be addressed individually by specific risk management measures. Therefore, RAC agrees that a broad restriction of the cobalt salts is feasible.

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.2.6. Risk characterisation

As described in section 1.2.4, the Dossier Submitter considers that the mechanism of action of the cobalt salts is non-threshold. Therefore, according to Annex I paragraph 6.4 of REACH the risk cannot be considered to be adequately controlled as no DNEL or PNEC can be determined.

Therefore, to assess the likelihood that effects are avoided when implementing the exposure scenario according to Annex I paragraph 6.5, excess cancer risks for the individual workers resulting from inhalation exposure to the cobalt salts are estimated by applying the dose-response relationship agreed by RAC. As discussed in section 1.2.4.2, the Dossier Submitter has applied the dose–response relationship derived for the lung cancer effect of the respirable fraction to characterise all types of cancer (local and systemic) associated with inhalation exposure to the cobalt salts as a precautionary approach to estimate the excess lifetime cancer risks in workers. The Dossier Submitter recognises the uncertainties introduced by this approach and the potential overestimation (or underestimation) of the worker cancer risks that may result.

The inhalation exposure levels (RWC 8h TWA) reported in the exposure scenarios from the registration dossiers have been used in the calculation of the excess lifetime cancer risk arising from each of the activities. The exposure levels were weighted by the annual frequency of the activity to account for the different exposure patterns in the different sectors of use. For the quantification of the excess lifetime cancer risks for each worker (individual excess lifetime cancer risks), the excess lifetime cancer risk resulting from each of the activities they may perform were added up. The resulting excess cancer risk levels can be considered as a reasonable worst case estimate of the individual excess lifetime cancer risk for workers in each sector of manufacture and use. A detailed explanation of the methodology used is presented in section B.10.

The individual excess lifetime cancer risk levels are shown in Table 5 below.

Table 5: Individual excess lifetime cancer risk levels for the different sectors of manufacture and use

Sector/Use	**Individual excess lifetime cancer risk levels**
Manufacture, plating process in surface treatment	$\geq 10^{-2}$
Manufacture of chemicals, manufacture of batteries, manufacture of pigments and dyes, use as a catalyst, passivation process in surface treatment, formulation and	$\geq 10^{-3}$

Sector/Use	Individual excess lifetime cancer risk levels
industrial use in biogas production, formulation of water treatment chemicals	
Manufacture of catalysts, formulation of surface treatment pre-formulations, fermentation and biotechnological processes, formulation of feed grade materials, use of water treatment chemicals	$\geq 10^{-4}$
Professional use in biogas production, humidity indicators	$\geq 10^{-5}$

It can be seen that individual excess lifetime cancer risk levels are above 10^{-5} for all sectors of manufacture and use of the cobalt salts. The major contributors to the cancer risk levels are those tasks with the highest potential for inhalation exposure, i.e. handling of cobalt salts in solid form and activities where high energy is applied (temperature and/or electrical currents) such as electroplating. This is the case in those sectors with the highest individual excess lifetime cancer risk levels, i.e. manufacture and electroplating where excess cancer risk levels above 10^{-2} are estimated, and in other sectors where excess cancer risk levels are above 10^{-3} (e.g. manufacture of chemicals, manufacture of batteries, etc.) and 10^{-4} (e.g. manufacture of catalysts, formulation of feed grade materials, etc.). The use of adequate risk management measures to control exposure arising from those tasks with the highest potential for inhalation exposure is therefore critical to ensure that excess cancer risk levels remain as low as possible. The individual excess lifetime cancer risk levels for each sector of use are shown in Table 6 below.

Table 6: Individual Excess Lifetime Cancer Risk levels (ELR)

Sector/use	ELR [1]	ELR (HPE) [2]
Manufacture of the cobalt salts	1.0E-02	8.8E-03
Manufacture of chemicals	5.3E-03	4.9E-03
Manufacture of batteries	3.5E-03	9.4E-04
Manufacture of catalysts	9.4E-04	9.4E-04
Manufacture of pigments and dyes	5.2E-03	n.a.
Use as catalyst	3.3E-03	n.a.
Use in surface treatment		
- Formulation of surface treatment solutions	2.9E-04	1.1E-04
- Passivation or anti-corrosion treatment processes	4.5E-03	4.4E-03
- Metal or metal alloy plating	1.2E-02	8.2E-03
Use in biotechnology		
- Formulation and industrial use of mixtures in biogas production	2.7E-03	1.6E-03
- Professional use in biogas production	1.6E-05	n.a.

Sector/use	ELR [1]	ELR (HPE) [2]
- Use in fermentation processes, in biotech and scientific research and standard analysis	1.9E-04	9.9E-05
- Formulation and use in feed grade materials	2.3E-04	1.7E-04
Bespoke uses		
- Use in humidity indicator cards, plugs and/or bags with printed spots	6.4E-05	n.a.
- Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	3.5E-03	1.8E-03
- Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	1.4E-04	-

[1] Individual excess lifetime cancer risk levels based on exposure levels weighted by time and frequency (RWC LT).

[2] Individual excess lifetime cancer risk levels based on exposure levels weighted by time and frequency (RWC LT) resulting exclusively from activities with a high potential for exposure, i.e. involving the use of cobalt salts in solid forms and electroplating (where applicable). Cleaning and maintenance activities are not included.

n.a.: not applicable (the use does not involve the use of cobalt salts in solid forms or electroplating according to the exposure scenarios of the registration dossiers).

It is noted that two sectors of use, i.e. the manufacture of pigments and dyes and the use as catalysts, which according to the description of the exposure scenarios involve the use of cobalt salts exclusively in liquid form (and, in the case of the latter, in a fully closed system), present individual excess cancer risk levels above 10^{-3}. The Dossier Submitter has not been able to fully elucidate the sources of exposure in these two sectors, where the conditions of use (liquid forms and closed systems) would anticipate lower levels of exposure and excess cancer risk values. As part of the stakeholder consultation, a company using cobalt sulphate in the manufacture of pigments reported that they had substituted the use of cobalt sulphate in powder form for aqueous solutions to reduce worker exposure. Unfortunately no measurements of the levels of worker exposure to cobalt before and after the substitution were provided and therefore the impact of using liquid forms instead of powder forms in the resulting cancer risk levels is not quantified. Nevertheless the potential for excess cancer risk levels in the range of 10^{-3} and above for activities involving exclusively liquid forms is recognised by the Dossier Submitter.

The Dossier Submitter notes that the registrants present a calculation of excess cancer risk for individual tasks and activities as an appendix to the Chemical Safety Report and that it results in values that are two orders of magnitude lower than those estimated by the Dossier Submitter. The reasons for the deviation are twofold. Firstly the registrants apply the dose-response derived by RAC only to the respirable fraction, and the ratio of the inhalable fraction to the respirable fraction assumed is 10. Secondly the registrants' excess lifetime cancer risk values are based on the typical exposure levels instead of the RWC (reported in the exposure scenarios). Further explanation on the differences between the risk assessment performed by the registrants and the Dossier Submitter are presented in section B.10. As a general conclusion, the Dossier Submitter considers that the risk assessment performed by the registrants significantly underestimate the risks resulting from the manufacture and use of the cobalt salts.

There is no general consensus in the EU on which excess cancer risk level may be considered unacceptable and indeed this is a purely political decision. According to the ECHA Guidance[13],

[13] ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (ECHA, 2012)

however, "the decision point for 'acceptable' lifetime (i.e., a working life of 40 years) cancer risk levels used for workers are generally around 10^{-5} but higher or lower levels have been considered to be tolerable under certain circumstances." Some European countries have applied lifetime cancer risk estimates in judging tolerable risk levels for workers. For instance, a lifetime cancer risk of 4 x·10^{-5} is the starting point in setting occupational limit values in the Netherlands, although this level may be proposed to be (temporarily) adjusted upwards (with 4·x 10^{-3} as un upper limit) depending on economic or technical reasons (by the Social Economic Council). Switzerland has used lifetime cancer risks in regulating asbestos, with a risk less than 10^{-3} being tolerable, and less than 4·x 10^{-5} being acceptable (ECHA, 2012). Germany identifies acceptable risk as "a value not associated with a specific substance that expresses the statistical probability of developing cancer, at an interim level of 4:10 000 and at the latest from 2018 at a level of 4:100 000", and the tolerable risk as "a value not associated with a specific substance, which expresses the statistical probability of developing cancer at a level of 4:1 000" (TRGS 910). The US Occupational Safety and Health Administration considers that a lifetime cancer risk for workers higher than 10^{-3} represents an unacceptably high risk and their goal is to reduce this risk to less than 10^{-5}. In the EU risk assessments of industrial chemicals carried out under Regulation 793/93, the Technical Meeting of member states' representatives agreed that a conclusion of concern should be drawn for all genotoxic carcinogens and the magnitude of the risk for each exposure scenario described as far as possible. In some cases quantitative risk estimates were included (either in the main body or as an annex to the risk assessment report) to assist in describing the risk. It can be deduced from some of these reports that the cut-off between concern and low concern about residual risk is in the region of 10^{-5} to 10^{-6} (ECHA 2012).

Considering the above discussion, the Dossier Submitter concludes that the individual excess cancer risk levels resulting from exposure to the cobalt salts are a reason for concern and should be addressed within the present restriction. The Dossier Submitter considers that individual excess cancer risks should be reduced to 10^{-5} or below to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts. Individual excess cancer risk levels below 10^{-5} result from a lifetime exposure to cobalt below 0.01 µg Co/m³.

In addition, the Dossier Submitter estimates that individual excess lifetime cancer risks at the actual worksites may be considerably higher than those calculated and presented in Table 5, taking into account that downstream users may deviate from the exposure scenarios proposed by the registrants and adopt their own risk management measures to ensure what the registrants consider the safe use of the substance, i.e. exposure levels below a DNEL value of 40 µg Co/m³. It is important to highlight that lifetime exposure to levels in the range of 40 µg Co/m³ result in excess cancer risk levels of 4 x 10^{-2}.

RAC considers the Dossier Submitter's approach to use linear extrapolation for the risk assessment of cobalt salts, combined with the assumption that the risk of systemic and upper respiratory tract cancers is similar to that of lung cancer, over-conservative and hard to justify as a reasonable worst case (RWC) scenario. Therefore, RAC re-calculated the excess lifetime risks for different uses using 50% as a conservative estimate of the proportion of respirable dust and a breakpoint approach as described by the German Ausschuss für Gefahrstoffe - AGS (TRGS 910, 2014). This approach is considered to better reflect the current scientific understanding on the lung carcinogenicity of cobalt and to provide a more realistic but still conservative estimate on the risks.
It assumes that the risk of cancer is reduced by a factor of 10 at the breakpoint exposure level identified based on toxicological data. In the case of cobalt, the breakpoint level is 0.5 µg Co/m³ (as respirable fraction).

Using this approach, the following excess lifetime risks were calculated for the

different exposure levels:

- **10 µg Co/m³ (as inhalable fraction), meaning 5 µg Co/m³ as respirable fraction corresponds to an excess lifetime risk of 4.8 x 10^{-3}**
- **RO1b 1 µg Co/m³ (as inhalable fraction), meaning 0.5 µg Co/m³ as respirable fraction corresponds to an excess lifetime risk of 5.25 x 10^{-5}**
- **RO1c 0.1 µg Co/m³ (as inhalable fraction), meaning 0.05 µg Co/m³ as respirable fraction corresponds to an excess lifetime risk of 5.25 x 10^{-6}**
- **RO1d 0.01 µg Co/m³ (as inhalable fraction), meaning 0.005 µg Co/m³ as respirable fraction corresponds to an excess lifetime risk of 5.25 x 10^{-7}**

According to RAC's analysis (see final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts), there are several activities that can result in exposures above the breakpoint level of 0.5 µg Co/m³ (corresponding to 1 µg Co/m³ inhalable fraction). These include e.g. manufacturing of cobalt salts, chemicals, pigments and batteries and the use of cobalt salts as catalysts in surface treatment. Using the approach above, these activities result in excess lifetime cancer risks that some are even > 10^{-3}. When taking this into account, RAC concluded that there are risks from exposure to cobalt that are not adequately controlled. See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.3. Justification for an EU wide restriction measure

The cobalt salts are manufactured and used in many (if not all) EU member states and pose a risk to the workers exposed that is not adequately controlled. At present, 15 member states have implemented regulatory measures to limit exposure of workers to the cobalt salts (section B.9.1.2). A Union-wide regulatory measure is needed to ensure a harmonised high level of protection of human health across the Union. Moreover, a Union-wide measure is preferable to varying regulatory standards and statutes in different EU member states because a unified regulation minimises the potential of market distortion.

RAC considers that a REACH restriction is at present the most appropriate regulatory measure to control the risks of the use of the five cobalt salts in the EU. In addition, RAC recommends that work should be initiated to set a BOELV for cobalt and its compounds covering all occupational exposures.

The limit values proposed here by RAC can be considered applicable also for cobalt metal and other cobalt compounds releasing cobalt ions in contact with body fluids.
See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

1.4. Baseline

The focus of this restriction proposal is on the carcinogenic effects of the cobalt salts through occupational inhalation exposure. Although the substances are also classified (under CLP) as skin sensitisers, respiratory sensitisers and for reproductive toxicity, and the results from epidemiological studies indicate evidence of occupational asthma has been found among

workers exposed to cobalt, these impacts are not considered in this impact assessment. However, they are discussed as an uncertainty in section 3.

The RAC dose-response relationship (section 1.2.4.2), and estimated typical and reasonable worst case exposure and risk levels (section B.10) are used with the estimates on the population exposed to derive an estimate of the expected annual cancer cases linked to the use of the cobalt salts per sector in Table 7. 10% of the workers in each sector are assumed to be exposed at the RWC exposure levels and 90% at the typical exposure levels. More details on the calculations are reported in section B.10. The assessment suggests that surface treatment, manufacture of cobalt salts, and manufacture of other chemicals are the sectors in which most cancer cases can be expected to occur. In total, the current manufacture and use of the cobalt salts is estimated to cause excess cancer risk to approximately 35 000 workers and result in approximately 40 cancer cases after lifetime exposure, i.e. one statistical cancer case per year. These human health impacts set the baseline against which possible restriction options are to be compared.

Table 7: Estimated annual cancer cases associated to exposure to five cobalt salts

Sector	Number of companies	Number of exposed workers	Excess lifetime cancer risk (typical)	Excess lifetime cancer risk (RWC)	Estimated number of cancer cases per year
Manufacture of cobalt salts	30	1600	1.40E-03	1.00E-02	9.04E-02
Manufacture of chemicals	44	4900	2.10E-03	5.30E-03	2.96E-01
Manufacture of batteries	Included in the manufacture of chemicals				
Manufacture of catalysts	7	400	5.10E-04	9.40E-04	5.53E-03
Manufacture of pigments and dyes	5	25	2.10E-03	5.20E-03	1.51E-03
Use as catalysts	8	400	8.00E-04	3.30E-03	1.05E-02
Surface treatment					
The formulation of surface treatment solutions	30	75	1.50E-04	2.90E-04	3.08E-04
Passivation or anti-corrosion treatment processes	2376	5900	2.10E-03	4.50E-03	3.45E-01
Metal or metal -alloy plating	594	1500	6.80E-03	1.20E-02	2.75E-01
Use in biotechnology					
Formulation and industrial use of mixtures in biogas production	1380	540	5.60E-04	2.70E-03	1.04E-02
Professional use in biogas production	12420	4860	1.60E-05	1.60E-05	1.94E-03
Use in fermentation, biotech, scientific research and standard analysis	300	900	1.90E-04	1.90E-04	4.28E-03
Formulation and use in feed grade materials	4400	14000	6.50E-05	2.30E-04	2.85E-02
Bespoke uses					
Use in humidity indicators cards, plugs and/or bags with printed spots	n.a.	n.a.	2.60E-05	6.40E-05	n.a.
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	n.a.	n.a.	4.70E-04	3.50E-03	n.a.
Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	n.a.	n.a.	6.00E-05	1.40E-04	n.a.
TOTAL	**21 594**	**35 100**	**-**	**-**	**1.07**

In parallel to the preparation of this restriction report, the Cobalt Institute (trade association of the cobalt-related industry) built an alternative method for estimating and valuing excess cancer cases. Based on a non-published draft report, their estimate is significantly (two orders of magnitude) lower than the Dossier Submitter's estimate above. The main reasons for the difference are stemming from assumptions maintained on the fraction of the airborne cobalt salts being inhalable/respirable, the relevance of the non-respirable fraction for determining the excess cancer risk, and the way the combined exposure estimates are defined and linked with the number of exposed workers. The Cobalt Institute report describing the methodology and results was not made publicly available by the time of submission of this restriction report.

The volumes of the five cobalt salts used annually in the EEA have doubled in the last 10 years. According to the Cobalt Institute, this increase will continue in the near future due to the increasing demand for rechargeable batteries in electric vehicles and biotechnology-health applications. More information on the volumes can be found in the market overview (annex A).

The available information does not suggest any trend in the implemented risk management measures, their respective costs, or in the exposed population (other than in relation to the increasing tonnage) that would change the annual excess cancer cases. For example there is no indication (at the time of developing the report) that the registrants have updated their Chemical Safety Assessment to take into account the previous RAC assessment on the non-threshold nature of the cobalt salts or taken this into account in updated relevant exposure scenarios.

For simplicity, the further assessment in this report is based on human health impacts derived from the exposure levels and exposed populations as estimated for the year 2018. Also the available risk management measures and their costs are assumed to remain the same. This assumption is justified as, even if the annual volumes change, it is likely that both the total costs of implementing additional risk management measures and the total human health impacts are affected proportionally. This means that even if the net benefits of the restriction would change, the cost-benefit ratio would remain the same for each of the industrial sectors affected.

2. Impact assessment

2.1. Introduction

The methodology for the impact assessment presented below is based on a comparison of the compliance costs with the monetised human health impacts avoided. The main results (economic and human health impacts) are provided per industrial sector when such data was available. However, as the data on exposure, the number of companies and potentially exposed workers is very limited for some sectors, the sector-specific results should be considered as indicative only. This means that the available information is not specific enough to allow for a very detailed assessment, but it provides robust order of magnitude estimates to support the decision making.

Volumes, risk levels, exposed populations and costs of implementing risk management measures are considered to remain constant in the baseline throughout the assessment period. The temporal scope of the analysis is 20 years, which corresponds to the assumed service life of the technical risk management measures. Both costs and benefits of the proposed restriction are annualised and presented in 2018 price levels. For the annualisation,

a 4% discount rate was used. The relevant price index is presented in appendix 4. The geographical boundary of the impact assessment is the EEA although non-direct effects of the restriction to actors outside the EEA cannot be excluded e.g. due to increased prices of EEA-produced products.

RAC and SEAC recommends to use 8 hour time-weighted average (8hTWA) instead of reference exposure value (REV) originally proposed by the Dossier Submitter. This affects the assessments of restriction options 1a, b, c and d. The main differences between these two limit values are the familiarity of the concept to the industry, and the frequency adjustment allowed to be made for the REV. The impact of this change is briefly discussed in appendix 9.

The results of the survey provided by the industry in the consultation are not in-line with the assumptions and analysis made by the Dossier submitter (DS) in this restriction report. The costs and benefits of the restriction options 1a and 1b with different assumptions on the compliance are discussed in appendix 10.

2.2. Risk Management Options

Restriction options

The following restriction options (RO) are identified and analysed:

1) RO1: Implementation of a reference exposure value to be used in the registrations and downstream users' Chemical Safety Assessments (CSA) and to be communicated through the extended Safety Data Sheet. Four values are assessed as restriction options: 10 µg Co/m^3 (RO1a), 1 µg Co/m^3 (RO1b), 0.1 µg Co/m^3 (RO1c) and 0.01 µg Co/m^3 (RO1d). Manufacturers and downstream users are required to demonstrate compliance with the reference exposure values to ensure an effective implementation of the restriction. All options include a derogation for the use of the cobalt salts as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003.

2) RO2: Minimum technical requirements for risk management measures (RMMs) to be implemented to control the risks from using cobalt salts with the highest potential for workers exposure (use in solid form and electroplating). Four sets are assessed as restriction options: mechanical ventilation (RO2a), LEV (RO2b), closed systems or partially enclosed systems with LEV (RO2c) and closed systems with integrated LEV (RO2d). A derogation for uses leading to exposure levels below 0.01 µg Co/m^3 (inhalable fraction) is included in all the options. Similar to RO1, the use of the cobalt salts as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003 is exempted from the requirements of RO2.

RO1 would ensure that sufficient measures are recommended and implemented by manufacturers and downstream users to ensure that risks resulting from exposure to the cobalt salts are controlled to an acceptable level.

RO2 focuses on uses with a high potential for exposure, i.e. handling of cobalt salts in solid form (powder, granules, etc.) and activities where high energy is applied (temperature and/or electrical currents) such as electroplating. Excess cancer risks arising from these activities are major contributors to the overall risk levels.

RO1: Implementation of a reference exposure value

RO1 consists of a reference exposure value to be implemented in the CSA by the registrants instead of a DNEL. The registrants will have to reconsider the exposure scenarios for the

different uses and activities that take place in each sector and determine whether the exposure values resulting from the use of the cobalt salts are below the reference exposure value set. If the exposure values are above the reference exposure value, the registrants will have to reconsider the operational conditions and risk management measures in the exposure scenarios in order to ensure that exposure levels are minimised below the reference exposure value.

Since the reference value set is based on lifetime exposure, exposure values to be compared with the reference level can be weighted by the duration and frequency of the activities to take into account the discontinuous nature of the use, where applicable. It should be stressed that the goal is to ensure that workers' exposures are below the reference exposure value and therefore potential combined exposure resulting from workers performing several tasks involving exposure to the cobalt salts should be taken into account in the Chemical Safety Assessment.

Downstream users are required to produce their own CSA under Article 37 (4) of REACH for any use outside the conditions described in the exposure scenarios. Similarly to the registrants, when developing their own CSA, downstream users will be required under RO1 to use a reference exposure value to demonstrate that worker inhalation exposure is controlled below this reference level. The same considerations apply to the downstream users' CSA as those already discussed above.

The identification of a reference exposure value to be used in their CSA by registrants and downstream users would ensure that sufficient RMMs are recommended and implemented by manufacturers and downstream users to ensure that risks resulting from exposure to the cobalt salts are controlled below a set reference level. For substances for which the manufacturers and importers are not required to produce a CSA, i.e. substances manufactured or imported below 10 tonnes per year, the supplier will ensure that the requirement to comply with the identified reference exposure value is communicated in the extended Safety Data Sheet.

The Dossier Submitter has assessed four different reference exposure values: 10 µg Co/m^3 (RO1a), 1 µg Co/m^3 (RO1b), 0.1 µg Co/m^3 (RO1c) and 0.01 µg Co/m^3 (RO1d) corresponding to an individual excess lifetime cancer risk level of 10^{-2}, 10^{-3}, 10^{-4} and 10^{-5}, respectively. Manufacturers and downstream users are required to demonstrate that their exposure levels are below the reference exposure values by monitoring worker exposure according to the requirements set out in appendix 1.

The use of the cobalt salts as additives in foodstuff materials is regulated by Regulation (EC) no 1831/2003 on additives for use in animal nutrition. The authorisation for the use of the cobalt salts in animal feed identifies a set of conditions to ensure the safety of the users including technical and organisational measures and labelling requirements. Therefore, the Dossier Submitter proposes to include a derogation for the use of the cobalt salts as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003.

RO2: Minimum technical requirements for RMMs

RO2 is based on setting minimum technical risk management measures (RMM) to control risks from the activities with the highest potential for worker exposure via inhalation.

As discussed in section B.10, the major contributor to the worker risk levels are those activities with a high potential for exposure, i.e. handling of cobalt salts in solid form (powder, granules, etc.) and activities where high energy is applied (temperature and/or electrical currents) such as electroplating. Excess cancer risks arising from these activities are major contributors to the overall risk levels, especially for sectors of use where risk values are above

10^{-3} (see Table 5 Individual Excess Lifetime Cancer Risk levels). The identification and implementation of the appropriate RMMs becomes critical to ensure that worker exposure to the cobalt salts are controlled.

The Dossier Submitter considers that the identification of a minimum set of RMMs to be implemented by manufacturers and downstream users at their worksites would ensure that appropriate RMMs are in place to control exposure to the cobalt salts. Four sets of minimum technical RMMs including: mechanical ventilation (RO2a), LEV (RO2b), total enclosure or partially enclosed systems with LEV (RO2c) and closed systems with integrated LEV (RO2d) have been assessed within RO2. Similar to RO1, the use of cobalt salts as additives in foodstuff materials regulated by Regulation (EC) no 1831/2003 on additives for use in animal nutrition will be exempted from the requirements of the restriction.

Additionally, a derogation for specific worksites where exposure levels are significantly low (below 0.01 μgCo/m^3) is assessed within RO2. The derogation is introduced to account for activities where the cobalt salts are used very infrequently and in very low quantities. This could be the case for example in the use of cobalt salts in fermentation processes where companies report the use of cobalt salts in powder form in very low quantities (around 25 g) for a few minutes several times per year (see annex B for further information on specific uses).

Restriction options not considered further

The following summarises briefly the restriction options that were rejected without a more detailed assessment because they did not seem to be effective or proportionate.

1) A requirement for the registrants to consider and communicate cobalt salts as non-threshold carcinogenic substances without setting any reference exposure value was considered, but rejected as the improvements in exposure and risk levels related to this option would be uncertain.

2) The Dossier Submitter does not consider it to be proportionate to propose a full ban for any of the existing uses. This is because of the magnitude of estimated human health impacts when appropriate risk management measures are implemented and the available information on the limited suitability of alternatives (see section E.2).

3) The Dossier Submitter does not consider a derogation for any specific sector appropriate except for feed grade material. The variability of the exposure data for those activities where the dataset is robust enough suggest that different conditions of use apply in different companies. On the other hand the low number of exposure data for some sectors of activities does not allow to determine the real exposure situation for specific sectors of use. In addition, downstream users may significantly deviate from the exposure scenarios presented by the registrants, resulting in less stringent risk management measures being applied at specific worksites.

4) The Dossier Submitter does not consider a full ban of the use of powder forms proportionate. During the stakeholder consultation, most sectors commented that for them it is not possible to switch to liquid forms of cobalt salts (see annex G). Under the restriction option 2 industry may still decide to switch to use liquid forms if that is a better option to them compared to installing the proposed risk management measures. Furthermore, the Dossier Submitter considers that sufficiently low risk levels can be achieved with technical and operational measures.

5) The Dossier Submitter does not consider a ban on historical uses of these cobalt salts that do not exist anymore proportionate, as the identified restriction options based on reference exposure value or minimum technical requirements for RMMs were considered

sufficient for all the identified existing uses. If industry re-starts ceased uses of cobalt salts, these will have to comply with the proposed restriction as well.

Regulatory risk management options other than restrictions

Listing to Annex XIV of REACH

The five cobalt salts covered by this restriction report were recommended by ECHA to be added to Annex XIV of REACH (list of substances subject to authorisation) in 2011. Instead, the European Commission requested ECHA to prepare the present restriction dossier. Moreover it is noted that the manufacture of cobalt salts and the manufacture of other chemicals (intermediate uses of cobalt) which are two of the sectors of highest concern cannot be regulated through the authorisation procedure under REACH.

Because of these reasons, this regulatory risk management option is not considered further.

Occupational exposure limit

Occupational exposure limits (OELs) are set for the protection of workers from chemicals risks. A binding OEL indicates the maximum exposure level as time weighted average over an 8h-shift and hence sets an exposure threshold to the individual worker exposed to a substance of concern.

A binding OEL could be an applicable and effective risk management option for cobalt salts as:

- Both the OEL and this restriction are targeted to prevent occupational exposure.
- The OEL would set the maximum exposure in a workplace without the need to identify RMMs and OCs that are most suitable for each individual company. This is more important for cases covering many industrial sectors or when there is variability inside the sector in terms of suitability of RMMs and OCs.

However, the applicability of a binding OEL may not be suitable in this case due to:

- The fact that it does not consider frequency of the activities leading to exposure and consequently may require disproportionate risk management measures for activities that take place very rarely or would not be stringent enough for activities taking place on a continuous basis.
- The non-threshold nature of the hazard, where an OEL may provide a false sense of safety as the basis of its derivation is not communicated.
- The length of time required for the development and implementation of a binding OEL. The risk levels identified in the manufacture and use of the cobalt salts require that actions are taken to decrease workers exposure without undue delay.

Recognising the potential benefits of OELs to regulate the cobalt salts and its similarities and differences with a reference exposure level set under REACH, the Dossier Submitter does not consider it as the most appropriate regulatory risk management for these non-threshold substances.

Voluntary industry action

Considering the level of risk associated to the use of these cobalt salts and the variety of industrial sectors covered, the Dossier Submitter does not consider voluntary action to be a practical and appropriate regulatory risk management option.

In contrary to Dossier Submitter, RAC considers it more appropriate to implement limit values of 1 µg Co/m³ and 0.5 µg Co/m³ as 8 h TWA, for inhalable and respirable fraction, respectively) rather than the proposed REV.

Although RAC supports a restriction for these cobalt salts, RAC recommends that work should be initiated to set a BOEL for cobalt and its compounds to cover all occupational exposures to carcinogenic cobalt compounds.

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

2.3. Industry response to restriction

Based on the responses received from the cobalt industry during the preparation of this restriction report (see annex E), suitable alternatives are not available for the current uses of cobalt salts. The available information does not indicate that production sites would have to close down due to the proposed restrictions under RO1 or RO2, however, this depends on the reference exposure level or the risk management measures selected. There are no indications that industry would switch from solid to liquid forms of cobalt under RO2 unless the requirements introduced by the restriction for the handling of the cobalt salts in solid forms are not technically or economically feasible. Whilst the Dossier Submitter considers that individual companies may have an incentive to react to the proposed restriction by moving to alternatives or liquid forms of cobalt salts, this has not been an assumption maintained in the impact assessment.

2.4. Economic impacts

Both RO1 and RO2 requires industry to implement new RMMs or to reduce the risk levels by other means. In this impact assessment, the economic impacts are estimated based on information on technical RMMs for both restriction options. It is noted that under RO1, industry can decide on the most effective measures to meet the reference exposure values. The Dossier Submitter recognises that the introduction of specific measures such as for example the wetting of the material if the process allows it or the use of coated solid forms may lead to a significant reduction in exposure levels. However, the selection of these measures are process specific and cannot be assessed at the generic level of a restriction proposal. On the other hand, the registrant or downstream user may select organisational measures or the use of personal protective equipment to reduce exposure should the operational conditions and technical measures be not effective enough to reach the required exposure levels. As it is not possible to determine the specific measures to be implemented by each sector of use, the cost and efficiency estimates provided under RO2 are used to estimate the economic costs also under RO1.

The implementation of technical risk management measures (RMMs) introduce both one-off and operating costs to companies, which these may at least partly pass through to their customers. The sets of identified RMMs, and a more detailed discussion of their costs, effectiveness and applicability for different industrial sectors and sites is provided in appendix 5, whilst the RMMs currently implemented by industry are described in section B.9.

The available information allows the Dossier Submitter to derive order of magnitude estimates on the cost of implementing different technical risk management measures. However, it does not allow identifying the exact cost that individual companies will be facing. This is, for example, because it is unknown how individual companies will react to the restriction and how the different technical possibilities at the affected sites affect the costs.

Most of the identified RMMs are estimated to cost between €170 and €16 000 per year and site in addition to any existing RMMs. Table 8 summarises the derivation of these annualised cost estimates. These are used in the calculation of the economic impacts, assuming that a specific set of RMMs is sufficient to reach the reference exposure value in RO1 and represent the mandatory measures proposed in RO2. The Dossier Submitter considers that the range presented for the cost of each set of measures is sufficiently reflecting the varying needs for additional RMMs (e.g. in terms of number of additional measurers) and the technical constraints of individual companies (e.g. the cost of implementing the same technical measure may vary between companies depending on the set up of the site). However, in the manufacturing of cobalt salts and other chemicals, both lower and higher end costs are assumed 10 times higher than in other sectors. This assumption reflects the different scale of the operations in those sectors.

Table 8: Derivation of annualised costs for the implementation of technical risk management measures for estimating the economic impacts of RO1 and RO2.

RMM set	Investment cost (€)		Annual operating cost (€)		Typical investment period (years)	Annualised cost per year (€)		Effectiveness (%)
	Low	High	Low	High		Low	High	
1	500	1 000	0	100	20	40	160	55.0
2	1 000	10 000	100	1 000	20	170	1 600	82.5
3	10 000	100 000	1 000	10 000	20	1 600	16 000	90.0
4	100 000	1 000 000	10 000	50 000	20	16 000	120 000	99.9

In addition to the cost of implementing risk management measures, RO1 and the derogation for uses with low risk levels under RO2 could introduce additional costs to industry for demonstrating that exposure levels below the reference exposure value (or derogation threshold) have been achieved. As the occupational health and safety legislation already requires monitoring of exposure to carcinogenic substances, the Dossier Submitter considers that only one additional measurement campaign (incremental to the baseline) would be carried out by each affected company as a response to the proposed restriction. Assuming a cost of €3 000 per company and considering the same temporal scope of 20 years as for the RMMs, gives annual cost of €210 per affected company for demonstrating the compliance with the proposed restriction. Depending on the requested reference exposure level, this introduces additional cost between €1 000 and €3 000 000 per year based on the number of companies that would be required to implement additional RMMs.

<u>RO1</u>

RO1 imposes a reference exposure value of 10, 1, 0.1 or 0.01 µg Co/m^3 corresponding to an estimated individual excess lifetime cancer risk of 10^{-2} to 10^{-5} (according to the dose-response relationship established by RAC). The required updating of the Chemical Safety Assessment and the exposure scenarios therein introduces administrative costs to the registrants. As the current Chemical Safety Assessment presents cobalt salts as threshold carcinogens, and as RAC already agreed that these are non-threshold carcinogens, the update of the information should take place regardless of this restriction. Therefore, these administrative costs are not considered incremental to the baseline.

Following the update of the exposure scenarios, changes in the operational conditions and the proposed risk management measures at the manufacturing and downstream user sites are

necessary to comply with the proposed restriction. The Dossier Submitter notes that some of these implementation costs could occur also without the restriction as a result of the registrants updating their Chemical Safety Assessments. However, this would depend on the exact changes proposed by the registrants and it would also affect the baseline cancer risk.

The industrial sectors that would be affected by RO1 in different reference exposure levels are listed in Table 9. It also provides the assumptions on the share of affected companies in those sectors that is used in this impact assessment to estimate the economic impacts and also the benefits. The number of affected companies is derived from this assumption.

Table 9: Share and number of affected companies per sector under RO1 for different reference exposure levels

Sector	**Share and number of affected companies**							
	RO1a		**RO1b**		**RO1c**		**RO1d**	
Manufacture of cobalt salts	10%	3	60%	18	100%	30	100%	30
Manufacture of chemicals	0%	0	60%	26	100%	44	100%	44
Manufacture of batteries	0%	0	10%	0	60%	0	100%	0
Manufacture of catalysts	0%	0	0%	0	60%	4	100%	7
Manufacture of pigments and dyes	0%	0	60%	3	100%	5	100%	5
Use as catalysts	0%	0	0%	0	60%	5	100%	8
Surface treatment				0				
The formulation of surface treatment solutions	0%	0	0%	0	60%	18	100%	30
Passivation or anti-corrosion treatment processes	0%	0	60%	1426	100%	2376	100%	2376
Metal or metal - alloy plating	10%	3	60%	356	100%	594	100%	594
Use in biotechnology				0				
Formulation and industrial use of mixtures in biogas production	0%	0	10%	138	60%	828	100%	1380

Sector	Share and number of affected companies							
	RO1a		RO1b		RO1c		RO1d	
Professional use in biogas production	0%	0	0%	0	0%	0	60%	7452
Use in fermentation, biotech, scientific research and standard analysis	0%	0	0%	0	60%	126	100%	210
Formulation and use in feed grade materials	0%	0	0%	0	10%	30	60%	180
Bespoke uses								
Use in humidity indicators cards, plugs and/or bags with printed spots	0%	n.a.	0%	n.a.	0%	n.a.	60%	n.a.
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	0%	n.a.	10%	n.a.	60%	n.a.	100%	n.a.
Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	0%	n.a.	0%	n.a.	10%	n.a.	60%	n.a.
TOTAL		6		1 967		4 060		12 316

The assumptions on the share of affected companies are derived by following approach:

- When RWC exposure level is above the reference exposure value, 10% of the companies are assumed to be affected.
- When typical exposure value is above the reference exposure value, 50% of the companies are assumed to be affected. However, when the typical exposure value is more than 10 times higher than the reference exposure value, 90% of the companies are assumed to be affected.
- These two estimates are summed up giving 0%, 10%, 50%, 60%, 90% or 100% of companies affected in total per sector.

The assessment suggests that depending on the reference exposure level, the number of affected companies vary from few companies (for RO1a) to more than 12 000 (for RO1d).

The available information allows for an indicative cost estimate of RO1 only. This is based on the following assumptions:

- The cost and effectiveness estimates derived for the four sets of technical risk management measures are applicable also for RO1. This means that other available means to reduce exposure to required level, including operational conditions, are not any cheaper for the industry.
- The difference between the RWC or typical exposure and the reference exposure values gives the required effectiveness of the set of RMMs and the related annual cost of implementing that set is used to estimate the economic impact. The annualised costs are presented in Table 8.

Table 10 summarises the economic impacts per sector and per reference exposure value.

Derogation for the animal feed sector under RO1

In the sector of formulation and use in feed grade materials, 300 companies out of 4 400 are estimated by the Dossier Submitter to be potentially affected by the RO1 (i.e. possibly having higher risk level than 10^{-5}). For the other 4 100 units the risk levels are not known but they are assumed to be very low based on the conditions of the regulation on animal feed. The exact estimate on affected companies, following the approach described above, depend on the reference exposure level. The results suggest that no companies in this sector would be affected by RO1a and 1b, 30 companies by RO1c and 180 companies by RO1d. With the sufficiently efficient sets of risk management measures, this translates to the economic impact of up to €3 500 000 per year (central estimate for RO1d). These costs would be avoided if the derogation were to be implemented.

Table 10: Economic impacts per sector for different reference exposure levels under RO1.

Sector	Costs (€ per year)							
	RO1a-low	**RO1a-high**	**RO1b-low**	**RO1b-high**	**RO1c-low**	**RO1c-high**	**RO1d-low**	**RO1d-high**
Manufacture of cobalt salts	1 061	4 910	496 336	3 540 974	4 910 295	35 164 230	4 910 295	35 164 230
Manufacture of chemicals	0	0	9 534	52 420	7 201 767	51 574 203	7 201 767	51 574 203
Manufacture of batteries	Included in the manufacture of chemicals							
Manufacture of catalysts	0	0	0	0	17 434	171 860	1 145 736	8 204 987
Manufacture of pigments and dyes	0	0	1 738	12 276	818 383	5 860 705	818 383	5 860 705
Use as catalysts	0	0	0	0	196 412	1 592 419	1 309 412	9 377 128
Surface treatment								
The formulation of surface treatment solutions	0	0	0	0	1 043	7 365	491 030	3 516 423
Passivation or anti-corrosion treatment processes	0	0	82 597	583 343	38 889 540	278 500 699	38 889 540	278 500 699
Metal or metal -alloy plating	106	491	82 597	583 343	9 722 385	69 625 175	9 722 385	69 625 175
Use in biotechnology								
Formulation and industrial use of mixtures in biogas production	0	0	23 564	225 874	2 376 555	17 304 914	22 587 359	161 755 456
Professional use in biogas production	0	0	0	0	0	0	263 621	1 219 717
Use in fermentation, biotech, scientific research and standard analysis	0	0	0	0	4 457	20 623	3 437 207	24 614 961
Formulation and use in feed grade materials	Not affected by restriction (use specific derogation included)							
Bespoke uses								

Sector	Costs (€ per year)							
	RO1a-low	RO1a-high	RO1b-low	RO1b-high	RO1c-low	RO1c-high	RO1d-low	RO1d-high
Use in humidity indicators cards, plugs and/or bags with printed spots	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TOTAL cost of implementing RMMs	1 167	5 401	696 366	4 998 230	64 138 270	459 822 193	90 776 733	649 413 684
Cost of demonstrating compliance	1 274	1 274	417 591	417 591	861 755	861 755	2 614 133	2 614 133
TOTAL	2 441	6 675	1 113 957	5 415 821	65 000 025	460 683 949	93 390 867	652 027 817

RO2

The industrial sectors manufacturing and using cobalt salts in solid form (powder, granules, etc.) include:

- Manufacture of cobalt salts
- Manufacture of chemicals
- Surface treatment
- Formulation and industrial use in biogas production
- Use in fermentation, biotech, scientific research and standard analysis
- Formulation and use in feed grade materials, and
- Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors.

In addition, RO2 covers electroplating[14] processes in the surface treatment sector even if cobalt salts are used in liquid form.

The available information allows for an indicative cost estimate of RO2 only. This estimate is based on an assumption that for RO2a 95%, RO2b 80%, RO1c 60% and RO1d 1% of the companies have already the identified technical risk management measures in place.

Table 11 summarises the economic impacts per sector and per required level of RMMs.

Derogation for the animal feed sector under RO2

For RO2, all 4 400 companies would be potentially affected. The exact estimate on affected companies, following the approach described above, depend on the required set of RMMs. The generic assumption on companies that have already implemented different sets of RMMs suggests that about 220 companies in this sector would be affected by RO1a, 880 by RO2b, 1760 by RO2c and 4356 companies by RO2d. With the required set of risk management measures, this translates to the economic impact of up to €300 000 000 per year (central estimate for RO2d). These costs would be avoided under RO2 if the derogation were to be implemented.

Derogation for excess lifetime cancer risk levels below 10^{-5} under RO2

The derogation complementing the RO2 for uses with exposure levels below 0.01 µg Co/m^3 reduces the number of companies affected by the restriction to some extent, but the exact number of companies or sites that could benefit from the derogation is unknown. For the purposes of this assessment, it is assumed that 30% of companies operating in the biotechnology sector will fall under this derogation. Individual companies in other sectors, such as formulation for surface treatment and formulation and use in biogas production, could also benefit from the derogation depending on the exposure levels at their specific sites. In addition, 4 100 companies in animal feeds sector could benefit from this derogation, but they are covered by the sector specific derogation. The Dossier Submitter estimates that 4-90 companies would benefit from the derogation depending on the level of required RMMs. This estimate does not consider the fact that the benefiting companies could in reality be those that have the most stringent RMMs already implemented, i.e. it is based on estimated proportions of companies which have already implemented the identified sets of RMMs described above. This translates in the economic impact of up to €6 000 000 per year (central estimate for RO2d). These costs would be avoided if the derogation is implemented.

[14] This includes an electroplating process performed with a hand held portable tool rather than a tank solution known as brush plating.

Table 11: Economic impacts per sector for different sets of RMMs levels under RO2.

Sector	Affected companies				Costs (€ per year)							
	RO2a	RO2b	RO2c	RO2d	RO2a - low	RO2a - high	RO2b - low	RO2b - high	RO2c - low	RO2c - high	RO2d - low	RO2d - high
Manufacture of cobalt salts	1.5	6	12	29.7	531	2 455	10 245	98 206	196 412	1 964 118	4 861 192	34 812 587
Manufacture of chemicals	2.2	8.8	17.6	43.56	778	3 601	15 026	144 035	288 071	2 880 707	7 129 749	51 058 461
Manufacture of batteries												
Manufacture of catalysts	0.35	1.4	2.8	6.93	124	573	2 391	22 915	45 829	458 294	1 134 278	8 122 937
Manufacture of pigments and dyes	Sector not affected											
Use as catalysts	Sector not affected											
Surface treatment												
The formulation of surface treatment solutions	1.5	6	12	29.7	53	246	1 025	9 821	19 641	196 412	486 119	3 481 259
Passivation or anti-corrosion treatment processes	118.8	475.2	950.4	2352.24	4 203	19 445	81 141	777 791	1 555 582	15 555 816	38 500 644	275 715 692
Metal or metal -alloy plating	29.7	118.8	237.6	588.06	1 051	4 861	20 285	194 448	388 895	3 888 954	9 625 161	68 928 923
Use in biotechnology												
Formulation and industrial use of mixtures in biogas production	69	276	552	1366.2	2 441	11 294	47 127	451 747	903 494	9 034 944	22 361 485	160 137 902
Professional use in biogas production	Sector not affected											
Use in fermentation, biotech, scientific research and standard analysis	10.5	42	84	207.9	371	1 719	7 172	68 744	137 488	1 374 883	3 402 835	24 368 811
Formulation and use in feed grade materials	Sector not affected (use specific derogation included)											
Bespoke uses												
Use in humidity indicators cards, plugs and/or bags	Sector not affected											

Sector	Affected companies				Costs (€ per year)							
	RO2a	RO2b	RO2c	RO2d	RO2a - low	RO2a - high	RO2b - low	RO2b - high	RO2c - low	RO2c - high	RO2d - low	RO2d - high
with printed spots												
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	Number of affected workers not available											
Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	Sector not affected											
TOTAL	234	934	1 868	4 624	9 551	44 193	184 412	1 767 706	3 535 413	35 354 127	87 501 465	626 626 572

2.5. Human health impacts

Improved control of exposures to the cobalt salts reduces the risk to individual workers and correspondingly the number of expected cancer cases. Independent of the restriction option and the exposure levels prevailing in each industrial sectors, the approach to estimate risk reductions and human health impacts is based on several assumptions about the effects of regulatory action. The Dossier Submitter recognises that the assumptions made are based on uncertain basis (for the reasons laid out), however, they provide an illustration of the potential risk reduction. The assumptions and the related uncertainties are further discussed in section 3.

One of the key assumptions of the impact assessment is that the dose-response relationship can be scaled down linearly to apply for exposure durations shorter than 40 years. In other words, it is assumed that 40 years of exposure to a specific concentration for 1 worker results in the same number of expected cancer cases as 1 year of exposure to the same concentration in 40 workers. Furthermore, the monetisation of cancer cases assumes that cancer cases would be avoided starting from the same year as the reduction in exposure, and no discounting is done to account for any latency period. The higher end value of €5 000 000 per fatal cancer case is used (ECHA, 2016).

Half of the cancer cases (50%) are assumed to be lung cancers stemming from the respirable fraction of the substance. The other half are not specified. This affects the valuation step as lung cancers are fatal more often than cancers on average.

The implementation of risk management measures to reduce occupational exposure to the cobalt salts may reduce exposure also to other hazardous substances including other cobalt-containing substances. Due to limited information on such exposure, these co-benefits are not further quantified in this restriction report.

In the identification of the RMMs, the Dossier Submitter has taken the following aspects into consideration:

- The occupational hierarchy of controls, whereby technical measures are prioritised over organisational measures and personal protective equipment based on their higher reliability and effectiveness in reducing the risks.
- The effectiveness of the individual RMMs.
- The RMMs implemented in the different sectors of use to control exposure.

Information regarding the effectiveness of risk management measures is rather limited. The effectiveness of technical measures has been reported in a study conducted for the development of an exposure control efficacy library (Fransman *et al*, 2008). According to their findings, complete enclosure (excluding LEV) may achieve an effectiveness of 97% in reduction of exposure, while partial enclosure with LEV may achieve an effectiveness as high as 94%. However, the authors point out that efficacy values as presented in the study might be an overestimation of the effect of the RMMs due to publication bias. Based on the study results, to achieve an effectiveness equal or above 90% with LEV as recommended in the registration dossiers, the use of partial enclosures or integrated systems (i.e. fixed systems encapsulated in a process or equipment) is required. Exterior LEV (fixed LEV systems with capture or receptor hoods not enclosing the contaminant source) present lower effectiveness with a range from 75 to 86%. These results are in line with the recommendations for the selection of RMMs systems to control airborne contaminants, where the containment of the source and the contaminant cloud is recommended to control exposure more effectively (HSE, 2017). Table 12 presents some indicative values for the effectiveness of various types of technical risk management measures to control inhalation exposure.

Table 12: Indicative effectiveness of risk management measures

Description	Effectiveness (%)	
	Fransman *et al* (2008)[1]	**HSE (2017)[2]**
Closed systems with integrated LEV	-	>99.9
Closed systems or partially enclosed systems with LEV	86-94	90- 99.9
LEV	75-86	<90
Mechanical ventilation	46-65	-

[1] Average and upper confidence limit value as reported in Fransman *et a*l study (2008)
[2] Approximate indicative range values as presented in the HSE (2017)

Information regarding RMMs implemented by industry or under consideration has been compiled in appendix 5. This information was provided by industry as part as the stakeholder consultation conducted by the Dossier Submitter. Unfortunately the technical specifications of the different RMMs are not available, neither the effectiveness (expected or achieved) in reduction of worker exposure.

Based on this information the following effectiveness rates are used in this impact assessment:

- 55% for the mechanical ventilation (RO2a)
- 82.5% for LEV (RO2b)
- 90% for closed systems or partially enclosed systems with LEV (RO2c)
- 99.9% for closed systems with integrated LEV (RO2d)

The Dossier Submitter is aware that to achieve the effectiveness of the risk management measures identified, appropriate organisational measures should be in place including effective maintenance and testing of the ventilation systems and appropriate training of operators. These measures are part of the requirements of the occupational health and safety legislation already in place. Specific requirements for the examination and testing of LEV systems may apply depending on member states (e.g. the HSE in the UK requires thorough examination and testing of LEV systems every 14 months, unless otherwise stipulated (HSE, 2017)).

RO1

The proposed reference exposure value should lead to a reduction in the exposure levels and therefore a reduction in the excess cancer risks in sectors where part of the industry is currently operating in risk levels higher than the reference exposure value. Similar to the assessment of economic costs, an indicative estimation of these benefits can be done assuming that:

- The number of affected companies are the same as described for the economic impacts.
- The average reduction in risk would be based on the effectiveness of the risk management measures required to meet the reference exposure level.
- The starting point for risk reduction is the RWC level for the first 10% of the companies (from the total number in that sector) and the typical exposure level to the rest of the affected companies.

Table 13 provides the estimated avoided human health costs per sector for RO1. Details of the calculation are provided in appendix 4.

RO2

The assessment of human health impacts for RO2 is based on the assumption that:

- The number of affected companies are the same as described for the economic impacts.
- The average reduction in risk would be based on the assumed effectiveness of the identified risk management measures under that restriction option.
- The starting point for risk reduction is the RWC level for the first 10% of the companies (from the total number in that sector) and the typical exposure level to the rest of the affected companies.

Table 14 provides the estimated avoided human health costs per sector for RO2. Details of the calculation are provided in appendix 4. The individual excess lifetime cancer risk values achieved with the required risk management measures will differ between industrial sectors depending on:

- exposure levels in the sector,
- contribution of the use of powder forms and electroplating to the overall risk levels in the sector, and
- site specific conditions of use of cobalt salts.

Derogation for the animal feed sector

The number of companies benefiting from the derogation for animal feed sector depends on the restriction option and the level of reference exposure value or risk management measures. In total 14 000 workers are estimated to be operating in the sector. The methodology described above for estimating the number of affected workers suggests that for RO1c 100 and for RO1d 600 workers could be operating in companies benefiting from the derogation. The increased human health cost from this derogation can be estimated to be €0-€5 000 for RO1 depending on the reference exposure level.

For RO2, the number of potentially affected workers is up to 14 000. However, most of them (around 13000) are assumed to be working in risk levels below 10^{-5}. The increased human health cost from this derogation can be estimated to be €1 000-€20 000 for RO2 depending on the required risk management measures.

Derogation for excess lifetime cancer risk levels below 10^{-5} under RO2

The number of companies with exposure levels (weighted by time and frequency) below 0.01 µg Co/m^3 operating without the four sets of risk management measures identified under RO2 is not known. The available cancer risk data suggests that at least in the biotechnology sector (formulation and use of feed grade materials, use in biogas production and use in fermentation processes, in biotech and scientific research and standard analysis) many companies could benefit from the derogation. In other sectors, the share of companies reaching the proposed exposure level with current measures in place is more limited.

Even if the total human health impacts cannot be estimated, it can be calculated that assuming 10 exposed workers per company, human health costs in a company operating at an exposure level of 0.01 µg Co/m^3 corresponding to an excess lifetime cancer risk level of

10^{-5} would be around €10 per year. Assuming that 30% of the workers in affected companies would be affected by the derogation in the biotechnology sector, suggests that human health costs would increase by less than €100 per year if the derogation is implemented. Additional 13 000 workers in the feed grade materials sector are estimated to be potentially affected by the derogation but they are not included in this estimate as they are covered by the use specific derogation.

Table 13: Human health impacts of RO1 per sector.

Sector	Excess lifetime cancer risk (typical)	Excess lifetime cancer risk (RWC)	Affected workers				Avoided cancer cases per year				Monetary value for avoided cancer cases per year (€)			
			RO1a	RO1b	RO1c	RO1d	RO1a	RO1b	RO1c	RO1d	RO1a	RO1b	RO1c	RO1d
Manufacture of cobalt salts	1.40E-03	1.00E-02	160	960	1600	1600	2.20E-02	5.54E-02	9.03E-02	9.03E-02	80 614	202 853	330 917	330 917
Manufacture of chemicals	2.10E-03	5.30E-03	0	2940	4900	4900	0.00E+00	1.24E-01	2.96E-01	2.96E-01	0	455 492	1 085 182	1 085 182
Manufacture of batteries			Included in the manufacture of chemicals											
Manufacture of catalysts	5.10E-04	9.40E-04	0	0	240	400	0.00E+00	0.00E+00	2.95E-03	5.52E-03	0	0	10 809	20 243
Manufacture of pigments and dyes	2.10E-03	5.20E-03	0	15	25	25	0.00E+00	6.29E-04	1.50E-03	1.50E-03	0	2 305	5 514	5 514
Use as catalysts	8.00E-04	3.30E-03	0	0	240	400	0.00E+00	0.00E+00	6.90E-03	1.05E-02	0	0	25 271	38 436
Surface treatment														
The formulation of surface treatment solutions	1.50E-04	2.90E-04	0	0	45	75	0.00E+00	0.00E+00	1.22E-04	3.07E-04	0	0	448	1 126
Passivation or anti-corrosion treatment processes	2.10E-03	4.50E-03	0	3540	5900	5900	0.00E+00	1.40E-01	3.45E-01	3.45E-01	0	512 778	1 263 453	1 263 453
Metal or metal - alloy plating	6.80E-03	1.20E-02	150	900	1500	1500	2.48E-02	1.60E-01	2.74E-01	2.74E-01	90 690	585 200	1 004 832	1 004 832
Use in biotechnology							0.00E+00	0.00E+00	0.00E+00	0.00E+00	0	0	0	0
Formulation and industrial use of mixtures in biogas production	5.60E-04	2.70E-03	0	54	324	540	0.00E+00	3.01E-03	6.76E-03	1.04E-02	0	11 019	24 770	38 250
Professional use in biogas production	1.60E-05	1.60E-05	0	0	0	2916	0.00E+00	0.00E+00	0.00E+00	6.42E-04	0	0	0	2 351
Use in fermentation, biotech, scientific research and	1.90E-04	1.90E-04	0	0	378	630	0.00E+00	0.00E+00	9.88E-04	2.99E-03	0	0	3 619	10 954

Sector	Excess lifetime cancer risk (typical)	Excess lifetime cancer risk (RWC)	Affected workers				Avoided cancer cases per year				Monetary value for avoided cancer cases per year (€)			
			RO1a	RO1b	RO1c	RO1d	RO1a	RO1b	RO1c	RO1d	RO1a	RO1b	RO1c	RO1d
standard analysis														
Formulation and use in feed grade materials	Not affected by RO1 (use specific derogation included)													
Bespoke uses														
Use in humidity indicators cards, plugs and/or bags with printed spots	2.60E-05	6.40E-05	Number of workers not available											
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	4.70E-04	3.50E-03	Number of workers not available											
Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	6.00E-05	1.40E-04	Number of workers not available											
TOTAL							0.05	0.48	1.02	1.04	171 304	1 769 647	3 754 813	3 801 257

Table 14: Human health impacts of RO2 per sector

Sector	Excess lifetime cancer risk (typical)	Excess lifetime cancer risk (RWC)	Affected workers				Avoided cancer cases per year				Monetary value of the avoided cancer cases per year (€)			
			RO2a	RO2b	RO2c	RO2d	RO2a	RO2b	RO2c	RO2d	RO2a	RO2b	RO2c	RO2d
Manufacture of cobalt salts	1.20E-03	8.90E-03	80	320	640	1584	9.79E-03	3.33E-02	4.50E-02	7.80E-02	35 873	122 130	164 891	285 682
Manufacture of chemicals	7.30E-04	4.90E-03	245	980	1960	4851	1.65E-02	5.69E-02	7.82E-02	1.39E-01	60 485	208 489	286 425	509 382
Manufacture of batteries	Included in the manufacture of chemicals													
Manufacture of catalysts	9.40E-04	6.80E-04	20	80	160	396	1.87E-04	1.34E-03	3.15E-03	9.04E-03	685	4 897	11 542	33 122
Manufacture of pigments and dyes	Sector not affected													
Use as catalysts	Sector not affected													
Surface treatment														
The formulation of surface treatment solutions	5.20E-05	1.10E-04	3.75	15	30	74.25	5.67E-06	2.51E-05	4.49E-05	1.07E-04	21	92	164	393
Passivation or anti-corrosion treatment processes	2.10E-03	4.50E-03	295	1180	2360	5841	1.83E-02	8.03E-02	1.43E-01	3.41E-01	66 884	294 290	525 344	1 250 946
Metal or metal -alloy plating	2.10E-03	8.21E-03	75	300	600	1485	8.47E-03	3.19E-02	4.90E-02	1.01E-01	31 024	116 877	179 443	368 506
Use in biotechnology														
Formulation and industrial use of mixtures in biogas production	1.60E-04	1.60E-04	27	108	216	534.6	5.94E-05	3.56E-04	7.78E-04	2.14E-03	218	1 306	2 849	7 828
Professional use in biogas production	Sector not affected													
Use in fermentation, biotech, scientific research and standard analysis	9.60E-05	9.90E-05	31.5	126	252	623.7	4.29E-05	2.53E-04	5.49E-04	1.50E-03	157	928	2 010	5 497
Formulation and use in feed grade materials	Sector not affected (use specific derogation included)													
Bespoke uses														

Sector	Excess lifetime cancer risk (typical)	Excess lifetime cancer risk (RWC)	Affected workers				Avoided cancer cases per year				Monetary value of the avoided cancer cases per year (€)			
			RO2a	RO2b	RO2c	RO2d	RO2a	RO2b	RO2c	RO2d	RO2a	RO2b	RO2c	RO2d
Use in humidity indicators cards, plugs and/or bags with printed spots	Sector not affected													
Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	Number of workers not available													
Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	Sector not affected													
TOTAL			777	3 109	6 218	15 390	0.05	0.20	0.32	0.67	195 347	749 010	1172670	2461356

2.6. Other impacts, practicability and monitorability

2.6.1. Distributional impacts

The benefits of the proposed restriction are mainly received by the workers in companies that have not yet implemented appropriate risk management measures. Their risk of developing cancer from occupational exposure to cobalt salts decreases. Also employers and member states may benefit e.g. due to savings in health care costs and reduced sick leave days. The costs are faced by the companies who have to implement additional risk management measures. These costs are at least to some extent transferred to consumers in form of higher prices of products. Competitors who have already the proposed risk management measures in place may take over market shares from the affected companies.

The excess cancer risk of individual worker depends on the level of implemented risk management measures at the specific site. The risks in some of the companies are clearly higher than what is demonstrated to be achievable in other companies operating in the same industrial sector. The Dossier Submitter does not consider this distribution of cancer risk justified, and it is one of the reasons to conclude that the proposed restriction is justified.

The economic impacts of complying with the proposed restriction may be more challenging to afford for the small companies. Detailed information of the sizes of affected companies is not available, but the Dossier Submitter assumes that in the sectors of surface treatment, biotechnology and within some of the bespoke uses like humidity indicators and water treatment chemicals, a significant number of companies may be small size enterprises. Many of the companies in these sectors are assumed to be affected by the proposed restriction. Recognising the potential challenges for small size companies to comply with the proposed restriction, the Dossier Submitter considers that the available information does not allow categorising companies based on their size nor assuming different reactions or impacts for small companies in comparison to bigger companies.

2.6.2. Enforceability and enforcement costs

RO1

RO1 can be enforced at different levels:

1) Manufacturers and importers: Enforcement can be carried out by checking that the exposure scenarios demonstrate that exposure to the cobalt salts under the conditions of use identified are below the reference exposure value and, in the case of manufacturers, that exposure scenarios are complied with.

2) Suppliers (manufacturers, importers and downstream users): The restriction can be enforced at the supplier level by checking that the Safety Data Sheet contains under Section 8.1 the requirement to control occupational exposures to the cobalt below the reference exposure value.

3) Downstream users: Enforcement can be carried out by checking that the exposure scenarios contained in the Safety Data Sheet are complied with or by reviewing the documentation prepared by downstream users of cobalt salts demonstrating that the exposure levels are below the reference exposure level.

The enforcement is part of normal enforcement of exposure scenarios and Safety Data Sheets under REACH. Enforcement of the derogation for the use of cobalt salts in animal feed can be done by checking that the cobalt salts in use are listed as authorised under Regulation (EC) no 1831/2003.The Dossier Submitter considers that RO1 is enforceable.

The enforceability of RO1 was put into question in the consultation both by member states and by the cobalt industry. According to the comments received, RO1 introduces a new concept, i.e. the "reference exposure value" which may be in contradiction with national OELs and result in conflicting requirements. Forum also considered RO1 as non-enforceable based on similar arguments. Although the Dossier Submitter recognises that the concept of cumulative exposure may be new in the context of the occupational legislation, it is regularly in use in the authorisation process under REACH for the authorisation of non-threshold carcinogens, such as chromium VI compounds, for which national OELs are already available. Exposure scenarios and resulting cumulative exposures are currently enforced by enforcement authorities at authorisation holders' workplaces. The "reference exposure value" based on cumulative exposure should be therefore enforceable in a similar way under a REACH restriction.

RO2

The enforcement of the proposed restriction can be carried out by visual inspection of the existing risk management measures. In case industry relies on the derogation for exposure levels below 0.01 µg Co/m^3, the enforcement can be carried out reviewing the documentation that demonstrates that the exposure values are below 0.01 µg Co/m^3. The methodology to determine exposure levels weighted over time and frequency to demonstrate that exposure levels are below 0.01 µg Co/m^3 is identified in appendix 1. Similar to RO1, enforcement of the derogation for the use of cobalt salts in animal feed can be done by checking that the cobalt salts in use are listed as authorised under Regulation (EC) no 1831/2003.

The Dossier Submitter considers that RO2 is enforceable.

Enforcement costs

The average administrative enforcement costs per restriction case are estimated to be around €50 000 annually for the EU. There is no information available to assume that this restriction would require more or less enforcement than an average case.

2.6.3. Practicality

RO1

Updating the CSA and the SDS is a requirement when new information on the hazard profile becomes available. Registrants, downstream users and suppliers are required to update the corresponding documents to reflect the conditions of the restriction under RO1.

The practicality of implementing adequate risk management measures to control exposure to the cobalt salts below a determined exposure level will depend on which reference level of exposure is considered justified. The more stringent the reference exposure value selected, the more technically challenging and expensive the risk management measures to be implemented are. In general terms, the Dossier Submitter estimates that to achieve exposure levels below a reference value of 1µg Co/m^3 (RO1b), the use of closed systems or, at least partially enclosed systems with LEV is required. These technical measures are already implemented in a significant number of sectors of use and are therefore considered to be technically and economically feasible except in the surface treatment sector where the continuous immersion of pieces may not allow an effective enclosure of the system. Full enclosure of the process with LEV may be required to lower exposure levels below 0.1 µg Co m^3 (RO1c) and below 0.01 µg Co/m^3 (RO1d). The implementation of fully enclosed systems with LEV is expensive and may present technical challenges, not only in the surface treatment sector but also in other activities such as the manufacture of the cobalt salts and the manufacture of chemicals. Nevertheless, the Dossier Submitter recognises that the

implementation of technical and organisational measures to achieve a reference exposure value may differ from those already discussed here. The fact that RO1 does not specify the risk management measures to be implemented to reduce exposure levels below a reference exposure value increases the practicality of the option for the downstream users. In some individual worksites it may be possible that the implementation of technical and organisational measures will not allow to reach the reference exposure values set and the use of high efficient RPE (APF 40 or above) will be required to meet the specified target.

Additionally the measurement of cobalt concentration in air below certain levels may require the use of analytical techniques with a higher sensitivity than those presently used by industry. According to information compiled from the Dossier Submitter, the most sensitive analytical procedure available for the measurement of cobalt concentration in air presents a limit of quantification calculated as 0.000 3 µg Co/m^3 (assuming to 2 hours sampling with a flow rate of 2L/min) (see appendix 1). However according to information provided by industry (Vetter *et al*, 2018) the minimum limit of quantification achieved in practice is in the range of 0.1 µg Co/m^3 with a typical value of 0.8 µg Co/m^3. The reasons for the difference may lay in the analytical methods selected by industry to comply with the regulatory limits in place at the different member states, ranging from 0.5 to 100 µg Co/m^3 (see section B.9.1.2). Cobalt measurement data presented by industry in the registration dossiers seem to indicate a quantification limit in the range of 1 µg Co/m^3. Nevertheless, the Dossier Submitter considers that measurement of cobalt concentration in air below 0.01 µg Co/m^3 can be performed if adequate analytical techniques are used.

RO1 defines the derogation from the restriction requirements for the use of cobalt salts in feed grade materials within the scope of Regulation (EC) no 1831/2003. Since the cobalt salts authorised under the animal feed regulation are listed and their uses identified, the derogation will not require any additional actions for the companies involved.

Table 15 below shows the practicality of each restriction option assessed within RO1, including the derogation. The practicality of each option has been assessed as high, medium or low. Three factors have been considered:

1) Technical feasibility: this factor describes to what extent the manufacturers and users of the cobalt salts will be capable to identify and implement technical, organisational and personal protection measures to ensure that exposure levels are below the reference exposure levels, taking into account the specificities of the processes involved.
2) Economic feasibility: the cost of the implementation of RMMs per company (see section 2.4 on economic impacts) is taken into account to determine whether the restriction option will be practical.
3) Analytical methods: the availability of measurement techniques and its adequacy to determine occupational exposure levels is considered in this factor.

Table 15: Practicality of restriction options under RO1

	Technically feasible	**Economically feasible**	**Analytical methods**	**Overall practicality**
RO				
RO1a	Yes	High	Yes	Demonstrated
RO1b	Yes	Medium	Yes	Demonstrated
RO1c	Yes	Low	Yes	Possible

	Technically feasible	Economically feasible	Analytical methods	Overall practicality
RO1d	Yes	Low	Yes	Challenging
Derogation				
Animal feed	Yes	High	-	Demonstrated

As can be seen in Table 15 above, the practicality of RO1a and RO1b is considered demonstrated while it is assumed that RO1c, and specifically RO1d may prove challenging to implement by all companies in all sectors of activity.

Finally, the derogation for the use of cobalt salts in feed grade materials within the scope of Regulation (EC) no 1831/2003 facilitate the implementation of RO1. It is to be noted that under REACH, substances used as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003 are exempted among others from the registration requirements (and therefore the need to perform a CSA) and the communication of risks through SDS.

RO2

The practicality of implementing RO2 will depend on the set of technical risk management measures selected as mandatory within the restriction proposal. The implementation of ventilation systems (mechanical ventilation and/or LEV), as identified in RO2a and RO2b is considered technically and economically feasible in all sectors of manufacture and use of the cobalt salts. In addition, the use of closed systems or at least partially enclosed systems with LEV is already implemented in a significant number of sectors of use and as discussed for RO1 above and is assumed to be technically and economically feasible, except for surface treatment operations. Based on the above discussion, the dossier submitter estimates that RO2a and RO2b present a high implementability while RO2c will be implementable in all sectors but surface treatment. On the other hand, the implementation of closed systems with LEV, as identified in RO2d, will present technical challenges in a number of sectors in addition to the high costs involved for each company, and is uncertain whether it can be implemented in practice by the different sectors of use.

RO2 identifies a derogation for all uses where exposure levels are below 0.01 µg/m^3. The derogation is introduced to account for activities where the cobalt salts are used in very low quantities and very infrequently. As discussed for RO1, the measurement of cobalt concentrations in air below 0.01 µg/m^3 can be performed if adequate analytical techniques are in use.

Similar to RO1, the derogation from the restriction requirements for the use of cobalt salts in feed grade materials within the scope of Regulation (EC) no 1831/2003 will not require any additional actions for the companies involved.

The practicality of all restriction options under RO2 (including the derogations) is presented in Table 16 below.

Table 16: Practicality of restriction options and derogations under RO2

	Technically feasible	Economically feasible	Analytical methods	Overall practicality
RO				

	Technically feasible	Economically feasible	Analytical methods	Overall practicality
RO2a	Yes	High	-	Demonstrated
RO2b	Yes	High	-	Demonstrated
RO2c	Yes (Uncertain for surface treatment)	Medium (Low for surface treatment)	-	Possible (Uncertain for surface treatment)
RO2d	Uncertain	Low	-	Uncertain
Derogations				
Exposure levels below 0.01 µg/m^3)	Yes	High	Yes	Demonstrated
Animal feed	Yes	High	-	Demonstrated

Transitional period

A transitional period of 24 months is proposed to provide sufficient time to plan (6 months) and implement the risk management measures required (18 months). It is expected that the update of the CSA and SDS will take place in the initial 6 months.

2.6.4. Monitorability

RO1 and RO2 can be monitored by enforcement authorities by measuring exposure levels at the worksites as part of site visits. Monitoring activities will have to take into account the use of adequate analytical methods depending on the reference exposure level selected.

Alternatively, the results of the implementation of RO1 and RO1 can be monitored by the enforcement authorities through the follow up of the RMMs implemented at the workplaces to comply with the restriction. Quantitative indicators can be developed to determine the number of companies which have implemented each type of RMMs within each sector and the exposure levels measured by these companies once the RMMs are implemented. This monitoring system would be preferable in case the enforcement authorities do not have the equipment and expertise to perform the measurement of exposure levels, as suggested by the Forum advice[15].

RAC is of the opinion (in line with the Forum's advice and a relevant number of contributions in the consultation) that implementation, enforcement and especially monitoring of the restriction as proposed by the Dossier Submitter will be extremely challenging.

Especially contributions of industry in the consultation point in the direction that:

- **the REV of 0.01µg/m³ is not achievable by many of the affected industry sectors**

[15] Forum advice on enforceability on restriction proposal regarding cobalt salts, April 2019.

- **neither in-house monitoring as performed by industry nor monitoring by enforcement authorities will be able to show compliance (or non-compliance) with the REV.**

The values as proposed by RAC are considered to be better enforceable and monitorable by Forum.

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

2.7. Proportionality

The cost imposed by a restriction can be considered proportionate to the risk reduction achieved if the benefits of reducing risks to human health and/or the environment are larger than the compliance costs for industry of implementing necessary RMMs or OCs. As in this restriction report the monetised benefits do not necessarily outweigh the costs with the applied methodology, a conclusive judgement on proportionality is more difficult to reach and warrants additional argumentation to support the proposal. The relevant information to assess the proportionality of the restriction options is summarised in this chapter.

The economics literature presents approaches for weighting different impacts. Weighting could be justified based e.g. on aversion to risk inequity in general and to cancer risk in particular, when high risk levels for workers are considered to be inacceptable for the decision makers. Unfortunately, the literature does not provide explicit guidance in defining the weights, nor provide straightforward answers when and how such approaches should be used. A brief discussion on the rationale for using such weighting approaches and their inherent challenges is provided in appendix 6.

The Dossier Submitter has assessed different reference exposure values and different sets of risk management measures to facilitate the decision on the desired level of worker protection. The monetised results described under economic and human health impacts are summarised in Table 17. As the assessment demonstrates, the applied methodology proposes net benefits only for RO1a and RO2a and for the derogations. However, the methodology may not be sensitive enough to address a regulatory action that would only affect few companies with very limited requirements.

To facilitate the overall comparison of the restriction options, Table 17 summarises also the qualitative information discussed under section 2.6.3 on practicality. The effectiveness, costs and practicality vary between the options. All options are considered to be monitorable and enforceable.

The following discusses the pros and cons of the restriction options 1 and 2.

RO1 is based on a reference exposure level to be implemented in the CSA and SDS plus a derogation for animal feed.

Pros:

- Reference exposure values will be communicated through the SDS, ensuring that the risks are known across all sectors of use.

- This would be the minimum regulatory intervention: registrants and DUs may decide upon the most adequate RMMs to be implemented at their worksite to reduce exposure to the required levels. This is also in line with the underlying principles of REACH.

Cons:

- Reduction in risks may be theoretically achieved with the use of PPE, even when adequate technical measures are available and feasible to implement.

RO2 is based on minimum technical RMMs to be implemented for solid forms and for electroplating and a derogation for animal feed and for activities with very low exposure levels (< 0.01 µg/m^3).

Pros:

- Adequate set of technical measures to be implemented throughout the industry following the hierarchy of control.

Cons:

- This option will not address the problem of communicating the risks of the non-threshold carcinogenicity of the substances.
- Actual effectiveness of RMMs may differ depending on the design of the technical measures, maintenance and testing, training of users, etc.
- Targeting of more specific RMMs for each sector of use is not possible, due to the number of sectors and the lack of specific information for each of them. This can be overcome if more specific information is received in the consultation.
- The risk reduction effectiveness is limited since it addresses exclusively the risks resulting from exposure to the cobalt salts in certain activities (use of solid forms and electroplating).

Therefore, the Dossier Submitter takes the view that RO1 is the most suitable option due to the analysis above. RO2 is rejected as it may have, for example, a lower risk reduction effectiveness.

According to the ECHA Guidance[16], "the decision point for 'acceptable' lifetime (i.e., a working life of 40 years) cancer risk levels used for workers are generally around 10^{-5} but higher or lower levels have been considered to be tolerable under certain circumstances". Although the Dossier Submitter recognises the economic challenges that the implementation of adequate risk management measures to reduce the risk levels below 10^{-5} may pose for a number of companies in several sectors of use, based on this guideline and the assessment performed, the Dossier Submitters concludes that RO1d is the most appropriate Union-wide measure to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts. Other restriction options would not ensure achieving this high level of protection.

In contrast to the Dossier Submitter, RAC concludes that the superiority of the proposed regulatory option RO1d over the other regulatory options in reducing the risks is not demonstrated. In addition, practicality aspects make RO1d extremely challenging.

According to RAC, the proposed derogations for use of cobalt salts in feeding stuff will not provide a comparable level of worker protection within the framework of Regulation (EC) no 1831/2003.

[16] ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (ECHA, 2012)

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

Table 17: Summary of restriction options

RO	Description	Affected workers[a]	Avoided cancer cases[b]/year	Benefit/ year (euros)	Cost/year (euros)	Benefit/Cost	Practicality[c]
RO1	**Reference exposure level in CSA and SDS plus derogation 1**						
RO1a	10 µg/m^3 (ELR =10^{-2})	300 (1%)	0.05 (5%)	200 000	3 000	50:1	Demonstrated
RO1b	1 µg/m^3 (ELR =10^{-3})	8 400 (24%)	0.48 (45%)	1 800 000	2 800 000	2:3	Demonstrated
RO1c	0.1 µg/m^3 (ELR =10^{-4})	15 200 (43%)	1.02 (95%)	3 800 000	260 000 000	1:70	Possible
RO1d	0.01 µg/m^3 (ELR =10^{-5})	18 900 (54%)	1.04 (97%)	3 800 000	370 000 000	1:100	Challenging
RO2	**Minimum technical risk management measures for solid forms and electroplating plus derogations 1 and 2**						
RO2a	Mechanical ventilation	800 (2%)	0.05 (5%)	200 000	30 000	7:1	Demonstrated
RO2b	Local Exhaust Ventilation	3 100 (9%)	0.20 (22%)	700 000	1 000 000	3:4	Demonstrated
RO2c	Closed systems or partially enclosed systems with LEV	6 200 (18%)	0.32 (35%)	1 200 000	19 000 000	1:20	Possible(Uncertain for surface treatment)
RO2d	Closed systems with integrated LEV	15 400 (44%)	0.67 (73%)	2 500 000	360 000 000	1:150	Uncertain
Derogations	**Description**	**Affected workers[a]**	**Cancer cases[b]/year**	**Monetised HH impacts/ year (euros)**	**Avoided Cost /year (euros)**	**-**	**Practicality[c]**
Derogation 1	Animal feed	0-990	0 - 0.0015	0 - 6 000	0 - 20 000 000	Clearly beneficial	High
Derogation 2	Exposure level <0.01 µg/m3	5 -90	0.000001 - 0.00002	4 -80	400 - 6 000 000	Clearly beneficial	High

[a] Total no of exposed workers (baseline)= 35 100; [b] Number of cancer cases (baseline)=1.07;[c] Including technical and economic feasibility and availability of analytical methods

3. Assumptions, uncertainties and sensitivities

The main assumptions and uncertainties and their potential impacts are presented in **Error! Reference source not found.** below. Furthermore, appendix 10 illustrates the impact of different compliance estimates based on the results of the survey provided by the industry in the consultation.

All in all, the Dossier Submitter estimates that the potential impact of the uncertainties in the assessment is from moderate to high and may result both in an overestimation or underestimation of the net benefits of the restriction.

The Dossier Submitter has performed a sensitivity analysis for those variables with the highest impact on the risk assessment at the request of RAC. Low and high values have been selected for each variable based on the Dossier Submitter's best judgment. The results of the analysis are shown in Table S3. In general terms, it is considered that the order of magnitude of the underestimation or overestimation of the risks may be up to one order of magnitude for some parameters. Although the combination of several variables may result in a higher order of variation, it may also have a counterbalance effect and decrease the overall range of uncertainty. However, due to the number of different combinations that may be possible and the complexities inherent to the variation of a number of parameters, this analysis has not been attempted.

Table 18: Assumptions and uncertainties

Assumptions/ Uncertainties	Description/ Justification	Reference	Impacts the following outcomes	Potential over/under estimation of net benefits of restriction	Potential magnitude of impact
Non-threshold effect	The suggested cancer mechanisms may have a threshold even if the current data does not allow identification of this.	Section 1.2.4.2 Section B.4.4.3	Risk estimates Baseline cancer cases Benefits of restriction	Over	High
Assumed linearity for low exposure levels	The dose response relationship were derived by linear extrapolation, which may lead to an overestimation of risks, especially at very low exposure levels.	Section 1.2.4.2 Section B.4.5	Risk estimates Baseline cancer cases Benefits of restriction	Over	High
Ratio inhalable to respirable fraction	The ratio inhalable to respirable fraction is estimated at 2 based on the Okamoto's study (1998).	Appendix 2	Baseline cancer cases Benefits of restriction	Over	Medium
Cancer risk from non-respirable fraction	According to RAC (ECHA, 2016), the non-respirable fraction should be considered as carcinogenic. The dose-response relationship for the non-respirable fraction was not derived since not enough data were available for this	Section 1.2.4.2 Section B.4.5	Risk estimates Baseline cancer cases Benefits of restriction	Over (small possibility for under estimation)	Medium

Assumptions/ Uncertainties	Description/ Justification	Reference	Impacts the following outcomes	Potential over/under estimation of net benefits of restriction	Potential magnitude of impact
	metric. By applying the dose-response function to the inhalable fraction, the Dossier Submitter extrapolates the cancer risk levels of the respirable fraction to the non-respirable fraction to characterise all cancer effects (local and systemic) resulting from exposure to the cobalt salts.				
Skin and respiratory sensitisation, asthma effect	The focus of the restriction is on the carcinogenicity of the cobalt salts. The quantification of impacts do not consider other health effects.	Section 1.2.4.1	Baseline impacts Risk reduction capacity Benefits of restriction	Under	Low
Reproductive toxicity	The focus of the restriction is on the carcinogenicity of the cobalt salts. The quantification of impacts do not consider other health effects.	Section 1.2.4.1	Baseline impacts Risk reduction capacity Benefits of restriction	Under	Low
Exposure values	The number of measurements vary between industrial sectors. In some sectors only one measurement is available for some activities and for some activities the exposure is based on modelling. Very few data are available in the literature to validate the data presented by industry.	Section 1.2.5.2 Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	High
Analytical methods	The measurement procedures presently used for the monitoring of cobalt concentration in air do not allow detecting values below 1µg Co/m^3. Exposure levels may be lower than those reported for some activities.	Section 2.6.3	Risk estimates Baseline cancer cases	Over	Low

Assumptions/ Uncertainties	Description/ Justification	Reference	Impacts the following outcomes	Potential over/under estimation of net benefits of restriction	Potential magnitude of impact
Concomitant exposure to other cobalt compounds	The measurements are from workplaces where the five cobalt salts and possibly other cobalt substances are manufactured and used. The measured cobalt levels may report exposure to a variety of cobalt compounds and not only to cobalt salts.	Section 1.5.2. Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Over	Low
Typical and reasonable worst case exposure level and risk reduction capacity	The estimation of the baseline cancer cases and risk reduction capacity is based on improvements from the reasonable worst case exposure levels (for 10% of the companies) and typical level (for the rest of the affected companies). This affects also the estimated costs under RO1, as the cost for each industrial sector is derived from the effectiveness needed to reach the reference exposure value. It is not clear if this is representative for the different risk levels in the affected companies.	Section 1.4 Section 2.5	Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	Low
Duration and frequency of the activities	Information is from limited sources and cannot be verified.	Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	High
Combined exposure	The estimation of the individual worker cancer risks is based on the combined exposure resulting from the worst case combination of tasks a worker can in theory conduct.	Section B.10	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Over	Medium

Assumptions/ Uncertainties	Description/ Justification	Reference	Impacts the following outcomes	Potential over/under estimation of net benefits of restriction	Potential magnitude of impact
Concomitant exposure to other cobalt salts by individual workers	The individual worker cancer risks estimates and the number of exposed workers take into account the exposure to one of the cobalt salts and do not consider the possibility of one worker to be involved in activities related to more than one cobalt salt, which could be the case especially in the manufacture of cobalt salts and other chemicals.	Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Under	Low
Industry response	It is assumed that all sites implement RMMs if affected by the restriction, or bare similar costs. Other response could be to change OCs under RO1 or to benefit from the derogation under RO2.	Section 2.3	Risk reduction capacity Cost of restriction	Under	Low
Cost of RMMs	Information is from limited sources and cannot be verified. It is not clear if the proposed range correctly and sufficiently reflects the differences in the possibilities to implement measures between individual sites. The assumed lifetime of the technical risk management measures is 20 years.	Section 2.4	Cost of restriction	Both	High
Effectiveness of RMMs	The effectiveness of the technical measures to be implemented is estimated from the literature and may be significantly lowered if not properly implemented and maintained.	Section 2.5	Risk reduction capacity Benefits of restriction	Over	Low to medium
Co-benefits of RMMs	The implemented risk management measures may introduce co-benefits by reducing exposure to other substances	Section 2.5 Appendix 5	Cost of restriction Benefits of restriction	Under	Medium

Assumptions/ Uncertainties	Description/ Justification	Reference	Impacts the following outcomes	Potential over/under estimation of net benefits of restriction	Potential magnitude of impact
	(including other cobalt compounds). This additional benefit has not been considered in the calculation of the impacts due to lack of information.				
Number of exposed workers per sector	Estimated number of exposed workers is provided by the industry. It is based on limited data and cannot be verified. According to information provided in the consultation the number of workers exposed to cobalt salts could be one order of magnitude higher.	Section 1.4 Section 2.4	Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	Medium to High
Number of exposed workers under RO2	All the potentially exposed workers in sectors affected by RO2 are assumed to be exposed to solid forms of cobalt salts. It is not possible to estimate the number of workers that will be exposed exclusively to powder forms.	Appendix 4	Risk reduction capacity Benefits of restriction	Over	Low
Number of sites per sector	Estimated number of companies per sector is provided by the industry. It is based on limited data and cannot be verified.	Section 1.4	Risk reduction capacity Benefits of restriction Cost of restriction	Both	Low to medium
Number of affected sites per sector for RO1	This assumption is made based on the distribution of exposure data. Higher number of affected sites would give higher total costs to implement RMMs with higher human health benefits. The ratio between cost and benefit can be assumed to remain the same.	Section 2.4	Risk reduction capacity Benefits of restriction Cost of restriction	No direct impact on cost benefit ratio. Over or under estimation of total costs and benefits.	High on total costs and benefits
Number of affected sites per sector for RO2	This assumption is based on information on already implemented risk management measures. Higher number of affected	Section 2.4	Risk reduction capacity Benefits of restriction Cost of restriction	No direct impact on C-B ratio. Over or under estimation of total costs and benefits.	High on total costs and benefits

Assumptions/ Uncertainties	Description/ Justification	Reference	Impacts the following outcomes	Potential over/under estimation of net benefits of restriction	Potential magnitude of impact
	sites would give higher total costs to implement risk management measures with higher human health benefits. The ratio between cost and benefit can be assumed to remain the same.				
Value of avoided cancer case	Higher end value provided in ECHA guidance	Section 2.5 Appendix 4	Benefits of restriction	Over	Low
Latency between exposure and cancer	No latency is assumed, the cancer cases are considered to occur in the same year as exposure.	Section 2.5	Benefits of restriction	Over	Low

Table S3. Sensitivity analysis on parameters affecting individual risk levels

Variable	Present Values	Low value for sensitivity analysis	High value for sensitivity analysis	Impact	Low range	High range
Mode of action	Non-threshold	Threshold at 1 µg/m3	Non-threshold	Individual risk levels	Safe use in seven sectors of use	ELR from 10^{-5} to 10^{-2}
Dose-response	Linear; 1.05 x 10^{-3}	Non-linear below 1 µg/m3: 1.05 x 10^{-4}	Linear; 1.05 x 10^{-3}	Individual risk levels	For those sectors with ELR ≤ 10^{-3}, ELR is divided by 10 ELR from 10^{-6} to 10^{-2}	ELR from 10^{-5} to 10^{-2}
Ratio of inhalable fraction to respirable fraction	2	10	1	Individual risk level	ELR divided by 10 * ELR from 10^{-6} to 10^{-3}	ELR from 10^{-5} to 10^{-2}
Cancer risk from non-respirable fraction	1.05 x 10^{-3}	Non-carcinogenic	1.05 x 10^{-3}	Individual risk level		
Exposure values	In the range of 1 to 10 µgCo/m^3	0.5 to 5 µgCo/m^3	10 to 100 µgCo/m^3	Individual risk levels	ELR divided by 2 ELR from 10^{-6} to 10^{-3}	ELR x 10 ELR from 10^{-4} to 10^{-1}
Duration and frequency of activities	Depending on the sector	Present values	Daily activity, i.e. 240 days/year	Individual risk levels	ELR from 10^{-5} to 10^{-2}	ELR x 2 up to x 10 depending on the sector. ELR from 10^{-5} to 10^{-2}

* Assuming the non-respirable fraction is non-carcinogenic

4. Conclusion

Based on the analysis presented, the Dossier Submitter concludes that the risks arising from the manufacture and use of the cobalt salts are not adequately controlled and this needs to be addressed at the Union level.

The Dossier Submitters considers that both restriction options assessed (RO1 and RO2) have their merits and would address to some extent the identified concerns. RO1 provides some flexibility to industry to identify and implement adequate measures to control the risks and will require monitoring arrangements to ensure that the implementation is effective in reducing the risks to an acceptable level. RO2 will ensure that adequate technical measures are implemented to control the risks arising from activities with the highest potential for occupational exposure, but is deemed to be less effective than RO1 in terms of reducing the risks and improving risk communication along the supply chain.

According to the ECHA Guidance[17], "the decision point for 'acceptable' lifetime (i.e., a working life of 40 years) cancer risk levels used for workers are generally around 10^{-5} but higher or lower levels have been considered to be tolerable under certain circumstances". Based on this guideline and the assessment performed, the Dossier Submitters concludes that RO1d is the most appropriate Union-wide measure to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts.

RAC agrees with the Dossier Submitter that a restriction of the five cobalt salts is at present the most appropriate EU wide action to address the identified risks of the use of cobalt salts in different workplaces in the EU.
RAC did not support the Dossier Submitter's proposal for a reference value of 0.01 µg Co/m^3, and instead proposed an 8 h TWA limit value of 1 µg Co/m^3 (as inhalable fraction) and 0.5 µg Co/m^3 (respirable fraction). Additionally, RAC considers it necessary to derive a BOEL for cobalt and its compounds. RAC recommends that this value should be identical to the limit values given in this restriction.
In addition, RAC does not support derogation for cobalt use as an additive in feeding stuff.

See further final RAC Opinion on an Annex XV dossier proposing restrictions on Soluble Cobalt Salts.

[17] ECHA Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health (ECHA, 2012)