EUROPEAN CHEMICALS AGENCY

STUDY REPORT ON THE CONDITIONS OF USE OF FIVE COBALT SALTS

Final report

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PUBLIC VERSION

Annankatu 18, P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | Fax +358 9 68618210 | echa.europa.eu

1. INTRODUCTION

1.1. Background

Cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate (‘the cobalt salts’ or ‘the five cobalt salts’) were prioritised for inclusion in Annex XIV to the REACH Regulation by the ECHA recommendation of 20 December 2011 (3rd recommendation[1]). 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 five 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[2].

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[3]. 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. The study report is included as an Appendix to this current report.

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 salts are genotoxic carcinogens by inhalation with a non-threshold mode of action; RAC[4] supported this conclusion. This work answered one of the key uncertainties raised in the previous report.

The present report (2017) aims to present a complementary picture to the initial study report based on the new data now available to ECHA. This new data includes the conclusion on the mode of action and new information contained in several updates (latest by July 2016) to the registrations dossiers. In this context, the present report is supplementary to certain parts of the initial study report only.

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

2 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

3 “A preliminary investigation into the conditions of use of five cobalt salts” Final report; ECHA, July 2013 (unpublished).

4 http://echa.europa.eu/documents/10162/13563/echa_sr23_project_en.pdf

1.2. Scope

The present report covers the following uses, as requested by the Commission:

1. Use in surface treatment
2. Use as a pigment for PET plastic
3. Use as a catalyst for the production of PTA/IPA/DMT and PET
4. Use as a catalyst in oxygen scavenging processes
5. Use in animal feed
6. Use in fertiliser
7. Use in biogas production
8. Use in biotechnology, pharmaceuticals and *in vitro* diagnostics
9. Use in humidity indicators

The report focuses on identifying those uses for which there may especially be a concern for workers considering the conditions of use of the cobalt salts, the inhalation exposure levels given in the registration dossiers and the corresponding excess lung cancer risks. Excess cancer risks levels are estimated based on the dose –response function developed as part of the assessment of the mode of action of the cobalt salts commissioned by ECHA.

1.3. Methodology

For the purpose of this investigation, ECHA has carried out a review of the registration dossiers for cobalt sulphate, cobalt dinitrate, cobalt dichloride, cobalt carbonate and cobalt diacetate, study.

ECHA performed a screening of the registration dossiers in July 2016 (last search 18/07/2016). For each cobalt salt, the Chemical Safety Reports (CSR) and the Occupational Exposure Scenarios (ES) submitted by the lead registrants were evaluated. No additional CSR or ES were available in ECHA's database.

Based on the screening of these dossiers, the operational conditions, risk management measures and resulting worker inhalation exposure levels were identified for each of the uses (this information is presented in Annex 1). Exposures levels were then used for the calculation of the excess cancer risks for workers based on exposure for a working lifetime (i.e. 40 years).

Exposure values used for the risk characterisation in this report are those provided in the registration dossiers. The methodology used to derive exposure values was not comprehensively assessed, since this was outside the scope of the study. Nevertheless, the methodology is briefly presented in the report to provide a better understanding of the exposure assessment performed by the registrants.

1.4. Structure of the report

Section 2 presents the main parameters of exposure for each of the uses and highlights those activities which give rise to exposure levels that might lead to a concern. Although each use is discussed independently, the conclusions are drawn together providing a comprehensive overview of the key drivers of exposure and the uncertainties identified across all uses under analysis.

Section 3 focuses on risk characterisation and presents the conclusions regarding the risk level arising for each of the uses.

A public version of the initial report on the investigation of the conditions of use of the five cobalt salts (ECHA, July 2013) is included as an Appendix to this document. The report presents a detailed overview of the information gathered in a targeted consultation carried out by ECHA in 2013 together with the information provided in the ESs of the registration dossiers available at the time of developing the report. Although the information of this initial report is partially superseded, especially regarding the ESs, it provides a useful insight of the uses of the five cobalt salts in the different sectors of activity included in the study.

2. OCCUPATIONAL EXPOSURE ASSESMENT

2.1. Exposure estimation methodology applied in the registration dossiers

Worker inhalation exposure estimation is based on measured and modelled data. Measured data are obtained through personal air monitoring data resulting from the use of the substance in similar processes, or calculated as read-across from exposure values resulting from the manufacture of similar inorganic cobalt compounds or of cobalt metal itself. A summary of the monitoring dataset used for the estimation of worker exposure levels for a number of cobalt compounds is presented in the CSR. For the cobalt salts, the number of measurements available varies from 12 to 120 depending on the activity. According to the information provided, the measurement values are either full shift representatives, or have been obtained during the entire task duration and then calculated as time weighted averages. Monitoring data are originally reported for cobalt and then recalculated for each of the cobalt compound based on their molecular weight. Only the total exposure is presented; there is no indication of, for example, the inhalable vs respirable fraction.

Modelled exposure data are based on MEASE. According to the CSR, the intrinsic emission potential of the substance (the so-called fugacity class) is one of the main exposure determinants in the MEASE tool. Cobalt sulphate, cobalt dichloride, cobalt dinitrate and cobalt carbonate in powder form are identified as having medium exposure potential based on the dustiness of the substances. For cobalt diacetate in powder form, a high potential for exposure is selected as input parameter in the modelling tool. Aqueous solutions are considered as having very low to low exposure potential depending on the activity performed. The input parameters for the modelling tool are available in the CSR.

Exposure estimation values are reported in µg per m^3 in the registration dossiers. For comparison purposes, these values have been back-calculated to µg Co per m^3 and presented as such in this report. All exposure values reported correspond to the inhalable fraction[5].

2.2. Use in surface treatment

2.2.1. Exposure Scenarios

For each of the five cobalt salts, the corresponding CSR presents five ES for their use in surface treatment. These ES are as follows:

5 There is no specific information available in the CSRs on the ratio of inhalation fraction to respirable fraction.

1. Formulation of metal surface treatment pre-formulations

2. Use at industrial site - Passivation processes

3. Use at industrial site - Plating process in surface treatment

4. Service life (worker at industrial site) - Industrial handling of surface treated articles (passivated/plated)

5. Service life (professional worker) - Industrial handling of surface treated articles (passivated/plated)

Each of the ES comprises a number of main Worker Contributing Scenarios (WCS) adding up to a total of 19 WCS. Please refer to Annex 1 for a full description of the main WCS.

2.2.2. Operational Conditions and Risk Management Measures

The Operational Conditions (OCs) and Risk Management Measures (RMM) for each of the five Exposure Scenarios as presented in the CSRs are compiled in Annex 1.

In general:

- Handling of cobalt salts in powder form (opening of containers, loading/ unloading, dosing, dosing, weighing, mixing) requires *integrated LEV (90% efficiency) and the use of RPE (APF 10/20)* to reduce inhalation exposure. No specific RMMs are considered necessary for the handling of aqueous solutions of the cobalt substances.

- *Closed semi-automated systems with integrated LEV (90% efficiency) and RPE (APF 10)* are required for dissolution of cobalt salts in powder form and for plating at industrial sites, while for manual brush plating, the contributing scenario specifies the *use of LEV (efficiency 78%) and RPE (APF 20)*.

- *No specific RMMs* to reduce inhalation exposure are required for passivation with aqueous solutions of cobalt salts. The concentration of cobalt salts in passivation solutions is set at 1 to 5%.

- For cleaning and maintenance tasks, the use *of RPE (APF 40)* is identified in all Exposure Scenarios.

- *No specific RMMs* are identified for handling of cobalt coated/plated articles at industrial or professional settings. Only low level energy process are considered in the exposure scenarios (PROC 21).

- All activities require the use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices to ensure safe handling of the substance.

2.2.3. Inhalation Worker Exposure estimation

Inhalation exposure levels based on measured data are provided for several WCSs including: handling of cobalt salts in powder form (including dissolution), plating, handling of articles and cleaning and maintenance. For the other WCSs modelled data based on MEASE are provided in the CSRs.

Inhalation worker exposure levels range from below 1 µg Co/m^3 to 24.5 µg Co/m^3.The activities which give rise to higher exposure levels are those involving the use of cobalt salts in powder form - specifically raw material handling and cleaning and maintenance, which show exposure levels ranging from 20 to 24.5 µg Co/m^3 respectively. It should be noted that these exposure levels are calculated based on measured data and considering that the required RMMs, including the use of RPE (APF10 to 40), are in place for the full duration of the activities (up to 8 hours).

Estimated exposure levels for plating activities are in the range of 4 to 5 µg Co/m^3. These exposure values are estimated based on measured data for a closed semi-automated process and taking into account the use of RPE (APF 10) for the full duration of the shift. Exposure levels for passivation are estimated at 0.6 to 1 µg Co/m^3 based on modelled data.

On the other hand, handling of surface treated articles at industrial and professional settings give rise to exposure levels in the range of 2.5 to 5 µg Co/m^3. This exposure levels are based exclusively on low level energy activities (PROC 21) such as transfer and moving of articles. Exposure values for high energy operations with cobalt coated/plated articles such as grinding, polishing, etc. are not provided.

2.2.4. Discussion

The exposure scenarios for the use of the five cobalt salts in surface treatment appear to cover the major tasks to be performed, including cleaning and maintenance, which may give rise to inhalation exposure for workers.

Although the RMMs and OCs defined in the exposure scenarios may cover the conditions of use in most settings, some of them may not be realistic for some workshops. Specifically, plating in a closed semi-automated process with integrated LEV may not represent the standard conditions of use for this activity. Moreover, several exposure scenarios (including plating itself) rely heavily on the use of RPE to reduce exposure for a duration up to 8 hours, which seems to question the efficiency of the engineering measures in place to control exposure.

Exposure levels estimated based on modelling depend heavily on the exposure potential assigned to substance/activity. Regarding the use of aqueous solutions of cobalt salts, a number of activities may produce aerosols which may lead to a higher potential for exposure. This may apply to activities such as the filling of solutions in the formulation of metal treatment solutions and passivation. For these activities, only modelled data are provided. Since the substance is used as aqueous solution, a very low emission potential is considered for the estimation of exposure in the CSR. However, this may lead to an underestimation of the inhalation exposure levels if aerosols are generated during these activities.

On the other hand, the ES do not consider the conditions of use and the estimated inhalation exposure values for handling activities of cobalt surface treated articles such as grinding, drilling, etc., which may take place in some workshops. These tasks may give rise to the highest exposure levels especially in professional settings if the adequate RMMs are not in place.

2.3. Use as a pigment for PET plastics

2.3.1. Exposure Scenarios

According to the registration dossiers, cobalt diacetate is the only cobalt salt which is used as a pigment for PET plastics. Three ES are identified in the CSR:

1. Use at industrial site – Production and industrial use of plastics and/or PET using cobalt diacetate as a colorant

2. Service life at industrial site –handling of plastics and/or PET in industrial settings

3. Service life professional worker- handling of plastics and/or PET in professional settings

A total number of six main WCS are presented for this use - four for the use of cobalt diacetate at industrial sites and two additional ones for service life of cobalt-containing plastics/PET. The conditions of use recommended for each WCS are compiled in Annex 1.

2.3.2. Operational Conditions and Risk Management Measures

According to the CSR, the conditions of use of cobalt diacetate at industrial sites are similar to those identified for the use of cobalt salts in surface treatment. They include, among others:

- *Integrated LEV (90% efficiency) and RPE (APF 20)* in activities that involve handling of cobalt diacetate in powder form (including loading, unloading, weighing, mixing, and dissolution).

- *Close semi-automated processes with integrated LEV (90% efficiency) and RPE (APF 10)* for further processing (including mixing, blending and extrusion).

- The use *of RPE (APF 40)* for cleaning and maintenance tasks.

- The use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices for all activities.

The “handling (abrasive processing) of cobalt-containing plastics/PET” is defined to take place with general ventilation (efficiency 17%) at industrial settings and, additionally, and only for professional workers, the use of RPE (APF 10) is required.

2.3.3. Inhalation Worker Exposure estimation

Measured data are provided for most of the worker exposure scenarios, with the highest measured values corresponding to the “handling (abrasive processing) of cobalt-containing plastics/PET at industrial sites” and to “cleaning and maintenance” activities, for which 8h TWA exposure values in the range of 22 to 24 µg Co/m^3 are estimated. Exposure levels resulting from the “handling of cobalt diacetate in powder form” are estimated at 18.5 µg Co/m^3. It should be noted that exposure levels are calculated taking the use of RPE into account for “cleaning and maintenance” activities (APF 40) and for “handling of cobalt diacetate in powder form” (APF 20), but not for “handling (abrasive processing) of cobalt-containing plastics/PET at industrial sites”.

Exposure levels for “handling (abrasive processing) of cobalt-containing plastics/PET by professional workers” are lower, in the range of 2.5 µg Co/m^3, since as stated above, the use of RPE (APF 10) is required for this activity.

2.3.4. Discussion

The ES provided define the conditions for the industrial use of cobalt diacetate as a pigment for PET as well as for handling cobalt-containing plastics/PET at industrial and professional settings.

The technical conditions defined, based on integrated LEV and semi-automated closed processes for mixing, blending and extrusion, seem characteristics of industrial sites where extrusion of plastics may take place. However, the heavy reliance on the use of RPE for a duration up to 8 h for several activities (including extrusion itself as well as handling of powder forms) introduces uncertainty regarding the efficiency of the engineering control measures in place to ensure adequate worker protection.

Similarly, reliance on the use of RPE by professional workers to reduce exposure to cobalt in handling of cobalt-containing plastic articles for a full shift may not be adequate to control exposure levels.

2.4. Use as a catalyst for the production of PTA / IPA / DMT and PET

2.4.1. Exposure Scenarios

According to the registration dossiers, cobalt diacetate is the only cobalt salt in use as a catalyst in the manufacture of PTA, IPA, DMT and PET. The CSR for cobalt diacetate presents one ES for this use:

1. Use at industrial site – Use as a catalyst

Two WCS are identified for this use, including loading/unloading, reaction, removal of wet splashes and cleaning and maintenance activities (Annex 1).

2.4.2. Operational Conditions and Risk Management Measures

Cobalt diacetate is used as a homogeneous catalyst in acetic acid solution. Following the description in the CSR, the formulated catalyst mixture is delivered in aqueous acetic solution, stored in a stock tank and then used in a closed system reactor before cobalt is recovered from the reactor solution. No specific RMMs to avoid inhalation exposure to cobalt diacetate are defined for the activities taking place in the manufacturing process expect for “cleaning and maintenance” tasks for which *the use of RPE (APF 40)* is specified.

As a general condition, the use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices are required to control worker exposure to cobalt diacetate in this use.

2.4.3. . Inhalation Worker Exposure estimation

Inhalation exposure values provided for this use are based on measured data. Similar to other uses of cobalt salts discussed previously, the highest inhalation exposure levels (in the range of 24 µg Co/m^3) are measured in the “cleaning and maintenance activities” where exposure to dust/powder is expected.

For the manufacturing process itself (including loading/unloading of the catalyst solution, reaction and the immediate removal of wet splashes), exposure values of 1 µg Co/m^3 are reported. It is not clear, however, whether sampling activities (either in open or close systems) are taken into account in the measured exposure values for the manufacturing process.

2.4.4. Discussion

The exposure scenario defines the activities giving rise to potential exposure to cobalt diacetate in the manufacture of PTA, IPA, DMT and PET. These activities include the major exposure contributing tasks that may take place in a closed reaction process, including cleaning and maintenance activities.

However, it is noted that sampling operations, which may give rise to direct inhalation exposure to workers, are not defined in the ESs. This could be a major contribution of exposure if performed in an open system and may require specific RMMs/OC to control exposure. The specific conditions under which sampling may take place should be identified to provide the required guidance for the safe use of the substance.

Measured exposure levels, in the range of 1 to 24 µg Co/m^3, are in line with those estimated for other uses of cobalt salts already discussed, and seem realistic under the conditions of use defined in the ESs.

2.5. Use as a catalyst in oxygen scavenging processes

2.5.1. Exposure Scenarios

The CSRs of cobalt sulphate, cobalt dichloride, cobalt dinitrate and cobalt carbonate present two ESs for this use:

1. Formulation – Formulation for water treatment chemicals, oxygen scavengers and corrosion inhibitors

2. Use at industrial site – Use of water treatment chemicals, oxygen scavengers and corrosion inhibitors

The ES cover four main WCSs corresponding to formulation, use, cleaning and maintenance tasks (Annex 1).

2.5.2. Operational Conditions and Risk Management Measures

According to the CSRs:

- Formulation of oxygen scavenger solutions involve handling of cobalt salts in powder form. For this task, including opening of containers, dosing, loading/unloading, weighing, mixing, re-packaging and sampling, i*ntegrated LEV (90% efficiency) and the use of RPE (APF 10)* are identified in the ESs.

- The use of formulated solutions at industrial sites, where exposure to aqueous solution with low exposure potential is expected, do *not require specific RMMs* to prevent inhalation exposure to workers.

- For cleaning and maintenance activities the *use of RPE (APF 40)* is identified.

- The use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices are defined to ensure safe handling of the substance for all activities.

2.5.3. Inhalation Worker Exposure estimation

The exposure levels provided in the registration dossiers are based on measured data for the formulation stage and on modelled data for the use of the formulation at industrial sites. Similar to previous uses of the cobalt salts already discussed, the highest exposure levels are measured in activities involving the use of cobalt salts in powder form, which include the “formulation of the oxygen scavenger solutions” and the “cleaning and maintenance activities”. Inhalation exposure levels reported for these activities are in the range of 20 to 24.5 µg Co/m^3 respectively. These values are measured considering the use of RPE (APF10 to 40) for the full duration of the activity (up to 8 hours).

On the other hand, exposure levels arising from the “use of the oxygen scavenger solutions” are estimated to be in the range of 3 to 5 µg Co/m^3 based on modelled data.

2.5.4. Discussion

The ES cover the main tasks that may give rise to exposure to cobalt salts from the formulation and use of water treatment chemicals (oxygen scavenger solutions) in industrial sites. It is noted that, according to the CSRs, the formulation of oxygen scavenger solutions require the use of integrated LEV to control worker exposure, which in practice implies the use of specific equipment which may not be available if formulation takes place in-situ, i.e. where the chemical products are used for water treatment.

Exposure levels reported vary significantly depending on the physical form of the cobalt salts, ranging from 3 to 5 µg Co/m^3 for aqueous solutions to 20 to 24 5 µg Co/m^3 for uses involving handling of cobalt salts in powder form. As previously discussed for other uses of cobalt salts control of exposure for cobalt salts in powder form require the use RPE for the full duration of activity, which may take place for up to 8 hours.

2.6. Use in fertilisers and/or feed grade materials

2.6.1. Exposure Scenarios

The CSR of cobalt sulphate, cobalt dichloride, cobalt carbonate and cobalt diacetate present the conditions of use in fertilisers and feed grade materials. Two ES are identified for each cobalt compound:

1. Formulation – Formulation of fertilisers and/or feed grade materials

2. Use by professional worker – Professional use of fertilisers

The formulation stage covers five WCS corresponding to raw material handling, formulation, filling, packaging and cleaning and maintenance while for the professional use, four WCS are identified including filling/dosing and spreading of solid and liquid fertilisers (Annex 1).

The use in fertilisers and feed grade materials is not identified for cobalt dinitrate.

2.6.2. Operational Conditions and Risk Management Measures

For the formulation stage:

- Raw material handling including powder forms requires the use of *integrated LEV (90 efficiency and of RPE (APF 10/20)*.

- The use of generic LEV (78 % efficiency) is required for the formulation of mixtures (liquid or solid) including mixing, blending and milling activities.

- The concentration of the cobalt salts is restricted to 1 to 5% in the formulated mixtures, except for cobalt diacetate for which a concentration lower than 1% is specified. Solid mixtures are formulated as granulates to reduce their inhalation exposure potential in subsequent uses.

- The packaging of solid mixtures and filling of aqueous solutions *do not require specific RMM* to prevent inhalation exposure.

- *RPE (APF 40*) is required for cleaning and maintenance activities.

For the activities covered by the professional use of fertilisers, no specific RMMs to control inhalation exposure are identified. These tasks take place either under general ventilation or outdoors, with the cobalt salts being used as solid granulates or as aqueous solutions.

The use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices are required to control worker exposure both at the formulation and at the professional use stage.

2.6.3. Inhalation Worker Exposure estimation

Inhalation exposure values reported in the CSR for this use are based on modelled data except for raw material handling and cleaning and maintenance activities at the formulation stage, for which measured data are presented.

The highest inhalation exposure levels to cobalt are estimated for those activities where the cobalt salts are handled in solid forms, either as powder or as granulates. This include "raw material handling" at the formulation stage, the "formulation of mixtures" as such, and "cleaning and maintenance" tasks where exposure to cobalt dust may be expected. Exposure values in the range of 20 to 24.5 µg Co/m^3 are reported for these activities. It is noted that these exposure values are estimated taking the use of RPE (APF 10/20/40) into account for a duration up to 8 hours, except for the formulation of mixtures as such, for which the use of RPE is not required. The use of solid fertilisers by professional workers gives rise to similar levels of exposure, i.e. up to 25 µg Co/m^3. No RPE is considered for this use.

As can be expected, activities which involve the use of cobalt salts as aqueous solutions give rise to significantly lower exposure levels. Estimated values range from 0.3 to 1 µg Co/m^3 for the formulation stage to 1.5 to 5 µg Co/m^3 for the professional use of fertilisers.

2.6.4. Discussion

The ES appear to cover the major tasks which may lead to inhalation exposure of workers from the use of the cobalt salts as fertilisers. However, the use of feed grade material by professional workers is not included. This activity which may take place indoors could potentially give rise to levels of exposure similar or higher to those arising from the use of cobalt-containing fertilisers.

On the other hand, the handling of the cobalt salts at the formulation stage require the use of integrated LEV (90% efficiency) to control worker exposure. Installations with integrated LEV may be typical for this use at industrial sites but are not encountered in professional settings where (i.e. farms) where fertilisers/feed grade material may be at use. It is to be understood therefore that according to the CSR, handling of cobalt salts as such will take place exclusively at industrial sites, while cobalt-containing fertilisers (i.e. mixtures) with a restricted content of cobalt are in use by professional workers.

Exposure values reported for this use in the CSR are in line with those previously discussed for other uses of cobalt salts. The highest exposure levels correspond to the professional use of fertilisers in solid form for which values up to 25 µg Co/m^3 (no RPE defined) are reported. Other activities give rise to inhalation exposure values in the range of 20 to 24.5 µg Co/m^3 taking into account the use of RPE for up to 8 hours.

2.7. Use in fermentation processes, in the biotech sector and in biogas production

2.7.1. Exposure Scenarios

For this use, three ES are presented in the registration dossiers of the five cobalt salts:

1. Formulation - Formulation of mixtures for use in biogas production

2. Use at industrial site – use in fermentation processes, in scientific research, standard analysis and biogas production

3. Use by professional worker – professional use of formulation in biogas production

The WCS vary depending on the cobalt salt in use. For example, production and packaging of solid formulations is identified in the ES of each cobalt salt except for cobalt diacetate, for which only formulation of aqueous solutions is identified. Similarly, the use by professional workers of cobalt salts in solid form is identified for all cobalt salts except for cobalt diacetate. A comprehensive description of the main WCS for this use is presented in Annex 1.

2.7.2. Operational Conditions and Risk Management Measures

In general:

- Formulation of mixtures takes place exclusively for the biogas sector including handling of cobalt salts in powder form and the production of solid formulations (except for cobalt diacetate) and aqueous solutions. These activities require the use of *integrated LEV (90% Efficiency) and RPE (APF 10/20)* according to the CSR. Similarly, packaging of solid formulations require *integrated LEV (90 % efficiency*) in place to reduce exposure, but no RPE. For the handling of solutions once formulated, *no specific RMMs* to avoid inhalation exposure are identified.

- In industrial sites, the handling of cobalt salts in powder form require the use of *generic LEV (78% Efficiency) and RPE (APF 10/20)* to control inhalation exposure to workers while where aqueous solutions and/or sealed bags are in use, no specific RMM are identified.

- *Closed systems* are identified in operations involving the use of the cobalt salts in powder form in industrial settings as well as *generic LEV (78% efficiency) an the use of RPE (APF 10).*

- Professional workers using cobalt-containing formulations in biogas production require the *use of RPE (APF 10)* for dosing solid material into the reactors, while *no specific RMMs* are required when liquid material is in use. Cobalt content is below 1%.

- For cleaning and maintenance activities the *use of RPE (APF 40)* is identified.

- The use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices are defined to ensure safe handling of the substance for all activities.

2.7.3. Inhalation Worker Exposure estimation

Exposure data are calculated based on measured and on modelled data. The highest exposure values correspond to the “handling of cobalt diacetate in powder form” at industrial sites where exposure levels in the range of 30 µg Co/m^3 are reported. Other activities giving rise to higher exposure values include the “handling of cobalt salts in powder form at the formulation stage” and “cleaning and maintenance activities” where the higher inhalation exposure values estimated are in the range of 20.5 to 24.5 µg Co/m^3 respectively. These values are measured considering the use of RPE (APF10 to 40) for the full duration of the activity (up to 8 hours).

The use of cobalt-containing mixtures (except for cobalt diacetate) in powder form by professional workers give rise to exposure levels up to 25 µg Co/m^3. This values is estimated taking the use of RPE (APF 10) into account for up to 8 h.

On the other hand, “handling of liquid solutions both at industrial and professional settings” give rise to much lower inhalation exposure values, as can be expected. Exposure levels in the range of 0.3 to 4.5 µg Co/m^3 are presented in the CSR.

2.7.4. Discussion

The ES describes the conditions of use define to control exposure to workers both for industrial and professional uses. The conditions of use described, including the RMMs identified to prevent inhalation exposure, appear to be standard conditions of use at the different settings. For example, the formulation of cobalt-containing mixtures require the use of integrated LEV (90 % Efficiency) which may be the case at industrial settings. Similarly, the use of the cobalt salts in closed systems is very likely to be encountered in fermentation processes and in the biotech sector where reactors are routinely used.

Exposure levels presented in the CSR vary significantly, from 1.5 to 30 µg Co/m^3, depending on the activity, cobalt salt, and form of the cobalt salt (solid/liquid solution) in use. Exposure levels at 30 µg Co/m^3 are the highest reported for any use and correspond to the “handling of cobalt diacetate in powder form” at industrial sites. For this use, generic LEV (78% Efficiency) and RPE (APF 10/20) are considered to be in place for a full shift (up to 8 h). It is noted that according to the CSR, cobalt diacetate is not used for the production of cobalt-containing mixtures in powder form but only as aqueous solutions.

Professional uses of cobalt-containing mixtures in solid form (except for cobalt diacetate) gives rise to inhalation exposure levels up to 25 µg Co/m^3. This value is estimated taking the use of RPE (APF 10) into account for up to 8 h. As previously discussed, the use of RPE does not seem adequate as RMM to control exposure up to 8 h in professional settings.

The conditions of use and exposure levels for other activities involving the use of cobalt salts in powder form and as aqueous solutions are in line with those previously discussed for other uses of cobalt salts.

2.8. Use in humidity indicators

2.8.1. Exposure Scenarios

Two ES are identified for the use of cobalt dichloride in humidity indicators. No other cobalt salt is in use according to the CSR. The ES are as follows:

1. Use at industrial site – Use in humidity indicator cards, plugs and/or bags with printed spots
2. Service life (professional worker) – Handling of humidity indicator cards or spotted bags

Five main WCS are identified for this use, including the handling of the cobalt salts as aqueous solutions and further processing, the handling of humidity indicators at industrial sites and by professional workers, and cleaning tasks. For a full description of the ES and WSC, refer to

Annex 1.

2.8.2. Operational Conditions and Risk Management Measures

Exposure to cobalt dichloride takes place exclusively as aqueous solution or already contained in humidity indicator cards or bags. The content of cobalt dichloride in the final product is between 1 to 5%. No additional RMMs are presented in the ES to prevent inhalation exposure of workers.

As a general requirement, the use of gloves, eye protection and certified safety clothing and shoes as well as general good occupational hygiene practices are defined to ensure safe handling of the substance for all activities.

2.8.3. Inhalation Worker Exposure estimation

Inhalation exposure values are based on modelled data. The emission potential of the substance is considered as very low. Exposure values range from 23 µg Co/m^3 for "handling of cobalt dichloride aqueous solutions" to 4.5 µg Co/m^3 for handling of humidity indicators both by industrial and by professional workers.

2.8.4. Discussion

The ES describe the condition of use of cobalt dichloride for the manufacturing and subsequent handling of humidity indicators in the form of cards or bags. The use involves the handling and processing of cobalt dichloride solutions in open systems where exposure to cobalt may take place. Modelling data is based on low emission potential which seems appropriate for the activities described where aerosol formation is not expected.

Estimated exposure levels vary from 4.5 to 23 µg Co/m3. These values can be considered as similar to those encountered for other uses where inhalation exposure to workers may arise from much higher emission potential forms such as powder and dust. Nevertheless, it is to be remarked that no specific RMMs to prevent inhalation exposure are required for this use and therefore exposure levels reported seem to reflect exposure values arising from the process where no specific control measures, such as containment, LEV or RPE, are in place.

2.9. Conclusion on exposure assessment

Inhalation worker exposure levels vary from 0.3 µg Co/m^3 to 30 µg Co/m^3, according to the CSR. In general, except for a few exceptions, exposure levels arising from inhalation exposure to cobalt salts in solid form (powder/dust) are calculated based on measured data, while exposure to cobalt-containing aqueous solutions and to cobalt salt granulates is estimated from modelling data (MEASE).

The activities which give rise to higher exposure levels are those involving the handling of cobalt salts in powder form at industrial sites and cleaning and maintenance activities where exposure levels up to 30 µg Co/m^3 are estimated. For these activities, LEV (minimum 78% efficiency) and the use of RPE (APF 10-40) are common requirements in all ES and for all cobalt salts, and may be routinely encountered in industrial settings. In general, the use of cobalt diacetate in powder form require more stringent RMM due to the higher emission potential assigned to this compound. It is noted along the ES for the different uses and cobalt salts that control of exposure to cobalt-containing powder or dust relies heavily on the use of RPE for activities that may take place for up to 8 h. For example, for formulation activities involving the handling of cobalt salts in powder form, the ES define the use of RPE (APF 10/20) for the full duration of the task. Similarly, activities at industrial sites or by professional workers involving handling of cobalt-containing articles - which may give rise to exposure to dust - require the use of RPE (APF 10/20) to control exposure. Reliance of control of exposure on the use of RPE for 8 hours does not seem adequate, especially for professional workers, where the measures to ensure the proper functioning of the equipment (fit-test, training, supervision, maintenance, etc.) may not be regularly in place. This is also not in line with the hierarchy of occupational control which prioritises the implementation of engineering control systems (automation, enclosure, ventilation) to the use of personal protective equipment (PPE).

In sum, exposure levels arising from exposure to cobalt-containing powder or dust which give rise to the highest exposure levels reported in the CSR (up to 30 µg Co/m^3), seem realistic and representative of the activities described in the ES. Nevertheless, the level of protection assumed from the use of RPE for activities which take place for up to 8 h may not be realistic, especially in the case of professional workers, who may rely on the use RPE as the only control measure to prevent exposure.

Exposure levels resulting from the use of cobalt salts as aqueous solutions are significantly lower, typically in the range of 0.3 to 5 µg Co/m^3. Conditions vary significantly depending on the concentration of cobalt salts in the solution and the activity performed. For example, for formulation of aqueous solutions (mixing) with no restriction on the content of cobalt salts, closed systems with integrated LEV (90% Efficiency) and RPE (APF 10) are required according to the ES. However, passivation in surface treatment with aqueous solutions with 1 to 5% of cobalt salts do not require any specific RMM to prevent inhalation exposure. For both activities it is assumed that the emission potential of the substance is very low. However it is not clear whether formulation and more significantly passivation does not give rise to aerosols which may significantly increase the potential for inhalation exposure to workers. The lack of measured data gives rise to uncertainty regarding the exposure levels reported for these activities.

On the other hand, exposure levels arising from exposure to aqueous solutions of cobalt salts at plating are calculated based on measured data. Nevertheless, according to the ES, exposure levels are measured for the activity taking place in a closed system with integrated LEV (90% Efficiency) and RPE (APF 10). Although the use of LEV and RPE may be standard practice at industrial sites, closed systems are not widely implemented for plating activities and may not reflect the conditions of use encountered in most surface treatment operations.

Overall, it is concluded that the exposure assessment as reported in the CSR is likely to be representative for most of the activities in the scope of this study demonstrating exposure to cobalt salts. However, the assessment presents a number of uncertainties that may lead to an underestimation of the inhalation exposure levels encountered in a significant number of workplaces. This is especially the case for passivation and plating activities where the conditions of use as defined in the ES do not seem to be applicable to small workshops where these operations may take place. Additionally, exposure levels may be significantly higher in those ES for which the use of RPE is required for up to 8 h, if the estimated effectiveness values cannot be achieved as discussed above.

Finally, some activities which may give rise to significant exposure to cobalt salts are not reflected in the ES. These include sampling in closed systems, handling of surface-treated articles with high energy processes (grinding, drilling, etc.) both at professional and industrial settings and professional uses including the use of cobalt-containing feed-grade materials.

3. RISK CHARACTERISATION

The five cobalt salts covered by this report should be considered carcinogens in relation to inhalational exposure only and as non-threshold substances as a genotoxic mode of action cannot be ruled out:

- carcinogenicity data are only available for local tumours in the respiratory tract in relation to inhalation exposure, thus dose response estimations can only be made for inhalation exposure.
- the current scientific findings and mode of action considerations may support the notion that water soluble cobalt substances may be threshold carcinogens although there are some uncertainties related to initiation by catalytic ROS generation and direct oxidative DNA damage. In addition, the genotoxicity data may indicate a non-threshold mechanism.
- thresholds have not been identified for the cobalt salts in relation to the carcinogenicity and genotoxicity in the respiratory tract.

These conclusions were supported by RAC[6] at RAC 37.It is to be noted that industry did not agree with this assessment and argue a threshold mechanism is most likely. Industries conclusion is due to their opinion that the catalytic ROS generation and direct oxidative DNA damage are the only mechanisms relevant to the cancer formation seen in animals. They dispute the evidence of genotoxic mechanisms that RAC accepted due to the route of exposure (ip), deficiencies in the studies showing genotoxicity and that the substance is an essential element. RAC disagreed with their view.

ECHA's contractor developed a dose response function for the carcinogenicity of the five cobalt salts. The dose response relationship was derived by linear extrapolation, which is to be considered as a very conservative approach, especially at very low exposure levels. In addition, the dose response derived is based only on the respirable fraction since no reliable data were available for inhalable particles. RAC agreed to this approach being used for the quantitative assessment of cancer risks.

Using the information extracted from the registration dossiers for the five cobalt salts, excess risk values have been calculated for the various uses of the salts. Since the content of respirable particles is not available, worker excess cancer risks have been estimated considering that 10% of cobalt inhalable particles are in the respirable range. Additionally, as sensitivity analysis, the excess cancer risk for workers have been derived assuming that 100 % of the cobalt exposure levels reported correspond to respirable particles. The results are shown in Annex 2.

For all uses, activities which give rise to exposure to cobalt salts in solid forms (powder/granulates/dust) result in excess cancer risk values in the range of 10^{-3} to 10^{-2}. Lower excess cancer risk values, in the range of 10^{-5} to 10^{-3}, result from, in general, activities involving exposure to aqueous solutions and handling of articles.

It has to be remarked that these risk levels are calculated considering an exposure of 8 hours per day, 220 days per year and for a working life of 40 years. Excess cancer risk values may be significantly lower if the actual duration and frequency of the activity is taken into account. This will be specially the case for activities which may take place for a short period of time (e.g. raw material handling in small workshops) or sporadically (e.g. cleaning and maintenance). On the other hand, since the activities are not restricted to a limited time or frequency in the registration dossiers, it is theoretically possible that real exposure values and

[6] http://echa.europa.eu/documents/10162/13563/rac_agreement_cobalt_salt_en.pdf

the corresponding excess cancer risks may be as presented in Annex 2.

Whilst there is no agreed level of excess cancer risk that is deemed unacceptable, risk levels in the range of 10^{-3} to 10^{-2} have been seen as requiring some level of risk management action. Additionally, the uncertainties identified regarding the exposure levels resulting from the use of cobalt salts, especially for passivation and plating activities and for those tasks for which control of exposure relies heavily on the use of RPE, may result in higher exposure levels and therefore higher excess cancer risks than those reported in this study.

4. ANNEXES

ANNEX 1 - Occupational Exposure Scenarios

ANNEX 2 – Worker Excess Cancer Risk

ANNEX 1-Occupational Exposure Scenarios

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM LEV	RMM RPE
Use #1	**Use in surface treatment**								
	Substance: Cobalt sulphate (1), Cobalt dichloride (2), Cobalt dinitrate (3), Cobalt carbonate (4), Cobalt diacetate (5)								
	1- Formulation of metal surface treatment pre-formulations (measured data & MEASE)								
	1.1- Raw material handling (measured data) (Opening of containers/dosing)	54 (1) 45 (2) 64 (3) 41 (4) 56 (5)	26,8B	nr	Solid (powder/dust), Aqueous solution/ Medium EP, High EP (5)	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%; APF=20 Efficiency 95% (5)
	1.2- Formulation of solutions (measured data& MEASE (5)) (Dissolution)	11 (1) 9 (2) 13 (3) 9 (4) 1 (5)	3,2	nr	Aqueous solution/ Very Low EP	nr	Ambient Temperature, Closed process, Semi-automated	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%; Not required (5)
	1.3- Filling of solutions (MEASE)	6 (1) 6 (2) 6 (3) 6 (4) 6 (5)	8B	5-25	Aqueous solution/ Very Low EP	nr	Ambient Temperature	Not required	Not required
	1.4- Cleaning & Maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from e.g. filters/overspill, or as waste)	64 (1) 54 (2) 76 (3) 49 (4) 73 (5)	8A,26		Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in operation)	Not required	APF=40 Efficiency: 97.5%
	2- Use at industrial site - Passivation processes (measured data & MEASE)								
	2.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	54 (1) 45 (2) 64 (3)	5,8B	nr	Solid (powder/dust)/ Medium EP,	nr	Ambient Temperature	Integrated LEV Efficiency:	APF=10 Efficiency: 90%;

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM	
								LEV	RPE
		41 (4) 56 (5)			High EP (5)			90%	APF=20 Efficiency= 95,5% (5)
	2.2- Dissolution of solid raw materials (measured data)	11 (1) 9 (2) 13 (3) 9 (4) 13 (5)	2,1	nr	Aqueous solution/ Very Low EP	nr	Ambient Temperature Closed process, Semi-automated	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%*
	2.3- Raw material handling (aqueous solutions as input materials) (MEASE) (Mixing, loading/unloading , weighing)	30 (1) 30 (2) 30 (3) 30 (4) 50 (5)	4,9	5-25; nr (5)	Aqueous solution/ Very Low EP	nr	-	Not required	Not required
	2.4- Passivation (MEASE)	2 (1) 2 (2) 2 (3) 2 (4) 2 (5)	13	1-5	Aqueous solution/ Very Low EP	nr	-	Not required	Not required
	2.5- Packaging and handling of passivated articles (measured data)	9 (1) 9 (2) 9 (3) 9 (4) 9 (5)	21	nr	Massive object/ very low EP	nr	Ambient Temperature	Not required	Not required
	2.6- Cleaning & Maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	64 (1) 54 (2) 76 (3) 49 (4) 73 (5)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in operation)	Not required	APF=40 Efficiency: 97.5%
	3- Use at industrial site-Plating processes in surface treatment (measured data & MEASE)								
	3.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	54 (1) 45 (2) 64 (3) 41 (4)	5,8B	nr	Solid (powder/dust)/ Medium EP, High EP (5)	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90% (5) APF=20

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM	
								LEV	RPE
		56 (5)							Efficiency= 95,5%
	3.2- Dissolution of solid raw materials (measured data)	11 (1) 9 (2) 13 (3) 9 (4) 13 (5)	2,1	nr	Aqueous solution/ Very Low EP	nr	Ambient Temperature Closed process, Semi-automated	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%*
	3.3- Raw material handling (aqueous solutions as input materials) (MEASE) (Mixing, loading/unloading , weighing)	50 (1) 50 (2) 50 (3) 50 (4) 50 (5)	4,9	nr	Aqueous solution/ Very Low EP	nr	-	Not required	Not required
	3.4- Plating (measured data)	11 (1) 9 (2) 13 (3) 9 (4) 13 (5)	13	nr	Aqueous solution/ Very Low EP	nr	Closed process (Closed pipe system, closed reaction vessel) Semi-automated	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%*
	3.5- Manual Brush plating (MEASE)	22 (1) 22 (2) 22 (3) 22 (4) 22 (5)	10	1-5	Liquid/ Low EP	nr	-	Generic LEV Efficiency: 78%	APF=20 Efficiency: 95%
	3.6-Handling of coated/plated articles (measured data)	9 (1) 9 (2) 9 (3) 9 (4) 9 (5)	21	nr	Massive object	nr	Ambient Temperature	Not required	Not required
	3.7- Cleaning and maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	64 (1) 54 (2) 76 (3) 49 (4) 73 (5)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in operation)	Not required	APF=40 Efficiency: 97.5%

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM LEV	RMM RPE
	4- Service life (worker at industrial site)-Industrial handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)								
	4.1-Handling of articles (measured data)	9 (1) 9 (2) 9 (3) 9 (4) 9 (5)	21	nr	Massive object	nr	Ambient Temperature	Not required	Not required
	5- Service life (professional worker)-Professional handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)								
	5.1-Handling of articles (measured data)	9 (1) 9 (2) 9 (3) 9 (4) 9 (5)	21	nr	Massive object	nr	Ambient Temperature	Not required	Not required
Use #2	**Use as a pigment for PET plastics**								
	Substance: Cobalt diacetate (5)								
	1- Use at industrial site – production and industrial use of plastics and/or PET using cobalt diacetate as a colorant								
	1.1- Raw material handling (measured data) (Loading/unloading, weighing, mixing dissolution, sampling)	56 (5)	26,8B, 15 9,15	nr	Solid, Aqueous solution/ High EP	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	APF=20 Efficiency: 95%
	1.2- Handling of liquids (MEASE) (Filling of liquids)	10 (5)	9, 8B	nr	Aqueous solution/ Very low EP	nr	Ambient Temperature	Not required	Not required
	1.3- Further processing (measured data) (Mixing, blending, extrusion)	13 (5)	14,2,4, 5,8B	nr	Aqueous solution/ Very low EP	nr	Max. Process Temperature: 180 ºC, Closed process, Semi-automated	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%
	1.4- Final handling of massive objects (measured	66 (5)	24,21	<1	Bound in article/	nr	Ambient	General	Not

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM	
								LEV	RPE
	data) (Abrasive processing)				Medium EP		Temperature	Ventilation Efficiency: 17%	required
	1.5- Cleaning and maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	73 (5)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure	Not required	APF=40 Efficiency: 97.5%
	2- Service life (worker at industrial site)– Handling of plastics and/or PET in industrial setting								
	2.1-Handling of massive objects (measured data) (Abrasive processing)	66 (5)	24,21	<1	Bound in article/ Medium EP	nr	Ambient Temperature	General Ventilation Efficiency: 17%	Not required
	3- Service life (professional worker)– Handling of plastics and/or PET in professional setting								
	3.1-Handling of massive objects (measured data) (Abrasive processing)	7 (5)	24,21	<1	Bound in article/ Medium EP	nr	Ambient Temperature	General Ventilation Efficiency: 17%	APF=10 Efficiency: 90%
Use #3	**Use as a catalyst for the production of PTA / IPA / DMT and PET**								
	Substance: Cobalt diacetate (5)								
	1- Use at industrial site – use as a catalyst								
	1.1- Use as a catalyst (measured data) (Loading/unloading, reaction)	3 (5)	1,2,8A	nr	Aqueous solution/ Very low EP	nr	Max. Process Temperature: 160 ºC (semi-closed process), 600 ºC (closed process), Indoors and outdoors	Not required	Not required
	1.2- Cleaning and maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	73 (5)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in	Not required	APF=40 Efficiency: 97.5%

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM LEV	RMM RPE
							operation)		
Use #4	**Use as a catalyst in oxygen scavenging processes**								
	Substance: Cobalt sulphate (1), Cobalt dichloride (2), Cobalt dinitrate (3), Cobalt carbonate (4)								
	1- Formulation for water treatment chemicals, oxygen scavengers, corrosion inhibitors (measured data)								
	1.1- Formulation (Opening of containers/dosing,loading/unloading, weighing, mixing, re-packaging, sampling)	54 (1) 45 (2) 64 (3) 41 (4)	26,8B, 2,4,5, 9,15	nr	Solid (powder /dust,crystal), Aqueous solution/ Medium EP	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%
	1.2- Cleaning & Maintenance (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	64 (1) 54 (2) 76 (3) 49 (4)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (system not in operation)	Not required	APF=40 Efficiency: 97.5%
	2- Use at industrial site-use of water treatment chemicals, oxygen scavengers, corrosion inhibitors (MEASE)								
	2.1- Use of formulation	10 (1) 10 (2) 10 (3) 10 (4)	8B,2	nr	Aqueous solution/ Very low EP	nr	Ambient Temperature	Not required	Not required
	2.2- Cleaning (Immediate removal of wet splashes)	50 (1) 50 (2) 50 (3) 50 (4)	8A	-	Aqueous solution/ Very low EP	nr	Ambient Temperature and Pressure (system not in operation)	Not required	Not required
Use #5 **Use #6**	**Use in fertilisers and/or feed grade materials**								
	Substance: Cobalt sulphate (1), Cobalt dichloride (2), Cobalt carbonate (4), Cobalt diacetate (5)								
	1- Formulation of fertilisers and/or feed grade materials (measured data & MEASE)								

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³⁾	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM	
								LEV	RPE
	1.1 Raw material handling (measured data) (Interim storage in un-opened container, loading/unloading)	54 (1) 45 (2) 41 (4) 56 (5)	26, 8B,9	-	Solid, Aqueous solution/ Medium EP, High EP (5)	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%; (5) APF=20 Efficiency= 95,5%
	1.2 Formulation (MEASE) (Mixing, blending, milling)	44 (1) 44 (2) 44 (4) 22 (5)	3,1,2	1-5 <1 (5)	Solid, Aqueous solution/ Medium EP, High EP (5)	nr	Ambient Temperature; Closed process	Generic LEV Efficiency: 78%	Not required
	1.3 Filling (MEASE) (Filling of liquids)	2 (1) 2 (2) 2 (4) 1 (5)	9, 8B	1-5 <1 (5)	Aqueous solution/ Very low EP	nr	Ambient Temperature	Not required	Not required
	1.4 Packaging (MEASE)	10 (1) 10 (2) 10 (4) 10 (5)	8B	<1	Solid (granulate)/ Low EP	nr	Ambient Temperature	Not required	Not required
	1.5- Cleaning & Maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	64 (1) 54 (2) 49 (4) 73 (5)	8A, 26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in operation)	Not required	APF=40 Efficiency: 97.5%
	2- Professional use of fertilisers (MEASE)								
	2.1 Filling/dosing of solid material (MEASE) (Filling of fertiliser spreader with solid material)	50 (1) 50 (2) 50 (4) 50 (5)	8A, 9	<1	Solid (granulate)/ Low EP	nr	Ambient Temperature	General ventilation Efficiency: 0%	Not required
	2.2 Filling/dosing of liquid material (MEASE) (Filling of fertiliser spreader with liquid material)	10 (1) 10 (2) 10 (4) 5 (5)	8A, 9	1-5 <1 (5)	Aqueous solution/ Very low EP	nr	Ambient Temperature	General ventilation Efficiency: 0%	Not required
	2.3 Spreading of solid fertilisers (MEASE)	50 (1) 50 (2)	8A	<1	Solid (granulate)/ Low EP	nr	Ambient Temperature;	Not required	Not required

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM LEV	RMM RPE
		50 (4) 50 (5)					Outdoors		
	2.4 Spreading liquid fertilisers (MEASE)	10 (1) 10 (2) 10 (4) 5 (5)	8A	1-5 <1 (5)	Aqueous solution/ Very low EP	nr	Ambient Temperature; Outdoors	Not required	Not required
Use #7 **Use #8**	**Use in fermentation processes, in the biotech sector and in biogas production**								
	Substance: Cobalt sulphate (1), Cobalt dichloride (2), Cobalt dinitrate (3), Cobalt carbonate (4), Cobalt diacetate (5)								
	1- Formulation of mixtures for use in biogas production (measured data & MEASE)								
	1.1-Raw material handling (measured data) (Opening of containers/dosing)	54 (1) 45 (2) 64 (3) 41 (4) 56 (5)	26	nr	Solid (powder/dust) Aqueous solution/ Medium EP, High EP (5)	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90% (5) APF=20 Efficiency= 95,5%
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	11 (1) 9 (2) 13 (3) 9 (4) 1 (5)	3	nr	Aqueous solutions/ Very low EP	nr	Ambient Temperature Closed process, Semi-automated	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90% (5) Not required
Except: (5)	1.3- Production of solid formulations (measured data) (Mixing, milling, sieving, blending)	54 (1) 45 (2) 64 (3) 41 (4)	3	nr	Solid/ Medium EP	nr	Ambient Temperature Closed process	Integrated LEV Efficiency: 90%	APF=10 Efficiency: 90%
	1.4- Filling of solutions (MEASE)	5 (1) 5 (2) 5 (3) 5 (4) 5 (5)	8A	<1	Aqueous solution/ Very low EP	nr	Ambient Temperature	Not required	Not required

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM	
								LEV	RPE
Except: (5)	1.5-Packaging of solid formulations (measured data) (Packaging of powders, granules or other solid formulations)	54 (1) 45 (2) 64 (3) 41 (4)	8A	<1%	Solid (powder/dust) Medium EP	nr	Ambient Temperature	Integrated LEV Efficiency: 90%	Not required
	1.6- Cleaning and maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from filters/overspill, or as waste)	64 (1) 54 (2) 76 (3) 49 (4) 73 (5)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in operation)	Not required	APF=40 Efficiency: 97.5%
	2- Use at industrial site: use in fermentation processes, in scientific research, standard analysis, in the biotech sector and in biogas production								
	2.1- Raw material handling (MEASE) (Loading/unloading, weighing)	22 (1) 22 (2) 22 (3) 22 (4) 90 (5)	9, 8B, 26	nr	Solid (powder/dust)/ Medium EP, (5) High EP	15-60 min; (5) nr	Ambient Temperature; Strict separation from areas contaminated	Generic LEV Efficiency: 78%; (5) Ind.use LEV Efficiency: 82%	APF=10 Efficiency: 90% (5) APF=20 Efficiency= 95,5%
Except: (1) & (5)	2.2- Operations /mixing in closed systems (MEASE)	22 (2) 22 (3) 22 (4)	3,2,1	nr	Solid (powder/dust)/ Medium EP	nr	Ambient Temperature Closed process**	Generic LEV Efficiency: 78%	APF=10 Efficiency: 90%
Except: (1), (4) & (5)	2.3- Handling at laboratory scale (MEASE)	11 (2) 11 (3)	15	nr	Solid (powder/dust)/ Medium EP	nr	Ambient Temperature	Generic LEV Efficiency: 78%	APF=10 Efficiency: 90%
	2.4- Handling of sealed bags (MEASE) (Loading of reactors, placing sealed biodegradable bags directly into the substrate dosing unit)	10 (1) 10 (2) 10 (3) 10 (4) 10 (5)	8B	nr	Massive object/ Very low EP	nr	Ambient Temperature	Not required	Not required

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³⁾	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM LEV	RMM RPE
	2.5- Handling of liquid stock solution (MEASE) (Dissolution in water, mixing, further handling, sampling)	10 (1) 10 (2) 10 (3) 10 (4) 10 (5)	5, 3, 8B, 9	1-5	Aqueous solution/ Very low EP	nr	Ambient Temperature	Not required	Not required
	2.6- Cleaning and maintenance (measured data) (Manual cleaning, repair and maintenance operations, removal of residuals from e.g. filters/overspill, or as waste)	64 (1) 54 (2) 76 (3) 49 (4) 73 (5)	8A,26	-	Solid (powder/dust)/ High EP	nr	Ambient Temperature and Pressure (System not in operation)	Not required	APF=40 Efficiency: 97.5%
	3- Use by professional worker: professional use of formulations in biogas production								
Except: (5)	3.1- Dosing of solid material (MEASE) (Dosing of solid mixture into the reactor)	50 (1) 50 (2) 50 (3) 50 (4)	8A, 9	<1	Solid/ Medium EP	nr	Ambient Temperature; Outdoors	Not required	APF=10 Efficiency: 90%
	3.2- Dosing of liquid material (MEASE) (Dosing of solutions into the reactor)	5 (1) 5 (2) 5 (3) 5 (4) 5 (5)	8A,9	<1	Aqueous solution/ Very low EP	nr	Ambient Temperature Outdoors	Not required	Not required
Use #9	**Use in humidity indicators**								
	Substance: Cobalt dichloride (2)								
	1- Use at industrial site-Use in humidity indicator cards, plugs, and/or bags with printed spots								
	1.1- Handling of liquid raw material (MEASE) (Mixing, loading/unloading, weighing)	50 (2)	5, 8B, 9	>25	Aqueous solution/ Very low EP	nr	Ambient Temperature	Not required	Not required
	1.2- Further processing (MEASE) (Heating, printing of bags, dispensing of solutions on paper, drying)	30 (2)	4, 8B, 9, 13	5-25	Aqueous solution/ Very low EP	nr	Ambient Temperature, 120 ^{0}C during heating	Not required	Not required

	Occupational Exposure Scenario / WCS	Exposure level TWA (µg / m³)	PROC	%	Physical Form / Maximum Exposure Potential (EP)	Maximum Exposure Duration	Technical Conditions	RMM	
								LEV	RPE
	1.3- Handling of humidity indicator cards or spotted bags (MEASE)(Handling of bags, assembly of humidity indicator plugs)	10 (2)	21	1-5	Massive object/ Very low EP	nr	Ambient Temperature	Not required	Not required
	1.4- Cleaning (MEASE) (Immediate removal of wet splashes)	50 (2)	8A	nr	Aqueous solution/ Very low EP	nr	-	Not required	Not required
	2- Service life (professional worker)-Handling of humidity indicator cards or spotted bags								
	2.1- Handling of humidity indicator cards or spotted bags (MEASE)	10 (2)	21	1-5	Massive object/ Very low EP	nr	-	Not required	Not required

*only required during occasional opening of closed system; ** except handling at laboratory scale
RCR: Risk Characterisation Ration, EP: Exposure Potential, nr: not restricted, RMM; Risk Management Measures, LEV: Local Exhaust Ventilation, RPE: Respiratory Protective Equipment

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ANNEX 2

	Cobalt sulphate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure level TWA (µg /m3)	Exposure level TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
Use1	**Use in surface treatment**				
	1- Formulation of metal surface treatment pre-formulations (measured data & MEASE)				
	1.1- Raw material handling (measured data)(Opening of containers/dosing)	54	20.50	2.15E-03	2.15E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	11	3.54	3.71E-04	3.71E-03
	1.3- Filling of solutions (MEASE)	6	2.28	2.39E-04	2.39E-03
	1.4- Cleaning & Maintenance (measured data)	64	24.29	2.55E-03	2.55E-02
	2- Use at industrial site - Passivation processes (measured data & MEASE)				
	2.1- Raw material handling (solid input materials) (measured data)(Mixing, loading/unloading, weighing)	54	20.50	2.15E-03	2.15E-02
	2.2- Dissolution of solid raw materials (measured data)	11	4.18	4.38E-04	4.38E-03
	2.3- Raw material handling (aqueous solutions as input materials) (MEASE)	30	11.39	1.20E-03	1.20E-02
	2.4- Passivation (MEASE)	2	0.76	7.97E-05	7.97E-04
	2.5- Packaging and handling of passivated articles (measured data)	9	3.42	3.59E-04	3.59E-03
	2.6- Cleaning & Maintenance (measured data)	64	24.29	2.55E-03	2.55E-02
	3- Use at industrial site-Plating processes in surface treatment (measured data & MEASE)				
	3.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	54	20.50	2.15E-03	2.15E-02
	3.2- Dissolution of solid raw materials (measured data)	11	4.18	4.38E-04	4.38E-03
	3.3- Raw material handling (aqueous solutions as input materials) (MEASE)	50	18.98	1.99E-03	1.99E-02
	3.4- Plating (measured data)	11	4.18	4.38E-04	4.38E-03
	3.5- Manual Brush Plating (MEASE)	22	8.35	8.77E-04	8.77E-03
	3.6-Handling of coated/plated articles (measured data)	9	3.42	3.59E-04	3.59E-03
	3.7- Cleaning and maintenance (measured data)	64	24.29	2.55E-03	2.55E-02
	4- Service life (worker at industrial site)-Industrial handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	4.1-Handling of articles (measured data)	9	3.42	3.59E-04	3.59E-03
	5- Service life (professional worker)-Professional handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	5.1-Handling of articles (measured data)	9	3.42	3.59E-04	3.59E-03
Use 4	**Use as a catalyst in oxygen scavenging processes**				
	1- Formulation for water treatment chemicals, oxygen scavengers, corrosion inhibitors (measured data)				
	1.1- Formulation	54	20.50	2.15E-03	2.15E-02
	1.2- Cleaning & Maintenance (measured data)	64	24.29	2.55E-03	2.55E-02

	Cobalt sulphate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure level TWA (µg /m3)	Exposure level TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	2- Use at industrial site-use of water treatment chemicals, oxygen scavengers, corrosion inhibitors (MEASE)				
	2.1- Use of formulation	10	3.80	3.99E-04	3.99E-03
	2.2- Cleaning(Immediate removal of wet splashes)	50	18.98	1.99E-03	1.99E-02
Use 5 & 6	**Use in fertilisers and/or feed grade materials**				
	1- Formulation of fertilisers and/or feed grade materials (measured data & MEASE)				
	1.1 Raw material handling (measured data)(Interim storage in un-opened container, loading/unloading)	54	20.50	2.15E-03	2.15E-02
	1.2 Formulation (MEASE)(Mixing, blending, milling)	44	16.70	1.75E-03	1.75E-02
	1.3 Filling (MEASE)(Filling of liquids)	2	0.76	7.97E-05	7.97E-04
	1.4 Packaging (MEASE)	10	3.80	3.99E-04	3.99E-03
	1.5- Cleaning & Maintenance (measured data)	64	24.29	2.55E-03	2.55E-02
	2- Professional use of fertilisers (MEASE)				
	2.1 Filling/dosing of solid material (MEASE) (Filling of fertiliser spreader with solid material)	50	18.98	1.99E-03	1.99E-02
	2.2 Filling/dosing of liquid material (MEASE) (Filling of fertiliser spreader with liquid material)	10	3.80	3.99E-04	3.99E-03
	2.3 Spreading of solid fertilisers (MEASE)	50	18.98	1.99E-03	1.99E-02
	2.4 Spreading liquid fertilisers (MEASE)	10	3.80	3.99E-04	3.99E-03
Use 7 & 8	**Use in fermentation processes, in the biotech sector and in biogas production**				
	1- Formulation of mixtures for use in biogas production (measured data & MEASE)				
	1.1-Raw material handling (measured data) (Opening of containers/dosing)	54	20.50	2.15E-03	2.15E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	11	4.18	4.38E-04	4.38E-03
	1.3- Production of solid formulations (measured data) (Mixing, milling, sieving, blending)	54	20.50	2.15E-03	2.15E-02
	1.4- Filling of solutions (MEASE)	5	1.90	1.99E-04	1.99E-03
	1.5-Packaging of solid formulations (measured data))	54	20.50	2.15E-03	2.15E-02
	1.6- Cleaning and maintenance (measured data)	64	24.29	2.55E-03	2.55E-02
	2- Use at industrial site: use in fermentation processes, in scientific research, standard analysis, and in biogas production				
	2.1- Raw material handling (MEASE)(Loading/unloading, weighing)	22	8.35	8.77E-04	8.77E-03
	2.4- Handling of sealed bags (MEASE)	10	3.80	3.99E-04	3.99E-03
	2.5- Handling of liquid stock solution (MEASE)	10	3.80	3.99E-04	3.99E-03
	2.6- Cleaning and maintenance (measured data)	64	24.29	2.55E-03	2.55E-02
	3- Use by professional worker: professional use of formulations in biogas production				
	3.1- Dosing of solid material (MEASE) (Dosing of solid mixture into the reactor)	50	18.98	1.99E-03	1.99E-02
	3.2- Dosing of liquid material (MEASE) (Dosing of solutions into the reactor)	5	1.90	1.99E-04	1.99E-03

	Cobalt dichloride	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
Use1	**Use in surface treatment**				
	1- Formulation of metal surface treatment pre-formulations (measured data & MEASE)				
	1.1- Raw material handling (measured data)(Opening of containers/dosing)	45	20.39	2.14E-03	2.14E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	9	4.08	4.28E-04	4.28E-03
	1.3- Filling of solutions (MEASE)	6	2.72	2.85E-04	2.85E-03
	1.4- Cleaning & Maintenance (measured data)	54	24.47	2.57E-03	2.57E-02
	2- Use at industrial site - Passivation processes (measured data & MEASE)				
	2.1- Raw material handling (solid input materials) (measured data)(Mixing, loading/unloading, weighing)	45	17.08	1.79E-03	1.79E-02
	2.2- Dissolution of solid raw materials (measured data)	9	4.08	4.28E-04	4.28E-03
	2.3- Raw material handling (aqueous solutions as input materials) (MEASE)	30	13.59	1.43E-03	1.43E-02
	2.4- Passivation (MEASE)	2	0.91	9.52E-05	9.52E-04
	2.5- Packaging and handling of passivated articles (measured data)	9	4.08	4.28E-04	4.28E-03
	2.6- Cleaning & Maintenance (measured data)	54	24.47	2.57E-03	2.57E-02
	3- Use at industrial site-Plating processes in surface treatment (measured data & MEASE)				
	3.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	45	20.39	2.14E-03	2.14E-02
	3.2- Dissolution of solid raw materials (measured data)	9	4.08	4.28E-04	4.28E-03
	3.3- Raw material handling (aqueous solutions as input materials) (MEASE)	50	22.66	2.38E-03	2.38E-02
	3.4- Plating (measured data)	9	4.08	4.28E-04	4.28E-03
	3.5- Manual Brush Plating (MEASE)	22	9.97	1.05E-03	1.05E-02
	3.6-Handling of coated/plated articles (measured data)	9	4.08	4.28E-04	4.28E-03
	3.7- Cleaning and maintenance (measured data)	54	24.47	2.57E-03	2.57E-02
	4- Service life (worker at industrial site)-Industrial handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	4.1-Handling of articles (measured data)	9	4.08	4.28E-04	4.28E-03
	5- Service life (professional worker)-Professional handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	5.1-Handling of articles (measured data)	9	4.08	4.28E-04	4.28E-03
Use 4	**Use as a catalyst in oxygen scavenging processes**				
	1- Formulation for water treatment chemicals, oxygen scavengers, corrosion inhibitors (measured data)				
	1.1- Formulation (Opening of containers/dosing,loading/unloading, weighing, mixing, re-packaging, sampling)	45	20.39	2.14E-03	2.14E-02
	1.2- Cleaning & Maintenance (measured data)	54	24.47	2.57E-03	2.57E-02

	Cobalt dichloride	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	2- Use at industrial site-use of water treatment chemicals, oxygen scavengers, corrosion inhibitors (MEASE)				
	2.1- Use of formulation	10	4.53	4.76E-04	4.76E-03
	2.2- Cleaning(Immediate removal of wet splashes)	50	22.66	2.38E-03	2.38E-02
Use 5 & 6	**Use in fertilisers and/or feed grade materials**				
	1- Formulation of fertilisers and/or feed grade materials (measured data & MEASE)				
	1.1 Raw material handling (measured data)(Interim storage in un-opened container, loading/unloading)	45	20.39	2.14E-03	2.14E-02
	1.2 Formulation (MEASE)(Mixing, blending, milling)	44	19.94	2.09E-03	2.09E-02
	1.3 Filling (MEASE)(Filling of liquids)	2	0.91	9.52E-05	9.52E-04
	1.4 Packaging (MEASE)	10	4.53	4.76E-04	4.76E-03
	1.5- Cleaning & Maintenance (measured data)	54	24.47	2.57E-03	2.57E-02
	2- Professional use of fertilisers (MEASE)				
	2.1 Filling/dosing of solid material (MEASE) (Filling of fertiliser spreader with solid material)	50	22.66	2.38E-03	2.38E-02
	2.2 Filling/dosing of liquid material (MEASE) (Filling of fertiliser spreader with liquid material)	10	4.53	4.76E-04	4.76E-03
	2.3 Spreading of solid fertilisers (MEASE)	50	22.66	2.38E-03	2.38E-02
	2.4 Spreading liquid fertilisers (MEASE)	10	4.53	4.76E-04	4.76E-03
Use 7 & 8	**Use in fermentation processes, in the biotech sector and in biogas production**				
	1- Formulation of mixtures for use in biogas production (measured data & MEASE)				
	1.1-Raw material handling (measured data) (Opening of containers/dosing)	45	20.39	2.14E-03	2.14E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	9	4.08	4.28E-04	4.28E-03
	1.3- Production of solid formulations (measured data) (Mixing, milling, sieving, blending)	45	20.39	2.14E-03	2.14E-02
	1.4- Filling of solutions (MEASE)	5	2.27	2.38E-04	2.38E-03
	1.5-Packaging of solid formulations (measured data)	45	20.39	2.14E-03	2.14E-02
	1.6- Cleaning and maintenance (measured data)	54	24.47	2.57E-03	2.57E-02
	2- Use at industrial site: use in fermentation processes, in scientific research, standard analysis, and in biogas production				
	2.1- Raw material handling (MEASE)(Loading/unloading, weighing)	22	9.97	1.05E-03	1.05E-02
	2.2- Operation in closed systems (MEASE)	22	9.97	1.05E-03	1.05E-02
	2.3- Handling at laboratory scale (MEASE)	11	4.98	5.23E-04	5.23E-03
	2.4- Handling of sealed bags (MEASE)	10	4.53	4.76E-04	4.76E-03
	2.5- Handling of liquid stock solution (MEASE)	10	4.53	4.76E-04	4.76E-03
	2.6- Cleaning and maintenance (measured data))	54	24.47	2.57E-03	2.57E-02
	3- Use by professional worker: professional use of formulations in biogas production				
	3.1- Dosing of solid material (MEASE) (Dosing of solid mixture into the reactor)	50	22.66	2.38E-03	2.38E-02

	Cobalt dichloride	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	3.2- Dosing of liquid material (MEASE) (Dosing of solutions into the reactor)	5	2.27	2.38E-04	2.38E-03
Use 9	**Use in humidity indicators**				
	1- Use at industrial site-Use in humidity indicator cards, plugs, and/or bags with printed spots				
	1.1- Handling of liquid raw material (MEASE) (Mixing, loading/unloading, weighing)	50	22.66	2.38E-03	2.38E-02
	1.2- Further processing (MEASE) (Heating, printing of bags, dispensing of solutions on paper, drying)	30	13.59	1.43E-03	1.43E-02
	1.3- Handling of humidity indicator cards or spotted bags (MEASE)	10	4.53	4.76E-04	4.76E-03
	1.4- Cleaning (MEASE) (Immediate removal of wet splashes)	50	22.66	2.38E-03	2.38E-02
	2- Service life (professional worker)-Handling of humidity indicator cards or spotted bags				
	2.1- Handling of humidity indicator cards or spotted bags (MEASE)	10	4.53	4.76E-04	4.76E-03

	Cobalt dinitrate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
Use1	**Use in surface treatment**				
	1- Formulation of metal surface treatment pre-formulations (measured data & MEASE)				
	1.1- Raw material handling (measured data)(Opening of containers/dosing)	64	20.58	2.16E-03	2.16E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	13	4.18	4.39E-04	4.39E-03
	1.3- Filling of solutions (MEASE)	6	1.93	2.03E-04	2.03E-03
	1.4- Cleaning & Maintenance (measured data)	76	24.44	2.57E-03	2.57E-02
	2- Use at industrial site - Passivation processes (measured data & MEASE)				
	2.1- Raw material handling (solid input materials) (measured data)(Mixing, loading/unloading, weighing)	64	20.58	2.16E-03	2.16E-02
	2.2- Dissolution of solid raw materials (measured data)	13	4.18	4.39E-04	4.39E-03
	2.3- Raw material handling (aqueous solutions as input materials) (MEASE)	30	9.65	1.01E-03	1.01E-02
	2.4- Passivation (MEASE)	2	0.64	6.75E-05	6.75E-04
	2.5- Packaging and handling of passivated articles (measured data)	9	2.89	3.04E-04	3.04E-03
	2.6- Cleaning & Maintenance (measured data)	76	24.44	2.57E-03	2.57E-02
	3- Use at industrial site-Plating processes in surface treatment (measured data & MEASE)				
	3.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	64	20.58	2.16E-03	2.16E-02
	3.2- Dissolution of solid raw materials (measured data)	13	4.18	4.39E-04	4.39E-03
	3.3- Raw material handling (aqueous solutions as input materials) (MEASE)	50	16.08	1.69E-03	1.69E-02
	3.4- Plating (measured data)	13	4.18	4.39E-04	4.39E-03
	3.5- Manual Brush Plating (MEASE)	22	7.08	7.43E-04	7.43E-03
	3.6-Handling of coated/plated articles (measured data)	9	2.89	3.04E-04	3.04E-03
	3.7- Cleaning and maintenance (measured data)	76	24.44	2.57E-03	2.57E-02
	4- Service life (worker at industrial site)-Industrial handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	4.1-Handling of articles (measured data)	9	2.89	3.04E-04	3.04E-03
	5- Service life (professional worker)-Professional handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	5.1-Handling of articles (measured data)	9	2.89	3.04E-04	3.04E-03
Use 4	**Use as a catalyst in oxygen scavenging processes**				
	1- Formulation for water treatment chemicals, oxygen scavengers, corrosion inhibitors (measured data)				
	1.1- Formulation (Opening of containers/dosing,loading/unloading, weighing, mixing, re-packaging, sampling)	64	20.58	2.16E-03	2.16E-02
	1.2- Cleaning & Maintenance (measured data)	76	24.44	2.57E-03	2.57E-02
	2- Use at industrial site-use of water treatment chemicals, oxygen scavengers, corrosion inhibitors (MEASE)				

	Cobalt dinitrate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	2.1- Use of formulation	10	3.22	3.38E-04	3.38E-03
	2.2- Cleaning(Immediate removal of wet splashes)	50	16.08	1.69E-03	1.69E-02
Use 7 & 8	**Use in fermentation processes, in the biotech sector and in biogas production**				
	1- Formulation of mixtures for use in biogas production (measured data & MEASE)				
	1.1-Raw material handling (measured data) (Opening of containers/dosing)	64	20.58	2.16E-03	2.16E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	13	4.18	4.39E-04	4.39E-03
	1.3- Production of solid formulations (measured data) (Mixing, milling, sieving, blending)	64	20.58	2.16E-03	2.16E-02
	1.4- Filling of solutions (MEASE)	5	1.61	1.69E-04	1.69E-03
	1.5-Packaging of solid formulations (measured data)	64	20.58	2.16E-03	2.16E-02
	1.6- Cleaning and maintenance (measured data)	76	24.44	2.57E-03	2.57E-02
	2- Use at industrial site: use in fermentation processes, in scientific research, standard analysis, and in biogas production				
	2.1- Raw material handling (MEASE)(Loading/unloading, weighing)	22	7.08	7.43E-04	7.43E-03
	2.2- Operation in closed systems (MEASE)	22	7.08	7.43E-04	7.43E-03
	2.3- Handling at laboratory scale (MEASE)	11	3.54	3.71E-04	3.71E-03
	2.4- Handling of sealed bags (MEASE)	10	3.22	3.38E-04	3.38E-03
	2.5- Handling of liquid stock solution (MEASE)	10	3.22	3.38E-04	3.38E-03
	2.6- Cleaning and maintenance (measured data)	76	24.44	2.57E-03	2.57E-02
	3- Use by professional worker: professional use of formulations in biogas production				
	3.1- Dosing of solid material (MEASE) (Dosing of solid mixture into the reactor)	50	16.08	1.69E-03	1.69E-02
	3.2- Dosing of liquid material (MEASE) (Dosing of solutions into the reactor)	5	1.61	1.69E-04	1.69E-03

	Cobalt carbonate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
Use1	**Use in surface treatment**				
	1- Formulation of metal surface treatment pre-formulations (measured data & MEASE)				
	1.1- Raw material handling (measured data)(Opening of containers/dosing)	41	20.28	2.13E-03	2.13E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	9	4.45	4.67E-04	4.67E-03
	1.3- Filling of solutions (MEASE)	6	2.97	3.12E-04	3.12E-03
	1.4- Cleaning & Maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	2- Use at industrial site - Passivation processes (measured data & MEASE)				
	2.1- Raw material handling (solid input materials) (measured data)(Mixing, loading/unloading, weighing)	41	20.28	2.13E-03	2.13E-02
	2.2- Dissolution of solid raw materials (measured data)	9	4.45	4.67E-04	4.67E-03
	2.3- Raw material handling (aqueous solutions as input materials) (MEASE)	30	14.84	1.56E-03	1.56E-02
	2.4- Passivation (MEASE)	2	0.99	1.04E-04	1.04E-03
	2.5- Packaging and handling of passivated articles (measured data)	9	4.45	4.67E-04	4.67E-03
	2.6- Cleaning & Maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	3- Use at industrial site-Plating processes in surface treatment (measured data & MEASE)				
	3.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	41	20.28	2.13E-03	2.13E-02
	3.2- Dissolution of solid raw materials (measured data)	9	4.45	4.67E-04	4.67E-03
	3.3- Raw material handling (aqueous solutions as input materials) (MEASE) (Mixing, loading/unloading , weighing)	50	24.73	2.60E-03	2.60E-02
	3.4- Plating (measured data)	9	4.45	4.67E-04	4.67E-03
	3.5- Manual Brush Plating (MEASE)	22	10.88	1.14E-03	1.14E-02
	3.6-Handling of coated/plated articles (measured data)	9	4.45	4.67E-04	4.67E-03
	3.7- Cleaning and maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	4- Service life (worker at industrial site)-Industrial handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	4.1-Handling of articles (measured data)	9	4.45	4.67E-04	4.67E-03
	5- Service life (professional worker)-Professional handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	5.1-Handling of articles (measured data)	9	4.45	4.67E-04	4.67E-03
Use 4	**Use as a catalyst in oxygen scavenging processes**				
	1- Formulation for water treatment chemicals, oxygen scavengers, corrosion inhibitors (measured data)				
	1.1- Formulation (measured data)	41	20.28	2.13E-03	2.13E-02
	1.2- Cleaning & Maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	2- Use at industrial site-use of water treatment chemicals, oxygen scavengers, corrosion inhibitors (MEASE)				

	Cobalt carbonate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	2.1- Use of formulation	10	4.95	5.19E-04	5.19E-03
	2.2- Cleaning(Immediate removal of wet splashes)	50	24.73	2.60E-03	2.60E-02
Use 5 & 6	**Use in fertilisers and/or feed grade materials**				
	1- Formulation of fertilisers and/or feed grade materials (measured data & MEASE)				
	1.1 Raw material handling (measured data)(Interim storage in un-opened container, loading/unloading)	41	20.28	2.13E-03	2.13E-02
	1.2 Formulation (MEASE)(Mixing, blending, milling)	44	21.76	2.29E-03	2.29E-02
	1.3 Filling (MEASE)(Filling of liquids)	2	0.99	1.04E-04	1.04E-03
	1.4 Packaging (MEASE)	10	4.95	5.19E-04	5.19E-03
	1.5- Cleaning & Maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	2- Professional use of fertilisers (MEASE)				
	2.1 Filling/dosing of solid material (MEASE) (Filling of fertiliser spreader with solid material)	50	24.73	2.60E-03	2.60E-02
	2.2 Filling/dosing of liquid material (MEASE) (Filling of fertiliser spreader with liquid material)	10	4.95	5.19E-04	5.19E-03
	2.3 Spreading of solid fertilisers (MEASE)	50	24.73	2.60E-03	2.60E-02
	2.4 Spreading liquid fertilisers (MEASE)	10	4.95	5.19E-04	5.19E-03
Use 7 & 8	**Use in fermentation processes, in the biotech sector and in biogas production**				
	1- Formulation of mixtures for use in biogas production (measured data & MEASE)				
	1.1-Raw material handling (measured data) (Opening of containers/dosing)	41	20.28	2.13E-03	2.13E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	9	4.45	4.67E-04	4.67E-03
	1.3- Production of solid formulations (measured data) (Mixing, milling, sieving, blending)	41	20.28	2.13E-03	2.13E-02
	1.4- Filling of solutions (MEASE)	5	2.47	2.60E-04	2.60E-03
	1.5-Packaging of solid formulations (measured data)	41	20.28	2.13E-03	2.13E-02
	1.6- Cleaning and maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	2- Use at industrial site: use in fermentation processes, in scientific research, standard analysis, and in biogas production				
	2.1- Raw material handling (MEASE)(Loading/unloading, weighing)	22	10.88	1.14E-03	1.14E-02
	2.2- Operation in closed systems (MEASE)	22	10.88	1.14E-03	1.14E-02
	2.4- Handling of sealed bags (MEASE)	10	4.95	5.19E-04	5.19E-03
	2.5- Handling of liquid stock solution (MEASE)	10	4.95	5.19E-04	5.19E-03
	2.6- Cleaning and maintenance (measured data)	49	24.24	2.54E-03	2.54E-02
	3- Use by professional worker: professional use of formulations in biogas production				
	3.1- Dosing of solid material (MEASE) (Dosing of solid mixture into the reactor)	50	24.73	2.60E-03	2.60E-02
	3.2- Dosing of liquid material (MEASE) (Dosing of solutions into the reactor)	5	2.47	2.60E-04	2.60E-03

	Cobalt diacetate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
Use1	**Use in surface treatment**				
	1- Formulation of metal surface treatment pre-formulations (measured data & MEASE)				
	1.1- Raw material handling (measured data)(Opening of containers/dosing)	56	18.61	1.95E-03	1.95E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	1	0.33	3.49E-05	3.49E-04
	1.3- Filling of solutions (MEASE)	6	1.99	2.09E-04	2.09E-03
	1.4- Cleaning & Maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
	2- Use at industrial site - Passivation processes (measured data & MEASE)				
	2.1- Raw material handling (solid input materials) (measured data)(Mixing, loading/unloading, weighing)	56	18.61	1.95E-03	1.95E-02
	2.2- Dissolution of solid raw materials (measured data)	13	4.32	4.54E-04	4.54E-03
	2.3- Raw material handling (aqueous solutions as input materials) (MEASE)	50	16.62	1.74E-03	1.74E-02
	2.4- Passivation (MEASE)	2	0.66	6.98E-05	6.98E-04
	2.5- Packaging and handling of passivated articles (measured data)	9	2.99	3.14E-04	3.14E-03
	2.6- Cleaning & Maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
	3- Use at industrial site-Plating processes in surface treatment (measured data & MEASE)				
	3.1- Raw material handling (solid input materials) (measured data) (Mixing, loading/unloading, weighing)	56	18.61	1.95E-03	1.95E-02
	3.2- Dissolution of solid raw materials (measured data)	13	4.32	4.54E-04	4.54E-03
	3.3- Raw material handling (aqueous solutions as input materials) (MEASE)	50	16.62	1.74E-03	1.74E-02
	3.4- Plating (measured data)	13	4.32	4.54E-04	4.54E-03
	3.5- Manual Brush Plating (MEASE)	22	7.31	7.68E-04	7.68E-03
	3.6-Handling of coated/plated articles (measured data)	9	2.99	3.14E-04	3.14E-03
	3.7- Cleaning and maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
	4- Service life (worker at industrial site)-Industrial handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	4.1-Handling of articles (measured data)	9	2.99	3.14E-04	3.14E-03
	5- Service life (professional worker)-Professional handling of surfaced treated articles (passivated/pleated)(measured data & MEASE)				
	5.1-Handling of articles (measured data)	9	2.99	3.14E-04	3.14E-03
Use 2	**Use as a pigment for PET plastics**				
	1- Use at industrial site – production and industrial use of plastics and/or PET using cobalt diacetate as a colorant				
	1.1- Raw material handling (measured data)	56	18.61	1.95E-03	1.95E-02
	1.2- Handling of liquids (MEASE)(Filling of liquids)	10	3.32	3.49E-04	3.49E-03
	1.3- Further processing (measured data)(Mixing, blending, extrusion)	13	4.32	4.54E-04	4.54E-03
	1.4- Final handling of massive objects (measured data)(Abrasive processing)	66	21.94	2.30E-03	2.30E-02

	Cobalt diacetate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	1.5- Cleaning and maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
	2- Service life (worker at industrial site) – handling of plastics and/or PET in industrial setting				
	2.1-Handling of massive objects (Abrassive processing)	66	21.94	2.30E-03	2.30E-02
	3- Service life (professional worker)– Handling of plastics and/or PET in professional setting				
	3.1-Handling of massive objects (measured data)(Abrassive processing)	7	2.33	2.44E-04	2.44E-03
Use 3	**Use as a catalyst for the production of PTA / IPA / DMT and PET**				
	1- Use at industrial site – use as a catalyst				
	1.1- Use as a catalyst (measured data) (Loading/unloading, reaction)	3	1.00	1.05E-04	1.05E-03
	1.2- Cleaning and maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
Use 5 & 6	**Use in fertilisers and / or feed grade materials**				
	1- Formulation of fertilisers and/or feed grade materials (measured data & MEASE)				
	1.1 Raw material handling (measured data)(Interim storage in un-opened container, loading/unloading)	56	18.61	1.95E-03	1.95E-02
	1.2 Formulation (MEASE)(Mixing, blending, milling)	22	7.31	7.68E-04	7.68E-03
	1.3 Filling (MEASE)(Filling of liquids)	1	0.33	3.49E-05	3.49E-04
	1.4 Packaging (MEASE)	10	3.32	3.49E-04	3.49E-03
	1.5- Cleaning & Maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
	2- Professional use of fertilisers (MEASE)				
	2.1 Filling/dosing of solid material (MEASE) (Filling of fertiliser spreader with solid material)	50	16.62	1.74E-03	1.74E-02
	2.2 Filling/dosing of liquid material (MEASE) (Filling of fertiliser spreader with liquid material)	5	1.66	1.74E-04	1.74E-03
	2.3 Spreading of solid fertilisers (MEASE)	50	16.62	1.74E-03	1.74E-02
	2.4 Spreading liquid fertilisers (MEASE)	5	1.66	1.74E-04	1.74E-03
Use 7 & 8	**Use in fermentation processes, in the biotech sector and in biogas production**				
	1- Formulation of mixtures for use in biogas production (measured data & MEASE)				
	1.1-Raw material handling (measured data) (Opening of containers/dosing)	56	18.61	1.95E-03	1.95E-02
	1.2- Formulation of solutions (measured data & MEASE (5)) (Dissolution)	1	0.33	3.49E-05	3.49E-04
	1.4- Filling of solutions (MEASE)	5	1.66	1.74E-04	1.74E-03
	1.6- Cleaning and maintenance (measured data)	73	24.26	2.55E-03	2.55E-02
	2- Use at industrial site: use in fermentation processes, in scientific research, standard analysis, and in biogas production				
	2.1- Raw material handling (MEASE)(Loading/unloading, weighing)	90	29.91	3.14E-03	3.14E-02
	2.4- Handling of sealed bags (MEASE)	10	3.32	3.49E-04	3.49E-03
	2.5- Handling of liquid stock solution (MEASE)	10	3.32	3.49E-04	3.49E-03
	2.6- Cleaning and maintenance (measured data)	73	24.26	2.55E-03	2.55E-02

	Cobalt diacetate	CSR Data	CSR Data	Based on RAC dose - response	
	Occupational Exposure Scenario / WCS	Exposure value TWA (µg /m3)*	Exposure value TWA (µg Co/m3)	Excess risk respirable fraction 10%	Excess risk respirable fraction 100%
	3- Use by professional worker: professional use of formulations in biogas production				
	3.2- Dosing of liquid material (MEASE) (Dosing of solutions into the reactor)	5	1.66	1.74E-04	1.74E-03

APPENDIX

A PRELIMINARY INVESTIGATION INTO THE CONDITIONS OF USE OF FIVE COBALT SALTS

Final report

July 2013

PUBLIC VERSION

1. INTRODUCTION

1.1. Background

Cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate ('the cobalt salts') were prioritised for inclusion in Annex XIV to the REACH Regulation by the ECHA recommendation of 20 December 2011. 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 previously 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).

The Commission, taking into account the ECHA recommendation, considered that at least one of the uses of these cobalt salts, surface treatment, poses a risk to workers' health which is not adequately controlled. It therefore decided to postpone the decision on the inclusion of these salts in Annex XIV until the conclusion of a restriction process following the procedures laid down in Articles 69 to 73 of the REACH Regulation. Consequently, the Commission considered that it should request ECHA to prepare a restriction dossier in accordance with the requirements of Annex XV to that Regulation. Moreover, the Commission identified additional uses of the five cobalt salts which might pose a risk to human health which is not adequately controlled and should be investigated before a decision is taken as to whether to include them within the scope of the Annex XV restriction dossier.

Therefore, on 21 December 2012, the Commission requested ECHA to conduct a preliminary investigation on the uses of the five cobalt salts with a view to refining the scope of the Annex XV restriction dossier. This investigation should consist of a targeted consultation with the main sectors of industry manufacturing or using cobalt salts for a number of specific uses, and a review of the relevant information available from the existing registration dossiers for these substances. While collecting this information, ECHA should also assess if the scope of the Annex XV restriction dossier should be extended to consider other cobalt salts.

The Commission indicated that ECHA should submit a report of the preliminary investigation on the uses of the five cobalt salts by mid-2013 whereupon, depending on the findings, the Commission would request ECHA to prepare an Annex XV restriction dossier in accordance with Article 69(1) of REACH.

1.2. Scope

The current report presents the information collected in the course of the investigation conducted by ECHA on the uses of cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate in accordance with the Commission's request of 21 December 2012.

The following uses, as identified by the Commission, are covered in the study:

10. Use in surface treatment
11. Use as a pigment for PET plastic
12. Use as a catalyst for the production of PTA/IPA/DMT and PET
13. Use as a catalyst in oxygen scavenging processes
14. Use in animal feed
15. Use in fertiliser

16. Use in biogas production
17. Use in biotechnology, pharmaceuticals and *in vitro* diagnostics
18. Use in humidity indicators

The report focuses on the conditions of use of the cobalt salts in each sector of application, with a view to assessing the potential for workers' exposure to dust, fumes and aerosols containing the substances. Although the investigation is mainly centred on the potential for workers' exposure via inhalation, the potential for dermal exposure has also been explored based on the available information.

1.3. Methodology

For the purpose of this investigation ECHA has carried out i) a review of the registration dossiers for cobalt sulphate, cobalt dinitrate, cobalt dichloride, cobalt carbonate and cobalt diacetate, and ii) a targeted consultation with the representative organisations and/or companies for those uses within the scope of this study. These activities are described in more detail below.

Review of registration dossiers

ECHA performed a screening of the registration dossiers in March 2013 in order to identify the registrants and uses for each of the five cobalt salts. The results of the screening exercise are presented in Annex 1 of this report. For each cobalt salt, the Chemical Safety Reports (CSR) and the Occupational Exposure Scenarios (ESs) submitted by the lead registrants were evaluated.

Targeted consultation

A targeted consultation involving the lead representative organisations for each sector of activity was launched in March 2013. For those sectors not represented by any organisation, the leading companies in the EU market were contacted individually by ECHA. Contact details were provided by the Cobalt Development Institute (CDI).

ECHA invited the identified organisations and companies to provide information on the conditions of use of the cobalt salts in their sector of activity via a written questionnaire (see Annex 2). Additionally, a webinar was held on 20 March 2013 where individual companies were encouraged to provide information via their sector organisations. However, a number of companies preferred on confidentiality grounds to submit the information directly to ECHA. In addition to the written consultation, ECHA held sector-specific meetings in Brussels on 6-8 May 2013 with the aim of giving industry the opportunity to clarify the data and provide further input where appropriate. In total, sixteen organisations and six companies were approached by ECHA and all but three provided information in the written consultation. Additionally, seventeen individual companies, mainly from the surface treatment and biotechnology and pharmaceutical sectors, submitted information on their own initiative to ECHA. Twelve organisations and six companies attended the sector specific meetings. The organisations and companies which provided information and/or attended the sector specific meetings are listed by sector of activity in Annex 3.

The information on the conditions of use of the five cobalt salts collected in the targeted consultation (from downstream user representative organisations and some downstream users themselves) was analysed and compared with the information provided in the ESs of the registration dossiers (submitted by manufacturers and/or importers). In particular, the following factors were taken into consideration where possible:

1. scale of operation

2. process characteristics
3. physical form in which the cobalt salt is used
4. amount and concentration of the substance
5. risk management measures
6. applicable regulatory frameworks
7. management systems and relevant standards

Special attention was paid to determining whether the ESs provided by the registrants covered the specific uses of the cobalt salts as identified by downstream users. In all cases discussed below, the ESs cover the uses examined in the study (albeit often described in quite generic terms), except where specifically stated.

Based on the findings, a qualitative assessment of the potential for workers' exposure to the cobalt salts, both via inhalation and dermal route, was made for each of the identified uses. This assessment was based on a verbal argumentation approach with no scoring assigned for any of the exposure determinants, and no formal or informal modelling of exposures, which was outside of the scope of work possible under this request. The assessment attempted to describe to what extent it can be said that there is a 'significant potential' for workers' exposure in each activity and use examined. However, this term has no formal interpretation or relationship with any technical or other approach to risk assessment. It is intended only to convey a sense of the implicit qualitative weighting applied to the factors outlined above when arriving at the assessment. Thus, it should not be inferred that the conclusions are necessarily related to the results which would be obtained from a full and proper risk assessment based on real data.

For the use of cobalt salts as a catalyst for the production of PTA/IPA/DMT and PET, the potential for environmental releases was also assessed, following a specific Commission request. It is to be noted that, due to the wide variety of different conditions in which they can take place in the different sectors of activities, maintenance activities are not considered in this report for any of the processes.

1.4. Structure of the report

The report consists of three chapters and corresponding annexes. Chapter 1 presents the general framework for the study including the methodology used. Chapter 2 provides an overview of the information obtained as well as the findings. Chapter 3 provides conclusions on the potential risks to workers' health as a result of the use of the cobalt salts, and discusses some issues for any future restriction exercise.

Each use is described in a specific section within Chapter 2. For each use (except for surface treatment), the information is presented according to the following structure:

1. *Use of cobalt salts*: identification of the volumes, technical function and interchangeability of the cobalt salts as well as future trends, where known;
2. *Supply chain*: description of the life cycle of the substance (excluding the waste stage), physical form(s) in which the substance is supplied, and concentrations, if applicable;
3. *Process description*: general overview of the processes in which the substance is used;
4. *Occupational exposure*: description of the operating conditions and risk management measures (RMMs), and brief comparison of the information provided in the ESs and in the consultation.

The information on the use of the cobalt salts for surface treatment is presented following the set of questions identified by the Commission in its request to ECHA of 21 December 2012. A general introduction on the use of cobalt salts in the sector is included as a general framework for the discussion.

The present report is a public version of the original report submitted by ECHA to the Commission in July 2013. Where applicable, the name of the companies and organisations contributing information has been anonymised. Similarly, numerical data, where declared as confidential, are presented as a range of values to avoid disclosure of the exact figures. Finally, information from the registration dossiers not publicly available is not included in the public version of the report.

2. USE CONDITIONS AND POTENTIAL FOR EXPOSURE

2.1. Use in surface treatment

2.1.1. Use of cobalt salts

Cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate have been identified as being used in surface treatment. The most comprehensive information regarding the volumes used in this sector has been provided by the Central Association of Surface Treatment Professionals Germany (ZVO). The volumes reported relate only to the German market and represent around 40 per cent of the total European market (ZVO). Based on these figures, the total volumes of cobalt salts used in the European surface treatment sector have been estimated and compared with the information made available by the Commission in its request to ECHA. The figures are shown in Table 1. It can be seen that the total volumes for the EU based on figures reported by industry in the consultation (over 1000 tonnes/year) are much larger than those initially estimated (approximately 300 tonnes/year).

Table 1: Reported and estimated volumes of cobalt salts used in surface treatment in 2012 (tonnes/year)

Cobalt salt	Reported by industry*	Estimate for EU	Initial estimate **
Cobalt sulphate	100	250	115
Cobalt dichloride	80	200	40
Cobalt dinitrate	245	613	100
Cobalt carbonate	<0.1	<0.25	3
Cobalt diacetate	25	63	30
Other	-	-	-
Total	**450**	**1126**	**288**

* Information corresponding to the German market (approximately 40% of the European market).
** Information provided by the Commission in its request to ECHA

The main application of cobalt salts in surface treatment is the generation of conversion layers (also called passivation) on zinc- or zinc alloy-coated metallic products for corrosion protection (around 95 per cent of total use according to ZVO). Other applications reported include metal or metal alloy plating (mainly gold-cobalt and tin-cobalt plating) for increased hardness and wear resistance and/or for metal colouring. Additionally, the use of cobalt salts in sealing solutions for anodised aluminium coatings has been reported by one individual company. The specific cobalt salts used for each application are discussed in the section below.

Cobalt salts in surface treatment applications are used in a great variety of industrial settings ranging from large scale manufacturing units specialised in surface treatment processes to metal workshops producing a wide array of metal pieces. The main sector of use of cobalt salts for surface treatment appears to be the automotive industry, although other applications in the construction, machinery, electronics, military, aerospace and satellite sectors have also been identified. There is also use by so-called 'after-sales services' which provide *in situ* maintenance and repair services to other companies.

It is to be noted that the use of cobalt salts in surface treatment is identified as an intermediate use in the registration dossiers. This however contradicts ECHA's assessment in the context of the prioritisation for inclusion of the cobalt salts in Annex XIV, whereby the identification of the use in surface treatment as intermediate is not considered justified.[7]

2.1.2. Specific information on conditions of use and alternatives

The information below is presented following the Commission's specific questions regarding the conditions of use of the cobalt salts in the surface treatment sector. It is important to highlight that the conditions of use might vary significantly across the sector, because of the wide diversity of industries and company types involved in the use of cobalt salts in surface treatment. Use of cobalt salts in surface treatment has been reported by metal workshops ranging from big operations to small scale units, by companies specialised in surface treatment services and by maintenance services providers. The total number of companies involved in surface treatment operations across Europe is not known. Although a number of organisations and individual companies have submitted information (see Annex 3) for this study, it is not clear how representative this sample is of the total sector and to what extent the conditions of use of cobalt salts in all types of settings are covered in the descriptions below.

Use of cobalt carbonate

The initial estimate provided by the Commission of the use of cobalt carbonate in the EU was three tonnes, but ZVO reported that less than 0.1 tonnes is used in the German market. If the German market represents 40 per cent of the total EU market, this implies a total EU volume of less than 0.25 tonnes. The exact figure is subject to uncertainty but it is probably safe to conclude that use of cobalt carbonate in surface treatment is low.

Cobalt carbonate is reported to be used as a pH regulator for passivation processes. However, this use of cobalt carbonate is not accepted practice. According to one company, the carbonate anion is not recommended in passivation systems, since it may lead to a defective surface appearance. Other compounds, such as caustic soda (sodium hydroxide) or acidic substances, are reported to be preferable for pH adjustment.

The use of cobalt carbonate in gold-cobalt alloy electroplating has also been reported by a number of companies. Nonetheless, the use of cobalt carbonate for gold-plating appears to be rare compared with that of cobalt sulphate. As an example, one company reports the production of cobalt sulphate-based electroplating solutions on 130 days per year and cobalt carbonate-based solutions on just four days per year. The reason behind the infrequent use of cobalt carbonate in electrolytic gold alloy plating has not been reported. No solubility

[7] See "Responses to Comments Document on ECHA's Draft 3rd Recommendation for the Group of recommended Cobalt (II) Substances

issues have been identified in the preparation of cobalt carbonate-based solutions.

Use of cobalt salts related to specific surface treatment processes and potential interchangeability

Cobalt dinitrate, cobalt dichloride, cobalt sulphate and cobalt diacetate are used in the generation of conversion layers in passivation processes. Cobalt dinitrate appears to be the most commonly used cobalt salt for this application, accounting for more than half of the total use of cobalt salts in passivation. According to the information supplied in the consultation, each cobalt salt provides specific characteristics to the protective coating (colour, optical appearance, thermal and corrosion resistance, etc.) and can influence the speed of the passivation process. However, due to the limited information available, it is not possible to draw a firm conclusion as to whether the cobalt salts will be readily interchangeable from a technical or economic perspective in passivation applications.

Cobalt sulphate and cobalt dichloride (in addition to cobalt carbonate already discussed above) are also used in metal alloy plating processes. The main process reported is gold-cobalt alloy electroplating, although other processes, such as zinc-cobalt, nickel-cobalt, nickel-cobalt-copper, tin-cobalt, etc., have also been identified. Cobalt sulphate appears to be the preferred cobalt salt for gold-cobalt electroplating, together with cobalt carbonate in very small amounts. Cobalt sulphate is also reportedly used in a large number of other cobalt alloy electroplating applications, while cobalt dichloride appears to be used for tin-cobalt and zinc-cobalt coatings specifically. Although no information has been provided regarding the interchangeability of the cobalt salts in electroplating applications, it might be inferred that, similar to the passivation processes, the choice of cobalt salt can affect the characteristics of the final coating. Specific surface characteristics such as ductility, grain size, etc. are referred to in the information supplied, which appear to be cobalt salt-specific.

Finally, cobalt diacetate is reported as being used in sealing solutions for freshly anodised aluminium coatings. This is the only cobalt salt identified as being used in anodising processes, which is the only use where a single cobalt salt is reported to be used (although only one company responded from this sub-sector).

Use of additional cobalt salts for surface treatment processes

No use of additional cobalt salts in surface treatment has been reported by industry.

Form in which the cobalt salts are supplied to passivation and electroplating applications

Formulators of passivation and electrolytic solutions use the cobalt salts in powder form (flakes have also been reported) or as highly concentrated solutions to produce passivation and electrolytic formulas. These formulas are supplied as concentrated solutions (typically with a concentration between one and five per cent of cobalt salt) to the surface treatment operations, where they are further diluted to prepare the working solutions used in the baths. Large scale surface treatment operations might prepare their own specific formulas, starting from the cobalt salts in powder or in highly concentrated solutions, for their own use and sometimes for further supply to other downstream users. No information was received on the number or proportion of companies using powder forms of the salts rather than solutions.

Formulation of cobalt salt solutions

The formulation of cobalt salt solutions can take place either at specialised formulators or at large scale surface treatment units, as described above. Cobalt salt manufacturing units might also supply surface treatment formulas as concentrated solutions to downstream users. No formulation at small scale operations has been identified in the information submitted by industry for this study.

Degree of automation of operations

From the information provided by industry, it is not clear to what extent operations are automated or require manual handling by operators. Formulation of cobalt salt solutions appears to be highly automated, although manual handling of the cobalt salts in powder form might be expected at some operations (of unspecified size). On the other hand, the degree of automation of surface treatment processes has not been specified by industry. Some operations, as for example *in situ* repair and treatment of pieces, are clearly manual. Large scale surface treatment processes are, however, expected to be automated to a large extent. Nevertheless, the preparation of surface treatment baths, the periodic adjustment of chemicals and routine bath-sampling and analysis have been identified as activities with direct intervention by workers.

Status of the search for alternatives

According to industry no valid alternatives to the cobalt salts have been identified so far. In fact it is remarked that the use of cobalt salts was developed by the automotive industry as an alternative to the use of chromium VI in passivation processes. No feasible alternatives are expected to be found in the near future. One company did suggest that the replacement of cobalt salts with nickel compounds could be a viable option in the longer term, but no further information was provided on this.

Potential workers' exposure to the cobalt salts and RMMs in place

Workers might be exposed to dust at the formulation stage if salts in powder form are weighed and added manually to the mixture vessel for batch production. Workers might also be expected to be exposed to fumes/aerosols during the packaging/bottling of salt solutions, depending on the level of automation of the operation.

Additionally, workers might be exposed to fumes/aerosols during the surface treatment process. Articles are immersed in tanks containing a working solution of cobalt salts (with a typical concentration between 0.1 and one per cent of cobalt salt) at temperatures ranging from 20 to 60 Celsius depending on the process. Concentrations of working solutions up to 20 per cent of cobalt sulphate have been identified in some electroplating activities. The use of cobalt salt solutions (up to 32 per cent of cobalt salts) by brush electroplating has also been identified for the *in situ* treatment of pieces that cannot be moved because of their size or characteristics.

Local exhaust ventilation (LEV) (no efficiency specified) and personal protective equipment (PPE) (including respiratory masks (FFP3, A2B2P3 cartridge), goggles, gloves (nitrile, PVC) and standard working clothes) are reported by all companies/organisations for the reduction of workers' exposure during formulation processes. LEV is also reported by all respondents as a standard control measure in electroplating operations, together with the use of goggles, gloves and working clothes. Some organisations also report the use of respiratory masks (PP3) as standard practice for electroplating processes, including brush plating in customer settings. It is important to highlight that some electroplating processes could result in the emission of cyanides, which require exhaust ventilation (vapour extraction units in tanks) to prevent workers' exposure. The use of LEV in passivation appears more variable. For instance, use of LEV is reported in Germany (ZVO) but not in Sweden (SYF) for those processes mentioned. The use of masks is not reported in either country. The use of goggles, gloves (nitrile, neoprene, PVC) and workings clothes appears to be standard practice.

In Germany, workplace air measurement as well as annual bio-monitoring of workers are reported as mandatory. (Information was not received on the situation in other countries.) The implementation of RMMs is reported to be related to the results of workplace air measurement exercises, although no specific measurements have been made available for the purpose of this study. One company does report occupational exposure measurements of cobalt in air below 0.001 mg/m^3 in electroplating processes with cobalt salts including cobalt dichloride, cobalt sulphate and cobalt carbonate.

Control measures reported by industry in the consultation are in line with, or even stricter than, those recommended by the registrants under similar conditions of use. For example, according to the ESs provided, no LEV is proposed at the formulation stage for the handling of cobalt salts, although the use of respiratory masks (FFP2) is defined. The standard practice reported by formulators includes LEV and the use of respiratory masks (P3) for this activity. Although LEV efficiency has not been reported, the RMMs implemented by formulators at the formulation stage are (according to the tier 1 exposure model tool MEASE) expected to reduce exposure by a greater amount than those proposed by the registrants.

2.2. Use as a pigment in PET

According to the PET manufacturers' representatives (CPME), none of the five cobalt salts covered by this study is currently used as a pigment in PET. Therefore, this use is not further considered in this report.

In more general terms, no use of the five cobalt salts as pigments in plastics has been identified (CPME).

2.3. Use as a catalyst in the production of PTA/IPA/DMT and PET

2.3.1. Use of cobalt salts

Cobalt diacetate is used as a catalyst in the manufacture of PTA, IPA and DMT, which are monomers commonly used in the production of polyester resins, including PET. PET is a polymer widely employed for the manufacture of plastic bottles and synthetic fibres. Cobalt diacetate is also reported as being used as a co-catalyst in the manufacturing process of PET itself (CPME).

Table 2: Reported volumes of cobalt salts used as a catalyst in the production of PTA/IPA/DMT and PET (tonnes/year)

Cobalt salt	Reported by industry*	Initial estimate **
Cobalt sulphate	-	-
Cobalt dichloride	-	-
Cobalt dinitrate	-	-
Cobalt carbonate	-	-
Cobalt diacetate	100 - 1000	600
Other	-	-
Total	**100 - 1000**	**600**

* Information submitted by industry for this studys
** Information provided by the Commission in its request to ECHA

No other cobalt salts have been identified for any of these uses (CPME). Thus, it could be inferred that there is no interchangeability of cobalt diacetate with other cobalt salts for this use. However, use in this application could be limited to cobalt diacetate on non-technical grounds (e.g. price). No further information on this was provided.

The volumes of cobalt salts used in this sector are shown in Table 2.

2.3.2. Supply chain

Cobalt diacetate is supplied either in powder form or as a catalyst solution. Catalyst solutions are mixtures of cobalt diacetate (in the range 1-50 per cent cobalt) and other co-catalysts in acetic acid solution. The form (powder or solution) and composition of the catalyst is technology-related.

According to the sector representatives, only one manufacturing site uses cobalt diacetate in powder form. This site has reportedly started the process of changing over to catalyst solutions although no information has been provided as to when this switch will actually occur.

The main suppliers of cobalt diacetate, both in powder and as catalyst solution, have been identified as manufacturers/importers of cobalt salts and/or fine chemicals.

2.3.3. Process description

The manufacture of PTA, IPA, DMT and PET takes place in industrial settings in large outdoor chemical installations which operate above atmospheric pressure and at elevated temperatures. Cobalt diacetate is input into the process as a catalyst solution of concentration below 50per cent and is further diluted in the process.

The process of preparing a catalyst solution when starting from cobalt diacetate in powder form has not been fully described by industry. As has been noted, according to the information provided by the sector representatives, the manufacturing site using cobalt diacetate in powder form has already started to switch towards the use of catalyst solutions for efficiency reasons. The timing for this switch has not been reported although engineering and construction work are apparently required to enable it.

According to industry, manufacturing plants are designed to ensure a rigorous containment of the products in the system and preventative maintenance and inspection programmes as well as LDAR (leak detection and repair) programmes are implemented to ensure process containment. Process vapours are collected and treated e.g. through catalytic oxidation. No on-site recovery processes for spent catalyst have been reported in the consultation; according to the registration dossiers' ESs, cobalt is recovered from the solution by precipitation in catalyst recovery units.

Manufacturing sites are ISO 9001 certified when fully operational. ISO 14001 and similar environmental management systems are reported to be implemented in all manufacturing units. OHSAS 18001 is also mentioned as a standard applied across the sector but the implementation level of this standard has not been reported.

2.3.4. Occupational exposure

Occupational exposure scenarios

Table 3 presents a number of important determinants of occupational exposure for the industrial use of cobalt diacetate as a catalyst, as defined in the ESs submitted by the registrants.

Table 3: Occupational exposure scenario for use as a catalyst for the production of PTA/IPA/DMT and PET

Description	PROC	Physical Form	%	Indoors/ outdoors	Exposure Duration	RMM*	
						LEV	RPE
Industrial use	1,2,8b	Solution	nr	Indoors & outdoors	nr	Not required	Not required

* gloves (EN 374) &, goggles required where direct contact to cobalt substances is possible; standard working clothes (long-sleeve overall) and safety shoes required for all activities

LEV: local exhaust ventilation; RPE: respiratory protective equipment; nr= not restricted

Operational conditions and risk management measures reported in the targeted consultation

According to the information supplied by the sector representative during the consultation, the PET manufacturing sector employs about 1 000 to 10 000 workers in the EU, of which less than 10 to 100 are potentially exposed to cobalt salts. The following routine activities could lead to workers' exposure during the manufacturing process:

- Unloading of catalyst solutions
- Sampling of process streams containing cobalt
- Analysis of samples

Catalyst solutions are delivered to the plants in containers, where they are unloaded via a dedicated system. Operators wear face and eye protection and gloves where possible exposure to the substance could occur. Use of respiratory protection is not reported for routine operations. Samples are taken at various locations in the process (outdoors), using a dedicated system. Procedures are in place to avoid dermal contact. Additionally, gloves, face and eye protection are reported to be worn to prevent skin and eye contact. The samples are analysed indoors in on-site laboratories located close to the production plant. Safety glasses and gloves are said to be used in the laboratory at all times as precaution against accidental spills. All activities involving the use of the solutions are reportedly performed by trained operators. According to the information provided, personal monitoring of operators' exposure via air has shown no measurable exposure to cobalt. In addition to specific PPEs, helmets, overalls (and/or PVC suit), safety footwear and hearing protection are required to be worn at the manufacturing site.

Additionally, the handling of cobalt diacetate in powder form in the manufacturing plant preparing their own solutions has been described as an outdoor activity with the use of respiratory protection (full mask, efficiency not reported) gloves and protective overall as standard practice for this activity.

Potential for workers' exposure to the cobalt salts

The potential for workers' exposure to cobalt diacetate in solution does not appear to be significant under the conditions of use described by industry in the consultation. Although the total amount of cobalt diacetate used by the sector is large, the high level of containment of the manufacturing process together with the quality, environmental and to some extent occupational management systems in place across the sector (ISO 9001, ISO 14001, OSHA 18001) could ensure that workers' exposure to cobalt diacetate is controlled. The exposure data, according to industry, show lack of measurable workers' exposure via inhalation from the activities described.

The amount of cobalt diacetate in powder used in the only manufacturing plant preparing their own catalytic solutions is reported to be 10 to 100 tonnes per year. The volumes of cobalt salts handled are estimated at 1 to 5 tonnes per batch preparation. From the information provided it seems that cobalt salts are loaded manually into the reactor by operators wearing full mask respiratory protection, goggles and overalls to prevent exposure to the cobalt salts. Respiratory masks (FFP2) and high efficiency local exhaust ventilation (90% efficiency) are recommended in the registration dossiers' ESs to ensure control of exposure via inhalation for similar activities in other uses of cobalt diacetate in powder form (e.g. use of cobalt salts in animal feed). However, the ESs for cobalt diacetate do not consider the handling of cobalt salts in powder form for the use of the substance as a catalyst. Under these circumstances it is not possible to assess to what extent the risk management measures, as reported by industry for the handling of cobalt diacetate in powder, ensure that workers' exposure via inhalation is controlled.

In sum, the use of cobalt diacetate in solution as a catalyst for the production of PTA/IPA/DMT and PET under the conditions described by industry, both in the registration dossiers and in the consultation, appears not to present a significant potential for workers exposure to the cobalt salt. Nonetheless, the use of *cobalt diacetate in powder* might lead to a significant workers exposure if the implemented risk management measures are not adequate to control exposure. Since the ES available in the registration dossiers does not cover the specific use of cobalt diacetate in powder as a catalyst for the production of PTA/IPA/DMT and PET, it has not been possible to assess to what extent workers' exposure may be controlled under the conditions reported at the consultation. It is to be noted that, according to industry, the use of cobalt diacetate in powder for this application takes place only in one manufacturing plant in Europe and it is to be discontinued.

2.3.5. Environmental releases

Cobalt diacetate solutions are handled in closed systems at all sites. According to the sector representative, plant design is such that no emissions of cobalt or cobalt diacetate to air are expected. Although personal monitoring measurements are reported as regular practice, no information regarding monitoring of site emissions to air was provided as part of the consultation.

Monitoring of cobalt emissions to water is reportedly done on a regular basis. From the information submitted by industry, it appears that monitoring results are within the emission limits defined by local legislation and/or site environmental permits, although no specific evidence of compliance has been provided. Spillages are reportedly contained and treated before disposal in line with the advice provided in the SDSs. According to the registrants' ES, cobalt is recovered from the reaction solution by precipitation in a catalyst recovery unit. The recovery process has not been defined in the information submitted by the sector representatives, although it is stated that cobalt as such is not disposed of as waste. No mass balance information was provided to assess the effectiveness of recovery processes.

As a whole, the information collected in the consultation is not detailed enough to permit any conclusion regarding the potential emissions to the environment from this use.

2.4. Use as a catalyst in oxygen scavenging processes

2.4.1. Use of Cobalt salts

Trace amounts of cobalt sulphate and cobalt dichloride are used in oxygen scavenger mixtures to increase the rate of oxygen removal in boiler feed water applications. Oxygen scavenger mixtures are based on sodium sulphite which is capable of reacting with and removing dissolved oxygen from boiler feed water and thus helping to prevent corrosion which might lead to failures of boiler systems.

Cobalt sulphate and cobalt dichloride are used interchangeably in this use, depending on the manufacturer, and the use of other cobalt salts has not been reported. Although, according to industry, other alternative catalysts, both organic and inorganic, have been evaluated, none has been found to be as effective as cobalt. Note that this does not necessarily mean that the use of other cobalt salts or other catalysts is not technically feasible; it does, however, imply that the two cobalt salts which are used are more economically feasible than the alternatives. In other words, it might be possible for operators to switch to alternative cobalt salts but only at some positive cost.

The reported volumes of cobalt salts used in this sector are shown in Table 4.

Table 4: Reported volumes of cobalt salts used as catalyst in oxygen scavenging processes (tonnes/year)

Cobalt salt	Reported by industry *	Initial estimate **
Cobalt sulphate	In use	3
Cobalt dichloride	In use	5
Cobalt dinitrate	-	1
Cobalt carbonate	-	-
Cobalt diacetate	-	-
Other	-	-
Total	**1-10**	**9**

* Tonnage as reported by industry
** Information provided by the Commission in its request to ECHA

2.4.2. Supply chain

Oxygen scavenger mixtures are produced at an unspecified number of sites. The major manufacturers represent around 60 per cent of the total EU market while an unknown number of smaller companies supply local markets.

According to industry, the two cobalt salts are supplied to oxygen scavenger mixture manufacturing sites in powder form. The suppliers of the two cobalt salts have been identified as fine chemicals manufacturers or distributors. The degree of purity of these two cobalt salts is reportedly a key factor in the performance of the oxygen scavenger mixtures.

Oxygen scavenger mixtures containing the cobalt salts are sold exclusively to industrial users. The total number of sites using oxygen scavenger preparations in Europe has been estimated at between 100 and 1000. Based on the volume reported in Table 4, this implies a quantity of use of around 1-100 kg per site per year. These two cobalt salts are restricted for consumer uses in concentrations above the classification limit, but below this, they could be used for domestic applications such as in household boilers. However, industry was not aware of any consumer, or indeed professional, use of these products. Mixtures may be supplied in powder form or as a solution, depending on the manufacturer.

2.4.3. Process description

According to industry the process takes place in batches. Cobalt salt powder is manually weighed and loaded into the blending vessel while bulk liquids are transferred from the storage tanks by pumps. Process temperatures are reported to be up to 80 Celsius in the blending vessel, which remains closed during the actual mixing. Finished products are filled into drums by gravity. Oxygen scavenger mixtures are also manufactured in powder form although no specific information regarding this process has been obtained, either from the consultation or from the registration dossiers.

According to the information provided in the consultation, oxygen scavenger solutions are supplied in drums, containers or tanker trucks to the customers' industrial sites where they are dosed automatically into the boiler systems. Where oxygen scavenger is supplied as a powder formulation, a pre-mix step is required. The product has to be dissolved into a 1 to 25 per cent solution before it is fed into the system. According to the manufacturers' instructions, the solution has to be prepared daily If the estimate above of volume used of 1-100 kg per site per year is correct, this implies that the quantity of cobalt salt powder used for the formulation of solutions will be around 5-500 g per day.

2.4.4. Occupational exposure

Occupational exposure scenarios

ESs for the formulation and industrial use of cobalt sulphate and cobalt dichloride as catalysts in oxygen scavenger processes are available in the associated registration dossiers. The main parameters for occupational exposure, as defined in the ESs, are shown in Table 5. Note that the ESs for the cobalt salts do not cover the industrial use of oxygen scavenger mixtures containing cobalt salts in powder form.

Table 5: Occupational exposure scenario for use as a catalyst in oxygen scavenging processes

Description	PROC	Physical Form	%	Indoors/ outdoors	Exposure Duration	RMM*	
						LEV	RPE
Formulation	2,4,5,8b ,9,15	Solid, crystal, solution	nr	Indoors	nr	LEV Efficiency: 90%	FFP2 APF:10
Industrial use	2,8b	Solution	nr	Indoors & outdoors	nr	Not required	Not required

* gloves (EN 374) &, goggles required where direct contact to cobalt substances is possible; standard working clothes (long-sleeve overall) and safety shoes required for all activities
LEV: local exhaust ventilation; RPE: respiratory protective equipment; nr: not restricted; APF=assigned protection factor

Operational conditions and risk management measures reported in the targeted consultation

According to the information supplied in the consultation, manufacturing of oxygen scavenger formulations involves the manual handling of the two cobalt salts in powder form (no particle size identified). The salts are weighed manually and loaded into the blending vessel. The ESs submitted by the registrants propose LEV (90 per cent efficiency) and FFP2 (APF=10) dust masks to ensure the safe use of the cobalt salts for this activity (duration not restricted).

According to one manufacturer, oxygen scavenger formulations are also prepared in powder form. The conditions have not been reported. It is to be noted that, according to this manufacturer, oxygen scavenging mixtures, both in powder and solution, are marketed with a cobalt salt content of 0.01 to 0.1 %, which is above the classification limit (0.01%).

Potential for workers' exposure to the cobalt salts

The potential for workers' exposure to cobalt salts at the *formulation stage* does not appear to be significant, considering the amounts of cobalt salts used per batch, the duration and frequency of the operations and the level of control reported in the consultation. It is acknowledged, however, that these reported conditions might not be representative of the whole sector, especially considering the number of small scale local manufacturers that may be involved in handling cobalt salts. In addition, filling of oxygen scavenger mixtures in powder or solution could also present a potential for workers' exposure to dusts or fumes where the concentration is above the classification limit (0.01%) and no adequate control measures are in place. Dermal exposure could also occur if the appropriate training and maintenance practices are not followed. Nevertheless, on the basis of the information provided in the registration dossiers and through the targeted consultation, the potential for workers' exposure to the cobalt salts used in formulation in this sector is not considered significant.

*The use of oxygen scavenger formulations in powder by industrial end-users involves a pre-*mix step which has been classed as PROC 5; according to the guidance on use descriptors, such a use 'provides opportunity for significant contact at any stage'. This could suggest a significant potential for exposure, although estimated volumes of use appear to be relatively low, at around 5-500g per site per day. The formulations manufacturer recommends the use of LEV (no efficiency defined) and PPE (respiratory mask, gloves, goggles and appropriate work clothes) as control measures in the use of powder, which is in line with the measures recommended in the ESs for *formulation.* It is to be noted that the ESs for the cobalt salts do not as such cover the industrial use of oxygen scavenger mixtures in powder. Thus, it is not possible to conclude whether the recommended risk management measures identified by the manufacturer of oxygen scavenger formulations are actually in place at end users sites to ensure control of workers exposure to the cobalt salts. *Oxygen scavenger solutions* are reportedly used in closed systems with no operator intervention required except for the changing of empty recipients. This activity has an estimated low emission potential and should not present any significant inhalation exposure of workers to the cobalt salts. However, dermal exposure might be expected through contact of the solution with the skin. Gloves and appropriate working clothes, as recommended by the manufacturer and the ESs, can be considered as standard at industrial sites. Considering that this is a one-off, occasional operation, the potential for dermal exposure might be considered as not significant.

It can be concluded that the *formulation of oxygen scavenger mixtures* under the conditions described in the registration dossiers and in the targeted consultation does not appear to present a significant potential for workers exposure to the cobalt salts. Additionally, the *end-use of oxygen scavenger mixtures* does not appear to present a significant potential for workers exposure if the risk management measures recommended by the formulations manufacturer are in place across the sector. However, it has not been possible to ascertain for this study to what extent these recommended risk management measures are actually implemented at end-users sites.

2.5. Use in animal feed

2.5.1. Use of cobalt salts

Cobalt is a component of Vitamin B12 and therefore essential for ruminants and some animal species with hindgut fermentation (e.g. horses) which can synthesise this vitamin. Cobalt is permitted for supplementation of animal diet in the form of salts, which are subject to authorisation as feed additives in the functional group classified as a ‘compound of trace elements’.

Following the entry into force of Regulation (EC) 1831/2003 on additives for use in animal nutrition, an application was submitted by the feed industry for the re-authorisation (for an unreported period of time) of cobalt sulphate, cobalt carbonate and cobalt diacetate as feed additives for all animal species. According to the information received in the consultation, the use of cobalt dichloride and cobalt dinitrate, already anecdotal, will be phased out by the end of 2013. These uses will be prohibited after a transition period for existing stocks, most probably by 2015-2016.

Table 6: Reported volumes of cobalt salts used in animal feed (tonnes/year)

	Reported by industry*		Initial estimate **
Cobalt salt	Current	Future	
Cobalt sulphate	In use	50	25
Cobalt dichloride	In use	0	1
Cobalt dinitrate	-	-	-
Cobalt carbonate	In use	166	120
Cobalt diacetate	In use	13	7
Other	-	-	-
Total	**100 -1000**	**100-500**	**153**

* Information submitted by industry for this study. The figure in the ‘Future’ column represents industry’s estimate of future volumes based on the introduction of regulatory measures recently adopted
** Information provided by the Commission in its request to ECHA

All salts of cobalt have the same use/function in feed, that is, as a precursor of vitamin B12 synthesis in the gut flora of certain animal species. According to industry, they can all substitute each other, but cannot be substituted by any other substance. The only exception is that cobalt carbonate is not used in liquid feed because of its poor water solubility.

Cobalt salts are usually incorporated into animal feed in powder form via a premixture (EMFEMA-FEFAC-FEFANA). This common (industrial) practice has been legally binding since the implementing regulation concerning the re-authorisation of cobalt salts entered into force in 2013.[8] Premixtures are defined as mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals under Regulation (EC) 1831/2003. Although the use of feed additives via drinking

[8] SANCO/10036/2013

water is possible, it is considered less reliable, since it is more difficult to regulate animals' water intake compared with their feed intake. Industry has not requested authorisation for this use and it will no longer be permitted.

The reported volumes of cobalt salts used in animal feed are shown in Table 6.

2.5.2. Supply chain

The cobalt salts used in animal feed are supplied in the form of pure salts (cobalt content ranging from 10-60 per cent) or feed additive preparations (cobalt concentration range from 1 to 10 per cent) to specialised plants where premixtures are manufactured. Typical concentration of cobalt in premixtures varies depending on the purpose, from 0.001-1 per cent, but is most often below 0.05 per cent. Not all premixtures contain cobalt as the inclusion depends on the customer's intended use and animal requirements.

The number of premixture manufacturing plants is estimated at 100 to 500 in Europe (EMFEMA, FEFAC & FEFANA). Of these units, according to industry, only a limited number of specialised ones actually handle pure cobalt salts. Most premixture manufacturers instead use diluted forms of cobalt salts (premixtures/preparations) supplied by these more specialised units.

Premixtures are supplied to compound feed manufacturers. Compound feed is defined as a mixture of at least two feed materials, whether or not containing feed additives, for oral animal feeding in the form of complete or complementary feed. It is produced by specialised companies or in some cases by farmers themselves. The number of specialised compound feed units handling premixtures containing cobalt salts is estimated at 1000 to 10 000 in Europe. The number of on-farm producers of compound feed containing cobalt salts is estimated to be limited to 10 to 100.

Feed manufacturing units have to comply with the rules on feed hygiene defined under Regulation (EC) No 183/2005. Operators have to be registered for mixing activities unless these activities are for the production of feed for use only on their own farm.

Cobalt content in compound feed is limited by legislation. The previous limit of 0.0002 per cent of cobalt in complete feed was lowered to 0.0001 per cent with the entry into force of the implementing regulation concerning the authorisation of the three cobalt salts. Cobalt content in complementary feed is limited to 10 times the maximum level in total feed, i.e. 0.001 per cent now (previously 0.002 per cent). Two specific types of complementary feed, 'mineral feed' and 'dietetic feed', can have higher cobalt content, however. For mineral feed, the cobalt content limit is fixed at 0.01 per cent (was 0.02 per cent), while the cobalt content in dietetic feed is not limited. Dietetic feed containing cobalt salts is supplied only in the form of drench (liquid) or bolus (rumen slow-release feed) and is currently under evaluation for authorisation.

2.5.3. Process description

Feed manufacturing takes place in small to very large units with different degrees of automation. Cobalt salts are handled manually and dispensed into a blender where the different ingredients are mixed. Weighing can take place manually in specific dispensaries off-line or automatically in large scale operations. Final products can take a variety of forms, including powder, semolina, pellets, paste and blocks (including bolus). Packaging is performed in semi-automated or fully automated lines depending on the manufacturing unit.

Farms can also produce their own compound feed by mixing feed materials they produce (such as cereals) with complementary feed they purchase. They might also handle premixtures for the manufacturing of their own compound feed.

2.5.4. Occupational exposure

Occupational exposure scenarios

ESs for the industrial use of cobalt salts in feed grade materials are provided by the registrants in the CSRs of cobalt sulphate, cobalt dichloride, cobalt carbonate and cobalt diacetate. The main parameters for exposure, as defined in the ESs, are shown in Table 7.

Table 7: Occupational exposure scenario for use in animal feed

Description	PROC	Physical Form	%	Indoors / outdoors	Exposure Duration	RMM*	
						LEV	RPE
Industrial use	8b, 9, 26	Various	nr	Indoors	nr	LEV Efficiency: 90%	FFP2 APF:10
	1,2,3	Solution, solid	<5	Indoors	nr	LEV Efficiency: 78%	Not required
	8b	Granule	<1	Indoors	nr	Not required	Not required

* gloves (EN 374) &, goggles required where direct contact to cobalt substances is possible; standard working clothes (long-sleeve overall) and safety shoes required for all activities

LEV: local exhaust ventilation; RPE: respiratory protective equipment; nr: not restricted; APF=assigned protection factor

Operational conditions and risk management measures reported in the targeted consultation

According to industry, cobalt salts are handled manually in specialised feed manufacturing units. The manual handling involves opening of the bags, dispensing and weighing (for small volumes of cobalt salts). Cobalt salts are supplied mainly in powder form, giving a potential for workers' exposure to dust. In addition to the manual handling of the cobalt salts, premixture packaging may take place in semi-automated lines where the presence of the operator is required. Although the cobalt content at the packaging stage is already diluted, the percentage of cobalt (typically 0.05 per cent) is above the classification limit for mixtures (0.01 per cent).

Similarly, the handling of premixtures at the compound feed manufacturing unit is done manually. Bags are opened at the reception and premixtures loaded into silos by operators. Packaging of final compound feed may take place in fully automated lines, although, due to the different scale of operations reported by industry, it is possible that the conditions differ in small units or at farm level. It is to be noted that the new authorisation for the use of cobalt salts determines that premixtures containing cobalt salts in powder must be supplied in pelleted form.

The risk management measures reported by industry differ slightly from (but are not inconsistent with) those reported in the registration dossiers' ES: Respiratory protective equipment (FFP2 mask) and LEV (78-90 per cent efficiency) are proposed by registrants to ensure safe handling of the substance at the formulation stage. It is to be noted that feed manufacturing units are required under the feed hygiene legislation (Regulation (EC) 183/2005) to have a HACCP (Hazards Analysis and Critical Control Plan) in place, demonstrating control of risks.

According to industry representatives (EMFEM, FEFAC & FEFANA), farmers usually mix feed materials that they produce with complementary feed containing cobalt salts below the classification limit (0.01 per cent). However, farmers can also use premixtures (cobalt content below 1 per cent) to produce their own compound feed. The registration dossiers do not cover professional uses of cobalt salts for animal feed and therefore no specific risk management measures are proposed to ensure safe handling of the formulations by farmers. No specific information regarding the conditions of use or the risk management measures at farm level has been made available in the targeted consultation.

Potential for workers' exposure to the cobalt salts

The implementing regulation on the authorisation of cobalt salts defines a number of provisions to minimise occupational exposure, specifically via inhalation. In particular the following measures have been introduced:

- Cobalt salts shall only be incorporated into feed in the form of premixtures;
- Premixtures containing cobalt salts in powder shall only be placed on the market in pelleted form;
- Cobalt maximum levels in complete feed shall be halved (from previous 0.0002 per cent to 0.0001 per cent);
- It is recommended to limit supplementation with cobalt to 0.0003 per cent in complete feed;
- Cobalt salts as feed additives shall be restricted to some animal species, i.e. ruminants, horse, rabbits and other hindgut fermenters and no longer permitted for other animal species (including pigs and poultry);
- Specific references are made to the need to take protective measures according to health and safety legislation;
- The use of appropriate protective gloves, respiratory and eye protection according to Directive 89/686/EEC are defined as mandatory for the handling of cobalt salts.

According to industry estimations, the implementation of these measures will result in a reduction in the use of cobalt salts to one third of present levels. The requirement to incorporate cobalt salts into feed via premixtures will ensure that cobalt salts in powder are only handled at specialised units where workers' exposure is considered to be controlled. Premixtures containing cobalt salts in powder form will have to be supplied in pellets with low emission potential.

In sum, under the conditions defined in the re-authorisation of cobalt salts for animal feed, the potential for workers' exposure to the cobalt compounds, even in the case of farmers using premixtures with a content above the classification limit, can be considered as not significant.

2.6. Use as fertiliser

According to the fertiliser industry association contacted for this study, no cobalt salts are used by their members for the manufacture of fertilisers. The only cobalt compound reported as being used is cobalt hydroxide, which is outside the scope of the present study. However, this association does not represent producers of organo-mineral fertilisers, and the Poland Ministry of the Economy reported to the European Commission on 14 June 2013 that Polish producers are using cobalt sulphates (in unspecified forms) to produce organo-mineral fertilisers. In addition, the Spain Ministry of Agriculture and Environment reported to the Commission on 14 June 2013 that there are a number of cobalt salts utilised in fertilisers which are sold on the Spanish market in liquid form (no information on solid form). ECHA contacted industry representatives and the Spain Ministry of Agriculture and Environment for further clarification, but no additional information has been received.

2.7. Use in biogas production

2.7.1. Use of cobalt salts

Biogas production is a technology based on the degradation of complex organic materials (such as energy crops, waste, sewage sludge and manure) to produce energy-rich, methane-based gas, called biogas. Biogas is used for electricity and heat production and as a replacement for natural gas.

Cobalt salts are used as a nutrient additive necessary for bacterial cell growth and reproduction in biogas production from energy crops. Other trace elements such as iron, copper, zinc, manganese, molybdenum, nickel, selenium, vanadium and tungsten might need to be added to the process for efficient biogas production. Cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate are all used interchangeably by the biogas industry as a source of cobalt.

The content of trace elements in the substrate determines the need for the addition of micronutrients to the process. Feed stocks with a high level of trace elements such as organic municipal waste do not require the addition of trace elements for effective methane production.

The reported volumes of cobalt salts used in biogas production are shown in Table 8.

Table 8: Reported volumes of cobalt salts used in biogas production (tonnes/year)

Cobalt salt	Reported by industry *	Initial estimate **
Cobalt sulphate	In use	-
Cobalt dichloride	In use	5
Cobalt dinitrate	In use	-
Cobalt carbonate	In use	-
Cobalt diacetate	In use	-
Other	-	-
Total	**<100**	**5**

* Information submitted by industry for this study
** Information provided by the Commission in its request to ECHA

2.7.2. Supply chain

Cobalt salts are mixed with other trace elements and supplied as mixtures to biogas production units. According to one industry representative (European Biogas Association), the formulation takes place in the same specialised units which manufacture premixtures for the animal feed sector.

Mixtures are usually supplied in powder form to biogas production units, with a cobalt salt concentration of around 0.25 per cent. They are packed in sealed biodegradable bags which can be dosed unopened into the digester, where the fermentation process takes place. Other forms of packaging are also commercially available but are not as widely used. Mixtures containing cobalt salts are also supplied in 'customer-made' solutions for continuous feeding into the digester. The use of solutions appears, however, anecdotal, due to their higher price.

2.7.3. Process description

No information has been provided during the consultation on the formulation stage of the use of cobalt salts for biogas production. In the absence of further information, it is assumed that the formulation process is similar to that already described for the manufacture of premixtures in the animal feed sector.

Biogas production may be done via batch or continuous processes. Mixtures are dosed in sealed biodegradable bags (and, rarely, as loose powder) into the feeding system of the digester. Mixtures may also be administered in solution directly into the digester. The amount of cobalt salts used is reported to be in the range of 5-100g per day (5-25 g per day being most common), depending on the substrate and the size of the reactor.

The fermentation residue (digestate) is used as an agricultural fertiliser. Trace elements contained in the digestate are thereby supplied to the agricultural soil. Cobalt salts content in the digestate may vary from 0.0001-0.001 per cent according to the registration dossiers and are therefore below the classification limit (0.01 per cent). Compliance with the Fertilisers Directive is required for this activity.

2.7.4. Occupational exposure

Occupational exposure scenarios

The main parameters for exposure, as defined in the ESs, are shown in Table 9.

Table 9: Occupational exposure scenario for use in biogas production

Description	PROC	Physical form	%	Indoors/outdoors	Exposure duration	RMM*	
						LEV	RPE
Industrial use	8b	Sealed biodegradable bags	nr	Indoors	nr	Not required	Not required

* gloves (EN 374) &, goggles required where direct contact to cobalt substances is possible; standard working clothes (long-sleeve overall) and safety shoes required for all activities

LEV: local exhaust ventilation; RPE: respiratory protective equipment; nr: not restricted; APF=assigned protection factor

Operational conditions and risk management measures reported in the targeted consultation

The only activity in biogas manufacturing units described by industry as showing a potential for exposure of workers to cobalt salts is the dosing of the mixtures into the digester. The registration dossiers consider this activity to take place indoors, and only with cobalt salts delivered in sealed biodegradable bags. Neither local exhaust ventilation nor respiratory masks are required for this activity in the ESs, although the use of goggles, gloves and long-sleeve overalls is recommended for safe handling of the cobalt salts. According to industry, the most common form in which cobalt salts are fed into the reactor is in biodegradable bags, fully sealed and containing the metal salts required for the biogas process. Biodegradable bags are fermentable and therefore degraded during the process, thereby avoiding the need to open the bags for the administration of the trace metals.

Cobalt salts may also be dosed as loose powder into the digester. The dosing of the cobalt salts, either in sealed biodegradable bags or as loose powder, takes place outdoors, where the substrate feeding system of the digester is located. This activity is performed daily by one operator for approximately half an hour. Respiratory masks (type not specified), goggles and gloves are reportedly required for the handling of cobalt salts as loose powder, while no specific risk management measures are identified for the use of sealed biodegradable bags.

Additionally cobalt salts may be administered as solutions into the digester. The solutions are provided ‘as is’ by the suppliers with no formulation of the solutions reportedly taking place at the biogas production units. According to industry, solutions can be fed into the digester continuously or daily depending on the degree of automation of the dosing process. Workers are required to use respiratory protection (type not specified), goggles and gloves for the handling of the cobalt salt solution.

Biogas production units vary widely in size from farms to big industrial-scale facilities. According to the biogas industry, there are around 13 000 production units in Europe with around 100 technology suppliers. Technologies and processes could differ significantly, possibly resulting in varying conditions of use of the cobalt salts within the sector. It is possible that the dosing operation takes place indoors or outdoors depending on the type and location of the biogas production unit.

Potential for workers’ exposure to the cobalt salts

Under the use conditions specified in the associated ESs, and the typical conditions of operation described by the biogas industry - both of which are based on the use of sealed biodegradable bags - the emission potential of cobalt salts is very low, whether the activities are performed outdoors, as described by industry in the consultation, or indoors, as reported in the ES. The packaging also prevents contact with the cobalt salts under normal conditions of use.

The use of mixtures in powder and solution form, although not very extensive according to industry, could present a higher potential for workers exposure than the use of sealed biodegradable bags. It is acknowledged that, under the conditions described by industry (use of respiratory masks, goggles and gloves), the potential exposure of workers, via both the inhalation and dermal routes, might be controlled, especially taking into account the low amounts of cobalt salts used by this sector (typical range of 5-25g per day). However, the ESs available in the registration dossiers do not, as would normally be expected, cover the specific conditions of use of the cobalt salts in these forms for the biogas sector. Other activities described in the ESs (e.g. fermentation) do not allow for a direct comparison with the conditions of use described by the biogas sector. Under these circumstances it is not possible to determine to what extent the conditions of use of the cobalt salts in powder and in solution, as reported by industry, ensure that workers’ exposure is controlled.

It can be concluded that the use of cobalt salts in the biogas sector under the typical conditions of use described by industry in the registration dossiers and in the targeted consultation, i.e. in sealed biodegradable bags, does not appear to present a significant potential for workers exposure to the cobalt salts. The conditions of use of the cobalt salts in other reportedly less used formats, i.e. powder form and solutions, might lead to a potentially higher exposure of workers and require the implementation of adequate risk management measures. Since these conditions of use are not addressed in the ESs of the registration dossiers, it has not been possible to assess whether the risk management measures as described by industry in the consultation do ensure that workers exposure to the cobalt salts is properly controlled.

2.8. Use in biotechnology, pharmaceuticals and *in vitro* diagnostics

2.8.1. Use of cobalt salts

Cobalt is an essential trace element for many living organisms. Cobalt compounds such as vitamin B12 and its derivatives are coenzymes in a number of metabolic processes. Cobalt can also be bound directly as a co-factor with cobalt-dependent enzymes for the activation of biochemical reactions.

According to the biotechnology industry, cobalt salts are commonly used in the sector as a source of cobalt to support cell growth in culture media and to activate the fermentation and enzymatic processes involved in the production of biological substances (including therapeutic peptides, vitamins, enzymes, antibiotics, single-cell proteins, organic substances and antibodies). The type of cobalt salt used appears to be process specific, with cobalt sulphate, cobalt dichloride and cobalt dinitrate being reported for different applications. No information has been provided regarding specific uses of cobalt carbonate or cobalt diacetate, although the use of these cobalt salts has been reported by the industry (EuropaBio). Cobalt dinitritate chloride is also reported to be used in small quantities in the manufacture of culture media in the biotechnology sector (EuropaBio).

Similarly, the cobalt ion is used in the pharmaceutical and *in vitro* diagnostics sectors as an essential nutrient in culture media to produce organic bio-molecules for pharmaceutical applications and diagnostic tests. The cobalt ion is derived from cobalt dichloride and, to a lesser extent, cobalt sulphate and cobalt dinitrate, depending on the cell culture in question (EFPIA-EBE, EDMA). Cobalt dichloride is additionally reported (EDMA) to be used as a co-factor in biochemical processes activated by terminal transferase in the *in vitro* diagnostics sector.

Cobalt dichloride has also been identified as a colorimetric comparison reagent in product analysis by the pharmaceutical and biotechnology industries (EuropaBio, EFPIA-EBE).

Table 10: Reported volumes of cobalt salts used in biotechnology, pharmaceuticals and in vitro diagnostics (tonnes/year)

Cobalt salt	Reported by industry*	Initial estimate**
Cobalt sulphate	In use	-
Cobalt dichloride	In use	15
Cobalt dinitrate	In use	-
Cobalt carbonate	In use	-
Cobalt diacetate	In use	-
Other: Cobalt dinitrate chloride	In use	-
*No total estimations available		

**Information provided by the Commission in its request to ECHA

No information regarding the total amount of cobalt salts used by these sectors has been submitted in the consultation. Annual amounts in the range of 1-200kg per site are reported by the sector organisations. There is no information on the total number of sites, although several thousand might be expected (see below). The highest consumption reported is around 300kg per year by one individual manufacturing site for the formulation of culture media. The information available concerning the volumes of cobalt salts in use is shown in Table 10.

2.8.2. Supply chain

The supply chain has not been described in detail by the different sectors concerned. The following description might not reflect all actors in the supply chain due to the wide variety of industries and processes involved in the bio-manufacturing of products.

Cobalt salts are supplied in powder form to laboratories and manufacturing units. The salts are usually supplied to laboratories in 5-100g bottles, although large scale operations may use larger bottles or bags. Use of solid pre-mix with a concentration below one per cent of cobalt dichloride has also been reported by one company. According to the different sector representatives, the degree of purity of the cobalt salts is a key factor in the process. Suppliers of the cobalt salts appear to be the manufacturers/distributors of fine chemicals for laboratory applications. Some companies may be suppliers of both cobalt salts and biotechnology applications (cell media, analysis kits, etc.).

Fermentation tools (culture media) containing cobalt salts are supplied by the biotechnology sector to the pharmaceutical and biopharmaceutical industries for the production of diagnostics and medicines. They are also used in the biotechnology industry for the manufacture of a variety of products (vitamins, food additives, enzymes, etc.). The cobalt content in the fermentation tools is, according to industry, typically below the classification limit of 0.01 per cent. Pharmaceutical companies also use cobalt salts directly for the preparation of culture media. Final products from fermentation processes do not contain cobalt salts.

In vitro diagnostics companies also supply analytical testing kits containing solutions of cobalt dichloride. Downstream users of this application have been identified as R&D laboratories. No consumer uses have been identified.

The number of manufacturing units and laboratories using cobalt salts across the biotechnology, pharmaceutical and *in vitro* diagnostics sectors is not known, nor is the number of laboratories using testing kits containing cobalt dichloride solutions further down the supply chain. The total number can be estimated in the thousands, however, considering that the pharmaceutical sector alone reports more than 660 000 employees in Europe, including 116 000 in research and development units.

Note that, although the uses and processes described for this sector generally take place in laboratory settings, they tend to relate to production uses of the cobalt salts, not research and development.

2.8.3. Process description

Industry has reported a number of different processes involving the use of cobalt salts. These processes have been grouped in the following categories, independent of the sector in which they take place:

- Preparation of culture media
- Fermentation/biochemical processes
- Quality control testing
- Product analysis

Cobalt is present in trace amounts in culture media. The formulation of the culture media is process-specific and can involve up to 100 different components (EuropaBio). In small scale fermentation processes, cobalt salts are typically incorporated into the culture media as a solution with a maximum concentration of cobalt salt reported in the region of three per cent (EFPIA-EBE). Cobalt salts can also be added in powder form to the fermenter for larger scale fermentation processes (EuropaBio). The concentration of cobalt salts in the culture media varies significantly depending on the type of media. The highest concentration of cobalt salts identified is 0.05 per cent (EuropaBio), but the pharmaceutical industry reports a cobalt salt content in culture media usually well below 0.01 per cent. The amount of cobalt salt in the culture media can vary from 10mg to 5kg (EuropaBio) with typical figures reported below 10g.

Industrial fermentation takes place in closed reactor tanks. A pre-culture might be prepared in shake flasks prior to inoculation in a 'seed' fermenter. Final products are recovered and purified in closed systems, once the fermentation has been completed. Any remaining cobalt in the fermentation broth is deactivated and disposed of as vitamin B12 (EDMA).

Cobalt dichloride is also used at laboratory scale in the *in vitro* diagnostics sector as a co-factor in enzymatic reactions. A stock solution with a cobalt salt concentration in the range 0.01-0.5 per cent is prepared by diluting 30-300g of cobalt dichloride (EDMA). The stock solution is further diluted and dispersed prior to being used as a reagent. Small quantities of stock solution are also supplied as a component of R&D analysis and *in vitro* diagnostic kits. The concentration of cobalt dichloride varies between 0.013 per cent and 0.325 per cent. The content of cobalt salt per kit is not specified, although 30g appears to be the total consumption per year for this activity. The kits are supplied to R&D laboratories.

Cobalt salts are sampled and tested to determine their purity and suitability for use in manufacture. Raw material quality-control practices using 1g of cobalt salt per activity have been reported by the biotechnology, pharmaceutical and *in vitro* diagnostic sectors. The specific test methods have not been identified.

Cobalt dichloride is further used in colour comparison assays for the determination of trace element impurities in products in the biotechnology and pharmaceutical sectors. A solution with three per cent cobalt dichloride (32g) is prepared and used as a reagent for the analysis (EuropaBio, EFPIA-EBE).

2.8.4. Occupational exposure

Occupational exposure scenarios

The main parameters for exposure, as defined in the ESs, are shown in Table 11.

Operational conditions and risk management measures reported in the targeted consultation

1) *Pharmaceutical and in vitro diagnostics uses*

Manufacturing takes place under GMP/GLP (Good Manufacturing Practices/Good Laboratory Practices) standards in the pharmaceutical and *in vitro* diagnostics sectors (EFPIA-EBE-EDMA).

Table 11: Occupational exposure scenario for use in fermentation processes

Description	PROC	Physical form	%	Indoors/outdoors	Exposure duration	RMM*	
						LEV	RPE
Industrial use	8b,9, 26	Solid/ powder	nr	Indoors	<60 minutes	LEV Efficiency: 78%	FFP2 APF: 10
	3,5,8b,9	Solution	<5	Indoors	nr	Not required	Not required

* gloves (EN 374) &, goggles required where direct contact to cobalt substances is possible; standard working clothes (long-sleeve overall) and safety shoes required for all activities

LEV: local exhaust ventilation; RPE: respiratory protective equipment; nr: not restricted; APF=assigned protection factor

Most of the processes described start with the preparation of a solution of the cobalt salts. Cobalt salts in powder form are handled under a dustless chemical hood by typically one to two, maximum five operators in laboratory settings. The activity lasts between five and 30 minutes and can take place from once per year to almost daily, depending on the site. Safety goggles, gloves and laboratory coats appear to be standard practice within the sectors. The use of respiratory masks (P1, P2 or FFP3) varies across sites. The handling of solution has been described by industry as taking place under laboratory conditions with local exhaust ventilation and the same risk management measures as described for the powder form. No local exhaust ventilation or respiratory protection is proposed in the registration dossiers for the handling of solutions.

The use of testing kits supplied by *in vitro* diagnostics companies to R&D laboratories involves handling highly diluted solutions of cobalt salts. Although the amount or concentration of cobalt salts has not been specified, it is reported that they are handled in laboratory settings by one operator for less than 60 minutes a few times per year. Protective clothing and gloves are reported by industry as mandatory.

2) *Biotechnology uses*

Handling of cobalt salts in the biotechnology sector can involve use in higher amounts (up to 5kg per activity has been reported). Direct addition of the cobalt salts to the culture media/fermenter without previous dilution has been reported in large scale fermentation processes. The activities can involve one to four operators. Local exhaust ventilation and the use of respiratory masks, together with gloves, goggles and microguard disposable coveralls, have been identified as standard practice by at least one large scale individual company. These conditions reflect the conditions of use proposed in the registration dossiers to ensure safe handling of the cobalt salts in powder form. The reported duration of the activity (up to 30 minutes) is within the duration of exposure prescribed in the registration dossiers (less than 60 minutes). For the handling of small quantities of cobalt salts, similar conditions of use are reported as in the pharmaceutical and *in vitro* diagnostics sector.

The handling of solutions in the biotechnology sector is reported to take place at some sites without local exhaust ventilation or respiratory masks, while other companies report the use of local exhaust ventilation. The risk management measures for the handling of the solutions do not seem to be related to the scale of the operation but with the occupational risk assessment for the activity. The conditions reported are in line with the conditions defined in the registration dossiers.

Potential for workers' exposure to the cobalt salts

It is to be noted that registration dossiers propose local exhaust ventilation (78 per cent efficiency) and the use of respiratory protection (FFP2 mask, APF:10) to ensure safe handling of the cobalt salts in powder form, while no specific risk management measures are required for the safe handling of solutions in fermentation processes.

Taking into consideration these requirements, the conditions of use (small quantities of cobalt salts, typically 10g, for five minutes under a fume hood in laboratories) and the level of control (PPEs and GMP/GLP standards) reported by the pharmaceutical and *in vitro* diagnostics sectors, the preparation and handling of cobalt salts solutions does not appear to present a significant potential for workers' exposure. A similar assessment can be made for the handling of cobalt salts solutions by R&D laboratories under the conditions described.

Although the scale of the operations in the biotechnology sector can be larger in some units than in the pharmaceutical and *in vitro* diagnostics sector, the conditions of use and the level of control in these operations are in line with those recommended in the registrations dossier and can be considered as standard for these types of activities. No significant potential for workers' exposure to the cobalt salts is therefore identified in this sector.

It can be concluded that the use of cobalt salts in the biotechnology, pharmaceuticals and *in vitro* diagnostics sectors under the conditions reported by industry in the registration dossiers and in the targeted consultation does not appear to present a significant potential for worker exposure to the cobalt salts.

2.9. Use in humidity indicators

2.9.1. Use of cobalt salts

Cobalt dichloride is used in humidity indicators in a variety of applications (military, semiconductors, in vitro diagnostics, etc.). The use is based on the salt's characteristic of changing colour precisely at differing humidity levels. Although other cobalt compounds are used by the sector (mainly cobalt bromide), cobalt dichloride is reportedly the only cobalt salt technically reliable for humidity indicator levels above 60 per cent relative humidity (RH) and/or high temperature exposure (>87 celsius). US military specifications (Mil-I-8835A) require the use of cobalt dichloride for humidity indicators. This suggests that no interchangeability of the cobalt salts can be considered technically feasible for this use.

Humidity indicators are supplied to the market in a number of formats, including plugs, cards and indicating silica gel sachets and canisters. Quantities used in each indicator unit are very small, but information on total use of cobalt salts in the sector is not available. The information reported regarding the volumes of cobalt salts used in this sector is shown in Table 12.

2.9.2. Supply chain

According to the information obtained for this study, humidity indicators are manufactured in the USA and imported into the EU as articles (humidity indicator plugs) and mixtures (humidity indicator cards and indicating silica gel sachets and canisters). Manufacturing might also take place in Asian countries although no detailed information has been supplied on any specific importer or manufacturer. No manufacture of humidity indicators has been identified in the EU at the time of writing this report.

Table 12: Reported volumes of cobalt salts used in humidity indicators

Cobalt salt	Reported by industry*	Initial estimate**
Cobalt sulphate	-	-
Cobalt dichloride	In use	0.5
Cobalt dinitrate	-	-
Cobalt carbonate	-	-
Cobalt diacetate	-	-
Other: Cobalt bromide	In use	-

* Information provided by individual companies
** Information provided by the Commission in its request to ECHA

Cobalt dichloride in solution (from 1 -50 per cent cobalt salt content) is supplied for the manufacturing of humidity indicator plugs and cards. The location of the cobalt dichloride supplier has not been made known. The final content of cobalt dichloride in the solutions contained in the products exported into the EU is in the range 0.01-5 per cent.

Cobalt dichloride-impregnated silica gel is used for the manufacturing of humidity indicator sachets and canisters. The silica gel is produced in China and supplied to a USA manufacturing plant. The final product is exported into the EU as a continuous strip wound onto a core or as individual packets sealed in a foil pouch. Indicating silica gel is also exported as sealed polymer canisters packed in poly-lined gallon cans. The concentration of cobalt dichloride in the silica gel is below 1 per cent.

Humidity indicator plugs are mainly used by military suppliers, and might also enter the EU already fixed into containers. Humidity indicator cards are supplied mainly to the semi-conductor industry to be incorporated into packaging. According to industry, this sector is in decline in the EU. Indicating silica gel sachets and canisters are supplied to medical diagnostic manufacturers which dispense them into their products, which are then used in laboratories for testing.

It has been reported that the industry has been unable to identify any consumer applications for humidity indicator and therefore that all uses are industrial or professional.

2.9.3. Process description

Manufacture of humidity indicator plugs and cards takes place in the USA and will therefore not be further discussed. Once the humidity indicators are imported into the EU, they are manually handled by industrial or professional workers. Plugs are installed in containers for outside visual monitoring of relative humidity within the container without the need to open the container itself. Installation might require the use of hand tools by workers. Humidity indicator cards are manually taken from the original packaging and inserted into the container or bag where humidity needs to be monitored. The packaging is immediately sealed. Humidity indicator cards are mainly used in the semiconductor industry (other end users are the electronics and laser manufacturing sectors) where most processes take place in clean rooms.

Indicating silica gel sachets and canisters are also currently manufactured in the USA. Silica gel indicators are automatically or manually inserted into medical diagnostic products. The silica gel is contained within the sachet or sealed canister. According to humidity indicator manufacturers, sachets are made of a strong tear resistant material. The medical diagnostic products are used in clinical laboratory settings by professional users. Labelling on the medical diagnostic product reportedly states that, if the sachets are breached, the whole kit should be thrown away and replaced.

2.9.4. Occupational exposure

Occupational exposure scenarios

The main determinants of occupational exposure for the industrial use of cobalt dichloride in humidity indicators, as defined in the ESs submitted by the registrants, is shown in Table 13.

Table 13: Occupational exposure scenario for use in humidity indicators

Description	PROC	Physical Form	%	Indoors/outdoors	Exposure duration	RMM*	
						LEV	RPE
Industrial use	4,5,8b,9,13	Aqueous solution	nr	Indoors	nr	Not required	Not required
	21	Indicator cards /bags	nr	Indoors	nr	Not required	Not required

* gloves (EN 374) &, goggles required where direct contact to cobalt substances is possible; standard working clothes (long-sleeve overall) and safety shoes required for all activities

LEV: local exhaust ventilation; RPE: respiratory protective equipment; nr: not restricted; APF=assigned protection factor

Operational conditions and risk management measures reported in the targeted consultation

The manufacture of humidity indicators involves the handling of cobalt dichloride in solution (cobalt salt content 1 - 50 per cent) or as impregnated silica gel (cobalt salt content below 1 per cent). No handling of cobalt salts in powder form is reported by the manufacturers. The number of workers at the manufacturing sites has not been reported.

The handling of humidity indicator plugs and cards could result in dermal and inhalation exposure to the cobalt salts impregnating the printed card. According to industry, both types of humidity indicators are supplied with safety data sheets that prescribe the use of gloves to avoid dermal contact with the cards. Inhalation exposure is disregarded by the manufacturer due to the low volatility of the impregnating solution.

On the other hand silica gel humidity indicators are handled in industrial or laboratory settings with strict control practices to avoid contamination of products and test samples. Workers are reported to be specifically trained to ensure an appropriate use of the products, including humidity indicators.

Potential for workers' exposure to the cobalt salts

The potential for workers' exposure to cobalt dichloride from the handling of silica gel humidity indicators and humidity indicator plugs and cards can be estimated as very low and therefore not significant. It is to be noted that the registration dossiers do not require any specific technical conditions or risk management measures to ensure the safe handling of humidity indicators.

In summary, no significant potential for workers exposure to the cobalt salts is expected under the conditions of use described in the registration dossiers and in the targeted consultation for the use of cobalt salts in humidity indicators.

3. CONCLUSIONS AND DISCUSSION

Table 14 presents a summary of the results of the current evaluation of the potential for worker exposure to the cobalt salts of interest in eight use sectors. (Use in surface treatment is considered separately, in line with the Commission's request to ECHA.) For the pigment in PET and fertiliser sectors, no evidence of use of the five cobalt salts was found in this study. Based on information obtained from this investigation, and the methodology employed to evaluate it, in three sectors (animal feed, biotechnology and humidity indicators) it was judged that the possibility of significant potential for workers' exposure (either via inhalation, dermal or both) to the cobalt salts under consideration is very low. For the remaining sectors, certain characteristics and information suggest that there is some potential for exposure, but it is not possible to judge how significant this is on the basis of the information obtained. This is discussed further below.

The use of cobalt salts in oxygen scavenging processes and biogas production exhibit some sector and/or user characteristics which could in principle indicate a higher potential for exposure. Neither use, in powder form, appears in the registrants' ESs for the relevant salt. Further, use is reported in powder form, across a potentially large number of sites, which often seem to be smaller-scale operating units (e.g. farms), where the extent of implementation of risk-management measures might be limited. Repeated use of powder could generate a potential for exposure in these types of settings. However, reported use volumes appear to be relatively low. (5-500g per site per day for oxygen scavenging is implied by the figures provided in the consultation; up to 100g/day is reported for biogas production.) In addition, no actual evidence of higher exposure potential in these cases was obtained through the current study. As a result, the extent to which there is significant potential for exposure in these two sectors is not clear.

The use of cobalt diacetate as a catalyst for the production of PTA/IPA/DMTE/PET is reportedly based on the powder form in one plant only but in relatively large quantities. The use of cobalt diacetate powder for this use is not in the registrants' ESs, and hence it is not possible to assess the appropriateness of the reported RMMs in place at this plant. This does not appear to be sufficient evidence to indicate a significant potential for exposure, although the possible existence of conditions generating exposure is acknowledged. Note also that, given that only one plant in the EU appears to be capable of using cobalt diacetate in powder form for this use (and is intended to switch to the use of solutions), this does not seem to present a case for EU-wide action (in the form of restriction), whatever the conditions of use at that plant.

The extent to which there is significant potential for exposure to cobalt salts in surface treatment has not been assessed, as this was not part of the Commission's request to ECHA. Nevertheless, the conditions reported by industry in general meet or are stricter than those recommended in the relevant ESs. It should be noted that information was provided from only a relatively small proportion of the overall sector, and the wide range of types of use and user could mean that reported use conditions do not hold in all situations.

Table 14: Summary of conclusions on potential for workers' exposure (not surface treatment)

Sector / Use	Summary
Pigment in PET	All use reported ceased
Catalyst in PTA/IPA/DMTE/PET	Only cobalt diacetate is used (100 to 1000 tonnes/year), primarily in solution form. Relatively large quantity of powder reportedly used at one single plant; reported RMMs seem appropriate, but use of cobalt diacetate powder not covered by registrants' ESs, so not possible to assess conditions of use and exposure potential.
Oxygen scavenging	Cobalt sulphate and dichloride are reported to be used, in powder form in low volumes (5-500g per day per site). Reported use conditions appear adequate, although the large number of small-scale operators in the sector could mean this conclusion does not hold everywhere. This use in powder form is not in registrants' ESs.
Animal feed	New regulations will have benign impacts on risk factors. Handling of powder only in large-scale, formal settings. Farm use only in very low concentrations (and mostly only in pellets in future). No significant potential for exposure expected in this sector.
Fertiliser	No use reported in inorganic fertilisers. Some reports of use in organo-mineral fertilisers, but no details received.
Biogas	No significant potential from use conditions in registrants' ESs, based on salts being used in sealed biodegradable bags. Use conditions reported for other forms (not in the ESs) seem reasonable. However, the large number of small-scale operators (e.g. farms) might mean these conditions are not met. Use volumes seem low (up to 100g per day per user reported).
Biotechnology, pharmaceuticals, *in vitro* diagnostics	Small quantities. Controlled (generally laboratory) conditions. (Use of cobalt dinitrate chloride also reported.) No significant potential for exposure expected in this sector.
Humidity indicators	Tiny quantities in 'product' form. (Use of cobalt bromide also reported.) No significant potential for exposure expected in this sector.

The overall conclusion is that the existence of a significant potential for exposure has not been demonstrated in any of the sectors considered in this report, although the picture appears quite uncertain in three of them. A number of points can be made in relation to this conclusion.

First, the information on which the conclusion is based is largely qualitative, incomplete, and possibly not representative of the full range of conditions which might be present in the various sectors considered. Only a small number of companies and organisations made representations in the consultation, especially relative to the total number of operators in some sectors. Few or no technical or quantitative data were provided on which a more formal assessment of exposure potential could be based. In addition, exposure potential does not automatically equate to risk, so even in those sectors where a potential for exposure is acknowledged, this does not imply the existence of any risk, let alone risk which is not adequately controlled.

Further, **use conditions for safe use are identified in the ESs on the basis of the**

DNELs derived in the registration dossiers. This derivation is subject to confirmation and hence, in the absence of this confirmation, there is some uncertainty about their validity. In particular, there is a question mark over whether the salts have a mode of action which exhibits threshold or non-threshold characteristics. Evaluations made in this study are based on a comparison of reported practice with conditions for safe use as stated in the registration dossiers, but if these conditions are erroneously based on a threshold assumption, this comparison is invalid.

Importantly, the consultation uncovered examples of apparent inconsistency between use conditions reportedly in place in some downstream uses and the conditions of use recommended in the relevant registration dossiers. In biogas production, for instance, some operators reportedly use cobalt salts in loose powder form when the registration dossier requires powder to be administered in sealed bags. Moreover, some companies appear to be using cobalt salts in applications which are not covered in the ESs in the registration dossiers. In the absence of ESs – presented by registrants or downstream users themselves – which have demonstrated under what conditions use can be considered safe, these inconsistencies are clearly an issue of concern.

4. ANNEXES

ANNEX 1- Overview of the information from the REACH registration dossiers

ANNEX 2- Questionnaire used in the targeted consultation

ANNEX 3- List of participants in the targeted consultation

ANNEX 1- Overview of the information from the REACH registration dossiers

Cobalt salt	CAS number	Identified Uses (as described in the registration dossiers)
Cobalt sulphate	10124-43-3	1. Industrial use in the production of cobalt carbonate 2. Industrial use in surface treatment processes (intermediate use) 3. Formulation and industrial use as water treatment chemical, oxygen scavenger, corrosion inhibitor 4. Manufacture and industrial use of batteries using cobalt sulphate 5. Industrial use in the manufacture of inorganic pigments & frits, glass and ceramic ware (intermediate use) 6. Industrial use in the manufacture of dyes for the textile ,leather, wood, and/or paper industry (intermediate use) 7. Industrial use in the manufacture of chemicals and in other wet-chemical processes as intermediate 8. Industrial use in fertilizers and/or feed grade materials 9. Industrial use as catalyst in synthesis processes 10. Industrial use in fermentation processes and/or biogas production 11. Professional use of fertilizers containing cobalt sulphate 12. Formulation, industrial and professional use for chemical pharmaceutical production
Cobalt dichloride	7646-79-9	1. Industrial use in the manufacture of cobalt carboxylates and resinates (intermediate use) 2. Industrial use in surface treatment processes (intermediate use) 3. Formulation and industrial use as water treatment chemical, oxygen scavenger, corrosion inhibitor 4. Industrial use in the manufacture of inorganic pigments & frits, glass and ceramic ware (intermediate use) 5. Industrial use in the manufacture of textile dyes (intermediate use) 6. Industrial use in the manufacture of chemicals and in other wet-chemical processes as intermediate 7. Industrial use in fertilizers and/or feed grade materials 8. Industrial use in fermentation processes, in the manufacture of reagents and use thereof in scientific research and standard analysis and/or biogas production 9. Industrial and professional use in humidity indicators cards, plugs and/or bags with printed spots 10. Professional use of fertilizers containing cobalt dichloride
Cobalt dinitrate	233-402-1	1. Industrial use in the manufacture of cobalt carboxylates and resinates (intermediate use) 2. Manufacture of cobalt dinitrate as an intermediate during catalyst production 3. Industrial use of cobalt dinitrate as intermediate in the manufacture of other cobalt compounds during catalyst production 4. Industrial use in surface treatment processes (intermediate use) 5. Formulation and industrial use as water treatment chemical, oxygen scavenger, corrosion inhibitor 6. Industrial use of cobalt dinitrate as intermediate in the manufacture of other cobalt compounds during battery production 7. Industrial use in the manufacture of chemicals and in other wet-chemical processes as intermediate

Cobalt salt	CAS number	Identified Uses (as described in the registration dossiers)
Cobalt carbonate	513-79-1	1. Manufacture of cobalt carbonate as an intermediate during catalyst production 2. Industrial use of cobalt carbonate as intermediate in the manufacture of other cobalt compounds during catalyst production 3. Industrial use in surface treatment processes (intermediate use) 4. Industrial use in the manufacture of inorganic pigments & frits, glass and ceramic ware (intermediate use) 5. Industrial use in fertilizers and/or feed grade materials 6. Industrial use in the manufacture of chemicals and in other wet-chemical processes as intermediate 7. Professional use of fertilizers containing cobalt carbonate 8. Industrial use in fermentation processes and/or biogas production
Cobalt diacetate	71-48-7	1. Industrial use as a catalyst 2. Industrial use in surface treatment processes (intermediate use) 3. Industrial use in the manufacture of inorganic pigments & frits, glass and ceramic ware (intermediate use) 4. Manufacture and industrial use of plastics and/or PET using cobalt diacetate as a colorant 5. Manufacture and industrial use of rubber adhesion agent using cobalt diacetate 6. Industrial use in the manufacture of chemicals and in other wet-chemical processes as intermediate 7. Industrial use in fertilizers and/or feed grade materials 8. Professional uses of plastics and/or PET containing cobalt diacetate 9. Professional use of fertilizers containing cobalt diacetate 10. Service life of tyres/shredded tyres 11. Service life of PET-bottles (food contact material 12. Service life of surface treated articles (anodic coating) 13. Professional use of service treated massive objects 14. Industrial use in the manufacture of dyes for the textile ,leather, wood, and/or paper industry (intermediate use) 15. Industrial use in the manufacture of hard metal (intermediate use) 16. Industrial use in fermentation processes and/or biogas production

ANNEX 2- Questionnaire used in the targeted consultation

SECTOR OF USE	

	Name of the organisation/company
	Contact details
	Is this information confidential? (Yes/No)

	Would you be willing to participate in a sector specific follow-up meeting around May 7/8 in Brussels? (Yes/No)	

Question	***Please indicate for your sector which of the following cobalt salts are used, the tonnage per year and the form (powder/solution/etc.) in which the salts are supplied to your premises***			
	Cobalt salt	***Used (Yes/No)***	***Tonnes/year***	***Form (powder/solution/etc.) in which is supplied***
Answer	***Cobalt sulphate***			
Answer	***Cobalt dichloride***			
Answer	***Cobalt dinitrate***			
Answer	***Cobalt carbonate***			
Answer	***Cobalt diacetate***			
Answer	***Others(specify)***			
	Is this information confidential (Yes/No)			

Question	***Please specify the number of sites and the average number of workers per site in the EU within your sector of activity where cobalt salts are used***
Answer	
	Is this information confidential? (Yes/No)

Question	***Please provide a brief description of the process in which each of the cobalt salts are used and specify which the technical function of the substance is.***		
	Cobalt salt	***Brief description of the process***	***Technical function of the cobalt salt***
Answer	***Cobalt sulphate***		
Answer	***Cobalt dichloride***		
Answer	***Cobalt dinitrate***		
Answer	***Cobalt carbonate***		
Answer	***Cobalt diacetate***		
Answer	***Others (specify)***		
	Is this information confidential? (Yes/No)		

(Only for use as a catalyst for the production of PTA/IPA/DMT and PET)

Question	***Please specify any releases of cobalt salts to the environment and any monitoring system in place***	
	Emissions to air and monitoring system used	
Answer		
	Emissions to water and monitoring system used	
Answer		
	Waste disposal of cobalt salts/solutions	
Answer		
	Is this information confidential? (Yes/No)	

The following set of questions are organised by cobalt salt and type of activity in which exposure to workers to cobalt salts may occur. **We kindly request you to fill in an independent table for <u>each cobalt salt and for each activity</u> in which workers may be exposed to cobalt salts** (preparation of a solution, filling of containers, etc.) In order to do so you may add (copy and paste) as many tables as needed. If there are significant variations in the use conditions and the risk management measures in place across the sector please specify them in the answers, indicating the main differences encountered.

Question	***Please describe the activities within the process in which the workers may be exposed to the cobalt salts and the conditions and risk management measures for each of the activities***
	Process in which the cobalt salt is used
Answer	
	Cobalt salt used
Answer	
	Brief description of the activity
Answer	
	Type of exposure (inhalation/dermal/oral)
Answer	
	Physical form of the cobalt salts (powder/solution/etc.)
Answer	
	Is the cobalt salt used in a mixture? If so, what is the concentration (in %)?
Answer	
	Amount (in kg) of cobalt salt used in the activity
Answer	
	Number of workers exposed to the cobalt salt during the activity
Answer	
	Duration of the activity (hours/day)
Answer	
	Frequency of the activity (days/year)
Answer	
	Is the activity an industrial activity (performed in an industrial setting) or a professional activity?
Answer	
	Is the activity performed outdoors or indoors?
Answer	
	If the activity is performed indoors, is there local exhaust ventilation (LEV)?
Answer	
	Is the use of respiratory masks mandatory during the activity? If so, specify which type.
Answer	
	Is the use of goggles mandatory during the activity? If so, specify which type
Answer	
	Is the use of gloves mandatory during the activity? If so, specify which type.
Answer	
	Is there other type of personal protection equipment mandatory during the activity? If so, specify which type.
Answer	
	Is this information confidential? (Yes/No)

ANNEX 3- List of participants in the targeted consultation

Use in surface treatment

SYF (The Swedish Electroplaters and Surface and Finishers Society)

ZVO (The Central Association of Surface Treatment Professionals Germany)

Company/Organisation 3

Company/Organisation 4

Company/Organisation 5

Company/Organisation 6

Company/Organisation 7

Company/Organisation 8

Company/Organisation 9

Company/Organisation 10

Company Organisation 11

Company/Organisation 12

Use as pigment for PET

CPME (Committee of PET Manufacturers in Europe)

Use as a catalyst in for the production of PTA/IPA/DMT and PET

CPME (Committee of PET Manufacturers in Europe)

Company/Organisation 14

Company/Organisation 15

Use as a catalyst in oxygen scavenging processes

Company/Organisation 16

Company/Organisation 17

Use for animal feed

EMFEMA (International Association of the European manufacturers of Major, Trace and Specific Feed Mineral Materials)

FEFAC (The European Feed Manufacturers' Federation)

FEFANA (EU Association of Specialty Feed Ingredients and their Mixtures)

Company/Organisation 21

Use as fertilisers

Company/Organisation 22

Use for biogas production

EBA (European Biogas Association)

Use in biotechnology, pharmaceuticals and in vitro diagnostics

Abpi (Association of the British Pharmaceutical Industry)

EBE (European Biopharmaceutical Enterprises)

EDMA (European Diagnostic Manufacturers Association)

EFPIA (European Federation of Pharmaceutical Industries and Associations)

EuropaBio (The European Association for Bioindustries)

Company/Organisation 29

Company/Organisation 30

Company/Organisation 31

Company/Organisation 32

Company/Organisation 33

Company/Organisation 34

Company/Organisation 35

Company/Organisation 36

Company/Organisation 37

Company/Organisation 38

Company/Organisation 39

Use as humidity indicator

Company/Organisation 40

Company/Organisation 41