Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on:

cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)

ECHA/RAC/RES-O-0000006741-74-01/F
ECHA/SEAC/RES-O-0000006840-74-01/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 17 February 2020) and SEAC's opinion (adopted 17 September 2020)

17 February 2020

ECHA/RAC/RES-O-0000006741-74-01/F

17 September 2020

ECHA/SEAC/RES-O-0000006840-74-01/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of:

Cobalt sulphate
- CAS: 10124-43-3
- EC: 233-334-2

Cobalt dichloride
- CAS: 7646-79-9
- EC: 231-589-4

Cobalt dinitrate
- CAS: 10141-05-6
- EC: 233-402-1

Cobalt carbonate
- CAS: 513-79-1
- EC: 208-169-4

Cobalt di(acetate)
- CAS: 71-48-7
- EC: 200-755-8

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, which supports both the RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended with further information obtained during the consultation on the Annex XV report and other relevant information resulting from the opinion making process.

PROCESS FOR ADOPTION OF THE OPINIONS

ECHA has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at http://echa.europa.eu/web/guest/restrictions-under-consideration on **19 December 2018**. Interested parties were invited to submit comments and contributions by **19 June 2019**.

ADOPTION OF THE OPINION

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: ***Tiina SANTONEN***

Co-rapporteur, appointed by RAC: ***Urs SCHLÜTER***

The opinion of RAC as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment was adopted in accordance with Article 70 of the REACH Regulation on **17 February 2020** (by written procedure).

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The opinion of RAC was adopted **by consensus**.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: ***Simone FANKHAUSER***

Co-rapporteur, appointed by SEAC: ***Ivars BERGS***

The draft opinion of SEAC

The draft opinion of SEAC on the proposed restriction and on its related socio-economic impact has been agreed in accordance with Article 71(1) of the REACH Regulation **on 12 March 2020**.

The draft opinion takes into account the comments from the interested parties provided in accordance with Article 69(6)(a) of the REACH Regulation.

The draft opinion takes into account the socio-economic analysis, or information which can contribute to one, received from the interested parties provided in accordance with Article 69(6)(b) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-

consideration. Interested parties were invited to submit comments on the draft opinion by **25 May 2020**.

The opinion of SEAC

The opinion of SEAC on the proposed restriction and on its related socio-economic impact was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on **17 September 2020**.

The opinion takes into account the comments of interested parties provided in accordance with Articles 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted **by consensus**.

Contents

1. OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

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

[1] See Appendix 1 of the Background Document for the calculation of exposure levels.

1.1. THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate)** is the most appropriate Union wide measure to address the identified risk in terms of the effectiveness, in reducing the risk, practicality and monitorability as demonstrated in the justification supporting this opinion, provided that the conditions are modified, as proposed by RAC.

The conditions of the restriction proposed by RAC are:

Substance Identity (or group identity)	Conditions of the restriction
– **Cobalt sulphate** – CAS no 10124-43-3 – EC no 233-334-2 – **Cobalt dichloride** – CAS no 7646-79-9 – EC no 231-589-4 – **Cobalt dinitrate** – CAS no 10141-05-6 – EC no 233-402-1 – **Cobalt carbonate** – CAS no 513-79-1 – EC no 208-169-4 – **Cobalt di(acetate)** – CAS no 71-48-7 – EC no 200-755-8	1) Shall not be manufactured, placed on the market or used as substances on their own or in mixtures in a concentration equal or above 0.01% by weight, unless: a) if required by article 14 of REACH, registrants have carried out in their Chemical Safety Assessment an assessment according to paragraph 6.5 of Annex I of REACH and have used a limit value of 1 µg Co/m³ (as 8 h TWA, for the inhalable fraction) and 0.5 µg Co/m³ (as 8 h TWA, for the respirable fraction) to demonstrate that all occupational inhalation exposures to cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) are below these limit values, and b) if required by article 37(4) of REACH, downstream users have carried out in their Downstream user Chemical Safety Assessment an assessment according to paragraph 6.5 of Annex I of REACH and have used a limit value of 1 µg Co/m³ (as 8 h TWA, for inhalable fraction) and 0.5 µg Co/m³ (as 8 h TWA, for respirable fraction) to demonstrate that all occupational inhalation exposures to cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) are below these limit values, and c) the supplier has provided the recipient of the substance on their own or in mixtures in a concentration equal or above 0.01% by weight with a Safety Data Sheet and exposure scenarios (where relevant) according to article 31 of REACH that includes the operational conditions and risk management measures to control occupational inhalation exposure below a limit value of 1 µg Co/m³ (as 8 h TWA, for inhalable fraction) and 0.5 µg Co/m³ (as 8

	h TWA, for respirable fraction). The Safety Data Sheet shall state the limit values under Section 8.1 Control parameters. d) the manufacturers and downstream users have implemented a monitoring programme to ensure that all occupational inhalation exposures to cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) are below a limit value of 1 µg Co/m³ (as 8 h TWA, for inhalable fraction) and 0.5 µg Co/m³ (as 8 h TWA, for respirable fraction).

In addition, RAC considers it necessary, and proposes to the European Commission, to derive a binding occupational exposure limit value (BOEL) for cobalt and its compounds according to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD). RAC recommends that this value should be identical to the limit values given in this restriction. In addition to the inhalation exposure, manufacturers, importers and users of the cobalt compounds should pay attention to the prevention of exposure via the skin.

1.2. THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on an evaluation of the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction initially proposed by the Dossier Submitter is not the most appropriate EU-wide measure.

Taking into account the conditions of the restriction as proposed by RAC, SEAC concludes that it is uncertain whether the restriction as amended by RAC is the most appropriate EU-wide measure. The uncertainties are related to proportionality aspects, to the discussion of whether a BOEL would be a more appropriate risk management measure to address the risks to workers and to the limitation of the restriction to the five specific substances under consideration.

2. JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

2.1. IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

2.1.1. Description of and justification for targeting of the information on hazards and exposure/emissions (scope)

Summary of proposal:

This restriction concerns the placing on the market, manufacture and use of five water soluble cobalt salts: cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt di(acetate) on their own or in mixtures in a concentration equal to or above 0.01% by weight in industrial and professional applications. Further referred to as 'five cobalt salts' under in this opinion, they have a harmonised classification as Carc 1B and Muta 2. Consumer uses are not expected and are therefore outside the scope of this restriction. The current use of these cobalt salts in the EU is 30 000 tonnes per year with the highest amounts used as transported isolated intermediates for the manufacturing of other chemicals. The volumes are expected to increase in future due to the increasing demand for rechargeable batteries and biotechnology-health applications. It has been estimated that 35 000 workers at around 20 000 industrial sites are exposed to the five cobalt salts.

ECHA made an assessment on the uses of cobalt salts in 2017 and using the RAC dose response for carcinogenicity (2016) calculated excess cancer risks in all sectors involving exposure to these cobalt salts in the range of 10^{-3} to 10^{-2}. Based on these findings, the European Commission requested ECHA to prepare an Annex XV restriction dossier covering these five cobalt salts and addressing risks at the workplace. In the current restriction dossier, the Dossier Submitter identified that cancer risks to workers are currently not adequately controlled and that risk management is required at the Union level.

These five cobalt salts are grouped since they have similar bioaccessibility and bioavailability properties, resulting in similar release of cobalt ions. The cobalt (II) ion is considered responsible for the carcinogenicity of cobalt. The Dossier Submitter notes that cobalt metal and several other poorly water-soluble compounds (e.g. cobalt oxide) have also been found to be soluble in biological fluids and can release cobalt (II) ions *in vivo*. Therefore, these cobalt compounds could also cause risks that might be addressed by this restriction proposal. However, due to the specific request of the Commission, this restriction has been limited to the five named cobalt salts.

RAC conclusions:

Regarding the scope:

- Cobalt (II) ions released in biological fluids from cobalt metal and cobalt compounds are recognised as the source of toxicity in humans. At the request of the Commission, the Dossier Submitter developed a restriction under the REACH regulation on the five registered soluble cobalt salts; this limited the scope of the restriction. RAC points out that not including other cobalt compounds in the scope has implications for the protection of workers, which are further discussed in the section on "justification whether the suggested restriction is the most appropriate EU wide measure". One

aspect – as identified by the Dossier Submitter – to note is that in occupational settings, possible co-exposure to different cobalt compounds may also make it difficult to monitor the exposure to the restricted cobalt salts only. **RAC supports the restriction targeted at the five soluble cobalt salts, but additionally recommends to the European Commission to derive a binding occupational exposure limit value (BOEL) for cobalt and its compounds according to directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD).**

- The current restriction proposal is targeted at **lung cancer risk**, which is dependent on cumulative working life exposure and is therefore meant to be adjusted for the frequency and duration of exposure. However, when exposure is averaged over the whole year, infrequent peak exposures may remain uncontrolled. These short term higher exposures are likely to be relevant for cobalt sensitisation and other non-cancer (respiratory) effects and the limit value should also be protective for these effects.

- The current restriction proposal concerns an air limit value and as such does not protect from skin sensitisation. In order to protect workers from the risk of skin sensitisation, risk management measures at the workplaces are needed for the prevention of skin exposure.

Key elements underpinning the RAC conclusion:

See further justifications in the following sections.

2.1.2. Description of the risks addressed by the proposed restriction

2.1.3. Information on hazards

Summary of proposal:

The hazard property on which this restriction is based is carcinogenicity. The five cobalt salts in the scope of this proposed restriction have a harmonised classification under the CLP regulation as: Carc. 1B (H350, may cause cancer) and Muta 2 (H341, suspected of causing genetic defects). In addition, they are classified as category 1 skin and respiratory sensitisers (H317, may cause an allergic skin reaction; H334, may cause allergy or asthma symptoms or breathing difficulties if inhaled).

It is assumed that the carcinogenicity and mutagenicity of cobalt compounds in general is driven by the cobalt (II) ions, which are released in the body. The Dossier Submitter's proposal on the dose-response of the carcinogenicity of cobalt salts is based on the RAC opinion from 2016. Since the human data on the carcinogenicity of cobalt is limited, the dose response is based on experimental data from animals, i.e. on the lowest BMDL10 value of 0.414 mg/m³ that was found for female rat tumours in NTP (1998) inhalation studies, in which mice and rats were exposed to cobalt sulphate heptahydrate by inhalation. A linear approach was used to derive the following dose-response for occupational exposure to respirable cobalt:

Excess risk (lung cancer, workers) = 1.05 x exposure level (as mg Co/m^3, respirable fraction)

Cobalt salts were assessed using a non-threshold approach because of the lack of identified thresholds and the uncertainties regarding the mechanisms involved. Although it was

recognised that inhalable particles also produce pre-malignant lesions (hyperplasia, metaplasia and atrophy) in animal studies, and therefore inhalable particles should also be considered as carcinogenic, it was not possible to derive a dose-response related to this fraction and the dose-response was therefore derived only for the respirable fraction.

However, the Dossier Submitter considered it appropriate to apply the dose–response relationship derived for lung cancer to characterise all cancer effects (local and systemic) resulting from inhalation exposure to the cobalt salts since it was not possible to exclude systemic and local carcinogenicity effects resulting from the deposition of particles to the upper respiratory tract and ingestion and/or absorption of cobalt. In animal experiments, cobalt sulphate inhalation caused a statistically increased incidence of pheochromocytomas at the highest dose in females. In males, a significant increase was seen only at the second highest dose, i.e. no dose response was seen. Since this was the only evidence on systemic tumours after exposure to soluble cobalt salts, RAC (2016) did not consider this evidence strong enough and concluded that cobalt salts are local carcinogens. However, inhalation studies with cobalt metal (see RAC opinion on the classification of cobalt metal, 2017) indicated neoplasms at several organ sites (pancreas, adrenal gland, hematopoietic system and kidney) which was considered to support the systemic carcinogenicity of cobalt.

Since the RAC (2016) opinion, two epidemiological studies have been published on the cancer risk caused by cobalt compounds (Sauni et al., 2017 and Marsh et al., 2017). Summaries of both studies have been included in the Background Document but the Dossier Submitter did not consider them to have an impact on the hazard characterisation. Neither of the studies provided any consistent evidence of increased cancer risk in humans.

The Dossier Submitter has presented an overview on the skin and respiratory sensitisation properties of the cobalt salts but has not quantified the hazard. According to the Dossier Submitter the conditions of the proposed restriction will lead to a reduction in occupational exposure that will result not only in a reduction of cancer cases but also in the prevention of new cases of skin and respiratory sensitisation among the exposed workers.

RAC conclusions:

- While RAC (2016) states in its conclusions that "*the cobalt salts may be considered genotoxic carcinogens using a non-threshold approach for risk assessment*" it also acknowledges that "*the current scientific findings and mode of action considerations 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*". Because of these threshold mechanisms, the use of a linear approach for dose-response is considered by RAC to be very conservative and is likely to result in the overestimation of risks especially at lower exposure levels (acknowledged also by RAC 2016 and agreed again during the opinion development of this restriction proposal).

- RAC chose to assess whether a mode of action-based threshold for cancer effects could be derived for cobalt following the methodology of the ECHA/RAC – SCOEL Joint Task Force (ECHA, 2017), which was recently added as an Appendix to ECHA R.8 Guidance (ECHA, 2019). However, it was concluded that the data was insufficient to derive such a health-based threshold. As a result, other options were assessed.

- RAC acknowledges that chronic inflammation is likely to play a role in the mode of action of cobalt-caused genotoxicity and cancer. An estimated threshold level for chronic pulmonary inflammation of **0.5 µg Co/m³ (respirable fraction)** is derived using animal data. This can be considered to present a breakpoint in the dose-response of cobalt carcinogenicity. It needs to be stressed, that due to the gaps in the knowledge about the carcinogenicity of cobalt, this cannot be identified as a health-based (fully safe) threshold below which cancer risks can be considered negligible. However, below this level, the cancer risk is likely to be reduced significantly compared to the risk estimated on the basis of linear extrapolation. Since inflammation and secondary genotoxicity at levels >0.5 µg/m^3 may enhance the cancer risk, the levels should be controlled below the breakpoint as an 8 h time weighted average (TWA) rather than a frequency and duration-adjusted reference exposure value (the latter as proposed by the Dossier Submitter).

- The use of the dose–response relationship derived for lung cancer to characterise other (upper respiratory tract and systemic) cancers is an additional conservative assumption made by the Dossier Submitter. As noted by RAC (2016), hyperplasia, metaplasia and atrophy in epithelial cells of the nose, and metaplasia of the squamous epithelium of the larynx, were seen in long-term animal studies at the highest dose. However, neither epidemiological nor animal studies have provided evidence of upper respiratory tract tumours. Therefore, RAC (2016) concluded that no dose-response can be derived for inhalable particles. In animal studies >40% of the respirable particles are expected to deposit in the head region (see the discussion under "key elements underpinning RAC's opinion") whereas about 4% end up to alveolar region. When taking into account the absence of tumours in the upper respiratory tract at the highest concentration tested (3.0 mg/m^3 cobalt sulphate hexahydrate) whereas already 0.3 mg/m^3 concentration resulted in increased incidence of pulmonary tumours, the risk of upper respiratory tract cancers is more than one order of magnitude lower than that of lung cancer. Even though in animal studies pheochromocytomas and pancreatic cancers were observed after the inhalation exposure to cobalt metal, the relevance of these systemic cancers to low level human exposures is unclear. As concluded by RAC in its opinion on the classification and labelling of cobalt metal (2017), the mechanisms of these cancers may be related to the high doses used in animal studies and may exert a threshold. Because of the clear potency difference (1-2 orders of magnitude), dose response for respirable particles is considered to cover also possible cancer risk caused by the non-respirable particles. Thus, applying the lung cancer dose-response to characterise the risk of other cancers caused by non-respirable cobalt dust is not considered appropriate from a toxicological point of view.

- The new large epidemiological study by Marsh et al (2017) from hard metal production does not show increased cancer risk associated with cobalt exposure in humans. However, based on this study it can only be concluded that humans are at least not more sensitive to cobalt than animals.

- The Dossier Submitter did not perform a quantitative hazard assessment for the other toxicological effects of cobalt, including respiratory sensitisation and other non-cancer lung effects as they were considered to be covered by the proposed reference exposure value. Although the quantitative dose-response data on the non-cancer lung effects are limited, the data by Nemery et al., 1992 suggests that at levels below 5 µg Co/m³

there is no effect on lung function in exposed workers. Based on this, **a limit value of 1 µg Co/m³ for the inhalable fraction** can be set by using an assessment factor (AF) of 5 for inter-individual differences. Although, the current data do not allow setting of a NOEC for asthma, based on the data available from three Member States and from an industry survey, asthma caused by cobalt seems to be uncommon nowadays. It is agreed by RAC that the limit value given above is likely to reduce the risk of respiratory sensitisation as well. Since cobalt sensitisation may be more related to daily exposure levels rather than cumulative exposure, this value should be used as an 8 h TWA value rather than a frequency- and duration-adjusted reference exposure value. Since an air limit value alone cannot protect from skin sensitisation, careful control of skin exposure at workplaces is also needed to protect workers from the risk of skin sensitisation.

Key elements underpinning the RAC conclusions:

Lung cancer

RAC evaluated the carcinogenicity of cobalt salts in 2016. That evaluation included the consideration of the mode of action of cobalt, which has an impact on the shape of the dose response for carcinogenicity. Cobalt salts (and elemental cobalt) do not cause direct mutagenicity but have been shown to cause DNA damage as displayed in Comet assays, chromosomal aberrations and micronuclei *in vitro*. *In vivo*, genotoxicity has been observed mainly after intraperitoneal administration. There are several studies which suggest that the main mechanisms of cobalt induced genotoxicity are induction of reactive oxygen species (ROS) and oxidative stress, inhibition of DNA repair and stabilisation/up-regulation of hypoxia-inducible factor (HIF-1α). The ToxTracker data (Hendricks et al., 2019) submitted during the consultation supports the role of oxidative stress and HIF-1α in the mode of action of cobalt. Chronic inflammation observed in animal inhalation studies at the levels causing carcinogenicity is likely to play a role in the genotoxicity of cobalt resulting in secondary genotoxicity via ROS production and oxidative damage. RAC concluded in its earlier assessment (RAC, 2016) that the current scientific findings and mode of action considerations support the notion that water soluble cobalt salts may be threshold carcinogens, given that inflammation and the main mechanisms of cobalt-induced genotoxicity are threshold events. However, RAC considered at that time that there are remaining uncertainties (as to e.g. the possibility of non-threshold mechanisms for genotoxicity and whether inflammation is a prerequisite for the carcinogenicity) and that the data is not sufficient to *identify* a threshold level for the genotoxicity and carcinogenicity of cobalt. Therefore, residual cancer risk at low exposure levels could not be totally excluded. This resulted in the selection of a non-threshold approach for the dose-response analysis: a BMDL10 of 0.414 mg/m^3 as cobalt sulphate hexahydrate (0.093 mg/m^3 as cobalt) based on lung tumours in rat inhalation carcinogenicity study (NTP, 1998) was selected as a point of departure for linear extrapolation. For workers, this resulted in a dose-response of 1.05 (mg/ Co/m^3)$^{-1}$ x exposure concentration for excess lung cancer risk (respirable fraction). It was, however, emphasised that this is a very conservative approach, which is likely to result in the overestimation of risks especially at lower exposure levels.

Human data on the carcinogenicity of cobalt and its compounds does not provide clear evidence on the carcinogenicity of cobalt. Since RAC's (2016) evaluation, two new studies have been published (Sauni et al., 2017 and Marsh et al., 2017), which should be considered. Sauni et al (2017) evaluated the cancer incidence among workers (995 males) employed in a Finnish cobalt plant. No clear association between cancer risk and exposure was found.

However, the study size was small. Marsh et al (2017) is the most recent study on the association between cancer and cobalt exposure. It concerns hard metal production and includes >30 000 exposed workers. Even though the study was related to the hard metal industry (production and processing of hard metal, e.g. cemented carbide), it is still considered relevant for cobalt salt assessment since also metallic cobalt releases cobalt ions in biological fluids and according to animal data the carcinogenic potency of cobalt and cobalt salts is rather similar in animals. The study did not show a clear association between cancer and cobalt exposure as increased risks for lung cancer was seen only in short-term workers (<1 y of exposure) and no dose-response with cumulative or mean cobalt exposures was seen. The highest exposure category in this study had cumulative exposure of >0.1275 mg/m^3-years, which can be calculated to correspond an average of 0.003 mg/m³ exposure for 40 years. At this exposure level the dose-response results in a lung cancer incidence of three extra cases / 1 000 exposed. This number of excess cancers derived from animal studies corresponds to a risk ratio of approximately 1.3 in humans. Naturally, some of these workers in the high exposure group may have been exposed to higher levels than 0.1275 mg/m^3-years. However, based on this study it can be only concluded that humans are at least not more sensitive to cobalt than animals.

Overall, human data have not shown any clearly increased cancer risk in occupationally exposed workers. This cannot, however, be used to exclude the cancer risk seen in animal studies. Neither does it provide additional information on a potential threshold for carcinogenicity. Thus, the quantification of cancer risk needs in the case of cobalt to be based on animal data.

In 2017, the RAC-SCOEL Joint Task Force (JTF) agreed on the concept of identifying mode of action based thresholds for genotoxic carcinogens if there is robust evidence of indirect genotoxicity and of the mode of action, and the data allow setting a threshold for the main mode of action (if not, the non-threshold approach is the default). An update of ECHA R.8 Guidance on dose-response includes a description of this concept (ECHA, 2019, Appendix 17). This mode of action based threshold approach has been applied by RAC for inorganic nickel compounds[2], benzene[3] and acrylonitrile[4]. For the present evaluation, RAC therefore examined the applicability of a mode of action based threshold approach for cobalt salts, as the mechanistic data (discussed in detail in the 2016 RAC evaluation) suggests that the dose-response of cobalt carcinogenicity may include a mode of action based threshold. With this in mind, the available data for cobalt was compared to that on inorganic nickel compounds. It can be concluded that regarding an *in vitro* mode of action, data on the genotoxicity of cobalt can be considered comparable to that for nickel. However, in contrast to nickel, there is no *in vivo* dose response data on the local genotoxicity of cobalt nor data allowing the derivation of N(L)OAECs for these genotoxic effects in relation to the N(L)OAECs for pulmonary inflammation. This is considered a crucial difference since even though it is likely that chronic

[2] Opinion on scientific evaluation of occupational exposure limits for Nickel and its compounds ECHA/RAC/A77-O-0000001412-86-189/F https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf/9e050da5-b45c-c8e5-9e5e-a1a2ce908335

[3] Opinion on scientific evaluation of occupational exposure limits for Benzene ECHA/RAC/ O-000000-1412-86-187/F https://echa.europa.eu/documents/10162/13641/benzene_opinion_en.pdf/4fec9aac-9ed5-2aae-7b70-5226705358c7

[4] Opinion on scientific evaluation of occupational exposure limits for Acrylonitrile ECHA/RAC/O-0000001412-86-188/F https://echa.europa.eu/documents/10162/13641/acrylonitrile_opinion_en.pdf/102477c9-a961-2c96-5c4d-76fcd856ac19

inflammation contributes to the genotoxicity and carcinogenicity of cobalt, genotoxic effects at the levels below the threshold for inflammation cannot be totally excluded. The lack of crucial data for cobalt precludes a mode of action based threshold to be identified. In principle, the non-threshold approach as proposed by the Dossier Submitter would thus be the default approach for cobalt.

However, RAC reiterates the very conservative nature of this approach, especially at very low exposure levels, and considers it likely that the dose-response curve in the lower exposure range is less steep than in the higher range. To better reflect this, RAC chose the sublinear approach introduced by AGS (TRGS 910, 2014) as an alternative, with lung inflammatory effects as the marker for the breakpoint in the dose-response for the genotoxicity and carcinogenicity of cobalt. Chronic inflammation is known to result in oxidative stress and to exaggerate DNA damage. Cobalt-induced inhibition of repair of DNA damage may further exaggerate genomic instability. Below the level for inflammation, remaining cancer risk cannot to be totally excluded (given the uncertainties surrounding any mode of action based threshold), but the cancer risk is likely to be reduced compared to the risks calculated on the basis of linear extrapolation since inflammation-related mechanisms do not play a role anymore.

In the mouse and rat inhalation carcinogenicity studies (NTP, 1998), inflammation was observed with very high incidences at all concentrations tested (0.3, 1 and 3 mg/m³ as cobalt sulphate hexahydrate). In the absence of a NOAEC for inflammatory effects for cobalt, the LOAEC of 0.3 mg/m³ as cobalt sulphate hexahydrate, corresponding to 0.067 mg/m³ as cobalt, was taken as the point of departure for calculating the exposure concentration representing the breakpoint in the dose-response curve. Following conversion of the point of departure into a worker equivalent dose of 0.034 mg/m³ (= 0.067 mg/m³ * 6h/8h * 6.7 m³/10 m³) and applying assessment factors of:

- 2.5 for remaining interspecies differences,
- 5 for worker intra-species differences, and
- 5 for dose-response/severity,

A reference exposure value of 0.00054 mg Co/m^3 (rounded as 0.0005 mg Co/m^3) can be derived for the respirable fraction. In the absence of cobalt-specific data informing on the degree of cancer risk reduction below this exposure value, RAC took a 10-fold lower cancer risk as a default (cf. AGS, 2014). Applying this approach, at exposure levels ≤0.0005 mg Co/m^3 the dose-response for excess lung cancer risk for workers becomes 0.105x the exposure concentration (as mg Co/m^3, respirable fraction). The remaining cancer risk in this lower exposure range can be considered as being below 5.25 x 10^{-5}. For exposure levels >0.0005 mg Co/m³ the dose-response for excess lung cancer risk for workers becomes steeper, 1.0576x the exposure concentration (as mg Co/m^3, respirable fraction) - 0.0004763.

Human data, suggesting LOAECs for non-cancer pulmonary effects at levels > 0.01 mg/m³ (as inhalable dust) and a NOEAC of 0.005 mg/m^3 can be used as supporting evidence and for the setting of a limit value for inhalable dust (for further description of this data see paragraph "*Chronic non-cancer lung effects and respiratory sensitisation*").

Upper respiratory tract carcinogenicity

Neither epidemiological studies nor animal studies have provided evidence of upper respiratory tract tumours. In animal studies with mice and rats (NTP, 1998), no tumours were seen at the highest concentration (3.0 mg/m^3 cobalt sulphate hexahydrate, = NOAEL for carcinogenicity in upper respiratory tract) whereas already 0.3 mg/m^3 resulted in increased incidence of pulmonary tumours both in mice and rats (=LOAEL for carcinogenicity in the lungs). However, the results indicated that both rats and mice develop hyperplasia, metaplasia and atrophy in epithelial cells of the nose, and metaplasia of the squamous epithelium of the larynx suggesting potential carcinogenicity in the upper respiratory tract.

Since no cancers were observed, it is not possible to derive a dose-response for the upper respirable tract cancers. This was concluded also by RAC (2016) (*"Although inhalable particles should also be considered as carcinogenic the dose-response related to this metric is far more uncertain as this will very much depend of the content of respirable particles. Thus, the most valid dose-response relationship for carcinogenicity is to be based on an exposure metric for respirable particles."*). These data, however, show that the upper respiratory tract is more than one order of magnitude less sensitive to the carcinogenic effects of cobalt compared to the lower respiratory tract.

When doing this kind of comparison, particle deposition to the different regions of the respiratory tract should be taken into account. Even though the median mass aerodynamic diameter (MMAD) of cobalt sulphate particles was in the respirable range (MMAD ± GSD 1.4-1.6 ± 2.1-2.2), considerable amounts of particles are also deposited in the upper respiratory tract. Multiple path particle deposition (MPPD) models can be used to estimate the deposited fractions in the different regions of the respiratory tract (AGS, 2013). Using the particle size distribution from the NTP (1998) studies, EBRC (2016) used an MPPD model to calculate that 44.2% of the particles are deposited in the upper respiratory tract in rats, 1.5% in the tracheobronchial region and 4.3% in pulmonary region. Thus, at the level of 0.67 mg Co/m^3 (NOAEL for upper respiratory tract tumours), a dose of 0.3 mg Co/m^3 was deposited to the upper respiratory tract (head) and 0.03 mg Co/m^3 was deposited in the alveolar region. When taking into account that increased cancer incidence in the alveolar region was observed already at a 10-fold lower concentration than the NOAEL for upper respiratory tract tumours, it suggests that the sensitivity of rat upper respiratory tract is one to two orders of magnitude lower than the sensitivity of lower respiratory tract. Because of the clear potency difference, the dose response for respirable particles is considered to cover also possible cancer risk caused by the non-respirable particles. Therefore, applying a lung cancer dose-response for upper respiratory tract tumorigenicity on the basis of animal data is not considered scientifically justified.

Systemic carcinogenicity

Carcinogenicity studies with soluble cobalt salts have not shown clear evidence of systemic cancers (RAC, 2016). The concern for systemic carcinogenicity has mainly been raised from the studies with cobalt metal, in which increased incidences of systemic cancers were seen in rats (but not in mice). Detailed descriptions of these studies have not been included in the Background Document but, as discussed in the RAC opinion on the classification and labelling of cobalt metal (2017), the main tumour types that increased in rats (but not in mice) after exposure to cobalt dust were pheochromocytomas and pancreatic cancers. Mononuclear cell leukaemia (MNCL) incidence was increased at all doses without a clear dose-response and

kidney cancers were increased in male rats at the highest dose level exceeding MTD.

Increased incidence of pheochromocytomas at high doses has been linked to lung damage associated hypoxia and cobalt promotion of a hypoxia-like state even with normal molecular oxygen pressure by stabilising hypoxia-inducible factor (HIF-1α), which is a major regulator of the adaptation of cancer cells to hypoxia. Also insoluble nickel metal (but not other nickel compounds) has caused similar increases in the incidence of pheochromocytomas at high doses, which were considered to be related to hypoxia rather than to systemic nickel levels (ECHA, 2018[5]).

If lung damage is considered as the main mechanism for pheochromocytomas in rats, the relevance of these tumours at lower exposure levels can be considered negligible. In addition, effects mediated via the activation of HIF-1α can be considered to exert a threshold. Another tumour type increased in male rats (but not in females or in mice) was pancreatic islet tumours. Increase in this tumour type has not been seen with soluble cobalt salts. Also in this case, a mechanism related to the hypoxia-mediated oxidative stress and facilitation of the growth of neoplasm by the degradation of oncogene MUC4 has been proposed (Joshi, 2016[6]). Thus, there are indications that these effects might not be relevant at lower dose levels. In addition, if the limit value for cobalt is set at 1 µg Co/m^3 inhalable fraction and 0.5 µg Co/m^3 respirable fraction, the systemic cobalt levels are likely to stay close to background levels seen in occupationally non-exposed general population (see Appendix 7 of the Background Document on the biomonitoring of cobalt).

Chronic non-cancer lung effects and respiratory sensitisation

The dossier includes a chapter on sensitisation but no quantitative assessment of sensitisation (respiratory or skin sensitisation) or other non-cancer lung effects has been made. Non-cancer lung effects in animals have been described in the paragraph "Lung cancer". There are only a few published studies which give some dose-response data on the non-cancer pulmonary effects in humans. Studies by Roto et al (1980[7]) and Swennen et al (1993[8]) reported effects on lung function at 0.1 mg/m³. Linna et al., (2003[9]) did not see effects on lung function in a cobalt salt manufacturing plant at an average cumulative exposure level of 1 mg/m³-years (since the average exposure duration was 22 years, the average exposure level in this study was ~0.045 mg/m³). Nemery et al., (1992[10]), on the other hand, showed lung function effects in diamond polishers already at an exposure level of 0.015 mg Co/m³. They identified a NOAEC of 0.0053 mg Co/m³ for lung function impairment in these workers. This NOAEC has been used e.g. by IPCS 2006 (CICAD 69, cobalt and inorganic cobalt compounds[11]) for the setting of a limit value for inhalation exposure. The workers may also have been exposed to occasional traces of other elements (copper, zinc, titanium, manganese, chromium, silicon dioxide and silicates, as well as iron) formed in diamond polishing. Nevertheless, the authors considered cobalt to be the only relevant exposure in these workshops. Verougstraete et al (2004[12]) demonstrated effects on lung function only in cobalt exposed smokers in a cobalt manufacturing plant. The exposure level in the highest exposure group in this study was 0.04

[5] ECHA (2018) Committee for Risk Assessment (RAC) Opinion on scientific evaluation of occupational exposure limits for Nickel and its compounds ECHA/RAC/ A77-O-0000001412-86-189/F and its annexes. Adopted 9 March 2018.
[6] Joshi et al., Oncogene. 2016 Nov 10;35(45):5882-5892. doi: 10.1038/onc.2016.119.
[7] Roto, Scand J Work Environ Health. 1980;6 Suppl 1:1-49
[8] Swennen et al, Br J Ind Med. 1993 Sep;50(9):835-42
[9] Linna et al., Am J Ind Med. 2003 Aug;44(2):124-32.
[10] Nemery et al. Am Rev Respir Dis. 1992 Mar;145(3):610-6.
[11] https://www.who.int/ipcs/publications/cicad/cicad69%20.pdf
[12] Verougstraete et al., Am J Respir Crit Care Med. 2004 Jul 15;170(2):162-6

mg/m³.

These human studies give information on the non-cancer lung effects in relation to inhalable cobalt dust levels at workplaces. If the standard AF of 5 is applied to the NOAEC of 0.005 mg/m³ (from Nemery et al., 1992) to account for the inter-individual differences, a limit value of 0.001 mg/m³ is derived for inhalable cobalt dust. Noting that the respirable fraction usually represents ≤50% of inhalable dust, a value of 0.001 mg/m³ is in accordance with the breakpoint level of 0.0005 mg/m³ derived for respirable dust on the basis of animal data providing additional support for the latter value.

The five cobalt salts covered by this restriction proposal have a harmonised classification as Resp. Sens. 1 as well as Skin Sens. 1 according to CLP. There are human data on the occupational asthmas caused by cobalt. However, data on the underlying dose-responses are limited.

Roto et al (1980) concluded that cobalt asthmas may occur already at exposure levels of <0.1 mg/m³ based on their study in cobalt salt manufacturing. Subsequently, Sauni et al (2010[13]) made an evaluation of the asthma cases diagnosed in the same cobalt salt manufacturing plant and concluded that exposure to cobalt sulphates in the department with average exposures of 0.03 mg/m³ (range 0.01-0.1 mg/m³) still resulted in an asthma incidence density (number of new cases per person-years) of 0.005. The total number of cobalt asthmas diagnosed between 1967 and 2003 in the plant was 22. This is the only study giving some dose-response information on asthma risk due to cobalt salts. Asthma in these cases could have been exaggerated by the co-exposure to sulphur dioxide, since in the chemical department with exposure to different cobalt species at the level of 0.12 mg/m³ (0.02-0.3 mg/m³) no asthma cases were identified. A study from a hard metal factory supports that cobalt asthmas may be caused by mean TWA exposures of <0.05 mg/m³ (Kusaka et al., 1986[14]). However, on the basis of these data it is not possible to set a threshold for cobalt respiratory sensitisation.

According to the information received by the Dossier Submitter from three Member States (representing approximately 3% of the population of the EU), there are one to three registered cases per year of occupational skin diseases and zero to one cases of asthma due to occupational exposure to cobalt. The information does not distinguish among exposures to different cobalt compounds. During consultation, the Cobalt REACH Consortium provided information on their survey on cobalt sensitisation cases. The number of asthma cases reported in the last 10 years by the companies participating in the survey was zero. The number of skin sensitisation cases was reported as less than 0.5 cases per year. Similarly, the number of cases reported results from exposure to cobalt and cobalt compounds and cannot be related to the specific cobalt compounds covered by the restriction proposal.

Frequency adjustment of the proposed limit value

The reference exposure value (REV) proposed by the Dossier Submitter is a frequency- and duration-adjusted limit value. Asthma risk may, however, be more related to high short-term exposures. In activities occurring infrequently, a frequency- and duration-adjusted reference value of 1 µg/m³ may allow short term exposures (≥0.03-0.1 mg/m³), which have been associated to the occurrence of asthma. In addition, a frequency adjusted REV may allow 8 h

[13] Sauni et al., Occup Med (Lond). 2010 Jun;60(4):301-6.
[14] Kusaka et al., Br J Ind Med. 1986 Jul;43(7):474-85.

exposures above the breakpoint, which may result in inflammation and secondary genotoxicity. Therefore, if the breakpoint level of 1 µg Co/m³ (inhalable fraction)/0.5 µg Co/m³ (respirable fraction) is applied as a limit value it should be used as an 8 h TWA level rather than a frequency and duration-adjusted reference value.

Other evaluations

The Dossier Submitter did not include an overall appraisal of the risk assessments performed by other bodies in the Annex XV report, although summaries of the assessments were included in Annex B. Assessments published before 2016 have also been summarised in RAC (2016). Inflammation was considered a critical endpoint by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) who established a pragmatic Occupational Exposure Limit (OEL) of 0.0025 mg Co/m^3 based on BMDL10 of 0.07 mg/m^3 (as cobalt) for inflammation in rats exposed to cobalt sulphate hexahydrate. OECD (2014) and REACH CSR considered carcinogenicity of the Co to include a threshold and considered the BMDL10 for cancer effects in animals as a suitable point of departure for the risk assessment. The German MAK Commission (Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area) concluded in 2007/2009 that no threshold could be derived for genotoxicity and cancer. Other assessments performed earlier (like IPCS 2006 cited above) based their limit values to other health effects (non-cancer lung effects like irritation or reduced lung function in humans).

2.1.4. Information on emissions and exposures

Summary of proposal:

Production volumes and sectors of use

The five cobalt salts are manufactured in and imported into the EU, and used in a wide range of sectors and applications. The total volume manufactured and imported is estimated at 37 400 tonnes/year (30 000 are used in the EU and 7 400 are exported). Approximately 85% of the cobalt salts are used as intermediates in the EU; 70% of the total volume is used as transported isolated intermediates. Table 1 below shows the sectors of use of the cobalt salts and the corresponding volumes for each sector.

Table 1: Estimated annual volume of cobalt salts by sector of use

Sector/Uses	Volume used in EU (tonnes 2011-2013)
Intermediate uses	
Manufacture of chemicals and batteries	26 600
Manufacture of catalysts	1 700
Manufacture of pigments and dyes	<<100
Non-intermediate uses	
Use as catalyst	700
Use in surface treatment (incl.: formulation, passivation and plating)	500
Use in biotechnology (incl. biogas, fermentation, health sector, animal feed and fertilisers)	400
Bespoke uses (incl. humidity indicators card, water treatment chemicals, laboratory reference standards)	<<100
Total	30 000

Source: Data extracted from information provided by the Cobalt Institute in the call for evidence for the preparation of this restriction dossier (Cobalt REACH Consortium Ltd., 2017)

Worker exposure

Workers may be exposed to the five cobalt salts in the manufacture and use of the substances via inhalation, dermal and (potentially) oral routes of exposure. The focus of the restriction dossier is on worker inhalation exposure. Dermal exposure (and potential oral exposure) is only briefly reported by the Dossier Submitter.

According to the registration dossiers, the cobalt salts are prepared and used as solids in powder form with a medium dustiness. Some of the processes (e.g. in animal feed, manufacture of catalysts, etc.) result in the transformation of the cobalt salts into dry solids (cakes, granules, pellets, etc.) with a lower potential for dust emission.

The five cobalt salts (except for cobalt carbonate) are also produced and used in liquid form, mainly as aqueous solutions. The use of aqueous solutions can lead to the generation of mists and fumes in high energy activities such as electroplating and hot metallurgical processes.

Particle size distribution

The particle size distribution of the aerosols (dust, fumes and mists) generated during manufacture and use is a key parameter in the occupational exposure to cobalt salts:

- Larger particles (> 100 µm in diameter) deposit easily and their contribution to inhalation exposure is less relevant.

- Smaller particles tend to become airborne and are inhalable (> 10 µm) or even respirable (< 10 µm).

According to industry, the ratio of the inhalable to respirable fraction for the five cobalt salts can be estimated at 10:1 (10% respirable dust) as a reasonable worst case, based on a report containing detailed particle size information from three workplaces (Vetter et al., 2016).

The Dossier Submitter considers that a fraction of 10% of respirable cobalt particles does not take into account the different scenarios where exposure to the cobalt salts may occur. Instead, based on a study conducted by Okamoto (1998), the Dossier Submitter proposes a ratio of two (50% respirable dust) as the reasonable worst case for the respirable fraction for cobalt salt particles.

Nevertheless, as discussed in section 1.2.4.2 of the Background Document, the Dossier Submitter proposed to apply the dose-response (derived for the respirable fraction) to the inhalable fraction as a preventive approach to take into account also the carcinogenicity effect of the non-respirable fraction.

Inhalation exposure

Air monitoring data, as presented in the registration dossiers (Cobalt REACH Consortium Ltd., 2018), are the basis for the exposure assessment of the Dossier Submitter. These data were obtained from a number of workplaces where cobalt and/or cobalt compounds are manufactured and handled. The measured values are based on personal sampling. The median value is reported for those sectors where it is available. The Reasonable Worst Case (RWC) is based on the 90th percentile unless otherwise stated. The values shown correspond to the activities within the sector showing the highest exposure levels in the exposure scenarios, excluding cleaning and maintenance. For intermediate uses, only activities where the cobalt salts are present are considered, i.e. before they are transformed into other substances.

The Dossier Submitter identified a number of limitations associated with these data, which introduced a significant level of uncertainty to the analysis:

- Exposure levels of cobalt reflect, in most cases, parallel exposure to a variety of cobalt substances and not only to the five cobalt salts within the scope.

- The number of available measurements remains unclear, to some extent, despite the efforts made by the Dossier Submitter (who was able to provide information about the number of measurements). However, for some exposure scenarios it is only known that the number of measurements is very low e.g.:
    - For surface treatment the number of measurements provided is extremely limited.
    - For use as a catalyst only six measurements with a high variability are available.
- The air monitoring data are highly variable for most of the activities:
    - The difference between the median and the RWC is in the range of two to five times but higher than ten times for some tasks (e.g. packaging activities).
    - This high variability may be explained by the fact that the database is composed of data from different workplaces and compiled over a number of years.
    - It nevertheless reflects a high variability in operating conditions and risk management measures for different workplaces.

For some of the exposure scenarios, for which specific monitoring data were not available, analogous data from other cobalt compounds and or activities have been used to estimate exposure (Cobalt REACH Consortium Ltd., 2018). Additionally, a number of exposure values are derived from modelling (MEASE (1.02.01)).

All exposure data presented in the registration dossiers correspond to the inhalable fraction.

An overview of exposure values as considered representative by the Dossier Submitter for each sector of use is shown in the table below. The values are compiled from the exposure scenarios of the registration dossiers.

Table 2: Exposure data (inhalable fraction) from the registration dossiers for the different sectors of manufacture and use (Cobalt REACH Consortium Ltd., 2018)

Sector/use/Activity	**Air concentration [a] µg Co/m³ (Median-RWC)**	**Exposure level [b] µg Co/m³ (RWC 8h TWA)**
Manufacture	54-808	8
Manufacture of chemicals	31-206	10
Manufacture of batteries	16-153	1
Manufacture of catalysts	12-21[c]	3
Manufacture of pigments and dyes	4-29	3
Use as catalysts	0.8-3[c]	3
Use in surface treatment		
- Formulation - Passivation - Plating	2-4[c] 2-4[c] 9-14[c]	0.7 4 7
Use in biotechnology		

Sector/use/Activity	Air concentration [a] µg Co/m³ (Median-RWC)	Exposure level [b] µg Co/m³ (RWC 8h TWA)
- Biogas production - Fermentation and biotech processes - Animal feed	- 1 -	5[d] 0.3 2[d]
Bespoke uses		
- Humidity indicators - Water treatment chemicals - Laboratory reference standards	0.2[c] 19-168 1	0.1 17 0.3

a. Air monitoring measurements based on personal samplers (except where otherwise stated). The Reasonable Worst Case (RWC) is based on the 90th percentile unless otherwise stated. The values shown correspond to the activities within the sector showing the highest exposure levels in the exposure scenarios, excluding cleaning and maintenance. For intermediate uses, only activities where the cobalt salts are present are considered, i.e. before they are transformed into another substances.
b. Exposure levels based on RWC air concentration, taking the use of RPE (if applicable) and the duration of the activity (but not the frequency of activities per year) into account.
c. RWC based on the 95th percentile or the maximum value.
d. Modelled value (MEASE (1.02.01))

In general terms, exposure levels (RWC 8h TWA) range from 1 to 10 µg Co/m³ for the majority of the uses of the cobalt salts:

- The manufacture of the cobalt salts and the manufacture of chemicals are associated with exposure values in the range of 8 to 10 µg Co/m³.
- The formulation of water treatment chemicals is associated with exposure of 17 µg Co/m³,
- Fermentation and biotechnology processes and the manufacture of humidity indicators show levels of exposure well below 1 µg Co/m³.
- For surface treatment, exposure values range from
    - 0.7 to 4 µg Co/m³ for formulation and passivation,
    - up to 7 µg Co/m³ for plating operations.

The scarce data on exposure related to similar activities gathered from the literature and other sources (see Table 3) do not contradict the values presented by the registrants.

Table 3: Exposure data from independent sources

Sector/use/Activity	Source	Exposure level µg Co/m³
Manufacture of cobalt sulphate and cobalt carbonate (among other cobalt compounds)	Sauni et al, 2014, epidemiology study in a cobalt manufacturing plant in Finland	20
Manufacture of cobalt metal		60
Compilation of cobalt exposure data from 2007 to 2017	France	
- Surface treatment activities - Feed grade materials		Median: 2, RWC: 75.5 Median: 1 RWC: 32.1
Passivation	Slovakia	below 4

The Dossier Submitter considers that the exposure levels reported in the registration dossiers can be used for risk assessment for all uses as presented in Table 2, in spite of the uncertainties mentioned above.

Especially relevant activities

The Dossier Submitter identifies a limited number of activities (see Appendix 3 of the Background Document where all the different tasks are described for each of the sectors of use, together with the exposure values and the operational conditions) that seem to have the potential for highest exposure:

- Tasks where the five cobalt salts are used in solid form (mainly as powder), e.g. loading, unloading, packaging, etc.
- Hot metallurgical process where the high temperatures increase the potential to generate airborne particles (e.g. calcination – heating to high temperatures in air or oxygen. Calcination is also used to mean a thermal treatment process in the absence or limited supply of air or oxygen applied to ores and other solid materials to bring about a thermal decomposition.)

These activities result in air concentrations of 200 µg Co/m^3 (RWC). On the other hand, the use of cobalt salts in aqueous solutions result in significantly lower inhalation exposure, ranging from around 0.5 to 5 µg Co/m^3. Electroplating, involving the use of electrical currents, results in air concentrations in the range of 14 µg Co/m^3 while passivation (without electrical current) results in air concentrations of 1 µg Co/m^3.

Combined exposure is expected – by the Dossier Submitter – to be higher for workers involved in several daily activities resulting in exposure to the cobalt salts.

Dermal exposure

No data on dermal exposure were available to the Dossier Submitter. The registration dossiers assess dermal exposure in a qualitative way and require the use of gloves and protective equipment to prevent potential dermal exposure. Good occupational hygiene practices are also recommended to prevent potential oral exposure to workers. Quantitative data regarding dermal exposure to the cobalt salts have been found neither in literature nor from other sources.

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

RAC conclusions:

The data presented by the Dossier Submitter about **tonnages** are extracted from information provided by the Cobalt Institute in the call for evidence for the preparation of the restriction dossier and seem rather outdated. The use of cobalt salts is predicted to increase in the coming years. Therefore, the available data adds an additional uncertainty to RAC's assessment (see below in chapter "Uncertainties in the risk characterisation").

Some of the uses mentioned in Table 1 (e.g. use in fertilisers) seem not to take place in the EU at present but are "traditionally" linked to the five cobalt salts and were therefore included in the initial request by the Commission.

In some sectors of activity, cobalt salts are used in forms with lower exposure potential (e.g. use of coated granules in animal feed, manufacture of catalysts as cakes or pellets). It is, however, difficult to take any such reduced exposure potential into account for risk assessment, as the effect of exposure reduction potential cannot be quantified.

From an exposure assessment and substance properties point of view it is an unrealistic

assumption to use the inhalable fraction as the full respirable fraction as proposed by the Dossier Submitter. The Dossier Submitter's approach is further discussed in the hazard characterisation section. RAC concluded that a ratio of two (50% respirable dust) is still a reasonable worst case for the ratio of the respirable to the inhalable dust fraction. RAC agreed to take forward different values (50% and 100% fraction of respirable dust) for risk assessment in order to simplify comparisons.

The available data set for inhalation exposure has a number of significant limitations, which introduces a substantial level of uncertainty. It is therefore critical for RAC's risk assessment to identify conservative exposure levels. Appendix 3 of the Background Document presents a complete picture of all relevant sectors and uses of cobalt salts and activities performed with cobalt salts as described in the registration dossiers. In Appendix 3 for each activity, the relevant exposure level is described.

The values given in Table 2 represent 8h time weighted average (TWA) exposure levels based on the RWC air concentration, taking the use of RPE (if applicable) and the duration of the activity (but not the frequency of activities per year) into account. It is to be noted that these values are estimated taking into account the activity with the highest exposure level for each sector of use and do not consider the potential cumulative exposure resulting from different activities performed on the same shift by the same worker.

These values are associated with uncertainties (as described below). However, these levels of exposure have been supported in principal by different contributions during the consultation.

As the use of cobalt salts does not take place on a continuous basis in most sectors, the Dossier Submitter has considered the frequency and duration of each task, as presented in the exposure scenarios from the registration dossiers, for the calculation of the excess cancer risk values for each sector of use. This has a significant impact on the time-weighted exposure levels resulting from different tasks. It is unclear if the frequency and duration considerations are representative for the tasks in question, as the data on frequency and duration of the activities – as reported by industry – are based on a very limited number of companies.

It was not possible to trace all of the calculations used by the Dossier Submitter and the Registrants to derive exposure concentrations. With the additional data provided by the Dossier Submitter it was possible to identify discrepancies between the 8h TWA RWC values for each sector of use as presented in Table 2 (equates to Table 4 in the Background Document) and those resulting from the combined annual exposure used for risk assessment (see Table 4). The 8h TWA RWC from Table 2 refer to the activity with the highest exposure level as 8h TWA for each sector of use. The exposure levels used for risk characterisation (Table 4) result from the highest annual combined exposure for workers taking the frequency and duration of each activity into account.

For some uses / activities the Dossier Submitter used modelled or analogous data. This use of modelling or analogous data is not justified in the dossier nor is the modelling transparent (input parameters, model outputs). Justification and reasoning for this "read across" and modelling are not available in the restriction proposal. During the consultation, the Cobalt REACH Consortium Ltd. and Cobalt Institute provided some justifications regarding the use of analogous data. The approach taken by industry is now transparently described and understandable. The clarifications provided in the consultation reduces the uncertainty of the analogous data to some extent. The modelled data are still uncertain.

Despite the limitations described above, RAC concludes that the level of exposure as presented in **Table 4** is in a reasonable order of magnitude given that information provided during the consultation by different contributors in principal confirms the order of magnitude of the exposure levels.

Table 4: Exposure data (inhalable fraction) used by RAC

Sector/use/Activity	**Exposure levels used by the Dossier Submitter for Excess Lifetime Risk calculation (µg Co/m³)**
Manufacture	9.5
Manufacture of chemicals	5.0
Manufacture of batteries	3.3
Manufacture of catalysts	0.9
Manufacture of pigments and dyes	5.0
Use as catalysts	3.1
Use in surface treatment	
- Formulation - Passivation - Plating	0.28 4.3 11.4
Use in biotechnology	
- Formulation and industrial use of mixtures in biogas production - Professional use in biogas production - Fermentation and biotech processes - Animal feed	2.6 0.015 0.18 0.22
Bespoke uses	
- Humidity indicators - Water treatment chemicals - Laboratory reference standards	0.061 3.3 0.13

Within the uses, only a limited number of tasks / activities seem to contribute in a relevant manner to the exposure. However, it was not possible to identify a pattern. Obviously it is possible to identify for each of the sectors the task / activity that contributes the largest fraction to the overall exposure. It was a relevant exercise to identify those activities with high inhalation exposure and try to address these by fit-for-purpose risk management measures and operational conditions. However, the result of this exercise is that the same or similar task are not equally important, from an exposure perspective, in different sectors of use. Therefore, it was not possible for RAC to identify a limited number of activities that could be addressed by means of standardised risk management measures or operational conditions.

Dermal exposure (and potential oral exposure) is only briefly discussed by the Dossier Submitter. This could be accepted by RAC due to the limited scope of the restriction and the risk that shall be addressed by the restriction. The lack of information on dermal exposure adds an additional uncertainty to RAC's evaluation (see below in chapter "uncertainties in the risk characterisation") because a full risk assessment would also include dermal aspects. This is especially relevant for these five cobalt salts as they are skin sensitisers.

Key elements underpinning the RAC conclusions:

Regarding the **ratio of respirable to inhalable dust,** Appendix 2 of the Background Document, and contributions in the consultation, include relevant information:

Industry assessment (resulting in a 10% respirable fraction):

- This assessment is based on two of the three workplaces monitored by the Institute of Occupational Medicine → only 11 data points
- Also in that study a relevant number of measurements show a ratio that is higher than 10 % respirable fraction, i.e. up to 23%
- Respirable particles can also be larger than considered in this assessment

Therefore, assuming a respirable fraction of 10% is not conservative.

The study by Okomato at al. (1998):

- is based on > 1 600 data points
- Shows a large variation in data depending on the type of work and, probably, also on the work conditions.
- 20% - 50% respirable fraction seems plausible

Therefore, a 50 % respirable fraction would be an appropriately conservative assumption.

During the consultation, the preventive approach (100% respirable fraction) of the Dossier Submitter was considered to be unrealistic. The Cobalt REACH Consortium Ltd. and the Cobalt Institute submitted additional information on the particle size distribution of cobalt containing alloys composed primarily of tungsten carbide and cobalt, which are used in cutting tools. However, this publication (Stefaniak et al., 2009) seems of limited relevance for the five cobalt salts considered here.

Overall, RAC considers 10% as the respirable fraction as unrealistic and concludes therefore that 50% respirable fraction is a more conservative assumption, based on the Okamata et al. (1998) study.

The dataset for inhalation exposure shows a number of deficiencies that add to the overall uncertainty of the risk assessment that needs to be quantified (see below in chapter "uncertainties in the risk characterisation"):

- It is considered a major deficiency by RAC that the registrant's exposure data could not be validated by independent sources.
    - The Dossier Submitter provided almost only data from the registration dossiers.
    - The scarce data on exposure related to similar activities gathered from the literature and other sources (see The scarce data on exposure related to similar activities gathered from the literature and other sources (see Table 3) do not contradict the values presented by the registrants.
    - **Table 3**) do not contradict the values presented in the registration dossiers. However, the presented data from independent sources are by no standards sufficient to validate the inhalation exposure situation at European workplaces.

- After some clarification by the Dossier Submitter, the RWC derivation is also not entirely transparent and obviously differs for different sectors:
    - Registrants used the 90th percentile value to define the RWC for datasets with at least six measurements.
    - Either the 95th percentile or the maximum were used as RWC for datasets with fewer than six measurements
- The use of cobalt salts does not take place on a continuous basis (i.e. not every day, not the full shift) in most sectors and this has a significant impact on the time weighted exposure levels resulting from different tasks.
- The registration dossiers identify the frequency and duration of each exposure scenario for which exposure levels are calculated. The Registrants and the Dossier Submitter consider these parameters as representative of the activities taking place in each sector.
- Additional data regarding inhalation exposure was provided during the consultation. These data principally confirmed the order of magnitude of inhalation exposure for workers.
    - The Cobalt REACH Consortium Ltd. and the Cobalt Institute submitted additional data, e.g. from the surface treatment sector with a significant number of data points (i.e. more than 20 measurements).
    - Other respondents to the consultation provided qualitative information claiming that monitoring in the past showed that national OELs were complied with.

Despite the limitations in the dataset for inhalation exposure, RAC considers the level of exposure presented in Table 4 to be in a reasonable order of magnitude and will use these values as the basis for risk assessment.

Due to the large number of scenarios and uses it is considered reasonable to only evaluate the frequency and duration of tasks in detail for one sample use: manufacture of cobalt salts.

For the manufacture of the cobalt salts the relevant tasks are presented in Figure 1 and show:

- The duration of the task per shift varies from approx. 15 minutes per shift to almost five hours.
- The frequency of the task (in how many shifts per year is the task in question performed) varies from 20 to 240 (everyday).
- The reasonable worst case (RWC, air concentration data) varies from five to more than 800 µg Co/m³. The RWC as an 8h TWA (incl. adjustment for RPE and exposure duration) varies from 0.03 to 7.7.

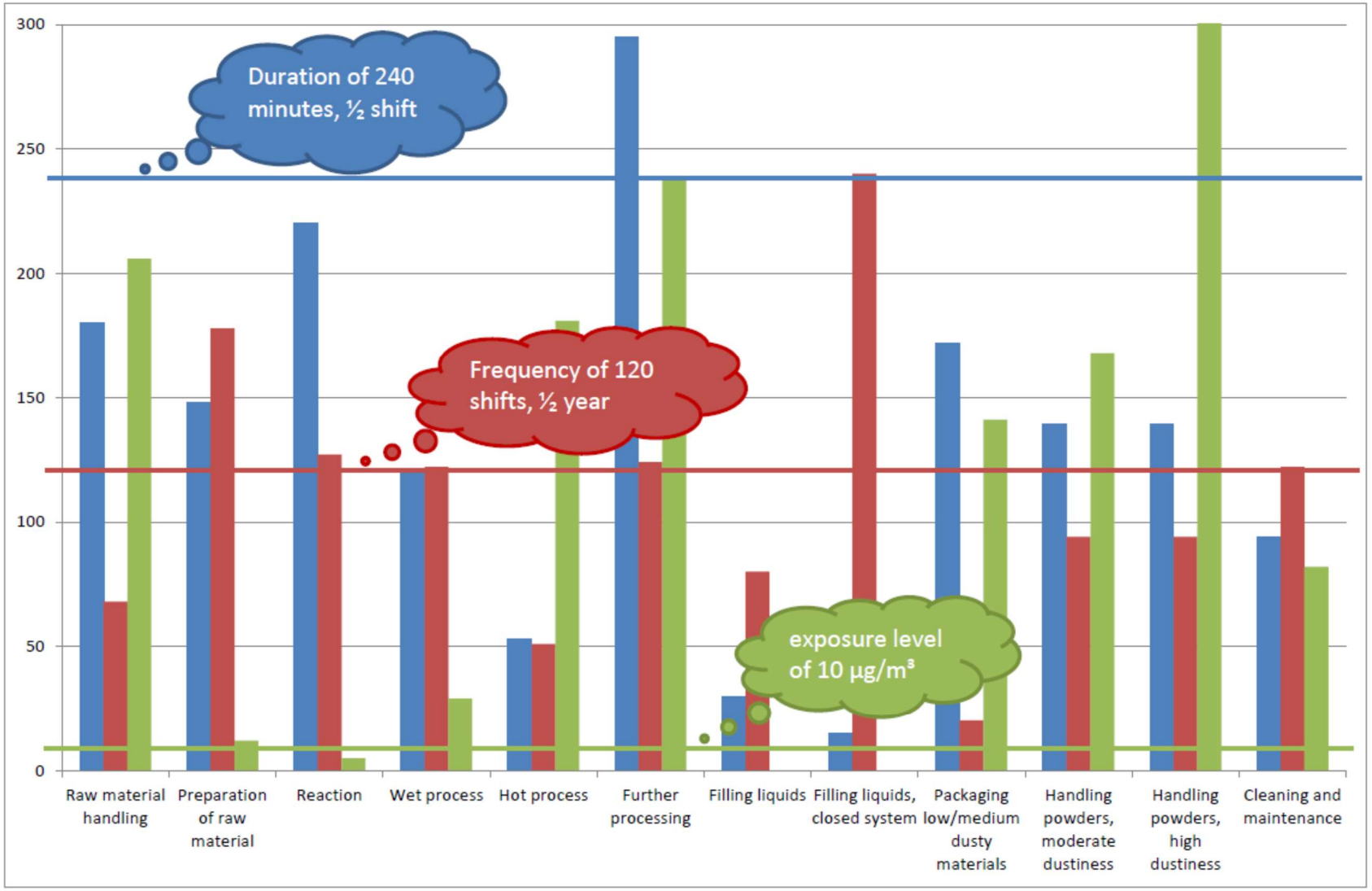

Figure 1: Manufacture of the cobalt salts

The situation is not identical, but sufficiently similar, for the other uses (manufacture of chemicals, manufacture of batteries, manufacture of catalysts, manufacture of pigments and dyes, use as catalysts, use in surface treatment, use in biotechnology and the bespoke uses) to reach the conclusion that an adjustment for duration and frequency is warranted on a task by task basis. The data on duration and frequency of the single tasks were made available to RAC by the Dossier Submitter and are documented in Appendix 3 of the Background Document.

As described above, it is not possible to identify a sub-set of specific tasks / activities with greater potential for exposure and that could be restricted separately.

2.1.5. Characterisation of risks

Summary of proposal:

Applying the RAC (2016) dose-response curve for the carcinogenicity of cobalt and the exposure assessment presented in the previous chapter, the Dossier Submitter calculated individual excess lifetime cancer risk levels significantly above 10^{-5} for all sectors assessed.

The major contributors to the cancer risk levels were those tasks with the highest potential for inhalation exposure, e.g. handling of cobalt salts in solid, dusty form and activities where high energy is applied (temperature and/or electrical currents), such as electroplating. This is the case in those sectors with the highest individual excess lifetime cancer risk levels, i.e. manufacture and electroplating where excess cancer risk levels are estimated at or above 10^{-2}.

In other sectors, excess cancer risk levels are above 10^{-3} (e.g. manufacture of chemicals, manufacture of batteries, etc.) and 10^{-4} (e.g. manufacture of catalysts, formulation of feed grade materials, etc.). Based on these findings, the Dossier Submitter identified that cancer risks to workers are not adequately controlled and that these risks need to be addressed at the Union level.

The Dossier Submitter proposed that individual excess cancer risks should be reduced to 10^{-5} or below to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts. Based on linear extrapolation, individual excess cancer risk levels below 10^{-5} result from a lifetime exposure to cobalt below 0.01 µg Co/m^3, i.e. this value was proposed to be applied as a reference exposure value (REV) for the occupational exposure to cobalt.

Even though it was recognised that the linear extrapolation is likely to overestimate individual excess life-time cancer risk, this was not taken into account in the proposal. Since there is no consensus on the acceptable cancer risk level for occupational exposure in the EU, the selection of a cancer risk level of 10^{-5} was based on REACH guidance (Chapter R8-Appendix 14, page 140), which states that "*the decision point for 'acceptable' lifetime (i.e., a working life of 40 years) cancer risk levels used for workers are generally around 10^{-5} but higher or lower levels have been considered to be tolerable under certain circumstances.*"

RAC conclusions:

As discussed above, the Dossier Submitter's approach to use linear extrapolation for the risk assessment of cobalt salts, combined with the assumption that the risk of systemic and upper respiratory tract cancers is similar to that of lung cancer, is considered over-conservative and

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

The risk at doses above the breakpoint can be calculated using the formula:

1.0576 x exposure concentration (as mg Co/m³, respirable fraction) - 0.0004763

The risk below the breakpoint follows the formula:

0.105 x exposure concentration (as mg Co/m³).

Using this approach, the following excess lifetime risks can be calculated for the different RO1 options proposed by the Dossier Submitter:

- RO1a 10 µg Co/m^3 (as inhalable fraction), meaning 5 µg Co/m^3 as respirable fraction corresponds an excess lifetime risk of 4.8 x 10^{-3}
- RO1b 1 µg Co/m^3 (as inhalable fraction), meaning 0.5 µg Co/m^3 as respirable fraction corresponds an excess lifetime risk of 5.25 x 10^{-5}
- RO1c 0.1 µg Co/m^3 (as inhalable fraction), meaning 0.05 µg Co/m^3 as respirable fraction corresponds an excess lifetime risk of 5.25 x 10^{-6}
- RO1d 0.01 µg Co/m^3 (as inhalable fraction), meaning 0.005 µg Co/m^3 as respirable fraction corresponds an excess lifetime risk of 5.25 x 10^{-7}

It is not possible to identify a dose-response or set a limit value for the respiratory sensitisation caused by cobalt. However, based on the available (although limited) data it can be anticipated that at the level of 1 µg Co/m^3 cases of asthma are unlikely.

According to RAC's analysis (see Table 4), there are several activities that can result in exposures above the breakpoint level of 0.5 µg Co/m^3 (corresponding to 1 µg Co/m^3 inhalable fraction). These include e.g. manufacturing of cobalt salts, chemicals, pigments and batteries and the use of cobalt salts as catalysts in surface treatment. Using the approach above, these activities result in excess lifetime cancer risks that for some are even > 10^{-3} (see further Table 5).

With the exception of catalyst manufacturing, mainly lower volume activities (e.g. the use in biogas production, in fermentation processes and feed grade materials) result in exposure levels below the estimated breakpoint of 0.5 µg Co/m^3. Assuming that at the breakpoint of 0.5 µg Co/m^3 the risk is lowered by a factor of 10 the estimated lifetime cancer risk at these tasks varies from <10^{-6} to approx. 5 x 10^{-5} (see Table 5 below).

Given that there are several uses/activities that show cancer risks even >10^{-3}, RAC concluded that there are risks from exposure to cobalt that are not adequately controlled.

It should be noted that when the breakpoint level of 1 µg Co/m³ (inhalable fraction) and 0.5 µg Co/m³ (respirable fraction) is applied as an 8 h TWA level (instead of as a frequency

adjusted level), it is likely to result in lower annual average exposures and therefore lower cancer risk in those low frequency scenarios which have higher short-term exposures.

Key elements underpinning the RAC conclusions:

The excess lifetime risks calculations made by RAC (in addition to those presented by the Dossier Submitter) are presented in Table 5. The RAC approach includes the proportion of 50% for respirable/inhalable dust, and the use of breakpoint at 0.5 µg Co/m^3 for the carcinogenicity of cobalt (see below).

Table 5: Risks calculated using Dossier Submitter's approach and RAC's approach. Colours: orange risk $<10^{-5}$, violet risk $<10^{-4}$

Sector/use	Exposure levels used for ELR calculation (µg/m³)	ELR estimated by Dossier Submitter with 100% respirable fraction and linear dose-response	ELR estimated by RAC with 50% respirable fraction and non-linear DR with a breakpoint at 0.5 µg/m³*
Manufacture of the cobalt salts	9.5	1.0E-02	4.6E-03
Manufacture of chemicals	5.0	5.3E-03	2.2E-03
Manufacture of batteries	3.3	3.5E-03	1.3E-03
Manufacture of catalysts	0.9	9.4E-04	4.7E-05
Manufacture of pigments and dyes	5.0	5.2E-03	2.1E-03
Use as catalyst	3.1	3.3E-03	1.2E-03
Use in surface treatment			
- Formulation of surface treatment solutions	0.28	2.9E-04	1.5E-05
- Passivation or anti-corrosion treatment processes	4.3	4.5E-03	1.8E-03
- Metal or metal alloy plating	11.4	1.2E-02	5.6E-03
Use in biotechnology			
- Formulation and industrial use of mixtures in biogas production	2.6	2.7E-03	8.8E-04
- Professional use in biogas production	0.015	1.6E-05	8.0E-07
- Use in fermentation processes, in biotech and scientific research and standard analysis	0.18	1.9E-04	9.5E-06
- Formulation and use in feed grade materials	0.22	2.3E-04	1.2E-05
Bespoke uses			
- Use in humidity indicator cards, plugs and/or bags with printed spots	0.06	6.4E-05	3.2E-05
- Formulation of water treatment chemicals, oxygen scavengers, corrosion inhibitors	3.3	3.5E-03	1.3E-03
- Use of water treatment chemicals, oxygen scavengers, corrosion inhibitors	0.13	1.4E-04	7.0E-06

*Breakpoint which is assumed to reduce the risk by a factor of 10.

The Dossier Submitter set a reference exposure value (REV) for cobalt salts corresponding to a cancer risk level of 1 x 10^{-5} derived using a linear approach. RAC recognises that the risk level of 1 x 10^{-5} is mentioned in REACH guidance as an example with a statement that lower or higher risk levels can be justified under certain circumstances. However, it should be noted that there is no political consensus on the acceptable risk level for carcinogenicity in the EU. In the case of authorisations, long review periods based on socio-economic considerations have been proposed by SEAC regardless of risk levels around 10^{-3}, or even higher, for example in some chromium(VI) and arsenic trioxide authorisations. As discussed in ECHA R.8 Guidance, Appendix 14, tolerable/acceptable cancer risk levels for workers usually vary between 10^{-3} – 10^{-5} in different (often outdated) Risk Assessment frameworks/countries. In addition, even greater risks have been accepted due to socio-economic reasons; an example of which is the binding occupational exposure level (BOEL, 2017) for Cr(VI) of 5 µg/m^3, which represents a calculated risk of 2*10^{-2} over 40 years occupational exposure. Transitional measures for Cr (VI) include, among others, an occupational limit value of 0.010 µg/m^3 until 2025 corresponding to an excess cancer risk level of 2*10^{-2}.

Compared to chromium (VI), which is a direct DNA-acting genotoxic carcinogen, the main mechanisms of cobalt genotoxicity and carcinogenicity are likely to include a breakpoint. Thus, the risk of lung cancer is likely to be significantly lowered compared to the risks estimated on the basis of linear extrapolation at exposure levels below this breakpoint. RAC has estimated that this breakpoint in the dose-response curve of cobalt lays around 0.5 µg Co/m^3 (respirable fraction). Below the breakpoint, the risk is assumed to be one order of magnitude lower. This is a default assumption used by the German AGS when setting tolerable and acceptable risk levels for this type of carcinogen. Using this approach, and the formulas given in the previous section, the cancer risks at exposure levels of 5 µg Co/m^3, 1 µg Co/m^3, 0.5 µg Co/m^3 or 0.1 µg Co/m^3 (as respirable fraction) can be calculated at 4.8*10^{-3}, 6*10^{-4}, 5.25*10^{-5}, 1*10^{-5}, respectively. On the basis of human data, it was possible for RAC to estimate a limit value of 1 µg Co/m^3 for the inhalable fraction in order to protect from non-cancer respiratory effects (effects on lung function). The respirable fraction represents usually ≤50% of inhalable dust meaning that at this level the levels of respirable dust are usually below 0.5 µg Co/m^3.

As can be seen from Table 5, despite these adjustments to the risk calculations there are still several uses which show risks >10^{-3}, meaning that risks from cobalt exposure are not adequately controlled.

The REV proposed by the Dossier Submitter is a frequency and duration-adjusted limit value. As discussed in the hazard section, if the breakpoint level of 1 µg Co/m^3 (inhalable fraction) and 0.5 µg Co/m^3 (respirable fraction) are applied as limit values, they should be used as an 8 h TWA level. These exposure levels do not necessarily result in significant increases above the normal background reference levels when cobalt exposure is biomonitored using urinary cobalt as a marker of systemic exposure (see Appendix 7 of the Background Document on biomonitoring). Biomonitoring can, however, be used to give indirect information on possible dermal exposure (including hand-to-mouth exposure). Monitoring and control of skin exposure is important because of the skin sensitising properties of cobalt.

2.1.6. Uncertainties in the risk characterisation

The main assumptions and uncertainties of the risk characterisation and their potential impacts are presented in Table 6 below.

In summary, the Dossier Submitter estimates that the potential impact of the uncertainties in the assessment range from moderate to high and may result both in an overestimation or underestimation of the net benefits of the restriction. Using the modified approach proposed by RAC, some overestimations in the risk characterisation are avoided.

Table 6: Assumptions and uncertainties

Assumptions/ Uncertainties	Description/ Justification	Reference to Background Document	Impacts the following outcomes	Potential over-/under-estimation of net benefits of restriction	Potential magnitude of impact
Non-threshold effect	The suggested cancer mechanisms may have a threshold even if the current data does not allow identification of this.	Section 1.2.4.2; Section B.4.4.3	Risk estimates Baseline cancer cases Benefits of restriction	Over	Originally high. Applying a breakpoint approach, the magnitude of over-estimation is lowered to low.
Assumed linearity for low exposure levels	The dose response relationship was derived by linear extrapolation, which may lead to an overestimation of risks, especially at very low exposure levels.	Section 1.2.4.2; Section B.4.5	Risk estimates Baseline cancer cases Benefits of restriction	Over	Originally high. Applying a breakpoint approach and risk reduction by a factor of 10 at the levels below the breakpoint, the magnitude of over-estimation is lowered.
Ratio inhalable to respirable fraction	The ratio inhalable to respirable fraction is estimated at 2 based on the Okamoto's study (1998).	Appendix 2	Baseline cancer cases Benefits of restriction	Over	Medium
Cancer risk from non-respirable fraction	According to RAC (ECHA, 2016), the non-respirable fraction should be considered as carcinogenic. The dose-response relationship for the non-respirable fraction was not derived since not enough data were available for this metric. RAC did not agree with Dossier submitter to apply the dose-response for respirable fraction to characterise all cancer	Section 1.2.4.2 Section B.4.5	Risk estimates Baseline cancer cases Benefits of restriction	Under	Low

Assumptions/ Uncertainties	Description/ Justification	Reference to Background Document	Impacts the following outcomes	Potential over-/under-estimation of net benefits of restriction	Potential magnitude of impact
	effects (local and systemic) resulting from exposure to the cobalt salts because of the potency difference evident from animal data				
Skin and respiratory sensitisation, asthma effect	The focus of the restriction is on the carcinogenicity of the cobalt salts. The quantification of impacts do not consider other health effects.	Section 1.2.4.1	Baseline impacts Risk reduction capacity Benefits of restriction	Under	Low
Reproductive toxicity	The focus of the restriction is on the carcinogenicity of the cobalt salts. The quantification of impacts do not consider other health effects.	Section 1.2.4.1	Baseline impacts Risk reduction capacity Benefits of restriction	Under	Low
Exposure values	The number of measurements vary between industrial sectors. In some sectors only one measurement is available for some activities and for some activities the exposure is based on modelling. Very few data are available in the literature to validate the data presented by industry.	Section 1.2.5.2 Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	High
Dermal exposure	Dermal exposure is only discussed briefly	Section 1.2.5.2	Dermal exposure might lead to skin sensitisation and allergies	Under	Low
Analytical methods	The measurement procedures presently used for the monitoring of cobalt concentration in air do not allow detecting values below 1µg Co/m^3. Exposure levels may be lower than those reported for some activities.	Section 2.6.3	Risk estimates Baseline cancer cases	Over	Low
Concomitant exposure to other cobalt compounds	The measurements are from workplaces where the five cobalt salts and possibly other cobalt substances are manufactured and used. The measured cobalt	Section 1.5.2. Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity	Over	Low

Assumptions/ Uncertainties	Description/ Justification	Reference to Background Document	Impacts the following outcomes	Potential over-/under-estimation of net benefits of restriction	Potential magnitude of impact
	levels may report exposure to a variety of cobalt compounds and not only to cobalt salts.		Benefits of restriction		
Typical and reasonable worst case exposure level and risk reduction capacity	The estimation of the baseline cancer cases and risk reduction capacity is based on improvements from the reasonable worst case exposure levels (for 10% of the companies) and typical level (for the rest of the affected companies). This affects also the estimated costs under RO1, as the cost for each industrial sector is derived from the effectiveness needed to reach the reference exposure value. It is not clear if this is representative for the different risk levels in the affected companies.	Section 1.4 Section 2.5	Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	Low
Duration and frequency of the activities	Information is from limited sources and cannot be verified.	Appendix 3	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Both	High
Combined exposure	The estimation of the individual worker cancer risks is based on the combined exposure resulting from the worst case combination of tasks a worker can in theory conduct.	Section B.10	Risk estimates Baseline cancer cases Risk reduction capacity Benefits of restriction	Over	Medium
Number of exposed workers per sector	Estimated number of exposed workers is provided by the industry. It is based on limited data and cannot be verified. However, the use of Co is expected to grow, which can lead to higher	Section 1.4	Baseline cancer cases Risk reduction capacity Benefits of restriction	Under	Medium to High

Assumptions/ Uncertainties	Description/ Justification	Reference to Background Document	Impacts the following outcomes	Potential over-/under-estimation of net benefits of restriction	Potential magnitude of impact
	number of affected worker per sector.				
Number of sites per sector	Estimated number of companies per sector is provided by the industry. It is based on limited data and cannot be verified. However, the use of Co is expected to grow, which can lead to higher number of affected sites in some sectors as new sites might be opened.	Section 1.4	Risk reduction capacity Benefits of restriction Cost of restriction	Both, depending on OCs/RMMs in the new sites.	Medium to high
Regrettable substitution	As this restriction proposal covers five specific Cobalt salts some users might substitute these five salts with other Cobalt compounds.	---	Risk reduction capacity	Over	unknown

At the request of the RAC Rapporteurs, the Dossier Submitter performed a sensitivity analysis for those variables with the greatest potential impact on the risk assessment. Low and high values were selected for each variable based on the Dossier Submitter's expert judgment. The results of the analysis are shown in Table 7. In general terms, it is considered that underestimation or overestimation of the risks may be up to one order of magnitude for some parameters.

Table 7: Sensitivity analysis on parameters affecting individual risk levels

Variable	Present Values	Low value for sensitivity analysis	High value for sensitivity analysis	Impact	Low range	High range
Mode of action	Non-threshold	Threshold at 0.5 µg/m³	Non-threshold	Individual risk levels	Safe use in seven sectors of use	ELR from 10^{-5} to 10^{-2}
Dose-response	Linear; 1.05 x 10^{-3}	Non-linear below 0.5 µg/m³: 1.05 x 10^{-4}	Linear; 1.05 x 10^{-3}	Individual risk levels	For those sectors with ELR ≤ 5*10^{-4}, ELR is divided by 10 ELR from 10^{-6} to 10^{-2}	ELR from 10^{-5} to 10^{-2}
Ratio of inhalable fraction to respirable fraction	2	10	1	Individual risk level	ELR divided by 10 * ELR from 10^{-6} to 10^{-3}	ELR from 10^{-5} to 10^{-2}

Variable	Present Values	Low value for sensitivity analysis	High value for sensitivity analysis	Impact	Low range	High range
Cancer risk from non-respirable fraction	1.05 x 10^{-3}	Non-carcinogenic	1.05 x 10^{-3}	Individual risk level		
Exposure values	In the range of 1 to 10 µgCo/m³	0.5 to 5 µgCo/m³	10 to 100 µgCo/m³	Individual risk levels	ELR divided by 2 ELR from 10^{-6} to 10^{-3}	ELR x 10 ELR from 10^{-4} to 10^{-1}**
Duration and frequency of activities	Depending on the sector	Present values	Daily activity, i.e. 240 days/year	Individual risk levels	ELR from 10^{-5} to 10^{-2}	ELR x 2 up to x 10 depending on the sector. ELR from 10^{-5} to 10^{-2}

* Assuming the non-respirable fraction is non-carcinogenic
** RAC notes that risk of 10^{-1} in manufacturing and electroplating is not in accordance with the available human evidence, which have not shown increased risks. An excess risk of 10^{-1} is so high that it should have been seen even in smaller cohorts.

Although the combination of several variables may result in a higher order of variation, it may also have a counterbalancing effect and decrease the overall range of uncertainty. However due to the number of different combinations that may be possible, and the complexities inherent to the variation of a number of parameters, this analysis has not been attempted.

In conclusion, there is considerable uncertainty in those aspects affecting the exposure assessment part, i.e. exposure assessment, substance properties (e.g. particle size distribution), and e.g. organisation of workplaces. However, as there is information mainly confirming the order of magnitude of the exposure, RAC considers the risk characterisation reasonably certain and concludes that for cobalt there is a need to reduce exposure in order to adequately control the (cancer) risks.

2.1.7. Evidence if the risk management measures and operational conditions implemented and recommended by the manufactures and/or importers are not sufficient to control the risk

Summary of proposal:

In registration dossiers, industry used a DNEL of 40 µg Co/m^3, and this has not been updated to take into account the RAC (2016) opinion on the carcinogenicity of cobalt salts. The available information does not suggest any trend in the implemented risk management measures, or in the exposed population that would have lowered the exposure, individual risk levels or the annual excess cancer cases.

The Dossiers Submitter derived a reference exposure value of 0.01 µg Co/m³ for the inhalable fraction of cobalt connected with an excess lifetime risks of 10^{-5}. This approach resulted in all relevant activities falling above the reference exposure value.

RAC identified a breakpoint of 0.5 µg/m^3 (respiratory fraction) for the carcinogenicity of

cobalt. RAC notes that in several activities this exposure level of 0.5 µg/m^3 is exceeded.

Both these approaches have in common that there are a relevant number of activities with exposure levels clearly above the respective reference/limit values. It is noteworthy that this conclusion also holds true even for a DNEL of 40 µg Co/m³ as proposed in registration dossiers.

RAC conclusions:

RAC agrees with the Dossier Submitter that based on the available exposure information, the risk management measures (RMMs) and operational conditions (OCs) implemented and recommended by the manufacturers and importers are not sufficient to control the risks. Additionally, according to the information provided in the registration dossiers and in the consultation there are a wide range and high diversity of exposure levels and RMMs and OCs implemented at workplaces even at those workplaces with similar activities but also between different industrial sectors.

Key elements underpinning the RAC conclusions:

RAC's conclusion is based on following arguments:

- In many sectors, estimated exposures are clearly above 0.5 µg Co/m^3 (respirable fraction), representing a cancer risk of > 5.25 x 10^{-5}. In some sectors (manufacturing, surface treatment) exposures may be even higher than 10 µg Co/m^3 (inhalable fraction, corresponding to 5 µg/m^3 as respirable fraction) representing a cancer risk of > 4.8 x 10^{-3}.

- Based on some of the reported exposure values even the DNEL reported in the registration dossiers is exceeded for some uses.

- During the consultation, information was provided confirming the overall picture regarding exposure at workplaces. Exposure levels have not changed for some uses and the level of protection (RMMs/OCs) are the same as documented in the registration dossiers. In fact, contributions during the consultation confirmed the exposure levels as presented in the registration dossiers.

2.1.8. Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

According to the Dossier Submitter, the cobalt salts are manufactured in a few but used in many (if not all) EU member states and pose a risk that is not adequately controlled. At present, 15 EU member countries have implemented regulatory measures (OELs) to limit exposure of workers to cobalt (section B.9.1.2) but these vary between the countries (5 µg/m³ in Germany to 500 µg/m³ in Latvia, all values given as 8h TWA limit values).

Using the RAC dose-response relationship from 2016, and estimating typical and reasonable worst case exposure, the Dossier Submitter estimated expected individual risk levels and annual cancer cases linked to the use of the cobalt salts per sector. According to the Dossier Submitter assessment, surface treatment, manufacture of cobalt salts, and manufacture of

other chemicals are the sectors with the highest exposure and risk. Highest individual excess cancer risks calculated for the manufacturing of cobalt salts and surface treatment sectors were in the order of magnitude of $1*10^{-2}$. In total, the current manufacture and use of the cobalt salts is estimated to cause excess cancer risk to approximately 35 000 workers and result therefore in approximately 40 cancer cases after lifetime exposure, i.e. one statistical cancer case per year.

Additionally, the volumes of the five cobalt salts used annually in the EEA is estimated to have doubled in the last 10 years and this increase is expected to continue in the future due to the increasing demand for rechargeable batteries in electric vehicles and biotechnology-health applications.

RAC conclusions:

RAC agrees with the Dossier Submitter that individual excess lifetime risks especially in some specific sectors of use exceed even a level of 1×10^{-3} and the information provided by industry in the consultation did not show any indication that the situation has changed. In addition, there is no cobalt-specific, EU wide regulatory measure (such as a binding OEL) implemented to limit the exposure to cobalt and the current OELs in Member States vary considerably. In conclusion, this means that the existing regulatory risk management instruments vary in the European Union and might lead to the above values for individual excess lifetime risks for lung cancer.

Key elements underpinning the RAC conclusions:

RAC's conclusion is based on following arguments:

- RAC agrees with the Dossier Submitter that individual excess lifetime risks especially in some specific sectors of use exceed a level of 1×10^{-3} (the level of 1×10^{-2} – also mentioned by the Dossier Submitter – is, according to RAC's evaluation, over conservative).

- There was no clear indication of the implementation of additional advanced RMMs or OCs by industry, e.g. during consultation.

There is no EU wide binding OEL for cobalt (or any other EU wide regulatory Co-specific risk management) and the current OELs in Member States vary.

2.2. JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter proposes to restrict the placing on the market, manufacture and use of five cobalt salts, where risks have been identified that are not adequately controlled. The substances are manufactured and used in a variety of sectors within the European Economic Area.

The proposal applies to placing on the market, manufacture and use of the five cobalt salts as substances on their own or in mixtures in a concentration equal or above 0.01% by weight (i.e. the specific concentration limit for carcinogenicity 1B according to the harmonised classification and labelling of the cobalt salts) in industrial and professional applications. No consumer uses were identified by the Dossier Submitter and those are therefore out of the scope of this restriction proposal.

On the basis of the information summarised above, the Dossier Submitter concludes that a Union-wide regulatory measure is needed to ensure a harmonised high level of protection of human health. Furthermore, a Union-wide measure is regarded as preferable to varying regulatory standards and statutes in different EU member states and a unified regulation is said to minimise the potential of market distortion.

SEAC and RAC conclusions:

Based on the key principles of ensuring a consistent level of protection across the Union and of maintaining the free movement of goods within the Union, SEAC and RAC support the view that any necessary action to address risks associated with the use of five cobalt salts should be implemented in all Member States.

Key elements underpinning the SEAC and RAC conclusions:

RAC:

As stated above, the five cobalt salts under consideration are manufactured and used in many, if not all, EU member states. They are used within different sectors such as the manufacture of chemicals, batteries, catalysts, in the pigments and dyes production, in surface treatment processes, in the biotechnology (and health) sector, etc. and for different activities. The five substances are included in the candidate list under REACH due to their carcinogenic and repro-toxic properties and have also been prioritised for inclusion in the authorisation list (Annex XIV). In addition, requirements relating to the European occupational health and safety legislation[15] apply, such as assessing and managing the risk of exposure to carcinogens or mutagens, reducing the use of relevant substances by replacing them with substances not dangerous or less dangerous, preventing worker exposure, using different technical measures such as closed technological systems, etc. Currently, 15 Member States have regulatory measures in place in order to limit the cobalt exposure to workers (only two Member States address specifically some of the five cobalt salts).

RAC confirms that risk management measures and operational conditions implemented and recommended by the manufacturers and importers throughout the Union are not sufficient to control the risks. RAC agrees with the Dossier Submitter that individual excess lifetime risks, especially in some specific sectors of use, exceed even a level of 1×10^{-3} and there was no indication of changes to these levels by industry during the consultation. RAC concludes that the existing European regulatory risk management instruments (e.g. current OELs in Member States) vary, which might lead to the above stated values for individual excess lifetime risks for lung cancer.

[15] Directive 2004/37/EC – carcinogens or mutagens at work, https://osha.europa.eu/en/legislation/directives/directive-2004-37-ec-carcinogens-or-mutagens-at-work

SEAC:

Taking RAC's conclusion into consideration, SEAC notes that an EU-wide regulatory action introduces equal standards of health protection throughout the Union and also throughout different sectors dealing with the same substances whilst at the same time facilitates the free movement of workers and goods.

2.3. JUSTIFICATION WHETHER THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of SEAC and RAC

Scope including derogations

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter assessed two restriction options:

- **RO1: Implementation of a reference exposure value (REV).** Four values were assessed as restriction options (with their estimated cancer risk levels):

Option	Reference Exp. Value (µg Co/m³)	Excess Lifetime Risk
• RO1a:	10	$1*10^{-2}$,
• RO1b:	1	$1*10^{-3}$,
• RO1c:	0.1	$1*10^{-4}$ and
• RO1d:	0.01	$1*10^{-5}$.

  For RO1 the Dossier Submitter suggests a derogation for the use of the five cobalt salts as an additive in feeding stuff.

- **RO2: Minimum technical requirements for risk management measures (RMMs)** to be implemented for those uses of cobalt salts with the highest potential for worker exposure. Four sets are assessed as restriction options:
  - RO2a: mechanical ventilation,
  - RO2b: LEV,
  - RO2c: closed systems or partially enclosed systems with LEV and
  - RO2d: closed systems with integrated LEV.

  A derogation for uses leading to exposure levels below 0.01 µg Co/m³ (inhalable fraction) is included in all the options. Furthermore, a derogation is foreseen for the use as an additive in animal feed.

The following risk management options, other than restriction, were considered, but not assessed further by the Dossier Submitter:

1. Listing on **Annex XIV** of REACH

The five cobalt salts were already recommended for inclusion in Annex XIV of REACH. However, it is noted that two of the sectors of highest concern (manufacture of cobalt salts, manufacture of other chemicals (intermediate uses of cobalt)) are not covered by authorisation.

2. A **binding occupational exposure limit value** (BOEL):

   A BOEL was in general considered as an applicable and effective risk management option for the five cobalt salts but, according to the Dossier Submitter, it was not suitable to address the identified risks due to the following reasons:

   - A BOEL does not consider the frequency that activities take place and consequently may require disproportionate risk management measures for activities that take place very rarely or would not be protective enough for activities taking place on a continuous basis.

   - The non-threshold nature of the hazard, where a BOEL may provide a false sense of safety as the basis of its derivation (and the remaining risk) is usually not communicated.

   - The length of time required for the development and implementation of a BOEL. The risk levels identified in the manufacture and use of the cobalt salts require that actions are taken to decrease workers exposure without undue delay.

3. **Voluntary industry action**:

   The Dossier Submitter does not consider any voluntary action to manage the risk being a practical and appropriate measure, given amongst others the number and variety of industrial sectors to be covered.

For all of the above-mentioned reasons, the Dossier Submitter considered the restriction with implementation of a reference exposure value (REV) of 0.01 µg Co/m^3 as the most appropriate regulatory risk management measure for the five cobalt salts within the scope.

RAC's conclusions:

- The Dossier Submitter proposed a broad restriction covering almost all uses of the five cobalt salts. Instead of defining appropriate operational conditions and risk management measures (which is not possible for so many sectors of use), the restriction proposal sets REV of 0.01 µg Co/m^3 (RO1d) for the inhalable fraction, assuming 100% of the inhalable fraction is respirable. Besides the very conservative value actually proposed (see discussion in previous chapters), the REV is a new concept, e.g. it is meant to be adjusted for the duration and frequency of exposure, which has not been defined or used previously in REACH or any other European legislation applying to the workplace. If this concept is introduced, then it is likely to require practical guidance to clearly differentiate it from a DNEL or BOEL.
- As discussed above, RAC considers it more appropriate to implement limit values of 1 µg Co/m^3 (as 8 h TWA, for inhalable fraction) and 0.5 µg Co/m^3 (as 8 h TWA, for respirable fraction) rather than the proposed REV. Exposure levels below these limit values are considered protective from lung inflammation and secondary genotoxicity

(which result in steeper increase in lung cancer risk above the limit values). They are also likely to protect from the other, non-cancer effects of cobalt.

- RAC notes that cobalt metal and other cobalt compounds can cause similar risks to the five cobalt salts covered by the restriction. RAC further notes that occupational exposure to cobalt is wider than just from the five cobalt salts within scope, and that not all the occupational cobalt exposures can be covered by a REACH restriction. These include for example exposures to cobalt fumes formed in hot processes, and cobalt exposures in waste management and the use of cobalt compounds as on-site intermediates.

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

The limit values proposed here by RAC can be considered applicable also for cobalt metal and other cobalt compounds releasing cobalt ions in contact with body fluids.

Regarding the proposed derogations that are included in RO1 and RO2 for the use as feed additives within the scope of Regulation (EC) no 1831/2003 on additives for use in animal nutrition, RAC concludes that within Regulation (EC) no 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 a number of aspects are addressed concerning the "safety of use of the additive for users/workers" (especially annex II, subchapter 3.3), e.g.:

- Toxicological risk assessment for user/worker safety (effects on the respiratory system, effects on the eyes and skin, systemic toxicity)
- Measures to control exposure

However, the measures and assessments for safety for users/workers are neither specific for cancer risk nor for cobalt or cobalt salts. Additionally, the assessments foreseen by applicants are not likely to be quantitative and therefore the level of protection that will be achieved in the framework of Regulation (EC) No 1831/2003 is unknown**.** Therefore, from a risk assessment point of view, RAC does not consider this derogation justified.

Key elements underpinning the RAC's conclusions:

The Dossier Submitter prepared this restriction proposal at the request of the Commission as risks were not adequately controlled from some uses (e.g. use of powder form in the surface plating) and as an alternative to authorisation of the five cobalt salts. For the five cobalt salts within the scope, restriction was considered more appropriate than authorisation, especially since with a restriction it is possible to cover also intermediate uses of cobalt salts in the manufacturing of other cobalt compounds, which are estimated to result in highest exposures. RAC agrees that in this sense restriction seems more appropriate than authorisation. As outlined in the conclusions above, for the five cobalt salts within the scope, RAC considers overall that a REACH restriction is at present the most appropriate regulatory measure to control the risks of their use in the EU.

However, as also outlined above, RAC additionally supports that a BOEL is derived for cobalt and its compounds. Based on the information received from consultation, approximately 50% of occupational exposures to carcinogenic cobalt compounds are not covered by the restriction. The majority of these exposures are caused by exposure to metallic cobalt or

cobalt containing fumes formed in hard metal industry. Since metallic cobalt is also a lung carcinogen with a potency at least similar to cobalt salts, there is a need to regulate these exposures as well. RAC agrees that at present it might be faster to implement the limit value under REACH to control occupational exposure to the growing use of the five cobalt salts within scope. But in order to control other occupational cobalt exposures (including also exposures outside the scope of REACH like occupational exposure to process fumes, waste management and on-site intermediates), a BOEL is likely to be the more efficient and comprehensive regulatory measure in the long term, provided it gives the same level of protection as the limit value proposed by RAC.

The Dossier Submitter did not consider a BOEL a suitable option, amongst others because a BOEL would not consider the frequency and duration of exposure and could result in disproportionate risk management measures for activities which take place only rarely. RAC agrees that from a scientific perspective, frequency and duration of exposure is an important parameter when calculating the risk of cancer caused by cobalt salts. However, the practical implementation of a REV, which takes frequency and duration into account, would amount to a new practise in occupational hygiene and would need at a minimum practical guidance to monitor and implement this at workplaces by the employer and by the enforcement authorities.

It can be argued that it is undesirable to introduce further competing risk/exposure values into the workplace. In addition, as discussed under the evaluation of the hazard assessment, a frequency- and duration-adjusted reference value of 1 µg/m³ or higher may allow short term exposures (≥0.03-0.1 mg/m³), which have been associated with the occurrence of asthma. A frequency- and duration-adjusted REV may also allow 8 h exposures above the breakpoint that may result in inflammation and secondary genotoxicity.

Another reason why the Dossier Submitter considered a restriction to be more appropriate than a BOEL was the non-threshold nature of the hazard, where a BOEL may provide a false sense of safety as the impact of socio-economic factors in the agreement process of a final limit value is not communicated. RAC agrees that the basis of individual BOELs given under CMD is not always transparently communicated. However, RAC does not consider that this reasoning given by the Dossier Submitter applies specifically to the cobalt salts. It should be also noted that a REV proposed by the Dossier Submitter, is a new concept, and may have similar communication challenges. This was supported by the comments received from the consultation and Forum's advice. In several comments, REV was commonly mixed up with an 8 h TWA value.

Regarding the derogation proposed by the Dossiers Submitter for the use of cobalt salts as feed additives within the scope of Regulation (EC) no 1831/2003, RAC evaluated the risk assessment foreseen for users and workers in that regulation and in Regulation (EC) no 429/2008 on detailed rules for the implementation. In these two regulations no specifications for quantitative workplace risk assessment are considered, no specific risk management measures for occupational risks (including cancer risks) are implemented, and no specific requirements for cobalt compounds are available. RAC did not perform further evaluations and enquiries in this regard.

Justification for the opinion of SEAC

Summary of proposal:

The following risk management options were identified and discussed by the Dossier Submitter in the restriction dossier:

I) The Dossier Submitter considered and further assessed two restriction options in the restriction dossier:

1. The implementation of a **reference exposure value (REV)**, (Restriction option (RO) 1, the proposed restriction):

   The Dossier Submitter proposes a reference exposure value to be implemented in the Chemical Safety Assessment (CSA) by the registrants, instead of a DNEL (currently used in the registration dossiers), which needs to be communicated down the supply chain through the extended Safety Data Sheet (SDS). Registrants will have to reconsider their current exposure scenarios (ES) for the different uses and activities that take place in each sector and determine whether the exposure values resulting from the use of the five cobalt salts are below the reference exposure value of the restriction. If the actual exposure values are above the reference value, operational conditions and risk management measures need to be reconsidered. The reference level is based on lifetime exposure, so adaptations (weighted by duration and frequency of the activities) can be made, where applicable. As the goal of the restriction is to ensure that workers' exposures are below the reference level, potential combined exposure resulting from workers performing several tasks involving the substances of concern should be taken into account in the CSA. If downstream users develop their own CSA (according to Article 37 (4) of REACH), the same obligations apply.

   According to the Dossier Submitter, setting a reference exposure value to be used in the CSAs by registrants and downstream users would ensure that sufficient RMMs are recommended and implemented by manufacturers and downstream users in order to ensure that risks resulting from exposure to the cobalt salts are controlled below the set level. For substances where no CSA needs to be prepared, i.e. substances manufactured or imported below 10 tonnes per year, the supplier needs to ensure that the legal requirements are communicated down the supply chain via the SDS.

   Manufacturers and downstream users of the substances are required to demonstrate compliance with the reference exposure value to ensure an effective implementation of the restriction. Four different reference exposure values and therefore four different ROs have been assessed:

   - RO1a: 10 µg Co/m³,
   - RO1b: 1 µg Co/m³,
   - RO1c: 0.1 µg Co/m³,
   - ***RO1d: 0.01 µg Co/m³ (the proposed restriction).***

   For RO1 the Dossier Submitter suggests a derogation for the use of the five cobalt salts as an additive in feedingstuffs within the scope of Regulation (EC) no 1831/2003.

In general and compared to other restriction and risk management options, the Dossier Submitter regards RO1 being the most appropriate EU-wide measure.

2. The implementation of **minimum technical requirements** for risk management measures (Restriction option (RO) 2):

   RO 2 is based on setting minimum technical requirements, i.e. risk management measures (RMM), in order to control risks from the activities with the highest potential for worker exposure via inhalation: handling of cobalt salts in solid form (e.g. powder, granules) and activities where high energy is applied (temperature and/or electrical currents), such as electroplating. Excess cancer risks arising from these activities are major contributors to the overall risk levels, especially for sectors of use where risk values are above 10^{-3}. The Dossier Submitter states that the identification and implementation of a minimum set of RMMs by manufacturers and downstream users at their worksites would ensure that appropriate risk management is in place to control the exposure to the five cobalt salts. Four sets of minimum technical requirements have been assessed:

   - RO2a: mechanical ventilation,
   - RO2b: Local exhaust ventilation (LEV),
   - RO2c: closed systems or partially enclosed systems with LEV,
   - RO2d: closed systems with integrated LEV.

   For RO2 the Dossier Submitter proposes a derogation for uses leading to exposure levels below 0.01 µg Co/m³ (inhalable fraction). Furthermore, the same derogation as suggested for RO1 applies, i.e. derogating the use of the five cobalt salts as an additive in feeding stuff within the scope of Regulation (EC) no 1831/2003.

II) Additional restriction options and other risk management options were **briefly considered, but not assessed further** by the Dossier Submitter, e.g. communication obligations, a full ban of the substances under consideration, a full ban of historical uses, listing of the substances to Annex XIV of the REACH regulation, implementing a BOEL, etc. More information is provided in section 2.2 of the Background Document.

SEAC's conclusions:

Restriction option 1 versus Restriction option 2: Both ROs are targeted towards a safe handling of the substances at the workplace in order to reduce the risks arising from the use of the five cobalt salts. I.e. industry is able to continue the use of the substances for which overall, no suitable alternatives are available according to feedback received during the consultation processes but for which individual worker risk levels have been identified by the Dossier Submitter.

RO1 is regarded as more appropriate than RO 2 due to several aspects. SEAC agrees that RO1 gives more flexibility to industry, as registrants and downstream users may decide upon the most adequate RMMs to be implemented at their worksite to reduce exposure to the required levels. Furthermore, this would allow for an alignment with RMMs already in place at different workplaces due to e.g. other legislation. On the other hand, reductions in risk could already be achieved by the use of personal protective equipment, even when adequate technical measures are available and feasible to implement.

However, occupational health and safety legislation requires companies to implement RMMs according to the specified hierarchy of control, i.e. companies are required to consider adequate technical measures before recommending the use of PPE. Furthermore, this RMM facilitates an appropriate communication of risk through the supply chain. Within RO2, no flexibility as regards the choice of RMMs is given as a fixed set of RMMs is specified and needs to be implemented by companies. I.e. RO2 doesn't allow considering different situations of different sectors and sites affected.

Whilst SEAC agrees with the Dossier Submitter that RO2a and RO2b can overall be regarded as technically feasible for companies affected, SEAC doubts that a fixed set of risk management measures according to RO2c and RO2d (partially enclosed/closed systems) can feasibly be implemented by all companies, due to the variety of sectors covered. Overall, SEAC agrees that RO1 gives industry more flexibility in choosing the most appropriate, site-specific, RMM and ensures appropriate communication of the risks of the non-threshold carcinogenicity of the substances down the supply chain.

The four restriction options assessed under RO1: Within RO1, the Dossier Submitter further assessed four different options (RO1a to RO1d), reflecting four different reference exposure limit values. The Dossier Submitter selected option RO1d, i.e. a value of 0.01 µg Co/m³ as the REV (a time and frequency weighted - so called - "reference exposure limit value"), leading to an excess lifetime cancer risk of 10^{-5}. The limit value was chosen by the Dossier Submitter according to this being the decision point for "acceptable" lifetime cancer risk levels used for workers according to the current ECHA Guidance[16].

RAC, in its opinion, focussed on an amended version of restriction option RO1b, supporting a limit value of 1 µg Co/m³ as 8h TWA. RAC's reasoning is given below and in the respective sections of this opinion:

- RAC concluded that the risk assessment performed by the Dossier Submitter is, due to a likely breakpoint in the dose-response for the carcinogenicity of cobalt (further information is provided in the respective RAC section of this opinion above), very conservative. Based on RAC's approach, the same excess lifetime cancer risk level is already achieved by implementing the limit value suggested under RO1b, i.e. 1 µg Co/m³ i.e. with these amendments, RO1c and RO1d (the initially proposed restriction) are no longer relevant from the Dossier Submitter's perspective.

- RAC recommends setting a restriction exposure value as 8h TWA instead of a REV as suggested initially in the restriction proposal. As regards this amendment, the Dossier Submitter concludes that such a change would not affect the socio-economic analysis such that the presented values could not be used for concluding on the costs and benefits of the four restriction options. To this, SEAC agrees. In detail, the Dossier Submitter concludes the following:

    - Practicality and implementability: an 8h TWA concept is more familiar to industry than a REV and is, based on comments submitted during the consultation, the preferred concept by industry; i.e. with recommending an 8h TWA, also the practicability and implementability of the restriction improve (more information is provided in the respective sections of this opinion).

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

Furthermore, the Dossier Submitter concludes that there are benefits from regulating different chemicals with similar concepts also under different legislations.

- Impacts: the removal of frequency adjustment (as considered initially by the REV concept) may increase the number of companies affected by the restriction. This is the case for companies that would have been below the REV due to activities causing exposure that do not occur every day. This may increase both costs and benefits of the restriction.

- Proportionality: the Dossier Submitter concludes that proportionality, based on cost-benefit considerations, may be slightly affected negatively as the frequency adjustment (as initially suggested under the REV concept) targets the restriction to companies with highest exposure potential.

Table 8 provides an overview of affected workers and avoided cancer cases per year for all restriction options assessed, based on the Dossier Submitter's and RAC's amended assessment.

Table 8: Overview of affected workers and avoided cancer cases per year for RO1a – RO1d

RO	**Data from Background Document**		**Revised data according to the risk assessment amended by RAC (respirable fraction with breakpoint)**
	Affected workers	**Avoided cancer cases/year**	**Avoided cancer cases/year RAC**
RO1a 10 µg Co/m³	300	0.05	0.02
RO1b 1 µg Co/m³	8 400	0.48	0.24
RO1c 0.1 µg Co/m³	15 200	1.02	0.27
RO1d 0.01 µg Co/m³	18 900	1.04	0.27

As can be seen from Table 8 above, RO1a, whilst resulting in lower costs than the other restriction options assessed (see respective section on costs), leads to a lower level of protection of workers as regards lung cancer. RAC concluded that the restriction exposure value suggested under RO1b and the other restriction options is likely protective also for other, non-cancer, effects of cobalt. This conclusion is, however, not valid for RO1a. No quantification of other, non-cancer, effects of cobalt was possible due to the non-availability of respective data.

During the consultation, stakeholders mainly provided comments on the proposed restriction option RO1d and expressed their concern with regards to the technical and economic

feasibility of the proposed exposure value. Stakeholders doubted whether this value could even be achieved by certain sectors and affected companies.

Furthermore, it is stated that for a large segment of the industry it is simply unknown whether technical feasibility is possible or not. Even though the consultation comments concentrated on RO1d, some comments were also submitted on the other restriction options, i.e. some stakeholder information is available to SEAC on RO1a, RO1b and RO1c, which indicates the following: RO1a is overall regarded as technically and economically feasible by industry. For RO1b, the industry concludes that a limit value of 1 µg Co/m³ might be technically feasible, however, economically challenging for some sectors/companies affected. Still, SEAC notes that in all sectors affected, a certain share of companies is already complying with this limit value.

SEAC concludes that, overall, industry faces few difficulties with implementing restriction options RO1a and RO1b and their respective conditions with a restriction exposure value as 8h TWA. This conclusion is, however, not valid for implementing the limit value suggested under RO1c, where comments provided indicated similar technical difficulties and economic challenges as for RO1d.

Overall, SEAC notes that for the broad scope covered by the restriction, technical feasibility seems to be more doubtful the stricter the limit value is set: the stricter the value, the more complex, uncertain and, most likely, costly is its implementation as well as respective monitoring and enforcement activities.

SEAC notes that a certain degree of uncertainty remains due to the following aspects: it is uncertain how representative the information submitted is for the large variety of sectors and companies covered; the focus of the consultation was on the proposed restriction option RO1d (i.e. a reference exposure limit value of 0.01 µg Co/m³), i.e. only limited information was provided on the other restriction options under consideration (i.e. RO1a, b and c); and finally, it is likely that the newly introduced concept of a reference exposure limit value was misunderstood and/or mixed-up with other, well-known concepts such as a DNEL or BOEL by some stakeholders and that some of the comments are rather referring to those concepts than to REVs.

Restriction options vs. other RMOs: During the consultation on the Annex XV report, several industry stakeholders and authorities stated that a BOEL would be a more appropriate risk management measure. It was stated that a BOEL is a well-known concept to industry as well as (enforcement) authorities whereas the suggested reference exposure limit value within RO1 is a newly introduced concept for which neither industry, nor authorities have the respective experience for its implementation and monitoring.

For the latter, however, SEAC notes that this is no longer fully relevant as RAC recommends switching from a REV to a restriction exposure value as 8h TWA, i.e. those two risk management options (BOEL under OSH and an 8h TWA under REACH) are more alike than the initially proposed restriction. Furthermore, stakeholders stated that a BOEL would also cover other cobalt compounds, which potentially pose a risk to workers and which are not in the scope of the proposed restriction. SEAC could not assess the appropriateness of a BOEL, i.e. in terms of its respective costs and benefits, as no such data was provided to the committee, either in the restriction dossier, or in the consultation on the Annex XV report.

During the consultation on the SEAC draft opinion, the above stated claims were reiterated by several stakeholders (industry and a Member State). One stakeholder submitted an extensive study which values the costs and benefits of introducing a BOEL on cobalt (covering all cobalt substances and compounds). The main conclusion of the study is that a BOEL covering cobalt and cobalt compounds with a comparable hazard profile is considered a more appropriate RMO than a REACH restriction targeted to five cobalt salts only. SEAC notes that the BOEL assessment results, based on a monetised cost-benefit perspective, in disproportionality. Nevertheless, the study highlights that a BOEL would benefit a significantly greater number of workers and would result in a greater number of avoided cancer cases compared to the proposed restriction. Although the study concludes that the estimated costs of a BOEL are also disproportionately high compared to the estimated benefits it also indicates that the benefit-cost ratios are, however, more favourable than those of the proposed restriction (for this conclusion, cost and benefit data from the alternative cost - benefit analysis is applied)[17].

Whilst SEAC notes the additional information provided and appreciates the effort taken by the stakeholder, SEAC stresses that several input factors (e.g. exposure data, number of affected workers, etc.) as well as the reports and models on which the alternative CBA is based do not allow for sufficient scrutiny by SEAC as the reports that are the basis for the assessment were not available to SEAC. Further reasoning is given in the section on "key elements" below.

Therefore, SEAC considers, as also stressed by the Dossier Submitter and the RAC, that a BOEL according to OSH could indeed be an applicable and effective risk management option for the five cobalt salts under consideration as well as for other cobalt compounds, which are not covered by the proposed restriction. For the latter, SEAC recognises RAC's recommendation to the European Commission to derive a BOEL according to Directive 2004/37/EC (CMD directive, for more information see relevant RAC sections of this opinion).

However, SEAC also notes that, if a risk from the use of other cobalt compounds is confirmed, a REACH restriction could be introduced for other cobalt compounds. SEAC notes that a BOEL (unlike a REACH restriction) could additionally address the use of cobalt compounds as on-site isolated intermediates and any potential cobalt exposure arising during the waste life-cycle stage.

i) SEAC's conclusion on the initially proposed restriction RO1d (0.01 µg Co/m³ as reference exposure limit value):

SEAC notes that several aspects question the conclusion of the Dossier Submitter that the proposed restriction option RO1d is the most appropriate EU-wide measure to manage the risks of the five cobalt salts. These are mainly related to the justification for the choice of the reference exposure limit value in the light of proportionality aspects and RAC's amended risk assessment, to the discussion whether a BOEL would be an (more) appropriate risk management measure to address the risks to workers, to the limitation of the restriction to the five specific substances under consideration only, as well as to practicality aspects. Furthermore, SEAC notes that the REV-concept, if implemented, would require a clear guidance for industry and (enforcement) authorities as regards its applicability and implementability in order to avoid any misinterpretation of this newly introduced concept.

[17] For further details see RCOM table on ECHA's website https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e181d575c8, comments # 624; #468 submitted by the CoRC and CI

ii) SEAC's conclusion on RO 1b (1 µg Co/m³ as 8h TWA, restriction option supported by RAC):

SEAC notes RAC's conclusion that RO1b most likely leads to a similar level of protection for workers like RO1d (the proposed restriction) as regards the cancer effects of cobalt. Furthermore, RAC concludes that a restriction exposure value of 1 µg Co/m³ as 8h TWA is likely protective also for other, non-cancer, effects of cobalt. However, SEAC notes that some aspects question the conclusion that this restriction option is the most appropriate EU-wide measure to manage the risks of the five cobalt salts. These are mainly related to proportionality aspects, to the discussion whether a BOEL would be an (more) appropriate risk management measure to address the risks to workers and to the limitation of the restriction to the five specific substances under consideration only.

iii) SEAC's conclusion on RO1c (0.1 µg Co/m³):

SEAC notes that several aspects question the conclusion that this restriction option is the most appropriate EU-wide measure to manage the risks of the five cobalt salts. These are mainly related to proportionality aspects, to the discussion whether a BOEL would be an (more) appropriate risk management measure to address the risks to workers, to the limitation of the restriction to the five specific substances under consideration only, as well as to practicality aspects.

iv) SEAC's conclusion on RO1a (10 µg Co/m³):

SEAC notes RAC's conclusion that RO1a does not lead to a similar level of protection for workers as the other options assessed under RO1, for both the cancer and non-cancer effects of cobalt. In addition to the lower level of protection, SEAC notes that some aspects question the conclusion that this option is the most appropriate EU-wide measure to manage the risks of the five cobalt salts.

These are mainly related to the discussion as to whether a BOEL would be an (more) appropriate risk management measure to address the risks to workers and to the limitation of the restriction to the five specific substances under consideration As regards proportionality aspects of RO1a, conflicting information is available to SEAC whether or not this is demonstrated. Further information is available in the respective sections of this opinion.

Any further details on SEAC's considerations are given in the respective sections below.

Key elements underpinning the SEAC's conclusions:

As regards the below aspects, SEAC notes the following:

- Reference exposure limit value (REV): Based on comments submitted during the consultation on the Annex XV report, SEAC notes that an 8h TWA concept is more familiar to industry as well as (enforcement) authorities than a REV and is clearly the preferred concept by industry. With recommending an 8h TWA instead of a time and frequency weighted concept such as the REV also the practicability and implementability of the restriction improve (more information is provided in the respective sections of this opinion). Furthermore, SEAC agrees with the Dossier Submitter's conclusion that there are benefits from regulating different chemicals with similar concepts also under different legislations. SEAC notes RAC's

recommendation to implement a restriction exposure value of 1 µg Co/m³ as 8h TWA.

- Justification for the choice of the limit value: The Dossier Submitter concludes that RO1d, and the reference exposure limit value of 0.01 mg Co/m³ respectively, was chosen due to this value being the decision point for "acceptable" lifetime (i.e. a working life of 40 years) cancer risk levels used for workers according to ECHA Guidance. The Dossier Submitter acknowledges the economic and practical challenges that are connected with the implementation of this limit value. However, none of the other restriction options would ensure this high level of protection.

  According to RAC's amended risk assessment, the risk level that the Dossier Submitter intended to reach is already achieved with RO1b (restriction exposure value of 1 µg Co/m³ as 8h TWA). Furthermore, RAC concludes that this option is likely protective also for other, non-cancer, effects occurring due to the exposure to cobalt. SEAC notes that whilst RO1b provides most likely a similar level of protection for workers, it results in lower costs and less issues regarding practicality, enforceability and monitorability (more information is provided in the respective sections of this opinion) than the initially suggested restriction. Still, proportionality could not be demonstrated on a CBA basis for RO1b. However, SEAC notes that other human health benefits, that couldn't be quantified due to scarce data, are expected to occur due to the implementation of a restriction. Furthermore, SEAC notes that the Dossier Submitter's main driver for framing this restriction are the individual risk levels for workers that have been identified during the development of the dossier.

- Exclusion of a binding Occupational exposure limit value (BOEL) under OSH from any further assessment: SEAC agrees to the Dossier Submitter's and stakeholders' view (expressed during the consultation) that a BOEL could be an applicable and effective risk management option for the use of the five cobalt salts. A BOEL is targeted to prevent occupational exposure and it gives companies the flexibility to identify and implement the most suitable RMMs and OCs, both aspects being similarities to the proposed restriction. Furthermore, SEAC notes that a BOEL is an established and well-known concept to industry and (enforcement) authorities. However, the Dossier Submitter also notes some drawbacks of implementing a BOEL for the five cobalt salts under consideration, e.g. the fact that it does not consider frequency of activities leading to exposure and resulting therefore in possibly disproportionate risk management measures (e.g. an overregulation) or the time needed to implement a BOEL (estimated between 5 to 10 years). SEAC notes that RAC's amended approach, i.e. suggesting and supporting a restriction exposure value of 1 µg Co/m³ as 8h TWA, shows similarities to implementing a BOEL, e.g. the above-mentioned consideration of frequency of activities (under the REV concept) is no longer applicable. During the second consultation, an extensive alternative CBA on implementing a BOEL on all cobalt and its compounds was provided by a stakeholder. Whilst SEAC appreciates the effort taken by the stakeholder, it was not able to sufficiently scrutinise the calculations provided in order to compare the results of the study to the proposed restriction and draw a conclusion on which RMO can be regarded as most appropriate. Even though the report transparently describes the approach and findings of the calculations, some of the tools (EBRC OEL cost of compliance model etc.) and report results used for the alternative CBA (e.g.

EBRC (2020) "An OEL Compliance Costs Tool", RPA (2020) "An Assessment of the compliance costs of potential OELVs for cobalt and its compounds") including any details on respective input factors (such as exposure information on which RAC would need to be consulted) and assumptions taken (such as the number of companies and/or workers affected, etc.), are not available to SEAC and no sufficient scrutiny of the information provided is therefore possible. Furthermore, the two scenarios compared within the alternative CBA (REACH restriction vs. a BOEL under OSH) reflect different situations, as the restriction under discussion is targeted to 5 cobalt salts whilst the CBA on the implementation of a BOEL covers overall cobalt and its compounds. SEAC can therefore not conclude on which of the two risk management options (REACH restriction vs. implementation of a BOEL) would be more appropriate from a cost-benefit perspective.

- Proportionality: SEAC notes that for none of the restriction options assessed, proportionality could be demonstrated on cost-benefit considerations (monetised assessment), except for RO1a, where no definite conclusion can be drawn. SEAC's detailed assessment of the proportionality of the four restriction options under consideration are given in the respective section of this opinion.

- Targeting the five cobalt salts under consideration: In SEAC's view, the limitation of the proposed restriction to only the five cobalt salts under consideration prevents the creation of a level playing field for companies that also use cobalt metal and other cobalt compounds. I.e. with the implementation of a restriction on the five cobalt salts, different legal requirements for cobalt substances apply in the EU.

  SEAC notes RAC's recommendation to the European Commission for the implementation of a bOEL for cobalt and its compounds according to Directive 2004/37/EC (CMD directive, for more information see relevant RAC sections of this opinion). SEAC therefore notes that also from a risk perspective, covering cobalt and its compounds is supported. Furthermore, targeting only the five cobalt salts under consideration might lead to issues as regards the enforceability and monitorability of the proposed restriction. More information can be found in the respective sections of this opinion.

- Alternatives: During the preparation of the restriction dossier, the cobalt industry indicated that no suitable alternatives have been identified for the current uses of the cobalt salts or are expected to be found in the near future. The Dossier Submitter notes that replacement of the cobalt salts had been identified as having occurred in some applications already (eftec, 2018b, report for the CI/CoRC). Additionally, one company reported that a research study is ongoing and first preliminary results will be available in 2020. SEAC notes that during the consultation, information was submitted that one of the possible responses from industry to the proposed restriction could be a switch to different substances, if they are not able to comply with the suggested limit value (mainly referring to the initially suggested REV of 0.01 µg Co/m³). In SEAC's view, there is at least an indication that for some uses within the broad variety of sectors covered by the restriction, companies are considering a substitution away from the cobalt salts. In Annex E of the Background Document, the Dossier Submitter gives a brief description of potential alternative substances and techniques considered for specific uses in the various sectors. However, from the information available to SEAC, it can be concluded that overall, technically and

economically viable alternatives are, if at all, only feasible for a very limited number of uses.

2.3.1. Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

The Dossier Submitter only evaluated the impact of RO1 and RO2 in detail. Other regulatory options (see above) were not evaluated for their effectiveness in reducing the identified risks.

Improved control of exposure to the cobalt salts reduces the risk to individual workers and correspondingly the number of expected cancer cases. Independent of the restriction option and the exposure levels prevailing in each industrial sectors, the approach to estimate risk reductions and human health impacts is based on several assumptions about the effects of the regulatory action. The Dossier Submitter recognises that the assumptions made are uncertain. However, they provide an illustration of the potential risk reduction.

In the identification of the RMMs, the Dossier Submitter has considered the following aspects:

- Occupational hierarchy of controls.
- Effectiveness of individual RMMs.
- RMMs currently implemented in the different sectors of use to control exposure.

RO1

According to the Dossier Submitter assessment, the proposed REV should lead to a reduction of exposure and therefore a reduction in excess cancer risks in sectors where part of the industry is currently operating in risk levels higher than the REV. An indicative estimation of these benefits was done assuming that the:

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

According to the Dossier Submitter's analysis, the implementation of the restriction with a reference limit value of 0.01 µg/m^3 (RO1d) would avoid 1.04 cancer cases/year whereas options RO1a-c would avoid 0.05-1.02 cancer cases per year.

RO2

The effectiveness of the RO2 was evaluated by the Dossier Submitter and is presented in the corresponding section of the Background Document.

RAC's conclusions:

The effectiveness of the proposed restriction in reducing the identified risks is difficult to evaluate with certainty due to the identified uncertainties (mainly in relation to exposure).

The volumes of the cobalt salts used (see above) are expected to increase in the future. Therefore, it is possible that risk levels and/or exposed populations may increase. This has an impact on the effectiveness of the restriction. Two scenarios are considered possible by RAC:

- Greater turnover of cobalt salts per industrial site and worker would cause a potential for higher individual exposure and risk
- More sites with similar use of cobalt salts would cause a similar individual exposure and risk, given that RMMs and OCs are comparable, but a higher number of exposed workers

The limit values as proposed by RAC (1 µg Co/m³ (as 8 h TWA, for inhalable fraction) and 0.5 µg Co/m³ (as 8 h TWA, for respirable fraction)) can reduce the cancer risk below the level of 5.25×10^{-5} and are also effective in protecting from the other, non-cancer effects of cobalt. Because of the breakpoint in the dose response curve, higher exposure levels than the proposed REV are therefore as effective, as long as they do not exceed 1 µg Co/m³ (inhalable). **Exposure levels above 1 µg Co/m³ (inhalable), are not considered effective in reducing cancer risk or the risk of non-cancer pulmonary effects** (inflammation, decrease in lung function); for instance, an exposure level of 10 µg Co /m³ (as presented in RO1a) is associated with a cancer risk of 4.8×10^{-3}.

RAC notes that the restriction:

- Does not cover a number of relevant sources of occupational exposure to cobalt (e.g. exposures to cobalt fumes formed in hot processes, exposures in waste management and the use of cobalt compounds as on-site intermediates).
- Faces challenges related to the co-exposure to different cobalt compounds that are not covered by this restriction (e.g. Co metal, Co oxides).

On the other hand, the restriction could provide a limit exposure value for the protection for workers in a relative short period of time in the growing sectors using these five soluble cobalt salts.

Key elements underpinning the RAC's conclusions:

RAC bases the above conclusions on the following points:

- The Dossier Submitter stated in the impact assessment the uncertainty of many of the assumptions and the indicative nature of the impact assessment. RAC agrees with the Dossier Submitter's assessment in this regard.
- During the consultation, most of the contributions doubted the effectiveness of RO1d (0.01 µg/m³) in reducing the identified risks. A number of contributions commented in favour of a BOEL. Other regulatory options were hardly commented. However, the contributions during consultation in this regard lack specific data to support the claims about the effectiveness of the proposed restriction. The most frequent claims were:
    - Technical impossibility to reduce the exposure below the proposed REV of 0.01 µg/m³.
    - Challenges in monitoring REV of 0.01 µg/m³ with the available monitoring methods not being sensitive enough.
    - Challenges in implementing an REV as a frequency- and duration-adjusted value.

- The RAC's proposal of 1.0 µg/m³ (inhalable fraction), 0.5 µg/m³ (respirable fraction) as an 8h TWA limit value was not discussed in the consultation.

2.3.2. Socio-economic impact

Justification for the opinion of SEAC

2.3.2.1. Costs

Summary of proposal:

Both restriction options (RO1 and RO2) require industry to implement new risk management measures (RMMs) or to reduce the risk levels by other means, leading to additional costs. The economic impacts assessed in this restriction are estimated based on information on technical RMMs for both restriction options. The Dossier Submitter states that whilst under RO1 industry can in principle decide on the most effective measures to meet the reference exposure limit value, these measures are process specific and cannot be assessed at the generic level of a restriction proposal. As it is not possible to determine specific measures to be implemented by each sector of use, the cost and efficiency estimates provided under RO2 are also used to estimate the economic costs under RO1.

For the implementation of technical risk management measures (RMMs) by companies according to a restriction, the Dossier Submitter assessed one-off and operating costs. The Dossier Submitter identifies a set of RMMs which are discussed as regards their costs, their effectiveness and their applicability to different industrial sectors and sites. This has been done based on information provided by manufacturers and downstream users related to RMMs at their workplaces and potential additional RMMs under consideration (see section B.9 of the restriction proposal).

Several factors were identified that are influencing the overall costs of different RMMs. These are i.a. *the size of a site* (production capacity, i.e. the volume of material manufactured/used), the *technical measures currently already in place* (i.e. whether or not technical measures involve new build or retrofit), *the location* (e.g. geographical/country-specific factors), *local supply chain and logistics* (e.g. differences in delivery and installation costs), *environmental conditions dependent on the location* (e.g. sensitive receptors, etc.) and *local regulatory requirements* (e.g. relating to health and safety). The Dossier Submitter consulted with engineering experts on the identified measures, their costs and the factors potentially influencing the costs. Furthermore, to assess the potential differences in costs between sites and the potential side benefits of the technical measures considered, information provided by industry has been reviewed. Detailed information is summarised in Appendix 5 of the restriction proposal.

The available information allows the Dossier Submitter to derive order of magnitude estimates on the costs of implementing RMMs. However, it was not possible to identify the exact costs that individual companies will face as it is unknown how individual companies will react to the restriction and how different technical possibilities at affected sites will affect the costs. It is estimated that the identified sets of RMMs will cost between €40 and €120 000 per year and site in addition to already existing RMMs. An overview of the derivation of annualised costs for both ROs is given in Table 8, section 2.4 of the Background Document.

It is assumed by the Dossier Submitter, that a specific set of RMMs is sufficient to reach the reference exposure limit value in RO1. Which set of RMMs is required by the companies depend on the required risk reduction capacity, i.e. the difference between the current exposure levels in that industry (based on the exposure date in the registrations) and the exposure level specified in the restriction option. The cost ranges given are regarded as providing a sufficient reflection of the varying needs for additional RMMs as well as the technical constraints of individual companies, i.e. the cost of implementing the same technical measure may vary between companies.

In addition to the above (investment and annual operating costs), costs may occur due to monitoring needs, i.e. demonstrating that exposure levels and/or derogation thresholds have been achieved. The Dossier Submitter considers that, as the occupational health and safety legislation requires monitoring of exposure of carcinogenic substances already, only one additional measurement campaign would be carried out by each affected company and calculates additional annual costs of €210 (€3 000 per company, considering a temporal scope of 20 years (same as for RMM)) per company for demonstrating compliance with the proposed restriction. Depending on the requested reference exposure limit value, this calculation leads to additional costs of between €1 000 and €3 000 000 per year based on the number of companies that would need to implement additional RMMs.

Economic impacts RO1:

The information available to the Dossier Submitter allows only for an indicative cost estimate of RO1. Considering low and high cost estimates the overall economic impacts for the restriction options assessed under RO1 are depicted in the table 2 below, which summarises the total cost of implementing RMMs and demonstrating compliance for all restriction options assessed under RO1 (a detailed overview of the estimated costs per option *and sector* is given in table 10 of the restriction report. Furthermore, table 9 summaries the share and number of affected companies per sector for different scenarios under RO1):

Table 9: Economic impacts for different reference exposure limit values under RO1

	Affected companies/Costs (€ per year)							
	RO1a 6		**RO1b 1 967**		**RO1c* 4 060**		**RO1d* 12 316**	
	low	**high**	**low**	**high**	**low**	**high**	**low**	**high**
TOTAL cost of implementing RMMs	1 167	5 401	696 366	4 998 230	64 138 270	459 822 193	90 776 733	649 413 684
Cost of demonstrating compliance	1 274	1 274	417 591	417 591	861 755	861 755	2 614 133	2 614 133
TOTAL	2 441	6 675	1 113 957	5 415 821	65 000 025	460 683 949	93 390 867	652 027 817

* Restriction options 1c and 1d are not relevant for the assessment after RAC adjusted the dose-response relationship. The proposed restriction (i.e. RO1d) was developed to achieve a risk level that can be achieved already by a lower exposure limit (i.e. RO1b).

The Dossier Submitter does not consider administrative cost for the cost assessment. This is due to the fact that Chemical Safety Assessments (CSA) need to be updated by registrants

regardless of the restriction as RAC agreed that the substances of concern are non-threshold carcinogens, whereas the current registrations present cobalt salts as threshold carcinogens.

As regards the derogation for the animal feed sector, 300 companies out of 4 400 are estimated by the Dossier Submitter to be potentially affected by RO1, as they formulate cobalt-containing preparations or premixtures which is assumed to lead to possibly higher risk levels than 10^{-5}. For the other companies manufacturing compound feeds, risk levels are not known but are assumed to be very low based on conditions of the regulation on animal feed. Whilst several companies would be affected by RO1c and RO1d if no derogation would be implemented, only few up to no companies are expected to be affected by RO1a and RO1b. Any arising costs, although expected to be low for the higher limit values, would be avoided if the derogation would be implemented.

Economic impacts RO2:

RO 2 covers only sectors where cobalt salts are used in solid form (i.e. powder, granules, etc.) and additionally the surface treatment sector performing electroplating processes, even if cobalt salts are used in liquid forms. The information available to the Dossier Submitter allows only for an indicative cost estimate of RO2. It is based on the assumption that a certain percentage of companies (estimated for each option) has already implemented the identified technical RMMs. Using the cost figures depicted in Table 8, section 2.4 of the Background Document, (low and high values for investment and operating costs) the Dossier Submitter arrives at overall economic impacts between **€9 600 and €627 000 000 per year**. Between **230 and 4 600 companies** are expected to be affected by this option, depending on which out of the four options assessed is chosen. Table 10 below summarises the total cost of implementing different sets of RMMs (a detailed overview of the estimated costs per option *and sector* is given in Table 11 of the restriction report. Furthermore, it gives the number of affected companies per sector for different scenarios under RO2).

Table 10: Economic impacts for different sets of RMMs under RO2

Affected companies/Costs (€ per year)							
RO2a		**RO2b**		**RO2c**		**RO2d**	
234		934		1868		4624	
Low	**High**	**Low**	**High**	**Low**	**High**	**Low**	**High**
9 551	44 193	184 412	1 767 706	3 535 413	35 354 127	87 501 465	626 626 572

Within RO2, the Dossier Submitter suggests two derogations from the restriction:

The first derogation is identical to the derogation proposed for RO1, i.e. for the use of the cobalt salts in the animal feed sector. All 4 400 companies would potentially be affected by RO2, the exact estimate for each of the four scenarios depends on the required set of RMMs and on the fact what is already implemented by companies: 220 companies would be affected by RO2a, 880 companies by RO2b, 1 760 companies by RO2c and 4 356 companies by RO2d. With the specific set of RMMs, this leads to an economic impact of up to €300 000 000 per year (central estimate for RO2d). These costs would be avoided in case the derogation would be implemented.

The second derogation suggested within RO2 applies to companies that can demonstrate excess lifetime cancer risk levels below 10^{-5}, i.e. is applicable to uses with exposure levels

below 1 µg Co/m³ after RAC adjusted the dose-response relationship (based on the original dose-response relationship below 0.01 µg Co/m³). This derogation would reduce the number of affected companies; however no updated figures based on the adjusted dose-response relationship are available to SEAC.

SEAC's conclusions:

In general, SEAC agrees that the approach taken by the Dossier Submitter, including the methods used and assumptions made, can be used to derive cost estimates for the implementation of a restriction and to compare them to the expected human health benefits. SEAC notes that the restriction proposal covers a multitude of sectors and companies, i.e. any cost (or other) assessment faces the challenge to present representative cost estimates whilst at the same time consider sector-specific and workplace-specific situations. Furthermore, companies might already have risk management measures in place, at least partly, due to the requirements of other EU legislation, e.g. the European occupational health and safety regulation, which also influences the magnitude of any additional cost.

In SEAC's view, these aspects have been considered in the cost assessment as far as information was available to the Dossier Submitter. However, SEAC notes that substantial uncertainties exist, mainly due to the before mentioned situation (varying sectors and situations covered by the restriction proposal, responses to the restriction uncertain), to the difficulties in establishing cost estimates for RO1 (and therefore transferring cost estimates from RO2 to RO1) and due to the limited feedback provided by industry during the preparation of the restriction proposal.

During the consultation on the Annex XV report, most stakeholders focused their comments on proposed restriction option (RO1d). However, one stakeholder provided an extensive cost-benefit analysis which also covered the other restriction options RO1a, RO1b and RO1c as well as an additional restriction option "AltRO1" with a REV of 20 µg Co/m³. I.e. stakeholder information is also available to SEAC on the other restriction options assessed by the Dossier Submitter.

Overall, several industry stakeholders claimed that the assessment performed by the Dossier Submitter substantially underestimates the costs of the restriction options under RO1 and RO2 due to several reasons (further pointed out below). Diverging information was provided about the possibility to comply with the respective values, which has an influence on the cost assessment. However, SEAC clearly notes fewer feasibility issues with the higher limit values proposed under RO1a and RO1b. Still, SEAC acknowledges that information provided in the consultation also indicates that under RO1a and RO1b, there are companies that do not seem to be able to comply with the restriction options under consideration and that costs other than compliance costs (as assessed by the Dossier Submitter) might occur (due to e.g. necessary changes in production processes, etc.).

These are considered in the alternative cost assessment provided by one stakeholder for both ROs (see documentation of the consultation). During the consultation on the SEAC draft opinion, one stakeholder provided an updated cost assessment for the exposure limit values suggested under RO1a and RO1b. This additional cost assessment is based on three different studies (Eftec, 2019a; EBRC, 2020; RPA, 2020)[18]. Table 11 gives an overview of the Dossier Submitter's costs assessment compared to the alternative cost assessments provided in the

[18] Non-confidential responses to the consultations on (i) the Annex XV report and (ii) the SEAC draft opinion are available on the ECHA website https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e181d575c8

consultation for all four assessed restriction options.

Table 11: Dossier Submitter and alternative cost assessments provided during the consultation processes

ROs	Costs DS's approach (€ million/year)	Alternative cost assessment (€ million /year)	Updated alternative cost (best estimate) assessment (€ million /year)
RO1a	0.002 – 0.007	11 - 567	125
RO1b(supported by RAC)	***1 - 5***	***42 - 987***	***374***
RO1c	65 - 461	74 – 1 526	n/a
RO1d (proposed restriction)	***93 - 652***	***84 – 1 720***	***n/a***

As can be seen from Table 11 above, the differences in cost estimates, specifically for the higher limit values and the upper ranges of the lower limit values, between the DS's and the alternative assessment are substantial. The "best cost estimates", provided to SEAC during the consultation on the SEAC draft opinion, lie within the ranges of the alternative cost assessment provided during the consultation on the Annex XV report. The differences are explained by, i.a., the following factors:

- the Dossier Submitter assumes that all companies will be able to comply with the suggested reference exposure limit values, whilst the third party assumes that a certain share of affected companies will need to change their process and/or use an alternative or need to cease production in the EU (assessing respective closure, relocation, process changing costs, etc.);
- the number of companies that is assumed to comply with each reference exposure limit value is claimed by the third party to be consistently overestimated by ECHA, i.e. more companies are affected and therefore covered by the third party assessment compared to the Dossier Submitter's assessment;
- the unit costs for implementing RMMs estimated by the third party are substantially greater than the estimates in the Background Document, specifically for RO1a and RO1b. This difference is explained by the different approaches taken: whilst the Dossier Submitter transferred the cost estimates from RO2 to RO1 (as explained above), the alternative approach considers the fact that there is no specific RMM that can be implemented in order to achieve compliance but a combination of measures is needed; stakeholders stated that no specific cost data on implementing the REVs was requested by the Dossier Submitter during the preparation of the restriction proposal. However, the Dossier Submitter did consult the industry on the costs and effectiveness associated with implementing specific risk management measures and linked these costs to complying with each REV; the consultation was said to be the first opportunity for companies to provide specific cost (and other, such as technical feasibility) information on implementing different REVs;
- there are significant differences in the cost of compliance between different sectors affected, particularly for the more stringent options; this is likely related to the process by which the cobalt salts are used as well as the risk management measures already in place.

- for the "triangulated costs of compliance" assessment provided during the consultation on the SEAC draft opinion, only a summary of the two additionally used cost assessments (EBRC, 2020; RPA, 2020) was available to SEAC. Whilst the results were transparently presented to SEAC within the report submitted during the consultation on the SEAC draft opinion, the assumptions taken as well as the tools and approaches used in the EBRC and the RPA cost studies cannot be scrutinised. Furthermore, SEAC notes that the cost estimates do anyhow lie within the ranges provided by the stakeholder during the first consultation (EFTEC (2019a) assessment).

SEAC notes that the alternative cost assessment (EFTEC (2019a)) submitted during the consultation on the Annex XV report is also a valid way forward to approach the cost assessment of the proposed restriction and can therefore, in principle, serve as a sensitivity analysis to the Dossier Submitter's cost assessment. However, SEAC notes an issue with one aspect of the alternative cost assessment: the Dossier Submitter identified a discrepancy in the reported number of companies currently being non-compliant with the respective limit values and therefore being affected by a restriction; i.e. the data reported in the stakeholder survey submitted during the consultation on the Annex XV report do not match with the data derived by the Dossier Submitter from registration dossiers. In addition, the data does not match with the exposure levels used in the human health impact assessment in the alternative cost-benefit analysis provided by industry.

SEAC cannot verify which of these data (compliance estimates from the survey or based on exposure data in the registration) are more reliable. However, SEAC notes that if the number of companies being affected by a restriction as assessed by the Dossier Submitter is an underestimation, this also has effects on the benefits assessment of the Dossier Submitter, i.e. the current estimated human health benefits would represent an underestimation as well. More information on the benefits and proportionality assessment is given in the respective section of this opinion.

In conclusion, SEAC considers it likely that the costs of implementing restriction options RO1a, RO1b, RO1c and RO1d were underestimated by the Dossier Submitter. However, SEAC notes that the alternative assessment provided during the consultation on the Annex XV report contains shortcomings which lead to uncertainties and it is likely that this alternative assessment represents an overestimation of costs, specifically in its comparison to the human health benefits (more information is provided in the section on benefits and proportionality).

Key elements underpinning the SEAC's conclusions:

For the following aspects of the cost assessment, SEAC notes the following:

- Cost categories assessed: SEAC agrees with the Dossier Submitter's approach to assess implementation costs, i.e. **investment cost** and **annual operating cost** as well as **monitoring costs**, i.e. costs to industry for demonstrating that reference exposure levels (RO1) or derogation thresholds (RO2) are achieved. Administrative costs to registrants for updating their chemical safety assessments (CSA) and exposure scenarios (ES) are disregarded due to a update already being necessary as RAC agreed in 2016 that the five cobalt salts are non-threshold carcinogens. SEAC agrees that the update of documents needs to be done regardless of a restriction.

However, SEAC notes that some administrative costs still might occur due to the proposed restriction as an amendment of the respective documentation (e.g. updating registration dossiers based on RAC's 2016 conclusion) might be necessary without undue delay and a further updating will be required, once a restriction enters into force.

- For investment costs and annual operating costs, the Dossier Submitter provides cost ranges in order to consider the different situations for the various sectors and companies affected (see section above) and concludes that they sufficiently reflect the varying needs for additional RMMs and the (technical and other) constraints of individual companies. However, information is said to be from limited sources and a respective verification was not possible for the Dossier Submitter i.e. it is unclear how representative the presented estimates are and whether they correctly and sufficiently reflect the actual situation under the ROs and the differences in the possibilities to implement measures within different sites. SEAC notes that whilst this approach attempts to consider different situations of different sectors and companies affected, it leads to a certain degree of uncertainty as regards the representativeness of the cost estimates. However, SEAC was provided with an alternative cost assessment during the consultation and values its results as useful additional information for sensitivity analysis.

- Monitoring costs: SEAC considers that the one-time cost of €3 000 per company, which was updated during the opinion making process to €6 000 per company, underestimated the likely situation, specifically for the lower REVs. In addition, SEAC doubts that a "one-time"-cost per company is sufficient to present a representative estimate for monitoring costs.

- Enforcement costs: the Dossier Submitter uses the average administrative enforcement costs per restriction case, €50 000 annually for the EU, for calculating the enforcement costs. It is assumed that this restriction wouldn't require more or less enforcement than an average case. SEAC agrees with the conclusion of the Dossier Submitter, considering that the enforcement is part of normal enforcement of exposure scenarios and Safety Data Sheets under REACH.

- Choice of cost estimates: as explained above, the Dossier Submitter uses the cost estimates provided under RO2 to also estimate the economic costs of RO1. The reason is that under RO2, concrete measures to manage the risks are suggested (and respective cost estimates can be made) whilst under RO1, only the "goal" is defined and the choice of the measures with which this goal can be reached is left to companies, which then themselves can decide on the measure to meet the reference exposure limit value. The approach was criticised by stakeholders during the consultation on the Annex XV report as it is assumed to not sufficiently reflect the actual situation under RO1 (underestimation of costs) as e.g. no single RMMs is regarded as being appropriate to reach the suggested reference exposure limit values, but rather a combination of measures is required (the lower the REV, the more complex is the implementation of RMMs). Furthermore, stakeholders

complained that they were not consulted on the costs of implementing different REVs during the preparation of the restriction dossier. SEAC acknowledges the difficulties to establish cost estimates for RO1 and agrees that, whilst the Dossier Submitter's approach is an attempt to establish respective cost estimates, it might not perfectly reflect the actual situation companies are facing due to the restriction. Additional information was provided by stakeholders during the consultation on the Annex XV report, which was further considered by SEAC in its evaluation.

- Companies affected: for both ROs assessed, the Dossier Submitter provides and explains the respective number and share of companies affected. This was also done for the derogations proposed under RO1 and RO2. During the consultation on the Annex XV report, stakeholders claimed that the number of companies affected by a restriction has been substantially underestimated by the Dossier Submitter. As pointed out above, SEAC notes that there is inconsistent exposure information reported in the registration dossiers compared to the survey that was performed by industry during opinion-making, which influences the number of affected companies for RO1a and RO1b. According to the Annex XV report consultation, substantially more companies are claimed to be affected by the suggested restriction options than assessed by the Dossier Submitter. Currently, SEAC cannot verify which of the reported estimates are more reliable but notes that this has an effect also on the benefits and proportionality assessment. No clarification on these inconsistencies was provided during the consultation on the SEAC draft opinion.

- Response to the proposed restriction: The Dossier Submitter assumes that all companies affected are able to comply with the proposed reference exposure limit values. The cost assessment builds on this assumption, i.e. costs of implementing measures are assessed (as pointed out above). The alternative cost assessment provided to SEAC is built upon the assumption that not all companies might be able to comply but instead need to change their process or even cease production in the EU. Costs are estimated based on this alternative scenario. In SEAC's view, this is a valid way of alternatively approaching the cost assessment of the proposed restriction even though a closure or relocation of business outside the EU is rather unlikely for the higher limit values suggested under RO1a and RO1b.

- Input received from third parties: as noted above, several stakeholders claimed the Dossier Submitter's assessment was a substantial underestimation of the costs of the proposed restriction. Other stakeholders claimed any cost assessment was meaningless, due to no such measures being available that would allow compliance, specifically with the lowest reference exposure limit value (the proposed restriction), but concern was also expressed for higher REVs. Most of the comments are not substantiated by any supporting evidence. However, one stakeholder provided an extensive alternative cost assessment which, in SEAC's view, provides a valid alternative way of approaching the cost assessment for RO1 and RO2. The assessment is built on different assumptions and respective cost estimates, e.g. as regards the response to the restriction (companies being able to comply with the restriction vs. ceasing or changing production processes), different unit costs for implementing RMMs (based on feedback provided by companies affected), revised number of companies affected etc. (as explained above; details can be found in the consultation documentation). SEAC regards this approach as an appropriate alternative way of assessing the costs of the proposed restriction which could serve as a sensitivity analysis to the Dossier Submitter's cost assessment. However, SEAC notes that the alternative approach also contains shortcomings and inconsistencies which lead to uncertainties as regards the cost estimates, e.g.:
    - SEAC has some concern with the survey conducted as it had to be performed in a short time frame and therefore, only limited feedback could be gathered which influences its representativeness; this is, in SEAC's view, specifically critical in order to verify the validity of the partly substantially higher cost figures that are reported in the alternative assessment (specifically for the higher REVs).
    - Part of the feedback provided by companies isn't substantiated by supporting evidence (e.g. cost figures, technical infeasibility of specific RMMs, etc.).
    - Inconsistency in the number of companies affected by a restriction (as pointed out above) which influences also the benefits and proportionality assessment of the restriction options under consideration. No clarification on these inconsistencies was provided during the consultation on the SEAC draft opinion.

  Overall, in SEAC's view, the alternative assessment also has clear limitations in terms of its assumptions (i.e. number of companies affected) and its representativeness for the broad spectrum of sectors and companies covered.

- Uncertainties: SEAC notes that there are several uncertainties present in both cost assessments (Dossier Submitter's and stakeholders'). The Dossier Submitter considers the uncertainties in their cost assessment to be high due to the abovementioned aspects. SEAC notes that this is also valid for the alternative cost assessment. In SEAC's view, the main sources for uncertainties are (non-exhaustive list, full information provided in the Background Document):

    - Number of companies affected by a restriction;
    - Diverging responses of companies to the implementation of a REV, i.e. being able to implement RMMs and comply with the REV or not, i.e. the need to change processes, cease production in the EU, relocate outside the EU;

- Representativeness of reported cost figures in industry surveys and also by the Dossier Submitter;
- Unit costs of risk management measures to be implemented;
- Possible misconception of the newly introduced concept of a REV, which might affect the information provided; however, based on RAC's amended approach (8h TWA instead of a REV), this aspect may not be as significant;
- Difficulties to establish reliable, representative cost estimates for RO1 due to broad scope of the restriction (different sectors covered, ranging from very specific, low volume uses (use in biotechnology) to broad, high volume uses (surface treatment)).

2.3.2.2. Benefits

Summary of proposal:

The individual risk of developing cancer due to occupational exposure to the five cobalt salts is the main driver for the restriction. According to the Dossier Submitter, improved control of exposures to the five cobalt salts reduces the risk to individual workers and correspondingly the number of expected cancer cases.

The estimated number of additional statistical cancer cases has been calculated using estimates of inhalation exposure to the five cobalt salts (based on the information provided in the exposure scenarios of the registration dossiers), the estimation of the number of exposed workers (based on information provided by industry) and the dose-response relationship endorsed by RAC for the assessment of the carcinogenicity effect of the cobalt salts via the inhalation route for workers and for the general population[19].

It is assumed that half of the cancer cases are lung cancer stemming from the respirable fraction of the substance; the other half is not specified. On average, lung cancer is more often fatal than other cancers. The higher end value of €5 000 000 per fatal cancer case is used (ECHA, 2016). The implementation of RMMs to reduce occupational exposure to the cobalt salts may also reduce exposure to other hazardous substances including other cobalt-containing substances. However, it was not possible to quantify these co-benefits due to limited information on such exposure.

The approach to estimate risk reductions and human health impacts is based on several assumptions about the effects of regulatory action. The Dossier Submitter recognises that the assumptions made are uncertain (for details see section on uncertainties). However, in the Dossier Submitter's view, they provide an illustration of the potential risk reduction due to the proposed restriction. Three main aspects have been taken into consideration, i.e. i) the occupational hierarchy of controls (technical measures are prioritised over organisational measures and personal protective equipment, due to their higher reliability and effectiveness in reducing risks), ii) the effectiveness of the individual RMMs and iii) the RMMs implemented in the different sectors of use to control exposure. In order to assess the effectiveness of RMMs, the following indicative values of various types of technical RMMs to control inhalation exposure were used:

[19] The REACH registration dossiers consider the cobalt salts as non-genotoxic carcinogens with a threshold mode of action, i.e. the dossiers have not been updated in order to take RAC's 2016 agreement into account.

Table 12: Indicative effectiveness of RMMs

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

[1] Average and upper confidence limit value as reported in Fransman *et al* study (2008)

[2] Approximate indicative range values as presented in the HSE (2017)

Based on this information, the following effectiveness rates are used in the impact assessment of the Dossier Submitter:

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

The Dossier Submitter states that appropriate organisational measures (including effective maintenance and testing of the ventilation systems and appropriate training of operators) need to be in place to achieve the above effectiveness rates. Such measures are part of the requirements of the occupational health and safety legislation already in place. Furthermore, specific requirements for the examination and testing of LEV systems may apply depending on member states.

Human health impact assessment for RO1:

The following (further to the above outlined) assumptions are made by the Dossier Submitter for assessing the human health benefits of RO1:

- The number of affected companies correspond to those used for the economic impact assessment;
- The average reduction in risk would be based on the effectiveness of the RMMs required to meet the reference exposure level;
- The starting point for risk reduction is the reasonable worst case (RWC) level for the first 10% of the companies (from the total number in that sector) and the typical exposure level to the rest of the affected companies.

A detailed overview of the excess lifetime cancer risk per sector, the number of affected workers per sector, the avoided cancer cases per year as well as the monetary value for avoided cancer cases (if available) are given per restriction option (from RO1a to RO1d) and per sector (for any details see Table 13 of the restriction dossier as well as Appendix 4). Table 6 below gives an overview of the total avoided cancer cases and the respective monetised

value per year and RO1:

Table 13: Total human health impacts for RO1

	Avoided cancer cases per year				Monetary value for avoided cancer cases per year (€)			
	RO1a	**RO1b**	**RO1c**	**RO1d**	**RO1a**	**RO1b**	**RO1c**	**RO1d**
TOTAL	0.05	0.48	1.02	1.04	171 304	1 769 647	3 754 813	3 801 257

As regards the suggested derogation for the animal feed sector, the number of companies benefiting from this derogation depends on the level of the reference exposure limit value, i.e. on the RO chosen (RO1a to RO1d). It is assumed that in total, 14 000 workers are operating in this sector, i.e., according to the approach used by the Dossier Submitter for estimating the number of affected workers, 100 workers for RO1c and 600 workers for RO1d could be operating in companies benefiting from the derogation. No companies (and therefore workers) are expected to be affected by RO1a and RO1b as companies operating in this sector are expected to be below the respective REVs. The increased human health cost from this derogation can therefore be estimated to range from €0 to €5 000 for RO1.

Human health impact assessment for RO2:

The Dossier Submitter bases his human health impact assessment for RO2 on the above outlined assumptions (see also section 2.5 of the Background Document.

The individual excess lifetime cancer risk values achieved with the required RMMs will differ between industrial sectors, depending on i) the exposure levels in the sector, the ii) contribution of the use of powder forms and electroplating to the overall risk levels in the sector and the iii) site specific conditions of use of cobalt salts.

Considering the four different options evaluated under RO2 (i.e. the four different sets of technical RMMs) and the above outlined assumptions taken by the Dossier Submitter, the monetised human health benefits range between **€195 000 and €2 500 000**.

A detailed overview of the excess lifetime cancer risk per sector, the number of affected workers per sector, the avoided cancer cases per year as well as the monetary value for avoided cancer cases (if available) are given per restriction option (from RO2a to RO2d) and per sector (for any details see Table 14 of the restriction dossier as well as Appendix 4). Table 14 below gives an overview of the total avoided cancer cases and the respective monetised value per year and RO2.

Table 14: Total human health impacts for RO2

	Avoided cancer cases per year				Monetary value for avoided cancer cases per year (€)			
	RO2a	**RO2b**	**RO2c**	**RO2d**	**RO2a**	**RO2b**	**RO2c**	**RO2d**
TOTAL	0.05	0.20	0.32	0.67	195 347	749 010	1 172 670	2 461 356

During the opinion making process, the Dossier Submitter provided, on request of RAC and SEAC, some further information on cases of occupational asthma and skin allergy related to occupational exposure to cobalt, which was provided by member states. The available data on the reported cases correspond to three member states only. The specific cobalt compounds to which exposure takes place are not identified. The information received suggests an incidence of 1 to 3 cases of skin diseases and 0 to 1 asthma cases per year related to exposure to cobalt compounds. However, the Dossier Submitter concludes that the information is too scarce to draw any firm conclusion on the prevalence of occupational skin diseases and asthma related to cobalt exposure in the EU. Moreover, there is no specific information on the number of cases that may result as a consequence of exposure to the five cobalt salts within the scope of the restriction dossier.

Derogations: The Dossier Submitter suggests two derogations for implementing RO2. The first derogation, i.e. the derogation applicable for the animal feed sector, equally applies for RO1, i.e. the same approach for calculating the increased human health cost due to the derogation is chosen as described already above.

The second derogation suggested for the implementation of RO2 covers excess lifetime cancer risk levels below 10^{-5}, i.e. companies with exposure levels below 1 µg Co/m³ operating without the suggested sets of RMMs (based on the original dose-response relationship below 0.01 µg Co/m³). However, the number of such companies is not known and therefore the total human health impacts cannot be calculated.

SEAC's conclusions:

In general, SEAC agrees that the approach taken by the Dossier Submitter can be used for estimating the benefits of a restriction. The methodology used is regarded as appropriate for assessing the human health impacts due the exposure to the five cobalt salts. However, as also noted by the Dossier Submitter, several assumptions and approaches taken within the human health impact assessment have underlying uncertainties such as the number of affected sites and exposed workers per sector, the estimated effectiveness of risk management measures, the linearity of the dose-response relationship, the latency between exposure and cancer which is not considered in the assessment, etc. However, SEAC notes that the assessment made should serve as an illustration of the potential human health benefits of a restriction and SEAC agrees that it can be used for this purpose.

For quantifying and monetising the human health benefits of the proposed restriction, the Dossier Submitter focuses on the carcinogenic effects of the five cobalt salts. Other potential co-benefits of the proposed restriction have been described qualitatively, as available data are too scarce to perform a quantitative assessment (see information above).

RAC regards the Dossier Submitter's approach to use a linear extrapolation combined with the assumption that the risk of systemic and upper respiratory tract cancers is similar to that of lung cancer (100% respirable fraction) as over-conservative which likely results in the overestimation of risks. Therefore, RAC re-calculated the excess lifetime cancer risk values (ELR) for the different uses based on the below assumptions and supports the following amended RO1b:

- Amended assumptions: ELR estimated with 50% respirable fraction and non-linear dose-response relationship with a breakpoint[20] at 0.5 µg Co/m³
- Restriction option supported: Restriction exposure value of 1 µg Co/m³ as 8h TWA

According to RAC, the amended approach better reflects the current scientific understanding of lung carcinogenicity of cobalt and provides a more realistic, but still conservative estimate of the risk. Following this approach, the avoided cancer cases per year and the monetised human health impacts of the four restriction options are reported in Table 15.

For other human health benefits that are expected to occur due to a restriction, no quantified values could be derived due to lack of representative data. RAC notes, however, that the restriction exposure value under RO1b (as 8h TWA) is likely protective also for other, non-cancer, effects of the cobalt salts. SEAC understands that this conclusion also holds for the lower values suggested under RO1c and RO1d, however, it is not valid for RO1a.

[20] Breakpoint assumed to reduce the risk by a factor of 10

Table 15: Avoided cancer cases and monetised human health benefits based on RAC's recommended risk assessment approaches for all four restriction options assessed

Restriction option	Avoided cancer cases/yr	Monetised human health benefits (€ mill/yr)
RO1a	0.02	0.086
RO1b (option supported by RAC)	0.24	0.885
RO1c	0.27	0.984
RO1d (the initially proposed restriction)	0.27	0.986

During the opinion making process, the Dossier Submitter recognised that there are inconsistencies with regards the number of companies that are expected to be affected by a restriction as they are currently not complying with the values proposed under the four restriction options, specifically for RO1a and RO1b.

The Dossier Submitter based its assessment on the exposure data provided by industry in registration dossiers. These data do not match the figures that are reported in the survey used for the alternative benefits assessment submitted during the consultation on the Annex XV report by industry.

The Dossier Submitter concludes that if more companies are affected by a restriction (as claimed by industry during the consultation) also more workers would be benefit from a restriction, which would increase the number of avoided cancer cases per year and the (monetised) benefits. This would imply that the Dossier Submitter's assessment represents an underestimation of the benefits, specifically of RO1a, RO1b and RO1c.

During the opinion making process, the Dossier Submitter provided an estimation of how this could influence the benefits assessment. The average human health benefits per company were assumed to remain the same as in the original assessment. However, the figure was applied to the larger number of potentially affected companies (as reported by industry during the consultation on the Annex XV report). Table 16 and Table 17 give an overview of how this could potentially affect the human health impact assessment.

Table 16: Estimated number of affected companies under each restriction option assessed

	No of affected companies in non-compliance, DS's estimate, based on registration dossier data	No of affected companies in non-compliance, industry's estimate
RO1a	6	4 618
RO1b	1 967	6 691
RO1c	4 060	9 135
RO1d	12 316	10 338

Table 17: Possible implications of number of affected companies on estimated avoided cancer cases per year for RO1a, RO1b and RO1c (options, where reported figures by industry substantially deviates from DS's data based on registration dossier data)

	Avoided cancer cases per year, DS's assessment using RAC's RA approach	**Avoided cancer cases per year, based on RAC's RA approach and higher number of affected companies**
RO1a	0.02	15.4
RO1b	0.24	15.65
RO1c	0.27	15.7

The Dossier Submitter notes that the approach was kept as simple as possible, likely resulting in an overestimation of human health benefits. SEAC notes that it could have been more appropriate to use the estimated exposed workers instead (this information is available both in the restriction report and in the cost-benefit analysis by the industry), as the human health benefit of the Dossier Submitter for RO1a is mainly based on companies in the manufacturing sector, which has a higher number of workers per site than other sectors.

However, no quantitative information on the exposure levels that lead companies to state they are cannot achieve the required exposure levels is available, neither to the Dossier Submitter, nor to SEAC. During the consultation on the draft SEAC opinion, a stakeholder provided an alternative to the approach taken by the Dossier Submitter, which is claimed to result in more reliable data on the avoided cancer cases per year. However, still no clarification on the inconsistencies between the number of affected companies based on exposure data provided by industry in the registration dossiers compared to the number of affected companies as claimed by the stakeholder during the consultation on the Annex XV report was provided.

SEAC does not agree to take the updated figures forward for the monetised cost-benefit comparison (and proportionality assessment respectively), neither those derived by the Dossier Submitter (Table 10), nor those provided during the consultation on the SEAC draft opinion by a stakeholder, as the uncertainties are too high and the above mentioned inconsistencies on the actual number of companies and workers affected by the proposed restriction have not been clarified.

SEAC notes that reliable information on the actual number of companies and workers affected is still not available. However, in SEAC's view, the reported higher number of affected companies by industry during the consultation is indeed an indication that the human health benefits could be greater than estimated by the Dossier Submitter.

SEAC concludes that the estimated monetised benefits of the four assessed restriction options, based on RAC's amended risk assessment, were likely to have been underestimated by the Dossier Submitter. This is due to the potential underestimation of the number of workers exposed and information provided during the consultation on companies potentially affected by a restriction.

However, due to several uncertainties, no more reliable estimate could be derived. SEAC notes that further benefits of a restriction are expected to occur that are not

part of the monetised figure, e.g. avoided cases of skin allergy and occupational asthma. However, in SEAC's view, any quantification and monetisation of those effects is doubtful due to lack of appropriate data.

In addition, SEAC notes that the Dossier Submitter's main driver for developing a restriction are the individual risk levels for workers, which have been identified during the assessment.

Key elements underpinning the SEAC's conclusions:

For the below aspects, SEAC notes the following:

- Quantified human health impacts: the restriction dossier focuses on the carcinogenic effects of the five cobalt salts. SEAC in general agrees with the approach and methodology used by the Dossier Submitter. However, SEAC notes the inherent uncertainties of this approach (assuming linearity of the dose-response curve, disregarding the latency of effects, etc.) which lead to a potential overestimation of human health impacts. Also RAC regards the assessment of the Dossier Submitter being overly conservative and amended the risk assessment. RAC's amended approach is considered to better reflect the current scientific understanding on the lung carcinogenicity of cobalt and provide a more realistic but still conservative estimate on the risk. Furthermore, and as explained above, SEAC notes that the number of potentially exposed workers might have been underestimated by the Dossier Submitter, which results in an underestimation of human health impacts and the benefits of a restriction. However, due to a lack of reliable data on potentially affected companies (and therefore workers exposed), SEAC agrees to take the human health impact assessment of the Dossier Submitter, based on RAC's amended risk assessment approach, forward for assessing the benefits of the four restriction options, noting that they likely represent an underestimation of the monetised human health benefits.

- Qualitatively assessed human health impacts: In addition to carcinogenicity, SEAC notes that the five cobalt salts are known to cause other severe health effects in workers. Cobalt compounds are reprotoxic substances as well as skin and respiratory sensitisers, e.g. causing occupational asthma. During the opinion making process, the Dossier Submitter explained that the proposed restriction is focused on the carcinogenicity of the five cobalt salts and a quantitative assessment was provided for this endpoint. However, it was agreed that qualitative information on occupational asthma and skin allergy arising from exposure to cobalt was added to the benefits assessment. SEAC notes that the information provided by the Dossier Submitter with regards to the number of work-related cases of skin diseases and asthma attributed to cobalt exposure, corresponding to three member states and covering therefore approximately 3% of the population of the EU only, is too scarce to draw any firm conclusion on the prevalence of occupational skin diseases and asthma related to cobalt exposure. Moreover, there is no specific information available on the number of cases that may result as a consequence of exposure to the five cobalt salts specifically under consideration. The Dossier Submitter stresses, that the implementation of RMMs to reduce occupational exposure to the cobalt salts may also reduce exposure to other hazardous substances, including other cobalt-containing substances. However, as for the skin and respiratory

effects, it was not possible to quantify any of these potential co-benefits. However, SEAC notes that such positive effects will most likely occur due to the proposed restriction. Furthermore, SEAC notes RAC's conclusion that the restriction exposure value suggested under RO1b is likely protective also for other, non-cancer, effects of cobalt salts and understands that this is also valid for RO1c and RO1d. However, this conclusion is not valid for RO1a.

- Information provided during the consultation: during the consultation on the Annex XV report, two substantiated comments were provided with regards to the human health benefits of a restriction. One stakeholder provided an alternative monetised benefits calculation for the carcinogenic effect as well as for the skin and respiratory sensitising effects of the cobalt salts, which concludes that the Dossier Submitter's approach overestimates the human health impacts. For the skin and respiratory sensitisation effects, which were described by the Dossier Submitter qualitatively, an attempt was made to also quantify and monetise these benefits. SEAC appreciates this attempt but agrees with the Dossier Submitter's conclusion that the information available is too scarce to draw any firm conclusion on the prevalence of occupational skin diseases and asthma related to the five cobalt salts and to derive monetised human health impacts. For the carcinogenicity assessment, the main differences are in the i) combined excess cancer risk estimates, the ii) total number of exposed workers and in the iii) estimated value of cancer cases. Several aspects of the alternative assessment lead to a reduction of the value of the benefits, such as the approach to assess the particulate fraction affected (inhalation exposure vs. respirable fraction exposure), any consideration of the worker's shift, the distribution of exposure levels (10% reasonable worst case and 90% typical level vs. 100% typical exposure level), consideration of the latency period of lung cancer, discounting rate (0% vs. 4%), etc. RAC concluded that the Dossier Submitter's approach is overly conservative and amended the risk assessment accordingly, e.g. as regards the particulate fraction affected (see respective sections of this opinion). Whilst SEAC agrees that the alternative assessment partly contains valid assumptions, SEAC has reservations with regards to the following: for calculating the statistical cancer cases, the number of affected companies (and workers) is based on information gathered through surveys. For RO1a, RO1b and RO1c, this number is higher than was estimated by the Dossier Submitter based on exposure information present in the registration dossiers. However, in the alternative assessment, this higher number of exposed workers was nevertheless combined with exposure information present in the registration dossiers but, according to the Dossier Submitter, the information in the registration dossiers does not suggest such high risk levels and non-compliance rates. I.e. the number of affected workers as assumed by industry does not correspond with exposure information present in the registration dossiers but was still used for calculating the statistical cancer cases. No clarification on these inconsistencies was provided during the two consultations. I.e., in SEAC's view, there are currently too many ambiguities present in the alternative benefits assessment in order to take it forward for comparing these to the costs of a restriction. Another stakeholder claimed that the human health impact assessment of the Dossier Submitter is a severe underestimation, as substantially more workers are exposed to cobalt in the EU than estimated in the restriction dossier and based their claim i.a. on the French SUMER survey (Surveillance Médicale des Expositions aux Risques professionnels) conducted in 2010, which indicates that 66 200 workers

are exposed to cobalt and cobalt compounds in France alone. Extrapolating this number to the whole European Union the stakeholder claims that around 660 000 workers are expected to be exposed to cobalt in the EU28. The Dossier Submitter concludes that, at this stage, it is not possible to ascertain which of the figures (provided by industry vs. provided in the SUMER survey) more accurately reflect the number of workers exposed to cobalt in industrial activities in France and the number of workers exposed to specifically the five cobalt salts in the EU respectively. However, the Dossier Submitter concludes that the number of workers considered in the restriction dossier, as already explained above, may be underestimated and this may result in an underestimation of the benefits of the evaluated restriction options. However, the uncertainties in the calculation of workers potentially affected are high (due to the number of assumptions that needed to be taken (more information is provided in the Background Document)) and therefore no figure can currently be derived that would be more reliably depict the workers affected. Whilst SEAC acknowledges the information provided in the consultation, it agrees with the Dossier Submitter's view that it is difficult to conclude on the actual number of workers exposed to specifically the five cobalt salts under consideration in the EU as information currently available (to SEAC and the Dossier Submitter) doesn't allow i) determining the actual number of companies affected (and therefore workers exposed) due to conflicting information provided in the registration dossiers and the information provided in the consultation and ii) distinguishing between exposure to the five cobalt salts under consideration and exposure to other cobalt compounds. Furthermore, as regards any reference to the SUMER survey, extrapolating the French data to the EU28 contains additional uncertainties. However, for concluding on the magnitude of the human health benefits of a restriction, SEAC notes that the number of exposed workers used in the human health impact assessment is most likely an underestimation. Further information on the both comments is available in the consultation documentation.

2.3.2.3. Other impacts

Summary of proposal:

The Dossier Submitter briefly discusses the following impacts in the restriction proposal:

Distributional impacts:

It can be seen from the sections "Costs and "Benefits", that the latter are mainly received by workers in companies that haven't yet implemented appropriate risk management measures as their risk of developing cancer from occupational exposure to cobalt salts decreases. Additionally, employers and member states may benefit, e.g. due to savings in health care costs and reduced sick leave days. Costs need to be borne by companies that need to implement additional risk management measures in order to comply with the proposed restriction. Those might partly be passed on to consumers through higher product prices. Competitors that have the appropriate risk management already in place might take over market shares from affected companies.

The excess cancer risk of individual workers depends on the level of implemented RMM at the specific side. The Dossier Submitter investigated that the risks in some of the companies are clearly higher than what is demonstrated to be achievable in other companies in the same

industrial sector. This distribution of risk of developing cancer is regarded as being unjustified by the Dossier Submitter and is one of the reasons to conclude that the proposed restriction is justified.

SEAC's conclusions:

SEAC notes the Dossier Submitter's considerations on the distributional impacts of the proposed restriction and the respective conclusion that the distribution of cancer is unjustified. However, the restriction dossier includes neither an assessment, nor a respective substantiation of the above claim. Only limited information is provided on how the proposed restriction would change the individual risk level distribution within the population affected. Furthermore, no information is given in the Background Document in order to judge whether any such changes are worth the cost of the proposed restriction. For the latter, however, SEAC notes that this is outside SEAC's remit.

SEAC notes that it has no information at hand that would allow for a proper scrutiny and examination of the Dossier Submitter's conclusion. However, SEAC notes that the Dossier Submitter is concerned about the individual risk levels that were detected during the development of this restriction proposal and their distribution amongst workers affected and that this was the main driver for framing the restriction proposal.

Key elements underpinning the SEAC's conclusions:

See section above.

2.3.2.4. Overall proportionality

Summary of proposal:

Proportionality:

The Dossier Submitter has assessed different sets of reference exposure values and minimum technical requirements (four of each, as pointed out above) for managing the risks arising from the use of the five cobalt salts. The monetised results described under economic and human health impacts are depicted in Table 18 below. Furthermore, this table also summarises the qualitative information as regards practicality aspects, including technical and economic feasibility and availability of methods:

Table 18: Summary of restriction options

RO	Affected workers	Avoided cancer cases/year	Benefit/ year (€)	Cost/year (€)	Practicality
RO1					
RO1a	300	0.05	200 000	3 000	Demonstrated
RO1b	8 400	0.48	1 800 000	2 800 000	Demonstrated
RO1c	15 200	1.02	3 800 000	260 000 000	Possible
RO1d	18 900	1.04	3 800 000	370 000 000	Challenging
RO2					
RO2a	800	0.05	200 000	30 000	Demonstrated

RO2b	3 100	0.20	700 000	1 000 000	Demonstrated
RO2c	6 200	0.32	1 200 000	19 000 000	Possible (Uncertain for surface treatment)
RO2d	15 400	0.67	2 500 000	360 000 000	Uncertain
Derogations	**Affected workers**	**Cancer cases/year**	**Monetised HH impacts/ year (€)**	**Avoided Cost /year (€)**	**Practicality**
Derogation 1 (Animal feed)	0-990	0 - 0.0015	0 - 6 000	0 - 20 000 000	High
Derogation 2 (Exposure level <0.01)	5 -90	0.000001 - 0.00002	4 -80	400 - 6 000 000	High

As can be seen from Table 18, the applied methodology reveals net benefits only for RO1a and RO2a. However, in the Dossier Submitter's view, the methodology may not be sensitive enough to address a regulatory action that would only affect few companies with very limited requirements. Therefore, additional argumentation is needed to support the proposal. The economics literature presents approaches for weighting different impacts, which could be justified based on e.g. aversion to risk inequity in general and to cancer risk in particular, when high risk levels for workers are considered to be unacceptable for the decision makers. However, no explicit guidance can be found in the literature for defining the weights. Moreover, no straightforward answers are provided for when and how such approaches should be used. The Dossier Submitter provides a brief discussion on the rationale for using such weighting approaches and their inherent challenges in the Appendix 6 to the Restriction Dossier.

In order to conclude on proportionality, the Dossier Submitter concludes for RO1 and RO2 the following:

RO1: The **advantages** of implementing a reference exposure value in the CSA and SDS together with the suggested derogation on animal feed is that these values will be communicated down the supply chain through the SDS, ensuring that the risks are known across all sectors of use. Furthermore, this is understood to be the least prescriptive regulatory intervention as registrants and downstream users may decide upon the most adequate RMMs to be implemented at their worksite to reduce exposure to the required level. According to the Dossier Submitter, this is in line with the underlying principles of REACH. The main **drawback** of RO1 is that the reduction in risk may be theoretically achieved with the use of personal protective equipment (PPE), even when appropriate technical measures are available and feasible to be implemented.

RO2: The **advantages** of implementing minimum technical requirements for managing the risks arising from the use of five cobalt salts with the suggested derogations on animal feed and for activities with very low exposure is that an adequate set of technical measures is to be implemented throughout the industry following the hierarchy of control. The drawbacks are that this option will not address the problem of communicating the risks of the non-threshold carcinogenicity of the substances. Furthermore, the actual effectiveness of RMMs may differ, depending on the design of the technical measures, maintenance and testing, training of users, etc. Also, targeting of more specific RMMs for each sector of use is not possible, due to the number of sectors and the lack of specific information for each of them

[to be adapted if more specific information is provided in the PC]. Lastly, the risk reduction effectiveness is limited since it addresses exclusively the risks resulting from exposure to the cobalt salts in certain activities (those with highest potential of exposure).

Due to the above considerations, the Dossier Submitter concludes that RO1 is preferable to RO2 as regards the question whether or not a restriction is the most appropriate EU-wide measure.

Within the four different RO1, the Dossier Submitter regards RO1d being the most appropriate RMM. This conclusion is drawn based on the following consideration: according to the ECHA Guidance[21], "the decision point for 'acceptable' lifetime (i.e., a working life of 40 years) cancer risk levels used for workers are generally around 10^{-5} but higher or lower levels have been considered to be tolerable under certain circumstances". Although the Dossier Submitter recognises the economic challenges that the implementation of adequate RMMs according to RO1d pose for a number of companies in several sectors of use, based on the cited guidance and the assessment performed, it is concluded that RO1d is indeed the most appropriate Union-wide measure to ensure a high level of protection of workers from the risk of developing cancer due to exposure to the cobalt salts. The other restriction options assessed would not ensure achieving this high level of protection.

Introducing risk equity as additional decision criterion: the main concern of the Dossier Submitter is the individual risk some workers are facing due to exposure to the cobalt salts and the respective unjustified distribution of cancer. The Dossier Submitter introduces a brief rational for justifying risk control beyond a standard CBA outcome, e.g. by considering other welfare criteria, risk equity concerns being one of them. According to the Dossier Submitter, the most noteworthy implications of this approach are:

- By accommodating risk equity as additional decision criterion, the optimal decision is no longer guaranteed to be efficient (Rheinberger & Treich, 2017)

- The approach is expressing the concern about individual risk exposure but ignores that reductions in risk come at a cost which may affect other dimensions of individual welfare

- The approach focuses on excess risk from exposure to cobalt salts, ignoring that prevailing background risks may be much larger

Further information on the approach can be found in Appendix 6 to the restriction dossier.

RAC's and SEAC's conclusions:

RAC's view:

Based on the evaluation of the available data, RAC concludes as follows:

- The superiority of the proposed regulatory option RO1d (over the other regulatory options) in reducing the risks is not demonstrated.
  - ➔ The proposed REV of 0.01 µg/m³ (as inhalable dust, weighted over frequency and duration) does not provide a higher level of protection. Other regulatory options

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

(0.1 or 1 µg Co/m³ as 8h TWA limit values, or a BOEL) can also provide a high level of protection, but not 10 µg Co/m³. This latter level is likely to result also in non-cancer health hazards (decrease in lung function, inflammation and respiratory sensitization), and a significantly higher cancer risk.

➔ Practicality aspects make RO1d extremely challenging.

- The proposed derogations will not provide a comparable level of worker protection within the framework of Regulation (EC) no 1831/2003.

  ➔ The risk management for workers/users within the framework of Regulation (EC) no 1831/2003 lacks concrete RMMs and level of protection.

SEAC's view:

SEAC's conclusion on the proposed restriction RO1d and on option RO1c: SEAC concludes that RO1c and RO1d are **not proportionate** from a (monetised) cost-benefit perspective, i.e., the costs (estimated investment, operating and other costs) clearly exceed the monetised human health benefits (avoided lung cancer cases). In SEAC's view, the additional consideration of qualitatively described human health benefits (see below) and the creation of co-benefits due to the implementation of RMMs and respective reduction of exposure to other hazardous substances is not expected to increase the overall benefits of RO1c and RO1d in a way that this influences the conclusion on proportionality. For RO1d, this was also confirmed by the Dossier Submitter.

SEAC's conclusion on the RAC-supported restriction option RO1b: even though the difference between costs and benefits is, depending on the approach (Dossier Submitter's vs. stakeholder's) used, not that substantial as for RO1c and RO1d, SEAC regards it likely that RO1b is **not proportionate** from a (monetised) cost-benefit perspective either, i.e. the costs (estimated investment, operating and other costs) are exceeding the monetised human health benefits (avoided lung cancer cases). Due to substantial uncertainties in both, costs and benefits assessment, SEAC's cannot conclude how the additional consideration of qualitatively described human health benefits (see below) would influence the conclusion on proportionality.

SEAC's conclusion on restriction option RO1a: in SEAC's view, **no definitive conclusion on proportionality** of RO1a can be drawn. Substantially different cost estimates have been provided by the Dossier Submitter and one stakeholder in the consultation processes. Even though SEAC regards the Dossier Submitter's estimate as being an underestimation of costs, the alternative assessment provided by industry contains several uncertainties as well and the huge differences in cost estimates compared to the Dossier Submitter's approach couldn't be sufficiently clarified. During the consultation on the SEAC draft opinion, an additional cost assessment approach was provided, establishing cost estimates based on three different studies. Whilst SEAC notes that the result of this assessment tends to disprove the proportionality of RO1a, its results could not be sufficiently scrutinised by SEAC as SEAC has no detailed insight in two of the studies (EBRC (2020) as well as RPA (2020)) on which the assessment is based. Furthermore, comparable health benefit estimates based on exposure levels behind these cost estimates are not available.

The above conclusions are based on the assessment provided by the Dossier Submitter, information received during the consultations and RAC's amended risk assessment. SEAC notes that the above conclusions contain a certain degree of uncertainty, as there are open

issues and substantial uncertainties for both, the cost and benefits assessment, which could not be addressed during opinion making (as explained in detail in the sections on costs and benefits and in the section below).

Qualitatively described benefits: SEAC notes that in addition to the monetised human health impacts, further (qualitatively described) benefits are expected to occur due to a restriction, e.g. avoided cases of skin allergy and occupational asthma due to the skin and respiratory sensitising effects of cobalt. However, due to the lack of representative data, no quantification of those impacts is currently possible. SEAC takes note of RAC's conclusion that a restriction exposure value of 1 µg Co/m³ as 8h TWA, as suggested under the amended RO1b, is likely protective also for other, non-cancer, effects of cobalt. SEAC understands that this conclusion also holds for RO1c and RO1d, however, it is not valid for RO1a.

Individual risk levels: SEAC notes the Dossier Submitter's concern that some workers are facing individual risk levels due to exposure to the five cobalt salts and the respective distribution of cancer is considered unjustified. The Dossier Submitter introduced a brief discussion on justifying risk control beyond a standard CBA outcome. Risk equity, the fact that some individuals are bearing larger risks than others, the respective concern and possible responses to this scenario are briefly discussed in the restriction proposal (details are provided in Appendix 6 of the Background Document). However, the Dossier Submitter only briefly introduces the idea of risk equity considerations as additional welfare criteria without providing any concrete assessment, nor any definite conclusion if and how such considerations would affect the proportionality discussion of the present case. That decision is left for the decision makers. Therefore, SEAC is not in the position to draw any firm conclusion on these aspects.

Derogation suggested for the animal feed sector: SEAC takes note of RAC's conclusion to not support the derogation suggested by the Dossier Submitter based on risk considerations. SEAC notes that several aspects of the restriction are relevant in order to conclude on granting/not granting the derogation: these are related to costs and benefits of implementing RMMs in order to comply to the proposed limit value, monitoring obligations in order to demonstrate that the required limit values are kept as well as REACH registration and communication obligations down the supply chain. As regards the latter, SEAC notes that cobalt salts used as additives in feedingstuffs are exempted from REACH registration and the communication obligations in the supply chain, so parts of the conditions of the restriction, are not applicable to companies using the substances as additives in feedingstuffs. As regards the other aspects, SEAC notes the following:

- RO1a and RO1b: based on the initial restriction proposed by the Dossier Submitter (implementation of a REV), no companies being targeted by the derogation would be affected under RO1a and RO1b if no derogation would be granted as these companies are expected to operate below the respective limit values, i.e. no additional costs and benefits are expected due to implementing risk management measures. However, also those companies need to be able to demonstrate that they are complying with the respective limit values, i.e. a monitoring programme still needs to be implemented, resulting in additional costs. I.e. the proportionality of these two restriction options would be affected slightly negatively. Due to the change from the REV concept to a restriction exposure limit value as 8h TWA (as suggested by RAC), the Dossier Submitter notes that a small number of companies are expected to be affected by the implementation of RO1b. No companies, however,

are expected to be affected by implementing restriction option RO1a. This conclusion is based on the information available to the Dossier Submitter and no specific information on the derogation was provided during the consultation. I.e. implementing restriction option RO1b, as supported by RAC, will induce additional costs and benefits. Based on the information provided by the Dossier Submitter in the restriction dossier, it is assumed that the proportionality would be affected slightly negatively as well. Any further details are given in the Background Document.

- RO1c and RO1b: between 30 and 180 companies would be affected under RO1c and RO1d inducing additional costs (through implementing RMMs in order to comply with the REVs and monitoring activities) and human health benefits (avoided cancer cases); however, the latter being very low (between 0 – 0.0015 cases based on the Dossier Submitter's conservative risk assessment, even lower based on RAC's risk assessment approach). Through a switch from the REV to the 8h TWA concept, even more companies are expected to be affected by a restriction. However, no concrete figures are available to SEAC. As above, SEAC assumes that the proportionality of the restriction would be affected slightly negatively, if no derogation would be granted for those uses. This conclusion is based on the information provided by the Dossier Submitter. Further details are given in the Background Document.

During the consultation on the SEAC draft opinion a stakeholder provided information in support of the derogation, which refers to the non-availability of alternatives and the legal framework being in place since 2014, establishing risk management measures to reduce worker and professional user exposure to cobalt already, i.e. any further regulatory action is said to result in double regulation[22]. Due to the above considerations which are based on the information available to SEAC when concluding on its opinion, SEAC supports the derogation as suggested by the Dossier Submitter.

Key elements underpinning the RAC's and SEAC's conclusions:

SEAC's above outlined conclusions are based on the following information currently available to the committee: table 19 depicts the initially performed cost benefit analysis of the Dossier Submitter, updated by RAC's amended risk assessment approach:

Table 19: Estimated number of companies affected, avoided cancer cases, human health benefits and costs as presented in the Background Document

	Avoided cancer cases per year	**Monetised HH benefits (million €/yr)**	**Total costs lower bound (million €/yr)**	**Total costs upper bound (million €/yr)**
RO1a	0.02	0.086	0.002	0.007
RO1b	0.24	0.885	1.1	5.4
RO1c	0.27	0.984	65	461

[22] For further information see comment #476 within the RCOM on ECHA's website https://www.echa.europa.eu/web/guest/registry-of-restriction-intentions/-/dislist/details/0b0236e181d575c8

RO1d	0.27	0.986	93	652

As can be seen from Table 19, according to the Dossier Submitter's initial assessment, which is based on information provided in the registration dossiers, RO1a is clearly proportionate from a cost-benefit perspective, whilst the other options are not.

Whilst the alternative cost benefit assessment provided by industry during the consultation on the Annex XV report concludes alike the Dossier Submitters assessment for RO1b, RO1c and RO1d (even though resulting in higher costs and lower benefits), the conclusion reads differently for RO1a, i.e. RO1a is clearly not proportionate from a cost-benefit perspective either. Table 20 summarises the results of industry's assessment:

Table 20: Estimated number of companies affected, avoided cancer cases, human health benefits and costs as presented by industry during the consultation

	Avoided cancer cases per year	**Monetised HH benefits (million €/yr)**	**Total costs lower bound (million €/yr)**	**Total costs upper bound (million €/yr)**	**Updated alternative cost best estimation (million €/yr)**
RO1a	0.02	0.2	11	567	125
RO1b	0.02	0.22	42	987	374
RO1c	0.03	0.23	74	1 526	n/a
RO1d	0.03	0.24	84	1 720	n/a

As can be seen from Table 20, industry concludes that all four restriction options are clearly not proportionate from a cost benefit perspective. As regards the two assessments (Dossier Submitter's and industry's), SEAC notes the following:

- Benefits: as already noted in the sections above, the Dossier Submitter identified inconsistencies with regards the number of companies (and therefore workers) affected (specifically for the higher limit values under RO1a and RO1b) due to diverging information provided by industry during the Annex XV report consultation compared to the information present in registration dossiers (the latter being the main basis for the Dossier Submitter's assessment). The number of affected workers as estimated by industry is greater than estimated by the Dossier Submitter. However, this figure does not correspond with the exposure information present in the registration dossiers (which does not indicate such high levels of non-compliance). Even though inconsistent, both were used by industry for calculating the statistical cancer cases. SEAC can therefore not agree to take this figure forward to compare it to the costs of a restriction. Based on the approach taken by industry, the Dossier Submitter considered whether the number of affected workers was underestimated in their original assessment and provided an estimation of how a greater number of affected workers could influence their benefits assessment

(details are given in the section on benefits above). SEAC therefore agrees that even though the updated figure cannot be regarded as more reliable as the initially calculated human health benefits (due to lack of robust exposure information, a simplified updated calculation (resulting most probably in an overestimation of human health benefits) and contradicting information provided by industry in the consultation and the registration dossiers), it can serve at least as an indication that the human health benefits could indeed be higher than originally estimated by the Dossier Submitter.

- Costs: as explained in detail in the section on costs above, SEAC considers it likely that the costs as estimated by the Dossier Submitter represent an underestimation. The above-mentioned differences on the number of companies potentially affected by a restriction are only one reason for this conclusion; some other factors were identified by industry. Whilst SEAC regards industry's assessment as an overestimation of costs, SEAC notes that the Dossier Submitter's assessment likely represents an underestimation, specifically if, as pointed out above, more companies are actually affected by a restriction. However, due to lack of appropriate data, no definite cost figure can be established by SEAC.

Consequently, SEAC notes that RO1c and RO1d are clearly not proportionate from a cost-benefit perspective (monetised impacts). RO1b is most likely not proportionate from a cost-benefit perspective (monetised impacts); both the assessment of the Dossier Submitter and those of industry conclude accordingly. Even though the Dossier Submitter underestimated the benefits (due to more companies (and therefore workers) being affected by a restriction), this would also affect the cost assessment. For RO1a, SEAC notes that no definite conclusion can be drawn based on the information currently available. Information provided during the consultation on the SEAC draft opinion tends to disprove the proportionality of RO1a. However, the results of the cost studies provided could not be sufficiently scrutinised by SEAC and comparable health benefit estimates based on exposure levels behind these cost estimates are not available.

As regards further aspects that need to be considered for concluding on proportionality, SEAC notes the following:

- Risk equity considerations: SEAC notes that the economic literature presents approaches for weighting different impacts, which could be justified based on e.g. the aversion to risk inequity in general and to cancer risk in particular. Such an approach may be applied if high exposure risk levels are considered to be unacceptable for the decision makers. The Dossier Submitter provides a brief discussion on the rationale for using such weighting approaches and their inherent challenges in Appendix 6 of the Background Document but does not provide any concrete assessment that would allow quantitatively evaluating the change in individual risk level distribution among the population affected. Without a specific methodology, and corresponding assessment explicitly provided in the Background Document, SEAC is not in the position to evaluate if and how the discussed approach would affect the overall conclusion on the proportionality of the proposed restriction. However, SEAC notes that individual risk levels have been identified by the Dossier Submitter during the investigation stage of this restriction proposal which were the main driver to establish this dossier. SEAC notes that currently no consensus on acceptable cancer risk level in Europe exists and that neither of the committees is in the position to decide on the acceptability of different risk levels.

- Affordability considerations: the Dossier Submitter did not provide any information on affordability and wider economic implications that may be caused by the suggested restriction. Whilst stakeholders note during the consultation that there might be sectors where compliance with the proposed restriction might be economically feasible (on the basis that these companies are already now in compliance with the suggested reference exposure limit value, usually companies infrequently using small amounts of cobalt salts for a short time period (e.g. in a laboratory environment)) several others claimed that the proposed restriction is unaffordable to a certain share of sectors and companies affected. Industry indicates that, in such cases, one of the most likely responses would be ceasing operations and relocating production outside the EU. Industry states that it might be less costly to relocate than to incur costs to comply with the proposed restriction. A relocation outside the EU is claimed to lead to job losses, weaken competitiveness, supply chain distortions, and wider implications to the EU economy, such as impacts on the lifetime, effectiveness, availability of final products/articles and respective market prices and the viability of recycling. Whilst SEAC notes the before mentioned aspects, it cannot conclude on any affordability and wider economic consequences of the proposed restriction, as industry's claims weren't substantiated by further supporting evidence. During the consultation on the SEAC draft opinion several stakeholders expressed their concerns on how the proposed restriction on the five substances (explicitly mentioning cobalt sulphate and cobalt dinitrate during the first consultation) might negatively influence (rechargeable) battery production in Europe, as this technology has been identified as a key technology for Europe fulfilling its obligations under the Paris Agreement. SEAC notes that this industry did not provide any exposure information during the development of the restriction. According to the Dossier Submitter, the estimated exposure levels are in the range of 1 µg Co/m³ (not based on measurements, but analogous data). Furthermore, SEAC notes that the before mentioned concerns provided during the consultation mainly referred to the initially proposed restriction of the Dossier Submitter (RO1d, a REV of 0.01 µg Co/m³). In SEAC's view a closure or relocation of business outside the EU is rather unlikely for the higher limit values suggested under RO1a and RO1b.

2.3.2.5. Uncertainties in the proportionality section

The uncertainties in the proportionality section are highlighted above and are summarised in the section on uncertainties and in the chapter "Uncertainties in the risk characterisation" of this opinion.

2.3.3. Practicality, incl. enforceability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Enforceability:

RO1, the proposed restriction: in order to conclude on enforceability, the Dossier Submitter concludes that the enforcement of the proposed restriction is part of normal enforcement activities of exposure scenarios and Safety Data Sheets under REACH. The

proposed derogation can easily be enforced, i.e. by checking that the cobalt salts used are listed as authorised under Regulation (EC) no 1831/2003. The proposed restriction can be enforced at different levels, i.e. at manufacturers' and importers' level, at the suppliers' level and at the downstream user level, e.g. enforcement can be carried out by checking that the exposure scenarios demonstrate that exposures are below the reference exposure value and are complied with. Furthermore, the SDSs can be checked whether or not they contain the respective information in the respective section and whether or not the exposure scenarios contained are complied with. Additionally, the documentation prepared by downstream users can be verified in order to check compliance.

The Dossier Submitter concludes that the proposed restriction (including RO1a and 1b) is enforceable.

RO2: enforcement of RO2 can be carried out by visual inspection of the existing risk management measures. This restriction option includes, in the addition to the derogation on the use of cobalt salts as additive in feeding stuffs, a derogation for uses which lead to an exposure below 0.01 µg Co/m³. This can be checked by reviewing the documentation that demonstrates compliance with this value. The methodology to determine exposure levels weighted over time and frequency to demonstrate compliance is given in Appendix 1 to the restriction proposal.

The Dossier Submitter concludes that RO2 is enforceable.

Enforcement costs: the Dossier Submitter concludes that the average administrative enforcement costs per restriction case, which are estimated to be around €50 000 per year for the EU, also applies in the current case. There is no indication that the present restriction would require more or less enforcement than an average case.

Practicality:

RO1, the proposed restriction: under RO1, the Dossier Submitter assessed four different reference exposure limit values, which lead to different conclusions as regards practicality aspects. Table 21 summarises the conclusions drawn by the Dossier Submitter:

Table 21: Practicality of restriction options under RO1

	Technically feasible	Economically feasible	Analytical methods	Overall practicality
RO				
RO1a (10 µg Co/m³)	Yes	High	Yes	Demonstrated
RO1b (1 µg Co/m³)	Yes	Medium	Yes	Demonstrated
RO1c (0.1 µg Co/m³)	Yes	Low	Yes	Possible
RO1d (the proposed restriction, 0.01 µg Co/m³)	*Yes*	*Low*	*Yes*	*Challenging*

As can be seen from the table above, the more stringent the reference exposure value, the more technically challenging and expensive is the implementation of the respective risk

management measures. To achieve the different values, the Dossier Submitter considers in general terms the following:

RO1b: the use of closed systems or at least partially enclosed systems with LEV required

RO1c and RO1d: most probably full enclosure of the process with LEV required.

For reaching the reference exposure value of RO1b the Dossier Submitter considers that the necessary technical measures are already implemented in a significant number of sectors and are therefore considered technically and economically feasible. An exception is the surface treatment sector, where the continuous immersion of pieces may not allow an effective closure of the system. The implementation of the above mentioned measures in order to reach the exposure values for RO1c and RO1d are regarded as being technically challenging and costly, not only in the surface treatment sector, but also in other sectors affected. However, the fact that RO1 doesn't specify the risk management measures to be implemented in order to comply with the reference exposure limit value and companies can therefore decide themselves on the most appropriate measure increases the practicality of this restriction option.

As regards the availability of analytical methods, the Dossier Submitter concludes that the most sensitive analytical procedure available for the measurement of cobalt concentrations in air presents a limit of quantification of 0.0003 µg Co/m³ (more information is listed in Appendix 1 of the restriction dossier). However, contradicting information was received from industry that claimed that the minimum limit of quantification achieved in practice is in the range of 0.1 µg Co/m³ with a typical value of 0.8 µg Co/m³. According to the Dossier Submitter, the reasons for the difference may lay in the analytical methods selected by industry to comply with the regulatory limits in place in different member states. In any case, the Dossier Submitter concludes that measurements of the suggested reference exposure limit value of RO1d are feasible, in case adequate analytical techniques are used. As regards the suggested derogation, the Dossier Submitter regards the practicality aspect being demonstrated.

Overall, for RO1 the Dossier Submitter concludes that practicality is demonstrated for RO1a and RO1b, whilst for RO1c it is regarded as possible and for RO1d, the proposed restriction, regarded as challenging.

RO2: under RO2, the Dossier Submitter assessed four different sets of technical risk management measures, which lead to different conclusions as regards practicality aspects. Table 22 summarises the conclusions drawn by the Dossier Submitter:

Table 22: Practicality of restriction options under RO2

	Technically feasible	Economically feasible	Analytical methods	Overall practicality
RO				
RO2a (mechanical ventilation)	Yes	High	-	Demonstrated
RO2b (LEV)	Yes	High	-	Demonstrated

	Technically feasible	Economically feasible	Analytical methods	Overall practicality
RO2c (enclosure with LEV)	Yes (uncertain for surface treatment)	Medium (uncertain for surface treatment)	-	Possible (Uncertain for surface treatment)
RO2d (closed systems with integrated LEV)	Yes	Low	-	Uncertain
Derogation				
Exposure levels below 0.01 µg Co/m³	Yes	High	Yes	Demonstrated
Animal feed	Yes	High	-	Demonstrated

As can be seen from table 22 above, the practicality of RO2 depends on the set of technical risk management measures required. RO2a and RO2b are considered technically and economically feasible in all sectors affected. The RMMs connected to RO2c are already implemented in a significant number of sectors of use and are likewise considered technically and economically feasible except for the surface treatment sector. However, for implementing measures obligatory under RO2d, technical and financial challenges are expected and it is uncertain whether this option is implementable in practice by different sectors of use. As regards the suggested derogation for the use of cobalt salts as additive in animal feedingstuff, the Dossier Submitter regards the practicality being demonstrated. The same conclusion is drawn for the second derogation phrased for RO2 in case adequate analytical methods are used.

Overall, for RO2 the Dossier Submitter concludes that practicality is demonstrated for RO2a and RO2b, whilst for RO2c it is regarded as possible and for RO2d as uncertain.

Transitional period: the Dossier Submitter proposes a 24 months transitional period which contains 6 months for adequate planning and 18 months for adequate implementation of the risk management measures required. The update of the CSAs and SDSs is expected to take place in the initial 6 months.

RAC's and SEAC's conclusions:

RAC:

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

- the REV of 0.01µg/m³ is not achievable by many of the affected industry sectors
- neither in-house monitoring as performed by industry nor monitoring by enforcement authorities will be able to show compliance (or non-compliance) with the REV.

On request of RAC the Forum provided additional advice on RAC's proposal of a limit value as an 8h TWA instead of the original reference exposure value proposed by the Dossier Submitter. For this approach, Forum gave a favourable advice. The limit values as proposed

by RAC seem enforceable and overall practical. RAC considers the proposal of 1 µg Co/m³ (as 8 h TWA, for inhalable fraction) and 0.5 µg Co/m³ (as 8 h TWA, for respirable fraction) as limit values for the five cobalt salts as practical and enforceable.

Additionally, it should be noted that for compliance of the 0.5 µg/m³ (respirable fraction) as an 8h TWA limit value it is not in every case necessary to monitor the respirable fraction. For reasons of practicability, RAC considers it sufficient to demonstrate:

- compliance with the 1.0 µg/m³ (inhalable fraction) as an 8h TWA limit value by workplace air monitoring and
- that the respirable fraction is less than 50% of the inhalable fraction for that particular use.

SEAC:

In SEAC's view, the enforceability and practicality of a restriction heavily depend on the level and type (REV vs. 8h TWA) of the restriction exposure limit value chosen. SEAC agrees to the issues pointed out by RAC above and concludes the following:

- for RO1d (the initially proposed restriction) and RO1c, respective implementation, enforcement and monitoring activities are technically and economically challenging up to impossible. **SEAC therefore expresses its concern as regards the enforceability and practicality of these restriction options**.

- for RO1b (option supported by RAC, albeit derived in a different manner to the Dossier Submitter) and RO1a, respective implementation, enforcement and monitoring activities are overall technically and economically feasible, specifically if implemented as 8h TWA. **SEAC therefore regards these restriction options as enforceable and overall practical.**

The above conclusions of SEAC are based on information presented in the Background Document, provided during the consultation and by Forum in its advice (on the proposed restriction option RO1d as well as on the RO1a and RO1b suggesting restriction exposure values as 8h TWA).

Additionally, for the below aspects, SEAC notes the following:

Transitional period: As regards the transitional period suggested by the Dossier Submitter, no substantiated information was brought forward to SEAC that 24 months would not be a sufficient timeframe for adequate preparatory and implementation work for the restriction exposure values suggested under RO1a and RO1b. Whilst some stakeholders confirm this period being a feasible timeframe for implementing respective risk management measures, others stated during the consultation on the SEAC draft opinion that specifically the manufacturing sectors, in particular the manufacture of cobalt salts, manufacture of catalysts and the manufacture of precursor chemicals for batteries might face difficulties to meeting a 24 month transition period for RO1a and (especially) RO1b. It was argued that a longer transition period for these sectors would facilitate more efficient planning and implementation of risk management measures and the identification of innovative cost solutions. While SEAC cannot verify the magnitude and likelihood of any related costs or other consequences for companies not being able to comply with the proposed transition period of 24 months, SEAC

acknowledges that difficulties (connected to some costs) might arise for specific companies to meet this deadline which might negatively influence the proportionality of the restriction. Companies have indicated during the consultation on the Annex XV report that it is not technically feasible to achieve the limit values suggested under RO1c and RO1d, i.e. SEAC notes that a longer time frame could be required to investigate and implement respective RMMs in order to comply with these values.

Derogation for use of the substances as additive in feedingstuffs: SEAC notes RAC's conclusion to not support the derogation from a risk perspective. SEAC notes that cobalt salts used as additives in feedingstuffs are exempted from REACH registration and the communication obligations in the supply chain so parts of the conditions of the restriction are not applicable to companies using the substances as additives in feedingstuffs. In SEAC's view, not granting the derogation could therefore affect the practicality and enforceability of the restriction as a large part of the overall concept of the restriction would not be applicable to companies operating in this sector.

Key elements underpinning the RAC's and SEAC's conclusions:

RAC:

RAC's conclusion is based on

- some assessments of the Dossier Submitter,
- the advice of Forum regarding the Dossier Submitter's proposal and RAC's proposal, as summarised above, and
- a relevant number of critical contributions to the consultation by affected industry (associations, individual companies)

All these contributions (even the assessment of the Dossier Submitter) refer to the original proposal of the Dossier Submitter and show clearly that the Dossier Submitter proposal for a REV of 0.01 µg/m³ is at least challenging regarding practicality and enforceability.

The Forum working group Enforceability of Restrictions considers that there are available methods to check limit values of 10 and 1 µg/m³ (inhalable fraction) as presented in RO1a and RO1b, respectively. ISO 15202 seems to deliver for 10 µg Co /m³ and the ISO 30011 seems to deliver for a limit value of 1 µg Co /m³. The Forum WG does not see major technical obstacles for the implementation of both values and to set a protective environment for workers. Industry has available methodology to demonstrate that the air quality of the workplace is at the required level. Enforcement authorities could check this information from industry or set contracts with laboratories to undertake these studies. From this it is clear that RAC's proposal for 1 µg Co/m³ (inhalable fraction) as an 8h TWA limit value is practical and enforceable.

Only a very limited number of contributions in consultation addressed the practicality of the REVs presented in RO1a and RO1b:

- 10 µg/m³ (inhalable fraction) is regarded as technically and economically feasible
- 1 µg/m³ (inhalable fraction) might be technically feasible, however, economically challenging

SEAC:

Enforceability aspects: Forum considers the four restriction options as enforceable as regards the identification of the regulated cobalt salts and mixtures containing these salts and the exemptions for feedingstuffs. Furthermore, in Forum's view, REACH inspectors will be able to check the respective documentation (CSA, ES, SDS) for the fulfilment of conditions 1a – 1c of the proposed restriction. Forum concludes that there are available methods to review the restriction exposure values suggested under RO1a and RO1b (as 8h TWA). Industry is believed to have the available methodology in order to demonstrate that the air quality of the workplace is at the required level. Enforcement authorities could check this information through laboratories: the methodology for sampling is available through the method so it should be possible for a (private) laboratory which is specialised or even accredited for a specific method to sample (including preparation), analyse and calculate the substance concentration in the air and to provide a respective report to the National Enforcement Authorities indicating if there is a concentration of cobalt salts above / below the limit value. If sampling is linked to the actual worker exposure portable sampling devices need to be provided during a certain period. These conclusions, however, do not hold for the lower limit values, e.g. suggested under RO1d (the initially proposed restriction). More details are given in the advice from Forum. Lastly, Forum sees a problem in the interference of the five cobalt salts with other cobalt sources but assumes that this could be limited to specific sectors. In those cases strategies for investigation of the different sources could be envisaged.

Practicality aspects: SEAC agrees to Forum's conclusion that the four restriction options are practical as regards the identification of the regulated cobalt salts and mixtures containing these salts and the exemptions for feedingstuffs. For RO1a and RO1b, the Dossier Submitter further concludes that there are no issues connected to the implementation of risk management measures in order to comply with the suggested limit values, i.e. also for this aspect, practicality is demonstrated. For RO1b, industry concludes that a limit value of 1 µg Co/m³ might be technically feasible but economically challenging for some sectors/companies affected. Still, SEAC notes that in all sectors affected, a certain share of companies are already complying with this limit value and notes Forum's conclusion that no major technical obstacles for the implementation of the restriction exposure values of RO1a and RO1b are expected and that it is possible for companies to set a protective environment for workers. These conclusions, however, do not hold for the lower limit values, e.g. suggested under RO1d (the initially proposed restriction). The Dossier Submitter concludes that the implementation of risk management measures to comply with RO1d will be challenging for all industries and specifically for some activities, such as electroplating, where it is not guaranteed that the affected companies will be able to fulfil the requirements. SEAC agrees to this conclusion which is further confirmed by comments received during the consultation. Additionally, the implementation of the lower limit values, specifically the one suggested under RO1d, is challenging from an economic point of view. Further information on this aspect is given in the section on costs.

2.3.4. Monitorability

Justification for the opinion of RAC and SEAC

Summary of proposal:

Monitorability:

The Dossier Submitter concludes that both assessed restriction options, RO1 and RO2, can be monitored by enforcement authorities through measuring exposure levels at the worksites as part of site visits. Any monitoring activities need to take into account the use of adequate analytical methods, depending on the reference exposure limit value.

RAC's and SEAC's conclusions:

RAC:

Taking into account the information provided in the Restriction dossier, information gathered during the consultation and the advice given by the Forum, RAC concludes that the monitorability of the proposed REV of 0.01 µg/m³ is at least challenging, considering the currently available analytical methodologies and the lack of sufficient expertise in Member States.

A level of 1.0 µg/m³ (inhalable fraction) and 0.5 µg/m³ (respirable fraction) as an 8h TWA limit (RAC's proposal) value is less challenging to monitor as confirmed by the additional Forum advice (see above). Forum confirms the availability of monitoring methods for workplace air for the proposed values for industry and authorities. The co-exposure of the cobalt salts with other cobalt species may still present a challenge, though.

RAC's and SEAC's reasoning is given below.

SEAC:

Taking into account the information provided in the Background Document, information gathered during the consultations and the advice given by the Forum, SEAC concludes that restriction options RO1a and RO1b (suggesting restriction exposure limit values as 8h TWA) are monitorable. Forum confirms that adequate analytical methods are available and a respective monitoring is therefore possible by companies affected as well as enforcement authorities (as pointed out above). These conclusions, however, do not hold for the lower limit values, suggested e.g. under RO1d, considering the currently available analytical methods and the lack of sufficient expertise in Member States.

Forum identified the problem of a possible interference with other cobalt sources at the workplace, but this could be limited to specific sectors. For those cases, strategies for investigation of the different sources could be envisaged.

Key elements underpinning the RAC's and SEAC's conclusions:

RAC and SEAC:

- According to information provided in the Restriction dossier, provided by Forum and monitoring experts, RAC and SEAC note that the proposed REV (RO1d, 0.01 µg Co/m³ weighted over time and frequency) value can be monitored in theory, but this is

regarded as very challenging in practice. With the available methods, monitoring is most probably possible only at very few workplaces at present; however, RAC and SEAC note that adequate analytical methods might be developed in future.

- Forum states that the equipment needed to perform the workplace air monitoring for RO1d is expensive and it is expected that there are currently only few laboratories in the EU that can do the respective testing. This statement was confirmed by comments received during the consultation.
- Forum considers that there are available methods to check values according to RO1a and RO1b. ISO 15202 seems to be sufficiently sensitive for 10 µg Co /m³ (RO1a) and the ISO 30011 for 1 µg Co /m³ (RO1b). Forum does not see major technical obstacles for the implementation of both values. Industry has available methodology to demonstrate that the air quality of the workplace is at the required level. Enforcement authorities could check this information from industry or set contracts with laboratories to undertake these studies.
- For the limit value proposed by RAC (1.0 µg/m³ (inhalable fraction), 0.5 µg/m³ (respirable fraction) as an 8h TWA limit value) the above also applies.
- Here it should be noted again, that for compliance with the proposed limit values monitoring of the respirable fraction is not always necessary.

2.4. UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

2.4.1. RAC

Summary of proposal:

Uncertainties and their influence on the risk characterisation are described in detail in the chapter "Uncertainties in the risk characterisation" above. RAC identified additional uncertainties in the chapters on:

- Justifications whether the suggested restriction is the most appropriate EU wide measure.
- Effectiveness in reducing the identified risks.
- Practicality, incl. enforceability.
- Monitorability.

The uncertainties in the above chapters are less quantifiable than those evaluated in the chapter on risk characterisation. Also the influence (over or underestimation of the impact) of these uncertainties is less clear.

RAC's conclusions:

RAC concludes that the uncertainties of the proposed restriction by the Dossier Submitter are significant. These uncertainties are not limited to single aspects of the proposal but affect a relevant number of different aspects of this dossier.

The main uncertainties of the Dossier Submitter's proposal (RO1d) are related to:

- Appropriateness of the best EU wide measure: setting of a BOEL for cobalt and cobalt compounds is also considered as a possible regulatory option.
- Effectiveness in reducing the identified risks:
    - the impact and effectiveness of RMMs is uncertain as only limited information

is available on this.
    - the experience on similar restrictions focusing on occupational exposures is very limited.
- Enforceability: the Forum's advice challenges the practicality of the proposed REV of 0.01 µg/m³.
- Monitorability: the available methods for workplace air monitoring can hardly achieve the necessary limit of quantification for monitoring compliance to the REV of 0.01 µg/m³.

RAC concludes also, that the restriction as proposed by the Dossier Submitter:

- does not cover a number of relevant sources of occupational exposure to cobalt (e.g. exposures to cobalt fumes formed in hot processes, exposures in waste management and the use of cobalt compounds as on-site intermediates);
- faces challenges related to the co-exposure to different cobalt compounds that are not covered by this restriction (e.g. cobalt metal, cobalt oxides).

Some of these uncertainties are addressed by RAC's proposal for a breakpoint approach and an 8h TWA limit value (1.0 µg/m³ (inhalable fraction) / 0.5 µg/m³ (respirable fraction)) for the restriction (rather than a linear approach and a REV that is to be weighted over frequency and duration). Other issues/uncertainties can be addressed by RAC's additional proposal to the European Commission to derive a binding occupational exposure limit value (BOEL) for cobalt and its compounds according to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD). This value should be identical to RAC's proposed limit value of 1.0 µg/m³ (inhalable fraction) and 0.5 µg/m³ (respirable fraction) as an 8h TWA limit value to ensure a similar level of protection to workers from exposure to the cobalt salts.

However, some uncertainties remain with regard to the effectiveness in reducing the identified risks, related to the limited experience on similar restrictions focusing on occupational exposures and to the impact and effectiveness of RMMs to be implemented by industry.

Key elements underpinning the RAC's conclusions:

RAC's conclusions on uncertainties are presented in the most affected chapters of this opinion:

- Uncertainties in the risk characterisation (especially in exposure assessment)
- Justifications whether the suggested restriction is the most appropriate EU wide measure
- Effectiveness in reducing the identified risks
- Practicality, incl. enforceability
- Monitorability

2.4.2. SEAC

Summary of proposal:

The Dossier Submitter estimates that the potential impact of the uncertainties in the assessment is from moderate to high and may result in both, an overestimation or underestimation of the net benefits of the restriction. A detailed overview of potential uncertainties is provided in section 3 of the Background Document.

SEAC's conclusions:

SEAC's conclusion on uncertainty aspects of the assessment and the corresponding justification is given in the respective section of this opinion. In summary, SEAC notes the following:

- Costs of the proposed restriction: based on the assessment provided by the Dossier Submitter and on information submitted during the consultation, SEAC concludes that the **costs of the four restriction options are likely to have been underestimated** by the Dossier Submitter. This is due to several reasons, specifically the limited amount of information that was available to the Dossier Submitter during the preparation of the restriction proposal. Further information is provided in the respective section of this opinion.
- Benefits of the proposed restriction: based on the assessment provided by the Dossier Submitter and on information submitted during the consultations, SEAC concludes that **the number of exposed workers might have been underestimated** by the Dossier Submitter, which leads to an underestimation of the monetised human health benefits. However, currently no figure can be derived that is more reliable. Additionally, SEAC notes that the proposed restriction is expected to generate benefits that couldn't have been quantified and monetised, due to limited information available. These qualitatively described benefits are not included in the monetised figure and need to be considered separately. Further information is provided in the respective section of this opinion.
- Proportionality of the proposed restriction: based on the Dossier Submitter's cost-benefit assessment, on RAC's amended risk assessment and on additionally provided information during the consultation, SEAC concludes that restriction options RO1d (initially proposed restriction) and RO1c are **not proportionate from a CBA perspective.** In SEAC's view, any additional consideration of qualitatively described human health impacts is not expected to increase the overall benefits of RO1c and RO1d in a way that this influences the conclusion on proportionality. SEAC concludes that RO1b is **likely not proportionate from a CBA perspective.** For **RO1a** SEAC notes that **no definite conclusion on proportionality** can be drawn. However, SEAC notes that specifically under RO1b, further human health impacts are expected which could not be quantified due to a lack of data. Additionally, SEAC notes that the main driver for the Dossier Submitter to frame and support this restriction are the individual worker risk levels that have been identified during the development of the dossier. Further information is provided in the respective section of this opinion.
- Enforceability, practicality and monitorability aspects: based on the information provided in the restriction dossier, submitted during the consultation and based on the advice given by the Forum, SEAC notes that there is a certain degree of uncertainty whether **restriction option RO1b is practical for all companies in all sectors affected.** However, based on feedback provided by the Forum on RO1a and RO1b, SEAC rates this uncertainty being low. Any conclusion on the enforceability, practicality and monitorability of RO1c and specifically RO1d is, on the contrary, **highly uncertain at present**.
- Restriction being the most appropriate RMO: SEAC notes uncertainties for concluding on whether a restriction according to options RO1a, RO1b, RO1c and RO1d can be regarded as the most appropriate RMO, mainly due to proportionality aspects, to the lack of assessment of other potentially suitable and appropriate RMOs (e.g. a BOEL)

and to the limitation of the restriction to the five specific substances under consideration. Any details are given in the respective section above.

Key elements underpinning the SEAC conclusions:

Further information on SEAC's justification is provided in the respective sections of this opinion.