Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Soluble Cobalt Salts

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

ECHA/SEAC/[Opinion N°(same as opinion number)]

Agreed

12 March 2020

17 February 2020

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

12 March 2020

[SEAC opinion number]

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

Chemical name(s): **Soluble Cobalt Salts**

EC No.:

CAS No.:

This document presents the opinions adopted by RAC and SEAC and the Committee's justification for their opinions. The Background Document, as a supportive document to both RAC and SEAC opinions and their justification, gives the details of the Dossier Submitters proposal amended for further information obtained during the consultation 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 **[date of adoption of the opinion]**. **[**The deadline for the opinion of SEAC was in accordance with Article 71(3) of the REACH Regulation extended by **[number of days]** by the ECHA decision **[number and date]]**[1].

[The opinion takes into account the comments of interested parties provided in accordance with Article[s 69(6) and][5] 71(1) of the REACH Regulation.**] [**No comments were received from interested parties during the consultation in accordance with Article[s 69(6) and][3] 71(1)**]**[6].

The opinion of SEAC was adopted **by [consensus**.**][a simple majority]** of all members having the right to vote. [The minority position[s], including their grounds, are made available in a separate document which has been published at the same time as the opinion**.]**[6].

[1] Delete the unnecessary part(s)

Contents

OPINION OF RAC AND SEAC

The restriction proposed by the Dossier Submitter is:

Column 1 Designation of the substance, of the group of substances or of the mixture	Column 2 Conditions of restriction
Cobalt sulphate CAS no 10124-43-3 and 10026-24 EC no 233-334-2 Cobalt dichloride CAS no 7646-79-9 and 7791-13-1 EC no 231-589-4 Cobalt dinitrate CAS no 10141-05-6 and 10026-22-9 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 and 6147-53-1 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 .[2] 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.

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 **Soluble Cobalt Salts** is the most appropriate Union wide measure to

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

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 and 10026-24 – EC no 233-334-2 – Cobalt dichloride – CAS no 7646-79-9 and 7791-13-1 – EC no 231-589-4 – Cobalt dinitrate – CAS no 10141-05-6 and 10026-22-9 – 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 and 6147-53-1 – 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 inhalable fraction) and 0.5 µg Co/m³ (as 8 h TWA, for respirable fraction) to demonstrate that all occupational inhalation exposures to the cobalt salts are below this limit value, 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 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 all occupational inhalation exposures to the cobalt salts are below this limit value, 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 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 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 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).

Additionally, RAC considers it necessary, and proposes this to the European Commission, to derive a binding occupational exposure limit value (BOELV) for Cobalt and its inorganic 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 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 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.

JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

IDENTIFIED HAZARD, EXPOSURE/EMISSIONS AND RISK

Justification for the opinion of RAC

Description of and justification for targeting of the information on hazard(s) and exposure/emissions) (scope)

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion:

See the opinion of RAC.

Description of the risk(s) addressed by the proposed restriction

Information on hazard(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Information on emissions and exposures

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Characterisation of risk(s)

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Uncertainties in the risk characterisation

See the opinion of RAC.

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Evidence if the existing regulatory risk management instruments are not sufficient

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

JUSTIFICATION IF ACTION IS REQUIRED ON AN UNION WIDE BASIS

Justification for the opinion of SEAC and RAC

Summary of proposal:

The Dossier Submitter suggests to restrict the placing on the market, manufacture and use of the five cobalt salts, henceforth “the 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. This includes the manufacture of chemicals, catalysts, battery production, surface treatment, fermentation processes, health applications, feed grade materials, biogas, etc. The substances are manufactured and used in many (if not all) EU member states. There are currently around 30 000 tonnes of cobalt salts used in the European Union per year, the volumes placed on the EU market having doubled in the past ten years. The rise in demand is expected to continue in the near future, mainly due to increasing demand of rechargeable batteries and biotechnology-health applications. It is estimated that currently around 35 000 workers at around 20 000 industrial sites are exposed to the substances, for which the Dossier Submitter concludes that the risk they pose to workers is not adequately controlled and risk management is required at the Union level. On request of the European Commission (EC), ECHA conducted an investigation on the uses of the cobalt salts in order to determine whether they pose a risk to human health which is not adequately controlled and should be addressed within the scope of an Annex XV restriction dossier. The report (2013) concluded that a significant potential for exposure to the cobalt salts could not be demonstrated for the uses covered by the study. However, this conclusion is based on a number of uncertainties, which could have a major impact on its outcome. Furthermore, several deficiencies in the registration dossiers were identified during the preparation of the report (for any details, please see the respective sections of the Annex XV restriction report and of this opinion respectively). Therefore, ECHA prepared a new report (2017) based on new data available which reveals excess cancer risk values in the range of 10^{-5} to 10^{-2} throughout the sectors concerned which lead to EC requesting ECHA to prepare the current restriction proposal. 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.

Due to the above summarised information, the Dossier Submitter concludes that a Union-wide regulatory measure is needed to ensure a harmonised high level of protection of human health across the Union. Furthermore, a Union-wide measure is regarded being preferable to varying regulatory standards and statutes in different EU member states as 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 support the view that any necessary action to address risks associated with the use of the five cobalt salts under consideration should be implemented in all member states.

Key elements underpinning the SEAC and RAC conclusions:

SEAC's view:

As stated above, the five cobalt salts under consideration are manufactured and used in many, if not all, EU member states in a variety of different sectors as pointed out above. EU-wide and national regulatory measures are already in place, e.g. the five substances are included in the candidate list under REACH due to their carcinogenic and reprotoxic 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[3] 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 workers' exposure, using different technical measures such as closed technological systems, etc.; furthermore, 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 confirmed 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 of the substances under consideration. 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 for improvement 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. 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.

[3] 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

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:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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 binding occupational exposure limit value (bOEL) etc. More information is provided in section 2.2 of the Background Document.

SEAC 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 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, the 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 fix 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 to the Dossier Submitter that RO2a and RO2b can overall be regarded 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 did further assess four different options (RO1a to RO1d), reflecting four different reference exposure limit values. The Dossier Submitter did choose option RO1d, i.e. a value of 0.01 µg Co/m³ as 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 is 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[4].

RAC in its opinion is focussing 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:

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

- RAC concluded that the risk assessment performed by the Dossier Submitter is, due to the 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: the risk level that the Dossier submitter intended to reach by suggesting this restriction (i.e. 10^{-5}) is already achieved by implementing the higher value suggested under RO1b. 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 (reference exposure limit value) as suggested initially in the restriction proposal. As regards this amendment, the Dossier submitter concludes that it won't affect the assessment in a way that the present figures couldn't 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). 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 1 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 1: Overview of affected workers and avoided cancer cases per year for RO1a – RO1d

RO	Data from restriction dossier		Revised data according to RAC's amended risk assessment (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 1 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 concludes 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 as regards the technical and economic feasibility of the respective value. Stakeholders doubted whether this value can even be achieved by certain sectors and companies affected. Furthermore, it is stated that for a large segment of the industry it is simply unknown whether technical feasibility is given 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 technically and economically feasible by industry. For RO1b, the cobalt 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 the 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. Overall, SEAC notes that a certain degree of uncertainty as regards the before mentioned conclusions 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 lastly, 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 the REVs.

Restriction options vs. other RMOs: During the consultation, several industry stakeholders and authorities stated that a binding Occupational exposure limit value (bOEL) would be a more appropriate risk management measure to approach the risks to workers arising from the use of the substances. 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 as 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 cannot assess this risk management option, i.e. respective costs and benefits of the implementation of a bOEL, quantitatively, as no such data was provided to the committee, neither in the restriction dossier, nor in the consultation. However, SEAC notes, 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. Further considerations on this aspect are given below.

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.

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 doesn't lead to a similar level of protection for workers like the other options assessed under RO1, for both, cancer and non-cancer effects of cobalt. Additionally 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 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 conclusions:

As regards the below aspects, SEAC notes the following:

- Reference exposure limit value (REV): Based on comments submitted during the consultation, 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 to 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 the 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 have been demonstrated on a CBA basis for RO1b. However, SEAC notes that other human health benefits, that couldn't have been 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. However, SEAC can neither conclude on the appropriateness, nor on any related cost-benefit and proportionality aspects of implementing a bOEL, as the Dossier Submitter did exclude this RMO from any further assessment.

- Proportionality: SEAC notes that for none of the restriction options assessed, proportionality could have been 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 using additionally 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. Furthermore, targeting only the 5 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). I.e. 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.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

Socio-economic impact

Justification for the opinion of SEAC

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 include the size of a site (the volume of material manufactured/used), the technical measures currently already in place (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 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 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 2: 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 3 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 3: 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 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 have at least partly already risk management measures in place due to requirements according to 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, the before mentioned 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), due to 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, most stakeholders focused in their comments on the proposed restriction option (RO1d). However, one stakeholder provided an extensive cost-benefit analysis which also covers 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 available to SEAC also 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 values suggested under RO1a and RO1b. Still, SEAC acknowledges that information provided in the consultation indicates that also under RO1a and RO1b, there are companies that doesn't seem to be able to comply with the restriction options under consideration and that 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 above mentioned alternative cost assessment provided by one stakeholder for both ROs (see documentation of the consultation). Table 4 below gives an overview of the Dossier Submitter's vs. the alternative cost assessment for all four assessed restriction options:

Table 4: Dossier Submitter's vs. alternative cost assessment provided during the consultation

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

As can be seen from table 4 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. This is 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 higher than the respective estimates in the restriction dossier, specifically for the higher REVs, i.e. RO1a and RO1b; this 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 state 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.

SEAC notes that the alternative version submitted during the consultation 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 of the above mentioned aspects of the alternative cost assessment: the Dossier Submitter identified a discrepancy as regards the reported number of companies currently being in non-compliance with the respective limit values and therefore being affected by a restriction; i.e. the figures reported in the stakeholder survey submitted during the consultation do not match the figures which are derived by the Dossier submitter based on the exposure data present in the registration dossiers. In addition, the figures do not match with exposure levels used in the human health impact assessment in the alternative cost-benefit analysis provided by the 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 exposure values under RO1a, RO1b, RO1c and RO1d have been underestimated by the Dossier Submitter. However, SEAC notes that also the alternative assessment provided during the consultation contains shortcomings which lead to uncertainties and it is likely that this alternative assessment represent 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 conclusions:

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

- Cost categories assessed: SEAC agrees to 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 CSA and ES are disregarded due to a respective update being necessary anyhow as RAC already agreed in 2016 that the cobalt salts are non-threshold carcinogens. SEAC agrees that the respective 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 with 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 tries 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 testing.

- Monitoring costs: SEAC had some concern that the assumptions made by the Dossier Submitter, i.e. a one-time cost of €3 000 per company, which was updated during the opinion making process to €6 000 per company, underestimate the situation, specifically for the lower REVs. Additionally, 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, being €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 concurs 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 the cost estimates: as explained above, the Dossier Submitter uses cost estimates provided under RO2 also for estimating 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 as it is assumed to not sufficiently reflect the actual situation under RO1 (underestimation of costs) as e.g. no single RMMs is regarded 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, it was criticised that stakeholders weren't consulted on implementing different REVs and therefore, feedback provided by industry couldn't specifically reflect on this newly introduced concept during the preparation stage 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, which is 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, 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 provided by industry during the REACH registration procedure, compared to the survey that was performed in order to provide sufficient information during the consultation of this restriction dossier, which influences the number of affected companies for RO1a and RO1b. According to the 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 figures are more reliable but notes that this has an effect also on the benefits and proportionality assessment. More information is provided in those sections.

- 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 pointed out in SEAC's conclusion section above, several stakeholders claimed the Dossier Submitter's assessment being a substantial underestimation of the costs of the proposed restriction. Other stakeholders claimed any cost assessment being 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 also the alternative approach 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.

Overall, in SEAC's view, also the alternative assessment provided has clear limitations as regards parts 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 himself rates the uncertainties surrounding his cost assessment being high due to the abovementioned aspects. SEAC notes that this is valid also 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)).

Benefits

Summary of proposal:

The individual risk of developing cancer due to occupational exposure to the cobalt salts is the main driver for the restriction. According to the Dossier Submitter, improved control of exposures to the 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 the estimates of inhalation exposure to the 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[5]. 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. Lung cancer is fatal more often than cancers on average. 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 based on uncertain ground (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:

Table 5: 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)

[5] 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.

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 6: 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 8 below gives an overview of the total avoided cancer cases and the respective monetised value per year and RO2:

Table 7: 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 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 appropriate for assessing the human health impacts due the exposure to the 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 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 did re-calculate 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[6] 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 on the risk. Following up on this approach, the avoided cancer cases per year and the monetised human health impacts of the four restriction options assessed are as depicted in table 8 below. For other human health benefits that are expected to occur due to a restriction, no quantified values could have been 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.

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

Table 8: 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 as regards the number of companies that are expected to be affected by a restriction as they are currently not complying with the respective values suggested under the four restriction options, specifically for RO1a and RO1b: the Dossier Submitter bases its evaluation on the exposure data provided by industry in the 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. 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 positively affected by a restriction which would increase the number of avoided cancer cases per year as well as 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 of SEAC, the Dossier submitter provided an estimation of how this could influence his 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 higher number of potentially affected companies (as claimed by industry during the consultation). Table 9 and Table 10 below give an overview of how this could potentially affect the human health impacts assessment:

Table 9: 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 10: 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 above approach was kept as simple as possible, resulting likely 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 stating they are not in compliance is at all available, neither to the Dossier Submitter, nor to SEAC. SEAC therefore agrees that even though the above updated figures cannot be regarded as more reliable as the initially calculated human health benefits (based on information from the registration dossiers), they can serve at least as an indication that the human health benefits could indeed be higher than originally estimated.

SEAC concludes that the estimated monetised benefits of the four assessed restriction options, based on RAC's amended risk assessment, have likely been underestimated by the Dossier submitter. This is due to the potential underestimation of workers exposed and information provided during the consultation on companies potentially affected by a restriction. However, due to several uncertainties, no figure that would be more reliable could have been derived in order to update the benefit's assessment accordingly. SEAC notes that further benefits are expected to occur due to a restriction that are not part of the monetised figure, e.g. avoided cases of skin allergy and occupational asthma due to the skin and respiratory sensitising effects of cobalt. However, in SEAC's view, any quantification and monetisation of those effects is doubtful due to lack of appropriate data. Additionally, 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 conclusions:

For the below aspects, SEAC notes the following:

- Quantified human health impacts: the restriction dossier focuses on the carcinogenic effects of the Cobalt salts. SEAC in general agrees to the approach and methodology used by the Dossier Submitter as presented in the restriction dossier. However, SEAC notes the inherent uncertainties of this approach (assuming linearity of the dose-response curve, disregarding the latency of effects, etc.) which are in general leading 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 as explained above and in the respective RAC section of this opinion. 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 respectively. 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: SEAC notes that also other as the quantitatively assessed effects of the substances are known to cause severe health effects in workers. Cobalt compounds are known as reprotoxic substances as well as skin and respiratory sensitizers, e.g. causing occupational asthma. During the opinion making process, the Dossier Submitter explained that the restriction dossier is focused on the carcinogenicity effect of the cobalt salts and a respective quantitative assessment was therefore provided for this endpoint. However, it was agreed that qualitative information on occupational asthma and skin allergy due to exposure to cobalt can be added to the benefits assessment. SEAC notes that the information provided by the Dossier Submitter as regards 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 specifically the five cobalt salts under consideration within this restriction dossier. The Dossier Submitter stresses, that the implementation of RMMs to reduce occupational exposure to the cobalt salts may reduce exposure also 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 the before mentioned potential co-benefits either. 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, two substantiated comments have been provided as regards the dimension of the human health benefits due to 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 quantify and monetise also 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 under consideration and to derive monetised human health impacts respectively. 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 decrease of the benefits value, 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 as regards the following approach: 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 what 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. 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 as estimated in the restriction dossier and based his 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 to 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 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 both comments is available in the consultation documentation.

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 cancer is regarded being unjustified by the Dossier Submitter and is one of the reasons to conclude that the proposed restriction is justified.

SEAC conclusions:

SEAC notes the Dossier Submitter's above summarised considerations about distributional impacts of the proposed restriction and the respective conclusion that the distribution of cancer is regarded being unjustified. However, the restriction dossier includes neither an assessment, nor a respective substantiation of the above claim: only limited information is e.g. provided on how the proposed restriction would change the individual risk level distribution amongst the population affected. Furthermore, no information is given in the dossier 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 this restriction dossier.

Key elements underpinning the SEAC conclusions:

See section above.

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 11 below. Furthermore, this table also summarises the qualitative information as regards practicality aspects, including technical and economic feasibility and availability of methods:

Table 11: 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 11 above, 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 inacceptable 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 being the minimum 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[7], "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

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

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.

SEAC conclusions:

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) are clearly exceeding 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 by 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. Even though SEAC regards the Dossier Submitter's estimate being an underestimation of costs, the alternative assessment provided by industry also contains several uncertainties, and the huge differences in cost estimates compared to the Dossier Submitter's approach couldn't be sufficiently clarified, as pointed out in the cost section above.

The above conclusions are based on the assessment provided by the Dossier Submitter, information received during the consultation 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 have been sorted out during SEAC's opinion making process (as explained in detail in the sections on costs and benefits and in the section below).

Qualitatively described benefits: SEAC notes that additionally 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 (any 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 feedingstuff are exempted from the REACH registration obligation 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 feedingstuff. 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 drawn based on the information available to the Dossier Submitter, 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 in the restriction dossier. Further details are given in the Background Document.

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 SEAC conclusions:

SEAC's above outlined conclusions are based on the following information currently available to the committee: table 12 depicts the initially performed cost benefit analysis of the Dossier Submitter, updated by RAC's amended risk assessment approach:

Table 12: 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
RO1d	0.27	0.986	93	652

As can be seen from table xx above, 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-benefits assessment provided by industry during the consultation 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 13 summarises the results of industry's assessment:

Table 13: 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)
RO1a	0.02	0.2	11	567
RO1b	0.02	0.22	42	987
RO1c	0.03	0.23	74	1,526
RO1d	0.03	0.24	84	1,720

As can be seen from table 13 above, 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 pointed out in the respective sections above, the Dossier Submitter identified inconsistencies as regards the number of companies (and therefore workers) being affected (specifically for the higher limit values under RO1a and RO1b) due to diverging information provided by industry during the consultation compared to the information present in the registration dossiers; the latter, being the main basis for the Dossier Submitter's assessment. The number of affected workers as estimated by industry is higher than what was 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 being inconsistent, both were used by industry for calculating the statistical cancer cases. SEAC can therefore not agree to take this figure forward for comparing it to the costs of a restriction. Based on the before mentioned approach taken by industry, the Dossier Submitter considered whether the number of affected workers was underestimated in his original assessment and provided an estimation of how a higher number of affected workers could influence his benefits assessment (any details are given in the section on benefits above). SEAC therefore agrees that even though the above 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 have 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.

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 inacceptable for the decision makers. 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 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 Restriction dossier 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. Furthermore, the before mentioned concern 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.

Uncertainties in the proportionality section

The uncertainties in the proportionality section are highlighted above and are summarised in the section on uncertainties of this opinion.

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. Also 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, 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. Furthermore, the documentation prepared by downstream users can be verified in order to check compliance.

I.e. 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.

I.e. 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 14 summarises the conclusions drawn by the Dossier Submitter:

Table 14: 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 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 possible and for RO1d, the proposed restriction, regarded 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 15 summarises the conclusions drawn by the Dossier Submitter:

Table 15: 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
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 xx 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 possible and for RO2d 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 and SEAC conclusions:

RAC's view:

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 reference value 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 reference value.

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 (0.01 µg Co/m³ weighted over time and frequency). For this approach, Forum gave a more favourable advice. The limit values as proposed by RAC seem enforceable and overall practical.

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's view:

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) 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 information was brought forward to SEAC that 24 months wouldn't be a sufficient timeframe for adequate preparatory and implementation work for the restriction exposure values suggested under RO1a and RO1b. However, companies have indicated during the consultation 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 feedingstuff: SEAC notes RAC's conclusion to not support the derogation from a risk perspective. SEAC notes that cobalt salts used as additives in feedingstuff are exempted from the REACH registration obligation 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 feedingstuff. 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 and SEAC conclusions:

RAC's view:

RAC's conclusion is based on

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

All these contributions (even the assessment of the Dossier Submitter) show clearly that some aspects are at least challenging regarding practicality and enforceability.
The Forum working group Enforceability of Restrictions considers that there are available methods to check both limit values (RO1a and RO1b) proposed. ISO 15202 seems to deliver for 10 µg Co /m³ (RO1a) and the ISO 30011 seems to deliver for a limit value of 1 µg Co /m³ (RO1b). 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.

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

- RO1a (10 µg/m³ (inhalable fraction)) is regarded as technically and economically feasible
- RO1b (1 µg/m³ (inhalable fraction)) might be technically feasible, however, economically challenging

It is important to note that the contributions in the consultation refer to the REV and not to the 8h TWA limit values as proposed by RAC.

SEAC's view:

- 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, 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 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.

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 and SEAC conclusions:

RAC's view:

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.

The value of 1.0 µg/m³ (inhalable fraction) 0.5 µg/m³ (respirable fraction) as an 8h TWA limit 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.

SEAC's view:

Taking into account the information provided in the Restriction dossier, information gathered during the consultation 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 and SEAC conclusions:

RAC's and SEAC's view:

- 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.

UNCERTAINTIES IN THE EVALUATION OF RAC AND SEAC

RAC

Summary of proposal:

See the opinion of RAC.

RAC conclusion(s):

See the opinion of RAC.

Key elements underpinning the RAC conclusion(s):

See the opinion of RAC.

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 restriction proposal.

SEAC 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 have likely 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 consultation, 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, however, could not have been quantified due to a lack of appropriate 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 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.