

**COMMENT ON****Annex XV restriction report for cobalt carbonate;  
cobalt di(acetate); cobalt dichloride; cobalt dini-  
trate; cobalt sulphate**

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WVMetalle would like to comment on the ECHA restriction proposal on the manufacture, placing on the market and use of the five cobalt salts with a special emphasis on the concept of a Reference Exposure Value (REV) and the missing in depth reflection of a much more targeted approach to guarantee adequate control by implementing a Binding Occupational Limit Value (BOELV) under the umbrella of the Carcinogens and Mutagens Directive (CMD).

WirtschaftsVereinigung Metalle (WVMetalle), the German Non-Ferrous Metals Association, represents the German Non-Ferrous (NF) metals industry towards politics and economy in order to maintain and establish measures at a very high level. Today, WVMetalle has about 670 member companies, including producers and processors of most base and special metals and compounds including cobalt containing alloys and cobalt compounds. WVMetalle is member of the German Industry Association (BDI) and of the European Non-Ferrous Metals Association (Eurometaux).

WVMetalle supports the activities to update the directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work and play an active role in this context by Dr. Wieske being a member of the DG Employment Working Party Chemicals (WPC) advising the tripartite Advisory Committee on Health & Safety at Work (ACSH). It is worth to mention that the WPC early in 2019 strongly recommended DG EMPL to give a priority mandate to RAC to evaluate Cobalt and its inorganic compounds towards a BOELV amending the CMD as all members of the tripartite WPC are convinced that a BOELV would be the most targeted and effective risk management option for the protection of workers for all uses of all Cobalt compounds.

The main aspect of the WVMetalle comment is therefore the way ECHA is examining the risk management option of setting an occupational exposure limit for cobalt or cobalt compounds. Prior to this, we would like to raise some further aspects with respect to the three bullet points at page 27 of the restriction proposal which describe why ECHA does not recognize the applicability of a binding OEL as suitable in this case:

- *The fact that it does not consider frequency of the activities leading to exposure and consequently may require disproportionate risk management measures for activities that take place very rarely or would not be stringent enough for activities taking place on a continuous basis.*

WVMetalle comment:

In contrast to this statement OSH legislation and especially OEL implementation is giving concrete advice regarding duration and frequency of uses. Every employer must undertake a qualified risk assessment in order to evaluate the risk and to define the according measures following the STOP principle. Together with an OEL, usually a short term value is established which gives further hints on how the exposure must be limited in case of exposure periods as short as 15 minutes. In any case it has to be ensured that the exposure is below the limit value with reference to a full shift.

- *The non-threshold nature of the hazard, where an OEL may provide a false sense of safety as the basis of its derivation is not communicated.*

WVMetalle comment:

OELs for carcinogens are established at EU level by amending the carcinogens and mutagens directive (CMD). A basic requirement under the CMD is minimization of exposure as the underlying assumption is that these substances do not have a safe level of exposure. Although this is no longer valid for a wide range of carcinogens for which a mode of action based threshold is assumed, this principle is still in place EU wide and well known by employers as well as employees.

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

WVMetalle comment:

It is irritating that ECHA is criticizing the length of time required for the development and implementation of a binding OEL having in mind that the discussion on the cobalt salts under REACH started as early as 2011 and only in 2018 the discussion resulted in the presented proposal for a restriction dedicated to five cobalt salts. Experiences on recent restriction proposals show that the time needed to complete discussion take easily a couple of years which is more than what has been needed to implement the recent waves of amendments for the CMD.

In addition, ECHA did not clarify why the use of the 5 cobalt salts in the scope of the restriction are especially associated with risks to be regulated and why this would justify a reference exposure value dedicated to these 5 cobalt compounds only. A BOELV as requested by the WPC would cover cobalt as well as all cobalt compounds within the scope of the CMD 2004/37/EC.

The following aspects are from our perspective strong further arguments underlining that the current restriction proposal by dossier submitter ECHA compared to establishing an EU-wide occupational exposure limit is neither convincing nor feasible:

- The restriction report refers to the RAC discussion and conclusion on the classification of cobalt metal and cobalt compounds. In addition, it is criticized that the registration dossiers have not been updated to take into account the RAC agreement in 2016. Unfortunately, it is not mentioned that the use of the extrapolation method (T25) for SCL is currently being examined in a separate process and therefore not used for the implementation of the cobalt and cobalt compounds classification proposals. This means that the underlying dose-response-relationship is as well under scrutiny. ECHA is neglecting this important parallel process within their own institution.
- ECHA does make reference within the restriction proposal to new epidemiological information (Sauni et al, 2017; Marsh et al, 2017). The second study is a large international occupational epidemiologic investigation of hard metal workers which involved 32 354 workers from three companies and 17 manufacturing sites. ECHA is then citing RAC, that the study showed no consistent evidence of elevated lung cancer mortality risk among cobalt exposed hard metal workers (ECHA, 2017b). In addition, ECHA mentions that RAC also recognized that excess risks from animal studies could be overestimated following the linearized approach, especially at very low exposure levels (ECHA, 2016). Nevertheless - and by mixing up hazard assessment aspects from classification discussions with risk assessment aspects for a potential restriction – ECHA is proposing a Reference Exposure Value extrapolated to an extremely low risk in workers and representing a very low exposure level. The restriction proposal is therefore neglecting RAC conclusions.
- Restriction proposal dossier submitter ECHA also extends the exposure risk relationship, which applies only to the alveolar fraction derived from animal studies, to the inhalable fraction and fixes the reference exposure value for the inhalable fraction as well. This is described “as a precautionary approach” but it is simply another aspect of the freely defined “REV” ignoring modern and toxicologically based occupational exposure limit setting procedure and guidance. The REV as such is an artificial construct which is by no means defined and therefore would create enormous irritation and misunderstandings.
- Having mentioned guidance for establishing occupations exposure limits, one should not forget that only recently, and supported by ECHA, the implementation of Appendix to IR&CSA Chapter R.8 (Guidance for preparing a scientific report for health-based exposure limits at the workplace) was sent to RAC and CARACAL for consultation. This guidance not only describes the findings of the ECHA/RAC-SCOEL Joint Task Force on alignment of methodologies, but also describes how to prepare in future a scientific report for health based exposure limits at the workplace in accordance with the Joint Task Force reports. It is hard to follow the argumentation of the dossier submitter for a REV for cobalt salts, when at the same time a new guidance is set up in order to establish relevant OELs at RAC level as mandated by DG EMPL via a Service Level Agreement signed in January 2019.
- The restriction proposal comes up with reference exposure value of  $0.01 \mu\text{g}/\text{m}^3$  with a corresponding risk of  $1.05 \times 10^{-5}$ . The context of existing risk concepts, e.g. in the Netherlands or Germany, are described. Nevertheless, it is correctly mentioned that there is no consensus in the EU on which excess cancer risk level may be considered unacceptable, and, indeed, this is a purely political decision. This kind of political decision should by no means be made by misusing this restriction proposal and can therefore not be accepted by WVMetalle, see page 21: *"The Dossier Submitter considers that individual excess cancer risks should be reduced to  $10^{-5}$  or below to ensure a high level of protection of workers from the risk of developing cancer due to exposure to*

*the cobalt salts*". In addition, it should be noted that within the German TRGS 910 traffic light model of minimizing risks of occupational cancer the tolerable risk, which expresses the statistical probability of developing cancer at a level of 4:1 000 is correlated for cobalt to 5 µg/m<sup>3</sup> and represents the limit above one has to use PPE mandatorily. The acceptable risk is fixed for the time being at a level of 4:10 000 (corresponding to 0.5 µg/m<sup>3</sup> for cobalt) and represents the limit below no further minimization is required.

- It is to be noted here that the German exposure risk relationship for cobalt is currently under review. Background for this review is the intention (a) to consider to a larger degree the RAC philosophy as recently established and used for the respective assessments for nickel, benzene and acrylonitrile and (b) to better integrate the rather nice fit of recent human data and experimental animal data with respect to ERR quantification into this assessment. We suggest to consider the outcome of the actual German discussion within your process as the update discussion is starting with a first consultation already on 25<sup>th</sup> June 2019, based on a detailed draft technical background paper of Stefaniak et al. 2009<sup>1</sup> on particle size distribution among cobalt exposed workers.
- With respect to the availability of measurement techniques a simple "Yes" is noted in the corresponding table 15 on page 47 of the restriction report. This is a clear contradiction to the recent German survey which provides an overview of validated measurement procedures for personal sampling and their suitability for use under workplace conditions following EN 482 standard ([https://www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AGS/pdf/Messverfahren.pdf?\\_\\_blob=publicationFile&v=4](https://www.baua.de/DE/Aufgaben/Geschaeftsfuehrung-von-Ausschuessen/AGS/pdf/Messverfahren.pdf?__blob=publicationFile&v=4)). Here, two methods are given for cobalt and its compounds, of which the presently most sensitive analytical technique, ICP-MS, has a limit of quantification (LOQ, called BG in the table) of 0.17 µg/m<sup>3</sup> (under the condition of getting a large sample volume of 1.2 m<sup>3</sup> sample air!). This actually means that even when using the most recent measurement technique the German acceptable risk level for cobalt at 0.5 µg/m<sup>3</sup> can only be controlled by deviations from the EN 689 specifications regarding the distance of the limit of detection to the actual limit value. The proposed REV of 0.01 µg/m<sup>3</sup> cannot be monitored or enforced with any existing validated technique for occupational emission values measurement and this even does not take into account that EN 689 foresees a LOQ of 10% of the limit value when measuring during one shift.

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<sup>1</sup> AB Stefaniak, MA Virgij and GA Day. Characterization of exposures among cemented tungsten carbide workers. Part I: Size-fractionated exposures to airborne cobalt and tungsten particles. Journal of Exposure Science and Environmental Epidemiology (2009) 19,475–491.