

ECHA public consultation on an Annex XV restriction dossier on five cobalt salts

27 February 2019

A response by the Cross-Industry Initiative for better regulation in chemical management

The *Cross-Industry Initiative (CII)* for better regulation in chemical management was set up between December 2014 and March 2015 as a coalition aimed at streamlining the management of chemicals. It is currently comprised of **over 60 organisations**: sectoral associations at the EU and national level as well as companies.

Our members represent manufacturers as well as downstream users of chemicals, large companies and SMEs. The remit of the CII targets exclusively cases in which the potential risks posed by chemicals are limited to the workplace environment.

The CII welcomes the opportunity to respond to the ECHA Public Consultation regarding the Annex XV restriction proposal for the use of five cobalt salts: cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate.

Scope of the CII comments:

The CII does not comment on the risk management of specific substances. The present CII comments relate to questions of principle regarding the REACH-OSH interface that are raised by the approach taken for the proposed Cobalt Salt Restriction. These questions fall into the remit of the CII's work.

CII comments:

The CII considers the restriction proposal applied to the five Cobalt Salts is not the appropriate policy instrument to manage risks posed by an exposure to chemicals in the work environment. The CII believes that the **proposed REACH restriction combined with a Reference Exposure Value (REV) circumvents the procedures foreseen by the legislator for the setting of binding Occupational Exposure Limits (OELs)**. While the proposed restriction aims at establishing a means of worker protection that is analogue to a Binding OEL, it may lead to confusion for those involved in the risk assessment and risk management in the workplace while not ensuring a higher level of safety for workers than the setting of a Binding OEL by means of the correct formal procedure would have. The CII regrets OELs were not considered as the best risk management option (RMO) and believes that the reasons given for this demonstrate severe misunderstandings of OSH legislation. We recommend the involvement of DG EMPL when assessing OSH directives and when workplace-specific risk management measures are considered. Our comments will focus on Section 2.2 of the Annex XV Restriction Report.

1. The Section of the Annex XV Report which provides arguments why in ECHA’s opinion an OEL under the CMD would not be the most appropriate risk management option reflects severe misunderstandings of OSH legislation:

- The Annex XV Report states that the “OEL would set the maximum exposure in a workplace without the need to identify RMMs and OCs that are most suitable for each individual company. [...] The fact that it does not consider frequency of the activities leading to exposure and consequently may require disproportionate risk management measures for activities that take place very rarely or would not be stringent enough for activities taking place on a continuous basis.”
- The CII observes that the Annex XV Restriction report does not take into account the thorough requirements for the site-specific determination and assessment of risk under Article 4 of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.¹ The directive specifically provides a list of factors to be taken into consideration, which cover the potential exposures in the workplace and offer the possibility for a risk assessment that reflects the real circumstances of use. These factors include the following:
 - their **hazardous properties**
 - information on safety and health that shall be provided by the supplier (e.g. the relevant safety data sheet in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (1))
 - the **level, type and duration of exposure**
 - the **circumstances of work involving such agents**, including their amount
 - any occupational exposure limit values or biological limit values established on the territory of the Member State in question
 - the effect of preventive measures taken or to be taken
 - where available, the conclusions to be drawn from any health surveillance already undertaken²
- As the above statements quoted from the Restriction Proposal document were erroneous, we ask ECHA to reconsider its conclusions on the suitability of setting OELs as an appropriate risk management measure for cobalt salts. Effectively, an OEL would ensure what the restriction aims to ensure, only in a way that is foreseen by the legislator and that is well understood by the individual companies that would have to comply.

2. The Annex XV Report wrongly claims that binding OELs under the CMD may provide a “false sense of safety” for non-threshold substances

- The legislator specifically developed the CMD for hazards with a non-threshold effect. Hence, the claim reads as if ECHA suggested that the legislator has adopted legislation that will instil workers with a “false sense of safety”. This is surely not ECHA’s intention and we believe this argument against OELs should be withdrawn.
- The Annex XV Report leaves it unclear what the advantage of a Restriction combined with a Reference Exposure Value would be in terms of preventing a “false sense of safety”. An OEL-entry for the substances under the CMD could explicitly indicate the non-threshold nature of the hazard.

¹ According to Article 1(3) of Council Directive 98/24/EC, for carcinogenic substances like Cobalt Salts the provisions of the Directive “shall apply without prejudice to more stringent and/or specific provisions in the [Carcinogens and Mutagens Directives]”.

² Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive with -in the meaning of Article 16(1) of Directive 89/391/EEC), Article 4, OJ EC No. L 393, p. 11-23.

3. The Annex XV Report raises the length of time for the development and implementation of a binding OEL as too long
 - We take this opportunity to recall that in 2015 the CII submitted proposals on how the setting of binding OELs could be sped up. We note that DG EMPL is currently reviewing the CMD and hope that our suggestions will be taken into consideration in this process.
 - The experience since 2015 demonstrates that OELs can be set within reasonable timelines when needed. The CII remains open to contribute to discussions on how the setting of OELs could become even faster.
 - The time needed for following the procedures foreseen by the legislator cannot be a reason for circumventing these procedures by disguising an OEL as a restriction combined with a Reference Exposure Value.
 - We would also like to recall that the first time a restriction proposal for the five cobalt restrictions was presented is more than 6 years ago.
4. The proposed restriction would likely create confusion in the mind of employers as to what procedures and measures need to be put in place
 - The CII would like to further highlight that a change of regulatory framework to impose restrictions combined with a REV instead of OELs is likely to create confusion in the mind of the employers in charge of applying the Risk Management Measures in the workplace as well as in the mind of the employees which are very familiar with legal binding OELs. Indeed, OSH and OELs have been used in the workplace for a long time; they are generally well-understood tools in companies' risk management and allow a swift implementation of the legislation. The OEL also imposes direct obligations to individual employers and constitute a reference for the elaboration of the risk management strategy in the workplace.
5. The proposed restriction may also lead to difficulties in terms of enforcement in some Member States, e.g. in Austria
 - In Member States with a clear distinction between chemical inspectors and inspectors responsible for enforcing workplace legislation, the restriction may lead to practical and legal difficulties. We understand that for example Austria may face difficulties in enforcing the restriction combined with a REV, whereas the enforcement of a binding OEL fits into the structure of its enforcement system. For example, to our understanding this was also the reason, why Austria voted against the NMP-restriction.
6. Concluding remarks
 - Considering that the nature of OELs and the now-newly developed and proposed option of restrictions combined with REVs are directly comparable, it appears that the use of restrictions with REVs are a circumvention of the procedure foreseen by the legislator for setting OELs. It avoids the hearing of Social Partners, the Impact Assessment by DG Employment and the legislative process and creates confusion for those who would have to implement the measures. It has been demonstrated in the past years that OELs can be set within reasonable timelines.
 - Considering that OSH and OELs cover risks from sources that do not fall under the scope of REACH (e.g. exposure stemming from articles used in the workplace and from process-related chemicals) and that OSH is well-known throughout the value chain, whereas REACH remains well-known rather at the registrant level, i.e. at the upper part of the supply chain, we would also note that it would seem important to ensure that statements on OSH and OELs by REACH-authorities remain accurate. Otherwise the EU runs the risk of discrediting an important pillar of its legislation established specifically to protect human health at the workplace.

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