Comments on the SEAC draft opinion and specific information requests

## Specific information requests

1. Some of the available information on impacts of different restriction options (e.g. in terms of current compliance with assessed exposure levels) is conflicting. Please provide any additional information regarding the impact (both in terms of human health benefits and sector-specific costs) of restriction options 1a and 1b (as amended by RAC).
2. The analysis of the derogation for animal feed sector in the Background document is based on limited information. Please provide information on the possible economic impacts of not derogating the animals feed sector, specifically for restriction options RO1a and RO1b (as amended by RAC). Please note that any information or claim needs to be substantiated by supporting evidence.
3. The Dossier Submitter proposes a 24 month transitional period before the restriction would become effective. Some information on the feasibility and its practicality was received in the first external consultation. However, the comments focused on the original restriction proposal RO1d by the Dossier Submitter, which has been amended by RAC. Please provide information on the practicality and impacts of the proposed transitional period for restriction options 1a and 1b (as amended by RAC).

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| **Ref.** | **Date/Name/Org.** | **Comments** |
| 452 | **Date/Time:** 2020/04/21 11:57  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Germany  **Company name confidential:** Yes | **Comments on the SEAC draft opinion:**  1 Cobalt salt is used as trace element in aqueous solution with no aerosol formation in the biopharmaceutical production at two sites for a very short exposure time (30 min) with very low amounts (< 5kg / year), knowing this may be not representative all over pharma industry and for sure not representative to all other Industry sectors. Workplace measurements showed that for our application both proposed restriction levels controlled and validated by OEL measurements are achievable.  Be aware that a binding OEL (bOEL) is not only better targeted, but the scope is also wider than a Restriction. An OEL is focused on workplaces and does cover significant more workers than covered by the Restriction of only 5 Cobalt salts. In Pharma Industry the OEL process is widely used and well trusted as an industry practice. The Restriction as proposed would lead to double regulation, considerable investment costs for compliance, even in areas where it is unnecessary, and ultimately it would put at risk the EU’s competitiveness in crucial industries like batteries and electionics. A bOEL would also cover exposure to all forms of cobalt in all EU workplaces.  Replacement of the Restriction Limit by an appropriate OEL with proportionate RMMs has following advantages:  • Process of Binding OEL is well understood and leads to acceptance in terms of implementation and enforcement.  • OEL ensures consistency across Member States.  • Process of OEL setting is expected to consider recent and new toxicological data in an appropriate way.  We support the position of the Cobalt Institute/Cobalt REACH Consortium and would urge you reject the Restriction in favour of a bOEL. |
| **Specific information 2:**  <redacted> is not affected from the animal feed sector |
| **Specific information 3:**  Due to the change from R01d to R01a and R01b respectively it is possible to maintain both options by using actual technical equipment. However, please take into account that our use is not representative to any other industry sector, because of the very short exposure time with very low amounts. |
| **SEAC Rapporteurs response:** |
| 456 | **Date/Time:** 2020/05/15 14:37  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Zentralverband Oberflächentechnik e.V.  **Org. country:**  Germany | **Comments on the SEAC draft opinion:**  The Zentralverband Oberflächentechnik e.V. (ZVO) understands the need to reduce and, if possible, avoid risks from chemicals from employees in companies, the environment and the population. Risk management measures have played an important role in surface technology for decades and there is extensive experience in the effectiveness of risk minimisation measures.  The ZVO is convinced that measures must be proportionate. In order to justify them, there must also be clear indications of the effectiveness of the measures envisaged.  The ZVO has examined the assessments by RAC and SEAC with interest and gives the following comments:  Table 4 shows the costs from the ECHA dossier as compared to the alternative impact assessment from industry during the first public consultation. Especially in the "relevant" case (because positively assessed by SEAC and RAC) R01b, the estimates differ by a factor of 8-1000! The data make it clear that the data base is insufficient to enable a reliable conclusion to be drawn about the economic effects.  Table 6 shows the benefits originally assumed from the ECHA dossier. It is striking that the maximum achievable effect according to ECHA can be at most one (!) prevented statistical cancer case per year. Since the derivation of the toxicological risks includes various safety factors and only takes statistical assumptions into account, the maximum possible effect can be classified as negligible or at least not observable.  In addition, the number of potentially affected companies or employees is also unclear (Table 10).  The expected benefits are quantified with amounts of less than € 1 to € 3.8 million / year (Tables 6 and 8), whereas the expected costs are a multiple thereof (Table 4).  The ZVO is convinced that both the uncertain database and the legitimate doubts about the proportionality of the planned measures at the present time do not allow a positive decision about a REACh restriction of the five cobalt salts. The ZVO would welcome a more precise analysis before this regulation can be pursued further. |
| **Specific information 1:**  We support the position of the Cobalt Institute/Cobalt REACH Consortium and would urge you reject the Restriction in favour of a bOEL. You might consider contacting their Government and Public Affairs Manager Mike Blakeney at mblakeney@cobaltinstitute.org for more information. |
| **SEAC Rapporteurs response:** |
| 467 | **Date/Time:** 2020/05/21 11:34  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Northvolt AB  **Org. country:**  Sweden  **Attachment:** | **Comments on the SEAC draft opinion:**  Northvolt consultation reply: draft opinion of the Committee of Socio-economic Analysis (SEAC) restricted use of Cobalt salts  Northvolt has carefully followed and monitored the RAC and SEAC processes and positions on restricted use of five (5) cobalt salts and would like to present three remarks for the EU Commission to take into consideration in the ongoing process to avoid severe and irreversible consequences for the European battery industry:  1. Occupational Exposure Limit is the most adequate policy tool for targeting cobalt salt hazardousness:  Considering regulatory options on regulating cobalt salt exposure, Northvolt believes Occupational Exposure Limits regulated within the Occupational Safety and Health legislations are the most accurate tools to limit negative effects from handling cobalt salts in the European market. The REACH regulation is not a proper policy tool and does not have proper evaluation processes in place to address the challenges in regulating workers health and safety. Importantly, OELs from OSH legislation are well-known for both companies and enforcement authorities. Whereas REACH matters are often handled by other experts with different sets of competence.  2. Socioeconomic analysis evaluating exposure levels must include battery industry data and impact assessment:  Socio-economic effects must evaluate social and economic impacts on the current and future battery industry, a new industrial category in Europe. Current industrial data in the analysis should, without delaying the regulatory process, be complemented with renewed data and figures from the battery industry and battery production to avoid unproportionate measures creating barriers for the expansion of the European battery industry. Indications from other battery stakeholders point at problems reaching levels corresponding to RO1b and RO1a, this means that the ambition to up-scale the battery industry in Europe might be severely affected.  3. Recognizing battery industry as a key technology provider in the European Green Deal reaching EU obligations under the Paris Agreement:  As the EU Commission has identified batteries as a key technology for Europe fulfilling its obligations under the Paris Agreement, the ongoing revision of the REACH regulation and the work performed by RAC, SEAC and ECHA must ensure a holistic perspective where ambitions to reach climate targets are not counteracted by extensive measures restricting chemical use. With battery production being a strategic asset for the European industry, Northvolt supports ambitious measures to protect workers against hazardous substances. It is important however that such protective measures are based on sound scientific evidence and constructed so that the aim and ambitions of the European Battery Alliance are still achievable in Europe. |
| **Specific information 1:**  Indications from the current battery industry in Europe points at unproportionate measures to reach the levels set by RO1b and RO1a and are concerned that these numbers have not been evaluated based on battery industry data. This could potentially mean that the ambition to up-scale the battery industry in Europe might be severely affected. Socioeconomic effects must evaluate social and economic impacts on the current and future battery industry, a new industrial category in Europe. Current industrial data in the analysis should, without delaying the regulatory process, be complemented with renewed data and figures from battery industry and battery production to avoid unproportionate measures creating barriers for the expansion of green technology.  Northvolt believes in ambitions workers protection. Considering regulatory options on regulating cobalt salt exposure, Northvolt believes Occupational Exposure Limits regulated within the Occupational Safety and Health legislations are the most accurate tools to limit negative effects from handling cobalt salts in the European Market. The REACH regulation is not a proper policy tool and does not have proper evaluation processes in place to address the challenges in regulating workers health and safety. Importantly, OELs from OSH legislation are well-known for both companies and enforcement authorities. Whereas REACH questions are often handled by other experts with different sets of competence. |
| **Specific information 3:**  If the proposed restriction limits were to be enforced without further assessment of the impacts on the battery industry, the restriction levels could potentially delay and impact the upscaling of the battery industry. The Gigafactories for battery production in Europe, currently being constructed, will start production within the next 24 months. If new sets of criteria and restrictions are enforced, this could potentially impact the design of these factories, forcing battery industry to rearrange processes or even redesign factory process steps. As Northvolt’s first Gigafactory Ett, one of the first Gigafactories in Europe, is not completed or operational today (start of production end-2021) the extent of the impact and the transitional period is hard to assess and fully understand. The restrictions and socioeconomic impact of the restrictions must be evaluated with regards to this aspect. Further assessments are needed.  As the EU Commission have appointed batteries as key technology for Europe fulfilling Europe’s obligations under the Paris Agreement the ongoing revision of the REACH regulation and the work performed by RAC, SEAC and ECHA must ensure a holistic perspective where the EU Commission’s ambition to reach climate targets are not counteracted by extensive measures restricting chemical use. Battery production being a strategic asset for European industry, Northvolt supports ambitious measures to protect workers against hazardous substances. It is important however that such protective measures are based on sound scientific evidence and constructed so that the aim and ambitions of the European Battery Alliance are still achievable in Europe. |
| **SEAC Rapporteurs response:** |
| 468 | **Date/Time:** 2020/05/21 14:05  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Cobalt Institute / Cobalt REACH Consortium  **Org. country:**  United Kingdom  **Attachment:** | **Comments on the SEAC draft opinion:**  The CoRC-CI, through our consultants eftec , have provided the SEAC with an updated and broadened analysis of the socio-economic impact of the proposed Restriction by triangulating three data sets (eftec 2019, EBRC 2020, RPA 2020) to produce a ‘best estimate’ of the total costs of compliance for each exposure limit value for the EU.  Please refer to the CoRC-CI response (submitted as a ZIP file) for full details. Relevant documents are: Joint Response Comments, Annex A and Annex B.  Our report concludes that:  • The costs of compliance for the REACH Restriction on the five cobalt salts are significantly higher than those reported by the dossier submitter.  • As a result, both proposed Restriction options (RO1a and RO1b) are not proportionate and likely highly unfavourable from a perspective of net benefits to society.  • An EU-wide binding OEL for cobalt and compounds (scope still to be decided) would be the more appropriate RMO.  • Further work will follow on quantified benefits, but our preliminary analysis shows that an OEL would provide significantly higher benefits than a Restriction, regardless of which exposure limit value is used (1, 10, or 20 µg/m3).  • The number of annual avoided cancers is below 1 under both Restriction options RO1a and RO1b.  • A transition period of 5 years may be more appropriate for the proposed Restriction in some cases. |
| **Specific information 1:**  Please refer to the CoRC-CI response. Relevant documents are: Joint Response Comments, Annex A and Annex B. |
| **Specific information 3:**  Please refer to the CoRC-CI response. Relevant documents are: Joint Response Comments, Annex A and Annex B. |
| **SEAC Rapporteurs response:** |
| 469 | **Date/Time:** 2020/05/22 12:45  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Tata Steel Europe  **Org. country:**  United Kingdom | **Comments on the SEAC draft opinion:**  Tata Steel Europe (TSE) is the second largest steel producer in Europe, with steelmaking in and manufacturing plants across The Netherlands, UK, Germany, France and Belgium. It manufactures a comprehensive range of steel products for the construction, automotive, engineering and packaging markets as well a number of specialist markets requiring advanced metallic coatings and electrical steels. The company has 12.4 million tonnes per year liquid steel capacity and in 2018-19 had a turnover of £7.07 billion. It employs more than 20,000 employees across its European locations.  The proposed cobalt salts restriction is of particular relevance to TSE as it uses cobalt sulphate and cobalt dichloride at a downstream processing site in Germany for the electrolytic plating of nickel-plated steel with cobalt.  The cobalt plated steel product is used for the casings of alkaline batteries. This is an environmentally important use of cobalt, as batteries using these casings have a substantially increased lifetime and output compared to other alkaline batteries.  TSE agrees with the opinion of SEAC that the proposed restriction is not the most appropriate EU wide measure to address the identified risk to workers from exposure to the five cobalt salts. Furthermore, TSE is in agreement with the Cobalt REACH Consortium-Cobalt Institute (CoRC-CI) that the introduction of a Binding Occupational Exposure Limit (bOEL) for cobalt would be the most appropriate EU wide measure to assess the identified risk.  The reasons for TSE’s position are, firstly, that implementation of the proposed restriction would lead to double regulation of worker exposure to cobalt. More than one cobalt exposure limit could be applicable in the same workplace, with these limits potentially applying to different forms of cobalt. Introduction of a bOEL would ensure consistent implementation and enforcement across EU Member States.  Secondly, a bOEL would apply to all sources of cobalt exposure in the workplace. This means that it would have a wider scope than the restriction, and would provide exposure protection to more workers across the EU. Thirdly, the OEL process is better tested and more trusted, with both industrial operators and regulators being more familiar with the use of OELs than the restriction as proposed. |
| **Specific information 1:**  TSE uses cobalt sulphate and cobalt dichloride at a downstream processing site in Germany for the electrolytic plating of nickel-plated steel with cobalt.  These two cobalt salts are maintained at a steady concentration in the electrolytic cells as a result of the electrochemical reactions occurring during the plating process. As cobalt metal is deposited on the steel strip, an equal quantity of cobalt ions enters the electrolytic solution through the dissolution of the cobalt anode. Consequently, the concentrations of the cobalt salts in the bath are held at a steady level, without any net production of the cobalt salts.  The cobalt plated steel product is used for the casings of alkaline batteries. This is an environmentally important use of cobalt, as its use in this application leads to a significant increase in the lifetime and output of alkaline batteries.  The impacts of the four different restriction options in ECHA’s proposal for a restriction on the use of five cobalt salts on TSE’s cobalt plating operations are quite different. In particular, TSE’s view is that the impacts of restriction options 1a and 1b would be significantly less than the impacts of restriction option 1d.  While restriction 1d would have a significant impact on all aspects of TSE’s cobalt electroplating operations, TSE would not expect restriction options 1a and 1b to have a significant impact on the day to day operations of the cobalt electroplating process. This conclusion is based on the levels of occupational exposure to cobalt in air in the vicinity of the cobalt plating line and electrolyte baths, which are consistently lower than the German occupational exposure limits of 5 µg Co/m3 (tolerable) and 0.5 µg Co/m3 (acceptable).  TSE would however expect restriction options 1a and 1b to have an impact on the periodic maintenance activities carried out on TSE’s cobalt electroplating process, in particular on the cleaning, reconditioning and refilling of the fabric covered cobalt anodes used in the electrolytic bath. This work takes around 6 hours and is carried out every other week. A residue of cobalt sulphate and cobalt dichloride that has dried onto the fabric can be a potential source of worker exposure to cobalt salts during this maintenance activity.  Worker exposure to cobalt salts during this work is currently maintained at acceptably low levels through the use of personal protective equipment (PPE). In order to be satisfied that the proposed Reference Exposure Levels for restriction options 1a and 1b would be met without the need to use PPE during these maintenance activities, there would however be a need to review and potentially improve the safe working procedures for this activity.  This would include reviewing the need for engineering controls to reduce the concentration of cobalt in air in the vicinity of this activity by e.g. increasing the air exchange rate in the room in which this activity takes place. This could potentially incur costs of around €50K, e.g. to purchase an air exchange system and a system to clean the exhausted air from the workshop. |
| **Specific information 3:**  The proposed transitional period of 24 months before the restriction would become effective would be sufficient for TSE to make the necessary improvements at this site. This would give sufficient time to carry out the work needed, including e.g. further exposure monitoring, in order to develop the most cost-effective solution to meet these requirements. |
| **SEAC Rapporteurs response:** |
| 473 | **Date/Time:** 2020/05/25 10:33  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  European Semiconductor Industry Association  **Org. country:**  Belgium | **Comments on the SEAC draft opinion:**  In terms of the protection of workers, it is believed that an EU wide binding OEL limit value would be a more appropriate manner in how to regulate cobalt salts than within the REACH framework as it would directly target the potential risk area (worker exposure) to be managed.  Risk management measures are implemented in semiconductor manufacturing environment which protects employees through the operation of a closed system so there is no direct exposure to where the cobalt salts can be used. Stringent risk mitigation measures are in place as standard, such as closed systems. Any potential risk is typically eliminated and controlled through the application of enclosed manufacturing equipment. Alongside this, automated chemical delivery systems are installed to create a barrier between workers and the process and protect against chemical and physical hazards in the work environment. Employees receive regular training's on the hazards linked to the use of these hazardous substances and the preventive measures to be adopted and maintained as standard. The semiconductor manufacturing industry sector employs stringent risk management measures and safety practices to prevent substance release at a manufacturing process level thus preventing worker exposure. |
| **Specific information 3:**  The propose transition period of 24 months would most likely be appropriate for option 1a or 1b but not for dossier submitter proposal as commented previously. |
| **SEAC Rapporteurs response:** |
| 474 | **Date/Time:** 2020/05/25 10:38  **Type:** MemberState  **Country:**  Germany | **Comments on the SEAC draft opinion:**  With regard to the proposed measure, the DE CA shares the opinion of SEAC, who is unsure whether the modifications of the restriction proposal suggested by RAC is the best measure. In its opinion, SEAC criticizes that the alternative derivation of a BOELV has not been sufficiently considered and assessed. The DE CA believes that the derivation of a BOELV for cobalt and equally effective inorganic divalent cobalt substances seems to be a more appropriate and expedient solution which can cover almost all cobalt compounds.  Additionally the DE CA has some comments to the Draft SEAC-Opinion considering occupational safety and health aspects:  1) RAC considers the restriction proposal as "most appropriate union-wide measure" if instead of the "reference exposure value" derived from the dossier submitter (DS;ECHA) of 0.01µg/m³, a "limit value of 1µg Co/m³ (8h TWA inhalable fraction) and 0.5µg Co/m³ (8h TWA respirable fraction) is set for the considered five Co-salts. Additionally, a BOELV for Co and its inorganic compounds shall be derived.  2) SEAC does NOT consider the original restriction as the "most appropriate union-wide measure" and expresses his doubts whether the modified proposal is the best regulatory option due to many concerns about proportionality, lack of evaluation of other measures (e.g. BOELV) and the consideration of only five salts.  With regard to the SEAC opinion, the traceability of the risk assessment is particularly difficult for us. The DE CA raised several questions during the public consultation of the Annex XV restriction dossier on the toxicological derivation of the reference values. However, the current opinion of the RAC for a corresponding assessment was not available for us. The DE CA can only assume that a new dose-response relationship with a breaking-point is included in this justification, but the DE CA was unable to examine the following aspects in detail:  1. the justification for the new dose-response relationship with breaking point (In the background document on the ECHA website under B.4.5 Dose-response relationship the original DRR and breaking point as a term does not appear)  2. the derivation of the 8h-TWA  3. the distinction of the limit values in inhalable fraction and respirable fraction (probably assuming 50% as respirable) and  4. the new calculation of cancer cases.  Additionally a justification for the assumption of cancer cases is missing, see p. 31: Citation: "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.” (probably based on the assumption that the respirable fraction is about 50%). The DE CA had commented during the public consultation of the Annex XV restriction dossier last year that systemic tumors in the low-dose range are unlikely. There appears to be some additional data on non-cancer effects such as asthma and skin sensitization (which were not considered in the original restriction proposal from the DS), however, the amount of data is too small to perform a reliable quantitative assessment. |
| **SEAC Rapporteurs response:** |
| 476 | **Date/Time:** 2020/05/25 11:37  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  FEFAC  **Org. country:**  Belgium  **Attachment:**    <redacted>  **Privacy comment:**  Commercial interest | **Comments on the SEAC draft opinion:**  FEFAC supports the exemption of feed use from the proposed restrictions considering that other measures are already in place under sectorial legislation and additional restrictions would be superfluous. |
| **Specific information 2:**  There is no alternative to the supplementation of feed with cobalt for ruminants, horses and animal species with hindgut fermentation (rabbits) as cobalt is an essential component for the synthesis of Vitamin B12 by these animals. EFSA stresses in its opinions released in 2009 and 20121 also that, for a potential replacement of cobalt by vitamin B12, there are not enough data to evaluate the consequences on health and economic performance of animals under field conditions.  Evaluating the costs of the two options as far as feed is concerned is difficult due to the many different scenarios. A legal framework is in place since 2014, establishing risk management measures to reduce workers’ and professional users’ exposure to cobalt:  - Introduction on the market of a diluted coated form of cobalt carbonate, reducing drastically the exposure of all workers at the level of premix & mineral feed plants, compound feed mills and farmers ;  - Obligation to deliver in a non-powder form feed containing cobalt salts other than coated cobalt carbonate to farmers.  - Measures required at the level of companies handling cobalt salts and premixtures highly concentrated in cobalt to reduce workers’ exposure.  The vast majority of the cobalt salts used in the feed chain nowadays is coated cobalt carbonate. Imposing restrictions on the top of the risk management measures would be superfluous. |
| **SEAC Rapporteurs response:** |
| 478 | **Date/Time:** 2020/05/25 12:12  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Merck KGaA  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  Please refer to section IV |
| **SEAC Rapporteurs response:** |
| 480 | **Date/Time:** 2020/05/25 12:20  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Catalysts Europe  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  Please see |
| **Specific information 1:**  Catalysts Europe members have contributed to the public consultation response prepared by Cobalt Institute. Please see the responses provided by Cobalt Institute. |
| **Specific information 3:**  Catalysts Europe members have contributed to the public consultation response prepared by Cobalt Institute. Please see the responses provided by Cobalt Institute. |
| **SEAC Rapporteurs response:** |
| 481 | **Date/Time:** 2020/05/25 12:28  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  RECHARGE aisbl  **Org. country:**  Belgium  **Attachment:** | **Comments on the SEAC draft opinion:**  RECHARGE is the advanced rechargeable and lithium batteries association in Europe. We contributed to the previous ECHA consultations.  The vast majority of advanced rechargeable battery chemistries are based on the use of cobalt and cobalt compounds as important materials to produce high-energy active (cathode) materials. These battery technologies are going to play a major role in a renewables-based electricity  generation and electric vehicles market. We therefore want to provide information on the impact of the proposed measures on our industry and the CO2 reduction ambitions of the European Union:  In their study on cobalt compounds, the Risk Assessment Committee (RAC) and Socio-Economic Analysis Committee (SEAC) have proposed several options for workers’ exposure values (RO1a to RO1d). RECHARGE is pleased that SEAC chose not to take forward RO1c and RO1d. We noted previously that RO1d was not technically feasible. For the following reasons, RECHARGE cannot support RO1a and RO1b as effective risk management measures:  • The REACH restriction approach is not equivalent to a binding OEL (bOEL), even if the exposure thresholds were similar. Contrary to bOELs, the scope of the restriction is limited to the identified compound(s) and hence does not represent an effective, overarching prevention measure.  • Predictable and streamlined regulation is an important prerequisite for industry investment in batteries and its supply chains. The proposed restriction could have the unintended consequence of disincentivizing long-term investments in the EU battery sector or making the EU battery sector uncompetitive globally.  • The double regulation associated with the implementation of both cobalt salts restrictions (REACH) and bOELs (OSH) is expected to result in higher costs for the battery industry. For detailed information on cost related to cobalt REACH restrictions and bOELs, please see the positions of the Cobalt Institute.  WHY AN OEL WOULD BE BETTER:  A binding Occupational Exposure Limit, even if set at the same level as a Restriction, offers several advantages:  • All workers exposed to cobalt and cobalt compounds in the workplace would be covered, not just those using the 5 cobalt salts.  • Companies would make one set of investments to meet the requirements of the OEL, rather than making one set for the Restriction and another for a future OEL, but without knowing the OEL requirements until after they are required to have implemented the REACH Restriction.  • It would be simpler to monitor because industry would measure total cobalt rather than trying to measure concentrations of cobalt salts in environments using a range of cobalt compounds.  • It would spread fixed investment costs across more workers at a wider range of facilities, making the costs and benefits more proportionate.  RECOMMENDATIONS FOR A BETTER CHEMICALS MANAGEMENT LEGISLATION:  1. RECHARGE calls upon the European Union to harmonize the implementation of the different pieces of chemicals management legislation. Risk-control must be at the center of the EU chemicals strategy.  2. RECHARGE supports the Better Regulation principle, opting for the regulation that has proven to best protect workers and the environment from potential risks. In the case of cobalt compounds, risks are associated with the manufacturing and end-of-life treatment of batteries but not with their use. Under Better Regulation, the reference regulation would therefore be the Occupational Safety and Health Framework Directive.  3. RECHARGE supports the implementation of OELs as outlined by the Occupational Safety and Health Framework Directive as the most effective mean to protect workers and the environment from battery substances, such as cobalt.  CONCLUSION:  Because the potential risks associated with substances used in batteries are limited to the professional workplace, RECHARGE promotes the implementation of harmonized Binding Occupational Exposure Limits under the Occupational Safety and Health Framework Directive as the most effective chemicals management measure. In contrary, restrictions under REACH will hamper technological advancements and will jeopardize continued investments in a European battery value chain. |
| **Specific information 1:**  Please see attachment |
| **SEAC Rapporteurs response:** |
| 483 | **Date/Time:** 2020/05/25 13:49  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Polish Chamber of Chemical Industry  **Org. country:**  Poland  **Attachment:** | **Comments on the SEAC draft opinion:**  Polish Chamber of Chemical Industry concern about the proposed Restriction on cobalt salts (through an 8-hour time-weighted average or 8h TWA) and would ask to consider assessing if adopting a binding Occupational Exposure Limit (bOEL) is a more appropriate Risk Management Option (RMO).  We attached our position paper and we kindly request the presented comments and suggestions be taken into account in the entire consultation process. |
| **SEAC Rapporteurs response:** |
| 485 | **Date/Time:** 2020/05/25 15:13  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  Aluminium federation  **Org. country:**  United Kingdom | **Comments on the SEAC draft opinion:**  Alfed have been in consultation with the uk users of Cobalt Sulphate in the field of anodising and the Cobalt institute  We believe that the proposed reference exposure limits are too low for a substance that has no proven carcinogenic evidence , and although we would wish to work with the Eu Commission on developing an acceptable threshold we believe that more time is needed to ascertain appropriate testing processes and also to better understand the quantity of cobalt sulphate actually present in the anodic film |
| **Specific information 1:**  A number of anodisers have been using cobalt as a colouring media in anodic films for mainly architectural process in the United Kingdom and related markets. The cobalt electro-colouring, Anolok process was developed and patented by Alcan several decades ago and results in a market leading anodic film colouration with exceptional UV and corrosion resistance, it is therefore specified for many architecturally projects.  The process uses cobalt sulphate, which is soluble in water, so enables cobalt metal to be electro-deposited into the pores of the anodised coat, electro-colouring the anodic film.  The REACH proposals on Cobalt sulphate threaten users of the Anolok process including both United Anodisers and Hydro with significant revenue and job losses  Therefore, it is of utmost importance to understand the mechanisms of exposure to the cobalt sulphate in the process and final anodic coat. Reviewing the documentation, we there are two areas of concern:  1, Exposure to Cobalt Sulphate on the production process  Our understanding of the proposed exposure levels is that the lower of the two levels, in an industrial environment will be difficult to determine. The Cobalt institute have proposed a maximum exposure level of 0.1g/ m³, which we believe is a manageable and measurable target in an industrial environment. Practical experience suggests that the crystalline cobalt sulphate in use with limited tank addition times will fall below the 0.1mg/m³ level but has to be confirmed. we would agree with the statement from SEAC:- SEAC in its draft opinion suggests a more acceptable binding occupational exposure limit (bOEL). We feel that this would be much easier to measure and to comply with.  2, Inclusion of Cobalt Sulphate in the Anodic film  We have approached specialist laboratories to establish a standardised test for cobalt sulphate and to determine the exact form of the cobalt itself within the anodic file, but as yet no laboratory can offer a standard test to measure at the levels proposed. Therefore, we request additional time to review and develop a test methodology for both Cobalt and Cobalt sulphate in the anodic film. Given that the electro-coloured anodic coating is hot water sealed after electrocoating, the perceived evidence is that cobalt must have been deposited as a metal and is therefore insoluble, so will be outside the scope of the proposed reach limitations  We therefore propose an additional review time of 12 months to allow quantitative analysis of the deposited cobalt and to fully understand the economic implications of the proposed new limits |
| **SEAC Rapporteurs response:** |
| 489 | **Date/Time:** 2020/05/25 16:35  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  Freeport Cobalt OY  **Org. country:**  Finland  **Attachment:**  <redacted>  **Privacy comment:**  Business Confidential Information | **Comments on the SEAC draft opinion:**  Freeport Cobalt is a manufacturer of several of these 5 Cobalt salts. We also act as Lead Registrant for Cobalt sulphate and Cobalt diacetate. Freeport Cobalt is an active member of Cobalt REACH Consortia (CoRC) and Cobalt Institute (CI). Freeport Cobalt references to CoRC-CI joint response to this public consultation.  Freeport Cobalt would like to highlight that the costs of compliance for the REACH restriction are far higher than suggested by the dossier submitter. E.g. estimated costs of 10 EUR/a (3000 EUR/a for 300 worker exposed) for restriction level RO1a is a fraction of annual costs for just respiratory protection equiment (RPE).  The proposed Restriction which is based on health data from animal testing is contradictury to epidemilogical data which have been collected and published over last years and which are showing that an proposed OEL of 20 µg/m³ is safe for human and doesn’t cause additional cancer cases. Freeport Cobalt support the proposal of CoRC and CI to implement a EU-wide binding OEL (BOEL) rather than a restriction of the cobalt salts.  Socioeconomic impacts on the restriction could be severe for Europe. Cobalt, which is a critical raw material for Europe, is used e.g. in batteries and the restriction would have a negative impact on battery manufacturing in Europe. This could also have an effect on European targets to reduce carbon dioxide emissions. |
| **Specific information 1:**  Please see annex |
| **Specific information 3:**  Please see annex |
| **SEAC Rapporteurs response:** |
| 494 | **Date/Time:** 2020/05/25 18:03  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  WirtschaftsVereinigung Metalle  **Org. country:**  Germany  **Attachment:** | **Comments on the SEAC draft opinion:**  • 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 already early 2019 strongly recommended to mandate RAC evaluating Cobalt and its inorganic compounds towards a BOELV amending the CMD. The tripartite WPC is - to my knowledge - still convinced that a BOELV would be the most targeted and effective risk management option to protect workers exposed to Cobalt and Cobalt compounds.  • WVMetalle agrees with SEAC considering that the restriction initially proposed by the Dossier Submitter is not the most appropriate EU-wide measure. SEAC already recog-nized that an EU-wide regulatory action like an BOELV 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. SEAC stressed as well that a BOELV within the OSH regulatory framework is an effective risk management option for the five cobalt salts under consid-eration as well as for other cobalt compounds, which are not covered by the proposed restriction.  • According to preliminary feedback from affected WVMetalle member companies the costs of compliance for the proposed REACH Restriction on the five cobalt salts are high-er than those reported, especially when considering option RO1b.  • It is to be noted here that the German exposure risk relationship for cobalt and its com-pounds is currently under review. Background for this review is the intention (a) to con-sider to a larger degree the RAC philosophy as recently established and used for the re-spective assessments for nickel, benzene and acrylonitrile and (b) to integrate recent human data and experimental animal data with respect to ERR quantification. We sug-gest considering the outcome of this discussion within your process as the discussion is already well advanced within German AGS subcommittee III (hazard assessment). |
| **Specific information 1:**  German technical Rule “TRGS 561: Activities involving carcinogenic metals and their com-pounds” (https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRGS/TRGS-561.html) applies to activities involving the exposure to carcinogenic metals and their inorganic compounds of category 1A or 1B. It therefore also refers to the German exposure risk relationship for to cobalt metal and inorganic cobalt compounds and contains as a basis for the risk management an overview of the exposure situation at certain workplaces including hard metal production and galvanizing. It is important to note that the main objective of this TRGS is to achieve an exposure level below the tolerable concentration, i.e. now 5 µg Cobalt /m³ for the respirable fraction. |
| **Specific information 2:**  As already stated within the General Comment section an EU-wide binding OEL for cobalt and compounds would be the more appropriate RMO. All workers exposed to cobalt and com-pounds in the workplace would be covered. This would include the animal feed sector where a relevant use of Cobalt compounds is to be recognized. A specific part of this area is addressed e.g. in German technical rule TRGS 529 on uses within Biogas-Plants  (https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/TRGS-529.html) which shows that specific occupational measures must be implemented to achieve save conditions for the use of this carcinogenic substances as essential trace elements. |
| **Specific information 3:**  As already said, 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. Anyway, also a BOELV must be checked with respect to the technical and socioeconomic feasibility. Depending on the proposed value a transition period of 5 years may be appropriate in some cases. |
| **SEAC Rapporteurs response:** |
| 500 | **Date/Time:** 2020/05/25 20:56  **Type:** BehalfOfAnOrganisation  **Org. type:**  Company  **Org. name:**  <redacted>  **Org. country:**  Netherlands  **Company name confidential:** Yes  **Attachment:**  <redacted> | **Comments on the SEAC draft opinion:**  No comments. Please see attachment. |
| **SEAC Rapporteurs response:** |
| 505 | **Date/Time:** 2020/05/25 12:49  **Type:** BehalfOfAnOrganisation  **Org. type:**  Industry or trade association  **Org. name:**  The Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI), France Horlogerie and others  **Org. country:**  France  **Attachment:** | **Comments on the SEAC draft opinion:**  Please find our comments in the attached document. Full organisation name: The Jewellery-making, Gold Jewellery-making and Silversmiths, Gift Makers and Decorative Arts Industries Trade Association (BOCI), France Horlogerie – Time and Microtechnics Industries (FHITM), the French Union of Jewellery, Silverware, Gems and Pearls (UFBJOP) and Francéclat, the French Watch, Clock, Jewellery, Silverware and Tableware Committee |
| **SEAC Rapporteurs response:** |