

Cobalt and Cobalt-containing Substances – Public Comments Summary Table

Comments on the draft screening assessment report for cobalt and cobalt-containing substances to be addressed as part of the Chemicals Management Plan (CMP) were submitted by AirBoss Rubber Compounding, BASF, Canadian Paints and Coatings Association (CPCA), Canadian Vehicle Manufacturers’ Association (CVMA), Cobalt Development Institute (CDI), Dow Chemicals, Forest Products Association Canada (FPAC), Hudbay Minerals, Mining Association of Canada (MAC), Sudbury Smelter and Nickle Rim South Mine Glencore, Teck Resources limited, Umicore, and Vale.

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| Methodology |  |  |
|             | The overall methodology used to determine ecological effects of cobalt in the assessment, including the use of chronic data and the species sensitivity distribution (SSD) derivation, is appropriate and consistent with the state-of-the-science. It also reflects our actual knowledge on the potential environmental effects associated with cobalt.   | Noted.   |
|             | The Normal statistical model, one of the four model types of the SSD Master software program for freshwater species found in the Ecological Effects section, does not fit the data well from a statistical point of view, especially in the lower quartile of the SSD. This results in the value of the estimated distribution at the 5 <sup>th</sup> percentile (i.e., HC 5) being considerably lower than the data used. In addition, a Biotic Ligand Model (BLM) was provided that considers the effect of pH and dissolved organic carbon (DOC) along with water hardness on cobalt bioavailability. The predicted no-effect concentration (PNEC) in the draft screening assessment is more conservative than the BLM HC 5. Also, the slopes are very similar, meaning that hardness plays the dominant role in the BLM response. It is suggested that the BLM and alternative modelling approaches (i.e., Gumbel or BurrliOZ) be used as a better fit for the data. | The SSD Master program that runs the four model types (Normal, Logistic, Extreme Value, and Gumbel) was used for the screening assessment. While the Gumbel model may visually appear to fit the data slightly better at the lower tail, the Normal model provided the best fit of the models tested upon visual inspection, lowest levels of statistical variability (residuals), even distribution of residuals, lowest confidence interval spread and best significance of the Anderson-Darling Statistic test (A2) = 0.284 (p< 0.05). The corrections for the influence of additional abiotic factors (e.g., pH, DOC) on cobalt toxicity in surface waters were not included in this screening assessment because water hardness is the key factor in organism response (as demonstrated in the analysis). |
|             | Several datasets have hardness characteristics that are outside the range of values used to develop the PNEC (52 – 396 mg/L). Therefore, the PNECs developed in these situations may over or under estimate toxicity. In some sites, worst case hardness assumptions have been made with no data.  | A linear extrapolation is not possible outside the hardness modifying model range. The relationship between toxicity and hardness is unknown at these hardness levels.   |
|             | Consideration of hardness characteristics and BLM could have an effect on the screening assessment outcomes, as some of the calculated risk quotients (RQs) are marginally over 1. For instance, consideration of other key modifying factors, such as DOC and pH (BLM) would further affect the resulting PNEC values, and hence, RQs.  | A linear extrapolation with the actual hardness model would still show RQs above 1 for these areas. In addition, for most sites of concern, RQs are elevated and the additional toxicity modifying factors (e.g., BLM) might only have resulted in minor variations in PNEC values. The BLM approach was therefore not used in the screening assessment.   |
|             | The large database on cobalt concentrations in human blood and urine is a valuable element of the CMP report. It was used in combination with intake estimates to verify a recently developed toxicokinetic mathematical model. It is  | Noted.   |

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|                                   | thought that this is the first time that the model has been used and verified on such a large dataset. This gives confidence that the model can be used for estimation of blood levels, urine levels and “internal exposure” to cobalt in other contexts.  |   |
|                                   | Where calculated RQ is equal to 1.0, the RQ is not >1 and therefore should not be shaded.  | RQs not greater than one are no longer shaded.  |
| Information sources and data used | The updated statistical treatment of the Quebec <i>Attestations d’assainissement</i> data should be used, rather than its original 2006 compilation. Based on industry’s analysis of these data, only one pulp and paper facility in Canada would be above the PNEC.   | The updated statistical treatment for mill effluent data provided shows three facilities with concentrations of concern (RQ>1). In the draft screening assessment, concentrations associated with the 3 facilities had a low sample size that prevented the identification of outliers.   |
|                                   | Several of the RQs in Table 17 found in Environment Canada (2013g <sup>1</sup> ) are marginally over 1. If extra data could be contributed to the PEC characterization, for several data-rich cases, the use of percentile calculations or a 95UCLM (95% upper confidence limit of the mean) could be used and several sites may be found to have an RQ of less than 1.  | The risk characterization of a particular data-rich site based on a single data point or statistical metric (e.g., 95UCLM) is not appropriate nor recommended. The entire distribution including all data points is considered. A dataset for which the calculated 95UCLM indicates a RQ <1 may still show RQ>1 on a considerable portion of the distribution (up to approximately 25-30%). In addition, RQs at or close to one may also be indicative of potential concern.                    |
|                                   | In the supporting documentation of Environment Canada, 2013g <sup>1</sup> , Tables 9 and 17 used an old, small dataset. It is not clear why these were used, when the same locations report under the <i>Metal Mining Effluent Regulations</i> (MMER) and Environmental Effects Monitoring (EEM) program. There is concern that the particular selection of data resulted in an over-statement of risk associated with cobalt. | A subset of EEM sites were selected based on mining operations that report releases of cobalt to the National Pollutant Release Inventory (NPRI). The screening assessment used the most recent EEM data available. Data covering multiple years may capture economic cycle and variance in releases. The EEM program is used in the screening assessment as an important line of evidence to determine toxicity for mines under the <i>Canadian Environmental Protection Act, 1999</i> (CEPA). |

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|       | In the Environment Canada (2013g <sup>1</sup> ) supporting documentation, Sites 1-10 (EEM) are not specifically identifiable and, in many cases, have limited datasets (N = 1-3). Predicted environmental concentration (PEC) characterization based on such limited datasets is potentially not reflective of actual environmental conditions. The data for these sites could not be verified, nor could additional relevant data be provided.   | Selection of test and control sites is predetermined in the study design—a regulatory requirement under the MMER. While some of the datasets used had low sample size, these individual sites were considered in the overall weight of evidence. Most sites affected by effluent releases have cobalt concentrations exceeding the PNEC (RQ>1), and percentiles were calculated if the number of observations (n) exceeded 11. Some of the descriptive statistics were recalculated for PECs, and new data added where appropriate.   |
|       | Text in the screening assessment on genotoxicity should be revised to capture the recent review of new and old cobalt genotoxicity data.  | The text has been revised in the screening assessment to reflect recent review of genotoxicity data.  |
|       | Some of the referenced ecotoxicity studies do not exhibit the level of quality acceptable to the scientific community for use in the screening assessment. In particular, six studies were evaluated and deemed unacceptable. Reasons for rejection were provided. Ecotoxicity data were also reviewed, and suggested revisions and reporting errors were noted.  | Upon further review, two of the six studies are no longer included in the screening assessment. The other four studies were found to be acceptable according to the standards used. Robust Study Summary (RSS) forms were completed to ensure reliability and acceptability of scientific standards. For the studies cited in the development of environmental quality guidelines, the Canadian Council of Ministers of the Environment (CCME) protocol criteria was followed and demonstrated the four studies to be acceptable for data of secondary quality. The screening assessment is updated to include recalculation of effects data to consider new EC10s calculated using the TRAP software and correction of errors in data reporting. |
|       | Further detail on the essentiality of cobalt, its presence in vitamin B <sub>12</sub> , and its addition to food under the <i>Food and Drug Regulations</i> should be included in the screening assessment. In theory cobalt levels in blood are above the limit of detection due its presence vitamin B12. Similarly, the screening assessment should reflect that vitamin B <sub>12</sub> does not contribute to any potential negative health effects of free cobalt, but has beneficial health effects. | Additional information was added to the screening assessment to clarify the presence of cobalt in vitamin B <sub>12</sub> , and health benefit of vitamin B <sub>12</sub> for humans. Also, it has clarified in the screening assessment that cobalt in vitamin B <sub>12</sub> does not release as free cobalt and therefore, does not contribute to negative health effects.  |
|       | Regarding surface waters of Ontario exposure data (supporting documentation, Environment Canada 2013g <sup>1</sup> ) the resolution of actual exposure levels is limited due to the suggested detection limit for cobalt release, which is elevated relative to the PNEC range. Further, the calculation of the minimum, mean and   | Revisions were made to incorporate non-detect values at half of the detection limit in the descriptive statistics for the Ontario exposure data in the supporting documentation (Environment and Climate Change Canada (ECCC) 2016d) and in the screening assessment. The Ontario exposure data often indicate elevated   |

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|       | percentiles values should incorporate non-detect values using ½ Method Detection Limit (MDL).   | episodic concentrations that are higher than the detection limit.  |
|       | Exposure data from Yukon surface waters (supporting documentation, Environment Canada 2013g <sup>1</sup> ) show that none of the identified areas contain active, operating mines. Some of the areas are geologically enriched and thus naturally release cobalt into the environment. The text should include natural mineralization and the reference to operational mines should be removed.   | Where applicable, data and information were adjusted to better reflect the particular sites and potential sources of cobalt. Sites associated with elevated natural cobalt levels are noted.   |
|       | The detection limit for cobalt in the Ontario database (Table 14, supporting documentation, Environment Canada 2013g <sup>1</sup> ) is not clearly reported and limits the resolution of actual exposure levels for some locations.   | More information on detection limits is now provided in the ECCC 2016d supporting document. The data indicates episodic concentrations that are higher than the detection limit.   |
|       | Porcupine River (identified in Environment Canada 2013g <sup>1</sup> , Table 14) has seen over 100 years of municipal and industrial inputs, and environmental concentrations may not reflect active discharges. Concentrations could be seasonal cycling in the environment between sediment sources and sinks.  | Porcupine River data does not seem to indicate a seasonal link related to cobalt concentrations and depth of the watercourse. Data available indicates that most of the cobalt likely originates from mining. Data gathered from sites in this area inform Environment and Climate Change Canada’s Environmental Effects Monitoring program (EEM). |
|       | Page 26, table 14, line 7, Supporting Documentation, Environment Canada 2013g <sup>1</sup> . Farr Creek is downstream of Crosswise Lake, which has significant tailings deposits related to historic mining activities. These may have acid mine drainage. No active mining appears to be in the vicinity of this site. This site does not appear to be monitored any longer (2005 data only).  | The screening assessment and the related supporting documentation are updated to mention that there are tailings deposits in Farr Creek from historical mining activities.   |
|       | Page 26, table 14, line 12, Supporting Documentation, Environment Canada 2013g <sup>1</sup> The range of values cited and the mean value calculated appear to be biased high, based on exclusion of non-detect data (18 out of 27 data points are non-detect). The minimum data point in the database is -0.14 µg/L (non-detect), but could be listed as < 1.5 µg/L. Emery Creek is the reference creek for an operating facilities mine site EEM program. Additional data from operator indicate a mean value of 0.8 µg/L (N = 5; range of 0.52 – 1.08 µg/L). These data support the statement above re: need to revise the PEC data calculations. | One recently submitted data point from the operator was not added to the screening assessment because concentrations will vary from year to year and the site is already considered in the EEM program. To be consistent, only Provincial Water Quality Monitoring Network reported concentrations were kept for this data set.                    |
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|  | More recent inhalation epidemiology studies with relevant lowest-observed-adverse-effects-concentration (LOAEC) and no-observed-adverse-effects-concentration (NOAEC) should be used in the screening assessment as the critical endpoint for inhalation toxicity of cobalt.   | The noted epidemiology studies were included in the screening assessment and considered during the end-point selection process.   |
|  | The test substance should be clearly indicated in the description of the two-year inhalation study on rats and mice.   | The sentence has been edited in the screening assessment to show the name of the test substance.  |
|  |  |   |
| <b>Confidential Business Information</b> | ECCC seems to have access to data not accessible to industries or Non Governmental Organizations (NGOs) who may want to analyze the documents and references further. For example, not all unpublished data were accessible to review the calculations of RQs. Thus, there is concern that some relevant data regarding other potential sources were not used or published, specifically the results of monitoring undertaken by ECCC of municipal wastewater treatment effluent and receiving waters, which can contribute significantly to metal release in the environment. These data should be made accessible. | Any person providing information to the Minister of the Environment under CEPA may request that information to be treated as confidential. The information can then be disclosed only when certain statutory criteria are met – see ss. 313 to 318 of the Act. As such, confidential information on facility locations of specific municipal wastewater treatment plants (WWTPs) could not be disclosed. Reports from 27 WWTPs across Canada provided information on wastewater, sludge and biosolids in the Ecological Exposure Section and no risk was identified for aquatic organisms.              |
| <b>Environmental Fate</b>                | Cobalt salts used in automotive refinish coatings are not expected to be released into the environment. Their function is to help paint dry on automobiles and through this process they become incorporated into the coating.   | It was concluded that, based on current uses and potential for exposure risks to aquatic organisms are not expected to be a concern for cobalt salts used in automotive refinish coatings.  |
|  | The current manufacturing and control process used in rubber manufacturing will not allow any chemicals to enter the environment. The very minimal amount released to the environment would be through disposal of cobalt product bags in the landfill. Not all paints and products containing cobalt are bioavailable when released to the environment.   | The quantified releases of cobalt-containing substances considered from these rubber sector were generally small (rubber sector) or very small (paints and coatings sector), and it was concluded that risks to the environment are not expected for these sectors.   |
|  | There are no direct releases of effluents expected from the majority of companies manufacturing industrial and architectural paint. Once powdered materials are incorporated into a paint matrix, there is no potential for release or exposure of cobalt substances.  | Potential releases of cobalt throughout the life-cycle of cobalt-containing substances were considered for a variety of sectors, including the paints and coatings sector. Due to a lack of available data emission factors from the Organization for Economic Co-operation and Development (OECD) Emission Scenarios Documents were used for these sectors. Further, powder manipulation may lead to releases. It was also determined that use of powdered materials containing cobalt may lead to limited environmental releases due to wet cleaning of plant surfaces and the exterior of equipment. |

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|                     | In the section on Sources, Uses and Releases to the Environment, under the subsection on Disposal, it should be recognized that cobalt will not leach from a landfill if it is encapsulated or trapped in a very stable matrix.   | A statement to this effect has been added to the Sources, Uses and Releases section.   |
|                     | The reporting and citation of NPRI data on cobalt in the screening assessment are ambiguous. Please specify if quantities of cobalt are for cobalt the element (normalized for total cobalt) or the total from the cobalt compounds. Further, NPRI data have a certain degree of uncertainty in their accuracy. This should be noted, considering the complexity of data reporting for facilities.                                | Reported cobalt data quantities were clarified and most were also presented as elemental cobalt in the screening assessment. Complexity and uncertainty related to reported NPRI data was noted. The year of data reporting is specified and the date of database consultation is referenced.  |
|                     | Some NPRI data seem incorrect. Also, the role of the threshold for cobalt of manufactured, processed or otherwise used (MPO) concentration should be included.  | The screening assessment reflects NPRI data at the time of access. The final screening assessment integrates more recent data submitted by facilities to the NPRI as of August 2015 for the reporting year 2011. Additions have been made to clarify the MPO concentration threshold in the screening assessment.  |
|                     | The screening assessment should note that diffuse sources such as agriculture are not required to report to the NPRI, yet may constitute significant sources of entry of metals into the aquatic environment.   | To the extent possible, all incidental or diffuse sources of cobalt released to the environment deemed significant are considered in the screening assessment (e.g. fossil fuel combustion, agriculture), even though certain releases may not be reported to the NPRI. No risk associated with the agricultural sector was identified.  |
| Ecological Exposure | <p>In Tables 4 through 8 in the Sector-specific Exposure Scenarios section, the column label of PEC range is questioned, since the data in the table are actual data and not a predicted value.</p> <p>The natural background concentrations of cobalt should be understood and then removed from the risk calculation. In this way, the anthropogenic contribution to the environmental risk is appropriately accounted for.</p> | <p>All concentrations considered in these tables, whether measured or modeled, are called PECs as they reflect potential concentrations in the receiving environment.</p> <p>In the screening assessment a total approach (rather than an added approach) was used as the background is included for both the PECs and PNECs. As such, <math>RQ = PEC_{total}/PNEC_{total}</math> (rather than <math>RQ = PEC_{added}/PNEC_{added}</math>). It was not possible to derive a <math>PNEC_{added}</math> because test results on background levels of the metal are usually not reported or below the detection limit. They are not subtracted from exposure values because excluding the background in the PEC would return inconsistent <math>PEC_{added}/PNEC_{total}</math> ratios that may underestimate risk.</p> |

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|                           | The current screening assessment uses a national water hardness average and a dilution factor of 10 for the receiving environment in calculating PECs. It is recommended to use either subsector effluent averages with national water hardness and dilution factors, or mill-specific effluent data with mill-receiving, environment-specific water hardness and dilution factors. Based on analysis of available information, both approaches demonstrate that the pulp and paper sector is below the PNEC. | The exposure scenarios were refined using specific hardness values rather than worst-case values. However, facility-specific dilution factors were not used. The dilution factor (DF) of a waterbody can vary by several orders of magnitude depending on flow events and velocities. The approach used was to limit the maximum dilution factor to a value of 10 to better reflect conditions near the discharge point when determining direct effects endpoints. This is based on the assumption that full dilution does not occur immediately upon release to large waterbodies. Revised RQs have been determined using site-specific hardness. Risks to aquatic organisms at a few pulp and paper facilities are still present. |
|                           | The screening assessment indicates that the forestry sector as a whole has a potential impact on the environment. It is recommended that ECCC use the available data to identify more accurately which sub-sector, or facility(ies) of the pulp and paper sector pose a risk. It is further recommended that ECCC clearly indicate this rather than flagging an entire sector as being of concern.  | Three facilities were identified as being of concern due to RQ results. These facilities represent a significant but small proportion (approximately 5%) of all facilities for which data was considered. While it does not seem to be a generalized trend, some specific facilities may release high concentrations of cobalt. The cobalt concentrations in the effluent are likely influenced by the type of pulping process and the use of cobalt-containing chemicals. The final screening assessment focuses on specific facilities where concerns related to cobalt releases are noted rather than the entire sector. Statements to this effect were added to the screening assessment.                                       |
|                           | To the extent that the context of any elevated cobalt concentrations in waters at sites considered in the screening assessment can be identified, it appears that the elevated concentrations arise from causes other than current releases in regulated effluent from metal mines or smelters.   | A reduction in the number of locations impacted by releases of effluents containing cobalt was noted in the new information. However, a significant number of sites are still affected by active mines, smelters or refineries.   |
|                           | In the Synopsis, the statement that “the bioaccumulation potential of cobalt is relatively low, yet it may still lead to levels causing harm to sensitive species at body concentrations higher than required for essentiality” is incorrect.   | The statement, supported by scientific literature, is an accurate summary of the conclusion for the bioaccumulation section.  |
| <b>Human Health Risks</b> | Polycythemia patients with 10-fold higher blood cobalt concentrations did not show any cardiac problems. This is an indication that the beer drinkers were extremely sensitive to cardiomyopathy (chronic disease of the heart muscle).   | Noted.  |
|                           | The text in the screening assessment should be changed to reflect that cobalt and cobalt sulfide are “currently” classified as category 3 mutagens because  | The sentence was reworded to reflect the chronology of the EU mutagenicity classification.  |



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|   | new data do not provide convincing evidence that soluble cobalt salts are mutagenic in the bacterial reverse mutations test systems.  |   |
|   | The new U.S. National Toxicity Program (NTP) conclusion (of December 2014) on the carcinogenicity of cobalt metal should be included in the screening assessment.   | The December 2014 NTP conclusion on cobalt metal was added to the screening assessment.   |
|   | Depending on the solubility, the toxicity of cobalt substances varies.  | The solubility of cobalt substances was considered in the screening assessment.   |
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| <b>Ecological Risk Characterization</b> | The frequency, magnitude and cause of RQs exceeding 1 from mining and base metals smelting and refining are overstated in the screening assessment, and should be reviewed based on input provided. The fact that cobalt-related problems were not identified during monitoring is indirect evidence of this. Cobalt concentrations are not currently problematic at the vast majority of metal and non-metal mines. The highest risk estimates identified likely represent site-specific matters (i.e., abandoned mine sites), not issues on a national scale. | Where applicable, the interpretation and description of the frequency and magnitude of elevated exposure concentrations were adjusted to better reflect the characterization of sites based on potential sources of cobalt and the potential for ecological effects due to high environmental concentrations. For example, sites with more elevated natural backgrounds due to mineral seeps were noted. Acid drainage (AD) from inactive or closed sites and/or tailings was also considered. Based on new information provided as part of the public comment period, there is a reduction in sites noted as being affected by active mines, smelters or refineries. However, a significant number of affected sites in water and sediments remain. Regarding the magnitude of risks for active mines, according to the EEM data, half to more than half of the sites examined in these media were found to have cobalt concentrations exceeding the PNEC. In soil, data points on cobalt concentrations in the top layer (0-5cm) were used and are consistent with relatively recent deposition. However, percentiles of data where RQ is greater than 1 for soil, is less important than for data on the sediments and water compartments. |

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|       |   | Cobalt concentrations in the receiving environment often exceeded PNECs by a large margin. Cobalt may also accumulate above concentrations of concern because it persists in the environment.  |
|       | For a more meaningful ecological risk characterization, the risks should concern individual sites over a meaningful area of the local receiving environment, similar to the approach used for human health considerations.  | Several lines of evidence were considered in the assessment and contributed to the ecological conclusion (i.e. RQs, proportion of locations or areas impacted, biological diversity, stability of the food chain, and persistence). A high number of sites - half to more than half of EEM mining sector sites for water and sediments compartments - had concentrations exceeding the PNEC. On average, the sites were impacted at a minimum of 3.5 km downstream the final discharge point and in total represent a very large impacted area. In addition, data indicate that metal releases from smelters and refineries may be detected 100 km from the source (Environment Canada, Health Canada 2001). Cobalt persists in the environment and may accumulate in soils and sediments. However, bioavailability of cobalt may decrease over time due to natural processes. Based on the weight of evidence in the assessment it is concluded that ecological risks from cobalt are occurring or may occur. |
|       | The final paragraph of the Summary and Conclusion of Ecological Risk Characterization should include a statement regarding the ageing of cobalt in soil and sediments.  | The following sentence was added: "...the bioavailability of cobalt in these compartments may be partially reduced by ageing processes."   |
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|       | The conclusions of a substance-specific assessment should take precedence over a group screening assessment. Thus, the four cobalt substances assessed under the earlier CMP Challenge should be excluded from the CEPA Schedule 1 grouping and, in turn, from any risk management action derived from the current grouping assessment. | In the Challenge phase of the CMP, the four substances were found to be non-toxic considering individual releases but potential concern was identified from combined exposure. This screening assessment of cobalt and cobalt-containing substances under the Substance Grouping Initiative of the CMP considered combined releases, including of the four substances. Cobalt and soluble cobalt-containing substances were determined to be of concern and proposed for addition to Schedule 1. As such, cobalt or any soluble cobalt compounds could be subject to risk management.  |

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|            | The phrase “cobalt and cobalt-containing substances” qualifies more substances than the 50 cobalt-containing substances identified in the draft assessment. It is suggested that the Government of Canada documents concerning substances should clearly outline the specific substances to be included, using Chemical Abstracts Service Registry Numbers (CAS RNs). Understanding in the regulated community of a designation of toxic under CEPA on the group as a whole is limited. The grouping approach should be explained in the screening assessment.  | The screening assessment is not limited to consideration of the 50 substances that met categorization criteria because any soluble cobalt compound released to the environment above levels of concern could be subject to risk management. Presence of cobalt in environmental media, food, or products on the Canadian market was also considered. Clarification of the grouping approach is provided in the Risk Management Approach document on the scope and implication of the toxic conclusion and proposed addition to Schedule 1 under CEPA.  |
| Conclusion | The conclusion to the draft assessment should include a definitive statement on Persistence, Bioaccumulation and Inherent Toxicity (PBiT) in order to complete the PBiT presentation and as good form.  | The screening assessment conclusion was updated to include a statement on persistence and bioaccumulation under the <i>Persistence and Bioaccumulation Regulations</i> .   |
|            | Cobalt and/or some of its compounds may meet the criteria under paragraph 64(a) of CEPA, but do not meet the criteria under paragraphs 64(b) and 64(c) of CEPA. However, cobalt compounds have solubility varying across a wide range and do not all contribute equally to environmental concentrations and potential ecological risks.   | Acknowledged.  |
|            | The draft screening assessment is based on the cobalt moiety. Certain substances within the assessment are recognized to be “sparingly soluble,” while others are not soluble. Thus not all cobalt substances should be determined as toxic under CEPA. In addition, not all cobalt compounds contribute to elevated concentrations in the environment due to differences in how certain cobalt substances are produced, used, recycled. Declaring “cobalt and cobalt-containing substances” toxic under CEPA and adding them to Schedule 1 (Toxic Substances List) of CEPA could negatively impact the value of certain cobalt substances. It could make trade difficult and reduce the likelihood of their removal from the environment. This may be contrary to the intent of CEPA The CEPA Schedule 1 group designation should reflect this and exclude these substances by using alternative wording, such as “dissolved cobalt in water” or, alternatively, “cobalt or cobalt-containing substances that are soluble and dissociate.” | Not all cobalt-containing substances will contribute to the CEPA toxic finding equally. However, the intent is not to conduct a systematic substance-by-substance analysis but rather to identify the potential for risk from exposure to the cobalt moiety. The screening assessment conclusion was revised to integrate elements of solubility and better define the ecological concern.<br><br>The proposed addition of “cobalt and its compounds” to the Toxic Substance List has been revised to “cobalt and soluble cobalt compounds” to better reflect the scope of the proposed risk management actions. |
|            | The draft screening assessment for cobalt has inappropriately assessed all aquatic cobalt measurements only for chronic risk rather than distinguishing   | The screening assessment focused on chronic effects data because these provide a more sensitive indicator of potential for harm for long-term  |

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|                 | between acute and chronic risk on the appropriate local and national scales. This should be corrected and the draft finding that cobalt is toxic under CEPA should be reconsidered.  | exposures, which are most relevant for environmental exposure associated with this moiety. Releases to the environment from sectors considered in the screening assessment are on-going or chronic. Acute toxicity scenarios are typically used for intermittent releases or spills which were not relevant in this screening assessment.  |
|                 | Municipalities should be the primary targets of risk management approaches as they constitute the main sources of releases of cobalt to the environment.   | There is no reported use of cobalt substances in publicly owned wastewater treatment plants (WWTPs) (EC and HC, 2014). A high concentration of cobalt was noted in one WWTP but the facility’s releases of cobalt are now managed to an extent where current releases should be below levels of concern. Large releases of cobalt at other WWTPs were not identified. <b>Current releases are expected to be below the level of concern.</b> |
| Risk Management | To help stakeholders better understand the scope and implication of the proposed listing of “cobalt and its compounds” on Schedule 1 of CEPA, notably any risk management that may follow, it is recommended to provide more clarity on the proposed nomenclature. To do so, it is suggested that the entry on Schedule 1 be very specific, and if possible, list specific cobalt-containing substances by CAS RNs. It is also suggested that the federal government publish guidance material to provide clarification. | The CAS RNs provided in the screening assessment are for reference purposes and do not represent all substances covered within the screening assessment. Cobalt or any soluble cobalt compound that contributes to measurements of cobalt in the environment above levels of concern is potentially subject to risk management. The Government of Canada has provided additional information in the Risk Management Approach.                |
|                 | Instead of changing the NPRI reporting threshold for “cobalt (and its compounds),” which, as configured today, is expected to provide sufficient information on the releases of cobalt, it is suggested to incorporate any additional reporting into the requirements of the risk management instruments. Any change to the NPRI should not be detrimental to the operation of the inventory, must follow due process, and be fully justified with credible analysis.  | The NPRI is a key resource that is used to identify pollution prevention priorities and support the risk management of chemicals. However, the current NPRI threshold does not provide an appropriate level of coverage of these facilities based on expected releases. The proposal to lower the NPRI threshold for “cobalt (and its compounds)” was subject to public consultation through the NPRI Consultation and Engagement Framework. |
|                 | Cobalt may be present in a number of products in an unwanted fashion (i.e., incidentally or naturally). It is suggested for regulatory certainty that exemptions be considered (i.e., products containing cobalt below a <i>de minimis</i> concentration).   | The screening assessment considers the incidental or natural presence of cobalt in raw materials, products, and in the receiving environment. At this time, ECCC and HC are not proposing to take actions for products containing cobalt or cobalt-containing substances because they were not identified as exposure sources of concern to the environment or human health.   |

| Topic | Summarized/Rolled-up Comment  | Summarized/Rolled- up Response   |
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|       | The conclusions in the Risk Management Scope for Cobalt and its Compounds do not appropriately consider the cause-effect chain. While acid drainage may lead to elevated concentrations of cobalt, the risk management solution is to prevent acid drainage, rather than to regulate cobalt concentrations in effluent.   | <p>In the screening assessment, liquid effluents from the final discharge point of active mining operations are identified as the main anthropogenic sources of cobalt to the aquatic environment in the vicinity of mining installations or tailings. However, the apportionment of the risk posed by process effluents versus acid mine drainage in the receiving environment is uncertain. Therefore, exclusively addressing acid mine drainage may not be sufficient to protect the environment.</p> <p>The current proposal is to amend Schedule 5 of the Metal Mining Effluent Regulations with the intent to collect data to better understand cobalt releases from metal mines and determine if it should be added to Schedule 4 in the future.”</p> |
|       | Ecological risks should be related to human activities, and those that are not present nationally should be addressed by provincial or territorial jurisdictions.   | While protection of the environment is a responsibility that is shared by federal, provincial, territorial and Aboriginal governments, the federal Minister of the Environment and Climate Change and the Minister of Health jointly assess and manage risks associated with toxic substances under the Act and may propose regulation(s) or instrument(s) to prevent or control releases and risks of exposure of any substance on Schedule 1 to the Act.   |
|       | While site-specific requirements for cobalt may be appropriate in a few rare circumstances (in which case local regulators should consider including cobalt in their operating permits, informed by site-specific Water Quality Objectives), evidence does not support the need for national baseline regulations. The Risk Management Scope should recognize this. | When a substance is added to Schedule 1 to the Act, the Government of Canada may propose to put in place a variety of risk management instruments, as appropriate in the circumstances. Water quality guidelines may be used by provincial authorities as voluntary instrument when issuing, amending, or renewing permits related to wastewater management. These are proposed as complimentary instruments.  |
|       | It is not clear that cobalt is elevated in the environment, nationally, at spatially relevant levels in the aquatic environment that would warrant the designation of cobalt as toxic under CEPA. For this reason, formal risk management planning, including the consideration of cobalt for inclusion in Schedule 4 of the MMER, is premature and inappropriate.  | The screening assessment identified a few industrial activities to be a cause for concern for cobalt. The metal mining sector is a major source of cobalt released to the environment. The Risk Management Approach proposes to amend Schedule 5 of the MMER to better understand anthropogenic release of cobalt to water from metal mining and determine if cobalt should be added to Schedule 4 in the future. The Government of Canada intends to extensively consult with Canadians and affected stakeholders when developing these risk  |

| Topic | Summarized/Rolled-up Comment  | Summarized/Rolled- up Response  |
|-------|---|---|
|       |   | management measures.  |
| Other | Include in the scope of the assessment that 50 cobalt substances were assessed. | Appendix 1 of the screening assessment provides a list of cobalt-containing substances identified for further action during categorization and included in the screening assessment. The screening assessment considers combined exposure to the cobalt moiety, from natural or anthropogenic sources, whether it is present in environmental media (e.g., water, sediment, soil, air), food or products. The screening assessment thereby considers cobalt in its elemental form, cobalt-containing substances and cobalt released in dissolved, solid or particulate form. As such, substances considered in this screening assessment are not limited to the 50 cobalt substances. All substances that have the potential to dissolve, dissociate and/or degrade to release cobalt through various transformation pathways can potentially contribute to the exposure of living organisms to bioavailable forms of cobalt. |
|       |   |   |
|       | The text on human health risk characterization could be edited for clarity.     | Changes were made to the text of human health risk characterization to address the comment.   |

1: This document is now referred to as ECCC (2016d)

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