

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in this table as submitted by the webform. Please note that the comments displayed below may have been accompanied by attachments which are not published in this table.

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Substance name: cobalt
CAS number: 7440-48-4
EC number: 231-158-0
Dossier submitter: Netherlands

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam	Masan Resources	Company-Downstream user	1
Comment received				
<p>The cobalt industry (CDI and CoRC), based on scientific research, have previously decided the following self-classifications for cobalt metal:</p> <ul style="list-style-type: none">• Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%• Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification• No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM). <p>Despite decades of research there are only a few alternatives to cobalt and it cannot be replaced in most hardmetal applications because it is the highest performing alternative. If the cobalt hazard classification proposal is accepted by ECHA, the socio-economic impact to the hardmetal business may include investing in further lowering (or eliminate) the occupational exposure, generating an increase of production cost potentially affecting the competitiveness of the industry. In addition, possible future authorisation and restriction affecting cobalt in hardmetal applications would lead to less productivity for manufacturing industry relying on hardmetal tools to operate.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
16.02.2017	United Kingdom	ICoNiChem Widnes Ltd	Company-Downstream user	2
Comment received				
<p>ICoNiChem Widnes Ltd is a UK based manufacturer of cobalt salts and solutions. ICoNiChem is member of the Cobalt Development Institute (CDI) and member of the Cobalt REACH Consortium (CoRC).</p>				

We fully support the technical position of the CDI/CoRC as outlined in the message to industrial stakeholders regarding the NL CLH proposal on Cobalt metal (Jan 2017)

With regard to the CLH proposal for cobalt metal ICoNiChem disagrees with the findings of the report submitted by NL Competent Authorities. We as a company feel that recent GLP compliant studies have been ignored in favor of older non-compliant studies. We support the classification below based on the available literature and studies;

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Canada	Sherritt International Corporation	Company-Manufacturer	3

Comment received

Sherritt International Corporation (Sherritt) strongly supports the Cobalt Development Institute/Cobalt Reach Consortium (CDI/CoRC) technical comments, and has provided input to those comments as well as into the CoRC/CDI Joint Response comments. Sherritt also strongly supports the comments on the Dutch Proposal submitted by the Nickel Institute, as well as the input submitted by Team Stainless; both of those organizations also support the CDI/CoRC technical comments.

The hydrometallurgical process employed by Sherritt to produce nickel does not allow the removal of cobalt to levels lower than are currently being achieved (on average roughly 0.09% with the current feed mix); Sherritt believes it is impossible to achieve cobalt levels below 0.01% in the nickel products using the existing process. If process modifications to achieve nickel product below 0.01% cobalt content were technically feasible, the revised process (additional process steps) would certainly require more energy and reagent input, increasing the greenhouse gas footprint of the refinery as well as increasing more local environmental impacts. Major technical modifications costing, at a minimum, tens of millions of euros, would be anticipated; such changes are not economically viable.

A Sherritt mortality study with a minimum follow-up period of 25 years corroborates the CDI/CoRC position that cobalt is not a high potency carcinogen by all routes of exposure, and that its carcinogenic mode of action must have a threshold.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment References 1 and 2 Sherritt Epidemiology Reports.7z

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Germany	<confidential>	Company-Manufacturer	4

Comment received

The Gühring Group is one of the world's leading manufacturer of precision tools, which supplies the mature original equipment manufacturer (OEM), aerospace and machine construction.

In order to provide our complete production chain, the Gühring Group owns two subsidiaries which are responsible for cemented carbide production. These are G-Elit Präzisionswerkzeug GmbH (Berlin, Germany) and Konrad Fridrichs GmbH Co.KG (Kulmbach, Germany). The first named company employs about 450 employees, the latter 150 employees. Except of these 600 employees, there are another 6.000 employees who are working for the Gühring Group.

We actively support the arguments of the „Cobalt REACH Consortium Ltd. – CoCR“ and the „Cobalt Development Institute – CDI“ (in cooperation with Eurometaux).

Due to the planned new classification we would be completely forced to change our production as well as our logistic processes in order to reach the intended limits. This will be continued in the adjustment of our packaging units and labelling. Summarised it means a very high investment for our company.

Additionally to above-mentioned investments we have recurring measurement costs in order to proof the compliance of the new limits.

The costs of disposal and recycling of waste are another expense factor.

The now focused limits of the CLH-Proposal are based on animal experimentations which generally can´t be directly transformed on human beings. Furthermore the critical point of the metal powder inhalation study (NTP, 2014) is that a much higher dose was used than in the Co sulphate study.

A lot of European Countries, for example the United Kingdom and Austria, set their limits higher than the CLH-Proposal.

Due to absorption of the higher production costs to our finished product there will be generated a competitive disadvantage of the European industry on the global market. Based on our higher prices and our higher handling costs the increasing prices will continue to the downstream industries (for example grinding of cemented carbide rods = more expensive disposal of cemented carbide dust)

The increased recycling costs will call the recycling circle in question.

Another central point concerns the irreplaceability of cobalt in the hard metal industry through other materials to reach the same quality in the near future. This was proven in several studies with different organisations.

The planned changes of the limits would lead to a plenty adaption of different regulations (for example REACH).

Moreover there´s a risk, that in future limitations in this area will be made without further researches. As we could see in the past we have to fear that similar regulations will be also extended to other products.

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Belgium	European Powder Metallurgy Association	Industry or trade association	5
Comment received				
<p>Powder metallurgy (PM) can be defined as the process of transforming powders materials into a desired shape or form with requested properties by different processes. The European market is currently large and has a turnover of 10 Billion euros with powder production exceeding 200,000 tonnes. Many sectors with the powder manufacturing industry will be affected by the CLH proposal for cobalt including Ferrous Structural and Functional PM (Press & Sinter), Metal Injection Moulding (MIM), Cold and Hot Isostatic Pressing (CIP and HIP), Metal Additive Manufacturing (AM or 3D Printing), Wet powder spraying, (dry) machining and Hard Metals (represented also by ITIA).</p> <p>Powder makers will be heavily impacted by the CLH proposal for cobalt metal. There will be an increase in costs for manufacturing powder products as well as a financial impact stemming from the reappraisal by some customer groups of the risks associated with use of the product, damaging sales. There is currently a wide variety of steel and stainless steel powders that are manufactured with a cobalt concentration between 0.01% and 0.1%. The very low SCL of 0.01% will therefore cause a negative classification of these products. For powder maker's downstream, the range of alloys handled in compliance with SDS will be extended since the level of Co is lower than 0.1% and they are not obliged to declare it</p>				

(Section 3 in SDS) at the current state. Powder makers are also sometimes requested by customers to produce tailored powder alloys with pure Co powder inside. Industry has already invested heavily in plants and equipment for safe handling of materials and these changes will cause further costs upwards of €1-2million per production site. Additional running cost such as energy costs, PPE and consumables will cost a further ca.€300,000 per year.

Cobalt being perceived as such a potent carcinogen will harm developing applications that utilise cobalt containing alloys. For example, 3D printing techniques used in medical devices, tooling and aerospace will face larger costs in handling cobalt products in their processes and disposal in their waste streams. If costs to guarantee safe use of Co are too high the production of Co-containing articles may be stopped. Probably the demand for Co-containing articles could be stopped from customer side (reputation -green products). Most cobalt containing alloys have specific qualities that cannot be replicated by other materials. Examples include Cobalt as binder for the Hardmetals Industry, alloys for dental and medical devices where cobalt confers biocompatibility and in aerospace alloys where cobalt confers excellent creep strength. Cobalt is also vital in making tool steel which unique properties are used in 3d printing, in permanent magnetic powders and in controlled expansion alloys such as Kovar.

Finally, the recycling of cobalt containing products above the SCL of 0.01% will be negatively impacted. The new classification for cobalt will cause contracted recyclers to charge higher costs to manufactures due to their reluctance of handling hazardous goods. Reprocessing of rejected material will also not be possible leading to a higher volume within the waste stream increasing cost for industry and having a negative impact on the circular economy. For internal recycling work place dust measurements will have to be intensified in order to check if the exposure is within the given limits. Additional, mainly technical RMM will have to be implemented if required. Depending on costs for additional RMM companies might stop internal in-house recycling.

The EPMA supports the technical position of the CDI/CoRC and has also provided input towards the preparation of the CoRC/CDI Joint Response comments.

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	United States		Individual	6
Comment received				
<p>I, Gary Marsh, as principal investigator of a large, ongoing, international epidemiology study of hardmetal workers exposed to tungsten carbide with cobalt binder, I believe that the ECHA should be aware of the objectives and design of our study and its anticipated publication dates. The following is a brief overview of the background and features of our study.</p> <p>In 2006, IARC labeled WC with a cobalt binder (WCCo) as a probable human carcinogen based on limited evidence in humans and sufficient evidence in animals that WCCo acted as a lung carcinogen. Metallic Co, with or without WCCo, remains a research priority for IARC for clarifying its potential carcinogenicity in humans (Ward et al. 2010, http://ehp.niehs.nih.gov/0901828/). In 2008, the American Conference of Governmental Industrial Hygienists (ACGIH) classified Co as A3 (confirmed animal carcinogen with unknown relevance to humans), but did not classify WCCo. A review of the scientific basis for the IARC decision revealed significant limitations in the primary occupational epidemiologic studies of French and Swedish workers on which it was based (Hogstedt and Alexandersson 1990, Lasfargues, et al. 1995, Moulin, et al. 1998, Wild, et al. 2000). To address these limitations, the International Tungsten Industry Association (ITIA) initiated an international, occupational epidemiologic investigation of hardmetal workers in 2011.</p>				

Earlier, the Pennsylvania Department of Health supported preliminary data collection efforts. The study was designed to overcome the methodological limitations of earlier studies by including a comprehensive, quantitative exposure assessment conducted by the University of Illinois at Chicago (UIC), country-specific cohort mortality studies in the US, Austria, Germany, Sweden and UK using both external and internal comparisons, direct (nested case-control study) or indirect statistical methods to adjust lung cancer risk estimates for potential confounding by smoking, and a pooled analysis of the international cohort data. The University of Pittsburgh serves as the coordinating center for the overall international study and is directing the pooled analysis.

The study includes 33,393 workers from 3 companies and 17 manufacturing sites (8 U.S., 3 German, 3 Swedish, 2 UK, and 1 Austrian), each independently conducted under the direction of country-specific occupational epidemiology experts (Austria-Hanns Moshhammer; Germany: Peter Morfeld and Mei Yong; Sweden: Hakan Westberg and Magnus Svartengren; UK: Damien McElvenny; US: Gary Marsh and Nurtan Esmen). The international study is larger, more robust and more definitive than any hardmetal epidemiology study done to date.

The primary research objectives of the international study are:

1. To investigate the total and cause-specific mortality experience of current and former hardmetal workers potentially exposed to W, Co and/or Ni at multiple US and European (EU) industrial sites that produced WCo, as compared with the experience of the corresponding national and local populations, with adjustment for potential confounding factors and with emphasis on lung cancer.
2. To characterize the past and current working environment of the study members from the sites relative to process, job title/function and potential for W, Co and/or Ni exposure.
3. To determine the relationship between level and duration of W, Co and/or Ni exposure and mortality from lung cancer with analytic adjustment to the extent possible for potential co-exposures, including tobacco-smoking habits, via direct internal adjustment with a nested case-control study or indirect adjustment using statistical methods.
4. To provide a framework for ongoing mortality surveillance of hardmetal workers.

Scientific articles describing the epidemiological results of the country specific studies, the exposure assessment and results of the pooled cohort data analysis will appear in 2017 as a series of online articles in the Journal of Occupational and Environmental Medicine.

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	Germany	<confidential>	Company-Manufacturer	7
Comment received				
we do agree with the CDI position				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	SSAB AB	Company-Downstream user	8
Comment received				
SSAB AB's position on the proposed Harmonised Classification and Labelling (CLH) for Cobalt Metal				
As a Swedish company within the steel sector we produce high strength steel that originate mainly from iron ore and partly from scrap. SSAB is a global company with production units in North America, Sweden and Finland. SSAB is a member of EUROFER and Jernkontoret and other national and international steel associations. As a company in Sweden we urge				

the Swedish authorities to reconsider the classification because of the weak scientific evidence.

Reference to other submissions

SSAB fully supports the technical position submitted by the Cobalt Development Institute / Cobalt Reach Consortium, as outlined in: "Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017".

As a company member of the European Steel Association (EUROFER) SSAB support the "EUROFER Carbon Steel Position Paper on the Harmonised Classification and labelling (CLH) for Cobalt Metal"

As SSAB depend on stainless steel in for example several chemical processes, SSAB also support the Team Stainless Position Paper for the Public Submission on the Harmonized Classification of Cobalt Metal.

SSAB is also a member in Jernkontoret, the Swedish Steel Producers Association and also a user of hardmetal and other special steels, therefore SSAB also support the arguments submitted by the Swedish Steel Producers Association (Jernkontoret).

SSAB support the current classification on cobalt, Skin Sens. 1; H317, Resp. Sens. 1; H334, Aquatic Chronic 4; H413, and the industries self classification as Carc 1B, H350i, inhalation route only.

Cobalt is present in iron ore and carbon steel as an impurity

In the production of steel in Sweden and Finland, SSAB use iron ore as the main source for iron. The iron ore used at SSAB may contain up to 0.1% cobalt probably as oxides. Of course the form in which the cobalt occur in the iron ore needs to be determined, if possible. SSAB will participate in investigating the form of cobalt in the iron ore pellets. Nevertheless the cobalt within the iron ore is added to the blast furnace and follows the iron to the steelworks where it also follows in the steel smelt. We believe most iron ore contain similar amount of cobalt, as it stay in the iron when melted. SSAB intend to participate in the examination of the amounts of cobalt in different iron ores. If most iron ores contain up to 0.1% cobalt, then all carbon steel needs to be classified as Carc 1B; H350 all routes, SCL 0.01% if this proposal become mandatory in CLP.

SSAB also depends on scrap as a source of iron. Probably all scrap known today contains cobalt above 0.1 %. If the proposed classification comes true, all scrap will be classified as dangerous and all carbon steel containing trace element of Co will be classified as Carc 1B, H350 all routes, SCL 0.01%.

Steel is a special type of mixture

All studies referred to in the classification proposal are to very clean cobalt powder or other similarly clean cobalt salts or other clean cobalt compounds. Then these different substances are administered orally, dermally and by inhalation and also by injection route. These substances referred to in the studies are not the least comparable to for example solid steels containing cobalt as an alloying element. The actual form of cobalt tested on the laboratory animals make a big different. Also the route of exposure is critical and depends on how the human body is functioning. For example the vitamin B12 is essential to the human body and is based on cobalt. The scientific evidence for the proposed classification must be understood as weak.

Historical view of iron and steel

In Sweden the iron and steel industry have historical roots back to the beginning of the 16-century. Iron ores are found in many mines in Sweden. Steel have been used for several hundred years, and before this time as iron. If this cobalt trace element has been a major problem from the beginning of the industrialization, the problem should have been recognized a long time ago.

Some other examples of unexpected and perhaps unintended consequences

For example would steel in general be allowed in the Swedish system called BASTA, and steels will therefore not be the first choice in the construction of buildings.

This classification could also affect the classification in the IMSBC code for the shipping of scrap in bulk on boats, and for example result in more expensive shipping costs.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment SSAB STATEMENT DOCUMENT on Cobalt Feb 2017.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	ASD Europe	Industry or trade association	9

Comment received

Having considered the material presented by the Cobalt Development Institute (CDI), ASD notes that this data provides a significant contribution to the Netherlands study on Cobalt classification. We understand that there seems to be a disagreement on potential for carcinogenicity of the substance depending on the various forms of Cobalt (inhalable vs. massive in particular). As an industry which has significant dependence on Cobalt alloys, we note that misclassification could result in application of impractical and unnecessary risk management measures which could have substantial effects on our industry. Consequently we urge that ECHA and member states closely analyse the CDI presented data.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Freeport Cobalt Oy	Company-Manufacturer	10

Comment received

Freeport Cobalt Oy acts as lead registrant for the cobalt substance. The company is also an active member of The Cobalt Development Institute and of The Cobalt REACH Consortium.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	ACEA	Industry or trade association	11

Comment received

Our comments are attached as below.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170224-Cobalt-CLP_ACEA-final.pdf

Date	Country	Organisation	Type of Organisation	Comment
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				number
24.02.2017	France	International Chromium Development Association	Industry or trade association	12

Comment received

It is likely that all commercially produced high carbon ferrochrome (main product from global chromium industry) contains more than 0.01% cobalt, the average is more or less 0,04% as per our review of various analysis used for commercial purposes.

Cobalt in ferrochrome is not intentionally added. If this proposal on SCL of 0.01% limit is adopted this will have significant consequences for European ferrochrome industry and it's downstream users in the Stainless steel and High-alloy steel industries.

In particular, the proposed 0.01% limit is a problem because

- it's not based on scientific data on ferroalloys and stainless steel and because
- globally such limit or classification do not exist in global business like stainless steel.

As a consequence European industry will loose image and markets because the markets of stainless steel would face difficulties.

Metallurgical grade chromium ore is processed into ferrochrome which is an alloy of iron and chromium with minimum chromium content of 45% by mass and maximum chromium content of 95% chromium by mass.

73% of the ferrochrome produced goes to stainless steels whilst the 27% remainder goes into alloy steels, special steels. Metallic chromium gives to stainless steel its unique anti-corrosion properties, there are no existing substitute for such essential application (surgery material, industrial kitchen, household appliances, pots and pans, food processing industry, bridges and infrastructure, building and architecture, exhaust systems, machine parts etc...)

Metallic chromium forms a passive and self-repairing layer on the surface of alloys preventing release of any other compounds and protecting against corrosion, therefore although ferrochrome and stainless steel contains classified metals like nickel and cobalt, the bio-availability of those constituents is very limited due to the alloying effect.

Cobalt is not used by the ferrochrome and stainless steel industries but it is a naturally occurring element in the chromium ore considered as an impurity. Ferrochrome seems to have a cobalt content equivalent to 0,04%.

This means that for our sector products there is no scientific argument to apply a Specific Concentration Limit (CL) for carcinogenicity that is lower than the Generic Concentration Limit 0.1%. If some other lower SCL is proposed this should be based on scientific facts. There are no scientific evidence that a lower SCL should apply for metal alloys.

The restriction on use of CMRs in consumer products (Annex XVII of REACH, entry 28-30) might not be applicable to ferrochrome as it is not present as such in consumer products. It is used as the most important alloying element for stainless steel. From stainless steel there are scientific data and peer reviewed studies that products do not cause such health effects or toxicity that is associated with the classification that would result from the proposed CO classification.

Metallic Chromium and chrome alloys are currently not classified as a CMRs.

Currently, it may not be possible to reduce cobalt content as impurity in ferrochrome by existing known and applicable technologies. The costs to update information according to the new classification would be minimal compared to the cost associated to loss of market due to downstream legislation

The cobalt classification should not be applicable to ferrochrome and stainless steel since cobalt is occurring only as a trace element but not intentionally used during the manufacturing process as a raw material.

There is no alternative of ferrochrome with its Co content as impurity in stainless steel grades.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	EPBA - European Portable Battery Association	Industry or trade association	13

Comment received

For the portable battery segment, Cobalt is being used in various battery chemistries and has as such a critical function in the overall performance of the given battery. Cobalt is used inside the battery which excludes any exposure by the consumer during normal use of the batteries. See attachment for further information on the use of Cobalt in portable primary and rechargeable batteries

ECHA note – An attachment was submitted with the comment above. Refer to public attachment EPBA comments paper_cobalt_24022017.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	CERATIZIT Group	Company-Downstream user	14

Comment received

For over 95 years, CERATIZIT has been a pioneer developing exceptional hard material products for cutting tools and wear protection. The privately owned company, headquartered in Mamer, Luxembourg, develops and manufactures highly specialized tungsten carbide cutting tools, inserts, rods and wear parts. The CERATIZIT Group is the market leader in several wear part application areas and develops successful new types of hard metal, cermet and ceramic grades used for instance in the wood and stone working industry.

With over 6,000 employees at 27 production sites and a sales network of over 60 branch offices, CERATIZIT is a global player in the hard metal industry. The leader in material technology is continuously investing in research and development and holds over 600 patents. Innovative hard metal solutions from CERATIZIT are used in machine and tool manufacturing and many other applications including automotive, aerospace and medical.

The internationally recognized CERATIZIT Group unites the four competence brands Cutting Solutions by CERATIZIT, Hard Material Solutions by CERATIZIT, Tool Solutions by CERATIZIT and Toolmaker Solutions by CERATIZIT. The hard metal expert also includes the subsidiaries WNT, Günther Wirth and CB-CERATIZIT as well as the tool manufacturers PROMAX Tools, Klenk, Cobra Carbide India, Becker Diamantwerkzeuge and Best Carbide Cutting Tools.

The hardmetal industry is a downstream user of cobalt as hardmetal is produced by directly mixing tungsten carbide with 3-30% cobalt. The tungsten carbide provides high hardness and wear-resistance while the cobalt, acting as a binder, adds strength to the hardmetal mixture. In 2015, the total hardmetal consumption in Europe was around 15,000t, accounting for approximately 66% of the tungsten consumption in Europe.

The hardmetal powder (tungsten carbide and cobalt metal) mixture is pressed and sintered at 1,500°C to produce articles approaching the hardness of diamond. Because of its unique properties, such as high melting point and ability to form a liquid phase with tungsten carbide, cobalt cannot be easily replaced in most hardmetal applications. Cobalt-containing hardmetal remains the highest performing alternative in nearly all applications.

Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The automotive, aerospace, energy and general engineering sectors all use hardmetal to facilitate the processing of steels, other metals, wood and composite materials. Also, the mining, construction, and oil and gas industries are dependent on high-performance hardmetal tools and applications for rock processing. Over the last 50 years, these industries have seen an increase in productivity largely due to the emergence of improved hardmetal tool technology, which is used worldwide across the industry.

The impacts of the proposed cobalt classification to the hardmetal industry are described in this section and are associated with classifications more stringent than the Cobalt REACH Consortium cobalt self-classification of Carcinogenicity Category 1B (Carc. 1B) through inhalation, Reproductive Toxicant Category 2 (Repro. 2), and non-mutagenic.

The hardmetal industry in the EU and CERATIZIT Group has for decades been continuously reducing exposures to cobalt. The current existing risk management measures in the hardmetal industry are established to control to a Generic Concentration Limit of 0,1% as recommended by the Classification, Labelling and Packaging (CLP) Guidelines for a substance classified as Carcinogenic 1B. The proposed low Specific Concentration Limit (SCL) of 0,01% would require "cobalt-free" hardmetal tools to be produced in entirely separate facilities.

In addition, the proposed carcinogenicity (Carc. 1B by all routes of exposure), reproductive (Repro. 1B), and mutagenicity (Muta. 2) classifications would trigger a major change in the manufacturing process of hardmetal. Production would have to change dramatically into an enclosed, highly automated system like the ones employed by the pharmaceutical industry, which will be extremely challenging if not impossible for article manufacturing.

Cobalt hazard classifications which are not scientifically supported will drive costs connected to a disproportionate risk management measures. In the EU, this could contribute to hardmetal industries moving production to regions outside of the EU. Furthermore, the increased handling and processing cost of recycling, triggered by the proposed classifications (Carc. 1b by all routes of exposure, Repro. 1B, and Muta. 2) could have a major effect on the amount of cobalt containing hardmetal scrap that is recycled. It is likely that, due to the strict classifications and a lower SCL for cobalt metal, large amounts of hardmetal will be processed outside of the EU.

Restricting the use of cobalt in hardmetal applications would lead to less productivity for both hardmetal manufacturers and users of hardmetal tools, as the manufacturing industry in Europe heavily relies on hardmetal suppliers to operate.

CERATIZIT Group and the hard metal industry are in favour of harmonising the cobalt's EU OEL as it would make all industries work towards the same goal. Currently national OELs range from 20 to 100 µg/m³.

Meanwhile, France has recommended a lower cobalt threshold limit value (TLV) of 2,5 µg/m³ whereas, based on cancer risk, Germany is introducing an ERB (Expositions-Risiko-Beziehung = Exposure Risk Correlation) with a tolerance limit (additional cancer risk of 4:1000 in 40 working years over 8-hour exposure) of 5 µg/m³ for cobalt (as for alveolar dust, and the criteria is <10 µm particle size for cobalt) including hardmetal, with an acceptable risk (additional cancer risk of 4:10000) limit until 2018 of 0,5 µg/m³. After 2018, the acceptable risk limit (additional cancer risk of 4:100 000) will be 0,05 µg/m³.

Other non-European occupational regulatory groups such as the American Conference of Governmental Industrial Hygienist (ACGIH) has made a distinction when cobalt is in the presence of tungsten carbide, and it is close to adopting a TLV-TWA (threshold limit value - time weighted average) of 5 µg/m³ for cobalt as thoracic particulate matter.

Further reducing the OEL/TLV based on the NL proposed carcinogenic (Carc 1B by all routes of exposure), reproductive (Repro 1B) and mutagenic (Muta 2) hazard classifications will put all the downstream cobalt users (not only the hardmetal industry) in a precarious economic and competitive situation as the cobalt exposure cannot be lowered infinitely without totally new and highly costly manufacturing processes.

For all mentioned points, CERATIZIT Group supports the technical position of the ITIA and CDI/CoRC (2017), (See Attached)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	France	Alliance des Minerais, Minéraux et Métaux (A3M)	Industry or trade association	15

Comment received

Considering the utmost importance of Cobalt and the possible consequences of its classification (see document attached), we invite RAC to conduct a thorough investigation, taking into account all evidence for a science based decision.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24_A3M_Co consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Agoria	Industry or trade association	16

Comment received

Agoria is concerned about the proposed CMR classification of cobalt and cobalt substances for several reasons. First of all Agoria is supporting the scientific comments of Cobalt Development Institute on the classification proposal. Our members, ranging from producers to users of cobalt, have supported and contributed to the development of the scientific comments prepared by the Cobalt Development Institute. Our comments are more related

on the downstream impact of this classification.

Cobalt is used within our industry in a large variety ranging from:

- the production of cobalt,
- batteries within different applications ranging from electric mobile equipment to electric vehicles,
- hard metal cutting tools in the production of metal parts
- the use and presence of cobalt as alloying element in numerous products
- surface treatment for specific technological reasons.

The proposed very low SCL of 0,01% for all exposure routes will be very challenging for our companies from an health and safety perspective given that cobalt is present in most applications above these concentrations.

Internally our companies are facing the following challenges:

- The classification will lead to the imposition of very stringent health and safety measures to ensure safe working conditions. It will be very challenging, nearly impossible, to implement in all circumstances these conditions to ensure the very low SCL for all exposure routes, Besides the production of cobalt, our indications are that this is also applicable to several other downstream applications such as the production, use and maintenance of hard metal tools, the cobalt plating of products, etc... This will involve in certain cases a complete change of the production technology already installed
- The business continuity / availability of the critical raw material cobalt will become more difficult for certain products as most products contain more than 0,01% cobalt

Externally our companies are facing the following challenges with this SCL for all exposure routes:

- For the clients of our companies, it will be difficult to ensure the concept of a 'safe product' given again the very low SCL as well as the fact that all exposure routes are considered, Some user sectors, such as the automotive industry, are pushing the get CMR free products which is in the case of cobalt rather challenging given the broad application of cobalt in several components of cars, whether it be in the batteries for electrical and hybrid vehicles or in alloying and/or surface treatment for specific applications,
- Hence the market will become 'cobalt' adverse, with a 'ban' of cobalt in articles, rather non-regulatory, due to the stringent classification. This will be challenging given that even impurities of cobalt will be above the SCL of 0,01%.

However for certain products, cobalt is technically and economically not substitutable such as hard metal tools, batteries, alloying elements for specific technical reasons or a surface treatment which gives a specific functionality to the product. The fact that cobalt is one of the critical raw materials for the European Union, is clearly highlighting this.

Several applications of cobalt are enablers for the green economy such as batteries for electrical vehicles. Given the criticality of cobalt, some companies (not active in cobalt at this stage) invested in specific R&D to develop complete new technologies/products to reduce the use of cobalt in certain applications in order to cope with this criticality. The rising uncertainty of the future regulatory pressure on the health and safety measures to apply in those innovative processes and products, will put those investments on hold and the decision to engage in a larger industrial investment and engage in completely new product lines with cobalt will be scrutinized. (This case is producing an innovative product with less cobalt in order to significant lower the content of cobalt in the global application. Thus still using cobalt for its unique functionality, but seriously reduce the total cobalt consumption). Companies will in this case not invest anymore in R&D nor in industrial production. This will lead to a higher global exposure to cobalt, given that the actual situation will be maintained as there are at this moment no technical and economical viable

alternatives for this product.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170224 PVAN Proposal of classification of Cobalt.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Agoria	Industry or trade association	17

Comment received

Agoria is concerned about the proposed CMR classification of cobalt and cobalt substances for several reasons. First of all Agoria is supporting the scientific comments of Cobalt Development Institute on the classification proposal. Our members, ranging from producers to users of cobalt, have supported and contributed to the development of the scientific comments prepared by the Cobalt Development Institute. Our comments are more related on the downstream impact of this classification.

Cobalt is used within our industry in a large variety ranging from:

- the production of cobalt,
- batteries within different applications ranging from electric mobile equipment to electric vehicles,
- hard metal cutting tools in the production of metal parts
- the use and presence of cobalt as alloying element in numerous products
- surface treatment for specific technological reasons.

The proposed very low SCL of 0,01% for all exposure routes will be very challenging for our companies from an health and safety perspective given that cobalt is present in most applications above these concentrations.

Internally our companies are facing the following challenges:

- The classification will lead to the imposition of very stringent health and safety measures to ensure safe working conditions. It will be very challenging, nearly impossible, to implement in all circumstances these conditions to ensure the very low SCL for all exposure routes, Besides the production of cobalt, our indications are that this is also applicable to several other downstream applications such as the production, use and maintenance of hard metal tools, the cobalt plating of products, etc... This will involve in certain cases a complete change of the production technology already installed
- The business continuity / availability of the critical raw material cobalt will become more difficult for certain products as most products contain more than 0,01% cobalt

Externally our companies are facing the following challenges with this SCL for all exposure routes:

- For the clients of our companies, it will be difficult to ensure the concept of a 'safe product' given again the very low SCL as well as the fact that all exposure routes are considered, Some user sectors, such as the automotive industry, are pushing the get CMR free products which is in the case of cobalt rather challenging given the broad application of cobalt in several components of cars, whether it be in the batteries for electrical and hybrid vehicles or in alloying and/or surface treatment for specific applications,
- Hence the market will become 'cobalt' adverse, with a 'ban' of cobalt in articles, rather non-regulatory, due to the stringent classification. This will be challenging given that even impurities of cobalt will be above the SCL of 0,01%.

However for certain products, cobalt is technically and economically not substitutable such

as hard metal tools, batteries, alloying elements for specific technical reasons or a surface treatment which gives a specific functionality to the product. The fact that cobalt is one of the critical raw materials for the European Union, is clearly highlighting this.

Several applications of cobalt are enablers for the green economy such as batteries for electrical vehicles. Given the criticality of cobalt, some companies (not active in cobalt at this stage) invested in specific R&D to develop complete new technologies/products to reduce the use of cobalt in certain applications in order to cope with this criticality. The rising uncertainty of the future regulatory pressure on the health and safety measures to apply in those innovative processes and products, will put those investments on hold and the decision to engage in a larger industrial investment and engage in completely new product lines with cobalt will be scrutinized. (This case is producing an innovative product with less cobalt in order to significantly lower the content of cobalt in the global application. Thus still using cobalt for its unique functionality, but seriously reduce the total cobalt consumption). Companies will in this case not invest anymore in R&D nor in industrial production. This will lead to a higher global exposure to cobalt, given that the actual situation will be maintained as there are at this moment no technical and economical viable alternatives for this product.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Norilsk Nickel Harjavalta Oy	Company-Manufacturer	18
Comment received				
Norilsk Nickel Harjavalta Oy is a member of Cobalt REACH Consortia (CoRC). Norilsk Nickel Harjavalta Oy supports Cobalt REACH Consortia General and Technical comments.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Nilar AB	Company-Importer	19
Comment received				
We are a Swedish SME company producing industrial NiMH batteries. In the batteries we have cobalt containing active materials. The battery contains other active materials (besides cobalt) which have similar hazard classes to those being proposed by the NL, with the exception of the proposed new routes for carcinogenicity oral and dermal. Stainless steel is used in some of the battery components, and the stainless steel can contain some cobalt present as an impurity (above the proposed SCL 0.01%). Dermal exposures to cobalt containing stainless steel during the battery manufacturing process would be occupational. The battery product is an Article that can contain parts with cobalt present as an impurity (above the proposed SCL 0.01%), which means that the end user could be exposed to dermal contact with these parts of the battery.				
Our largest concern is if the regulations of cobalt in longer term would give restrictions for our battery product we are producing. For example, if there will be specific regulation concerning uses of cobalt containing products/articles. If we need to substitute cobalt in our product this mean extensive and expensive R&D work from our side, giving high cost, where it is not given that we can achieve the same performance and robustness as with cobalt containing active materials. This will reduce the possibilities on the world market for our products as well as for other European cobalt containing battery products both regarding cost and performance, especially in relation to Asia that are very strong in producing				

batteries having cobalt containing products. Europe needs improve their competitiveness in this sector in order to be able to produce and manufacture products for vehicles and energy storage solutions needed in a sustainable environment and economy.

Many batteries are containing cobalt today, for example: lithium ion batteries and nickel metal hydride batteries. These technologies are becoming more and more important in consumer electronics, electric vehicles and energy storage solutions, and are highly dependent on cobalt containing active materials in order to get the required life and performance in the products. These are many times a prerequisite for enabling sustainable solutions for transport and electricity generation. This industry will be highly influenced by regulations on cobalt content. Cobalt content is also highly influencing the recyclability incentive of products, where higher cobalt content increases the economic incentive for recycling a product. High recyclability of a product is very desirable in a circular economy.

We support the CDI/CoRC technical position.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	RIO TINTO	Company-Manufacturer	20
Comment received				
<p>Rio Tinto (RT) is a world leading mining company with iron ore, copper, bauxite, coal and diamonds mines. Rio Tinto Iron and Titanium (RTIT) is part of the Energy and Minerals division exploiting coal, uranium, borates, lithium, and ilmenite mines. RTIT is a leading company for titanium oxide used as white pigment in the plastic, paper and paint industry but also in many other applications amongst other cosmetics and food. Ilmenite ore is a combination of titanium oxide and iron oxide. The iron oxide is converted during the smelting of the ilmenite into cast iron for the casting industry as ductile iron known under Sorelmetal name. But also this cast iron is transformed at the steel plant into steel billets for the drilling industry and iron and low alloy steel powders mainly for the automotive industry. All together RTIT produces 1 million tonne of iron products, 500 kt steel billets, 330 kt Sorelmetal and 170 kt iron powders. Rio Tinto Metal Powders (RTMP) is a world leading metal powder producer since 1968 and its ATOMET powders are famous on the world P/M (powder metallurgy) market for its purity and consistency. RTMP is the unique producer of iron powders by using iron from ilmenite ore instead of scrap. RTMP (formerly Quebec Metal Powders) was the first iron powder producer to be certified ISO 9001, 14001, TS16949 and until today have always satisfied automotive requirements in terms of non-presence of banned substances by the Reach legislation. But our pure iron powders are also used in non-automotive applications like plastic filler, friction, welding, Metal Additive Manufacturing (AM or 3D Printing). Furthermore iron powder is approved by FDA (Food & Drug Administration) for food contact or iron fortifier in cereals, seed cleaner, pharmaceutical, groundwater remediation.</p> <p>By changing the CLH classification for cobalt from 0.1% (meaning you add voluntary cobalt to the alloy) to 0.01% (impurity level present in the ilmenite ore or in the steel scrap), this change will conduct to classify all iron and steel products carcinogen! We have actually a similar situation with the intended CLH classification for nickel metal.</p> <p>It is in contradiction with the specific applications iron powder is bringing beneficial effect. All the automotive industry will be impacted by using steel components that are classified carcinogen because of the natural presence of cobalt impurity into in iron.</p> <p>This intended new classification will have a catastrophic impact not only on our company but to the steel and metal powder industries. Today it is not physically possible to reduce the cobalt content present in the ore or the liquid steel to levels below 0.01%.</p> <p>Rio Tinto supports 100% the comments submitted by the CDI (Cobalt development</p>				

Institute) as well as the EPMA (European Metal Powder Industry Association). This CLH classification proposal for cobalt is erroneous.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	VDA, Verband der Automobilindustrie e.V.	Industry or trade association	21

Comment received

Cobalt is an important material for the production of modern and efficient vehicles and in most cases not replaceable or reducible. Normally the use of cobalt takes place in the upstream supply chain and not by the OEMs or their direct suppliers. The main applications for Cobalt are plating, passivation, alloys, printed circuit boards, magnets, batteries etc. The proposed classification as carcinogen with the extremely low Specific Concentration Limits (SCL) would have negative effects on the mentioned applications and the manufacturing of components. Furthermore heavy metal oxides are important materials for the aspired electric mobility of vehicles. Cobalt compounds e.g. are currently needed for the production of powerful batteries. In addition they possess a high potential for the development of more efficient batteries in future. A tight regulation of cobalt would have negative effects on the manufacturing of such seminal batteries in Europe. With regard to a politically favored buildup of a European battery manufacturing, the proposed classification would be counterproductive.

The proposed SCL is so low, that also alloys with small quantities of Cobalt impurities would be affected by the proposed classification. Especially affected would be nickel alloys, since in nature Cobalt and Nickel are often intrinsically tied to each other and thus also a multiplicity of Nickel alloys would have to be classified as carcinogen 1b. Nickel plays a crucial part in the production of vehicles. (see also attached VDA Position)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment VDA Position on cobalt.zip

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Tikomet Oy	Company-Manufacturer	22

Comment received

Tikomet Oy supports the technical position of the CDI/CoRC (2017) as outlined in the message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal in January 2017.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tikomet Oy Response - Co CLH.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Finnish Steel and	Industry or trade	23

Comment received

Finnish Steel and Metal Producers employ 15,000 people in Finland and have a turnover of EUR 9.5 billion. The Finnish metal processing industry is famed for its highly efficient use of energy and raw materials. In some processes we are indeed proud to be the global leaders. More than half the copper and a third of the nickel used globally is made using a flash smelting method developed in Finland, which self-generates the energy required in the process.

Metal processing companies manufacture and process steel and copper products, refined steel, zinc and nickel. The Business is shifting towards even more highly processed specialty products and related services. In this sector, expertise, automation and the efficient use of the newest technologies take centre stage. Recycling is an integral part of the industry. In Finland, more than 90 per cent of discarded steel products are re-processed. More than 80 per cent of globally produced copper is recycled.

The Netherlands proposal for a harmonized hazard classification of cobalt is as following:

- Carcinogenic category 1B H350 (all routes of exposure) with a specific concentration limit (SCL) of $C \geq 0,01\%$
- Mutagenic category 2 (H341)
- Reprotoxic category 1B (H360F)

The existing hazard classification of cobalt metal is as following:

- Skin sensitizer 1 (H317)
- Respiratory sensitizer 1 (H334)
- Aquatic toxicity chronic 4 (H413)

Finnish Steel and Metal Producers fully supports the Position Papers of Cobalt REACH Consortia/CDI, Team Stainless and Eurofer. Including the scientific data submitted by the Cobalt Industry and the consequences of the proposed classification of cobalt for metal alloys like steel, stainless steel, high-alloy steel, superalloys and their secondary feed materials.

Finnish Steel and Metal producers want to raise also the problem with CLP-classifications concerning metal alloys in a more general aspect. For the purposes of hazard classification in CLP Regulation, metal alloys are considered to be mixtures, and they are currently classified on the basis of the amount of a hazardous substances content in the alloy (mixture), following the principle of the Globally Harmonized System (GHS)/Classification, Labelling and Packaging (CLP) Mixtures rule.

Still, CLP Regulation recognises that metal alloys are special preparations rather than simple mixtures. That's why e.g. they don't need to be labelled in every case.

We want to highlight that massive metal alloys behave differently than its separate alloying elements (substances in the alloys). And the alloying process in massive metal alloys strongly eliminates the release and exposure to any single alloying element. That's why hazardous classification of single alloying elements of massive metal form should not be used as such for basis of hazardous classification of massive metal alloys. When eg. Cobalt is present in the massive metal alloy, the hazardous classification should be based on the measured release and exposure to the hazardous component and not the concentration of the alloying element cobalt.

We want to remind that OECD -level validation for bioelution tests for massive metal alloys is going on. ECVAM (The European Union Reference Laboratory for Alternatives to Animal Testing) is leading the validation work, and the work is supported by ECHA's and CLP's

competent authorities. After this work is concluded and implemented metal alloys can be classified on scientific basis. Today, steel industry is collaborating on projects to collect additional information on the bioelution based bioavailability of cobalt in steel.

If massive metal alloy is CLP-classified it limits its use in consumer products, and e.g. in public procurement, which is due to environmental labels like EU Ecolabel which are used in procurement decisions. CLP-classifications have a tightening influence in waste legislation. Furthermore, the list of substances of very high concern (SVHC) in REACH-chemical legislation is based on CLP-classification of substances.

EU's Circular Economy Strategy wants to enhance reuse and recycling of material flows. Metals are the most recycled materials in the world. To maintain or even enhance this excellent situation CLP-classification of massive metals alloys should be accomplished using risk based criteria taking account bioavailability and bioelution.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment MJ kannanotto_cobalt.docx

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Teknikföretagen	Industry or trade association	24

Comment received

A harmonized classification must be based on scientific data. Teknikföretagens understanding is that the proposal for a revised classification for cobalt metal (Carc 1B (all routes of exposure), SCL 0,01%, Repro 1B, Muta 2) is not scientifically supported, and therefore it can't be supported.

Teknikföretagen believes that the classification should be by inhalation only, as the weight of evidence does not support an "all routes of exposure" conclusion. Similarly, the classification for Mutagenic (M) and Reprotoxic (R) is not justified scientifically. In addition, the proposed Specific Concentration Limit (SCL) of 0.01% is extremely stringent and not based on evidence. Teknikföretagen does therefore not support the new suggested classification of Cobalt.

Examples of materials containing cobalt include steel and hard metal. Both are widely used within the engineering industry. Hard metal and steel are materials that the engineering industry build its production lines upon. Examples of hard metal applications are drilling, milling, turning, sawing and wire drawing as well as parts in engines, pumps, valves and injectors. Without hard metal we would not be able to produce high-quality products in an effective way, which would dramatically affect the competitiveness of our members. The handling of materials containing cobalt would have to be changed dramatically if cobalt metal would be classified as Carc 1B (all routes of exposure) or Repro 1B. Avoiding skin contact with all steel and hardmetal in a modern society would be difficult. For more information see also the Swedish Steel Producers Association Jernkontoret's response regarding the suggest Cobalt Classification.

Teknikföretagen fully supports:

1. The technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.
2. Jernkontoret's view points submitted 20170224 to ECHA via the web site consultation module for public consultation of the proposed new Cobalt Classification

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Spain	Spanish Association of Frits, Glazes and Inorganic Pigments	Industry or trade association	25

Comment received

ANFFECC is the National Association that includes the producers of frits, glazes and inorganic pigments in Spain. The Association currently includes 23 members. The members of ANFFECC are the largest producers in Europe for frits, glazes and inorganic pigments. Approximately 1950 T/year of cobalt-containing substances are used in our sector, representing a sales volume of million euros.

The proposed harmonised classification and labelling for cobalt metal would have a negative impact in our sector mainly due to its potential consequences for other cobalt substances if similar classification is proposed for cobalt insoluble compounds in the future.

Metallic cobalt as such is not commonly used in our sector. However, tricobalt tetraoxide and other cobalt compounds are key raw materials for the manufacture of complex inorganic pigments and frits.

Cobalt substances are essential to obtain certain colour ranges and cannot be substituted. During the pigment manufacturing process, raw materials are transformed via calcination and the resulting inorganic pigments contain cobalt ions bound to the crystalline structure.

In the case of the frits, during the manufacturing process, raw materials are transformed via melting and the resulting substances contain cobalt ions confined into the vitreous structure of the frit.

These substances are exclusively manufactured at industrial sites by trained workers and their main end uses are ceramics, glass and metals, plastics and paints or coatings. Anffecc fully supports the scientific and technical position of the Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC). The attached letter of support provides details on the potential impacts of the cobalt CLH proposal in our sector.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Letter of support Co- Public Consultation.docx

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	AB Sandvik Materials Technology	Company-Manufacturer	26

Comment received

As a producer of high alloy steels and nickel base alloys, utilizing scrap as well as virgin materials (like nickel) as raw materials in the production, the presence of cobalt is unavoidable also in those of our products that are not intentionally alloyed with cobalt. Therefore, AB Sandvik Materials Technology, member of Jernkontoret (Sweden), EUROFER and Team Stainless fully supports the comments sent in to this Public Consultation from the above mentioned organizations. They, in turn, support the CDI/CoRC comments.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	Wirtschaftsvereinigung Metalle (WVMetalle)	Industry or trade association	27
Comment received				
<p>The discussion on Cobalt metal classification and the extremely low SCL of 0.01% for the Carc end-point is heavily affecting the whole metals producing und processing industry. Members of our federation are amongst others producers of magnets, hard metal, batteries, alloys and catalysts in which cobalt is absolutely not substitutable. Cobalt-concentrations of < 0.1% are often unavoidable impurities from raw materials, master-alloys, recycled materials or scraps. For those alloys for which Cobalt impurities are explicitly mentioned in the standards, specifications go up to 0.3 %. Typical high purity metals used as basis for Cobalt containing alloys like Nickel specify Cobalt to be < 0.03%. Consequently, typical Cobalt free Nickel alloys (50%-Ni-Fe-alloy) made by using high purity grade Nickel would therefore to be classified. In addition the consequences of the proposed classification on the recycling of metals would be tremendous and should be kept in mind during the further steps.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24 WVMetalle commenting on Co CLH proposal.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Wirtschaftskammer Österreich	Please select organisation type..	28
Comment received				
see PDF attached				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_170_StN CLH Cobalt.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	BASF SE	Company-Manufacturer	29
Comment received				
<p>As a general position we support the comments submitted by the Cobalt Development Institute (CDI) and as a registrant of the substance, we support the comments of the Cobalt REACH Consortia (CoRC)</p> <p>We disagree with the addition of Carc. 1B, H350 (all routes) with a SCL of 0.01%, Muta. 2, H341 and Repr. 1B, H360F to the harmonized classification.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Sandvik Mining and Rock Technology	Company-Downstream user	30
Comment received				
<p>WHO WE ARE AND WHAT WE DO</p> <p>Sandvik Mining and Rock Technology is one of the world's leading supplier of rock tools, equipment, tooling solutions, service and know-how for the mining and construction industry. A majority of the tools produced by Sandvik are hardmetal tools containing cobalt. Sandvik Mining and Rock Technology supplies a large number of mining and construction</p>				

equipment which uses the hard metal tools as an integral part of the application in rock drills and mechanical cutting machinery. In addition, hardmetal is used in wear protection for crushing and screening of rock and in hammers & breaking tools used for construction purposes. The supporting steel constructions provided as a part of the mining and construction equipment also contain cobalt.

With extensive investments in research and development, we create unique innovations and set new productivity standards together with our customers. These include the world's major mining and construction industries. Sandvik Mining and Rock Technology has 14,000 employees.

As a manufacturer of hardmetal tools we recycle used material to guarantee our customers a future supply of tools and at the same time being mindful of our resources. Since the mid 90's Sandvik has a global recycling system where we buy back used tools, and in 2015 we recycled about 88% of sold hardmetal weight.

We are part of the global industrial group Sandvik, an engineering group in tooling, materials technology, mining and construction, being members of international organisations ITIA (International Tungsten Industry Association), CDI (Cobalt Development Institute) and CoRC (Cobalt REACH Consortium). We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

In Sweden we are also members of Jernkontoret (member of Eurofer (European Steel Industry)) and Teknikföretagen (member of Orgalime (European Engineering Industries Association)). They also support the technical position of the CDI/CoRC (2017).

HARDMETAL

Hardmetal is produced by mixing cobalt (3-30%) directly with tungsten carbide. The tungsten carbide provides high hardness and wear resistance while the cobalt acting as binder adds strength to the hardmetal mixture. Cobalt (Co) is used as a binder in hardmetal products for a large number of applications ranging from small inserts for the metal cutting industry to large mining tools. The typical properties utilized in hardmetal are the excellent wear resistance and good mechanical properties at high temperatures. Because of its unique properties, such as high melting point and ability to form a liquid phase with tungsten carbide, cobalt cannot be replaced in most hardmetal applications.

Hardmetal products and tools are integral to the functioning of almost all mining and construction industries in the EU and are used to drill or cut rock in mines, mines exploration and construction sites. The proposal has major direct and indirect impact on us and our customers when it comes to hardmetal production and handling of mining and construction applications are containing cobalt.

SUBSTITUTION

So far no one has succeeded replacing cobalt in the main application areas of hardmetal e.g. metal cutting tools for turning, milling and drilling or mining applications. Nickel and Ni-Fe and Co-Ni-Fe alloys have been investigated since the very beginning of the hardmetal industry

Cobalt's unique wetting behaviour, which is a prerequisite for producing hardmetal, has however been proven hard to mimic. It must be possible to sinter the material and at the same time tailor other physical and chemical properties in order to get the required product performance. Many properties are today simply not possible to replicate with alternative binders and today's production processes cannot be used as is if cobalt is replaced. Large

investments and more research in both the material and processing techniques are necessary (raw material powders, mixing, pressing, sintering, finishing, coating, etc.). According to current knowledge changing the binder worsens the performance of the tool and reduces the productivity at the customer's site. This could mean much slower progress in mining and road tunnelling, and will increase tool replacement up to 10 times. Frequent tool changes are also a health and safety risk factor the industry is working to reduce. Changing the binder composition would change the whole industry and affect the whole value chain -including consumers. Today within our R&D functions Sandvik pursue both internal and external competence activities that are investigating the possibilities to use new type of binders, identifying both possibilities and obstacles in materials and processes. Sandvik Group and others have actively put a lot of effort during the past 50 years to find alternatives to cobalt. Despite of the efforts cobalt remains the only alternative in most applications. Reference A: Norgren et al. 2014.

COBALT IN STEEL

Some types of the steel contain intentionally added cobalt and other types of steel contain cobalt as impurity in concentrations from 0,01 - 0,1%. The specific concentration limit SCL of 0,01% would have an disproportionate effect on all steel used in industry, and make recycling of potentially cobalt contaminated steel- and cobalt containing steel products very difficult. Today >80% of the downstream steel is recycled. Without recycling many downstream and related industries with both low value and highly alloyed scrap arising's would find their recycling rates greatly impaired. Given the scale of the steel industry, landfill is neither an economic nor an environmental solution. Given the criticality of some of the stainless steel constituents this would be very detrimental for the concept of circular economy and it could lead to an acceleration of resource depletion and overuse of natural resources.

SAFETY

Safety is a fundamental part of our business and Sandvik's concern for our employees is a top-priority.

Since many years Sandvik has handled cobalt materials in manufacturing with caution. For decades we have been monitoring and continuously decreasing the exposure to cobalt. We have an extensive global program including e.g. health monitoring and an internally defined exposure limit that has to be met on each site where exposure to cobalt is possible. The limit corresponds on our sites to the level of the lowest OEL known to us being published until the end of 2016.

Through the program we have actively worked to decrease cobalt exposure for our employees through a series of actions, including technical and engineering measures, organizational and administrative measures, personal protective equipment (PPE) and information and training of concerned employees and contractors to ensure that the work environment is safe and continuously improving.

We have also participated in many studies, and together with researchers from universities we have looked into our workers' cobalt exposures to learn more and to improve our global program decreasing the exposure to cobalt.

THE CLASSIFICATION WE CAN SUPPORT

We support implementing harmonised classification for cobalt metal for carcinogenicity and reproductive toxicity at the level of current self-classification by CoRC (Carcinogenicity Category 1B through inhalation and Reproductive Toxicant Category 2). Harmonised classification spreads effectively the information about the health hazards associated with cobalt metal. The current self-classification of cobalt metal is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance.

THE PART OF THE PROPOSED CLASSIFICATION WE DO NOT SUPPORT AND WHY

Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforms the industry into using closed processes similar to the ones in the pharmaceutical industry. Undertaking that kind of

changes is very challenging or impossible in an industry like ours. It also requires innovations and totally new techniques.

Lowering exposure below the level where no additional health benefit/improvement can be seen only generates a higher cost because of disproportionate risk management measures and causes unnecessary anxiety/concern among the workforce. It should be carefully investigated if there is increased risk of the proposed effects associated with exposure via other than inhalation routes of exposure before introducing such a classification at the level of category 1B having a big impact on majority of European industries. More details about affected industries can be found in the ITIA response.

Some of the direct and indirect impacts of a cobalt hazard classification, which is not based on scientific facts and which does not give additional health benefit/improvement, need to be mentioned:

- Merely increasing the cost of manufacturing in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing industry in the extremely competitive global market.
- It contributes to considering moving production to regions outside of the EU.
- Recycling of hardmetal and steel in the EU would become more expensive contributing to the recycling being moved outside of the EU.
- A possible future restriction for using cobalt in hardmetal would cause dramatic changes to the industry in the EU, where only ready products would be imported into the EU since metal and other material working would need to be done outside of the EU.
- A possible future authorisation requires extensive administration, costly investments and makes the future of the industry uncertain contributing to considering moving production to regions outside of the EU.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference x Sandvik Mining and Rock Technology response 20170221 V0 4-CH comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Mining and Steel Association	Please select organisation type..	31

Comment received

Hinsichtlich der vorgeschlagenen harmonisierten Einstufung von Kobalt Metall fordern wir:

- anstelle der harmonisierten Einstufung als Carcinog. 1 B (alle Expositionswege), H 350, Spezifischer Konzentrationsgrenzwert 0.01% , die harmonisierte Einstufung als Carcinog. 1 B nur für den Inhalationsweg vorzusehen;
- anstelle der harmonisierten Einstufung als Repr. 1 B, H360F es bei einer vorläufigen Selbsteinstufung von Repr. 2 zu belassen, bis die von ECHA angeordneten Testverfahren abgeschlossen sind;
- anstelle der harmonisierten Einstufung als Muta. 2 H341 keine Einstufung für Mutagenität vorzusehen und
- vor Erlassung eines Rechtsaktes die Ergebnisse ausstehender Studien (zu pränataler Entwicklungstoxizität an einer zweiten Tierart und einer EOGRTS Studie) aufgrund anhängiger Testvorschläge abzuwarten und
- aufgrund der weitreichenden sozioökonomischen Folgen vor der Verabschiedung eines Rechtsaktes eine Folgenabschätzung (impact assessment) zur Abschätzung der Reichweite der wirtschaftsschädlichen Auswirkungen durchzuführen.

Die harmonisierte Einstufung von Kobalt-Metall, insbesondere der niedrige SCL von 0.01% hat weitreichende Konsequenzen nicht nur für die Kobaltindustrie, sondern darüber hinaus für weitere Metallbranchen in Österreich und Europa. Deshalb sollte diese Einstufung mit

größtmöglicher Sorgfalt und mit bestmöglichen Daten erfolgen. Diese ist unseres Erachtens im vorliegenden Dossier nicht der Fall und könnte insbesondere durch Abwarten der ausstehenden Studienergebnisse und durch eine Folgenabschätzung zu wirtschaftlichen Auswirkungen (Impact Assessment) deutlich verbessert werden.

Einige Metalle und eine Vielzahl von Metalllegierungen enthalten Kobalt-Metall in einer Konzentration von mehr als 0.01%.

Stahl

Stahl – sowohl Kohlenstoffstahl als auch Edelstahl – enthalten oft Kobalt in einer Konzentration, welche höher als der vorgeschlagene SCL von 0.01% ist. Bei Kohlenstoffstahl ist Kobalt oft als Verunreinigung, vorhanden, weil mit Kobalt verunreinigte Eisenschrotte als Rohstoffeinsatz herangezogen werden. Darüber hinaus enthalten insbesondere Stahllegierungen Kobalt als Legierungsbestandteil. Kobalt wird vielfach in Edelstahlsorten oder in Spezialstählen hinzulegiert um die mechanischen Eigenschaften zu verbessern.

Unsere Mitgliedsunternehmen erzeugen Rohstahl, Stahllegierungen, Halbzeug und Fertigerzeugnisse aus Stahl (Kohlenstoffstahl und Edelstahl). Die Anwendungen sind sehr vielseitig: Automotive, Bau, Energie, Maschinen(bau), Metallwaren, Haushaltswaren, Verpackung und Engineering. Vielen Stahlanwendungen stellen nachhaltige, ressourceneffiziente Lösungen im Sinne des Umweltschutzes dar und sind in einer modernen, komplexen Welt nicht mehr wegzudenken. Falls in weiterer Folge es zu einem Verbot von Stahl für die vielfältigen alltäglichen Anwendungen kommt, hätte dies verheerende Folgen nicht nur für die Stahlindustrie, sondern auch für viele nachgelagerte Industrien, da die Stahlbranche eine tragende Rolle in der Wertschöpfungskette vieler nachgelagerter Wirtschaftszweige der verarbeitenden Industrie hat.

Hartmetalle

Hartmetalle bestehen aus dem besonders harten Wolframcarbids und duktilem Kobalt. Der Anteil an Kobalt und die Korngröße des Wolframcarbids wirken sich dabei auf die Gebrauchseigenschaften des Hartmetalls, wie Härte, Biegebruchfestigkeit und Bruchzähigkeit aus. Aus Hartmetallen, welche sich durch außergewöhnliche Härte und Verschleißfestigkeit auszeichnen, fertigt man vor allem Werkzeuge zum Fräsen, Bohren oder Stanzen, sowie chirurgische Geräte aber auch Kugeln für Kugelschreiberminen. Der Umgang mit Kobalt in Hartmetall-Betrieben ist heute durch umfangreiche Arbeitsschutzmaßnahmen (Schutzmasken, Absaugvorrichtungen, etc.) streng geregelt. Moderne Hartmetallwerke sind mit Filteranlagen ausgestattet, die eine Freisetzung verhindern. In den fertig verarbeiteten Werkstücken ist das Kobalt fest gebunden, sodass aus fertigen Werkstücken keine Kobalt-Partikel freigesetzt werden und keine Gefahr für den Anwender darstellen.

Nickellegierungen:

Die Einstufung von Kobalt (Co – Metall) mit einem SCL von 0,01 % erscheint für sämtliche Nickellegierungen als extrem problematisch denn laut allen gängigen Normen beinhalten viele Nickellegierungen bis zu 1% Co als unvermeidliches Begleitelement im Nickel.

Bioverfügbarkeit:

Es ist wichtig, darauf hinzuweisen, dass sich Kobalt-Metall in Stahl oder anderen Stoffen wie eine Legierung verhält. Bei Legierungen ist für Zwecke der harmonisierten Einstufung das Konzept der Bioverfügbarkeit besonders zu berücksichtigen. Dies bedeutet, dass nur der tatsächlich aus der Legierung herausgelöste und bio-verfügbare Teil eines Einzelstoffes für die Einstufung relevant ist. Denn die Freisetzung eines matrixgebundenen Einzelstoffes ist bei Metallen oder Metalllegierungen deutlich reduziert. Einige Metallbranchen führen derzeit Bioelution-Tests durch, um die reduzierte Freisetzung und geringere Bioverfügbarkeit zu belegen. Zudem sind kobalthaltige Metallerzeugnissen mit Zinn, Zink oder organisch

beschichtet und verhindert diese Beschichtung ebenfalls die Freisetzung von Kobalt-Metall.

Recycling und Energie:

Würde Kobalt wie vorgeschlagen harmonisiert eingestuft werden, würde ein großer Teil der eingesetzten Schrotte für die Metallgewinnung als gefährlicher Abfall qualifiziert werden, weil viele Schrotte, wie insbesondere Eisen- oder Wolframschrotte mit Kobalt verunreinigt sind. Dies läuft klar gegen die Intention einer Kreislaufwirtschaft, weil viele Schrottsorten nicht mehr am Markt absetzbar und in der Produktion einsetzbar wären. Sie müssten entweder mit Primärmaterial verdünnt werden oder würden ins EU-Ausland verkauft werden. Schrott als Einsatzmaterial für die Metallgewinnung wird damit verknappt. Damit wird die Rohstoffbeschaffung schwieriger und teurer ohne dass damit ein besonderer Nutzen für die Umwelt oder Gesundheit von Menschen verbunden wäre. Das Ziel einer gesicherten Rohstoffversorgung und das Recycling bzw. eine funktionierende Kreislaufwirtschaft werden durch die harmonisierte Einstufung von Kobalt gefährdet.

Eine Vielzahl von Erzeugnissen wie Katalysatoren, Magnete, Batterien, Drähte, Freileitungsseile, etc. bestehen aus Metallen, die mehr als 0.01% Kobalt als Verunreinigung enthalten. Diese Erzeugnisse sind Teil innovativer Lösungen für zukünftige Herausforderungen wie Steigerung der Energie- und Ressourceneffizienz, mehr Nachhaltigkeit, bessere elektrische Energie –und Datenübertragung, Ausbau der erneuerbaren Energien, Umsetzung der Energiewende, Elektromobilität uä. Die harmonisierte Einstufung von Kobalt würde die Erreichung dieser Ziele behindern, da die Erzeugung und Vermarktung dieser Erzeugnisse wegen des dann negativen Images oder der verbundenen Mehrkosten erschwert würde.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Non Ferrous Metals Association	Industry or trade association	32
Comment received				
<p>Hinsichtlich der vorgeschlagenen harmonisierten Einstufung von Kobalt Metall fordern wir:</p> <ul style="list-style-type: none">• anstelle der harmonisierten Einstufung als Carcinog. 1 B (alle Expositionswege), H 350, Spezifischer Konzentrationsgrenzwert 0.01% , die harmonisierte Einstufung als Carcinog. 1 B nur für den Inhalationsweg vorzusehen;• anstelle der harmonisierten Einstufung als Repr. 1 B, H360F es bei einer vorläufigen Selbsteinstufung von Repr. 2 zu belassen, bis die von ECHA angeordneten Testverfahren abgeschlossen sind;• anstelle der harmonisierten Einstufung als Muta. 2 H341 keine Einstufung für Mutagenität vorzusehen und• vor Erlassung eines Rechtsaktes die Ergebnisse ausstehender Studien (zu pränataler Entwicklungstoxizität an einer zweiten Tierart und einer EOGRTS Studie) aufgrund anhängiger Testvorschläge abzuwarten und• aufgrund der weitreichenden sozioökonomischen Folgen vor der Verabschiedung eines Rechtsaktes eine Folgenabschätzung (impact assessment) zur Abschätzung der Reichweite der wirtschaftsschädlichen Auswirkungen durchzuführen.				

Sozioökonomische Auswirkungen:

Die harmonisierte Einstufung von Kobalt-Metall, insbesondere der niedrige SCL von 0.01% hat weitreichende Konsequenzen nicht nur für die Kobaltindustrie, sondern darüber hinaus für weitere Metallbranchen in Österreich und Europa. Deshalb sollte diese Einstufung mit größtmöglicher Sorgfalt und mit bestmöglichen Daten erfolgen. Diese ist unseres Erachtens im vorliegenden Dossier nicht der Fall und könnte insbesondere durch Abwarten der ausstehenden Studienergebnisse und durch eine Folgenabschätzung zu wirtschaftlichen Auswirkungen (Impact Assessment) deutlich verbessert werden.

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Konzept der Bioverfügbarkeit besonders zu berücksichtigen. Dies bedeutet, dass nur der tatsächlich aus der Legierung herausgelöste und bio-verfügbare Teil eines Einzelstoffes für die Einstufung relevant ist. Denn die Freisetzung eines matrixgebundenen Einzelstoffes ist bei Metallen oder Metalllegierungen deutlich reduziert. Einige Metallbranchen führen derzeit Bioelution-Tests durch, um die reduzierte Freisetzung und geringere Bioverfügbarkeit zu belegen. Zudem sind kobalthaltige Metallerzeugnissen mit Zinn, Zink oder organisch beschichtet und verhindert diese Beschichtung ebenfalls die Freisetzung von Kobalt-Metall.

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Albemarle Europe SPRL	Industry or trade association	33

Comment received

Although Albemarle is not using or producing Cobalt metal, we are concerned about a part of the rationale for the proposed classification as it may affect other Cobalt compounds that we are using or producing in our catalyst business unit. As a member of the Cobalt REACH consortium and CDI we have also contributed to the comments of these organisations and support the comments of the Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC).

Date	Country	Organisation	Type of Organisation	Comment number
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24.02.2017	Luxembourg	FEDIL - The voice of Luxembourg's industry	Industry or trade association	34
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Comment received

About FEDIL
As of 2017, FEDIL - the voice of Luxembourg's industry – represents more than 550 affiliate members from 37 sectors of activity. Moreover, our membership represents 95% of the manufacturing industry in Luxembourg and, in a more general way, contributes to 35% of the global annual GDP in Luxembourg.

General comments about the cobalt metal CLH proposal and the hard metal using industries:
FEDIL wants to underline that the use of hard metal tools is an essential factor in regards to the productivity of the industry we represent. Indeed, the vast majority of companies working with hard metals in Luxembourg and in the EU use tools made of tungsten carbide with Cobalt as a binder inside. Moreover, cobalt is mainly used in the metal industry for super alloys, wear resistant coatings, corrosion resistant alloys or spring alloys.

Thus, FEDIL wants to raise awareness that the proposed classification of cobalt metal and other cobalt compounds under the cobalt metal CLH proposal and its implementation in the EU Member States will have a major impact on industries using hard metal tools. Indeed, the proposed carcinogen directive would require all employers to eliminate or minimize the employee's exposure to CLP category 1 carcinogens, mutagens and in some countries also reproductive toxicants.

While FEDIL entirely supports any investigation with the aim of potentially improving human health or environment by lowering human exposure to category 1 carcinogens or mutagens, we would like to stress that lowering exposure below the level where no additional benefit or improvement to health or environment would be obvious will have a major impact on cost-effectiveness and competitiveness of the hard metal industry in Luxembourg AND within the EU.

We therefore recommend to conduct an in-depth investigation studying increased risk of cancer or reproductive effects associated with dermal contact prior to introducing such a classification at the level of category 1B.

Furthermore, FEDIL entirely supports the technical position of the Cobalt Development Institute (CDI) and the Cobalt Reach Consortium (CoRC).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170223_ECHA_PC_General_Comments_CLP.docx

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	China	ZIGONG CEMENTED CARBIDE CO., LTD.	Company-Manufacturer	35

Comment received

1. Cobalt has been widely used in Global Carbide production for a long time, based on our production history of more than 50 years, though we use hundreds of tons of cobalt, while we do not find the association between carcinogenicity and cobalt exposure in the hardmetal industry, therefore we support the classification of cobalt metal as Carcinogenic Category 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%.

2. Cobalt play an important roles in the carbide production, carbide is called "the teeth of

the industry", and carbide is one the most important materials for tools production and the related application, and there are not other materials could be an alternative material, so it is strongly suggested to do more examination and testing in a big scope and field with enough longer time, otherwise it is not a cautious and responsible action.

3. When do the related carcinogenicity examination or other examinations, should take cobalt with other metals into comparing together, should not treat Cobalt specially and individually, should be handled in a whole system with others.

4. It is strongly recommended to do more examination and industry analysis on cobalt, then do a conclusion based on a long term following study and examination.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Jernkontoret	Industry or trade association	36

Comment received

The proposal for a revised classification for cobalt metal (Carc 1B (all routes of exposure), SCL 0,01%, Repro 1B, Muta 2) is not scientifically supported. Jernkontoret does not oppose a harmonized classification as long as it is based on scientific data. Jernkontoret agrees cobalt metal should be classified as Carcinogenic (C) Category 1B based on the available evidence. However, Jernkontoret believes that the classification should be by inhalation only, as the weight of evidence does not support an "all routes of exposure" conclusion. Similarly, the classification for Mutagenic (M) and Reprotoxic (R) is not justified scientifically. In addition, the proposed Specific Concentration Limit (SCL) of 0.01% is extremely low and not based on evidence.

Examples of materials containing cobalt include all Stainless steels and more than 50 % of carbon steels and other alloyed steels, hardmetal and all types of iron based scrap. All steel types are widely used within the engineering industry and steel is the most versatile industrial material in the world. The thousands of different grades and types of steel developed by the industry make the modern world possible. Steel is 100% recyclable and therefore is a fundamental part of the circular economy. As a basic engineering material, steel is also an essential factor in the development and deployment of innovative, CO2-mitigating technologies, improving resource efficiency and fostering sustainable development. Some types of Stainless steel contain intentionally added cobalt and other types of steel contain cobalt as impurity in concentrations up to 1%. The specific concentration limit SCL of 0,01% would therefore have a big impact on the steel industry, its production of, and the use of steel in products. This could lead to bans of steel in daily applications, such as furniture, cutlery, food applications, medical devices, vehicles, as well as in construction, energy, mechanical engineering, and many other engineering applications such as the generation of renewable energy and oil and gas which are recognised as bringing huge benefits to society.

On top of that the very successful recycling of steel would be jeopardised as steel scrap could be considered as hazardous waste with serious consequences for the Circular Economy and Resource Depletion. Steel is one of the most recycled materials in the world. However, with the current proposal, when steel products containing cobalt over the

proposed Specific Concentration Limit (SCL) of 0.01% will eventually become available as scrap, they would be classified as dangerous and therefore not be recycled and they would have to be landfilled. Given the scale of the steel industry, landfill is neither an economic nor an environmental solution and would be highly detrimental for the concept of Circular Economy.

The source of cobalt as an impurity come both from scrap contaminated with cobalt alloys as well as cobalt coming from the iron ore and other alloying ores. In the periodic table of elements cobalt is next to the right of iron, and on the right side of cobalt you find nickel. All of the transition metals in the D-block appear to follow each other and especially they attach to iron. Therefore it would probably be very difficult to develop a process to remove all cobalt from the iron matrix/smelt. In the steel industry cobalt is following the iron in all cases. Only very low contents can be found in the iron- and steel making slags.

Cobalt in the steel behaves like an alloy. The REACH Regulation recognises that alloys are special preparations rather than simple mixtures and behave differently from the individual alloying constituents when incorporated within the alloy matrix. This so-called 'alloying' effect in steel strongly limits the bio-availability of the individual constituents which means that the health risks of using cobalt in steels are very limited.

Hardmetal contains typically of 3-10% cobalt and is used to process metal, rock and other materials. The manufacturing industry, mining and construction industries are all important customer segments for the steel industry who are dependent on high-performing and wear-resistant hardmetal tools and wear parts. Probably all of our member companies and their customers use hard metal in their production. Examples of hardmetal applications are drilling, milling, turning, sawing and wire drawing as well as parts in engines, pumps, valves and injectors.

The handling of materials containing cobalt would have to be changed if cobalt metal would be classified as Carc 1B (all routes of exposure) or Repro 1B. In Sweden the Carcinogen directive (2004/37/EC) implemented in (AFS 2014:43) require that if the CMR substance cannot be eliminated or handled in a closed system, all exposure should be avoided.

Avoiding skin contact with all stainless steel and probably more than 50 % of carbon steel and other alloyed steels as well as hardmetal would be impossible in an modern society.

The current Cobalt REACH Consortium self-classification of cobalt as Carc 1B through inhalation does not cause those problems, as exposure via inhalation is easier to avoid. Exposure via air is traditionally regulated with OELs and working methods have been designed/optimised to minimise dust exposure.

The proposed Muta 2 classification has an indirect effect leading to extremely low OELs (Occupational Exposure Limits) and restrictive handling through low DMELs.

Because the current proposal can have serious consequences for the Swedish Steel industry and industries manufacturing and using several materials including steel containing cobalt, all data must be validated and truly applicable to all types of mixtures to support a harmonized classification.

Jernkontoret is The Swedish Steel Producers Association. Jernkontoret safeguards the steel industry's interests within a number of areas that are of special importance for the competitiveness of the steel companies. Jernkontoret task is to safeguard the steel industry's interests through acting to ensure the best possible preconditions for the steel industry's operations in Sweden. Jernkontoret is also a member of EUROFER.

Jernkontoret supports:

- 1.The technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.
- 2.EUROFER Position Paper on the Harmonized Classification and Labelling (CLH) Proposal for Cobalt Metal
- 3.Team Stainless Position Paper for the Public Submission on the Harmonized Classification of Cobalt Metal

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	EUROBAT	Industry or trade association	37
Comment received				
<p>RECHARGE – EUROBAT Comments on the proposed CLH for Cobalt Metal</p> <p>RECHARGE (European Association for Advanced Rechargeable Batteries) and EUROBAT (Association of European Automotive and Industrial Battery Manufacturers) would like to provide the following input to the consultation on the proposed CLH for Cobalt metal:</p> <ol style="list-style-type: none"> Co metal is mainly used as an intermediate for the manufacturing of other cobalt compounds used as active materials for electrodes manufacturing However, Co metal is present as an impurity above the proposed SCL of 0.01% in several metals (nickel, stainless steel, alloys) widely used in the battery manufacturing: <ol style="list-style-type: none"> This impurity is not economically removable Technical feasibility has to be considered RECHARGE and EUROBAT support the CDI/CoRC technical comments <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment RECHARGE-EUROBAT input to CLH Cobalt metal consultation.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Cobalt REACH Consortium/Cobalt Development Institute	Industry or trade association	38
Comment received				
<p>The CoRC/CDI Joint Response Comments [13,013 words]</p> <p>1- INTRODUCTION</p> <p>The purpose of these comments is to present additional relevant socio-economic information, which is not included in the CLH proposal. These comments also present the possible implications of the proposed classifications, on the cobalt industry and use sectors for cobalt as well as on other metals and materials (containing cobalt). It is important to understand these implications of the proposed classifications relative to the existing cobalt self-classification that the industry has implemented (since 2013). The proposed end-points of the CLH proposal are considered to go against the scientific weight of evidence, and as a result, this presents many unintended consequences. These comments provide an overview of important information that should be taken into consideration by the Commission, ECHA, and MS CA's, regarding the CLH case for cobalt. Please note that the CDI/CoRC have made a separate submission of detailed technical comments on each end-point of the CLH proposal; these joint response comments prepared by the CoRC/CDI provide complementary information which has been collated through consultation with many industry stakeholders.</p>				

The Cobalt Development Institute (CDI) is an international non-profit industry trade association composed of the major producers, users, recyclers, and traders of cobalt [CDI 2017a]. The Cobalt REACH Consortium Ltd. (CoRC) is a separate wholly-owned subsidiary of the CDI formed to support the implementation of REACH and CLP for the cobalt industry [CoRC 2017]. There are three Cobalt REACH Consortia (Blue, Red, Green) that cover many cobalt compounds (28 in total). The co-registrants of these cobalt compounds are Regular members of the Consortium or companies that have a Letter of Access with CoRC. Cobalt compounds are used in a wide variety of applications (e.g. alloys, automotive, batteries, catalysts, chemicals, driers, electronics, hardmetal, magnets, medical devices, pharmaceuticals, pigments, steels, surface treatments, etc.) [CDI 2006a]. There are many Downstream User (DU) companies and industry associations for these various sectors, who can also participate in the activities of the CoRC and CDI. We have therefore consulted many industry stakeholders about the potential implications of this CLH proposal on their uses of cobalt and their sectors, as shown in our Annex 1 document (see pdf copy uploaded separately). Many of these industry associations and sector groups have contributed input to our joint response comments, as outlined below.

These sectors employ tens/hundreds of thousands of people in Europe. The manufacturers/importers (M/Is) of cobalt metal alone employ around 20,000 people for various types of jobs (e.g. sales, HR, finance and distribution) and the Downstream User sectors (a large number of which are Small and Medium Sized Enterprises - SMEs) contribute billions of Euros per year to the EU economy directly from production and employment as well as indirectly (e.g. goods and services dependent on them) [eftec and wca, 2015]. These range from well-established products like batteries and catalysts, to emerged technologies (e.g. hard metal powder and hard metal tools) and rapidly growing uses like 3D printing for medical applications and as prosthetic devices (e.g. hip replacements). These comments provide summary information which emphasises the importance and value of the manufacture and uses of cobalt in Europe.

Cobalt metal is primarily obtained as a co-product from the mining and production of nickel and copper [CDI 2016]. Therefore, cobalt can be unintentionally present as an impurity (above the proposed low SCL of 0.01%) in a wide range of primary (raw) materials, intermediate complexes, and secondary (recycled) materials. This means many important materials/alloys could also be classified (CMR), which could lead to further unintended consequences of the cobalt CLH proposal. For example, cobalt is naturally present in the raw materials (e.g. nickel matte, ferroalloy) used to manufacture stainless steel, and is considered to be a benign (nonreactive) and beneficial impurity (e.g. conferring hardness/durability). It is technically very difficult, energy intensive, and very costly, to remove the cobalt impurity from stainless steel. This step is also unnecessary as studies and decades of use, have shown there are insignificant releases from stainless steel [Eurofer 2016; FIOH 2010]. Further examples are provided below.

2 – CURRENT SELF-CLASSIFICATION AND LABELLING

We note that Section 2.4 of the CLH proposal (current self-classification and labelling based on the CLP Regulation criteria, page 9), is taken from the C&L inventory, which contains numerous CLP notifications made by legal entities that are outside the joint submission, and includes self-classifications based on products that may contain impurities of other classified substances. It should be clearly noted that there is an existing self-classification for cobalt metal which has been agreed by the joint submission (REACH co-registrants), and shown in the C & L Inventory as follows: Carc 1B (H350i); Repr 2 (H361f); Acute Tox. 4 (H302); Resp Sens 1B (H334); Skin Sens 1 (H317); and Aquatic Chronic 4 (H413).

The joint industry self-classification (Carc 1B H350i, Repr 2, non-Muta) should not be confused with the other miscellaneous CLP notifications listed in Section 2.4 of the CLH proposal. It is also important to highlight that the existing joint industry self-classification of Carc 1B for cobalt metal is for the inhalation route only (H350i). This self-classification has been in place since December 2013, based on a thorough review of the NTP draft report (NTP TR 581) on cobalt metal [NTP 2013]. All physical forms of cobalt metal are self-classified, based on the risk that a massive form may become partially inhalable through abrasion during normal handling and use.

The CDI and CoRC members have prepared and submitted separate detailed technical comments regarding each CMR end-point. The manufacturers and importers of cobalt have already taken the necessary steps for appropriate labelling and packaging of their cobalt products for this industry self-classification, as outlined below.

In December 2013, the cobalt industry communicated the following points regarding the self-classification of cobalt metal [CoRC 2013]. Based on their external and internal review of the NTP draft report (NTP1 Study 60311 – 05), the members of the CDI and CoRC self-classified cobalt metal as a Category 1B carcinogen by inhalation (H350i; May cause cancer by inhalation). All physical forms of cobalt metal are self-classified, based on the risk that a massive form may become partially inhalable through abrasion during normal handling and use. Only inhalable forms of cobalt metal may be hazardous. Massive forms of cobalt metal and alloys do not need to be labelled, if they do not present a hazard to human health by inhalation in the form in which they are placed on the market. Under the GHS mixture rules, all mixtures (i.e. alloys) containing >0.1% cobalt metal would carry the same self-classification.

The industry has already taken the proactive decision to implement this self-classification (Carc 1B, H350i), and has already incurred the direct costs related to this implementation. The proposed classification for Carc 1B all routes, which extends this classification to dermal and oral exposure routes, is considered to go beyond the scientific evidence, and to present further direct costs to the industry. These aspects are explained in section 3 below.

The CoRC regularly reviews the classification of its cobalt substances under the EU CLP Regulation. Following detailed discussion on grouping and read-across for long-term oral human health endpoints, CoRC took the decision to self-classify cobalt metal, and many other cobalt substances as Toxic to Reproduction Category 2. However, this self-classification is applied as a precautionary measure, and is adopted on a provisional basis. Testing proposals have been submitted under the EU REACH Regulation for sub-chronic repeated dose toxicity, developmental toxicity and Extended One Generation Reproductive Toxicity (EOGRTS) on analogous cobalt substances. These Repr 2 self-classifications will be reviewed once the proposed testing has been completed. The CoRC/CDI consider the CLH proposal for Repr 1B is therefore premature, since this end-point is currently subject to ongoing testing requirements and review by the Regulators (ECHA, MSC, EC).

The cobalt industry has already incurred costs of ~30 million (EUR) for implementation of REACH. The specific costs for the Repro-toxicity studies alone are estimated to be ~2 million (EUR). These costs represent a direct impact to industry, and therefore the information generated should be seriously taken into consideration by the ECHA Committees.

3 - IMPLICATIONS OF CLH PROPOSAL ON COBALT INDUSTRY

The REACH registration dossier (joint submission) for cobalt metal has been updated to include the industry self-classifications (Carc 1B H350i, Repr 2). The manufacturers and

importers of cobalt have updated their extended safety data sheets (eSDS) and labelling for their products accordingly. There have already been direct costs to these companies (i.e. eSDS updates, labelling and packaging changes) related to changes in the self-classification of cobalt metal, and other cobalt-containing products.

The manufacturer/importers were asked to estimate the annual average cost for updating eSDS, labelling, packaging (€k) due to the proposed CLH changes to classifications for cobalt metal. It has been reported that these costs could be on the order of several thousand to tens of thousands (EUR), depending on the size of the company and the range of products handled [Cobalt Producers, 2017]. Based on the total number of cobalt registrants, (Manufacturers and Importers), this would represent an annual cost of €500,000. However, these direct costs would be considered minor compared to other direct costs associated with changes to the manufacturing processes, and possible indirect costs associated with loss of market, etc., that would arise from the proposed CLH changes.

The proposed very low SCL (0.01%) is considered overly stringent and would result in significant additional costs to many downstream users and SMEs across a variety of sectors, and beyond the cobalt industry. These additional costs would be unnecessary since the GCL (0.10%) has already been implemented through the existing self-classification and the science does not support the more severe classifications in the CLH proposal. It has also been reported that there could be further unintended consequences of this proposed very low SCL (0.01%) on other metals and materials containing cobalt as an impurity. These implications are illustrated by the case of cobalt present as an impurity in other metals, stainless steel and other alloys. It is not economically feasible for most sectors to attempt to remove the cobalt impurity, to below such a stringent SCL, and this would also present implications for energy and raw material consumption.

The proposed CLH (CMR end-points) would require changes to the eSDS and packaging. However, there would be more significant costs associated with changes to the working practices, and to the workplace itself (e.g. additional extraction equipment, monitoring and control measures, RPE, PPE). These direct costs for the manufacturers would include costs for the companies to review/revise their manufacturing practices, and to re-examine potential occupational exposures throughout the substance's life cycle, and down the supply chains.

Industry has already put in place measures to prevent respiratory and skin sensitisation. But since the CLH proposal is for Carc1B via all routes of exposure (i.e. oral and dermal in addition to inhalation), there would be additional requirements and extra costs involved for companies to re-examine and minimize oral and dermal contact for a wide range of applications. The proposed classification of Repr 1B (with GCL of 0.30%) presents similar implications to the workplace as for the proposed Carc 1B (all routes). The proposed Muta 2 classification, (i.e. presumed non-threshold mode of action for cobalt), would mean that the REACH DNEL (Derived No Effect Level) would become a DMEL (Derived Minimum Effect Level) instead, which would entail additional compliance costs associated with a much lower occupational exposure levels (OEL).

The necessary workplace changes for the proposed CMR end-points could include for example, changes to equipment used in the production process, as well as a possible change over of production into an enclosed highly automated system, which would involve both a redesign and an increase in capital expenditure and construction costs. There would also be changes to staffing levels, and extra management costs involved in making these transitions. Some of these workplace changes could result in increased energy consumption, and could consume additional resources, which would impact on the overall resource efficiency and sustainability of the production process, as well as climate change targets.

These workplace changes would require time and costs, and there could be wider use of PPE, gloves, etc. until such time that these measures can be implemented.

The manufacturers (and Downstream User companies) would need to conduct more in-depth assessments of the types of CLH compliance measures and the associated impacts and direct costs. Therefore, much new information on these aspects should become available for consideration in the cobalt CLH case. We would expect that the costs will vary depending on the size of the manufacturer but in some cases this could be on the order of millions of Euros per company.

For the Downstream Users of cobalt, there are many different sector-specific EU regulations (e.g. Food Contact Legislation) that could restrict the uses of cobalt-containing products/articles, depending on the final CLH for cobalt. These DU companies would need to expend much time/effort (indirect costs) on making future requests for exemptions and derogations from a wide range of downstream legislation. These DU companies would incur costs to provide information on the suitability/feasibility of substitution/alternatives, and costs for new studies and R&D activities. Many of these DU companies are SMEs and/or operating under financial constraints or tight margins in a highly competitive market, and may not have the in-house expertise for these activities or be able to afford such costs.

The CLH proposal would ultimately result in an increase in the manufacturing costs in the EU, which would lead to higher prices for cobalt and cobalt-containing products in the EU. This would place European cobalt producers at a competitive disadvantage compared to other non-EU producers. There could be market impacts resulting from the higher level of stigmatisation associated with the CLH proposal, which is considered overly stringent for all three end-points. This stigma combined with the possibility for future Authorisation or Restriction under REACH, could create much uncertainty in the market regarding the future supply of cobalt, and continued use of cobalt in key applications in the EU. Note that cobalt has been formally identified as a critical raw material (CRM) by the EC, and is considered vital to the security and growth of several important sectors of the EU economy, namely rechargeable batteries, magnets, electronics, and super alloys (aerospace and defence) [EC 2010; EC 2014].

As noted, the Manufacturers and DU companies will need to re-examine potential occupational exposures throughout the cobalt life cycle, including review of the End of Life (EoL), Waste and Recycling stages. Depending on the required changes to these processes or working practices, and the associated costs, the current recycling activities for the recovery/reuse of cobalt could become impracticable and/or unprofitable. The CLH proposal for cobalt metal therefore presents an unintended consequence, in that the overly stringent CMR classification and the very low SCL (0.01%) being proposed, could effectively undermine the current recycling initiatives for cobalt, (as well as for many other metals, alloys and materials that contain cobalt above the proposed SCL). For primary materials, such as nickel, only a small portion of producers are able to remove cobalt to a level below the proposed SCL. A market premium could therefore arise in the EU for that material creating an additional economic hurdle. Due to the stigmatisation, there is a risk the European Manufacturers could feel compelled to only use primary materials instead of using secondary (recycled) materials. This could lead to creation of Waste issues instead, if these cobalt-containing materials are no longer being recovered in the EU. This shift would make the EU more dependent on imports of raw materials in general (i.e. not only cobalt). In summary, this means the current CLH proposal is contrary to sustainability aims, and does not support the goals for the EU circular economy (i.e. could break the loop), and creates more uncertainty in security of supply.

The current recovery and recycling rates for cobalt in the EU are very good, and the End of

Life Recycling Rate (EOL-RR) of cobalt is estimated at 68% by UNEP (United Nations Environmental Programme), and is higher than for most other metals, as reported on the MIS (Material Information System) for SETIS (Strategic Energy Technology Information System) [EC 2016a]. The import/export flows of primary/processed cobalt materials, and the functional recycling of cobalt (secondary materials) are illustrated in the Material System Analysis (MSA) of cobalt (and other CRMs) conducted for the EC [Bio by Deloitte 2015]. Several of the use sectors for cobalt report good recycling efficiency, for example up to 90% for the hardmetal sector [ITIA 2017], and also high (e.g. 90%) for rechargeable batteries [PEF 2016]. The recovery/recycling rate for stainless steel (which contains cobalt as an impurity) is also high (e.g. 80% globally) [Eurofer 2016]. The achievement of these good recycling initiatives in many key industry sectors for the EU would be negatively impacted (threatened) by this overly stringent CLH proposal for cobalt metal.

There are a number of initiatives on waste management and resource efficiency within the EU. For example, in 2008 the European Commission launched the Raw Materials Initiative (COM(2008)699) to boost resource efficiency and promote recycling (one of three pillars). More recently, the resource-efficient Europe flagship initiative is part of the Europe 2020 strategy, and is a key part of the wider (ongoing) discussion on working towards a circular economy within the EU. It is particularly important to maintain and recycle the stock of cobalt within the EU as it has been identified as one of the critical raw materials, fundamental to Europe's economy [EC 2014].

4 - UNINTENDED CONSEQUENCES OF CLH PROPOSAL - COBALT IMPURITY

In summary, there are several direct and indirect consequences of the CLH proposal, in that there would be respective costs for the cobalt industry as well as other metals and materials (besides cobalt) and for many important industrial sectors. These affected stakeholders will need to conduct new studies to re-examine the presence (content) of cobalt in all their materials/products. These groups will also need to expend time/effort (indirect costs) on making future requests for exemptions and derogations from a wide range of downstream legislation. These other metal associations and sector groups are currently reviewing their cases, and more information will become available about these potential impacts/costs for consideration in the cobalt CLH case. The following comments are provided to illustrate the key points communicated to the Cobalt Secretariat from several industry associations for other metals and materials, several of whom have submitted their own detailed comments independently.

4.1 - Presence of cobalt in Stainless Steel

Team Stainless considers that the Netherlands' harmonized classification proposal will have significant negative consequences for steel, in particular for stainless steels, high-alloy steel, super alloys and their secondary feed materials, and for the critical applications in which they are used. As well as supporting the scientific data being submitted by the Cobalt Industry (CDI/CoRC), the Team Stainless (stainless steel, high alloy steel, super alloys) and Eurofer (carbon-steel and other alloy steel) submissions to the public consultation will provide additional human exposure data and other peer reviewed, published references for consideration in the scientific review being conducted. To illustrate the scale of these negative consequences more clearly, further information is also given with respect to the value chain and end uses of the materials impacted. To fully understand the impact of this proposal for steel please refer to the submissions mentioned integrally [Team Stainless, 2017; and Eurofer 2017].

4.2 - Presence of cobalt in Powder Metallurgy

The EPMA considers that Powder makers will be heavily impacted by the CLH proposal for cobalt metal. There will be an increase in costs for manufacturing powder products as well as a financial impact stemming from the reappraisal by some customer groups of the risks associated with use of the product, damaging sales. There is currently a wide variety of steel and stainless steel powders that are manufactured with a cobalt concentration between 0.01% and 0.1%. The very low SCL of 0.01% will therefore cause a negative perception of these products. For powder maker's downstream, the range of alloys handled in compliance with MSDS (Material Safety Data Sheet) will be extended. Industry has already invested heavily in plants and equipment for safe handling of materials and these changes will cause further costs upwards of £1.5million (€1.73million) per production site. Additional running cost such as energy costs, PPE and consumables will cost a further £250,000 (€290,000) per year [EPMA 2016].

4.3 - Presence of cobalt in Nickel

The Nickel Institute considers there will be major implications for the nickel industry, both direct and indirect, if the CLH proposal for cobalt metal is implemented as currently proposed by the Netherlands. The direct consequence for nickel producers is that most nickel metal and all ferronickel will be classified as a carcinogen (category 1B) for all routes of exposure as cobalt is unavoidably present as a trace element above 0.01%. The cobalt impurity in nickel originates from the various nickel ores, and it is not technically possible to remove all cobalt from nickel during the refining process. A few grades of nickel and most grades of ferronickel may also contain cobalt at a concentration above the 0.3% level whereby a classification of repro-toxicity is triggered. Such an overly strict classification would cause heavy negative downstream effects [NI 2016].

The major use of nickel and ferronickel is in stainless steel applications [NI, 2016], and it would also lead to the classification of stainless steel as a carcinogen and reprotoxic substance due to the unavoidable presence of cobalt as a trace element. As such, the classification of ferronickel and most grades of nickel as a CMR category 1B may lead to indirect restrictions in certain applications as many regulations and directives in the EU restrict the use of CMR Cat. 1 substances. These applications include as an example medical devices, where Ni-containing stainless steel is used amongst others because of its ability to undergo stringent cleaning regimes such as repeatedly disinfecting or sterilizing medical devices at high temperatures to ensure patient safety; food contact material where Ni-containing stainless steel fulfils the very demanding requirements with respect to sanitation and corrosion resistance to ensure food safety, etc. In fact, the Nickel Institute has currently identified at least 19 pieces of legislation in the EU which contain hazard-based provisions or reasoning [NI 2016].

Furthermore, cobalt is deliberately added to some alloys to impart critical properties of hardness, high temperature strength and corrosion resistance. These alloys are extensively used across a wide range of industries in the most demanding applications including in jet engines, land based turbines, medical implants, tool steels, cutting and drilling tools, the chemical and the oil and gas Industries [NI 2016].

There would also be an effect on the recycling of stainless steel scrap due to the presence of cobalt which is unavoidably present in the supply chains of the secondary supply and other feeds for stainless steel. Stainless steel enjoys a high recycling rate and stainless steel scrap is critical for the economics of stainless steel production in Europe. Any reduction in the availability of stainless steel scrap would negatively impact stainless steel production in Europe. The CLH proposal for cobalt could have a major unintended detrimental impact on the recycling activities for other metals in Europe, which would be contrary to the EU initiatives for the Circular Economy [NI 2016; and Eurometaux 2016].

4.4 - Presence of cobalt in Copper

The ECI (European Copper Institute) considers there will be severe direct and indirect implications for copper if the CLH proposal for cobalt is applied. Direct regulatory implications include the likelihood of triggering new and stricter classification requirements for most types of copper UVCBs (Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials), such as copper final slags, and copper alloys intentionally containing cobalt. Indirect market consequences include the downstream legislation that copper materials containing more than 0.01% of cobalt would be subject to. It includes costs related with the changes to e-SDS, re-labelling requirements, and changes to transport and packaging, higher insurance premiums, renewal/update of a permit changes to industrial processes and increased management costs [ECI 2016].

Additionally, the CLH proposal could indirectly affect the recycling value chain established for high-quality copper scrap. Copper scrap contains cobalt as impurity. When the scrap is used to produce copper alloys considered "cobalt-free", cobalt remains as impurity in the alloys in quantities that could surpass 0.01% w/w. It is technically impossible to reduce below 0.01% the content of cobalt in alloys when using copper scrap as raw material. To avoid classifying copper alloys, producers will be forced to source exclusively from virgin raw materials not containing cobalt as impurity. It will affect the well-established copper scrap recycling value chain [ECI 2016].

4.5 - Presence of cobalt in Ferro Alloys

Euroalliages the Association of European ferro-alloy producers, consider the CLH proposal will have serious implications for the ferro-alloys industries, in particular in the ferrochromium and ferromolybdenum industry and its downstream users in the Stainless steel and High-alloy steel industries. Nearly all commercially produced high carbon ferrochrome (main product from global chromium industry) contains more than 0.01% cobalt, which is not intentionally added. Also ferromolybdenum can contain more than 0.01% cobalt. Ferrochrome or ferromolybdenum as such is not present in consumer products. Metallic Molybdenum, Molybdenum alloys, metallic Chromium and chrome alloys are not classified as a CMRs. Metallic chromium/molybdenum gives to stainless steel its unique anti-corrosion properties. Low Carbon ferrochrome (LC FeCR) is also used in special stainless steel for defence applications [Euroalliages 2017].

4.6 - Presence of cobalt in Final Slags from Pyrometallurgical Processes

The Final Slags Task Force and Euroalliages, consider the cobalt CLH proposal poses unintended implications for products that contain cobalt as an impurity, in particular final slags from the non-ferrous metal industry and from the production of ferroalloys (FeCr). Final slags are put on the market as a non-hazardous product (not as waste) and have been registered under REACH. Final slags may contain Co as an impurity mostly in concentrations higher than 0.01 % and below 0.1%. The main applications of these slags are construction (road construction, embankments), mine backfill, concrete applications and other fill applications, clinker production or mineral addition to blended cements, abrasive blasting, soil fortification, dyke fortification, where these materials are subject to compliance with European standardized specifications. The classifications and standards would need to be revisited due to the cobalt CLH proposal [Final Slags Task Force, 2017; and Euroalliages 2017]. The uses of final slags can conserve natural resources and energy. The report on 'Barriers to the Circular Economy' [EC 2016b], indicates that there is a market potential for slags (out of primary and secondary metal production) which can be used as a material in the construction sector. It is expected that potential classification of final slags as

carcinogen will damage the market perception on current and future uses. It is estimated that the market possibility of final slags will substantially decrease and increase the burden to landfill. This would be in contradiction with the objectives of the circular economy and resource efficiency [Euroalliances 2017].

4.7 - Presence of cobalt in Precious Metals

The EPMF (European Precious Metals Federation) reports that cobalt is found in precious metal alloys such as those used in medical devices in the body. Should the CLH proposal lead to the classification of cobalt as Carc 1B via all routes, the alloys used in these devices would be classed as carcinogenic as they contain cobalt above the proposed SCL. Even if these materials are given an exemption under the Medical Devices Regulation, the stigmatisation of being labelled a carcinogenic material will still lead to a loss of business. Furthermore, precious metal alloys that contain cobalt are currently undergoing research, due to their specific desired material properties, for applications in new medical devices. The CLH proposal for cobalt metal threatens to undermine this research. There are currently no available alternatives for cobalt-containing precious metal alloys within medical devices. The development of these alloys took more than three years with the final product not going on the market for a further 7 years. Even if a new substitute is found after animal and clinical, studies it could take 10 years before it can be used on the market. Should the CLH proposal for cobalt go ahead, gold coatings that also use cobalt will be affected. Cobalt is also found in XRF standards for precious metal applications, and these uses would also be undermined by the CLH proposal [EPMF 2016].

Therefore in summary, these examples illustrate that there needs to be careful consideration of the CLH proposal (Carc 1B all routes and low SCL), as the presence of cobalt as an impurity would have wider implications for a variety of sectors and important end uses. The existing self-classification for cobalt (Carc 1B H350i) does not pose such unintended consequences for massive materials or alloys.

5 – JUSTIFICATION ACTION NEEDED AT COMMUNITY LEVEL

With regards to the justification that action is needed at Community level (Section 3, page 9), the CLH proposal notes that ‘a substance fulfilling the criteria for classification as CMR substance shall normally be subject to harmonised classification (CLP article 36.1).’ This brief justification in the proposal is based solely on the hazard end-points (CMR). The industry has already implemented a self-classification for cobalt and therefore a harmonised classification which is in line with this self-classification would be a sufficient Risk Management Option.

There is other important information that should be considered with regards to the need and nature of the actions to be taken at Community level. It is important to consider the proportionality, validity, and potential impacts of the proposed classifications. In this regard, as noted in the detailed technical response, the CoRC/CDI consider that: (a) the proposal for Carc 1B (H350, all routes, very low SCL 0.01%) is overly stringent; (b) the proposed Repr 1B is premature given that the testing proposal for the REACH-mandated testing (EOGRS) is currently being reviewed by the Regulators and this activity will be on-going in parallel to the CLH case; and (c) the Muta 2 proposal is unfounded, given that cobalt is a bio-essential element, and internationally recognised as being non-mutagenic, as confirmed by a scientific peer review [Kirkland et al., 2015] and regulatory fora [OECD CoCAM, 2014]. The scientific basis for our technical challenges of the CLH proposal is presented in our detailed technical comments submitted separately by CDI/CoRC. These joint response comments outline other important information that needs to be considered regarding the potential impacts of this CLH proposal on the cobalt industry, as well as potential

unintended consequences for many important sectors of the EU economy.

The European Commission has identified certain raw materials including cobalt, as being critical raw materials (CRM) that are “economically and strategically important” [EC 2010; and EC 2014]. There have been several studies and surveys conducted on CRMs to examine the possible impacts on key applications, that depend on cobalt such as Batteries, Magnets, Electric Motors and Drives, and Super Alloys [CRM Innonet 2015]. Furthermore, the MIS for SETIS [EC 2016a], identifies several material-related energy technologies that depend on cobalt, including: Bioenergy; Carbon Capture and Storage; Nuclear Energy; and Concentrated Solar Power.

The CRM Alliance notes that “legislation affecting CRMs should require a socio-economic analysis of any potentially harmful impacts to the supply and use of CRMs on upstream European producers as well as to downstream European supply chains as a first step in the regulatory process” [CRM Alliance, 2015]. Therefore, the CDI/CoRC request that ECHA and the EC conduct such a socio-economic assessment, on the potential impacts of this cobalt CLH proposal on all affected industries, before taking their decision for the new ATP (Adaptation to Technical Progress).

6 - MANUFACTURE AND USES

The CLH proposal (Section 2.1, page 14) simply states that information on Manufacture is ‘Not relevant’, without any explanation being provided. The CoRC/CDI therefore provide summary information which emphasises the importance of cobalt manufacture and uses in Europe.

In the CLH proposal (Section 2.2, page 15) it is noted that ‘cobalt has many uses including use as an intermediate and for the production of magnets, varistors, batteries, alloys and catalysts.’ This one sentence is inadequate to convey the scope and importance of these uses to the EU economy.

To provide more up-to-date information for the REACH registration dossier and in support of on-going activities with other regulatory processes, the CoRC conducted detailed surveys with the EU Manufacturers/Importers and Downstream Users of cobalt (and other cobalt compounds). This survey programme included the following studies: Data collation for the update of use/volume information in the REACH Registration dossiers (IUCLID sections 3.5 and 3.7) [wca and eftec, 2015a]; a Material Flow Analysis (MFA) and value chain analysis of cobalt [eftec and wca, 2015]; and Collection of data/information on possible substitutes/alternatives for cobalt [wca and eftec, 2015b].

The majority (approximately 93%) of raw materials which are used to manufacture refined cobalt are imported into the EU, with the remaining (7%) being produced within the EU28 [eftec and wca, 2015]. The MFA study conducted for cobalt showed that on average, each year around 28,000 tonnes of cobalt metal is manufactured in or imported into the EU28 (average over the period 2011 to 2013). Of the cobalt metal that is manufactured and imported, more than half (56%) is used within the EU28 (sold or internally used); and the remainder (44%) is used outside of the EU28. The production value of the refined cobalt metal manufactured in, or imported into, the EU28 is estimated at €672 million per year (based on mean average cobalt price 2011 to 2013 from Metals Bulletin data in Roskill 2014).

The MFA study also estimates the value added by EU companies at each stage in the supply chain. In the case of EU M/Is, a large proportion of their costs comes from the importing of raw materials (e.g. cobalt-containing raw materials) and the value added by EU M/Is comes

from producing refined cobalt metal, and other services like distribution, storage and sales services). The value added by M/I's activities (predominately from EU Manufacturers rather than from importers) is estimated at €98 million per year (i.e. it excludes the cost of purchasing the cobalt-containing raw materials and other materials) [eftec and wca, 2015].

Based on the current price of cobalt the annual value added by EU M/I's would be higher than those previously quoted above and below, because the official cobalt cash seller and settlement price for 21 February 2017 was US\$48,000/tonne (~€45,575/tonne), as quoted by the London Metal Exchange. Given that the volume of cobalt metal manufactured and imported into the EU28 has remained similar between 2015 and 2016 (CoRC/CDI) the production value of cobalt metal manufactured in, or imported into, the EU28 is estimated at ~€1.27 billion per year; with an associated value added of ~€185 million per year.

Cobalt metal is then used by the downstream users (DU's) alongside other raw materials, equipment, and labour for producing finished products, therefore the value added by the DUs from the use of the metal itself cannot be fully attributed to cobalt metal. It was not possible to determine from the survey responses alone what proportion of value is added due to the use of cobalt metal and what is added by the other raw materials etc. However, even if the cobalt metal is used in very small quantities, it may be essential to the finished product and therefore the value added cannot be based on the relative quantities of each raw materials used. From the survey studies carried out by CoRC, the total value added that was estimated (by broad use category) was considered highly relevant. This is because an inability to use cobalt would affect the continued production of these DU products (i.e. it would impact upon all the value added: raw materials, equipment and labour used) [eftec and wca, 2015].

The survey study on possible substitutes/alternatives for cobalt [wca and eftec, 2015b], showed that in general, the companies are aware of the hazardous properties of cobalt and the importance for the safety of their workers but feel that cobalt confers their product with specific properties and the market would not accept the possible alternative products. For many of the uses identified, companies indicated that the time required to implement alternatives would result in a significant loss in efficiency, productivity and performance. In many sectors, awareness of possible regulatory constraints is growing and R&D activities are ongoing and are being given higher priority (including collaborations with universities and institutes) but more work is needed. Companies noted that for many potential alternatives, such as other metals, there were safety concerns similar to those for cobalt substances [wca and eftec, 2015b]. In summary, the possibility and availability of substitutes/alternatives depends on the application, and the various sectors have reported that there are not very many feasible alternatives to use of cobalt in these applications.

Cobalt metal has eight broad uses, and is used to make numerous final products. As noted, approximately half (56%) of the cobalt metal manufactured/imported into the EU, is used within the EU28. The main broad use categories identified from the survey responses, and the estimated volumes (as percentage of the total), are as follows: Chemicals (55%); Carbide tools (12%); Batteries (10%); Catalysts (8%); Metallurgical (8%); Magnetic alloys (6%); Pigments (1%) and Electronics (<1%) [eftec and wca, 2015]. The following specific comments are provided regarding the implications of the CLH proposal for each of these main broad uses of cobalt.

6.1 – CHEMICALS

The largest use (~55%) of cobalt metal within the EU28 is within the chemicals sector where it is used to make other cobalt chemicals, such as cobalt salts and cobalt oxides [CDI 2006b]. The use of cobalt metal to produce other cobalt compounds is an intermediate use,

and therefore outside the scope for potential future Authorisation under REACH. The other cobalt compounds produced will be assigned their own classifications, according to REACH and CLP requirements. These various uses include: Adhesives/Cobalt soaps; Decolourising; Driers/Paints/Inks; Electroplating; Agriculture and Medicine; Animal Feed; and Specialist Chemicals. There are different industry associations for each use sector. Several of these sector groups do not use cobalt metal directly, but have indicated their support for the CDI/CoRC technical position regarding the CLH proposal.

The value of cobalt metal used in the EU (i.e. excluding sales outside the EU) by the chemicals sector was estimated at ~€202million per year, based on a cobalt metal price of €24,100/tonne (mean three-year average from 2011 to 2013). Note that the current value of cobalt metal is even higher (€45,575/tonne) compared to the average price in 2011-2013.

The refined cobalt is then used as an intermediate to produce other cobalt compounds so it is not appropriate to estimate the value added, in this case [eftec and wca, 2015]. In order to estimate the value added, further data is firstly required to understand how much of each cobalt compound is being made with the cobalt metal and how many end-user products are then being made with each cobalt compound. It was deemed better to avoid estimating a value added for this sector (in order to avoid 'double counting') with any resulting value added being more appropriate to fully assign to each resulting cobalt compound made (e.g. the value of using cobalt oxides are fully attributed to the cobalt oxide supply chain rather than a partial value being assigned to cobalt metal). However, the importance and value of these cobalt compounds should not be underestimated, and further analysis has been carried out by CoRC/CDI which demonstrates the significance of these cobalt compounds.

6.1.1 – Surface Treatment Sector

The Cobalt Secretariat contacted the SEA (Surface Engineering Association) and Vereniging ION (representing the surface technology companies in the Netherlands) to discuss the possible implications of the cobalt CLH proposal on the surface treatment sector in Europe.

The SEA considers the CLH proposal for cobalt metal will cause significant detrimental socioeconomic effects for the surface treatment industry in Europe. The industry is currently suffering from increased regulation of other compounds which have caused a great cost; the CLH proposal for cobalt metal, should it go ahead, would add further burden to an industry already at breaking point [SEA 2016]. Cobalt metal is intentionally used in many different processes for surface treating including, thermal spraying, phosphate layering, polish buffs and powder spraying. Of these uses, all are essential and have important benefits to different industries. Coating surfaces with cobalt containing sprays is essential for preventing corrosion of certain products. For some appliances, such as in aerospace, these non-corrosive properties are vital for securing the safety of the general public. In some of the uses, cobalt has already been identified as the preferred alternative to previous substances. It will therefore be hard to find a suitable substitute to cobalt. Furthermore, the research required for finding a suitable alternative would be very costly, particularly for an industry which is predominantly (92%) comprised of Small to Medium Enterprises (SME). Even if a suitable alternative is found from this research, further testing on the safety and efficacy of the substitute substance could take 10 years to complete. There could also be requirements for standards and approvals, as well as time to achieve market acceptance. The Carc 1B all routes of exposure classification and the SCL of 0.01% would require manufacturers to conduct additional studies (i.e. bioelution tests) for proving that there is no cobalt release from surfaces that have been coated [SEA 2016]. This would make EU surface treatment companies less competitive compared to companies outside of the EU, who would not have to comply with this strict SCL. Therefore, the CLH proposal could lead

to surface treatment companies deciding to relocate outside of the EU, or see their market share eroded through increased imports of articles [SEA 2016].

Vereniging ION have reported that cobalt is used throughout the surface treatment industry, and consider the proposed CLH for cobalt metal could impact on the surface technology industry in many areas, including: Pigments (powder coatings); Dyes by anodising; Enamel – ground/basic enamels; Galvanizing - zinc-cobalt baths; nickel-cobalt baths; tin-cobalt baths; Brush plating; Electroforming; Electro less deposits of cobalt in the electronics; Polishing Baths (for aluminium); Ceramic materials used in flame spraying; Welding of cobalt-containing stainless steel types; Additive of phosphate layers (such as chemical pre-treatment); PVD (Physical Vapor Deposition) and CVD (Chemical Vapor Deposition); and Heat treatment of steel [Vereniging ION, 2017]. It should also be noted that cobalt is being used as a substitute for other metals (such as chromium and cadmium), and the surface technology industry has already done much work with that prospective. If these many uses of cobalt are subject to further regulatory actions (e.g. authorisation or restriction), then the industry will have to re-examine new suitable alternatives, which would entail significant time/effort and research costs. Vereniging ION notes their goal is to reduce SVHCs (substances of very high concern) as much as possible, and they actively support the industry with knowledge transfer and research programs. The ION motto is: substitute if possible, and authorise when necessary (with realistic authorisation terms) [Vereniging ION, 2017]. The surface technology industry will be looking closer into the many implications of the proposed CLH for cobalt metal, and would appreciate an opportunity to further clarify their position.

6.2 - CARBIDE & OTHER TOOLS

The second major use (~12%) of cobalt metal within the EU28 is within the carbide and other tools sector, where cobalt is combined (used as the binder) with other substances/materials (e.g. tungsten carbide) to produce hard-wearing alloys for use in manufacture of drilling/cutting tools and machinery, that are then used in the construction, mining, and oil & gas sectors [CDI 2006c]. These cobalt and other powder alloys applications are represented by the EPMA (European Powder Manufacturers Association), and by the ITIA (International Tungsten Industry Association). Both these associations have prepared separate response comments on the CLH proposal, and have also contributed to CoRC/CDI joint response comments, as outlined below.

The estimated value of cobalt metal used in the EU (i.e. excluding sales outside the EU) by the Hardmetal and Carbide Tools sector is approximately ~€43million per year, based on a cobalt metal price of €24,100/tonne (mean three-year average from 2011 to 2013). Note that the current value of cobalt metal is even higher (€45,575/tonne) compared to the average price in 2011-2013. The value added by cobalt metal M/I's for the Hardmetal and Carbide Tools sector is estimated at ~€11million per year [eftec and wca, 2015].

The downstream users (DUs) use cobalt metal as well as other raw materials to make their various carbide tool products, which can also go in to other tool products and equipment. The final end-user products sold by these DUs are valued at least €5billion per year. The EU28 value added by DUs, is estimated at least ~€3billion per year. These values (based on available Eurostat data) are considered an underestimate of the total value of the sector [eftec and wca, 2015].

6.2.1 - Powder Metallurgy Sector

The EPMA describe Powder Metallurgy (PM) as the process of transforming powders materials into a desired shape or form with the requested properties, by using different

technological processes (e.g. Press & Sinter, MIM, HIP, AM, etc.). The European market for PM products is currently large and has a turnover of €10billion per year with powder production exceeding 200,000 tonnes [EPMA, 2016]. Many sectors with the powder manufacturing industry will be affected by the CLH proposal for cobalt including: Ferrous Structural and Functional PM (Press & Sinter), Metal Injection Moulding (MIM), Cold and Hot Isostatic Pressing (CIP and HIP), Metal Additive Manufacturing (AM or 3D Printing), Wet powder spraying, (dry) machining and Hard Metals (represented also by ITIA).

The various uses for powder metallurgical (PM) production in the EU are as follows (showing percentage splits based on value for year 2014): PM Structural Parts/Bearing (Fe based alloys) (26 %); Hard Materials (WC) (32%); Diamond Tools (16%); PM Semi Part (8%); Sintered Magnet (8%); MIM (3%); and HIP (3%) [EPMA, 2016]. The hard materials are mainly using WC-Co alloys, and about half (50%) of the MIM/HIP market is Stainless Steel. Note that the Hard Metals sector is represented by ITIA, and the Stainless Steel sector is represented by ISSF (International Stainless Steel Federation).

In particular, the 3D Printing applications are a growing industry, and very important to the EU economy. Globally, the 3D printing is predicted to grow at a compound annual growth rate of 28.5% between 2016 and 2022, with an estimated market value of ~\$30 billion (~€28 billion) by 2022 [Markets and Markets, 2016]. Currently, the EU market represents 28% of all global revenue from the market [UPS and CTA, 2016]. Within Europe, a future focus of the market is expected to be on the application of 3D printing for medical applications [Transparent Market Research, 2013], which includes the use of cobalt-chrome alloys for dental and medical implants.

The EPMA notes that cobalt being perceived as such a potent carcinogen will harm developing applications that utilise cobalt containing alloys. For example, 3D printing techniques used in medical devices, tooling and aerospace will face larger costs in handling cobalt products in their processes and disposal in their waste streams. If costs to guarantee safe use of Co are too high the production of Co-containing articles may be stopped. Probably the demand for Co-containing articles could be stopped from customer side (reputation -green products). Most cobalt containing alloys have specific qualities that cannot be replicated by other materials. Examples include alloys for dental and medical devices where cobalt confers biocompatibility and in aerospace alloys where cobalt confers excellent creep strength. Cobalt is also vital in maraging tool steel which unique properties are used in 3D printing, in permanent magnetic powders and in controlled expansion alloys such as Kovar [EPMA 2016].

Finally, the EPMA explains that recycling of products containing cobalt above the proposed SCL of 0.01% will be negatively impacted. The new classification for cobalt will cause contracted recyclers to charge higher costs to manufacturers due to their reluctance of handling hazardous goods. Reprocessing of rejected material will also not be possible leading to a higher volume within the waste stream increasing cost for industry and having a negative impact on the circular economy. For internal recycling, work place dust measurements will have to be intensified in order to check if the exposure is within the given limits. Additional, mainly technical RMM will have to be implemented if required. Depending on costs for additional RMM companies might stop internal in-house recycling [EPMA 2016].

6.2.2 - Hardmetal Sector

The hardmetal industry is a downstream user of cobalt as hardmetal which is produced by directly mixing tungsten carbide with typically 3-30% cobalt. The tungsten carbide provides high hardness and wear resistance while the cobalt acting as binder adds strength to the

hardmetal mixture. In 2015, the European tungsten consumption was around 19,000 tonnes, and approximately 66% (12,540t) was consumed in the manufacture of hardmetals as follows: 12,540t tungsten (which is equivalent to 13,360t of tungsten carbide), was used in the manufacture of hardmetal; and typically 10% cobalt (binder agent) is mixed with tungsten carbide to produce approximately 15,000t hardmetal [ITIA 2017].

The ITIA reports that Hard metal tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The automotive, aerospace, energy and general engineering sectors all use hard metals to facilitate the processing of steels, other metals, wood and composite materials. Also, mining, construction, oil and gas industries are dependent on high-performance hardmetal tools and applications for rock processing. Over the last 50 years, these industries have seen an increase in productivity largely due to the emergence of improved hard metal tool technology. Cobalt metal (usually added in powder form before sintering) is used as the binder in hard metals. It is the highest performing alternative in most applications. Under the very stringent CLH proposal for cobalt metal, most hard metal powders will be classified as a Carc 1B for all routes of exposure, Repr 1B and Muta 2. Due to the scope of the Carcinogen or Mutagens at Work Directive, there will be prohibitive increases in manufacturing costs should the proposed CLH be implemented [ITIA 2017].

The direct impacts of the proposed classification to the hardmetal industry are described in this section and are associated with classifications more stringent than the cobalt industry self-classification of Carc 1B through inhalation, and Repr 2. For 'cobalt-free' hardmetal the current existing processes in the hardmetal industry are established to control to a Generic Concentration Limit of 0.1%. The proposed low Specific Concentration Limit (SCL) of 0.01% would require "cobalt-free" hardmetal tools to be produced in entirely separate facilities. Production process re-engineering would not only affect manufacturers but also downstream users, leading to a cost increase of many hardmetal containing products. In addition, the proposed carcinogenicity and reproductive classifications would trigger a major change in the manufacturing process of hardmetal. Production would have to change dramatically into an enclosed, highly automated system like the ones employed by the pharmaceutical industry, which will be extremely challenging if not impossible for article manufacturing [ITIA 2017].

The increased cost in manufacturing hardmetal will have negative consequences for the industry in the EU, as hardmetal products will rise in expense (due to an increase of manufacturing costs), making them less competitive in an extremely competitive global market. A cobalt hazard classification which is not scientifically supported will drive costs connected to disproportionate risk management measures. In the EU, this could contribute to hardmetal industries moving production to regions outside of the EU where hazard classifications are more in agreement with the cobalt industry classification position, and possibly only final products (articles) would be imported into the EU [ITIA 2017].

Additional impacts to industry by the proposed classification would also affect downstream users not only via more expensive tools, but also via changed handling including investments for closed machines. A possible future inclusion in the Candidate List will include an increased cost for tracing and analysing the cobalt content in products [ITIA 2017].

The ITIA also consider from the cobalt CLH proposal there will be effects on innovation and substitution. For metal working tools and other cutting operations WC-Co (tungsten carbide cobalt) combinations are far superior to other alternatives for the vast majority of applications. During the past 50 years, many efforts have been taken to find alternatives to replace cobalt as a binder in hardmetal. However, the tool life and performance of other

binder systems including nickel, chromium and iron is drastically reduced and such alternative binder systems still contain at least 5% of cobalt [Norgren et al. 2014]. Alternative materials to hardmetal, such as ceramics and Cermets have been found to be only useful in specialized or niche applications. Other ultra-hard materials, such as polycrystalline diamond (PCD) and cubic boron nitride (CBN) perform very well, but due to their brittleness they must be applied to a substrate of cobalt containing hardmetal as support [ITIA 2017].

The increased handling and processing cost of recycling, triggered by the proposed classifications could have a major effect on the amount of cobalt containing hardmetal scrap that is recycled. It is likely that, due to the strict classifications and a lower SCL for cobalt metal, large amounts of hardmetal will be processed outside of the EU, where cobalt hazard classification are more in agreement with the cobalt industry position. The current recycling rate of up to 90% for used tools in the EU is likely to fall drastically causing a higher use of imported raw materials [ITIA 2017].

6.3 - BATTERIES

The third major use (~10%) of cobalt metal within the EU28 is within the Batteries sector. The cobalt is used as an intermediate to manufacture other chemicals that are the active components of the battery. The main applications are for rechargeable batteries, which are essential for promoting a green circular economy [Recharge 2017a]. There are three types of high density batteries that use cobalt: nickel-cadmium (Ni-Cd) batteries in standby and other industrial applications (e.g. railways, aviation, telecom, etc.); nickel metal hydride (Ni-MH) batteries in hybrid electric vehicles and portable applications; and lithium ion (Li-ion) batteries in telephones and computers, and the developing electric mobility market. These applications are represented by RECHARGE (The Advanced Rechargeable & Lithium Batteries Association) and EPBA (European Portable Batteries Association).

The estimated value of cobalt metal used in the EU (i.e. excluding sales outside the EU) by the Battery sector is ~€36million per year, based on a cobalt metal price of €24,100/tonne (mean three-year average from 2011 to 2013). Note that the current value of cobalt metal is even higher (€45,575/tonne) compared to the average price in 2011-2013.

The value added by cobalt metal M/I's for the Batteries sector is estimated at ~€10million per year. The production values for finished goods (batteries made at some stage using cobalt metal) is estimated at ~€1billion, based on data from Eurostat (PRODCOM codes for rechargeable battery products). The EU28 value added by DUs, is estimated at ~€319million per year (for rechargeable battery products) [eftec and wca, 2015].

The European Portable Battery Association reports that cobalt is utilised in portable batteries in both the primary and rechargeable segment. For the primary batteries, cobalt is used in the metal casing of alkaline batteries. The cobalt layer is on the inner surface of the battery casing and therefore an exposure/contamination during handling or use of alkaline batteries by consumers is not possible [EPBA 2016].

For rechargeable batteries, Cobalt is used in the cathode and anode within NiMH batteries. In these batteries, the amount of cobalt in the anode and the cathode varies between 2-6% and is usually in the metal form or oxyhydride form. The trend by manufacturers and suppliers is to aim to reduce the cobalt content due to cost however no viable alternative has been found to date. For the NiMH battery, the lowest cobalt content achieved so far is higher than the proposed SCL, and so the input materials would be affected by the proposed classification. For the Lithium Ion batteries, the LCO type (Lithium Cobalt Oxide) have the most content of Cobalt in an alloy. The alloy of the Lithium Cobalt Oxide battery

can be more than 50% w/w. Cobalt is an important element of this alloy. The NiMH and Lithium ion batteries are mainly imported articles with no intended release of chemicals (REACH) therefore the CLH consequences are more on the end of life (EoL) management stage of the life cycle [EPBA 2016].

RECHARGE reports that cobalt metal is mainly used as an intermediate for the manufacturing of other cobalt compounds used as active materials for electrodes manufacturing. However, cobalt metal is present as an impurity above the proposed SCL of 0.01% in several metals (nickel, stainless steel, alloys) widely used in the battery manufacturing. This impurity is not economically removable, and technical feasibility also has to be considered [Recharge 2017b].

6.4 - CATALYSTS

Another major use (~8%) of cobalt within the EU28 is within the Catalysts sector where cobalt and its compounds are used to manufacture other cobalt compounds (precursors) that are used to produce catalysts for use in the petrochemical, plastics, and detergents sectors [CDI, 2006b]. This is an intermediate use of cobalt, and therefore outside the scope for potential future Authorisation under REACH. However in some niche cases the metal itself is used in catalysts.

The use of cobalt as an intermediate in catalyst preparation applications supports the Climate Change initiatives for reduction of Greenhouse Gases. For example, the commercialization of the fuel employed by cars is only possible after it has been refined with catalysts containing cobalt compounds which help make it more eco-friendly through the reduction of sulphur and nitrous oxide emissions. In particular, one tonne of cobalt compounds applied as catalyst mixture contributes to a SO_x emission reduction of 25,000 tonnes and a NO_x emission reduction of 750 tonnes per year [EPPA 2012]. The catalyst applications are represented by the ECMA (European Catalysts Manufacturers Association), and ECMA has contributed to these joint response comments.

According to the European Chemical Industry Council [CEFIC, 2015], the European Catalysts market represents over 20% of the world market, and reached a value of over €3 billion in 2012 (based on about 600,000 metric tonnes). Note this data represents the entire catalyst market, (i.e. including catalysts that were not produced using cobalt metal or cobalt compounds), but clearly shows the importance of EU catalyst producers to the global market [eftec and wca, 2015].

The ECMA report that Catalysts represent a major use sector for cobalt and cobalt compounds, and the use of catalysts is integral to a sustainable planet. A major use of cobalt compound containing catalysts for example includes oil desulphurisation whereby the sulphur moiety is removed from the petroleum stream reducing the greenhouse gas content of the air exhaust. Cobalt containing catalysts are also integral for the use in the plastics industry both in the synthesis of plasticisers and in the OXO process (to produce aldehydes from alkenes) [ECMA 2017].

The ECMA note that cobalt and its compounds are essential to the catalyst industry due to its availability and unique catalytic properties. Other alternatives to cobalt do exist however these tend to be the precious metals, for which availability and higher cost are limiting factors for industrial use. Furthermore, some of these alternatives to cobalt such as palladium and platinum are more readily poisoned by impurities, which reduces the performance of the catalyst. It is possible for other base metals including nickel and iron to substitute for cobalt in the catalyst in some cases, however these other metals can have lower performance and efficiency, which can increase cost and frequency of catalyst changes [ECMA 2017].

6.5 - METALLURGICAL ALLOYS

Another major use (~8%) of cobalt within the EU28 is within metallurgical alloys applications in the medical, aerospace and defence, and energy sectors. In the medical sector, cobalt and cobalt alloys are used in dental alloys and implants (e.g. crowns and fillings), medical implants (e.g. stents, pacemakers), medical devices, and prosthetics (e.g. knee and hip replacements) [CDI, 2006d]. For example, cobalt-chrome alloys are used in orthopaedic and dental implants due to their biocompatibility, and high resistance to corrosion and wear resistance. These medical devices/implants are Articles, and not covered by CLP (EC 2009), although the substances used to manufacture the Article (e.g. cobalt, cobalt alloys) would be subject to CLP (require a classification). In the Aerospace sector, cobalt is used to produce super-alloys for specialist applications (e.g. aero-engines, jet turbines, etc.) where high temperature strength and wear resistance is important. In the Energy sector cobalt is used in steam turbines, power plant protective coatings and on wind turbine blades for renewable energy. All these key sectors represent high value to the EU economy, both in terms of production and consumption.

The estimated value of cobalt metal used in the EU (i.e. excluding sales outside the EU) by the Metallurgical alloys sector is approximately ~€29million per year, based on a cobalt metal price of €24,100/tonne (mean three-year average from 2011 to 2013). Note that the current value of cobalt metal is even higher (€45,575/tonne) compared to the average price in 2011-2013.

The value added by cobalt metal M/I's for metallurgical alloys is estimated at ~€8million per year. The total annual average production value of the manufacture of products of cobalt metallurgy is €334m for the period 2011 to 2013. However, this value (based on Eurostat data) is considered an underestimate, and the average production value for metallurgical products is believed to be closer to ~€1.4billion per year (based on respondent data). The EU28 value added by DUs, is estimated at ~€104million per year [eftec and wca, 2015].

6.5.1 – Medical Devices Sector

MedTech Europe, is the European trade association representing the medical technology industries. Med Tech Europe considers the CLH proposal for cobalt metal (Carc 1B by all routes, and low SCL 0.01% applied to "all forms of cobalt metal") is too broad and not based on actual risk. The use of cobalt and cobalt based alloys in the solid form should be clearly excluded from the CLH proposal. Otherwise this could create a deleterious impression on the use of viable implant materials in the medical devices sector, which have satisfied the needs of the medical community for a long time without a correlation to CMR. As stainless steels (99% of which contains cobalt as an impurity above the proposed SCL) and other cobalt-containing alloys are used in the medical sector, Med Tech Europe predicts a potentially large impact on future regulation and compliance [Med Tech Europe, 2016].

The toxicity of a cobalt-containing material depends on whether the cobalt is released from the article. If the cobalt is alloyed with certain metals and elements, it is encapsulated in the article so that it is not released and the body does not assimilate it. Moreover, cobalt based alloys in articles are presently extensively used, for example, in knee implants, spinal implants, coronary stents and associated instruments without issues of cobalt toxicity. The CLH proposal could cause upstream impacts on the production of these implants, (e.g. on the use of cobalt alloys as mixtures), which are industrial and/or professional uses. If this CLH proposal proceeds and results in an Authorisation or Restriction, the regulatory burden on this sector to prove what we know, the use Medical Devices containing Cobalt in an alloy is safe, is enormous. The requirement for, and applicability and consequences of a possible

future Restriction would have to be assessed on a case-by-case basis. Derogations would need to be prepared to allow for continued use of cobalt in these articles, which would require considerable efforts and present significant costs for the European medical community [Med Tech Europe, 2016].

The SSINA (Specialty Steel Industry of North America) reports there is no viable substitute for the use of cobalt in alloys used for medical implants. Cobalt-based alloys replaced the previous use of stainless steel alloys for medical implants due to better durability and wear resistance in these applications. The carcinogenicity of implants made from stainless steel and specialty alloys, including cobalt-based alloys, was evaluated by IARC (International Agency for Research on Cancer), and implants of cobalt-based alloys (and other metal implants) are not classifiable as to their carcinogenicity [IARC, 1999]. Significantly, the long history of use of cobalt-based alloys in medical implants does not indicate an increased risk of cancer, mutagenicity, or reproductive toxicity [Visuri et al., 2006; and Visuri et al., 2010]. For certain implant applications, ceramics and titanium alloys may be viable substitutes. However, these materials are not suitable for all implant applications, and cobalt-based alloys generally exhibit greater durability and wear resistance. For example, titanium lacks the wear resistance to be viably used for a femoral ball. Similarly, ceramic cannot be used for femoral stems due to lack of toughness and durability. Cobalt-based alloys are superior options because they combine all of the desired characteristics for a wide range of implant applications [SSINA 2016].

One specific application of this is in hip replacements, where cobalt chromium has long been used in the stem and ball of the implants. Based on Eurostat information, there were over 860,000 hip replacement operations conducted in 23 EU Member States in 2013, up from approximately 845,000 in 2012 [Eurostat, 2016a]. Between 2005 and 2013, the hip replacement market in Europe has grown at 3.5% and is expected to reach \$2.3 billion (~€2.2 billion) in 2019 [ABMRG, 2014]. One major contributor to this rise in the market is the aging population within the EU, where the share of the population aged 65 years and over (i.e. those at greatest risk of requiring hip replacement surgery) across the EU28 rose by 2.3% between 2005 and 2015, and is projected to rise by a further 9.5% 2015-2060 [Eurostat, 2016b; and Data Bridge 2017]. Therefore, the demand in the European market for hip replacement implants is expected to continue to grow into the future.

6.5.2. – Aerospace Sector

The Aerospace sector consumes approximately 55% of all super-alloys [Roskill 2013, based on 2012 data]. Although, cobalt-based alloys only consist of approximately 5.7% of the world market (in 2012) for super-alloys [Roskill, 2013], cobalt is also found as an impurity, or at low levels by design, within Nickel-based super-alloys, which makes up the majority of the global super-alloy market. There are also several niche applications for cobalt-containing (maraging) steels in the aerospace and military industries (e.g. torque shafts, rocket motor castings, etc.).

Aeronautics is one of the EU's key high-tech sectors on the global market [DG GROW 2017; and ASD 2015]. This sector provides more than 500,000 jobs and generated a turnover of close to EUR 140 billion (in 2013). France is the second-largest consumer of aerospace composites (which includes super-alloys) globally in 2013, after the USA [Markets and Markets, 2014]. The EU is a world leader in the production of civil aircraft, including helicopters, aircraft engines, parts and components; and the EU has a trade surplus for aerospace products, which are exported all over the world.

The EU through the 'Advisory Council for Aeronautics in Europe' has a vision for 2050 which sets a number of goals, all of which will rely on new technology and some on much higher

engine efficiency and dramatically reduced emissions. Without super alloys and innovation incorporating a wide spectrum of materials it is questionable whether these goals will be met. The EU aerospace industry needs to incorporate the very latest in metallurgical innovation and technology and should a range of strategically important metals not be available such as cobalt and nickel based super-alloys, specialty stainless steels, high-strength permanent magnets and state-of-the-art electronics then this multi-billion Euro industry will not be able to compete in the global market. The global aerospace market for super-alloys is forecasted to grow consistently at a CAGR of 2.6% from 2015 to 2020 [Lucintel 2015].

Furthermore, there is a particular global emphasis on End of Life aircraft management such that aircraft are decommissioned, dismantled and recycled in safe and environmentally responsible conditions. The objective is to optimise recycling and value of aircraft materials and reduce the quantity of waste to be eliminated (EcoSmart). The proposed classification (Carc 1B all routes, and very low SCL) would have a profoundly negative impact on this sustainable development goal.

6.6 - MAGNETIC ALLOYS

Another use (~6%) of cobalt within the EU28 is for magnetic alloys used in the manufacture of permanent magnets for a range of 'high tech' applications in the automotive and other sectors. Cobalt is ferromagnetic and is commonly alloyed with aluminium and nickel to produce powerful magnets. For example, Alnico and SmCo magnets are used in relatively niche markets, including electric motors, guitar pickups, microphones, sensors, loudspeakers, medical instruments and generators; while NdFeB magnets are used in a host of applications requiring miniaturisation such as efficient motors and actuators or disc drives, sensors, etc. [CDI 2017b].

The estimated value of cobalt metal used in the EU (i.e. excluding sales outside the EU) by the Magnetic Alloys sector is approximately ~€22million per year, based on a cobalt metal price of €24,100/tonne (mean three-year average from 2011 to 2013). Note that the current value of cobalt metal is even higher (€45,575/tonne) compared to the average price in 2011-2013.

The value added by cobalt metal M/I's for Magnetic alloys is estimated at ~€6million per year. The total annual average production value, based on the PRODCOM codes for the manufacture of permanent magnets and articles intended to become permanent magnets was €335million for the period 2011 to 2013. However, this value (based on Eurostat data) is considered an underestimate, and the average production value for magnetic alloys is believed to be closer to ~€1.7billion per year (based on respondent data). The EU28 value added by DUs, is estimated at ~€114million per year [eftec and wca, 2015].

The UK Magnetics Society reports cobalt is present in the three types of permanent magnets: neodymium (NdFeB), nickel-cobalt (AlNiCo) and samarium cobalt (SmCo). Permanent magnets are hard to manufacture and are done so using powders which are then compressed and heated to create the massive form alloy. The magnetic alloy manufacturers will be impacted the hardest by the proposed CLH for cobalt metal as they will have to apply for derogations and collect new data proving that there is no release of cobalt from magnets. The time and costs for preparing an application for such a derogation will be an additional burden for European manufacturers who already face heavy competition from outside Europe [UK Magnetics Society, 2016].

The metallic bonding and structure created during the manufacturing of the alloys mean that there is insignificant release of cobalt later in the manufacturing chain. The alloys can

be broken down again into the constituent elements, but this takes a major effort requiring strong chemicals, and is rarely done. More commonly, the magnets are powdered and recycled in their alloy state by the manufacturers. Currently research groups are investigating initiatives to increase the amount of permanent magnets that are recycled in Europe. The basis behind the project is that the EU is dependent on the rest of the world for importing permanent magnets. Should the strict CLH proposal for cobalt metal be implemented, then recycling will not be possible, leaving the EU heavily dependent on the import of permanent magnets [UK Magnetics Society, 2016].

Permanent magnets using cobalt are critical products, and are almost the only kinds of magnets used in many devices such as generators, motors and actuators. In turn, these devices are used in many applications of the modern world, including wind turbines, computer disc drives, electric vehicles, aircraft and mobile phones. The magnetics industry is vitally important to key sectors of the European economy (i.e. manufacturing, energy generation, communications, transport, etc.). In this regards, the EU Commission has conducted several studies on Cobalt as a critical raw material [Oakdene Hollins and Fraunhofer, 2013; and EC 2014].

6.7 – PIGMENTS

Another use (~1%) of cobalt metal within the EU28 is within the pigments sector. This use of cobalt (and other cobalt compounds) is as an intermediate in the manufacture of inorganic pigments, which are used in glazes for ceramics, glass, and enamels [CDI 2006b]. Note that other cobalt compounds (e.g. oxides) are typically used in the manufacture of the inorganic pigments. These inorganic pigments are substances that are assigned their own classifications, according to REACH and CLP requirements. There are specific industry associations within the pigments sector, several of whom have submitted their own comments independently [IP Consortium 2017; and Frits Consortium 2017].

6.8 - ELECTRONICS

Another use (<1%) of cobalt within the EU28 is within articles produced in the electronics sector. Small amounts of cobalt are used in the electronics industry in the manufacture of magnetic recording material, matched expansion alloys for use in optical and laser instruments, and leads/connectors in semi-conductor applications [CDI 2006e]. Even though the volume of cobalt used may be small, these electronic applications are highly specialised and have high value for the electronic products that are made, and are therefore important to several key sectors such as Automotive, Computing, Communications, Medical, etc.

6.9 - CONCLUDING COMMENTS RE MANUFACTURE AND USES

The above information regarding the manufacture and eight broad uses of cobalt demonstrates that there needs to be careful consideration of the overly strict CLH proposal as this would pose substantial costs and disruption to the manufacturers, as well as significant socioeconomic impacts on a wide variety of key sectors and important end uses. The existing self-classification for cobalt (Carc 1B, H350i) does not pose such potential for socioeconomic impacts on the European economy.

In total, the value added by EU cobalt metal manufacturers (and by EU importers, but to a lesser extent) is estimated to be around ~€185 million per year (based on total revenue at ~€1.27 billion per year). However this value added to the EU economy, is a small proportion of the value added which would be at risk by the CLH proposal. As noted above, cobalt metal is directly used by downstream users across the EU, as well as indirectly,

whereby EU companies that use other metals would also be affected when cobalt is present as an impurity above the levels proposed in the CLH proposal. Cobalt also supports numerous 'mega-sectors', where only a small amount may be used but its use is critical or essential for enabling key technologies (e.g. aerospace, automotive, batteries, catalysts, electronics, manufacturing, medical, etc.).

These downstream users would be negatively affected by the CLH proposal, firstly by the costs of compliance with the CLH proposal, and secondly, from possible losses in sales (and therefore a reduction in their value added to the EU economy from their activities), if the added compliance costs and market stigmatisation from the proposed CLH, results in a reduction in their competitiveness, limits their ability to pass on costs, limits their use of recycled materials, affects their resilience to deal with changes in the market, and affects their ability to invest in R&D and innovation.

7 - OTHER INFORMATION Section of the CLH Proposal

We note that no other information has been provided in the CLH proposal document (Section 6, page 150). However, there is much other important information that should be considered with regards to this CLH proposal, and for the cobalt CLH case.

For example, it should be noted that two new epidemiology studies were initiated to examine occupational exposures of workers in the cobalt industry. The first study examines workers involved in the manufacture of cobalt metal [Epidemiology study – in progress 2017] and the final results from this epidemiology study are expected to be released this year (2017), and will provide new information which is highly relevant for the cobalt CLH case. To generate additional information related to carcinogenicity and cobalt exposure in the hardmetal industry, the leading producers participated in a five-country international epidemiological study that included > 30 000 workers [Hardmetal workers Epidemiological study - in progress 2017]. These findings are undergoing peer-review and are expected to be published during the first half of 2017.

Furthermore, we note that the results of the NTP cobalt metal study are being carefully assessed together with other available information, obtained or being developed by the CoRC and CDI, to determine the possible relevance for the science-based evaluation of other cobalt compounds. The CDI/CoRC have developed a science-based approach to grouping and read-across for the carcinogenicity end-point, which considers all the cobalt compounds including cobalt, and this approach has been previously discussed with the Dutch Authorities (NL RIVM) on several occasions since the 2014 listing of the CLH proposal for cobalt (and other cobalt compounds – tbd) on the Registry of Intentions. The CDI/CoRC have exchanged correspondence with the NL (RIVM) and have provided new information and several study reports to NL RIVM directly (as shown in our Annex 2 document - see pdf copy uploaded separately).

The CoRC has completed the initial stage of the REACH mandated testing for the Reprotoxicity end-points, and the plans for the next stage of testing (EOGRTS proposal) are currently under review by the regulators (ECHA, MSC, EC). These testing proposals are for two specific cobalt substances, which have been selected as reference substances for several different groups of cobalt compounds. It is expected that these parallel REACH requirements for the Carc and Repr end-points should be identified as other information in the CLH proposal, and will be considered in-depth within the CLH case(s) for cobalt.

8 - REFERENCES Shown in the CLH Proposal

In closing, we note that the CLH proposal document (References, Section 7, page 150)

provides only a single reference (CDI/CoRC 2015 confidential), however the CDI/CoRC have provided much new information and several study reports to NL RIVM, as shown in the listing provided in our Annex 2 document (see pdf copy uploaded separately).

9 - REFERENCES for the CoRC/CDI Joint Response Comments

Please note that in total, there are 70 references cited in the comments outlined above, and the full references are provided in the formatted version of the CoRC/CDI Joint Response Comments (see pdf copy uploaded separately).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Zip of CoRC-CDI Joint Response Comments (3 Documents).zip

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	AB Sandvik Coromant	Company-Downstream user	39

Comment received

For more detailed information about impacts of the proposal, please read the attached document [Reference 1 Sandvik Coromant response 20170223].

Hard metal is produced by mixing cobalt (3-30%) directly with tungsten carbide. Hard metal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The proposal has major direct and indirect impact on us when it comes to hard metal production and handling of products containing cobalt. It would also affect our customers that would lower their productivity and increase their energy consumption. The proposal can have a negative impact on the competitiveness of the EU manufacturing industry in the extremely competitive global market, possibly contributing to production and recycling moving to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Coromant response 20170223].

Eliminating cobalt could mean impossibility to machine certain materials or, for example, slower machining increasing the cost of producing a turbine engine by up to 1000% or making a motor block of a truck cost 10 times more. Part of such cost increase comes from higher energy consumption in our customers' production processes. That would change the whole industry and affect the whole value chain including consumers.

Since many years has Sandvik Coromant handled cobalt materials in manufacturing with caution. For decades we have been monitoring and continuously decreasing the exposure to cobalt. We support the current self-classification of cobalt metal, which is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. Overly strict classification, which is not based on scientific facts and which does not give additional health benefit/improvement, leads to disproportionate risk management measures and costs.

MEMBERSHIPS AND SUPPORT.

We are part of the global industrial group Sandvik, an engineering group in tooling, materials technology, mining and construction, being members of international organisations ITIA (International Tungsten Industry Association), CDI (Cobalt Development Institute) and CoRC (Cobalt REACH Consortium). We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH

proposal on Cobalt Metal. January 2017.

In Sweden we are also members of Jernkontoret (member of Eurofer (European Steel Industry)) and Teknikföretagen (member of Orgalime (European Engineering Industries Association)). They also support the technical position of the CDI/CoRC (2017).

Sandvik Coromant is also a member in the European Powder Metallurgy Association (EPMA) who also has been supporting the Cobalt Secretariat (CDI/CoRC).

THIS IS US.

Sandvik Coromant is the world's leading supplier of metal cutting tools, tooling solutions, service and know-how for the manufacturing industry. A majority of the tools produced are hard metal tools containing cobalt. Our customers include the world's major automotive, aerospace, and energy industries. Sandvik Coromant has 8,000 employees (of which 4,700 are based in Europe), and is represented in 130 countries.

We recycle used material to guarantee our customers a future supply of tools and at the same time being mindful of our resources. Since the mid 90's Sandvik has a global recycling system where we buy back used tools, and in 2015 we recycled about 88% of sold hard metal weight.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Sandvik Coromant response 20170223.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Wirtschaftsvereinigung Stahl e.V. / Stahlinstitut VDEh e.V.	Industry or trade association	40

Comment received

The Stahlinstitut VDEh e.V. / Wirtschaftsvereinigung Stahl e.V. represent the German Steel industry. We fully support the scientific arguments submitted by the Cobalt Development Institute / Cobalt Reach Consortium to the Public Consultation and the positions of EUROFER and EUROFER Stainless to challenge this classification proposal and the Specific Concentration Limit.

The German steel industry annually produces 42,1 million tonnes of steel with an amount of secondary material of appx. 19 million tonnes. Steel is brought on market in a massive form. In practice this means that the alloying elements and impurities like cobalt are not available for inhalation, oral or dermal ingestion and therefore cause no risk.

The proposal for Carc. 1B (all routes of exposure) in combination with a (Specific Concentration Limit) SCL of 0.01% also leads to the classification of mixtures containing ≥ 0.01% Co as Carc. 1B. This SCL cannot be justified for products with no availability for cobalt (massive steel products). A differentiation between biological available forms and non-biological available forms should be made.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Deutsche Edelstahlwerke Specialty Steel GmbH & Co. KG	Company-Manufacturer	41

Comment received

We fully support the scientific arguments submitted by the Cobalt Development Institute/Cobalt REACH Consortium to the Public Consultation and the positions of EUROFER, EUROFER TEAM STAINLESS and Stahlinstitut VDEh e.V./Wirtschaftsvereinigung Stahl e.V..

In the following, we provide company-specific additions:

We see no sense in the proposed classification for Carc. 1B (all routes of exposure) in combination with a (Specific Concentration Limit) SCL of 0.01%. This leads to the classification of mixtures containing $\geq 0.01\%$ as Carc. 1B. In our opinion, cobalt can be safely applied also in high concentrations in the steel. Steel powder, also with high cobalt fractions, must also be able to be processed by the industry. A differentiation between biological available forms and non-biological available forms depending on the type of use should be made.

A classification of 0.01% cobalt would affect almost all the steels produced in the company. This applies not only deliberately cobalt alloyed steel. The additional financial expenses resulting from this classification would not be paid by the customer. It must also be assumed that various steels would no longer be sold. Many jobs in the company would be affected.

We have been producing special steels for many decades, also in powder form. Some steel grades have high cobalt contents. These steels have proven their worth in their application. At present no substitution of the cobalt can take place at any point.

Here are some examples:

- steels for high wear resistance for human joints (more frequent surgery for replacement of the implants would be catastrophic for patients) and dentures;
- steels for safety applications (e.g., personal security);
- Steels for machine tools with high hardness and wear resistance (otherwise many workpieces could no longer be mechanically worked on);
- Steels for tools which must have a special hardness;
- Substances to put on to increase the wear resistance of surfaces.

In addition, cobalt-alloyed steel powders are used for new, future-oriented technologies in context of shaping.

Numerous products from other manufacturers are processed in our company: cobalt-alloyed steels are forged, rolled or melted.

About 90% of the substances we use are recirculation scrap. In the case of a classification of 0.01%, these would probably have to be largely replaced by pig iron as a raw material. The additional demand for steel alloys would increase dramatically.

The proposed classification as a probable precursor to the exile of these steels cannot, in our opinion, be represented in socio-economic terms.

According to our findings, the cobalt bound in the steel matrix does not pose a direct threat to humans in the usual use. The safety measures must be taken in the case of mechanical or thermal treatment. In addition to cobalt, this is also true for thousands of other substances.

In the case of applications of steel powders with cobalt parts, cobalt is also bound in a matrix. In our opinion, we must differentiate between whether these powders are further processed industrially with appropriate professional safety measures (eg encapsulation or extraction) or whether they are available to the end user. Powders are only used in industrial processes with all necessary measures of occupational safety and health.

In practice this means that the alloying elements und impurities like cobalt are not available for inhalation, oral or dermal ingestion und therefore cause no risk.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany		Individual	42
Comment received				
<p>With 80% of our alloy spectrum Cobalt is not added intentionally. In consequence of impurities (for details the attachment) these alloys however do contain Cobalt in an amount exceeding 0.01%, and thus would be affected by a lower concentration limit of 0.01%.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 160608 Original Eng.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Austria	Boehlerit Gmbh & co.KG	Company-Manufacturer	43
Comment received				
<p>Although Boehlerit welcomes efforts to ensure safety and health of its employees, the board of the RIVM and all other involved committees should consider the consequences which further reducing the specific concentrations of cobalt and its compounds in all possible areas of contamination bring for all involved companies.</p> <p>Small and medium hardmetal producing companies (as Boehlerit) usually struggle already with reaching the currently allowed threshold values especially for cobalt dust in room air. Processing and finishing of raw hardmetal bodies into tools or suitable wear parts involves steps of grinding, milling, turning an drilling, many of which are done in a pre-sintered state in which the material is still very brittle and produces a lot of dust during machining. Many of these operations are carried out manually on open machines. Although all these work stations are generally supplied with exhaust systems, they remain open to the surrounding air so that a certain amount of hardmetal dust (including cobalt) escapes in the air. With the best available exhaust systems and additional protection of the employee by respirators the current threshold values could be barely reached. A further reduction of Co-values towards 0.01% would mean severe changes in the production lines of all hardmetal producing and processing companies.</p> <p>Of course there are technical solutions available, which ensure the needed dust-free room climate. The microchip industry lives with these since their beginning. But solutions which are suitable for companies working in the area of micro-production are not applicable for the metal processing industry, where parts weighing up to 50 and 70 kg have to be machined in the open. Under these conditions it is nearly impossible to ensure clean-rooms. Therefore the only possible solution would be to equip the workers with a mobile closed-circuit air-supply and gas-tight helmets which leads to heavy duty working and creates a high number of new jobs under difficult working conditions. At Boehlerit at least 50 workers (male & female) would suffer under these new working conditions. The acceptance of such</p>				

measures by the people would surely be not very high and in the end further increases the lack of suitable personnel. On the other hand the supply of the technical equipment plus intensified analytical measurements together with the necessary rise of workers salary due to severe working conditions would cause unproportioned production costs, which will endanger the existence of many of the smaller and medium sizes companies (including Boehlerit).

The discussion of replacing cobalt in hardmetals has been going on for 50 years now. Many research projects have been carried out to find a proper solution, but none was found. The combination of tungsten carbide and cobalt shows such outstanding properties (hardness – toughness relation), which give hardmetals the number one position as tooling material. So far no other system was able to replace WC/Co.

As a result of the tightened production measures prices for European hardmetal tools would increase considerably and European tooling companies would lose further ground in a market, which is constantly infiltrated by cheap Asian products (often produced without severe health regulations). The tooling industry in the EU as a whole would suffer from considerable losses, which in the end results in companies closing down and an increasing rate of unemployment. The RIVM and all the other involved boards should consider the implications which a tightened health regulation for cobalt-containing products brings about, before putting it into action.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Belgium	EUROFER	Industry or trade association	44

Comment received

The Netherlands' harmonized classification proposal will have significant negative consequences for steel, in particular for stainless steels, high-alloy steel, superalloys and their secondary feed materials, and for the critical applications in which they are used. However, not only stainless steel is affected by this proposal. It also has significant effects for carbon-steel. The EUROFER Position Paper elaborates on the consequences of the proposal on the steel industry in general and in particular the non-stainless steel applications.

A significant part of the carbon steel grades contain cobalt as an impurity in the steel. Although few regular standard cobalt analyses are done, it is estimated that for over 50% of the commercially produced steel grades exceed the level of the proposed SCL for carcinogenicity of 0.01% Co metal. The source of this cobalt is because it is present as naturally occurring impurity in raw materials like iron ores and in particular in scrap. In particular steel grades completely produced out of scrap (by the Electric Arc Furnace route) almost all contain over 0.01% cobalt.

In some specific cases cobalt is intentionally added e.g. HSS steels, steels for high temperature/aerospace applications. Cobalt is an essential part of elevated-temperature alloys. Cobalt increases the resistance to deformation at high temperatures. These alloys are used in nearly every boring and milling machines. Cobalt is an essential part of permanent magnets and dental-alloys. These cases strongly resemble the situation for stainless steels grades where cobalt is intentionally added for mechanical purposes. There are no viable substitutes for cobalt in these applications.

If this proposal is adopted in its current form, it will mean that all these grades will become classified in the same way as cobalt metal. Should scrap containing over 0.01% cobalt be considered as a hazardous waste this proposal could be seriously detrimental to recycling. Cobalt metal is not metallurgical problematic at these levels as there are no adverse mechanical or chemical properties induced by its presence.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final EUROFER Carbon Steel Cobalt Input to CLH PC 22.02.17.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Norway	Glencore Nikkelverk AS	Company-Manufacturer	45

Comment received

Glencore Nikkelverk AS is a founding member of the Cobalt REACH Consortium (Corc) and we are also member of Cobalt Development Institute. Glencore Nikkelverk AS has been actively involved in the development of the scientific arguments provided by the Cobalt Reach Consortia and the Cobalt Development Institute (CDI) to this public consultation. Glencore Nikkelverk AS strongly supports the scientific input, provided by Corc and CDI, to this public consultation of a harmonised classification of Cobalt metal.

The Netherlands' harmonized classification proposal will have significant negative consequences for users and down-stream users of Cobalt metal, as particularly described by "Team Stainless" in their contribution to this public consultation. Glencore Nikkelverk is a Cobalt metal manufacturer based in Norway, and our concern is that the regulatory burden that follows, if Netherlands harmonized classification proposal gets accepted without major adjustments will be difficult to comply with and could jeopardize our ability to continue manufacturing in Europe in the future.

Glencore Nikkelverk AS appreciates the requirements for industry to provide high quality scientific data for regulatory purposes given in the REACH regulation. We believe that decisions based on high quality science are to the best for both industry and the society. This is also the reason why Glencore Nikkelverk AS have been actively involved in all relevant Reach consortia, to ensure that our Reach dossiers are of high scientific quality. A proposal for a harmonised classification for a substance, submitted in 2017, is therefore expected to reflect industry's contribution to REACH. By that we understand that e.g. studies with Klimisch score 1 and 2 (often submitted by industry as part of our REACH obligations) are ranked higher than those with lower score (sometimes old studies of unknown quality).

Due to the potential consequences this classification proposal could have for our industry, and the fact that Cobalt metal is a data rich substance, we believe it is of outmost importance that a "weight of evidence" approach is used to finalise a harmonised classification for Cobalt metal.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Seco Tools AB	Company-Downstream user	46

Comment received

For more detailed information about impacts of the proposal, please read the attached document [Reference 1 Seco Tools response 20170221].

Hardmetal is produced by mixing cobalt (3-30%) directly with tungsten carbide. Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The proposal has major direct and indirect impact on us and our customers when it comes to hardmetal production and handling of products containing cobalt. The proposal can have a negative impact on the competitiveness of the EU manufacturing industry in the extremely competitive global market, possibly contributing to production and recycling moving to regions outside of the EU. Impacts of the CLH proposal are described more closely in the

attachment [Reference 1 Seco Tools response 20170221].

Eliminating cobalt could mean impossibility to machine certain materials or, for example, slower machining increasing the cost of producing a turbine engine by up to 1000% or making a motor block of a truck cost 10 times more. That would change the whole industry and affect the whole value chain including consumers.

Since many years has Seco Tools handled cobalt materials in manufacturing with caution. For decades we have been monitoring and continuously decreasing the exposure to cobalt. We support the current self-classification of cobalt metal, which is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. Overly strict classification, which is not based on scientific facts and which does not give additional health benefit/improvement, leads to disproportionate risk management measures and costs.

MEMBERSHIPS AND SUPPORT.

We are part of a leading global engineering group in tooling, materials technology, mining and construction, being members of international organisations ITIA (International Tungsten Industry Association), CDI (Cobalt Development Institute) and CoRC (Cobalt REACH Consortium). We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

We are also members of Jernkontoret (member of Eurofer (European Steel Industry)) and Teknikföretagen (member of Orgalime (European Engineering Industries Association)) in Sweden. They also support the technical position of the CDI/CoRC (2017).

Seco Tools is a leading global provider of metal cutting solutions for milling, turning, holemaking and toolholding. A majority of the tools produced are hardmetal tools containing cobalt. Seco Tools has 4,300 employees (of which 3,000 are based in Europe), and the headquarters is located in Fagersta, Sweden. We are present in more than 50 countries.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Seco Tools response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Pramet Tools, s.r.o.	Company-Downstream user	47

Comment received

For more detailed information about impacts of the proposal, please read the attached document [Reference 1 Dormer Pramet response 20170221].

Hardmetal is produced by mixing cobalt (3-30%) directly with tungsten carbide. Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The proposal has major direct and indirect impact on us and our customers when it comes to hardmetal production and handling of products containing cobalt. The proposal can have a negative impact on the competitiveness of the EU manufacturing industry in the extremely competitive global market, possibly contributing to production and recycling moving to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Dormer Pramet response 20170221].

Eliminating cobalt could mean impossibility to machine certain materials or, for example, slower machining increasing the cost of producing a turbine engine by up to 1000% or making a motor block of a truck cost 10 times more. That would change the whole industry and affect the whole value chain including consumers.

Since many years has Dormer Pramet handled cobalt materials in manufacturing with caution. For decades we have been monitoring and continuously decreasing the exposure to cobalt. We support the current self-classification of cobalt metal, which is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. Overly strict classification, which is not based on scientific facts and which does not give additional health benefit/improvement, leads to disproportionate risk management measures and costs.

MEMBERSHIPS AND SUPPORT

We are part of a leading global engineering group in tooling, materials technology, mining and construction, being members of international organisations ITIA (International Tungsten Industry Association), CDI (Cobalt Development Institute) and CoRC (Cobalt REACH Consortium). We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

We are also members of SST (Association of Engineering Technology) in Czech Republic. This organisation is a member of CECIMO (European Association of the Machine Tool Industries).

THIS IS US

Dormer Pramet develops, markets and sells a broad range of rotary and indexable tools. A majority of the tools produced are hardmetal tools containing cobalt. The core offer includes drilling, milling, threading and turning tools for the general engineering sector. The company has more than 1,400 employees (of which 850 are based in Europe), and offices in 20 countries, serving over 100 countries. Dormer Pramet has production facilities in Europe and South America and a highly developed logistics network. Dormer Pramet is part of a leading global engineering group in tooling, materials technology, mining and construction.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 DormerPramet response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Fachverband Pulvermetallurgie e.V. (FPM) / Federation of Powder Metallurgy in Germany (FMP)	Industry or trade association	48

Comment received

The Fachverband Pulvermetallurgie e.V. represents the economic interests of the producers of sintered parts, metal powders and hardmetals in the German-speaking countries. "Powder metallurgy" (PM) includes the production of metallic (ultra-fine) powders as well as the mechanical compaction of these powders in forming tools with subsequent sintering at high temperatures into finished parts.

In the sintering process formed components are produced by using various powders (e.g. iron, tungsten carbide or mixtures of alloys of various compositions with different amounts of cobalt). Production steps include the pressing process followed by sintering under a protective gas atmosphere or in vacuum.

The advantage of powder-metallurgically produced parts is that these parts can be produced in large quantities even with complex geometry without mechanical finishing.

By saving several cost-intensive production steps, the PM technology leads to parts with tight dimensional tolerances and a considerably more cost-effective and resource-efficient production compared to other types of production.

Cobalt containing alloys have specific properties, qualities and functionalities. Therefore they cannot be replaced by substitutes (e.g. hard metal sector). A switch to other materials would have serious consequences (e.g. costly product tests).

On the basis of the various production steps of PM mentioned above and with the knowledge of the wide uses of cobalt-based alloys in the PM sector, it is obvious that the proposed classification of Carc. 1B (all routes of exposure) together with a Specific Concentration Limit (SCL) of 0.01% would have serious and disproportionately negative direct and indirect impacts on the PM sector.

The proposed very low SCL of 0.01% and the inclusion of all routes of exposure (oral, dermal and inhalation) will lead to fundamental revisions and adjustments of established and efficient manufacturing practices in the PM sector. New production processes and changes to working practices (e.g. closed systems) will result in high additional investments and therefore to disproportionate production costs and ultimately to higher prices of PM products potentially affecting the global competitiveness of the sector. In addition, there will be further measures which need to be implemented to reduce occupational exposure due to the minimizing principle for CMRs (e.g. wider use of PPE, gloves).

With regard to possible indirect effects of the CLH proposal the market impact from CMR stigmatization plays an important role. This will negatively affect whole supply chains with unpredictable impacts on sales. Furthermore downstream sectors will also face larger costs in handling cobalt products (e.g. reducing of occupational exposure). At worst a full phasing out of cobalt containing products would be initiated.

Other negative side-effects and legal consequences will also affect the recycling industry and the circular economy: In the EU waste needs to be classified as hazardous where waste contains a substance known to be carcinogenic cat. 1A or 1B in a concentration of more than 0.1%. For cobalt containing waste this will result in higher recycling costs and therefore in higher cost for primary and secondary materials. Finally recycling initiatives could be undermined.

Other important information to be taken into account in the classification process are:

- the hardmetal epidemiological study (conducted by University of Pittsburgh during 2006 to 2016 covering data of more than 30,000 hardmetal workers) looking into the association between cobalt exposure and cancer in the hardmetal industry (not published yet)
- and the Finnish epidemiological cohort study on cancer incidence in cobalt production (Finnish male cobalt production workers).

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Vale Base Metals	Company-Manufacturer	49
Comment received				
<p>General Comments</p> <p>Vale SA (Vale) is a Brazilian multinational diversified metals and mining company. It is the world's largest producer of iron ore and iron ore pellets and the world's largest producer of nickel. Vale's base metal business is headquartered in Toronto, Canada and is dedicated to mining and processing the non-ferrous metals nickel, copper, cobalt and the associated precious metals, including gold, silver and the platinum group metals. Vale Base Metals has mining operations in Brazil, Canada, Indonesia, and New Caledonia as well as fully-owned and joint venture refineries in China, South Korea, Japan, the United Kingdom and Taiwan. Vale Base Metals is a member of the Cobalt Development Institute (CDI), Cobalt REACH Consortium (CoRC), Nickel Institute, Nickel REACH Consortium, Copper REACH Consortium,</p>				

European Precious Metal Federation (EPMF) and Precious Metal REACH Consortium (PMC). Vale Base Metals supports the specific technical and socioeconomic contributions made by these organisations to this public consultation and in our view the CLH proposal to classify cobalt metal for Carcinogenicity 1B; H350 by all routes (with the Specific Concentration Limit of 0.01%), Reproductive Toxicity 1B; H360f and Mutagenicity; H341 is not justified. As a primary producer of cobalt metal we are very concerned by the implications of the CLH proposal on manufacturers and downstream users of cobalt, that could negatively impact our markets in Europe and beyond. Full details of the repercussions are set out in the CDI/CoRC's Joint Response Comments, but the area of particular concern to Vale is the unintended consequences of the cobalt impurity in nickel and stainless steel. As most grades of nickel and virtually all grades of ferronickel contain greater than 0.01% cobalt, the carcinogenicity classification will apply under the CLH proposal. In fact, most grades of ferronickel contain >0.3% cobalt, which means they will also be classified as Reproductive Toxicity 1B. As the major use of nickel and ferronickel is in stainless steel production the acceptance of the Netherland's proposal would lead to the classification of stainless steel as carcinogen category 1B by all routes. This would have both direct and indirect negative consequences on the numerous and critical applications of stainless steel, particularly where corrosion resistance and durability are essential. For example, the food processing sector including kitchen equipment, pots, pans and cutlery, etc; the medical sector where patient safety is paramount; and the vital water treatment and processing sector. Full details of the damaging implications of this CLH proposal for nickel metal and stainless steel are included in the Nickel Institute's and Team Stainless input to the public consultation.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of frits (Frit Consortium)	Industry or trade association	50

Comment received

The Frit Consortium is the organization that manages the REACH and CLP obligations of companies that manufacture or import frits into the EU. The Consortium currently includes 34 members from different European countries, mainly Spain, Italy and Germany. Our members are the largest producers in Europe for frits. Approximately 375 T/year of cobalt-containing substances are used in our sector at EU level, representing a sales volume of 120 million euros.

The proposed harmonised classification and labelling for cobalt metal would have a negative impact in our sector mainly due to its potential consequences for other cobalt substances if similar classification is proposed for cobalt insoluble compounds in the future.

Metallic cobalt as such is not used in our sector. However, tricobalt tetraoxide and other cobalt compounds are important raw materials for the manufacture of certain types of frits. During the manufacturing process, raw materials are transformed via melting and the resulting substances contain cobalt ions confined into the vitreous structure of the frit. These substances are exclusively manufactured at industrial sites by trained workers and their main end uses are ceramics, glass and metals.

The Frit Consortium fully supports the scientific and technical position of the Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC). The attached letter of support provides details on the potential impacts of the cobalt CLH proposal in our sector.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support FRIT.pdf

Date	Country	Organisation	Type of Organisation	Comment
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				number
23.02.2017	Spain	EEIG of Inorganic Pigments (Inorganic Pigments Consortium)	Industry or trade association	51
Comment received				
<p>The Inorganic Pigments Consortium manages the REACH and CLP obligations of companies that manufacture or import inorganic pigments into the EU. The Consortium currently includes 25 members from different European countries, mainly Spain, Italy, Germany and UK. Our members are the largest producers in Europe for inorganic pigments. Approximately 3500 T/year of cobalt-containing substances are used in our sector at EU level, representing a sales volume of 110 million euros.</p> <p>The proposed harmonised classification and labelling for cobalt metal would have a negative impact in our sector mainly due to its potential consequences for other cobalt substances if similar classification is proposed for cobalt insoluble compounds in the future.</p> <p>Metallic cobalt as such is not commonly used in our sector. However, tricobalt tetraoxide and other cobalt compounds are key raw materials for the manufacture of complex inorganic pigments. Cobalt substances are essential to obtain certain colour ranges and cannot be substituted. During the pigment manufacturing process, raw materials are transformed via calcination and the resulting inorganic pigments contain cobalt ions bound to the crystalline structure. These substances are exclusively manufactured at industrial sites by trained workers and their main end uses are ceramics, metals, plastics and paints or coatings.</p> <p>The Inorganic Pigments Consortium fully supports the scientific and technical position of the Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC). The attached letter of support provides details on the potential impacts of the cobalt CLH proposal in our sector.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support IP.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Walter AG	Company-Downstream user	52
Comment received				
<p>For more detailed information about impacts of the proposal, please read the attached document [Reference 1 Walter AG response CLH-Prop_CO_20170222].</p> <p>Hardmetal is produced by mixing cobalt (3-30%) directly with tungsten carbide. Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The proposal has major direct and indirect impact on us and our customers when it comes to hardmetal production and handling of products containing cobalt. The proposal can have a negative impact on the competitiveness of the EU manufacturing industry in the extremely competitive global market, possibly contributing to production and recycling moving to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Walter AG response CLH-Prop_CO_20170222].</p> <p>Eliminating cobalt could mean impossibility to machine certain materials or, for example, slower machining increasing the cost of producing a turbine engine by up to 1000% or making a motor block of a truck cost 10 times more. That would change the whole industry and affect the whole value chain including consumers.</p>				

Since many years has Walter AG handled cobalt materials in manufacturing with caution. For decades we have been monitoring and continuously decreasing the exposure to cobalt. We support the current self-classification of cobalt metal, which is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. Overly strict classification, which is not based on scientific facts and which does not give additional health benefit/improvement, leads to disproportionate risk management measures and costs.

MEMBERSHIPS AND SUPPORT.

We are part of a leading global engineering group in tooling, materials technology, mining and construction, being members of international organisations ITIA (International Tungsten Industry Association), CDI (Cobalt Development Institute) and CoRC (Cobalt REACH Consortium). We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

We are also members of FPM (Fachverband Pulvermetallurgie), which is part of WSM (Wirtschaftsverband Stahl- und Metallverarbeitung) in Germany.

Walter AG is one of the world's leading metalworking companies. Walter AG offers a wide range of precision tools for milling, turning, drilling and threading applications. A majority of the tools produced are hardmetal tools containing cobalt. Walter AG works together with its customers to develop custom solutions for fully machining components for use in the aviation and aerospace industries, as well as automotive, energy, and general engineering. With over 3,600 employees worldwide, (of which 2,600 are based in Europe), together with its numerous subsidiaries and sales partners, Walter AG serves customers in over 80 different countries.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Walter AG response CLH-Prop_CO_20170222.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Wolfram Bergbau und Hütten AG	Company-Downstream user	53

Comment received

Wolfram Bergbau und Hütten AG (WBH) is a world-leading tungsten powder and tungsten carbide producer. It has two sites in Austria; St. Martin and Mittersill, and has approximately 400 employees. WBH uses primary raw materials, produced in its own mine in Mittersill, Austria, as well as recycled material. WBH has an increased focus on recycling by investing to double the recycling capacity of hardmetal tools in the facility in St. Martin, Austria. The proprietarily developed recycling process is clean, efficient and provides powder with the same high quality and properties as from virgin raw materials. Recycling and alternative raw material sourcing is growing in importance for the hardmetal industry. Hardmetal is produced by mixing cobalt (3-30%) directly with tungsten carbide. Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. As a major supplier to European customers in the hardmetal industry, the proposal has major direct and indirect impact on us when it comes to hardmetal production and handling of products containing cobalt. The proposal will have a negative impact on the competitiveness of the EU manufacturing industry in the extremely competitive global market, possibly contributing to production and recycling moving to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 WBH response 20170221]. Eliminating cobalt could mean impossibility to machine certain materials or, for example, slower machining increasing the cost of producing a turbine engine by up to 1000% or

making a motor block of a truck cost 10 times more. That would change the whole industry and affect the whole value chain including consumers.

Since many years Wolfram Bergbau und Hütten AG has handled cobalt materials in manufacturing/recycling with caution. For decades we have been monitoring and continuously decreasing the exposure to cobalt. We support the current self-classification of cobalt metal, which is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. Overly strict classification, which is not based on scientific facts and which does not give additional health benefit/improvement, leads to disproportionate risk management measures and costs.

MEMBERSHIPS AND SUPPORT

We are part of a global industrial group, an engineering group in tooling, materials technology, mining and construction.

We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

We are a member of the international organisation ITIA (International Tungsten Industry Association), the European Fachverband für Pulvermetallurgie e.V. (FPM) and the Austrian Fachverbände der Nichteisenmetallindustrie (NE-Metall) and Bergbau und Stahl.

They also support the technical position of the CDI/CoRC (2017).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 WBH response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	United Kingdom	International Tungsten Industry Association	Industry or trade association	54

Comment received

The International Tungsten Industry Association (ITIA) is registered under Belgian law as a not-for-profit trade association with scientific purposes in support of the tungsten industry. A majority large part of the tungsten produced is used by the hardmetal industry which is also a downstream user of cobalt. ITIA's members are from 21 countries, including mining companies, processors, manufacturers, consumers, trading companies and recyclers of tungsten and its compounds.

There are 16 ITIA member companies in the European Union with three of the world's largest producers of tungsten products, HC Starck, Plansee/Ceratizit group and Sandvik Machining Solutions AB. Non-EU ITIA member companies include Global Tungsten & Powders Corp and Kennametal Inc with headquarters in the US, and several enterprises in China; many of them have strong production presence in the EU. Details about ITIA and a list of ITIA's member companies can be found on www.itia.info.

One of ITIA's major tasks is to co-ordinate the extensive work programme of the Health, Safety and Environment Committee regarding issues related to tungsten and its compounds, including:

- monitoring proposed legislation, regulatory and/or classification issues;

- developing scientific data on the impact of tungsten on human health and the environment;
 - managing the Tungsten REACH Consortium, a collaboration among the world's leading producers and processors of tungsten and tungsten compounds, which was established by ITIA in response to the EU's "REACH" legislation; to assist the industry in the development of scientific data and to support registration of several soluble and insoluble tungsten compounds. The Consortium is open to ITIA members and non-members alike.
- In response to the 2017 Public Consultation on the Netherlands' proposal for Harmonised Classification and Labelling (CLH) for cobalt, ITIA is submitting the following information for your consideration.

Hardmetal - Essential for Many EU Industrial Sectors

The hardmetal industry is a downstream user of cobalt as hardmetal is produced by directly mixing tungsten carbide with 3-30% cobalt. The tungsten carbide provides high hardness and wear-resistance while the cobalt, acting as a binder, adds strength to the hardmetal mixture. In 2015, the total hardmetal consumption in Europe was around 15,000t, accounting for approximately 66% of the tungsten consumption in Europe.

The hardmetal powder (tungsten carbide and cobalt metal) mixture is pressed and sintered at 1,500°C to produce articles approaching the hardness of diamond. Because of its unique properties, such as high melting point and ability to form a liquid phase with tungsten carbide, cobalt cannot be easily replaced in most hardmetal applications. Cobalt-containing hardmetal remains the highest performing alternative in nearly all applications.

Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to sharpen, drill, cut or mill various components. The automotive, aerospace, energy and general engineering sectors all use hardmetal to facilitate the processing of steels, other metals, wood and composite materials. Also, the mining, construction, and oil and gas industries are dependent on high-performance hardmetal tools and applications for rock processing. Over the last 50 years, these industries have seen an increase in productivity largely due to the emergence of improved hardmetal tool technology, which is used worldwide across the industry.

Taking Responsibility

The hardmetal industry in the EU has for decades been continuously reducing exposures to cobalt. Safety and health of employees is a high priority and the industry is continuously investing in technical and engineering controls, organisational and administrative control procedures, personal protective equipment, information and training of employees. Exposure is monitored by conducting industrial hygiene measurements and regular health surveillance of workers to ensure that the work environment is safe and continuously improving.

As mentioned above, to generate additional information related to carcinogenicity and cobalt exposure in the hardmetal industry, the leading producers participated in a five-country international epidemiological study that included data of more than 30,000 workers in the hardmetal industry. These findings are undergoing peer-review and will be published by the end of 2nd Quarter 2017.

Direct Impact of Proposed Harmonised Classification

The direct impacts of the proposed classification to the hardmetal industry are described in this section and are associated with classifications more stringent than the CoRC's cobalt

self-classifications of Carcinogenicity Category 1B through inhalation and Reproductive Toxicant Category 2.

The current existing risk management measures in the hardmetal industry are established to control to a Generic Concentration Limit of 0,1%. The Netherlands proposed low Specific Concentration Limit (SCL) of 0,01% would require "cobalt-free" hardmetal tools to be produced in entirely separate facilities. The re-engineering of the production process would not only affect manufacturers but also downstream users, leading to a cost increase of many hardmetal-containing products.

In addition, the proposed carcinogenicity and reproductive classifications would trigger a major change in the manufacturing process of hardmetal. Production would have to change dramatically into an enclosed, highly automated system like the ones used by the pharmaceutical industry, which will be extremely challenging - if not impossible - for article manufacturing.

Indirect Impact of Proposed Harmonised Classification

a. Increasing of Hardmetal Manufacturing Costs

The increased cost in manufacturing hardmetal will have negative consequences for the industry in the EU, as the expense of hardmetal products will rise (due to an increase of manufacturing costs), making them less competitive in an extremely competitive global market. A cobalt hazard classification which is not scientifically supported will drive connected costs to disproportionate risk-management measures. In the EU, this could contribute to hardmetal industries moving production to regions outside the EU where hazard classifications are more in agreement with the cobalt industry's classification, and possibly only final products (articles) would be imported into the EU.

b. Concern when Using Hardmetal-Containing Products/Articles

Additional impacts to industry from the proposed classification would also affect downstream users not only via more expensive tools but also via changed handling, including investments in closed machines. A possible future inclusion in the Candidate List will include an increased cost for tracing and analysing the cobalt content in products.

c. Limited Possibility for Substitution Alternatives

During the past 50 years, many efforts have been taken to find alternatives to replace cobalt as a binder in hardmetal (Kieffer and Benesovsky 1965). However, the tool life and performance of other binder systems including nickel, chromium and iron is drastically reduced and such alternative binder systems still contain at least 5% of cobalt (Norgren et al 2014). Alternative materials to hardmetal, such as ceramics and cermets have been found to be only useful in specialised or niche applications. Other ultra-hard materials, such as polycrystalline diamond (PCD) and cubic boron nitride (CBN), perform very well but, due to their brittleness, they must be applied to a substrate of cobalt containing hardmetal as support.

d. Limitation of Recycling Activities

The increased handling and processing cost of recycling, triggered by the proposed classifications, could have a major effect on the amount of cobalt containing hardmetal scrap that is recycled. It is likely that, due to the strict classifications and a lower SCL for cobalt metal, large amounts of hardmetal will be processed outside of the EU, where cobalt

hazard classifications are more in agreement with the existing cobalt industry position. The current recycling rate of up to 90% for used tools in the EU is likely to fall drastically, causing a higher use of imported raw materials.

e. Possibility for Authorisation or Restriction under REACH

Restricting the use of cobalt in hardmetal applications would lead to less productivity for both hardmetal manufacturers and users of hardmetal tools, as the manufacturing industry in Europe relies heavily on hardmetal suppliers to operate. If the use of cobalt required authorisation in the future, an authorisation for the use in hardmetal would need to be granted because, as explained above, there are no alternatives to cobalt despite years of research and development. However, the uncertainty of the future granting of authorisation in the EU could contribute to the possibility that global industries might consider moving production to regions outside the EU.

f. Impact of an Unnecessarily Low Occupational Exposure Limit (OEL)

ITIA is in favour of harmonising the cobalt's EU OEL as it would make all industries work towards the same goal. Current national cobalt OELs range from 20 to 100 µg/m³. Meanwhile, France has recommended a lower cobalt threshold limit value (TLV) of 2,5 µg/m³ whereas, based on cancer risk, Germany is introducing an ERB (Expositions-Risiko-Beziehung = Exposure Risk Correlation) with a tolerance limit (additional cancer risk of 4:1000 in 40 working years over 8-hour exposure) of 5 µg/m³ for cobalt (as for alveolar dust, and the criteria is <10 µm particle size for cobalt) including hardmetal, with an acceptable risk (additional cancer risk of 4:10000) limit until 2018 of 0,5 µg/m³. After 2018, the acceptable risk limit (additional cancer risk of 4:100 000) will be 0,05 µg/m³.

Other non-European occupational regulatory groups such as the American Conference of Governmental Industrial Hygienist (ACGIH) has made a distinction when cobalt is in the presence of tungsten carbide, and it is close to adopting a TLV-TWA (threshold limit value - time weighted average) of 5 µg/m³ for cobalt as thoracic particulate matter.

Further reducing the OEL/TLV based on the NL proposed carcinogenic (Carc 1B by all routes of exposure), reproductive (Repro 1B) and mutagenic (Muta 2) hazard classifications will put all the downstream cobalt users (not only the hardmetal industry) in a precarious economic and competitive situation as the cobalt exposure cannot be lowered infinitely without totally new and highly costly manufacturing processes.

Conclusion

ITIA is in favour of and supports efforts to harmonise cobalt's EU OEL to make all industries work to the same standard. ITIA shared comments with the Cobalt Secretariat (CoRC and CDI) regarding the hardmetal sector and supports the technical position of the CDI/CoRC (2017) as outlined in the message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal in January 2017.

Please contact me at +44 20 8996 2221 or by email (info@itia.info) if you have any questions or require further information.

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Kieffer and Benesovsky. Co-free binders have been investigated for 80 years, without success. In: Hartmetalle Springer Verlag, Wien. 1965.

Kirkland D, Brock T, Haddouk H, Hargeaves V, Lloyd M, Mc Garry S, Proudlock R, Sarlang S,

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	EBRC	Please select organisation type..	55

Comment received

Non-compliance with the provisions for proposing a harmonised classification in accordance with regulation (EC) 1272/2008 and the underlying guidance documents

The CLH report does not comply with Regulation 1272/2008 (Annex I: 1.1.1.4) and ECHA Guidance on the preparation of dossiers for harmonised classification and labelling (Version 2.0, August 2014) and Guidance on the Application of the CLP Criteria (Version 4.1, June 2015). In particular a relevance, reliability and adequacy screening was either not performed or not documented transparently on the selected references/studies. Neither the summary tables for the endpoints under review (Tables: 14, 49, 57 and 71) contain any relevance, reliability or adequacy rating, nor does the summary and discussion section of each endpoint provide evidence for a differentiated evaluation of the hazard data taking into account relevance, reliability and adequacy of each reference.

Due to the data richness of the cobalt database for all endpoints under review, a weight-of-evidence approach is obviously required in order to resolve the question of classification according the explicit instructions in the underlying guidance documents. Such an evidence-based approach involves an assessment of the relative values/weights of different pieces of the available information that have been retrieved and gathered in previous steps. To this end, a value needs to be assigned to each piece of information. The weight given to the available evidence will be influenced by factors such as the quality of the data, consistency of results/data, nature and severity of effects, relevance of the information for the given regulatory endpoint. In all cases, the relevance, reliability and adequacy for the purpose have to be considered (ECHA, 2011).

Sadly, the RIVM CLH report presents a mode of action analysis (Section 4.10.3, p. 114ff) which was merely copied almost word-by-word exclusively from the US NTP Report on Carcinogens (2016), without consideration of any further scientific evidence and even without clear accentuation of third party opinion. Although one might assume that the scientific review of the US NTP is comprehensively reported in the Report on Carcinogens, the differences between the regulatory methods by the US NTP and the EU need to be respected:

- the information reviewed in the US NTP Report on Carcinogens must come from publicly available, peer-reviewed sources (see section Background and Methods on page iii), whereas a proposal for harmonised classification and labelling shall consider “any relevant information from registration dossiers”, but also “other available information may be used” (Regulation (EC) 1272/2008, Annex VI, Part 2, 3rd para.)

- the US NTP Report on Carcinogens is a scientific review of human exposure, disposition and toxicokinetics, cancer studies in humans and experimental animals, and mechanistic data, which undergoes a review by an independent ad hoc expert panel. The procedure therefore follows a strict scientific approach with no direct regulatory action. On the other hand, the RIVM Proposal for Harmonised Classification and Labelling represents a report with direct regulatory consequences, i.e. a legally binding classification

Due to the different methods used in the preparation of these reports and their different legal consequences, the RIVM Proposal for Harmonised Classification and Labelling should therefore fulfil a higher level of comprehensiveness (Regulation (EC) 1272/2008, Annex VI, Section 2), and should apply a rigorous relevance and reliability screening of the underlying information used to propose legal action. Due to the inappropriate use of a “copy-and-paste” exercise when presenting crucial information on the mode of action for the cobalt carcinogenicity, it is concluded that the RIVM Proposal for Harmonised Classification and Labelling (i) does not review all available scientific information and (ii) does not provide an independent analysis of the mode of action for cobalt carcinogenicity.

A mode of action analysis should be performed to assess the overall level of concern (Regulation (EC) 1272/2008, Annex I: 3.6.2.2.6). Such a mode of action for carcinogenesis is a biologically plausible sequence of key events leading to an observed effect, supported by robust experimental observations and mechanistic data (Sonich-Mullin et al., 2001; Boobis et al., 2006).

References

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Sonich-Mullin C, Fielder R, Wiltse J, Baetke K, Dempsey J, Fenner-Crisp P, Grant D, Hartley M, Knaap A, Kroese D, Mangelsdorf I, Meek E, Rice JM, and Younes M (2001) IPCS Conceptual framework for evaluating a mode of action for chemical carcinogenesis. *Regul Toxicol Pharmacol* 34, 146-152

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Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Hille & Müller Steel, Tata Steel Europe	Company-Downstream user	56

Comment received

The Netherlands' harmonized classification proposal will have significant negative consequences for steel, in particular for stainless steels, high-alloy steel, superalloys and their secondary feed materials, and for the critical applications in which they are used. A significant part of these steel grades contain cobalt as an impurity in the steel. However in some specific situation like Alkaline Battery production with cobalt plated steel, the cobalt is intentionally added.

Globally TSE is the leading producer of electroplated steel for alkaline battery components. In Europe a substantial volume of cobalt-plated steel for batteries and batteries made with cobalt plated material is being imported. These cobalt plated steels are produced out of cold rolled steel which is subsequently plated with nickel and cobalt. In the plating process the cobalt layer is deposited as a distinct metal layer on top of a nickel plated steel strip. After the plating process the steel is annealed and this is alloying the iron, nickel and cobalt to form a layer with optimum surface conductivity that makes the product uniquely effective for battery production.

When used in batteries (cobalt layer is inside the battery) it significantly increases the lifetime (shelf life) and output of a battery. This is the main argument to use cobalt and it strongly contributes to a more energy efficient and sustainability use of batteries. This effect however is cobalt specific. Cobalt cannot be replaced by any other metal/material without losing this property. Research is ongoing to reduce the cobalt content in the plating layer. For specific applications the cobalt concentration as part of the total strip thickness ranges from 0.04 - 0.08%. As this is >0.01%, it might become a problem when the SCL will be set at 0.01%. Even if the Co content would be halved, it would still be above a 0.01% concentration limit.

Cobalt free batteries cases are well known and on the market, however the quality (lower conductivity) is less and the cost is higher compared to cobalt plated batteries cases. The cobalt is replaced by nickel here. The shelf time of the batteries will therefore significantly decrease and this will mean a significant energy and sustainability loss.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tata Steel Hille and Muller Position paper.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Arno Friedrichs Hartmetall GmbH & Co.KG	Company-Downstream user	57

Comment received

The proposal classification and labelling would entail considerable costs because of the numerous measures to be taken. It would certainly severely limit the competitiveness of hard metal prodmarket impact from CMR stigmatization:

- negaucers in Europe. Here are some direct and indirect impacts in loose order and without claiming to be complete:

Direct impacts:

- review/revise of manufacturing practices; production processes and changes to working

practices could be changed to minimize occupational exposure (e.g. move to closed systems, dust prevention measures, wider use of PPE, gloves, etc.)

- re-examine potential occupational exposures due to the minimizing principle for CMRs leading to intensified work place measurements
- modifications and amendments of eSDS, packaging etc.
- waste needs to be classified as hazardous where waste contains a substance known to be carcinogenic cat. 1A or 1B in a concentration of > 0.1%: higher recycling costs for cobalt containing materials

Indirect impacts:

- increased manufacturing costs would lead to higher prices in EU
- market impact from CMR stigmatization:
 - negative impact on supply chains because sales of cobalt based alloys will likely reduce significantly due to customer perception (phasing out without need)
 - larger costs in handling cobalt products in downstream sectors (e.g. due to minimize occupational exposure)
- review of sector-specific regulation concerning uses of cobalt-containing articles
- looking at substitution/alternatives on a long term distance
- impact on circular economy: recycling initiatives could be undermined
- cobalt containing alloys have specific qualities, properties and functionalities that cannot be replicated by other materials (e.g. hardmetal); a switch to other materials would have serious consequences (e.g. costly product tests)

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	RECHARGE	Industry or trade association	58
Comment received				
As Cobalt is a substance of major usage in batteries, RECHARGE association has been involved in the classification process of the various cobalt compounds. As a result, the usage of cobalt in batteries represents a significant share (in the range of 25%) and is growing with the usage of rechargeable lithium batteries in many new applications from communications to electric mobility. Concerning cobalt metal, it is not used in rechargeable batteries as such, but used as an intermediate in the manufacturing process, and transformed into the cobalt compounds used as active materials of batteries electrodes.				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Team Stainless / Eurofer	Industry or trade association	59
Comment received				
The Netherlands' harmonized classification proposal will have significant negative consequences for steel, in particular for stainless steels, high-alloy steel, superalloys and their secondary feed materials, and for the critical applications in which they are used. As well as supporting the scientific data being submitted by the Cobalt Industry, the contributors to this submission provide additional human exposure data and other peer reviewed, published references for consideration in the scientific review being conducted. To illustrate the scale of these negative consequences more clearly, further information is also given with respect to the value chain and end uses of the materials impacted. A more comprehensive description of the value chain and end uses of the material impacted, together with the scientific comments, can be found in the attached document.				
To provide context for the scientific comments that follow under the specific comments of				

this submission, it is critical to understand where cobalt is to be found in alloys in common use today. An understanding of the exposures that result from these uses, and the manufacturing processes involved, is essential for an interpretation of the epidemiology, test work, and reported experience of these exposures both in the workplace and the general public.

The presence of cobalt in steel, stainless steel and specialty alloys

There are two classes of steel materials containing cobalt, one in which cobalt is deliberately added as an alloying addition, and another in which cobalt is present as a trace element.

- Deliberately alloyed with cobalt

The first are the specialty alloys to which cobalt imparts specific qualities of exceptional hardness, high-temperature strength, corrosion resistance, wear resistance, reduced thermal expansion, and, sometimes, magnetic properties. Cobalt is a vital component of specialty alloys (or 'superalloys') which are critical in the manufacture of jet engines and other aerospace components, land-based turbines for power generation, cutting tools, magnetic materials, and a variety of important medical applications (e.g., femoral heads, femoral stems, acetabular cups, spinal rods, dental implants, pacemaker leads, and heart stents). In these cobalt-based alloys, iron is no longer the main constituent; the percentage of cobalt ranges from 18% to 66% depending on the alloy grade. (Typical ranges include 32-66% for implants; 18% or more for aerospace and other specialized alloys). For other (e.g., nickel-based) alloys in which cobalt is intentionally added, the percentage ranges from 0.5% to 21%. Tool steels/alloys contain up to 10% cobalt.

While a few specialty stainless steel grades are specifically alloyed with cobalt, the vast majority of stainless steels fall into the second category of products in which cobalt is present as a trace element.

- Cobalt as a trace element

The vast majority of stainless steel grades do not have cobalt metal as a deliberate alloying addition. Cobalt metal is naturally present as a trace element in the alloys at levels in excess of the proposed SCL for carcinogenicity of 0.01% Co metal. Almost all stainless steels contain more than 0.1% Co metal. In many cases, it is also higher than 0.3% Co metal, and can rise to 1% or in exceptional circumstances to 2% Co metal in some cases due to the use of specialty alloy scrap. The residual presence of cobalt in alloys is unavoidable, as it is a ubiquitous naturally-occurring element that is present as a trace element in raw materials such as pure nickel cathode and briquette, ferronickel, ferrochrome, and all secondary feeds (recycled scrap) of stainless steel where the required nickel and chromium contents are obtained from a very efficient blending of many different secondary materials of varying composition. Furthermore, cobalt cannot be removed during the production of stainless steel itself.

The main alloying elements used to make stainless steel sit next to each other in the Periodic Table (Cr Mn Fe Co Ni) and so are always present, and naturally occurring, in the ores of all the metals. It is not surprising, therefore, that cobalt is present as a trace element in all of them.

Most tramp metals (i.e. trace elements which are considered to be unimportant or unwanted) are subject to tight controls due to the negative metallurgical impact they would have on the steel product (e.g., copper). Residual cobalt, however, imparts positive metallurgical qualities to the final product and, therefore, is not typically considered a concern in most stainless steel grades. Even where attempts are made to specifically avoid the presence of cobalt, as in so-called "cobalt-free" grades of stainless steel which are required for nuclear applications, most still have a specified concentration limit higher than the proposed SCL of 0.01% Co. Such special grades can only be produced using high purity nickel which is only available from a few, limited sources. The ability to make any reduction in the cobalt content of the various primary feeds during refining is a function of the type of ore, and the extraction and refining process used. For some feeds, such as FeCr, there is no such process available. Only a few producers of pure nickel have proprietary processes that can produce pure nickel at levels below 0.01% Co. Indeed the ASTM B39 specification that

is the basis of the London Metal Exchange contract for pure nickel sets the cobalt composition limit at max. 0.15%, a level which also exceeds the default GCL usually applied to cat 1B carcinogens. In summary, the proposed specific concentration limit of 0.01% Co is below the background level of cobalt in the supply chain for all stainless steel grades.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final - Team Stainless Position Paper for the Cobalt Issue (signed).pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Svemin	Industry or trade association	60

Comment received

The proposal for harmonised classification and labelling of Cobalt metal will have a great impact on the industry as manufactures and downstream users.

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Final Slags Task Force of Eurometaux	Industry or trade association	61

Comment received

Summary:

The Final Slags Taskforce of Eurometaux, representing the European non-ferrous metals industry takes the opportunity of the Public Consultation on the Annex XV proposal, to inform regulatory stakeholders on the potential unintended consequences of the proposed CLH on Cobalt metal.

The Final Slag Taskforce brings together experts from the main non-ferrous metals manufacturing companies. It has been set up to represent and support the producers of final slags from the non-ferrous metals industry and the production of ferro-alloys in the context of relevant European legislation such as REACH , CLP, Circular Economy and construction products Regulations.

The members of the Final Slag Taskforce support the technical position of the CDI/CoRC (Cobalt Development Institute / Cobalt REACH consortium, 2017). We particularly support the classification of cobalt massive as Carc. 1B for the inhalation route only, H350i, with a Generic Concentration Limit (GCL). We question the validity and proportionality of the very low specific concentration limit of 0.01% for the classification as Carcinogen 1B in the CLH proposal.

Final slags :

Final Slags are co-produced out of the metals pyrometallurgical refining and recycling processes (e.g. smelting and refining of metal concentrates and metal scrap, recycling of Li-ion batteries from electromobility and electronics, recycling of electronic scrap and (industrial) consumables, refining of complex by-products, ...).

Final slag primarily consist of iron silicate and calcium-aluminium silicates, in which metals contents have been reduced to the lowest levels that are economically and technically viable. However, most final slags still contain cobalt as an impurity in concentrations higher

than 0.01 % and below 0,1%.

The tonnages of these slags produced every year are very significant, for example it is estimated that >10 million tons of final slags are produced at EU level. Currently, most of these final slags are put on the market as a non-hazardous product (not as waste).

Uses of final slags are in construction (road construction, embankments), mine backfill, concrete and asphalt applications and other fill applications, clinker production or mineral addition to blended cements, abrasive blasting, soil fortification, dyke fortification. Therefore, final slags are included in EN standards for construction products, for example:

- EN 13242:2002+A1:2007 - Aggregates for unbound and hydraulically bound materials for use in civil engineering work and road construction. European Standards relevant for slag are:
- EN 13043 "Aggregates for bituminous mixtures and surface treatments for roads, airfields and other trafficked areas".
- EN 197-1:2011 - EN 197-1:2011 Cement - Composition, specifications and conformity criteria for common cements
- EN 12620:2002+A1:2008 - Aggregates for concrete
- EN 13139:2002 - Aggregates for mortar
- EN 15167-1:2006 - Ground granulated blast furnace slag for use in concrete, mortar and grout - Definitions, specifications and conformity criteria
- EN 13383-1:2002/AC:2004 Armourstone

The uses of slags contribute to a circular economy, by avoiding environmental burdens of landfilling, conservation of natural mineral resources (aggregates) and energy.

In July 2016, the European Commission has issued its final report on "Regulatory barriers for the Circular Economy". The report underlined that there is a market potential for slag (out of primary and secondary metal production) which can be used as a material in the construction sector [EC 2016b]

The use of final slags in industrial applications is considered as best available technique to prevent and reduce the quantities of waste sent for disposal from non-ferrous metals production [EC BAT conclusions, 2016]

Expected impact of the cobalt metal CLH proposal on Final slags:

Iron silicate slags are subject to self-classification according to the requirements of the CLP regulation. By applying the classification criteria for mixtures based on presence by weight of classified ingredients (cobalt) and specific concentration limit of 0.01%, many of the currently non-hazardous final slags will meet the criteria for classification as Carcinogen 1B.

This classification could heavily affect the refinement and recycling business in Europe. The construction sector is particularly sensitive to hazard statements. It is difficult to predict how the regulatory scene will evolve in the future, however it is a fact that potential restrictions, or limits on the content of dangerous substances in construction products is a trend in the construction sector.

We expect that potential classification of final slags as carcinogen 1B will damage the market perception on current and future uses of the final slags. We estimate that the market possibility of final slags will substantially decrease and in the end will result in non-acceptance of final slags as construction applications (e.g. cement, concrete cement and abrasive blasting, soil and dyke fortification). We expect that customers may not make the

effort to acquire the necessary permits and comply with the exposure restrictions in accordance with the carcinogens directive to treat carcinogenic substances (slags), or they may be concerned about reputational impairment due to handling of hazardous substances. Customers will instead opt for non-dangerous substances such as natural aggregates instead of recycling products.

The latter will consequently force the EU refining and recycling business to turn a large tonnage valuable product (currently no burden for landfill) to a waste for landfill leading to significant environmental impacts. This is in contradiction with the objectives of the landfill directive and objectives for resource efficiency. The European industry has invested substantially during the last 10-15 years to reduce the non-ferrous metal content in final slag in order to ensure stable and safe product. Natural aggregates are becoming scarce and more expensive and successful application of secondary aggregates such as final slags as construction materials is saving natural resources and CO2 emissions. The potential hazardous classification would negatively affect the innovation initiatives and research on sustainable applications of the final slags.

In addition, the EU refining and recycling business will also be faced with an impact on the global competitiveness since this classification is only applied in EU but not outside. The additional disposal fees (i.e. cost for landfill has been estimated in the range between 15-50€/ton) will deliver a serious debit to the global competitiveness of metals and recycling industry in the EU. In the end, it will compromise the ability of EU's refiners/recyclers to contribute to a circular economy by closing the loop on waste (e.g. promotion of clean mobility versus the recycling of Li-ion batteries containing certain percentages of cobalt).

References:

EC 2016b. European Commission final report on "Regulatory barriers for the Circular Economy". July 2016
http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8986&lang=en

EC BAT conclusions, 2016, COMMISSION IMPLEMENTING DECISION (EU) 2016/1032 of 13 June 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the non-ferrous metals industries

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final Slags TF Eurometaux Comments on Co CLH proposal 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	European Copper Institute	Industry or trade association	62
Comment received				
The European Copper Institute, ECI, with transparency register number ID 04134171823-87, as the representative of the European Copper Industry and a member of the Copper Alliance, takes the opportunity to inform regulatory stakeholders on the outcome of the effects of the proposed CLH on substance Cobalt.				
Cobalt metal is present as an impurity in copper substances at very low concentrations. It is found in Copper final slag, a by-product of smelting and refining process. It is intentionally added to copper alloys to increase the strength of the alloys, and it is also unintentionally				

present as an impurity in copper alloys considered "cobalt-free". Further, high-quality copper scrap also contains traces of cobalt.

The proposed cobalt classification entry of Carc.1b with a specific concentration limit (SCL) of 0.01 % will affect copper products and substances containing cobalt. Directly, by changing the classification and the substance requirements for transport, trading and handling. Indirectly, by reducing the markets of copper products and disrupting the recycling value chain.

Specifically, for copper final slag, with a content of cobalt up to 0.21% w/w, 100% of copper slag will meet the criteria for classification as Carc. 1b if solely the mixtures rules are applied to the content by weight of the individual components. If the bioaccessible fraction of cobalt in copper final slag is taken into account, ECI's preliminary assessment suggests that still 30-50% of copper slags will meet the classification criteria for classification as Carc. 1b. This will create a bad reputation for copper final slag, reduce its use, and force European producers to landfill copper final slag.

Copper alloys considered "cobalt free" that unintentionally contain cobalt as an impurity in concentrations that vary between 0.011 to 0.3%. w/w will meet the criteria for classification as Carc. 1b. (ECI is currently undertaken tests to understand better what is the bioaccessible fraction of cobalt in copper alloys. The results are expected in March 2017).

Classifying cobalt-free copper alloys as Carc. 1b will not only change the perception of copper alloys and reduce its potential uses, but it will also disturb the recycling flows of copper scrap. Cobalt is present as an impurity in copper scrap, a raw material used by European manufacturers of copper alloys. While substantial efforts have been made in the last years to optimise the use of copper scrap, when copper scrap is used to produce alloys it remains technically impossible to reduce the level of impurities in the alloys beyond current limits. If cobalt-free alloys are classified as Carc 1b based on the level of impurities, European producers will have to use only virgin sources of raw materials to produce cobalt-free alloys and avoid the classification as Carc 1b. In the end, it will hamper the ability of European producers to use copper scrap as raw material, forcing them to use virgin materials, and could result in an increased export of high quality scrap outside Europe.

ECI supports the technical position of the CDI/CoRC (Cobalt Development Institute/Cobalt REACH consortium, 2017), as outlined in the Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal of January 2017. Particularly ECI supports the classification of cobalt massive as Carc. 1b for the inhalation route only, H350i, with a Generic Concentration Limit (GCL). ECI would also like to stress that the bioaccessible fraction of cobalt in copper substances/mixtures containing cobalt differs from the content in weight. For some, the bioaccessible fraction is lower than the content of cobalt in weight by several orders of magnitude. The establishment of a concentration limit should take into account the specificities of the behaviour of cobalt in copper substances and mixtures.

In the document attached are explained in detail the effects of the proposed classification on Copper Final Slag, Copper alloys and recycling. The number of tables and figures in the document requires to be shared in .pdf format.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170222_ECI-PC-Cobalt-CLH_public-attachment.pdf

Date	Country	Organisation	Type of Organisation	Comment number
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22.02.2017	Belgium	Nickel Institute	Industry or trade association	63
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Comment received

The Nickel Institute (NI) represents the producers of nickel and ferronickel some of which also produce cobalt. The Nickel Institute provides comments that the Dutch proposals for harmonized classifications of cobalt metal are not scientifically supported and have the real potential to create a cascade of significant unintended consequences for it will adversely restrict nickel and nickel containing materials such as stainless steel and alloys in many end use sectors that can create unnecessary public concern, and costs to European society as well as to the European Industry.

REPROTOX CATEGORY 1B:

Reproductive studies need to be considered in a weight-of-evidence approach (WOE), taking into account the reliability, consistency and quality of the studies. This is an absolute requirement to be able to distinguish between direct Cobalt ion effects, and effects that are secondary to lung or systemic generalized toxicity. The existing combined data for Cobalt metal and soluble Cobalt salts do not support a Category 1B reproductive toxicity classification for Cobalt metal. Definitive studies of fertility and developmental effects of Cobalt ion must be conducted (e.g., EOGRTS) and the reprotoxic potential of Cobalt metal assessed once these studies are completed.

GERM CELL MUTAGEN CATEGORY 2:

Mutagenicity studies need to be considered in a WOE, taking into account the reliability, consistency, relevance, and quality of the studies. This is an absolute requirement to be able to distinguish between the potential of Cobalt ion to directly induce heritable DNA-chromosomal mutations in germ cells, and effects that are only seen in vitro or that indicate cell damage but not heritable changes. A WOE assessment of the current data does not indicate germ cell mutagenicity concerns for Cobalt metal. This is consistent with the 2014 OECD conclusion that there is no evidence of genetic toxicity for Cobalt salts.

CARCINOGEN CATEGORY 1B:

While a Carc 1B via inhalation classification for cobalt metals is warranted based on the results from the recent NTP inhalation carcinogenicity study, the significance of the increased incidence of tumors at sites other than respiratory tract observed in the Cobalt metal inhalation study need to be considered separately. A weight of evidence assessment of the scientific evidence by the NI does not support cobalt metal being classified as a carcinogen category 1B for all routes of exposure. The criterion for classification of Cobalt metal as a Cat 1B carcinogen based on tumors at systemic sites is not fulfilled. If cobalt metal was indeed capable of inducing tumors at distant sites through the release and absorption of Cobalt (ions) in a non-threshold manner, then the same events would be expected to be induced by the Cobalt (II) ion from soluble salts. This is not supported by the test results with the salts or by human data. The potency calculation needs to take these factors into account, together with the latest epidemiological data.

BACKGROUND: Cobalt in Nickel and Nickel-Containing Materials

Cobalt is frequently naturally occurring with nickel. Most grades of nickel and ferronickel contain cobalt as a trace element which originates from the various nickel ores. It is not technically possible to remove all cobalt from nickel during the refining process. Cobalt is a high value by-product, and so what can be removed and recovered by the refiner is already done today, depending on the chemistry of the refining process employed. As a result, a

small proportion of cobalt remains in refined nickel as a residual impurity. Typically, this is less than 0.15% Cobalt for Class 1 LME deliverable pure nickel (see the ASTM B39 specification for pure nickel.) Ferronickel is produced pyrometallurgically, and so there is no opportunity to separately recover any of the trace element composition of cobalt. Because of this, residual cobalt also carries through into nickel-containing alloys including stainless steel. Because cobalt is also present as a trace element in other raw materials used to produce stainless steel, including ferrochromium and scrap, cobalt is unintentionally, but unavoidably present in stainless steel and other alloys. Because of the high recycling rate for nickel containing materials, the residual cobalt stays in the nickel-containing materials supply chain.

Thus, the Dutch cobalt classification proposal (Dutch Proposal) is of concern to nickel producers because of its potential impact on the classification of nickel and nickel-containing materials such as nickel-containing stainless steels and alloys. The proposed SCL is so low that many materials in widespread and common use today may be impacted, in spite of extensive experience of safe use. There is the potential for public concern to be raised unnecessarily.

CLASSIFICATION OF METALS AND ALLOYS – information from bioelution test results:

Alloys are defined as special preparations under REACH (EC, 2006) and thus considered as mixtures for the purpose of classification. An alloy is defined as a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are in fact "solid solutions" where the constituent metals are either "dissolved" in the parent metal, or are chemically combined as "phases" or "precipitates" within the crystal matrix. The metal composition of an alloy can affect the release of Cobalt (II) ion and its' in vivo bioavailability. Studies are ongoing at the NI and the REACH Cobalt Consortium to assess the relative bioaccessibility of Cobalt ions from different physical forms of Cobalt metal and Cobalt-containing alloys in relevant biological fluids.

In conclusion the NI would like to emphasise that substances should be classified based on a weight of evidence, taking into account all relevant studies as well as the quality of the studies considered. Where further studies are progressing which could also inform the classification of a substance, as is the case for cobalt with respect to reprotoxicity (definitive EOGRTs), any classification proposals should await the outcome of such studies. Finally, specifically with respect to metals and alloys, ECHA is currently considering the applicability of bioelution test results to refine the current concentration-based CLP approach for the classification of alloys.

IMPACT OF DUTCH PROPOSAL ON NICKEL AND FERRONICKEL

Because of the presence of residual cobalt as a trace element in nickel metal and ferronickel, the 0.01% SCL for the carcinogenicity classification of cobalt metal in the Dutch proposal would result in most nickel metal and ferronickel grades being classified as a carcinogen category 1B via all routes of exposure. Hence, the proposal for a 0.01% SCL for cobalt metal needs to be well justified scientifically, which the NI submits is currently not the case.

Most grades of ferronickel may also contain cobalt at a concentration above the 0.3% level hence triggering a classification for these materials as Reprotox Category 1B.

The major use of nickel and ferronickel is in stainless steel production which has many, many useful and often critical applications in society. The classifications resulting from the acceptance of the Dutch Proposal would have a direct negative effect on many applications of the safe and valuable material that is stainless steel. It would lead to the classification of stainless steel as carcinogen category 1B by all routes. As such, indirect effects of the

classification of cobalt for nickel and ferronickel would be felt in applications such as, for example, in the medical sector, the food processing sector, and water treatment. In the medical sector, nickel-containing stainless steel is used because of its corrosion resistance, durability, and its ability to undergo stringent cleaning regimes such as repeatedly disinfecting or sterilizing medical devices at high temperatures to ensure patient safety. In the food sector, nickel containing stainless steel fulfils the very demanding requirements with respect to sanitation, corrosion resistance, and food safety. It is the material of choice for most applications in the food processing industries, in industrial kitchen equipment, and for pots, pans, cutlery etc. It is also used extensively in water treatment and water supply piping.

Furthermore, the classification of nickel and ferronickel as a carcinogen and reprotoxic category 1B may lead to indirect restrictions in certain applications as several regulations and directives in the EU restrict the use of CMR Cat. 1 substances. In fact, we have identified at least 19 pieces of legislation in the EU which contain hazard-based provisions or reasoning. Typically, the legislation presumes that alternatives to the hazardous substance or material are available and that one-to-one substitution is possible. Such an approach discards the notion of exposure and risk, which are crucial factors for metals and their alloys. It is highly important that classification proposals are based on the latest scientific information available, and are not unnecessarily conservative or restrictive.

GENERAL COMMENTS ON POTENTIAL FOR DOWNSTREAM IMPACTS

Unlike the classification of many complex chemicals, metals are naturally occurring and so are to be found widely in the environment. As these metals sit next to each other in the Periodic Table, they are often found in combination in nature, and can never be completely separated during processing. Pure metals are the basis of alloys, which in turn have been the building blocks of our civilization for thousands of years. They are the start of long and complex value chains where the end uses are extremely varied and are often critical in supporting our modern way of life and standard of living. At the end of their life, metals are infinitely recyclable, limited only by the ability to collect and segregate them from other materials, and so are some of the most highly recycled materials in society today.

Imprecision, or over-precaution, in interpreting the scientific data on the pure metals has the potential to create a cascade of unintended consequences in many end use sectors that can create unnecessary public concern, and costs to society, as well as Industry.

To illustrate this, nickel is just one source of trace element cobalt in materials used in countless downstream applications. Nickel is used extensively in the form of stainless steels and other alloys and coatings in many downstream sectors such as engineering, building and construction, transportation, power generation (fossil, nuclear and renewables), coinage, electronics, and the chemical industry, as well as the medical and food processing and water treatment industries referenced earlier. In the EEA alone the Nickel Industry is proportionately responsible for generating 237,400 direct jobs, and 594,000 indirect jobs. Between 2010 and 2014 nickel and related downstream industries generated output of Euro 187 Billion. The 'value add' to society in the EEA was Euro 51 Billion. While it is not possible today to say with precision to what extent these jobs and this value is put at risk by these proposals on cobalt metal classification, it is clear to us that there is real risk over time. When demand is constrained and compliance costs increase in the context of unwarranted classifications, then dis-investment and lack of new investment are predictable outcomes overtime.

CONCLUSION

Hence, before the Dutch Proposal is acted upon it seems prudent to suggest that there be a full understanding of the implications of the consequent classifications. Given that a large number of regulations include hazard-based requirements linked to the CLP harmonised

classification means that the impact of classification goes far beyond simply providing information on the potential hazard and intrinsic properties of a substance. It can trigger unintended regulatory and non-regulatory consequences potentially leading to the ban, restriction, and stigmatization of safe materials and alloys.

In the absence of such understanding, the Dutch Proposal, if accepted, will carry with it bans or restrictions of safe products, especially nickel-containing stainless steels, that generate significant economic or social benefits, whilst posing no realistic threat to human health.

For more complete information, please refer to the document attached.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170220-Co metal implications for Ni - input in consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	H.C. Starck	Company-Downstream user	64

Comment received

H.C. Starck is a leading supplier of high-performance technology metals for high-tech products and global company with 15 manufacturing facilities and almost 2,700 employees worldwide. Cobalt is used as a component in a variety of metal powder alloys and hardmetal powders.

The International Tungsten Industry Association (ITIA) and the Cobalt Development Institute/Cobalt REACH Consortium (CDI/CoRC) provided consolidated responses on behalf of their members. As a member of ITIA and CoRC H.C. Starck fully supports and subscribes to the comments submitted to this consultation by ITIA and CoRC.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	Kennametal Inc.	Company-Downstream user	65

Comment received

Kennametal is a full member of CDI (Cobalt Industry Association) and ITIA (Tungsten Industry Association). Kennametal supports the position and substantiation of the comments by these two organizations. Kennametal produces many hardmetal products. Hardmetal consists of tungsten carbide powder with 3-30% cobalt which acts as a binder. The powder mixture is pressed and sintered at 1500oC to produce articles approaching the hardness of diamond. Cobalt cannot be replaced in most hardmetal applications due to its unique physical properties including a high melting point and ability to form a liquid phase with tungsten carbide. Cobalt-containing hardmetal is the highest performing alternative in nearly all potential applications. Despite decades of research, the alternatives to cobalt as a hardmetal binder is extremely limited and even with these alternatives, the applications for use are specialized.

Hardmetal products and tools are integral to the functioning of almost all manufacturing industries in the EU and are used to, mine sharpen, drill, cut or mill various components. The automotive, aerospace, energy and general engineering sectors all use hardmetal tools to process steels, other metals, wood and composite materials. Also the mining, construction, oil and gas industries are highly dependent on high-performance hardmetal tools for drilling and earthworks applications. Over the last 50 years, these industries have

experienced increased productivity worldwide, largely due to the emergence and broad use of improved hardmetal tool technology.

The proposed classification would significantly impact hardmetal producers and the industries which rely on hardmetal tools and products. These proposed classifications are more stringent than the Cobalt REACH Consortium cobalt self-classification of Carcinogenicity Category 1B through inhalation, and Reproductive Toxicant Category 2. For decades the EU hardmetal industry has continuously monitored occupational exposures to cobalt, and has developed and implemented controls to reduce cobalt exposures. The currently existing controls are designed to address a Generic Concentration limit of 0,1%. In addition, the proposed carcinogenicity and reproductive classifications would trigger a major change in the hardmetal manufacturing process. Production would have to change dramatically into an enclosed, highly automated system like the ones employed by the pharmaceutical industry. Manufacturing complex articles from hardmetal will become extremely challenging, if not impossible, and the EU hardmetal industry will face significant competitive disadvantages against other regions.

A cobalt hazard classification which is not scientifically supported will result in significant financial costs for disproportionate engineering controls, resulting in a manufacturing shift to regions outside the EU.

Furthermore, increased costs for engineering controls will adversely affect the circular economy for hardmetal by negatively impacting recycling activities. The proposed classifications would have a major effect on the amount of cobalt containing hardmetal scrap that is recycled. Currently, 90% of hardmetal tools are recycled and the proposed classifications, including a lower SCL for cobalt metal, will cause this value stream to be processed outside of the EU.

Restricting the use of cobalt in hardmetal applications would lead to less productivity for both hardmetal manufacturers and users of hardmetal tools, as the manufacturing industry in Europe heavily relies on hardmetal suppliers to operate.

We are in favour of harmonising cobalt's occupational exposure limit (OEL) in the EU. A harmonised OEL will ensure that all industries work towards a common goal regardless of geographic location within the EU. Currently national OELs range from 20 to 100 µg/m3.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02 Kennametal Cobalt CLH Response.pdf

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Sweden	Outokumpu Oyj	Company-Manufacturer	66
Comment received				
<p>If the Netherland's proposal is adopted, these classifications will have significant negative consequences for stainless steel. Outokumpu manufactures more than 2 million tons of stainless steel annually in Europe that would be affected. At the same time there is scientific data to be considered from current and historical exposures to this material indicating that the proposed classification would result in over-classification of stainless steel. Classifying millions of tons of stainless steel that is used for kitchenware, hospital equipment and in buildings as carcinogenic and reprotoxic when scientific evidence indicated that the material should not be classified could create a major distortion on the market.</p> <p>Outokumpu supports the scientific data provided by the cobalt industry and wants to provide additional information with the respect to the stainless steel value chain.</p> <p>The vast majority of Outokumpu stainless steel grades do not have cobalt metal as a deliberate alloying addition. Cobalt metal is naturally present as a trace element in the alloys at levels in excess of the proposed SCL for carcinogenicity of 0.01% Co metal. Almost all stainless steels contain more than 0.1% Co. In many cases, it is also higher than 0.3%</p>				

Co, and in some cases up to 1 % Co.

It is technically and economically not feasible to remove the Cobalt from the steel cycle. Cobalt is a naturally-occurring element that is present as a trace element in our raw materials such as recycled steel scrap, various forms of nickel, and ferrochrome. Cobalt cannot be removed during the stainless steel production process.

Outokumpu supports the comments submitted by Team Stainless. More than 7 Millions tons of stainless steel is produced every year in the EU, using millions of tons of steel scrap, containing cobalt over the proposed classification limits. Decades of use have demonstrated that stainless steel is safe, and beneficial for human health and the environment.

If steels containing cobalt as impurity were to be classified, it could lead to stigmatisation of stainless steel. In turn leading to unwarranted public concern and exclusion from well intentioned, but hazard based, initiatives such as "toxic-free construction products", "green procurement" etc.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Belgium	Euroalliages	Industry or trade association	67

Comment received

EUROALLIAGES is the European association of Ferro-Alloys and Silicon producers, representing about 95% of the sector in Europe.

The proposed very low specific concentration limit (SCL) of Cobalt Metal set to 0.01 % for Carc. 1B; H350 (all routes) will have serious impact on the ferro-alloys industries, in particular in the ferrochromium and ferromolybdenum industry and it's downstream users in the Stainless steel and High-alloy steel industries, as well as on the market of ferrochromium, by-products of the production of the corresponding ferro-alloys (see Non-Ferrous Metal BREF).

We support the technical points outlined by the Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC) regarding Reproductive Toxicity 1B; H360F, Mutagenicity 2; H341 and Carcinogenicity 1B; H350, Specific Concentration Limit (SCL) 0.01%.

The purpose of this note is to focus on the potential socio-economic implications of such classification proposal.

Use of FeCr and FeMo in steel industry

Cobalt which is a naturally occurring element in the chromium ore is considered as an impurity, it is therefore an unavoidable element. Nearly all commercially produced high carbon ferrochrome (main product from global chromium industry) contains more than 0.01% cobalt, which is not intentionally added. Also ferromolybdenum can contain more than 0.01% cobalt.

Metallurgical grade chromium ore is processed into ferrochromium which is an alloy of iron and chromium with minimum chromium content of 45% by mass and maximum chromium content of 95% chromium by mass. 73% of the ferrochromium produced goes to stainless steels whilst the 27% remainder goes into alloy steels, special steels. Ferrochromium seems to have a cobalt content equivalent to 0.04 %.

Ferrochrome or ferromolybdenum as such is not present in consumer products. Metallic Mo, Mo alloys, metallic Chromium and chrome alloys are not classified as a CMRs.

Metallic chromium/molybdenum gives to steel its unique anti-corrosion properties, there are no existing substitute for such essential application (surgery material, industrial kitchen, household appliances, pots and pans, food processing industry, bridges and infrastructure,

building and architecture, exhaust systems, machine parts etc...) Metallic chromium forms a passive and self-repairing layer on the surface of alloys preventing release of any other compounds and protecting against corrosion, therefore although ferrochrome and stainless steel contains hazard classified metals like nickel and cobalt, the bio-availability of those constituents is very limited due to the alloying effect. There are scientific data and peer reviewed studies demonstrating that stainless steel products do not cause such health effects or toxicity that is associated with the classification that would result from this cobalt CLH proposal.

Use of LC FeCr in defence applications

Low Carbon ferrochrome (LC FeCr) is also used in special stainless steel for defense applications.

The European Defence Association (EDA) has issued this month a Study on REACH and CLP's Impact on the Defence Sector (Final Report of 16.12.16). Among the key findings, EDA underlines e.g.:

- The unpredictability surrounding the regulatory fate of SVHCs creates substantial uncertainties and risks for the defence industry
- REACH challenges the competitive position (level playing field) of EU defence companies in export markets and causes industry to consider relocation to avoid the REACH constraints for SVHCs used in article production and manufacturing processes. Such relocation risks are seen as a major risk to Security of Supply by most Ministries of Defence.
- In addition to REACH and CLP, other EU regulations (e.g. BPR, ODS, POP) may each separately force substitution steps in rapid succession on military applications or upstream uses, leading to regrettable substitution – hence unnecessary cost and effort in wasted R&D activities – and possible EU policy inconsistency

The cumulative impacts described above create a significant risk to maintaining cost effective military capabilities. The increased through life cost is unavoidable. Defence exemptions will not guarantee the availability of chemicals necessary to maintain defence equipment. The import of chemicals and articles also poses a risk due to insecurities that a global supply chain may bring. As a result, some MoDs strongly believe that REACH may impact the actual operability of the Armed Forces.

Use of FeCr – impact on circular economy

Ferrochromium (FeCr) and ferromolybdenum (FeMo) slags have been registered under REACH. Those slags are not hazard classified. The main applications of FeCr slag are in road construction (use in asphalt and concrete), in landfill cover and drainage, in embankment fills, as raw material for production of insulation material, in construction material for building - foundations, freeze insulations, surface drainage systems, ...), as sandblasting.

FeCr are subject to compliance with standardized specifications such as EN 13242:2002+A1:2007 - Aggregates for unbound and hydraulically bound materials for use in civil engineering work and road construction. European Standards relevant for slag are: EN 197: Cement ; EN 206: Concrete ; EN 13139, 12620 etc.: Aggregates ; EN 13383: Armourstones; EN 12945: Fertiliser; EN 13285: Unbound mixtures; EN 14227: Slag bound mixtures; EN 15167: GGBS in Concrete.

A potential SCL of 0.01 % related carc. cat 1B classification would heavily affect innovation initiatives/ research.

In July 2016, the European Commission has issued its final report on "Regulatory barriers for the Circular Economy". The report underlined that there is a market potential for slag (out of primary and secondary production) which can be used as a material in the construction sector. An identification of concrete value chains, subsectors, and economic activities is outlined. This potential is applicable to all ferro-alloys slags, therefore including FeCr slags.

Only for FeCr slag, the quantity produced yearly in Europe amount approximately 700 000 T. Landfilling of this large amount of material would become a mandatory path should the

SCL be adopted. This is in total contradiction with the objectives of the circular economy and the landfill directive.

This is also in contradiction with resource and energy efficiency. Indeed, natural aggregates are becoming scarce and more expensive. In addition, there is an urgent need to reduce the waste level produced by several industries. The successful application of FeCr slags as construction materials is saving natural resources and CO2 emissions.

Enforcement and controls

As underlined, if adopted this SCL will trigger a huge amount of other classifications, for alloys, mixtures, slags etc. How this will be enforced and controlled is of concern, knowing that Member States are facing more and more difficulties in enforcing the growing number of regulations and legal provisions? It is so true that Member States have indicated in the report of May 2016 that "insufficient financial and human resources are impeding the successful operation of REACH and CLP in their countries":

http://ec.europa.eu/environment/chemicals/reach/pdf/final_report_2016.pdf

A lack of proper control will induce a distortion of competition between EU and non EU operators as well as a lack of traceability of goods put on the European market for goods which will be supposed to be of high concern.

Proportionality

Finally, we would like to recall recital 130 of REACH stating that 'Since the objectives of this Regulation, namely laying down rules for substances and establishing a European Chemicals Agency, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives'.

We therefore wondering what is the proportionality of such SCL knowing that it ´s not enough based on sound scientific data on the one hand and the huge impact it will have on EU industry on the other hand, and in particular its impact on competitiveness due to the fact that this classification would only apply in the EU.

We have also have provided input to the CoRC/CDI 'Joint Comments'.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	France		MemberState	68
Comment received				
The detailed analysis of toxicokinetic data convincingly supports that bioavailability of cobalt is expected to be similar to the bioavailability of classified soluble cobalt compounds. In addition, cobalt-specific data provide evidence that justify the proposed classifications for mutagenicity, carcinogenicity and fertility and corroborate the similarity of toxicity profile of cobalt and cobalt soluble compounds. Further details are discussed in the respective commenting sections.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	United Kingdom	Outokumpu Stainless ltd	Company-Manufacturer	69
Comment received				
If the Netherland's proposal is adopted, these classifications will have significant negative consequences for stainless steel. The potential impacts of this proposal on both the wider				

economy and regional business are huge. At the same time there is scientific data to be considered from current and historical exposures to these substances that indicate this classification would result in over-classification of stainless steel. Outokumpu supports the scientific data provided by the cobalt industry and wants to illustrate further the negative consequences of this proposal and provide information with the respect to the stainless steel value chain.

The vast majority of Outokumpu stainless steel grades do not have cobalt metal as a deliberate alloying addition. Cobalt metal is naturally present as a trace element in the alloys at levels in excess of the proposed SCL for carcinogenicity of 0.01% Co metal. Almost all stainless steels contain more than 0.1% Co. In many cases, it is also higher than 0.3% Co, and in some cases up to 1 % Co.

It is technically and economically not feasible to remove the Cobalt from the steel cycle. Cobalt is a naturally-occurring element that is present as a trace element in our raw materials such as secondary feeds (recycled scrap), pure nickel, ferronickel, ferrochrome. Cobalt cannot be removed during the stainless steel production process.

Outokumpu supports the considerations submitted by Team Stainless and wants to further point out that the weight of evidence speaks against this severe classification. More than 7 Millions tons of stainless steel is produced every year in the EU, using millions of tons of steel scrap, containing cobalt over the proposed classification limits. Decades of use have demonstrated that stainless steel is safe, and beneficial for human health and the environment.

If steels containing cobalt as impurity were to be classified, it could lead to stigmatisation of stainless steel. In turn leading to unwarranted public concern and exclusion from well intentioned, but hazard based, initiatives such as "toxic-free construction products", "green procurement" etc.

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	Germany	The Cobalt Development Institute and Cobalt REACH Consortium	Industry or trade association	70

Comment received

General comments into Co metal CLH proposal Public Consultation

Weight of evidence

Cobalt, as most other metals, can be considered a "data rich" substance. A search on PubMed for the terms "toxicity" AND "human" AND "metal name" yields results at least in the thousands (1062 for cobalt) of published papers. For comparison, an organic substance recently discussed at RAC yields 6 results when searching the terms "toxicity" AND "human" AND "substance name". This presents any hazard and risk assessment with the challenge of dealing with "data richness". The aspect of "Quantity" is referenced as one of the factors contributing to "weight of evidence (WoE)" in the ECHA Practical Guide 2: "How to report weight of evidence", the other factors being Reliability, Adequacy and Relevance.

"Quantity" as a factor of WoE signifies that all studies should be included in an assessment, however, especially when many studies for a certain endpoint are available, there needs to be a score for the "reliability" of each study. The Practical Guide suggests: "to communicate the reliability, the Klimisch score should be assigned: 1 = reliable without restrictions, 2 = reliable with restriction, 3 = not reliable 4 = not assignable.". The Guide further suggests a stringent consideration of relevance and adequacy. These aforementioned factors allow an assessor to deal with problems that can arise if there are a large number of studies, giving overall conflicting results. For these cases, the Practical Guide states:

“4.2.2. How to deal with conflicting study results

A weight of evidence approach should be used when several studies are available which give conflicting results. The weight allocated to each study will be case-dependent and will depend on the test method, quality of the data and the endpoint under consideration. For example, the ready biodegradability test is known to be a stringent test method. If you have six poor quality studies showing a substance is not readily biodegradable and one good quality study using a test method recommended in REACH, indicating ready biodegradability, a conclusion of ready biodegradability would normally apply due to the stringency of this test method.”

The example illustrates that the hazard- and risk assessment should be based on data from the more stringent and reliable test, and should not be influenced by the number of studies reporting a certain result. The example also illustrates that test methods recommended in REACH, and testing conducted as part of REACH, may overturn existing data, even if the REACH test is “outnumbered” by older studies.

The full WoE approach (Reliability, Adequacy, Relevance & Quantity) was applied in all assessments carried out by the Cobalt Development Institute (CDI)/Cobalt REACH Consortium (CoRC). In some cases, this has resulted in conclusions which differ from previous ones formed prior to REACH. In one particular case, the endpoint mutagenicity, the full WoE evaluation carried out by the CDI/CoRC was elevated to the OECD Cooperative Chemicals Assessment Meeting (CoCAM) for a discussion as part of the OECD Chemicals Assessment Programme on High Production Volume chemicals. The compounds under discussion were four soluble cobalt salts (Co sulfate, Co dichloride, Co dinitrate, Co acetate and their common toxic moiety, the Co ion). Despite the existing classification for the soluble cobalt salts as Muta 2, and the proposed classification of Co metal as Muta 2, the OECD CoCAM conclusion was as follows:

“In-vitro mammalian mutagenicity: The overall conclusion is that cobalt salts/compounds do not induce biologically relevant gene mutation responses in mammalian cells.” and “In summary, soluble cobalt salts do not elicit any mutagenic activity either in bacterial or mammalian test systems. (...). It was concluded that effective protective processes exist in vivo to prevent genetic toxicity with relevance for humans from the soluble cobalt salts category.”

The difference in the resulting conclusion, although based on the same dataset, stems from the application of stringent Reliability, Adequacy and Relevance considerations in the case of the CDI/CoRC and CoCAM assessments. It is worth noting that recent discussions at the RAC (soluble Co salts) and the current CLH proposal for Co metal lack any Reliability, Adequacy and Relevance scoring, and appear to be predominantly based on the aspect of Quantity. In the view of the CDI/CoRC, any evaluation that is part of REACH or the CLH process would benefit from a full application of the guidelines set out in the ECHA Practical Guide 2: “How to report weight of evidence”.

Specific comments on the proposal text, section 4.1, page 18-19

The CLH proposal for Co metal states on page 18 that inhaled cobalt (Co) metal particles may have a very slow clearance from the lung (> 400 days). This statement does not reflect the data correctly, and the CLH text later negates the earlier statement by commenting that the long clearance time of longer than 400 days is probably an artifact (page 23 of the CLH report) of the model. This reflects the interpretation of the NTP Technical Report 581, where the original lung clearance data are reported (page 74), stating that slow clearance phase half-lives were 789 days, 167 days, and 83 days for 1.25 mg/m³, 2.5 mg/m³, and 5 mg/m³, respectively. The apparent lack of achievement of steady state and long half-life at 1.25 mg/m³ are likely spurious findings due to uncertainty

in the model." The statement on page 18 gives a false impression of a long residence time and poor clearance of Co in the lung.

Page 19 of the CLH report describes the tissue distribution of Co after inhalation exposure to Co metal. The highest systemic exposure (the highest Co levels in a non-portal of entry tissue) occurred in the liver. The absence of any neoplasms in the liver strongly indicates that Co is not a high-potency systemic carcinogen, and argues against the need for an assumption of carcinogenicity by all routes of exposure, as well as against the need to apply a Specific Concentration Limit, which is based on a non-threshold assumption. If Co was a non-threshold carcinogen by all routes of exposure, neoplasms would be expected to occur in the tissue of highest systemic exposure, the liver. The absence of findings in the liver cannot be reconciled with the proposal of Carc 1B (H350; all routes of exposure), and an SCL of 0.01%.

Specific comments on section 4.1.3, pages 27-31

It is recognised that for systemic effects (e.g. reproductive effects) the bioavailable metal (i.e. metal ion) at target sites (e.g. sex organs) will be responsible for the observed effects (e.g. fertility effects), see Cassarett and Doull, Toxicology, 8th Edition, Chapter 23 "Metals". Current research by the Cobalt REACH Consortium (CoRC) shows that a biological target of cobalt (Co), HIF1-alpha (hypoxia inducible factor) is responsive to any form of soluble cobalt ion, whether it is "delivered" by the dichloride, sulfate, dinitrate, or any other compound that is able to release sufficient amounts of Co ion in aqueous solution. Based on the concept of the metal ion as relevant toxic unit, the carcinogenicity of Co sulfate was read across as a harmonised classification to 4 additional Co substances that have similar solubility in aqueous solution.

Also, biomonitoring for exposure to metals and metal compounds is based on the notion that the metal ion is the toxicologically significant unit. Biomonitoring is therefore conducted by measuring the levels of metal ion in either blood or urine. This is a well-founded and well-accepted practice in occupational hygiene, and a requirement by many workplace regulations.

This implies that the metal-containing substances with highest in vivo systemic metal bioavailability will have the highest potency; while the ones with the lowest in vivo metal bioavailability will have the lowest potency or may even lack the hazard altogether, if the bioavailability of the metal ion is below the threshold for the adverse effects. The maximum achievable in vivo bioavailability at target organs (e.g. sex organs) for a given substance is limited by the animal toxicity (e.g. mortality) associated with the exposure.

For local effects after repeated exposure, such as lung tumours after inhalation, it is recognised that the bioavailable metal (e.g. Co^{2+}) at target lung sites does contribute to the carcinogenicity of the metal substance but may not be its sole driver. Particle/surface effects can also contribute to tumour formation (e.g. via activation of macrophages and ROS generation). Particle characteristics will also determine how much of a substance will deposit in the respiratory tract, where within the respiratory tract it will deposit and how the substance will be cleared. This is why bioavailability alone is usually not a good predictor of toxicity by repeated inhalation exposure.

Bioelution tests in synthetic biological fluids provide a worst case scenario for in vivo bioavailability of metal ions. "Bioaccessibility" data generated by these tests can be used for grouping and read across of metal compounds, in a weight of evidence approach, as long as there is a good understanding of their applicability and limitations. For example, equal metal ion release in gastric fluid from metal compounds may suggest equal in vivo systemic bioavailability, and this assumption can be made conservatively in the absence of any in

vivo data.

However, when in vivo data on toxicokinetics or toxicity exist, these data should be used to refine the prediction based on bioelution results. For example, even if two substances have the same in vitro bioaccessibility in gastric fluid, their physical form can interfere with metal absorption in the g.i. tract and thus their in vivo bioavailability. Co metal (e.g. 1 mg) and Co chloride (4.3 mg) release similar amounts of Co ions in synthetic gastric fluid (same bioaccessibility). Yet, for this to translate into the same metal absorption (and in vivo bioavailability), the mortality and overall toxicity of these equivalent doses in animals would have to be the same. If it is not the same, this would reflect a difference in absorption, indicating that a direct read-across based on bioelution data alone would not be warranted. This is the case for Co metal and Co chloride that have similar bioaccessibility in gastric fluid in vitro, but different mortality and overall toxicity following per oral exposure in vivo.

How can loading affect bioaccessibility? For substances that release high amounts of metals, higher loadings can limit the reaction and yield lower absolute metal release per gram of sample. The difference of metal ion release at high and low loadings (per gram sample) is small (usually a few percent), as seen for cobalt in lysosomal fluid. The data in gastric fluid are currently being generated and can be shared. The CLH report argues that exposure to Co metal via gavage (bolus dose) would constitute a high loading, and this could limit dissolution and thus result in lower bioavailability (and reproductive toxicity effects) than if the dose were given in feed through the course of the day.

This argument is inconsistent with the following facts:

1. the difference of metal ion release at high and low loadings (per gram sample) is small (usually a few percent). These data are currently being generated for Co metal and can be shared.
2. the administration of food together with Co metal may result in lower g.i. absorption than if it is given as a single dose without food (food interference with metal absorption is well documented for many metals, such as iron).
3. gavage administration will result in a bolus dose with higher blood peak levels than those that can be achieved by ingestion of Co metal with feed; blood peak levels are usually the levels related to the toxic reproductive effects.
4. when metals are given in drinking water at high levels, the animals stop drinking the water (palatability issues) which can confound the results. This was observed in a study with CoCl₂ administration at 100, 200 or 400 ppm CoCl₂ in drinking water. The mice in the high dose group drank 18-26% less water than control or lower dose animals (Pedigo, George et al. 1988). This is avoided by using gavage.

Furthermore, the calculations included in the Dutch report did not include the most relevant dose: since the MTD for Co metal was 30 mg Co/kg, the concentration in the stomach at that dose (following the same assumptions made in the report) would have been 0.1 g/l, which is not a "high loading".

Reference

Pedigo, N. G., W. J. George and M. B. Anderson (1988). "Effects of acute and chronic exposure to cobalt on male reproduction in mice." *Reprod Toxicol* 2(1): 45-53.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachmts Co metal PC.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Repr appendix, CONFIDENTIAL.pdf

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	France	FEPA	Industry or trade association	71

Comment received

Cobalt metal is an essential raw material for the production of different types of abrasive products (metal and organic bonded abrasives). The proposed classification of all forms of cobalt metal as carcinogen and reprotoxic category 1B will have severe impacts on the European abrasive industry – for the production of abrasives as well as for the downstream users of abrasives. Abrasives are essentially required in Europe for various industries such as automotive, aeronautic, turbine industry, mechanics, medical, stone and construction, etc. In particular, the high quality of European abrasive products is a guarantor for other industries to produce high quality products. Abrasive suppliers are solutions providers of these industries to develop new technologies for the future, saving energy and raw materials. A replacement of cobalt metal (cobalt is typically included in the matrix of the final product) is not possible without loss of important technical parameters of the abrasive tool.

The European Abrasive industry is well aware of its responsibility towards the protection of worker and has implemented appropriate exposure control and occupational safety measures to avoid a potential exposure of workers and the environment. Appropriate ventilation systems where required as well as personal protective equipment (PPE) including eye protection, gloves, overalls, apron, special work clothes are standard in the European abrasive industry.

Furthermore, FEPA fully supports the general and specific comments submitted by the Cobalt Secretariat (CDI/CoRC).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEPA_Answer to the public consultation cobalt metal_1.pdf

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	France	MFPM : Manufacture Française des pneumatiques Michelin	Company-Downstream user	72

Comment received

- Michelin supports the position of the Consortium of Cobalt and CDI.
- As a tyres manufacturer, we are particularly concerned by the classification of the Cobalt metal, as we use cobalt salts (dedicated to guarantee the link between rubber and metallic wires) susceptible to release Co²⁺ ions. Indeed, two kinds of salts may be used : soluble and insoluble ; the soluble salts, by hydrolysis, generate Co²⁺ ions, that, when bioavailable, act according to a threshold mechanism explained by studies carried out by the Consortium of Cobalt. The insoluble salts don't hydrolyse, so they don't release Co²⁺ ions.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Germany	TIGRA GmbH	Company-Manufacturer	73
Comment received				
<p>We support the technical position of the Cobalt REACH Consortium Ltd. (CoRC) and the Cobalt Development Institute (CDI).</p> <p>Relevant information for the classification should be available soon from studies not published yet:</p> <p>(1) Epidemiological cohort study on cancer incidence in cobalt production (Finnish male cobalt production workers)</p> <p>(2) Hardmetal epidemiological study (University of Pittsburgh, 2006 to 2016, 30,000 hardmetal workers)</p> <p>looking into the association between cobalt exposure and cancer in the hardmetal industry</p>				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Spain	UNESID. Spanish Steel Association	Industry or trade association	74
Comment received				
<p>An specific SCL of 0,01% should not applied for Massive forms and alloys (as Steel) Cobalt is present as impurities (unintentionally added) in many Steel alloys</p> <p>A consultation within Spanish steelmaking plants shows that</p> <ul style="list-style-type: none"> - around 20% of the common C steel cast up to a 0,03% - 50% of the "special Steels" (high carbon, medium alloyed steel etc), up to 0,3% - almost all of high alloyed (including stainless steel) are above that amount. up to 0,5 or even 1%. <p>All this composition are similar within the ferrous scrap: when products end up its useful life and become a waste for been recycled again in our steelmaking plants.</p> <p>In the case of ferroalloys, 2,5% for FeNi is reasonable maximum concentration, but it uses to be bellow 1,5%.</p> <p>Such an unjustified classification, which includes massive forms and alloys, would very negatively affect all those steel alloys, which does include intentionally Cobalt in its composition among which we should highly the Maraging Steel (extremely hard and strength steels). These steels account up to 13% Co. Even when the production of these steels is very limited in tonnage they are relevant as are used for protection heavy duty civil construction vehicles and machinery (yellow line), mining machinery (mills, crushers, protections in storage silos etc) , weapons, craftshafts, etc</p> <p>Classification</p> <p>Source of exposition is almost limited to inhalation in a relevant amount. The existing information shows that other sources of exposition are negligible.</p> <p>Therefore, a reasonable option if deemed necessary would be to address the exposition /protective/health measures to</p>				

Date	Country	Organisation	Type of Organisation	Comment number
10.02.2017	France	Shepherd Mirecourt S.A.S.	Company-Manufacturer	75
Comment received				
The Shepherd Chemical Company, US manufacturer, owns a production site in EU that is				

leader in production of Metal specialties chemicals more specifically Cobalt carboxylates. The Shepherd Chemical Company also produces Cobalt carboxylates in the US as well as Cobalt inorganic salts and Cobalt oxides/hydroxides.

The Shepherd Chemical Company is a member of the Cobalt Development Institute (CDI) and a member of the Cobalt REACH Consortium (CoRC).

On request of the Cobalt Industry, the CDI/CoRC toxicologists reviewed the CLH proposal for Cobalt metal. The Shepherd Chemical Company fully supports the scientific position of the CDI and CoRC. Currently, CDI/CoRC and its members propose the following classification of Cobalt metal for the endpoints scrutinized by NL Competent Authorities based on available literature and studies:

- Carcinogenicity: Carc 1B, H350i - Only the inhalation route is considered relevant and the Generic Concentration Limit (GCL) is applied;
- Mutagenicity: no classification;
- Reprotoxicity: Repr 2, H361f as a precautionary statement with a testing program still on-going to strengthen database.

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	Germany		MemberState	76
Comment received				
The German CA agrees to the proposed classification of Cobalt.				

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Agoria	Industry or trade association	77
Comment received				
Agoria is supporting the scientific comments of Cobalt Development Institute on the classification proposal. Our members, ranging from producers to users of cobalt, have supported and contributed to the development of the scientific comments prepared by the Cobalt Development Institute. Our comments are more related on the downstream impact of this classification.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Norilsk Nickel Harjavalta Oy	Company-Manufacturer	78
Comment received				
Norilsk Nickel Harjavalta Oy is a member of Cobalt REACH Consortia (CoRC). Norilsk Nickel Harjavalta Oy supports Cobalt REACH Consortia General and Technical comments on Carcinogenicity.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Nilar AB	Company-Importer	79
Comment received				
We support the CDI/CoRC technical position. For us the proposal for Carc. 1B (all routes of exposure) combined with a Specific Concentration Limit of 0.01% means that the handling of stainless steel components in our production of battery packs will be affected with additional requirements in the handling of				

such materials to avoid dermal contact. The battery product is an Article that can contain parts with cobalt present as an impurity (above the proposed SCL 0.01%) in the casing, which means that the end user could be exposed to dermal contact with these parts of the battery. Then end users can be affected with restrictions on dermal contact with stainless steel components on the battery casing exposed to the end user or that costly remedies to avoid such contact must be implemented.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	RIO TINTO	Company-Manufacturer	80

Comment received

Cobalt is naturally present in many metallic ores and is not generated by human influence. Our ilmenite ore contains iron oxide with a cobalt content of around 0.01%. When transformed into iron or steel powders, in particular into fine powders (-45µm), the impurity level of Co could achieve 300 ppm (0.03%). We do not use cobalt at all in our different productions.

Reducing the cobalt content with the current equipment is not possible and by changes of manufacturing processes, if at all available, would cause considerable cost in producing pig iron, steel billets and iron & low alloy steel powders that would never be competitive compared to the other producers. The proposed classification would indeed affect the total supply chain of the steel industry (steel scrap is not "cleaner" than our ore as issued from ore).

Following this logic just a simple example: forks and knives in stainless steel (containing 0.02% cobalt) used every day or in surgery would be classified as Carc 1B

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	United Kingdom	UK Steel	Industry or trade association	81

Comment received

UK Steel and its members are in full support of the scientific arguments presented by the Cobalt Development Institute (CDI) and the Cobalt REACH Consortia on the classification of Cobalt metal as a Carcinogen category 1B. Alike the CDI and Cobalt REACH Consortia, we do not agree that the available evidence supports the Netherlands 'all route of exposure' conclusion, and concur that only the 'inhalation route' should be considered for classification. Please see attached document for further information.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FINAL - UK Steel CLH Cobalt metal response 24 02 17.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	VDA, Verband der Automobilindustrie e.V.	Industry or trade association	82

Comment received

Route of exposure:

The proposed classification of cobalt as carcinogen 1b does not consider the crucial route of exposure sufficiently. The VDA is convinced that the classification for Cobalt as carcinogen 1b for all exposure routes is not adequately proved.

VDA follows the statement of the German competent authority for OSH the AGS (Ausschuss für Gefahrstoffe - Committee for Hazardous Substances), who is also responsible for the classification of substances. Due to the available studies the AGS determined 2014 that Cobalt has to be classified as carcinogen 1b only for inhalable dusts. The justification was published and is attached to this comment (unfortunately available only in German). Compact forms of alloys containing Cobalt cannot release dusts. Therefore a classification of these alloys as carcinogen 1b is not justified.

SCL:

The proposed concentration level of 0.01% leads to an unjustified classification for many metal alloys as carcinogen 1b, which contain Cobalt only as impurities. As mentioned before a lot of Nickel alloys would be affected by all negative impacts and legal consequences of such a classification, since Cobalt and Nickel are often tied to each other in nature.

A higher concentration level correlates also to the current view of the German competent authority for OSH (AGS). Based on available knowledge of the AGS the concentration level for Cobalt as an ingredient of mixtures/alloys was defined on 0.1% and documented in the attached Technical Rule for Hazardous Substances 905 (TRGS 905) (unfortunately available only in German).

In the opinion of the VDA this concentration level has to be used for the harmonized classification.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment VDA Position on cobalt.zip

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Tikomet Oy	Company-Manufacturer	83

Comment received

The hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as Carcinogenic Category 1B by the inhalation route. The oral and dermal routes of cobalt exposure presented in the CLH proposal are not supported by the epidemiological studies on hardmetal workers. An extensive epidemiological study of more than 30,000 workers in the hardmetal industry has recently been carried out and the study publications are undergoing peer-review. This study examines the association between carcinogenicity and cobalt exposure in the hardmetal industry and is coordinated by the University of Pittsburgh and participated by ITIA's largest hardmetal producers. We recommend that the epidemiological study is included in the RAC assessment of cobalt's carcinogenicity.

We support the classification of cobalt metal as Carcinogenic Category 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tikomet Oy Response - Co CLH.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Finnish Steel and Metal Producers	Industry or trade association	84

Comment received

Massive metal alloys behave differently than its separate alloying elements (substances in

the alloys). And the alloying process in massive metal alloys strongly eliminates the release and exposure to any single alloying element. That's why hazardous classification of single alloying elements of massive metal form should not be used as such for basis of hazardous classification of massive metal alloys. When cobalt is present in the massive metal alloy, the hazardous classification should be based on the measured release and exposure not the concentration of the alloying element cobalt.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment MJ kannanotto_cobalt.docx

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Teknikföretagen	Industry or trade association	85
Comment received				
We support the current industry self-classification as Carc 1B via inhalation only.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Spain	Spanish Association of Frits, Glazes and Inorganic Pigments	Industry or trade association	86
Comment received				
-				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Letter of support Co- Public Consultation.docx				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	AB Sandvik Materials Technology	Company-Manufacturer	87
Comment received				
AB Sandvik Materials Technology fully supports the comments given by Jernkontoret (Sweden), EUROFER and Team Stainless.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	Wirtschaftsvereinigung Metalle (WVMetalle)	Industry or trade association	88
Comment received				
Carc. 1B; Limitation to inhalational route: Quite recently in German Hazardous Substance Committee (AGS, supporting German ministry on labour and social affairs) an intensive debates on workplace limit values for Cobalt and Cobalt in hard metal took place. As a side outcome it was concluded to classify Cobalt metal nationally as Carc 1B, based on the NTP study (2014) although the limitations of the NTP study are very evident (systemic tumours do not correlate with levels of Cobalt in target tissues, tumours only occur in one species and sex, biological relevance of tumours is questionable, lack of a historical controls for the type of rat used). Consequently, this classification is transduced into national law but at the same time it is limited to dusts of cobalt metal in an inhalable form. This important limitation to the inhalational route only is				

neglected within the RIVM proposal and should be corrected.

Carc. 1B; Specific Concentration Limit should be withdrawn:

The proposed SCL of 0.01 % would result in any mixture (including especially alloys) containing $\geq 0.01\%$ Cobalt to be classified as Carc. 1B. We support the CDI line of argumentation that Cobalt metal and Cobalt compounds are not genotoxic in vivo (OECD CoCAM) and that an essential element like cobalt cannot be recognized as a high potency cancerogenic substance. In addition the need for an SCL for massive forms of mixtures containing Cobalt should not be concluded on at this moment. There is an ongoing European activity to develop an internationally accepted test guideline for bioelution. This initiative includes clarification on the interpretation of Art. 12(b) of the CLP Regulation regarding classification of a substance in a mixture that is not biologically available. It should be noted in this context that a Cobalt containing alloy (as all alloys) is by no means a brittle material but a very ductile metallic mixture from which particulate matters can only be released easily. Therefore, the SCL proposal for mixtures containing Cobalt should be withdrawn.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24 WVMetalle commenting on Co CLH proposal.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Wirtschaftskammer Österreich	Please select organisation type..	89
Comment received				
see PDF attached				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_170_StN CLH Cobalt.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Sandvik Mining and Rock Technology	Company-Downstream user	90
Comment received				
<p>Hardmetal powders are classified as Carcinogenic Category 1B by the inhalation route based on thorough analysis of available data and scientific assessment done by the CDI/CoRC and ITIA following the CLP classification guidance. The available data including epidemiological data from hardmetal industry does not indicate the other routes of exposure (oral and dermal) presented in the CLH proposal being relevant for carcinogenicity. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>To generate additional information related to carcinogenicity and cobalt exposure in the hardmetal industry, the leading producers of hardmetal participated in an international epidemiological study that included > 30 000 hardmetal workers, which is larger than the previous studies together giving it significant statistical power. Publications from this study are undergoing peer-review and are expected to be published during the first half of 2017. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity.</p> <p>IMPACTS of the Carc 1B proposal:</p> <p>A) The proposed low Specific Concentration Limit (SCL) of 0,01% would force us to produce "cobalt-free" hardmetal tools in entirely separate production lines. That requires investments and is impossible in sites where the space is limited.</p>				

B) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

C) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Mining and Rock Technology response 20170224].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference x Sandvik Mining and Rock Technology response 20170221 V0 4-CH comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Mining and Steel Association	Please select organisation type..	91

Comment received

Wir unterstützen die wissenschaftlich fundierte Argumentation des Cobalt Development Institutes (CDI) und des Cobalt REACH Consortium, und sind der Auffassung, dass sich die harmonisierte Einstufung von Kobalt Metall als Carcinog. 1 B allein auf den Inhalationsweg beschränken sollte. Ein spezifischer Konzentrationsgrenzwert (SCL) von 0.01% ist – wie das Cobalt Development Institut richtig ausführt, auf dessen Eingabe wir hiermit verweisen - wissenschaftlich nicht begründet, weil die Annahmen der Niederlande einer high potency und eines Karzinogens ohne Schwellenwert unzutreffend sind. Deshalb sollte der SCL rechtlich nicht verankert werden. Zudem führt der sehr niedrige SCL infolge eines Dominoeffektes zur FolgeEinstufung aller anderen Metalle und Metalllegierungen mit mehr als 0.01% Kobalt Metall zu weitreichenden wirtschaftsschädigenden Folgen für viele Metallbranchen.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Non Ferrous Metals Association	Industry or trade association	92

Comment received

Wir unterstützen die wissenschaftlich fundierte Argumentation des Cobalt Development Institutes (CDI) und des Cobalt REACH Consortium, und sind der Auffassung, dass sich die harmonisierte Einstufung von Kobalt Metall als Carcinog. 1 B allein auf den Inhalationsweg beschränken sollte. Ein spezifischer Konzentrationsgrenzwert (SCL) von 0.01% ist – wie das Cobalt Development Institut richtig ausführt, auf dessen Eingabe wir hiermit verweisen - wissenschaftlich nicht begründet, weil die Annahmen der Niederlande einer high potency und eines Karzinogens ohne Schwellenwert unzutreffend sind. Deshalb sollte der SCL rechtlich nicht verankert werden. Zudem führt der sehr niedrige SCL infolge eines Dominoeffektes zur FolgeEinstufung aller anderen Metalle und Metalllegierungen mit mehr als 0.01% Kobalt Metall zu weitreichenden wirtschaftsschädigenden Folgen für viele

Metallbranchen.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Albemarle Europe SPRL	Industry or trade association	93

Comment received

We think that the extension of the classification for carcinogenicity beyond the tested route of exposure, inhalation is not justified. All relevant tumors in the NTP studies are occurring in the respiratory tract. Other tumors observed in the NTP studies are either common secondary effects of lung tumor formation or not statistically significant. The quoted difference to historical control data in the CLH dossier is not correct, as this study was the only inhalation study with this sub strain of rats performed by NTP. There are other statistical methods that can be applied and these are submitted by the CDI and CoRC.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium		MemberState	94

Comment received

Two carcinogenicity studies were performed with cobalt metal via inhalation at doses of 0, 1.25, 2.5 and 5 mg/m³ and showed positive results with significant increases in bronchiolar/alveolar neoplastic lesions in the lung with an incidence of 4, 50, 78 and 88% in rats and 4, 30, 40 and 76% in mice. Alveolar/bronchiolar carcinomas were induced in a dose-dependent way in both species. These neoplasms incidence were significantly increased in all treated groups and were outside the HCD in both species. Adrenal tumours were also observed in one study, in male and female rats, after inhalation of cobalt sulphate heptahydrate and appeared to be dose-related and exceeding HCD. As malignant and benign tumours were increased in the lung and adrenal medulla after treatment with cobalt metal or related cobalt compounds, in two species (except for adrenal tumours), in both sexes, BECA agrees to classify cobalt as Carc. 1B.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	FEDIL - The voice of Luxembourg's industry	Industry or trade association	95

Comment received

FEDIL entirely supports the technical position of the Cobalt Development Institute (CDI) and the Cobalt Reach Consortium (CoRC).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170223_ECHA_PC_General_Comments_CLP.docx

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	China	ZIGONG CEMENTED CARBIDE CO., LTD.	Company-Manufacturer	96

Comment received
we support the classification of cobalt metal as Carcinogenic Category 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%.
ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Jernkontoret	Industry or trade association	97

Comment received
<p>Jernkontoret supports the current industry self-classification as Carc 1B via inhalation only. Jernkontoret also supports the technical comments from CDI/CoRC, The EUROFER Position Paper on the Harmonized Classification and Labelling Proposal for Cobalt Metal and Team Stainless Position Paper for the Public Submission on the Harmonized Classification of Cobalt Metal.</p> <p>Some specific and not very common types of stainless steel contain intentionally added cobalt as an alloying metal and other types of steel contain cobalt as impurity in concentrations –up to 1%. The specific concentration limit SCL of 0,01% would therefore have a big impact on the steel industry and its customers and the society as a whole. Iron ore and iron production have historical roots from the Iron age which in Sweden started around 1000 before Christ. In Sweden the iron ore mines started around 1000 year after Christ. So since then the population has been handling iron and steel products contaminated with cobalt. The amount of cobalt in iron ores depend on the mines. In some mines the occurrence of cobalt in the iron ore pellets is stable around the proposed SCL at 0.01%. It is therefore logic to think most iron ores will be found to have cobalt impurities in those levels. Although the iron ore pellets contain of oxidized material, also cobalt probably occur as an oxide. But when smelted in the blast furnace both the iron and cobalt will turn metallic, and also stay that way during the use of the iron- and steel as solids until it oxidizes (in nature) or is re-smelted.</p> <p>Handling of materials containing cobalt would need to change if cobalt metal had a harmonized classification as Carc 1B (all routes of exposure) or Repro 1B. Carcinogen directive (2004/37/EC) and its implementation in Sweden (AFS 2014:43) require that if the CMR substance cannot be eliminated or handled in a closed system, all exposure should be avoided. Avoiding skin contact with all stainless steel and more than 50 % of carbon steel and other alloyed steels as well as hardmetal would be impossible and a modern society without those materials would not work. The current Cobalt REACH Consortium self-classification of cobalt as Carc 1B through inhalation does not cause those problems, because only exposure via inhalation has to be avoided. Exposure via air is traditionally regulated with OELs and working methods have been designed/optimised to minimise dust exposure.</p> <p>Jernkontoret recommends Sweden not to support the proposed classification as long as the scientific support is missing. Jernkontoret also recommends Sweden to carefully consider the scientific background of the proposal and the probable future effects of the proposal.</p>

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	EUROBAT	Industry or trade association	98

Comment received
1. Co metal is mainly used as an intermediate for the manufacturing of other cobalt

compounds used as active materials for electrodes manufacturing

2. However, Co metal is present as an impurity above the proposed SCL of 0.01% in several metals (nickel, stainless steel, alloys) widely used in the battery manufacturing:

- a. This impurity is not economically removable
- b. Technical feasibility has to be considered

3. RECHARGE and EUROBAT support the CDI/CoRC technical comments

ECHA note – An attachment was submitted with the comment above. Refer to public attachment RECHARGE-EUROBAT input to CLH Cobalt metal consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Cobalt REACH Consortium/Cobalt Development Institute	Industry or trade association	99

Comment received

Please note that the CDI/CoRC have made a separate submission of detailed technical comments on this end-point of the CLH proposal.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Zip of CoRC-CDI Joint Response Comments (3 Documents).zip

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	AB Sandvik Coromant	Company-Downstream user	100

Comment received

Hard metal powders are classified as Carcinogenic Category 1B by the inhalation route based on thorough analysis of available data and scientific assessment done by the CDI/CoRC and ITIA following the CLP classification guidance. The available data including epidemiological data from hard metal industry does not indicate the other routes of exposure (oral and dermal) presented in the CLH proposal being relevant for carcinogenicity. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

STUDY TO BE PUBLISHED summer 2017. Publications from an international epidemiological study coordinated by the University of Pittsburgh related to carcinogenicity and cobalt exposure in hard metal industry are undergoing peer-review and are expected to be published during the first half of 2017. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity. IMPACTS of the Carc 1B proposal:

A) The proposed low Specific Concentration Limit (SCL) of 0,01% would force us to produce "cobalt-free" hard metal tools in entirely separate production lines. That requires investments and is impossible in sites where the space is limited.

B) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires totally new, currently not known techniques.

C) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Coromant response 20170223].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Sandvik Coromant response 20170223.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Wirtschaftsvereinigung Stahl e.V. / Stahlinstitut VDEh e.V.	Industry or trade association	101
Comment received				
steel in a massive form is not bioavailable, please regards general comments				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Deutsche Edelstahlwerke Specialty Steel GmbH & Co. KG	Company-Manufacturer	102
Comment received				
Cobalt is bound in a matrix. Therefore it is not bioavailable und primarily for human beings unproblematic. In the case of thermal or mechanical processing, work safety measures must be taken anyway, irrespective of cobalt. Please regard general comments.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany		Individual	103
Comment received				
we are in support of the technical position of the CDI-CoRC				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 160608 Original Eng.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Austria	Boehlerit GmbH & co.KG	Company-Manufacturer	104
Comment received				
There can be no doubt, that cobalt and its compounds are carcinogenic but there seems to be little to no proof why the concentration limit of 0.01% was chosen, especially since the CLH proposal is based on a study which used very high cobalt concentrations for their medical-biological testing.				

Date	Country	Organisation	Type of Organisation	Comment number

23.02.2017	Belgium	The Beryllium Science and Technology Association	Industry or trade association	105
Comment received				
Please see position paper.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Beryllium Science and Technology Association - Cobalt CLH Consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Belgium	EUROFER	Industry or trade association	106
Comment received				
EUROFER fully supports, the scientific arguments provided by the Cobalt REACH Consortia and the Cobalt Development Institute and Team Stainless. With respect to the Carcinogenicity classification in particular, TSE supports the proposal that cobalt metal should be classified as a Carcinogen Category 1B based on the available evidence. However, TSE contends that the weight of evidence does not support an “all routes of exposure” conclusion, and that only the inhalation route of exposure should be considered for this classification.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final EUROFER Carbon Steel Cobalt Input to CLH PC 22.02.17.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Norway	Glencore Nikkelverk AS	Company-Manufacturer	107
Comment received				
Glencore Nikkelverk AS has been appraised of, and supports, the Scientific arguments provided by the Cobalt REACH consortia and the Cobalt Development Institute for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Seco Tools AB	Company-Downstream user	108
Comment received				
Hardmetal powders are classified as Carcinogenic Category 1B by the inhalation route based on thorough analysis of available data and scientific assessment done by the CDI/CoRC and ITIA following the CLP classification guidance. The available data including epidemiological data from hardmetal industry does not indicate the other routes of exposure (oral and dermal) presented in the CLH proposal being relevant for carcinogenicity. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017. STUDY TO BE PUBLISHED summer 2017. Publications from an international epidemiological study coordinated by the University of Pittsburgh related to carcinogenicity and cobalt exposure in hardmetal industry are undergoing peer-review and are expected to be published during the first half of 2017. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity.				

IMPACTS of the Carc 1B proposal:

A) The proposed low Specific Concentration Limit (SCL) of 0,01% would force us to produce "cobalt-free" hardmetal tools in entirely separate production lines. That requires investments and is impossible in sites where the space is limited.

B) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

C) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Seco Tools response 20170221].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Seco Tools response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Pramet Tools, s.r.o.	Company-Downstream user	109

Comment received

Hardmetal powders are classified as Carcinogenic Category 1B by the inhalation route based on thorough analysis of available data and scientific assessment done by the CDI/CoRC and ITIA following the CLP classification guidance. The available data including epidemiological data from hardmetal industry does not indicate the other routes of exposure (oral and dermal) presented in the CLH proposal being relevant for carcinogenicity. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

STUDY TO BE PUBLISHED summer 2017. Publications from an international epidemiological study coordinated by the University of Pittsburgh related to carcinogenicity and cobalt exposure in hardmetal industry are undergoing peer-review and are expected to be published during the first half of 2017. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity.

IMPACTS of the Carc 1B proposal:

A) The proposed low Specific Concentration Limit (SCL) of 0,01% would force us to produce "cobalt-free" hardmetal tools in entirely separate production lines. That requires investments and is impossible in sites where the space is limited.

B) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

C) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Dormer Pramet response 20170221].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 DormerPramet response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Fachverband Pulvermetallurgie e.V. (FPM) / Federation of Powder Metallurgy in Germany (FMP)	Industry or trade association	110

Comment received

The Fachverband Pulvermetallurgie e.V. (Federation of Powder Metallurgy in Germany, FMP) fully supports the technical position of the „Cobalt REACH Consortium Ltd. –CoRC“ / „Cobalt Development Institute – CDI“.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Vale Base Metals	Company-Manufacturer	111

Comment received

Vale Base Metals is a member of the Cobalt Development Institute/Cobalt REACH Consortium and Nickel Institute and supports the technical input of these organisations to this public consultation.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of frits (Frit Consortium)	Industry or trade association	112

Comment received

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support FRIT.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of Inorganic Pigments (Inorganic Pigments Consortium)	Industry or trade association	113

Comment received

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support IP.pdf

Date	Country	Organisation	Type of Organisation	Comment number
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22.02.2017	Germany	Walter AG	Company-Downstream user	114
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Comment received

Hardmetal powders are classified as Carcinogenic Category 1B by the inhalation route based on thorough analysis of available data and scientific assessment done by the CDI/CoRC and ITIA following the CLP classification guidance. The available data including epidemiological data from hardmetal industry does not indicate the other routes of exposure (oral and dermal) presented in the CLH proposal being relevant for carcinogenicity. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

STUDY TO BE PUBLISHED summer 2017. Publications from an international epidemiological study coordinated by the University of Pittsburgh related to carcinogenicity and cobalt exposure in hardmetal industry are undergoing peer-review and are expected to be published during the first half of 2017. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity.

IMPACTS of the Carc 1B proposal:

A) The proposed low Specific Concentration Limit (SCL) of 0,01% would force us to produce "cobalt-free" hardmetal tools in entirely separate production lines. That requires investments and is impossible in sites where the space is limited.

B) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

C) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Walter AG response CLH-Prop_CO_20170222].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Walter AG response CLH-Prop_CO_20170222.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Wolfram Bergbau und Hütten AG	Company-Downstream user	115

Comment received

Hardmetal powders are classified as Carcinogenic Category 1B by the inhalation route based on thorough analysis of available data and scientific assessment done by the CDI/CoRC and ITIA following the CLP classification guidance. The available data including epidemiological data from hardmetal industry does not indicate the other routes of exposure (oral and dermal) presented in the CLH proposal being relevant for carcinogenicity. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

STUDY TO BE PUBLISHED summer 2017. Publications from an international epidemiological study coordinated by the University of Pittsburgh related to carcinogenicity and cobalt exposure in hardmetal industry are undergoing peer-review and are expected to be published during the first half of 2017. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity.

IMPACTS of the Carc 1B proposal:

A) The proposed low Specific Concentration Limit (SCL) of 0,01% would force us to produce “cobalt-free” hardmetal tools in entirely separate production lines. That requires investments and is impossible in sites where the space is limited.

B) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

C) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 WBH response 20170221].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 WBH response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	United Kingdom	International Tungsten Industry Association	Industry or trade association	116

Comment received

Proposed Classification from Carcinogenic Category 1B by Inhalation Only to Carcinogenic Category 1B by All Exposure Routes

Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as Carcinogenic Category 1B by the inhalation route based on information about cobalt’s carcinogenicity. The other routes of cobalt exposure (oral and dermal) presented in the CLH proposal are not supported by previous and most current epidemiological studies on hardmetal workers.

ITIA’s leading hardmetal producers participated in an epidemiological study coordinated by the University of Pittsburgh. The study collected and analysed data from more than 30,000 workers in the hardmetal industry from five different countries (Austria, Germany, Sweden, United Kingdom, and United States) from 2006 to 2016. The study is much bigger than all the previous studies together, giving it significant statistical power. Study publications are undergoing peer-review and will be available by the end of 2nd Quarter 2017.

The study examines the association between carcinogenicity and cobalt exposure in the hardmetal industry. Because of the scope and the exceptional size of the study, it is highly relevant to the RAC assessment of cobalt’s carcinogenicity and should be included.

Based on available scientific data, we support the classification of cobalt metal as Carcinogenic Category 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	EBRC	Please select organisation type..	117

Comment received

Lack of systemic carcinogenicity of cobalt and cobalt sulfate

The CLH report states in the section "comparison with the criteria" (page 121), that "Three possible modes of action are proposed, all of which are relevant for human."

The mode of action analysis was in fact not performed by the report author, but copied from the NTP Report on Carcinogens without further modification (see also comment on mode of action analysis given in the "General comments").

The CLH report states in the section "comparison with the criteria" (page 121), that "Cobalt metal (as well as cobalt sulphate heptahydrate) induces benign and malignant lung (in rats and mice) and adrenal tumours (in rats) after inhalation exposure. Cobalt metal also induces adenomas/carcinomas in pancreatic islets of male rats."

The report does not perform an assessment whether the systemic tumours were (i) significant elevated above historical controls and (ii) a consequence of direct test substance induced effects or secondary to the exposure. Such an analysis is provided below:

Two chronic inhalation bioassays are available, in which groups of 50 male and 50 female rats and mice were exposed for 6 hours per day, 5 days per week for 105 weeks to aerosols containing 0, 0.3, 1.0, or 3.0 mg/m³ cobalt sulfate or cobalt metal of 0, 1.25, 2.5 or 5 mg/m³ (NTP, 1998 and 2014).

Systemic Neoplastic Lesions Associated with Inhalation Exposure to Cobalt Sulfate

The adrenal medulla of the rat kidney was the primary systemic site at which increased incidence of neoplastic lesions was observed. Pheochromocytoma, lesions originating from chromaffin cells of the adrenal medulla, were observed in both male and female rats but not in mice. Pheochromocytoma are commonly observed lesions in unexposed rats, the historical control rate in male rats being 28% (range 8 – 50%) for benign, complex or malignant lesions, somewhat higher than the rate observed in female rats of 6.4% (range 2 – 14%). The incidence of benign complex or malignant pheochromocytoma was statistically elevated in male rats exposed to 1.0 mg/m³ cobalt sulfate (adjusted rate 74%) and in female rats exposed to 3 mg/m³ (adjusted rate 28%). Behl et al (2015) attach significance to this observation in spite of lack of evidence for antecedent hyperplasia as a result of cobalt sulfate exposure. In contrast Greim et al (2009) have reviewed the appearance of chemically induced pheochromocytoma in rats and suggested that they will arise with increased frequency under conditions of hypoxia and other perturbations of physiological homeostasis. Citing lack of evidence that such secondary lesions are indicative of risk for humans, they further indicate that such lesions are not relevant for either classification or risk assessment. Increased incidence of renal lesions was not observed in mice, providing further indication that lesions in cobalt sulfate treated rats represent secondary impacts of physiological stress upon the incidence of spontaneous tumours and not direct systemic impacts of chemical exposure.

Exposed mice did exhibit increased incidence of chronic inflammation of the liver, oval cell hyperplasia and haemangiosarcoma. These effects were more pronounced in male mice but the incidence of haemangiosarcoma, which occur spontaneously in mice, was only

significant in the 1 mg/m³ treatment group. The lesions observed in treated animals were also morphologically similar to those that occurred spontaneously. The available data thus do not suggest a significant impact upon the liver.

The inhalation studies conducted with cobalt sulfate hexahydrate thus provide evidence of carcinogenic activity for pulmonary tissue, but systemic toxicity is limited and there is little evidence that carcinogenic impacts are exerted as a result of systemic exposure. The sporadic associations that are present (pheochromocytoma in rats and haemangiosarcoma in mice) are most likely spontaneous lesions not directly related to chemical exposure. In the specific case of pheochromocytoma, an increased incidence would be expected due to the pulmonary toxicity of treatment, impaired lung function and resulting hypoxia.

Systemic Neoplastic Lesions Associated with Inhalation Exposure to Cobalt Metal

A variety of systemic neoplastic lesions were observed in rats with inhalation exposure to cobalt metal. In particular lesions of the adrenal medulla (pheochromocytoma), pancreas (islet neoplasms) and leukaemia arose with a frequency that attained statistical significance. These lesions are technically a result of inhalation exposure to cobalt metal. However, for purposes of classification and risk assessment a determination must be made of whether these lesions are direct impacts of cobalt metal or secondary lesions that have arisen as a result of impaired physiological function induced by cobalt metal (Regulation (EC) 1272/2008, Annex I, Section 3.6.2.2.1). Prolonged exposure to cobalt metal causes progressive injury to the lungs and nose of male and female rats, inducing a spectrum of inflammatory and toxic responses that include hyperplasia, metaplasia and necrosis. The doses used in the cobalt metal inhalation studies generally approximated and then exceeded the "maximum tolerated dose", defined by NTP (2006) as that dose yielding a 10% reduction in body weight and generally regarded as the highest dose that does not alter the test animal's longevity or well-being because of non-cancer effects. The high frequency of pulmonary adenomas and carcinomas (the primary lesion observed in the NTP studies) further compromised the health and physiological status of test animals. Any increases in the incidence of tumours at sites other than the respiratory tract, particularly if known to occur with a measurable spontaneous frequency, must be carefully evaluated.

Results must also be interpreted given the known impacts of cobalt upon physiological processes that might modulate the incidence and/or growth rate of spontaneous tumours. For example, Goldwasser (1958) established that cobalt caused erythrocytosis through stimulation of erythropoietin. This effect is largely mediated by the ability of cobalt to stabilise a subunit of hypoxia-inducible factor-1 (HIF-1) that plays a significant role in oxygen homeostasis (Epstein et al., 2001; Yuan et al., 2003).

The incidence of benign and malignant pheochromocytoma of the adrenal medulla increases as a function of exposure to cobalt metal. With a rate of 40.2% and 13.6% in the male and female chamber controls of this study, this high frequency spontaneous lesion has been observed to increase in past NTP inhalation studies (NTP, 2016) as a function of pulmonary damage (fibrosis and inflammation) by inhaled particulate matter. Combined with the observations of Greim et. al. (2009) that increased incidence of this lesion can be secondary to the induction of hypoxia and HIF-1, increased lesion incidence is not probably a specific effect of cobalt but rather a secondary manifestation of pulmonary toxicity. As such, these secondary lesions do not provide a basis for classification or risk assessment.

The incidence of pancreatic islet neoplasms was also increased in the cobalt metal inhalation study. As NTP noted (NTP, 2016) this was the first inhalation study NTP had conducted that exhibited an increase in neoplasms of the pancreas. Neoplastic lesions in female rats were elevated in the 5 mg/m³ treatment group (7.2% adjusted incidence vs. 2.2% in chamber

controls) but the increase was not statistically significant and dose dependent increases were not detected at lower exposure levels. Male rats had statistically significant increased incidence of lesions in the 2.5 and 5 mg/m³ treatment groups, providing the basis for the NTP conclusion that there was some evidence for carcinogenic activity in the pancreatic islets. Several factors lend uncertainty to the significance of this observation. Such lesions were not observed in cobalt sulfate inhalation studies which, in theory, would have provided higher levels of systemic distribution due to greater solubility. The responses observed were elevated above those observed in historical controls – but the historical incidence rate is based upon only 100 animals. The true spontaneous incidence of this lesion is thus less than precisely defined. Finally, the responses observed at 2.5 and 5 mg/m³ cobalt metal exposure, exposure levels with weight reductions (11% and 29%, respectively) suggest that the cobalt metal MTD had been exceeded. These exposure levels were further associated with significant hypoxia related to treatment induced neoplastic and non-neoplastic lesions of the respiratory tract. Whereas hypoxia has been suggested to have inhibitory effects upon cell growth, more recent studies (Joshi et al., 2016) have observed that hypoxia may modulate oncogene function in a fashion that facilitates the growth of existing pancreatic neoplasms. The reported increase in pancreatic cancer is thus considered to reflect modulation of spontaneous tumour growth by hypoxia.

Finally, exposure to cobalt metal was associated with mononuclear cell leukaemia in female rats with adjusted rates increasing from 35.7% in chamber controls to approximately 60% in treated groups. Once again this lesion was not observed in cobalt sulfate studies. Moreover, the high spontaneous rate of leukaemia in female rats is loosely defined and based upon only 100 animals. Whether the incidence in cobalt metal treated animals is outside the range to be expected is uncertain. Although the incidence in treated animals is greater than that in chamber controls, there is no indication of dose response. Finally, as noted earlier, cobalt is known to stimulate erythropoietin to an extent sufficient to cause erythroid hyperplasia (NTP, 2016). The ability to modulate haematopoiesis may have an impact upon the development of high frequency spontaneous leukaemia. Erythropoietin enhances chemically induced leukaemia in the rat (Sugiyama et al., 2002) and can plausibly be expected to impact the development of spontaneous lesions.

Summary of Systemic Lesions

Taken as a whole, although a variety of systemic tumours were observed in cobalt metal treated rats, none of the neoplasms at systemic sites studied provide the basis for classification or risk assessment. Increased incidence of rat pheochromocytoma, also observed in studies of cobalt sulfate, have been extensively documented to be enhanced by hypoxia and are not specific impacts of cobalt. As detailed by Greim et. al. (2009), the appearance of such lesions secondary to pulmonary damage and neoplasms does not provide the basis for classification or risk assessment. Neoplasms at other tissue sites (pancreatic tumours and leukaemia) were not observed in studies of cobalt sulfate and were only increased in a single sex (males for pancreatic, females for leukaemia). For each of the latter lesions interpretation of tumour incidence is complicated by limited (and therefore imprecise) definition of incidence in historical controls. Moreover, mechanisms exist whereby secondary effects of cobalt can plausibly be expected to increase the frequency of spontaneous lesions. Lung tumours induced through inhalation exposure are the strongest most appropriate and only basis for the classification of both cobalt metal and cobalt sulfate.

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Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Hille & Müller Steel, Tata Steel Europe	Company-Downstream user	118
Comment received				
Tata Steel Europe (TSE) fully supports, the scientific arguments provided by the Cobalt				

REACH Consortia and the Cobalt Development Institute, Team Stainless and Eurofer. With respect to the Carcinogenicity classification in particular, TSE supports the proposal that cobalt metal should be classified as a Carcinogen Category 1B based on the available evidence. However, TSE contends that the weight of evidence does not support an “all routes of exposure” conclusion, and that only the inhalation route of exposure should be considered for this classification.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tata Steel Hille and Muller Position paper.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Arno Friedrichs Hartmetall GmbH & Co.KG	Company-Downstream user	119

Comment received

- waste needs to be classified as hazardous where waste contains a substance known to be carcinogenic cat. 1A or 1B in a concentration of > 0.1%: higher recycling costs for cobalt containing materials
market impact from CMR stigmatization:
- negative impact on supply chains because sales of cobalt based alloys will likely reduce significantly due to customer perception (phasing out without need)
- larger costs in handling cobalt products in downstream sectors (e.g. due to minimize occupational exposure)

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	RECHARGE	Industry or trade association	120

Comment received

We challenge the proposed classification of cobalt carcinogenicity by oral and dermal route, as lacking scientific evidence. In this approach, we support the technical position of the CDI/CoRC (2017), as outlined in:
Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal, January 2017.
In addition, we consider that the consequences of this classification in combination with the proposed SCL of 0.01% would have high and unexpected consequences on our industry: although cobalt is not used in its metallic form in the active material of batteries, it is present as an impurity above the proposed SCL of 0.01% in several metals (nickel, stainless steel, alloys) widely used in the battery manufacturing, particularly for the batteries casings. In this typical usage, the metal is not submitted during usage to specific abrasion or bio-elution process, and therefore cannot be suspected to release cobalt impurity. The removal of the cobalt impurity is not economic, and the technical feasibility has to be considered. As an example in the field of the circular economy, it can be mentioned that the recycling processes of batteries are generally separating the cobalt from other recycled metals in order to valorise his economical value. Nevertheless, the removal of the remaining cobalt to achieve the impurity level that would be required exceeds the present time processes capabilities.

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Team Stainless / Eurofer	Industry or trade association	121

Comment received

Team Stainless (TS) has been appraised of, and supports, the scientific arguments provided by the Cobalt REACH Consortia and the Cobalt Development Institute. With respect to the Carcinogenicity classification in particular, TS supports the proposal that cobalt metal should be classified as a Carcinogen Category 1B based on the available evidence. However, TS contends that the weight of evidence does not support an "all routes of exposure" conclusion, and that only the inhalation route of exposure should be considered for this classification. These opinions support those of the Cobalt Development Institute and the Nickel Institute. Similarly, TS supports the case against the repro 1B and Muta 2 classifications.

Metals are rarely used in the pure form, and are usually alloyed with other metals. This produces the wide range of mechanical, corrosion resistant, and aesthetic properties that make metals essential for our modern existence. The alloy CMR classification follows from the composition of the alloy according to current regulations (classified alloy ingredient above the GCL or SCL). It is therefore critical to consider the experience of using that alloy during the manufacturing process, and in service, to evaluate if any of the health effects on workers or the general public predicted based on having a cobalt metal content > 0.01% (e.g., carcinogenicity-all routes of exposure) are realistic. This is especially true where there is supporting human data available in terms of epidemiology. This can provide insights and a 'real world verification' of the assumptions and interpretations of test results (especially the assigned SCL) derived from testing the pure metals forming the alloy. We believe this is missing from the analysis underpinning the Dutch proposed classifications and SCL for cobalt metal. The long-term exposure in the workplace and among the general public to stainless steel for many decades can greatly inform the science under consideration.

In spite of residual cobalt levels present in the stainless steel and other cobalt containing alloys greatly in excess of the proposed SCL, as described above, there is no evidence of systemic cancers in the workplace associated with this exposure as shown by different epidemiological studies, one of which involves more than 30,000 workers^{1,2,3,4}.

Significantly, the long history of use of cobalt-based alloys in medical implants does not indicate an increased risk of cancer, mutagenicity, or reproductive toxicity. There is extensive literature suggesting no increased risk of cancer from cobalt in hip implant patients, who are systemically exposed to cobalt at concentrations above that of the general population^{5,6}.

Meanwhile, the use of stainless steel in its many applications is recognized as bringing huge health benefits to the general population in hospitals and schools, and in hygienic food processing in factories and kitchens. We are not aware of any reported negative health effects of the kind predicted by the current proposal. The scale of the exposed cohort in society is significant enough to demonstrate such an effect were it present, we believe. The safe use of stainless steel is acknowledged in the EU's Toy Directive (Toy Safety Directive 2009/48/EC, Annex II, section III, clause 6). Stainless steel is listed as safe for use in contact with drinking water, according to the 4MS (four member state) initiative to harmonize the selection of hygienic materials for use in contact with drinking water⁷.

Team Stainless believes this demonstrates, as a minimum, evidence of a practical threshold effect, and challenges the conclusion of 'all routes of exposure', at least when in alloy form. The SCL of 0.01% Co is not justified on the basis of this evidence.

For the purposes of hazard classification, alloys are considered to be mixtures and they are currently classified on the basis of the amount of a hazardous substance present, following the principle of the GHS/CLP Mixtures Rule. The underlying principle of the Mixtures Rule is a convention and has no scientific basis. In addition, the REACH regulation recognises that alloys are "special preparations" rather than simple mixtures. In practice, they are 'solid solutions', and behave differently from the individual alloying constituents when incorporated within the alloy matrix. This so-called 'alloying effect' in stainless steel, and other specialty alloys, strongly limits the bio-availability of the individual constituents.

Members of Team Stainless are in the process of collecting additional information on the

bioelution-based predicted bio-availability of cobalt from stainless steel. Despite the complexity of the technical and political aspects that could create precedents, it should be acknowledged that a proper scientifically justified classification scheme for alloys as mixtures containing hazardous substances is required which better reflects the unique properties of alloys, the true toxicity of the materials, and is health protective while not being unnecessarily over-conservative and restrictive.

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final - Team Stainless Position Paper for the Cobalt Issue (signed).pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Svemin	Industry or trade association	122
Comment received				
We support the technical comments and the position of the REACH Consortium Ltd (CoRC) and the Cobalt Development Institut (CDI)				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Final Slags Task Force of Eurometaux	Industry or trade association	123
Comment received				
The members of the Final Slag Taskforce of Eurometaux support the technical position of the CDI/CoRC (2017). We particularly support the classification of cobalt massive as Carc. 1B for the inhalation route only, H350i, with a Generic Concentration Limit (GCL). We question the validity and proportionality of the very low specific concentration limit of 0.01% for the classification as Carcinogen 1B in the CLH proposal.				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final Slags TF Eurometaux Comments on Co CLH proposal 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	European Copper Institute	Industry or trade association	124

Comment received

The European Copper Institute supports the technical position of the CDI/CoRC (Cobalt Development Institute / Cobalt REACH consortium, 2017), as outlined in the Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal of January 2017.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170222_ECI-PC-Cobalt-CLH_public-attachment.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Nickel Institute	Industry or trade association	125

Comment received

The NI strongly supports the CoRC comments in opposing the Dutch proposal to classify Co metal as a Carcinogen Category 1B for all routes of exposure and with a SCL of 0.01%:

(1)The proposal to classify Co metal as Carc 1B via inhalation is warranted based on the results from the recent NTP inhalation carcinogenicity study. Chronic cobalt metal inhalation exposure consistently induced lung tumours in rats and mice, in agreement with the results from the Co sulphate studies, and as it would be expected for Co(II) mediated effects;

(2)The significance of the increased incidence of tumors at sites other than respiratory tract observed in the Co metal inhalation study need to be considered separately for a) tumors that are known to occur spontaneously with high frequency in aging rats (e.g., pheochromocytomas and mononuclear cell leukemias), and b) rare tumors that were observed only in one sex and only in rats (e.g., kidney, pancreas). The former types of tumors have been observed in many studies and are due to non substance-specific rat responses to respiratory distress (pheochromocytomas) or were not dose dependent in the Co metal study (leukemia). The significance of the latter types of tumors cannot be reliably evaluated due to the lack of proper historical controls. However, it is unlikely that these tumors were induced by the Co ion since they were not observed in the carcinogenicity study with Co sulphate, or in human populations exposed to Co ions orally or from implants.

(3)Cobalt metal should be considered as a threshold carcinogen based on mode of action and mutagenicity profile.

(4)The potency calculation used in the Dutch Proposal assumed cobalt metal to be a direct acting carcinogen based on consideration of an incomplete dataset. We understand that there is a very recent epidemiological study that could provide valuable data for assessing risks to humans from exposure to different chemical forms of cobalt. Due to the far reaching long term consequences of the current proposal it is important to consider all the available data as part of the review.

A weight of evidence assessment of the scientific evidence by the NI does not support cobalt metal being classified as a carcinogen category 1B for all routes of exposure. The

criterion for classification of Co metal as a Cat 1B carcinogen based on tumors at systemic sites is not fulfilled. If cobalt metal was indeed capable of inducing tumors at distant sites through the release and absorption of Co (ions) in a non-threshold manner, then the same events would be expected to be induced by the Co (II) ion from soluble salts. The fact that Co sulphate did not reproduce these results in rats or mice, together with the fact that neither workers exposed to Co-containing aerosols, nor patients with cobalt-containing prostheses whose blood Co levels are significantly elevated have shown increased cancer risk, strongly indicate that:

- 1)cobalt is not a systemic carcinogen or
- 2)if it is a carcinogen, it certainly is not a high potency one.

Thus, the low SCL, as calculated by the Dutch Authorities, is not warranted as it does not take all the relevant data (including epidemiological data) into account.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170220-Co metal implications for Ni - input in consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	United States		Individual	126

Comment received

Executive Summary

On January 10, 2017, a public consultation was issued for the harmonized classification and labeling proposal of cobalt metal (CAS No. 7440-48-4) by the Netherlands National Institute for Public Health and the Environment (RIVM) to comply with the European Union's REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals). RIVM (2016) proposed a harmonized classification for the following endpoints: carcinogenicity category 1B (H350; may cause cancer without specification for exposure route) with a specific concentration limit of 0.01%, mutagenicity category 2 (H341; suspected of causing genetic defects), and reproductive toxicity category 1B (H360F; may damage fertility).

We conducted an independent review of the epidemiological, toxicological, and mode of action (MoA) literature to evaluate the scientific evidence cited by RIVM as supportive of the proposed harmonized classification. In addition, we evaluated the determinations provided in the RIVM proposal in light of the European Chemical Agency guidance for classifying carcinogens (ECHA, 2015). Based on our review of the available information, we conclude that the 2016 RIVM CLH proposal for cobalt is inconsistent with ECHA (2015) guidance for classifying carcinogens, mainly because a weight-of-evidence (WoE) analysis was not conducted. Following ECHA (2015) guidance, a substance's carcinogenic potential should be examined by considering all available human and experimental animal studies, supporting mutagenicity and MoA information, and the strength of evidence for carcinogenicity. Below is a summary of these lines of evidence for cobalt substances:

- Human Evidence: Inadequate for carcinogenicity classification.
- Experimental Animal Evidence: Inhalation exposures to cobalt substances consistently demonstrate progressive cellular damage (e.g., hyperplasia) and adenomas or carcinomas in the alveolar and bronchiolar tissues of rats and mice. These effects are observed across multiple sub-chronic and chronic inhalation studies in both sexes and multiple rodent strains. Conversely, increased tumor incidence at distal sites (adrenals, kidneys, pancreas) following inhalation are specific to sex, species, strain, and exposure route. None of the available oral toxicity information demonstrates concordance with target organ sites observed in inhalation bioassays. Further, no significant observations of hyperplasia are

consistently observed in oral studies at doses below those causing frank toxic effects. Thus, there is no direct evidence that indicates oral or dermal exposures to cobalt result in tumor incidence.

□ Supporting Evidence: Although cobalt compounds have been demonstrated to interact with DNA in vitro, these results have not been reproduced in vivo. In addition, certain aspects of the animal bioassays may confound interpretation of the carcinogenicity findings. For example, adrenal pheochromocytomas observed in rats appear to be a secondary response to the chronic pulmonary inflammation and fibrosis induced by cobalt, and not a direct effect of systemic exposure to cobalt. Increased incidences of mononuclear cell leukemia, pancreatic tumors, and kidney tumors are limited to only one sex or one species exposed to cobalt metal via inhalation. No supporting evidence is available for these tumor types in any sub-chronic or chronic experiments using either inhalation or oral exposures. Some significant carcinogenic responses for cobalt metal were apparent only at or above the maximally tolerated dose (i.e., adrenal pheochromocytomas and pancreatic islets). These results (along with available mutagenicity and MoA information) suggest that cobalt induces carcinogenicity via nongenotoxic mechanisms. This nongenotoxic MoA may partially explain the tumor incidence observed at distal sites during the chronic inhalation bioassays. The weight of carcinogenicity and mutagenicity evidence (including tumor incidence, species and gender specificity, and MoA evidence) indicates that tumors associated with inhalation exposures are specific to the portal of entry and likely act via nongenotoxic MoAs. The supporting evidence regarding whether cobalt substances are carcinogenic by either the oral or dermal routes of exposure is not sufficient. Accordingly, a carcinogenicity classification for cobalt substances specifying inhalation (H350i) most appropriately reflects the available evidence.

1 Introduction

The European Union's REACH regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) includes a provision to develop standardized hazard classifications for chemical substances. The REACH regulation No. 1272/2008 describes the classification, labeling, and packaging of substances and mixtures (hereafter referred to as the CLP) and is intended to ensure harmonized risk classification and labeling throughout the European Union. Member States, manufacturers, importers, and downstream users may propose a harmonized classification and labeling of a substance according to relevant guidance (ECHA, 2015). These proposals are subject to a public review consultation, after which the ECHA risk assessment committee (RAC) prepares a scientific opinion. On January 10, 2017, a public consultation was issued for the harmonized classification and labeling proposal for cobalt (CAS No. 7440-48-4) by the Netherlands National Institute for Public Health and the Environment (RIVM).

Specifically, the REACH Bureau for RIVM (RIVM, 2016) prepared a 2016 proposal for the harmonized classification and labeling for cobalt metal for the following endpoints: carcinogenicity category 1B (H350; may cause cancer without specification for an exposure route) with a specific concentration limit of 0.01%, mutagenicity category 2 (H341; may cause genetic defects), and reproductive toxicity category 1B (H360F; may damage fertility). RIVM (2016) stated the following as support for the carcinogenicity 1B; H350 (no exposure route specified) classification proposal:

The criteria in table 3.6.3 of CLP state that the route of exposure should be stated if it is conclusively proven that no other routes of exposure cause the hazard. It is recognized that the cobalt compounds that currently have a harmonized classification for carcinogenicity are limited to the inhalation route (H350i). However, there are no carcinogenicity studies using other routes of exposure. However, the adrenal tumors, together with toxicity to internal organs as the testes and the results of tissue burden studies indicate that cobalt is distributed through the body after inhalation exposure. In our opinion, this means that it

cannot be excluded that exposure via for example the oral route, may result in carcinogenesis, provided that the internal concentration of cobalt is high enough. Therefore, inclusion of a specific exposure route (i.e. inhalation) is not advised....

...Cobalt metal induces lung and adrenal tumors after inhalation exposure in both sexes of rats and mice. Since it cannot be excluded that oral exposure may result in carcinogenesis, cobalt should be classified as Carc 1B; H350, without specification for an exposure route. In addition, an SCL [specific concentration limit] of 0.01% should be applied...

Prior to the RIVM CLH proposal, the Cobalt REACH consortium cobalt metal registrants self-classified this substance (all physical forms) as a category 1B carcinogen from only the inhalation exposure pathway (H350i; may cause cancer by the inhalation route of exposure). Thus, the RIVM CLH proposal represents a departure from the existing self-classification by the registrants (i.e., a change from the potential to cause cancer from inhalation only to the potential to cause cancer from any route of exposure). To examine this proposed classification change, we conducted a critical independent weight-of-evidence (WoE) review of the epidemiological and toxicological literature on which RIVM based its conclusions. In addition, we evaluated the determinations provided in the RIVM CLH proposal in light of the ECHA CLP guidance for classifying carcinogens (ECHA, 2015).

In the following sections, we discuss the available scientific evidence for cobalt substances and comment on whether the WoE supports the classification of Carc. 1B: H350 for all routes of exposure. We conclude the following:

- The 2016 RIVM CLH proposal for cobalt does not follow ECHA (2015) guidance for classifying carcinogens; in that a thorough WoE evaluation was not provided. Thus, the proposed carcinogenicity classification lacks adequate support and should be reconsidered following a WoE evaluation.
- The weight of carcinogenicity and mutagenicity evidence indicates that tumors associated with inhalation exposures are specific to the portal of entry and likely act via nongenotoxic MoAs.
- Specifically, systemic tumors (i.e., adrenal pheochromocytomas, mononuclear cell lymphoma, adenoma or carcinomas in the pancreatic islets, and kidney adenomas or carcinomas) identified following inhalation exposure in experimental animals are either related to a secondary nongenotoxic mechanism (associated with generation of reactive oxygen species), confounded by species-specific elevated incidence rates, or are unreliable due to the limited availability of historic control information for certain rodent species (F334/NTac rats).
- The supporting evidence regarding whether cobalt substances are carcinogenic by either the oral or dermal routes of exposures is not sufficient. Rather, the results from experimental animal studies show consistent effects that are specific to the inhalation route.

2 Overview of Human Health Hazard Information

As described in Section 3.6.2.2 of the guidance on the application of the CLP criteria, hazard classifications for carcinogens should be determined from the following general types of data:

- Human (epidemiological) data establishing a causal relationship between exposure to a substance and the development of cancer, and
- Animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity.

Numerous compilations of human and experimental animal information are available for cobalt substances, including the RIVM CLH proposal and REACH substance dossiers (e.g., OECD, 2014; ATSDR, 2004; Danish Environmental Protection Agency, 2013; RIVM, 2001; NTP, 1998; 2014; 2016). The RIVM CLH proposal cites epidemiology, toxicology,

mutagenicity, and toxicokinetic information as support for the proposed carcinogenicity classification for cobalt (Category 1B carcinogen – H350; may cause cancer without specification for an exposure route). Below we provide a brief summary and WoE evaluation of carcinogenic responses observed in human and experimental animal studies based on WoE principles as detailed by ECHA (2015) in Annex I: 3.6.2.1. Our WoE analysis considers numerous factors (e.g., quality, reliability, and coherence between human, in vivo animal, and in vitro data) and also relies on recommendations from numerous sources (e.g., ECHA, 2015; McGregor et al., 2010; Boobis et al., 2006; 2008; Meek et al., 2014; Rhomberg et al., 2013). Relevant data are examined below in relation to potential carcinogenic responses from inhalation, oral, and dermal exposures.

2.1 Inhalation Exposure

Human Studies

Several cobalt cohort and case-control studies have been published in the peer-reviewed literature (Tüchsen et al., 1996; Mur et al., 1987; Moulin, et al. 1993; 1998; 2000; Wild et al., 2000; Grimsrud et al., 2005; O'Rorke et al., 2012; Rogers et al., 1993 [all as cited in NTP, 2016]). These studies focused on cancers (e.g., lung, esophageal, oral cavity, pharyngeal, and laryngeal) in occupational settings. NTP's robust review of the epidemiology evidence (included in the RIVM CLH proposal) concluded that the available human studies are inadequate for evaluating the causal relationship between cobalt inhalation exposure and the development of cancers along the respiratory tract (NTP, 2016). Significant limitations identified include: inadequate detail on cobalt forms, limited exposure-response information, and co-occurrence with other potentially carcinogenic substances (e.g., tungsten carbide, nickel, and smoking). Taken together, the human inhalation studies are inadequate for cancer classification by the inhalation route of exposure.

Experimental Animal Studies

Three chronic animal bioassays report the carcinogenic responses associated with inhalation exposure to cobalt substances (NTP, 1998; 2014; Wehner et al., 1977). A summary of the statistically significant treatment-related findings are discussed below and presented in Tables 1 and 2.

□ Cobalt sulfate (NTP, 1998): Male and female rats (F344/N) and mice (B6C3F1) were exposed to cobalt sulfate heptahydrate via aerosol inhalation (0, 0.3, 1.0, or 3.0 mg/m³) for 6 hours/day, 5 days/week, for 105 weeks. Significant dose-dependent non-neoplastic (e.g., inflammation; epithelial hyperplasia, interstitial fibrosis) and neoplastic effects (e.g., alveolar and bronchiolar adenomas or carcinomas) were observed in the respiratory tract of male and female rats and male and female mice. In addition, significant dose-dependent neoplastic effects were observed in the adrenal medulla (i.e., benign or malignant pheochromocytomas) of female rats but were not significant in male rats (not supported by increased incidence of hyperplasia in the adrenal gland) (Table 2). No effects were observed in the adrenal medullas of male or female mice.

• Prior to the 2-year studies for cobalt sulfate, NTP (1991) performed 13-week inhalation studies with the same strains of rats and mice at concentrations of 0, 0.3, 1, 3, 10, and 30 mg/m³. Similar lesions were noted in the 13-week study (as in the 2-year study) in the lungs (bronchiolar epithelial regeneration and alveolar epithelial hyperplasia) of both male and female rats and mice at ≥3 mg/m³. No significant histopathological effects were observed in the adrenal glands, pancreas, or kidneys.

□ Cobalt metal (NTP, 2014): Male and female rats (F344/NTac) and mice (B6C3F1) were exposed to cobalt metal via particulate aerosol inhalation (0, 1.25, 2.5, or 5.0 mg/m³) for 6 hours/day, 5 days/week, for 105 weeks. Significant dose-dependent non-neoplastic (e.g., inflammation; epithelial hyperplasia, interstitial fibrosis) and neoplastic effects (e.g., alveolar and bronchiolar adenomas or carcinomas) were observed in the respiratory tract of

male and female rats and male and female mice. In addition, significant dose-dependent neoplastic effects were observed in the adrenal medulla (i.e., benign or malignant pheochromocytomas) of female and male rats. However, progressive hyperplasia of the adrenal gland was not significantly greater than controls in male rats and, although significant, hyperplasia was not dose-dependent in female rats (Table 2). No effects were observed in the adrenal medullas of male or female mice. Additional significant neoplastic findings were reported for only male rats (i.e., adenoma or carcinoma of the pancreatic islets) or only female rats (i.e., mononuclear cell leukemia). Equivocal findings included renal tubule adenomas or carcinomas (combined) in the male rat and pancreatic islet carcinomas in the female rats (at the highest concentration).

- Prior to the 2-year studies for cobalt metal, NTP (2014) performed 13-week inhalation studies with the same strains of rats and mice at concentrations of 0, 0.625, 1.25, 2.5, and 5 mg/m³. Similar lesions were noted in the 13-week study (as in the 2-year study) in the respiratory tract and specifically the lung (bronchiolar and alveolar epithelial hyperplasia) in both male and female rats and mice at ≥ 1.25 mg/m³. No significant histopathological effects were observed for the adrenal glands, pancreas, or kidneys.

- Wehner et al. (1977): Male Syrian golden hamsters were exposed to a cobalt (II) oxide aerosol (0 or 10 mg/m³) for 7 hours/day, 5 days/week throughout their lifespan. No significant carcinogenic findings were noted for the cobalt exposed animals. The authors reported effects in the lung (i.e., interstitial pneumonitis, diffuse granulomatous pneumonia, fibrosis of alveolar septa, and bronchial and bronchiolar epithelial [basal cell] hyperplasia). This study has several limitations, including that only one dose was tested, limited historical control data were available, limited study details were published, and there was poor survival over the duration of the assay. NTP (2016) noted that this study has limited utility for evaluating potential cancer hazards.

2.2 Oral Exposure

Human Studies

Only one epidemiology study evaluated the oral route of exposure. Berg and Burbank (1972) investigated eight trace metals (including Co) in water supplies throughout ten basins in the United States, and mortality from 34 types of cancer. The concentration of cobalt in the water ranged from 1-19 $\mu\text{g/L}$; no association was found between cancer mortality and cobalt concentration (Berg and Burbank, 1972). This study is of limited utility for CLP classification because it uses an inadequate study design, as ecological studies do not look at individual exposures, and the results are confounded by co-exposures with other substances and cannot be used to draw conclusions regarding carcinogenic potential of elemental cobalt alone.

Experimental Animal Studies

There are no oral carcinogenicity studies in the peer-reviewed literature. ECHA (2015; Annex I: 3.6.2.2.3) indicates that, "[i]n the absence of data from conventional long-term bioassays or from assays with neoplasia as the end-point, consistently positive results in several models that address several stages in the multistage process of carcinogenesis should be considered in evaluating the degree of evidence of carcinogenicity in experimental animals." Therefore, additional repeated dose studies that contain additional evidence for key events in carcinogenic processes (e.g., changes in organ weight or hyperplasia and inflammation or other pre-neoplastic lesions in target organ tissues) are described below (Boobis et al., 2009; Luijten et al., 2016).

There are several repeated-dose studies described in the REACH dossier and published toxicological reviews ranging from 3 days to 7 months in duration in rats, mice, guinea pigs, and canines. Most of these studies have been identified in the REACH (2016) dossier as unreliable, due to methodological constraints (e.g., limited methods information, limited test compound identity, or only one dose tested). None of these studies reported

pathological (macroscopic or microscopic) changes in the distal sites identified in the inhalation carcinogenicity bioassays that have been associated with tumor development via inhalation exposure (i.e., adrenal glands, pancreas or renal tubules) (see Section 2.1.1). Only LPT (2013, 2015), sponsored by the Cobalt Reach Consortium Limited, performed guideline studies:

□ Laboratory of Pharmacology and Toxicology (LPT, 2015): LPT performed an OECD Guideline 408 – repeated-dose 90-day oral toxicity study in rodents. In this study, male and female CD rats were exposed to cobalt chloride by oral gavage (0, 3, 10, or 30 mg/kg bw-day) for 90 days. An additional 28-day recovery period was included for selected animals. The only significant treatment-related findings were reduced body weights (males at 10 mg/kg bw-day and males and females at 30 mg/kg bw-day). Some hematological parameters were different than those in controls (i.e., increased hemoglobin content, erythrocyte number, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, activated partial thromboplastin time, and a decrease in platelet number). In addition, altered bone marrow histopathology was noted at doses ≥ 10 mg/kg-day; however all hematological and histological parameters subsided after 4 weeks of recovery. No other organ related changes (macro- or microscopic) were reported, including in the lung, adrenal glands, kidney and pancreas.

□ Laboratory of Pharmacology and Toxicology (LPT, 2013): LPT performed an OECD Guideline 422 – combined repeated-dose toxicity study with the reproduction/developmental toxicity screening test. In this study, male and female CD rats were exposed to cobalt powder by oral gavage (0, 30, 100, 300, or 1000 mg/kg-day) for 28 days (for adult males) or 59 days (for adult females). Effects on adult animals included premature mortality at ≥ 100 mg/kg-day with changes in the gastrointestinal tract following macroscopic inspection. Some instances of adrenal and pulmonary lesions were noted only in the highest dose group (100 mg/kg-day) following macroscopic inspection. However, histopathological inspection did not indicate any changes to any organ (including the lung, kidney, and adrenal glands) related to cobalt treatment, and no correlation was found between the microscopic and macroscopic observations.

The repeated dose information for cobalt compounds does not show a concordance between target organs via the oral route of exposure as compared to the inhalation route of exposure. Adverse histopathological effects in rodents generally occur at elevated doses near or above the maximum tolerated dose (MTD). Further, the organs identified with tumors via inhalation exposures (i.e., lung, adrenal gland, kidney, and pancreas) were unaffected via oral exposures.

The RIVM CLH proposal stated that "it cannot be excluded that exposure via, for example the oral route, may result in carcinogenesis, provided that the internal concentration of cobalt is high enough." However, the lack of histopathological changes (e.g., hyperplasia, cellular hypertrophy) across oral studies does not support this conclusion. Further, Luijten et al. (2016) reviewed alternative approaches for evaluating carcinogenicity from repeated dose studies. The authors noted that the absence of histopathological risk factors in any tissue was highly predictive of a lack of carcinogenic potential in the rat. Thus, the lack of histopathological findings from oral studies does not support the assumption that carcinogenic responses found in inhalation bioassays would be elicited by other exposure routes.

2.3 Dermal Exposure

No human or experimental animal studies investigated the chronic toxicity or carcinogenicity of dermal exposure to cobalt compounds (OECD, 2014; ATSDR, 2004; Danish Environmental Protection Agency, 2013; RIVM, 2001; IOMC, 2006; ECHA, 2016). To date, only dermal irritation and sensitization studies have been reported for cobalt compounds.

2.4 Other Routes of Exposure

There are a number of non-physiological route-of-exposure studies available for cobalt substances (e.g., intramuscular, subcutaneous, intraperitoneal and intratracheal injections or instillations). As noted in the CLP guidance (ECHA, 2015), these routes of exposure are not directly relevant to humans, and studies using these nonstandard routes provide supporting evidence only and should be interpreted with caution. Moreover, the CLP guidance states that locally observed tumors at the site of exposure, "would not normally be considered reliable indications of carcinogenicity as they most likely arose from the abnormally high local concentration of the test substance and would lead to a lower category classification or no classification." Available studies have been reviewed elsewhere and results were generally inconsistent and/or neoplasms were noted only locally at exposure sites (as discussed in NTP, 2016; OECD, 2014; IOMC, 2006; IUCLID, 2000). One intratracheal instillation study reported an increased incidence of alveolar and bronchiolar neoplasms in male rats following exposure to cobalt oxide (Steinhoff and Mohr, 1991), which supports the results found in the rodent lung found in the NTP inhalation bioassays. However, none of these studies described specific neoplasms in the adrenal glands, kidney, or pancreas.

2.5 Genotoxicity Studies

Genotoxicity studies have been reviewed by several international agencies (e.g., OECD, 2014; ATSDR, 2004; Danish Environmental Protection Agency, 2013; RIVM, 2001; IOMC, 2006; NTP, 2013; 2014; Kirkland et al., 2015). OECD (2014) provided the following summary of available genotoxicity studies:

In summary, soluble cobalt salts do not elicit any mutagenic activity either in bacterial or mammalian test systems. However they induce some genotoxic effects in vitro, mainly manifest as DNA strand or chromosome breaks, which are consistent with a reactive oxygen mechanism, as has been proposed by various authors. A weight-of-evidence approach was applied, considering positive as well as negative in vivo clastogenicity studies and the absence of such chromosome damage in humans that are occupationally exposed to inorganic cobalt substances. It was concluded that effective protective processes exist in vivo to prevent genetic toxicity with relevance for humans from the soluble cobalt salts category.

In addition, Kirkland et al. (2015) concluded that cobalt is capable of inducing genotoxicity in vitro, but not in vivo, and theorized that much of the in vitro genotoxicity was likely due to oxidative stress. Consistent with this, many reviews of the available information suggest cobalt exerts its carcinogenicity by nongenotoxic mechanisms (OECD, 2014; RIVM, 2001; Kirkland et al., 2015; NTP, 2016; 2014; Suh et al., 2016). The CLP guidance (2015, p. 378) notes that it is genotoxic carcinogens that are generally suspected to be carcinogenic by any route, so the lack of in vivo genotoxicity and possible nongenotoxic MoAs, further support the hypothesis that cobalt and its compounds are not likely to be carcinogenic by any route. Cobalt's MoA, with particular relevance to the tumors observed via inhalation, is further discussed in Section 4.0.

2.6 Toxicokinetics Studies

The toxicokinetics of cobalt and cobalt compounds is influenced by its chemical form, solubility, dose, particle size, route of exposure, and the nutritional status, sex, and age of the species exposed (NTP, 2016; Danish Environmental Protection Agency, 2013; OECD, 2014; IOMC, 2006; ATSDR, 2004; RIVM, 2001). Cobalt distribution in the body is primarily dependent upon route of exposure. Following occupational exposure, the primary site of cobalt is the lung; with clearance and translocation mechanisms distributing cobalt to other sites, including lymph nodes, liver, spleen, and kidneys, depending on the form of cobalt.

After inhalation exposure, the primary site of cobalt in experimental animals is the lung; with tissue distribution to liver, kidney, trachea, spleen, bones, and heart (ATSDR, 2004). NTP (2014) performed tissue burden studies with cobalt metal in rats and mice and found that after inhalation exposure (for 2 weeks, 3 months, or 2 years), cobalt concentrations were distributed in tissues similarly in both species (in order of decreasing concentration: lung = liver > kidney > femur > heart > serum > blood ~ testes). Generally, toxicokinetic information suggests the rate of translocation of cobalt from the lungs is faster in rodents than man (at least for smaller insoluble particles), suggesting more rapid systemic distribution in rodents. Likewise, soluble cobalt compounds are absorbed faster in the lungs than insoluble compounds, resulting in a longer retention time for insoluble chemicals in the lungs; however, deposition in the lungs depends on particle size and breathing pattern, with smaller particles entering the bloodstream faster than larger particles (NTP, 2016). Soluble cobalt compounds are more also readily absorbed in the GI tract following oral exposure than insoluble compounds (NTP, 2016). Oral exposure studies in animals indicate that cobalt is absorbed and rapidly distributed; however it does not significantly accumulate in any specific organ with age (NTP, 2016). Human oral exposure studies suggest that ingested cobalt absorption is controlled by solubility (20-45% for aqueous forms and 10-25% for solid forms) (NTP, 2016). Systemic distribution results in the greatest concentrations observed in whole blood, cardiac, kidney, and liver tissues (Tvermoe et al., 2015; Unice et al., 2014). Dermal absorption studies are limited, but indicate that cobalt is retained within the skin and absorption is related to the capacity of the skin to transform applied cobalt to soluble cobalt ions (NTP, 2016). Taken together, multiple factors affect the toxicokinetics of cobalt and cobalt compounds. For example, the route of exposure strongly influences the deposition of cobalt and its compounds, as cobalt appears to accumulate primarily at the site of entry. Notable species specific differences include lung translocation rates and elimination half-lives (i.e., slower in man), and these may account for species differences in toxicological responses.

2.7 Summary of Hazard Information

To summarize the available hazard information for all routes of exposure:

- Human evidence: Inadequate for carcinogenicity classification.
- Experimental animal studies: Inhalation exposures to cobalt substances consistently demonstrate progressive cellular damage (e.g., hyperplasia) and adenomas or carcinomas in the alveolar and bronchiolar tissues of rats and mice. These effects are observed across multiple sub-chronic and chronic inhalation studies in both sexes and multiple rodent strains. Conversely, increased tumor incidence in distal sites (adrenals, kidneys, pancreas) following inhalation are generally specific to sex, species, strain, and route. None of the available oral toxicity information demonstrates concordance with target organ sites observed in inhalation bioassays. Further, no significant observations of hyperplasia are consistently observed in oral studies at doses below those causing frank toxic effects.
- Mutagenicity information: Cobalt compounds have been demonstrated to interact with DNA in vitro; but these results have not been reproduced in in vivo. The available evidence suggests that cobalt induces carcinogenicity via nongenotoxic mechanisms that exhibit thresholds. This nongenotoxic MoA (MoA) may partially explain the tumor incidence observed at distal sites during the chronic inhalation bioassays (further discussed in Section 3).

Based on the WoE considerations presented in Sections 3.6.2.3.2 and 3.6.2.3.3 of the CLP guidance (ECHA, 2015), it is evident that carcinogenic responses are related to the portal of entry, and that certain distal site tumors are not relevant for humans (i.e., observations are species, sex, or strain specific). Toxicological responses predictive of carcinogenic activity (at sites other than the lung) are inconsistent between studies and exposure routes. Thus, the WoE does not support classifying all routes of exposure as potentially carcinogenic to humans; rather, the inhalation exposure route specification should be retained (H350i).

3 Relevance of Tumors in Non-respiratory Tissues from Chronic Inhalation Studies

As discussed in Section 2, to evaluate the potential carcinogenicity of cobalt, NTP conducted chronic inhalation studies of cobalt metal in F344/NTac rats and B6C3F1/N mice (NTP, 2014), and cobalt sulfate heptahydrate in F344/N rats and B6C3F1/N mice (NTP, 1998). Both forms of cobalt caused an increased incidence of lung tumors in rats and mice of both sexes, as well as an increased incidence of adrenal pheochromocytomas in rats of both sexes, but not in mice. In addition, the cobalt metal study reported increased incidences of tumors in the pancreas and kidney in male rats and of mononuclear cell leukemia (MCL) in female rats.

There is evidence that the pheochromocytomas are a rat-specific phenomenon in response to inhalation exposure and, thus, are not related to systemic exposure to cobalt. The evidence for the other tumors in non-respiratory tissues in the cobalt metal study is limited (as discussed below), and these tumors are likely not related to systemic exposure of cobalt.

3.1 Pheochromocytomas are Specific to the Inhalation Exposure Route

An increased incidence of adrenal pheochromocytomas was observed in rats in the NTP chronic inhalation studies with cobalt metal and cobalt sulfate heptahydrate (NTP, 1998; 2014), suggesting that systemic exposure to cobalt may induce tumors in the adrenal gland of rats. There is evidence that the pheochromocytomas in the NTP cobalt studies are a secondary response to cobalt-induced lung toxicity, however, and are not directly caused by systemic exposure to cobalt (Gopinath, 1995; Ozaki et al., 2002). For example, Ozaki et al. (2002) evaluated the potential correlation between non-neoplastic chronic pulmonary lesions and pheochromocytoma incidence among nine NTP particulate inhalation bioassays in male F344 rats and reported a significant overall association between the occurrence of pheochromocytoma and the severity of inflammation and fibrosis. Consistent with this, NTP (1998) noted that although the historical control rates of pheochromocytomas in rats are similar among inhalation and oral feed studies, a positive response is more likely to occur in inhalation studies compared to other exposure routes.

Adrenal gland neoplasms can develop from inflammation and fibrosis in the lungs, as these obstructive pulmonary effects can cause a reduction in gas exchange area, leading to systemic hypoxia followed by hyperventilation (NTP, 2014; 2016; Ozaki et al., 2002). Systemic hypoxia leads to chronic stimulation of catecholamine from the adrenal medulla and subsequent chromaffin cell proliferation, medullary hyperplasia, and neoplasia (NTP, 2014; 2016; Ozaki et al., 2002). There were no clinical signs of cyanosis in the cobalt-exposed rats in the NTP studies, but many exhibited abnormal breathing, and there were some observations of increased medullary hyperplasia in rats exposed to cobalt metal (NTP, 1998; 2014).

Although the mechanism for a secondary response to cobalt-induced lung toxicity has not been fully established, hypoxia can induce expression of the hypoxia inducible factor (HIF) transcription factors, and cobalt metal can stabilize HIF-1 by inhibiting degradation of the subunit HIF-1 α (Greim et al., 2009; Keith et al., 2012; NTP, 2014; Suh et al., 2016). HIF expression is elevated in many human cancer cell types and HIFs are involved in regulating genes related to tumor growth and progression (Keith et al., 2012). Thus, hypoxia-induced expression of HIFs, as well as cobalt-induced stabilization of HIF-1, may be driving pheochromocytoma formation in rats exposed to cobalt by inhalation (Suh et al., 2016).

Together, the available evidence strongly indicates that the pheochromocytomas observed in rats in the chronic inhalation studies with cobalt are a secondary response to the chronic

pulmonary inflammation and fibrosis, and not a direct effect of systemic exposure to cobalt. This is supported by the complete lack of hyperplasia, pheochromocytomas, or any histopathological findings in the adrenal gland in a subchronic rat study with oral exposure to cobalt dichloride (LPT, 2015), and indicates that the increased incidences of pheochromocytomas in rats exposed to cobalt via inhalation are specific to the exposure route and not relevant to other exposures. Further, this effect appears to be a rat-specific effect, as similar responses were not observed in male or female mice in either of the carcinogenicity bioassays (NTP, 1998; 2014).

3.2 Other Distal Tumors Do Not Constitute Sufficient Evidence for Carcinogenicity

The CLP guidance for carcinogenicity classification states that there is "sufficient" evidence of carcinogenicity in experimental animals when there is an increased incidence of malignant or combined benign and malignant neoplasms in either two or more species, two or more independent studies in one species, or both sexes of a single species in a well-conducted, Good Laboratory Practices (GLP)-compliant study (ECHA, 2015). Alternatively, a single study in one species and sex may be considered to provide sufficient evidence if malignant neoplasms occurred to an unusual degree with regard to incidence, site, type of tumor, or age at onset, or when there are strong findings of tumors at multiple sites (ECHA, 2015). The guidance states that evidence is "limited" if carcinogenicity is restricted to a single experiment or if the substance increases the incidence of only benign neoplasms or lesions of uncertain neoplastic potential (ECHA, 2015).

In the NTP chronic inhalation study with cobalt metal, there were increased incidences of tumors in the pancreas and kidney in male rats and of MCL in female rats (NTP, 2014). These increased tumor incidences do not meet the CLP criteria for sufficient evidence of carcinogenicity, however, and should be considered limited evidence. In addition, the NTP cobalt metal study suffers from several limitations that complicate the interpretation of the results for these tumors. These limitations are described below, followed by a discussion of the three tumor types with limited evidence of carcinogenicity from the NTP cobalt metal study.

In the chronic inhalation study of cobalt metal, NTP (2014) noted that tumors observed in pancreatic islet cells and the kidney are relatively rare in rats, and the increased incidences of these tumors in the cobalt metal study did not show clear exposure-response relationships. Thus, a comparison to historical control rates for these tumor types was relied on for interpretation of the results. The historical control data used for the cobalt metal study were extremely limited, however, as the F344/NTac rat has only been used in a few NTP studies, and the cobalt metal study is the only inhalation study with these rats in the historical control database (NTP, 2014). Thus, the historical control incidences for other exposure routes were used for comparison, but this consisted of data for only 100 F344/NTac rats (NTP, 2014; 2016). In addition to the limited number of rats in the historical control dataset, the fact that the exposure route differed between the test animals and the historical controls decreases the likelihood of a meaningful comparison, as exposure route and housing conditions (i.e., individual chambers in inhalation studies vs. group housing in oral studies) can greatly affect tumor rates (Haseman et al., 1998). Overall, the historical control data are currently too limited for understanding the incidence of spontaneous neoplasms in F344/NTac rats, and should not be relied upon for comparisons to cobalt-exposed animals.

The cobalt metal study is also limited by the impaired health of the animals at the exposure concentrations used (NTP, 2014). Survival of female rats was significantly decreased in the 2.5 mg/m³ exposure group, as was survival of male mice in the 2.5 and 5 mg/m³ exposure groups. Mean body weights were decreased by more than 10% in male and female rats in the 2.5 and 5 mg/m³ exposure groups during most of the study, suggesting that the MTD

was exceeded. In addition, thinness and abnormal breathing were noted as exposure-related clinical findings in the rats and mice. These findings, along with the sharp increase in tumor rates in the lowest exposure groups, indicate that the study used exposures that were too high, inducing overt toxicity and potentially leading to changes in carcinogenic response, and obscuring exposure-response relationships for precursor lesions (Suh et al., 2016). Thus, the results of this study should be interpreted with caution, and they are likely not relevant to human risk. Below is a discussion of the three tumor types with limited evidence of carcinogenicity from the cobalt metal study, bearing in mind the potential for confounding results at or above the MTD.

The incidences of mononuclear cell leukemia (MCL) were significantly increased in the chronic inflammation study of female rats at all exposure concentrations of cobalt metal, but with no clear exposure-response relationship. Incidences of MCL were not increased in male rats or in mice of either sex in the chronic inhalation study of cobalt metal (NTP, 2014), nor in any animals in the chronic inhalation study of cobalt sulfate heptahydrate (NTP, 1998). MCL is a common spontaneous neoplasm in female F344 rats with little relevance to human health risk (Haseman et al., 1998; Suh et al., 2016; Maronpot et al., 2016), and as noted above, there are considerable limitations with the historical control data for the cobalt metal study. Further, while blood concentrations of cobalt increased with increasing dose at two weeks and three months (NTP, 2014); the MCL incidence was only increased (with a non-dose-dependent trend) in one sex of one species, and only in one chronic inhalation study of cobalt (see Table 2). Thus, the occurrence of this neoplasm was likely a species-, sex-, and strain-specific effect not related to cobalt exposure, and does not meet the CLP guidance for sufficient evidence of carcinogenicity in experimental animals.

In the cobalt metal study, there was a significant increase in the incidences of pancreatic islet cell tumors in male rats (rate of 13-21%), with a positive exposure-response relationship for carcinoma and adenoma combined, but no such relationship for pancreatic adenoma alone and no increase in incidence of carcinoma alone (NTP, 2014). The increased incidences exceeded the historical control rates for pancreatic neoplasms, which were quite low (0-2%) (NTP, 2014). An increased incidence of pancreatic islet cell carcinoma (rate of 6%) was also reported in female rats in the highest cobalt metal exposure group, but this increase was not statistically significant. NTP (2014) deemed this result as equivocal evidence of pancreatic islet cell carcinoma in female rats, although the observed tumor rate did exceed the historical control rate of 1%.

As noted above, however, the historical control data for the F344/NTac rats used in the NTP cobalt metal study are extremely limited and thus, the range of spontaneous incidences of tumors in these rats may actually be greater than currently reported. Others have examined the incidence of spontaneous pancreatic islet tumors in control male rats of a similar strain (F344) in chronic inhalation studies conducted by the NTP (with final pathology evaluations reported as of January 1, 1997) and reported a range of 2-16% for adenomas and 0-8% for carcinomas (Haseman et al., 1998). A more recent study reported an increase in spontaneous pancreatic islet cell adenoma over time in male F344 rats in control groups of carcinogenicity studies conducted at a research facility in Japan, with average incidence rates increasing from 10.5% in 1990-1999 to 20.5% in 2005-2009, and overall ranges increasing from 0-18% to 15-31% over these same time periods (Kuroiwa et al., 2013). Although the bioassays in the Japanese facility were not conducted using inhalation exposure (Ando et al., 2008; Kuroiwa et al., 2013), these studies suggest that the limited historical control data for the NTP cobalt metal study are of questionable utility for comparison to incidences in exposed groups until more data on this specific rat strain are available. Overall, the significantly increased incidences of pancreatic islet cell tumors after chronic inhalation exposure to cobalt were limited to one sex of one species, in one

study with one form of cobalt, and the rarity of these tumors in male F344/NTac rats cannot be established without a more comprehensive set of historical control data. Thus, the results for these tumors do not meet the CLP guidance for sufficient evidence of carcinogenicity in experimental animals.

In the cobalt metal NTP study, the incidences of kidney adenoma and carcinoma combined were increased in male rats at the lowest and highest concentrations of cobalt metal and slightly exceeded historical control rates, but the increases were not statistically significant (NTP, 2014). The NTP (2014) noted that kidney neoplasms are relatively rare, so the observed tumors may have been related to cobalt exposure. However, no exposure-related preneoplastic lesions were observed in the kidneys. An extended histopathological evaluation indicated the number of tumors in the control group (n = 3) was similar to that in the highest exposure group (n = 5) and higher than in the two lower exposure groups (n = 1 per group) (NTP, 2014). As noted above, the limitations of the historical control data do not allow for a comprehensive evaluation of spontaneous tumor incidence in the specific rat strain used in the cobalt metal study. Intracellular levels of cobalt were increased in the kidney after two weeks of exposure (NTP, 2014), however the observed kidney tumors were not significantly increased and were limited to one sex of one species, in one study with one form of cobalt, and it is unclear whether and to what extent the incidences were increased above historical control incidences. Thus, these results for kidney tumors do not meet the CLP guidance for sufficient evidence of carcinogenicity in experimental animals.

Overall, the evidence for carcinogenicity is limited for the hematopoietic, pancreatic, and renal tumors observed in the chronic inhalation study of cobalt metal, due to limitations of the historical controls, potential confounding by high toxicity at the exposure concentrations used, and a lack of clear exposure-response relationships. These tumors were not increased in the chronic inhalation study with cobalt sulfate heptahydrate, and it has recently been suggested that cobalt metal and cobalt sulfate heptahydrate have a similar carcinogenic potency (Suh et al., 2016). Thus, these tumors may not be related to systemic exposure to cobalt.

3.3 Conclusions

The WoE does not indicate that cobalt directly induces tumors in non-respiratory tissues of rats. Rather, the available evidence strongly indicates that the pheochromocytomas observed in rats after chronic inhalation exposure to cobalt metal and cobalt sulfate hexahydrate are a secondary response to the chronic pulmonary inflammation and fibrosis induced by cobalt, and are not a direct effect of systemic exposure to cobalt. Further, the evidence for increased incidences of MCL, pancreatic tumors, and kidney tumors in rats exposed to cobalt metal via inhalation is limited, and these tumors are also likely not related to systemic exposure to cobalt. Thus, the incidence of distal tumors does not constitute sufficient evidence for carcinogenicity.

4 MoA for Cobalt Carcinogenicity

Multiple lines of evidence support a non-mutagenic MoA (MoA) for cobalt carcinogenicity. Various forms of cobalt have been tested for genotoxicity in vitro and in vivo, and the results of these studies indicate that poorly soluble cobalt compounds are not genotoxic, but that soluble cobalt compounds and ultrafine cobalt metal can induce genotoxicity in some in vitro tests, but not in vivo (Kirkland et al., 2015; Suh et al., 2015). The genotoxic effects of soluble cobalt observed in vitro were DNA damage, chromosome aberrations, micronucleus formation, and other clastogenic effects in mammalian cells, with no clear evidence of gene or point mutations in bacterial or mammalian systems (Kirkland et al., 2015; RIVM, 2001). Thus, cobalt does not appear to be mutagenic, even though it can induce DNA damage and clastogenic effects in vitro. This is consistent with most other carcinogenic metal compounds, for which direct interaction of metal ions with DNA is of minor importance for

carcinogenesis (Hartwig, 2013).

Oxidative stress can cause DNA damage, and cobalt has been shown to induce oxidative stress through the generation of reactive oxygen species (ROS), such as hydroxyl radicals (ATSDR, 2004; Beyersmann and Hartwig, 2008; Kirkland et al., 2015). These radicals cause the types of nonmutagenic effects on DNA observed with cobalt exposure, such as DNA strand breakage and chromosome aberrations (Beyersmann and Hartwig, 2008; Klaunig et al., 2011; Kirkland et al., 2015). In the NTP chronic inhalation studies of cobalt metal and cobalt sulfate heptahydrate, mutation analysis of lung tumors from exposed animals showed that G to T transversions in codon 12 of the Kras gene were the most common mutation, and this particular type of mutation is commonly associated with ROS generation (Hong et al., 2015; Behl et al., 2015). DNA damage and chromosome instability from ROS generation can lead to abnormal regulation of cell growth and tumor formation, and ROS can also function as a mitogenic signal (Beyersmann and Hartwig, 2008; Klaunig et al., 2011).

Oxidative stress in the respiratory tract can also induce cytotoxicity and inflammation (Park et al., 2009; Valavanidis et al., 2013). Cobalt exposure induced inflammation, alveolar proteinosis, and alveolar/bronchiolar hyperplasia, adenoma, and carcinoma in the chronic NTP studies (NTP, 1998; 2014), so a plausible MoA for cobalt-induced carcinogenicity is through cytotoxicity and DNA damage from ROS, leading to the continuum of non-neoplastic, pre-neoplastic, and neoplastic lesions observed. Such a MoA would be expected to exhibit a threshold, with protective processes offered by antioxidant enzymes and the high binding capacity of cobalt to serum albumin and other biomolecules at lower exposures (Paustenbach et al., 2013; Kirkland et al., 2015; Hong et al., 2015). Such a protective effect may explain the absence of chromosome damage observed after cobalt exposure in vivo compared to in vitro cellular systems (Kirkland et al., 2015).

As noted above, the increased incidence of pheochromocytomas in rats in the chronic inhalation studies with cobalt is likely a secondary response to cobalt-induced pulmonary toxicity. Similarly, the lung tumors are likely a secondary response to cobalt-induced pulmonary toxicity and ROS generation. As there is no clear evidence to support a direct-acting, mutagenic MoA for cobalt carcinogenicity, it is likely that cobalt acts as a carcinogen in rats and mice through secondary effects generated from its toxicity at the site of exposure, and such effects exhibit a threshold. This is consistent with a lack of systemic carcinogenic effects of cobalt exposure.

5 Conclusions

We performed an independent review of the epidemiological, toxicological, and MoA literature to evaluate whether the scientific evidence supports the carcinogenic classification proposed by RIVM (2016) (Category 1B carcinogen – H350; may cause cancer without specification for an exposure route). This analysis was conducted following the WoE guidelines developed by ECHA (2015) for classifying carcinogens. Based on our review of the available information, we conclude:

- The 2016 RIVM CLH proposal for cobalt is inconsistent with ECHA (2015) guidance for classifying carcinogens, most notably because a thorough WoE analysis was not conducted. Therefore, the carcinogenicity classification presented in the current RIVM CLH proposal lacks adequate support and should be re-evaluated using a WoE process.
- While incidences of certain tumors were significantly increased in a dose-response fashion following inhalation exposure of cobalt compounds, there are key factors to consider before assuming they support a non-specific exposure route carcinogenicity classification:
 - Tumor type and background incidence rates: Certain tumors are specific to rodents, and/or have an elevated spontaneous occurrence rate in rodents, and are thus not

appropriate to extrapolate to humans. The WoE indicates that adrenal pheochromocytomas observed in rats are a secondary response to the chronic pulmonary inflammation and fibrosis induced by cobalt, and are not a direct effect of systemic exposure to cobalt. In addition, the use of the rat strain F344/NTac provides inconclusive evidence due to the relatively limited characterization of historical control tumor incidence.

- Multi-site/Multi-Species/Multi-Sex tumor occurrence: If a substance causes tumors at multiple sites and/or in more than one species, then this provides strong evidence of carcinogenicity. However, if tumors are unique to a species or tissue, then other biological factors may need to be considered. Increased incidences of MCL, pancreatic tumors, and kidney tumors are limited to only one sex or one species (i.e., rats) exposed to cobalt metal via inhalation. No supporting evidence is available for these tumor types in any sub-chronic or chronic experiment using either inhalation or oral exposures. Thus, the distal site tumors following inhalation exposures are not likely reflective of systemic exposures to cobalt.

- Maximal Tolerated Dose: Excessive toxicity (above the MTD, which is characterized by an approximately 10% reduction in body weight gain) can affect carcinogenic responses in bioassays. In some instances, this may result in repeated cellular damage and regenerative hyperplasia, and lead to spontaneous tumor development as a secondary effect, rather than a direct result of the chemical itself. Some significant carcinogenic responses for cobalt metal (NTP, 2014) were apparent only at or above the MTD (adrenal pheochromocytomas and pancreatic islets). Thus, this result is likely confounded by the elevated exposures and may partially explain why these tumor types were identified in only one rodent species and sex.

- Mode of Action: According to the CLP guidance, carcinogens are typically classified as genotoxic (cause direct genetic alterations) or nongenotoxic (affect cellular processes, and do not involve direct DNA alterations). Also, a nongenotoxic MoA (e.g., chronic stimulation of cell proliferation) implies a practical threshold above a certain dose level that may lead to a downgrading of a Category 1 to Category 2 classification (ECHA, 2015). The in vitro and in vivo mutagenicity data support the hypothesis that observed tumor incidence, and specifically systemic tumors (adrenal pheochromocytomas, mononuclear cell lymphoma, adenoma or carcinomas in the pancreatic islets, and kidney adenomas or carcinomas) are induced by a secondary nongenotoxic mechanism (associated with generation of reactive oxygen species).

Overall, there is not sufficient evidence or supporting evidence that indicates that cobalt is carcinogenic by either the oral or dermal routes of exposures. Rather, the results from experimental animal studies show consistent effects that are specific to the inhalation route and, therefore, a carcinogenicity classification specifying inhalation (H350i) most appropriately reflects the available evidence.

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment [Gradient_Co_Comments.pdf](#)

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	H.C. Starck	Company-Downstream user	127
Comment received				
H.C. Starck fully supports and subscribes to the comments submitted to this consultation by ITIA and CoRC.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	Kennametal Inc.	Company-Downstream user	128
Comment received				
Based on available scientific data cobalt metal should be classified as Carcinogenic Category 1B through inhalation only.				
Following the CLP classification guidelines, the hardmetal industry including Kennametal has self-classified powder mixtures of tungsten carbide and cobalt metal as Carcinogenic Category 1B by the inhalation route. This self-classification is based on scientific studies evaluating cobalt's carcinogenicity. The other routes of cobalt exposure (oral and dermal) presented in the CLH proposal are not supported by previous and most-current scientific				

studies.

ITIA's leading hardmetal producers have recently participated in an epidemiological study coordinated by the University of Pittsburgh. The study included more than 30,000 hardmetal workers from five different countries (Austria, Germany, Sweden, United Kingdom, and United States). The sample size for this study is orders of magnitude larger than any previous study, allowing for greater statistical significance. Study results are currently undergoing peer-review and are expected to be available by the end of 2nd Quarter 2017. The study examines the association between carcinogenicity and cobalt exposure for workers in the hardmetal industry. This study's scope and exceptional size make it highly relevant for the current assessment of cobalt's carcinogenicity and we urge the RAC to consider these upcoming results when making determinations on carcinogenicity.

Overall, Kennametal supports the Cobalt Industry Association/Cobalt Reach Consortium (CDI/CoRC) industry position to maintain cobalt metal as a Carcinogenic Category 1B for inhalation only.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02 Kennametal Cobalt CLH Response.pdf

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Sweden	Outokumpu Oyj	Company-Manufacturer	129

Comment received

Outokumpu supports support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal, January 2017. In addition, in view of scientific evidence we stress that the proposed SCL of 0.01% is overly conservative for metallic alloys, instead we ask for a SCL of 1% or higher for alloys.

Despite residual cobalt levels present in the stainless steel and other cobalt containing alloys greatly in excess of the proposed SCL of 0.01%, there is no evidence of systemic cancers in the workplace associated with this exposure as shown by different epidemiological studies. One of these studies was conducted at one of Outokumpu's production sites. The study covered persons that had worked on the production site in Finland between 1967 and 2004 and the conclusion was that overall cancer incidence was not elevated and lung cancer risk was decreased by about 20%

Reference

Huvinen M, Pukkala E. Cancer incidence among Finnish ferrochromium and stainless steel production workers in 1967–2011: a cohort study. *BMJ Open* 2013; 3: e003819. doi: 10.1136/bmjopen-2013-003819.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Belgium	Euroalliages	Industry or trade association	130

Comment received

We support the CDI/CoRC technical response and we refer to it.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	France		MemberState	131

Comment received				
<p>By inhalation, cobalt clearly induces lung tumours in rats from the lowest dose as well as pheochromocytoma from the mid-dose in both sexes and pancreatic islet tumours in male from the mid-dose. These are considered as sufficient evidences of carcinogenicity. In addition, at the highest dose there is limited evidence of induction of kidney tumours in males and of pancreatic islet tumours in females (above HCD for this rare tumour type). As explain in detail by NTP analysis, the lung tumours cannot be related to lung overload. In addition, the tumour profile of cobalt is very similar, although not identical, to the tumour profile of cobalt sulphate with lung tumours in male and females rats and mice and pheochromocytomas in male and female rats. Data on cobalt oxide in rats also show induction of lung tumour but it is limited to the high dose in males and more equivocally in females. It is not known whether tissues other than respiratory tract were examined in this study.</p> <p>It is noted that the characteristic tumour profile of cobalt is not only local carcinogenicity but also includes in particular pheochromocytomas. Although it does not preclude that several MoA may act together in the carcinogenic process, involvement (at least in part) of an hypoxia-like mode of action is probable, which is a systemic specific mode of action (hypoxia-like effect also observed by oral route). This further support that the classification is not restricted to inhalation.</p> <p>Overall, on the basis of experimental data on cobalt, classification Carc 1B is considered to be fully justified. Application of a SCL of 0.01% is also supported on the basis of the calculation mentioned with a T25 below the threshold for high potency. It is also consistent with SCL applied for the other classified cobalt compounds.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	United Kingdom	Outokumpu Stainless ltd	Company-Manufacturer	132

Comment received				
<p>Outokumpu supports the scientific arguments of CDI/CoRC technical comments. However, in view of scientific evidence we stress that the proposed SCL of 0.01% is overly conservative for metallic alloys, instead we ask for a SCL of 1% or higher for alloys. Despite residual cobalt levels present in the stainless steel and other cobalt containing alloys greatly in excess of the proposed SCL of 0.01%, there is no evidence of systemic cancers in the workplace associated with this exposure as shown by different epidemiological studies. One of these studies was conducted at one of Outokumpu's production sites. The study covered persons that had worked on the production site in Finland between 1967 and 2004 and the conclusion was that overall cancer incidence was not elevated and lung cancer risk was decreased by about 20%</p> <p>Reference Huvinen M, Pukkala E. Cancer incidence among Finnish ferrochromium and stainless steel production workers in 1967–2011: a cohort study. <i>BMJ Open</i> 2013; 3: e003819. doi: 10.1136/bmjopen-2013-003819.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	Germany	The Cobalt Development Institute and Cobalt REACH Consortium	Industry or trade association	133

Comment received				
<p>The CDI/CoRC agree with the proposed classification as Carc 1B, however, with limitation to</p>				

the inhalation route.

CDI/CoRC position: classification as Carc 1B (H350i)

Summary

There is sufficient evidence for a classification of cobalt metal (Co) as an inhalation carcinogen Cat 1B, however, the data on the systemic neoplasms are not sufficient to warrant a Cat 1B classification for the oral or dermal route of exposure.

- In contrast to the lung findings, there is no exposure-response between the Co concentration in air and the systemic neoplasms; also there is no dose-response relationship between Co levels in the systemic tissues, where measured, and the neoplastic findings.
- The adrenal pheochromocytoma are a known consequence of hypoxia and respiratory distress.
- Mononuclear cell leukaemia in Fisher rats is known to occur at high and extremely variable rates.
- Both above types of cancer "may not be providing reliable evidence of treatment related carcinogenicity." (Guidance on the Application of the CLP Criteria Version 4.1 – June 2015)
- There are serious issues with the F344 NTac rat colony used in the Co metal study. This is the only inhalation carcinogenicity study ever conducted at the NTP with this rat strain, due to rapidly declining health in this colony. The complete lack of a historical control for the F344NTac rats makes it impossible to evaluate the relevance of the systemic findings. After adjusting for the false positive rates, the kidney and pancreas findings show no clear correlation with Co exposure.
- Historic use of Co as per oral treatment in humans to combat anaemia, addition of bioavailable Co to animal feed, and Co release from failed hip implants all have led to elevated Co levels, yet, there was no positive epidemiology indicating elevated cancer risk in any of those populations.

Specific concentration limit

The CDI/CoRC disagree with the proposed SCL of 0.01%, and suggest the application of the generic concentration limit (GCL) of 0.1%.

CDI/CoRC position: GCL of 0.1%

Summary

The SCL is proposed based on a calculation using the T25 model, which is specific to non-threshold carcinogens with high carcinogenic potency. Co is not a non-threshold genotoxic carcinogen, as its database for mutagenicity is largely negative. Also, the concept of "high carcinogenic potency" cannot be reconciled with the complete absence of neoplasms in highly exposed tissues such as the liver or alimentary system in the NTP study with Co metal. An SCL of 0.01% is not scientifically warranted and has wide-reaching unintended consequences.

DETAILED COMMENTS

Table of contents

- 1) Introduction
- 2) Detailed examination of the criteria for classification in the context of the systemic cancers observed in the Co metal inhalation study
 - Adrenal gland pheochromocytoma
 - Systemic tumours, common: mononuclear cell leukaemia

- Rare systemic tumours in the context of historical control data
 - Systemic tumours, rare: kidney and pancreatic islets
 - Systemic effects, general comments
- 3) Conclusion
 - 4) Comments related to the SCL
 - 5) Errors in table 14
 - 6) References

1) Introduction

The proposal for Carc 1B is appropriate based on the NTP Co metal inhalation study (Behl and Hooth 2014), and the selection of the category matches the industry self-classification, which was implemented in December 2013. The industry self-classification is limited to the inhalation route of exposure, reflecting a number of considerations outlined in this document.

The soluble Co salts carry a harmonised classification as inhalation carcinogens (H350i), based on an inhalation carcinogenicity NTP study with Co sulfate (Bucher 1998). One important difference between the studies was the choice of exposure levels. The doses in the Co metal study produced generalised toxicity and a significant weight reduction that exceeded that MTD (maximum tolerated dose). The weight reduction in the male rats on day 716 was 29% from control weight in the Co metal study, versus 4% in the Co sulfate study. Weight loss of greater than 25% is considered "substantial severity". An appropriate MTD should only produce "moderate severity" of up to 20% in weight reduction (www.lasa.co.uk/pdf/lasa-nc3rsdoselevelselection.pdf). This indicates that an overall moribund state was reached in the Co metal, but not in the Co sulfate study. Consequently, the systemic findings in the Co metal study may be related to the overall very high exposures and moribund state of the animals towards study end. The consistent and cobalt-specific findings in both studies were the lung tumours.

Assuming a common mode of action based on the Co ion, and considering the consistent and exposure-response related findings of lung tumours in both studies (Co sulfate and Co metal), the CDI and CoRC have self-classified Co metal as an inhalation carcinogen, and propose that the harmonised classification should remain limited to the inhalation route.

Only the local cancer findings (lung adenoma and carcinoma) fulfil the criteria for a Category 1B classification, in that the neoplasms were observed in two or more species of animals, and there is a causal relationship between the agent and an increased incidence of malignant neoplasms as confirmed by a direct relationship between exposure, dose to target (lung) and response (lung neoplasms). Furthermore, only the lung neoplasms were consistent between Co sulfate and Co metal.

By contrast, the systemic findings were not consistently observed in both inhalation studies. The systemic findings were only observed in one sex of one species (rat), and need to be compared against the criteria below, whereby a classification as a Category 1B Carcinogen is warranted if tumours occur to "an unusual degree":

- A single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites.

In the view of CDI/CoRC, it has been concluded incorrectly that the systemic neoplastic findings were related to Co or occur to an "unusual degree" as described in the Guidance. The data on the systemic neoplasms is, in the view of CDI/CoRC, not sufficient to warrant a

Category 1B classification for oral or dermal route of exposure, as is summarised below.

The Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 lists some examples of findings where “the tumour incidence in the treated group may be significantly above the concurrent control but could still be within the historical incidence range for that tumour type in that species and therefore may not be providing reliable evidence of treatment related carcinogenicity.

Some examples of animal tissues with a high spontaneous tumour incidence are:

- Adrenal pheochromocytoma in male F344 rats (NTP, 2007a), Sprague-Dawley rats (NTP, 2005; RIVM, 2001; Ozaki et al., 2002);
- Mononuclear cell leukaemia in F344 rats (NTP, 2007a; RIVM, 2005)”

These are important considerations for the relevance of a neoplastic finding for classification. Before reviewing the individual systemic neoplasms, the importance of a comparison with the historical control needs to be discussed.

Rare systemic tumours in the context of historical control data

Historical control data are needed to decide whether a tumour is “rare” (background rate of < 1%) or “common” (background rate > 1%), and is needed to interpret the significance especially of rare tumours and of marginally increased tumour incidences. In the NTP Co metal inhalation study, the tumours in kidney and pancreas can probably be considered “rare”, however, in this context, it needs to be outlined that there are no historical control data for the F344 NTac strain (the F344N colony at Taconic laboratories) and inhalation exposure route (in that strain) at NTP. In total, only two carcinogenicity studies were carried out at NTP with the F344 NTac rats, one by inhalation (the Co metal study) and one by p.o. route of exposure (TR 583, Bromodichloroacetic Acid, drinking water study). The “historical control” used by the NTP in the Co metal report consisted of only 100 animals, which actually includes the concurrent control (50 animals), with the addition of another 50 animals of study TR 583, exposed by a different route of exposure. This is not what would constitute a “historical control”. For comparison, a typical historical control database would consist of around 50 studies by the same route of exposure, and several thousand animals (Deschl, Kittel et al. 2002). The lack of a historical control and its influence on the interpretation of the study outcome is discussed in more detail in an appendix to this commenting section (Carc appendix).

The rat colony F344NTac used in the Co metal inhalation study

Only one inhalation carcinogenicity study was conducted at the NTP with the F344NTac rat. It is important to realise that the F344NTac rats had developed a number of problems specific to this colony, including “declining fertility, sporadic seizure activity, and chylothorax” (King-Herbert and Thayer 2006) (chylothorax is the disruption of the flow of lymph into the thoracic duct, resulting in pleural effusion and nutritional deterioration due to major loss of electrolytes, proteins, lipids and vitamins, often accompanied by immune deficiency).

A specialty group set-up by the NTP (“rat breakout group”) notes that these issues “have occurred within the past 5 years in the NTP F344/N rat colony.” (King-Herbert and Thayer 2006). The NTP Co metal inhalation study range finders were finalised in 2005, meaning that the study design for the chronic study, including selection of rat strain and colony were already decided and underway by the time this report was issued. The report continues that “These issues are unique to our F344/N colony maintained at Taconic Farms, Inc. and to the best of our knowledge do not appear in other colonies maintained for commercial purposes at Taconic or other suppliers. The reasons for the development of these conditions in this specific colony have not been identified” (King-Herbert and Thayer 2006). This led to the strong recommendation of the expert group to discontinue the use of this rat strain and colony (King-Herbert and Thayer 2006), which was implemented by the NTP immediately.

2) Detailed examination of the criteria for classification in the context of the systemic cancers observed in the Co metal inhalation study

Adrenal gland pheochromocytoma

There were exposure-concentration dependent increases in the incidences of benign and malignant pheochromocytoma (combined) in all substance-exposed male and female rats. This effect was not observed in mice.

In a statistical re-evaluation of nine 2-year NTP inhalation studies, a range of lung effects (chronic active inflammation, interstitial fibrosis, alveolar epithelial hyperplasia, squamous metaplasia, proteinosis, and histiocytosis) and their association with pheochromocytoma was investigated. It was concluded that there is an overall association between lung impairment by any cause and an elevated incidence of adrenal pheochromocytoma in NTP inhalation studies (Ozaki, Haseman et al. 2002, Greim, Hartwig et al. 2009). The elevated incidences of pheochromocytoma in rats after inhalation exposure to Co metal are considered to be rat specific responses to respiratory distress, with no causal relationship to Co. Also, there is no indication for an involvement of genotoxic mechanisms in the induction of pheochromocytoma by chemicals in animals (Ozaki, Haseman et al. 2002, Greim, Hartwig et al. 2009).

Further, reviews of publicly available Co toxicokinetic studies (mainly from oral exposure) by the CDI as well as by Finley et al, 2012, do not indicate that the adrenal gland is a target organ of Co. Co levels in that tissue were not examined in the current NTP Study.

Supporting evidence is available from a 90-day repeated dose toxicity study via the oral route in rats with cobalt dichloride (Hansen 2015) (this study is available in the REACH dossier for all Co compounds). Male and female rats were exposed for 90 days p.o. to "0 mg CoCl₂-hexahydrate/kg bw/day", that is to background levels of Co in the standard rat diet, and to "30 mg CoCl₂-hexahydrate/kg bw/day", that is to an additional dose of a soluble Co compound on top of baseline levels in the diet. Since Co is an essential trace element, it is actually added in form of a bioavailable Co salt to standard rat diet at 2.1 mg Co/kg diet, and as Vit B12 at 100 µg/kg diet (Standard Diet for Rats and Mice ssniff® R/M-H V1530-1534). Experiments cannot be conducted with a control group that has no exposure to Co, as this would create deficiency symptoms in the animals, and no longer constitute a healthy control group.

The conclusion that Co does not target the adrenal medulla is corroborated by the complete absence of adverse effects towards the adrenal medulla (benign and malignant pheochromocytoma, hyperplasia) observed in the above 90-day oral repeated dose toxicity study. These data support the conclusion that the findings of pheochromocytoma are not related directly to cobalt, but are a result of hypoxic conditions in the lung.

Systemic tumours

Systemic availability of Co by inhalation exposure was studied by the NTP in the 2 week range finding study. Co levels in all measured tissues increased with a direct dose-response with the increasing exposure level, allowing the conclusion that exposure concentrations correlate directly with the dose of Co in the tissues of interest also in the 2 year inhalation bioassay.

In the case of the lung carcinoma/adenoma, a dose-response relationship between Co exposure, Co levels in lung and the occurrence of lung adenoma/carcinoma is evident, giving support to a causal relationship between Co levels and cancer in this tissue.

However, the linear rise of Co exposure levels is not matched by a rise in any of remote tumour findings (kidney, mononuclear cell leukaemia, pancreas). Based on this lack of

dose-response, there is insufficient evidence to conclude on a Co-related mode of action of cancer in those tissues. Further, the 2-week range finding experiment revealed that the highest increase in Co tissue levels was observed in the liver, in both male and female rats and mice, in some cases exceeding the concentrations observed in the lung. It is relevant to note the complete absence of liver tumours, despite the high local Co concentrations, in the NTP 2 year cancer study.

The animals (mice and rats) were exposed for 2 years to Co metal particles in whole body inhalation chambers. During this study, there was presumably significant exposure to the skin; however, skin tumours did not occur at an elevated degree. Further, significant exposure to the alimentary tract had presumably occurred, by transport of Co metal particles via the mucociliary escalator and subsequent swallowing, as well as by grooming. There is, however, no report of tumours in the alimentary system.

The absence of cancer in the systemic tissue with the highest Co levels (liver), together with the lack of dose-response between Co levels and cancer incidence in the tissues with distal-site cancers, show that there is no evidence for a causal relationship between Co exposure and the occurrence of tumours.

Systemic tumours, common: Mononuclear cell leukaemia (MNCL)

While there was an increase in MNCL at all exposure levels in female rats, the increase was not exposure level-related (incidence was highest at the lowest exposure level). In addition, there was no significant increase of MNCL in male rats.

As stated in the CLP guidance, MNCL occurs with a high spontaneous rate, and occurred at 42% and 36% in the controls, males and females, respectively. The incidence of MNCL is high across all exposure groups in the male rats, including controls (42%, 50%, 44%, 44% in control, 1.25, 2.5 and 5 mg Co/m³ exposure groups, respectively); it is also high in all female rats with 36%, 62%, 61%, 59% in control, 1.25, 2.5 and 5 mg Co/m³ exposure groups, respectively. The female control animals display an in fact somewhat low incidence of MNCL. These data reflect the general observation that MNCL is a common tumour type, and that Fisher rats are generally prone to developing MNCL as they age (Suckow, Weisbroth et al. 2006). Extremely elevated incidences of MNCL have been previously observed in a number of chronic bioassays and 2-year carcinogenicity studies in F344 rats (Haseman, Hailey et al. 1998, Caldwell 1999). The analysis of the spontaneous neoplasm incidences in F344 rats from chamber controls of 18 two-year inhalation studies carried out by the NTP revealed a frequent occurrence of MNCL in males (57.5%, range 34-70%) and in females (37.3%, range 24-54%) (Haseman, Hailey et al. 1998). The data show that MNCL occurs in untreated aged rats at extremely high and variable rates. The conclusion that MNCL is a Co related tumour based on the data in female rats cannot be substantiated when taking into account the data from both sexes, and when taking into account the high and variable occurrence of this common tumour.

MNCL is uncommon in most other rat strains, and its background incidence in the Fisher rat has increased significantly over time (Caldwell 1999). MNCL has not been found in other mammalian species and no histologically comparable tumour is found in humans. In the light of the well-known occurrence of MNCL in the Fisher rat, this result does not meet the criteria for a classification as a human health hazard Cat 1B.

Kidney, adenoma/carcinoma combined – There was a minimal increase in the incidence of these tumours in male rats, although not statistically significant. Because of this slight increase an extended review using “step-sections” was conducted. Using these extended data there is no evidence of a carcinogenic response in male rats, which is supported by the lack of an increase in tubular hyperplastic changes or in kidney tumours in female rats or in male and female mice.

The neoplasms in the kidney were slightly above the concurrent control data, but not

statistically significant and no overall positive trend was established. In the light of these arguments, these findings do not appear to warrant a classification as a Cat 1B carcinogen for human health hazard assessment.

Pancreatic islets –There was a small increase in islet-cell tumours in the mid- and high-dose male rats but not in female rats (a small but not statistically non-significant increase was seen in the highest dose group). Mice did not display this effect.

These tumours are rare and they were seen for the first time in an NTP study. Also, the F344 NTac rat was used for the first, and only, time in an NTP inhalation study. It is impossible to interpret these findings, and the statement in the NTP report that there was “equivocal evidence of carcinogenic activity” is considered justified. This level of evidence should not be taken as a basis for a human health hazard classification as a Cat 1B carcinogen.

In summary, the systemic neoplasms include:

- two findings which “may not be providing reliable evidence of treatment related carcinogenicity” (MNCL and adrenal pheochromocytoma), according to the CLP guidance
- kidney neoplasms in male rats which were not statistically significant when compared to concurrent control, showed no dose-response and were rated by the NTP as “equivocal evidence of carcinogenic activity”
- a rare pancreas tumour which was observed for the first time in NTP studies, and which cannot be statistically evaluated due to the lack of a historical control.

In the interpretation of the systemic neoplastic findings, several further aspects cast doubt on the relevance of these observations:

- There is a lack of an exposure-response relationship
- There is a complete lack of a historical control database for this rat colony (F344NTac)
- This rat colony is uniquely sensitive and had developed a number of spontaneous diseases that immediately (after one inhalation study) led to the discontinuation of the use of this colony at NTP
- The systemic neoplasms, except for the adrenal pheochromocytoma, have not been observed in another rat colony of the same strain (F344 from Simonsen Laboratory (Gilroy, CA))

Finally, it needs to be considered that cobalt, as soluble salts, has a historic use (in the 1950s through mid-1970s) as a long-term treatment for anaemia in children (Jaimet and Thode 1955), kidney patients (Duckham and Lee 1976) and pregnant women (Holly 1955). Some patients (Duckham and Lee 1976) underwent several 12-week treatment courses of 0.18 mg Co/kg bw/day. The use of cobalt as an anaemia treatment was eventually discontinued because of its interference with iodine metabolism. None of the human studies reports concerns related to neoplastic findings.

There are case studies of cobalt supplementation in women with menopausal symptoms (fatigue, hot flashes, insomnia, anxiety). Cobalt was prescribed “because of its safety in quantities ordinarily found in dietary surveys” (Wright 2005) at doses up to 1.12 mg Co/day as a long term treatment to alleviate the symptoms, without any reports of carcinogenic concerns related to this exposure.

Co soluble salts are added to animal feed (ruminants, rabbit and horses) at a levels of 0.3 mg Co/kg complete feed (EFSA 2012), without any concern for a carcinogenic hazard from this exposure.

The NTP evaluated the database of patients exposed systemically to Co from hip implants made from alloys containing Co. Despite several cases of significantly high and long term exposure, there was no conclusive finding indicating that Co is carcinogenic by this route of exposure (ORoC 2016).

Workers have been exposed to Co metal in the workplace for many decades, yet the

epidemiological data are still unclear regarding a cancer risk from cobalt for humans. Workplace exposure occurs predominantly by inhalation, but dermal and per oral exposure may also occur. The ORoC recently (2016) reviewed the epidemiological database related to Co exposure in humans, and thoroughly examined the evidence of 9 studies which met the quality criteria for inclusion in the cancer evaluation. These studies are occupational cohort or nested case-control studies conducted in five independent populations, including a cohort of female Danish porcelain painters (Tuchsen, Jensen et al. 1996); a cohort of French electrochemical workers (Mur, Moulin et al. 1987, Moulin, Wild et al. 1993); French cohorts of hard-metal workers (Moulin, Wild et al. 1998, Wild, Perdrix et al. 2000); stainless and alloyed steel workers (Moulin, Clavel et al. 2000); and Norwegian nickel refinery workers (Grimsrud, Berge et al. 2002, Grimsrud, Berge et al. 2003, Grimsrud, Berge et al. 2005). The number of exposed subjects combining all studies is over 20,000, however, after scrutinising this database, the ORoC concluded that there was inadequate evidence for Co exposure being related to lung cancer. Only a few studies included non-lung neoplastic endpoints, and these were again rated as inadequate to conclude that Co exposure caused any non-lung neoplasms. The fact that no clear evidence was produced by 9 epidemiological studies of sufficient quality for a cancer evaluation (ORoC, 2016) cannot be reconciled with the present proposal that Co metal is a highly potent carcinogen (with a need for an SCL) by all routes of exposure.

Taken together, the observations in humans (workers and patients) and livestock strongly suggest that there is no carcinogenic potential of cobalt by the oral or dermal route, and that cobalt is not a high potency carcinogen by all routes of exposure.

The CDI/CoRC are aware that two epidemiological studies in the Co industry have been completed and are close to publication. These are highly relevant data, and provide a cohort even larger than the above epidemiological studies combined. It is requested that these data should be taken into account when discussing this CLH proposal.

3) Conclusion

Due to the lack of a correlation between Co exposure levels and systemic neoplastic findings, there is no conceivable Co-related mode of action for the distal-site neoplasms. The lack of a historical control database prevents a conclusion on the biological as well as statistical significance of these findings. It is also impossible to assess whether there was an "unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites", since the usual degree of spontaneous tumours in F344/NTac rats is not known.

There is insufficient evidence to conclude that the systemic neoplasms are caused by or related to Co. None of the systemic findings fulfil the classification criteria for Carc 1B, therefore a classification of Co metal as Carc 1B for "all routes of exposure" is not warranted.

The CDI/CoRC propose to classify Co metal as inhalation-only carcinogen (H350i), since only the lung findings of the NTP study fulfil the criteria for classification as Cat 1B.

4) Specific concentration limit (SCL)

The CDI/CoRC disagree with the proposed SCL of 0.01%, and suggest the application of the generic concentration limit (GCL) of 0.1%.

The proposal for an SCL is based on the precedence case of the Co soluble salts, and a calculation using the "T25" method. This method is based on a publication by Sanner, Dybing et al. (2001), and applies specifically to non-threshold carcinogens. The use of a non-threshold model for Co is not supported by any data, and is incorrect in the view of the CDI/CoRC.

By applying the T25 model, the authors of the present CLH proposal inherently assume that

Co metal acts as a non-threshold carcinogen. This is not supported by the cobalt genotoxicity database: a direct acting, non-threshold genotoxic carcinogen would not give rise to a largely negative database for mutagenicity, as is the case for Co metal. Further, a non-threshold assumption cannot be reconciled with the absence of any neoplasms in highly exposed tissues such as the liver or alimentary system in the NTP study with Co metal. Finally, Co is added to standard rat diet in the ionic form, as a soluble Co salt, as well as in the form of Vit B12 (at much lower levels). This reflects the normal human dietary intake of between 40 and 80 µg Co (in an inorganic form) per day, together with a recommended daily intake of 2.4 µg vitamin B12 (containing approx. 4% Co). Optimal intake in cattle is recommended as 200 µg Co/kg dry matter diet (Stangl, Schwarz et al. 2000a, Stangl, Schwarz et al. 2000b).

It is impossible to reconcile these dietary intakes with the assumption of a direct-acting, non-threshold, genotoxic carcinogen. Even more illogical is the predication that Co in any form is a direct-acting, non-threshold, genotoxic carcinogen by all routes of exposure.

All evidence indicates that Co is an inhalation carcinogen with a non-genotoxic, thresholded mode of action.

This is, however, not only a scientific issue. The enforcement of an SCL at 0.01% for Co, in combination with the predication that Co is a genotoxic carcinogen (Carc 1B) by all routes of exposure would lead to a carcinogenicity classification (all routes) for about 99% of stainless steels, a large proportion of brasses, and some metals which contain Co as an impurity (such as nickel), due to these metals' co-occurrence in ores. This would have a major negative impact on metal recycling and the circular economy, amongst other consequences.

The impact on the non-cobalt metal sector, and other industry sectors (e.g. rechargeable batteries, catalysts, etc.) is so large, that additional work is currently being undertaken to better understand the consequences.

5) Errors in table 14

Table 14:

Table 14 of the CLH proposal would benefit from an inclusion of the respective animal strain used in each test.

On page 35, third row, the finding of "decreased sperm motility" needs to be removed from the ≥ 0.625 mg/m³ "list of findings", as "decreased sperm motility" was reported in the NTP report (TR 581, NTP 2014) from ≥ 1.25 mg/m³.

On page 37: NTP, 1991 16-day rat study a NOEC of 25 mg/m³ is mentioned, but this concentration was not tested and the NOEC should be 5 mg/m³.

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachmts Co metal PC.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Repr appendix, CONFIDENTIAL.pdf

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	France	FEPA	Industry or trade association	134
Comment received				
The CDI and CoRC, as the main holders of scientific data on cobalt, have prepared thorough				

scientific comments on this point. FEPA is supporting these comments.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEPA_Answer to the public consultation cobalt metal_1.pdf

Date	Country	Organisation	Type of Organisation	Comment number
19.02.2017	Australia		Individual	135
Comment received				
Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	France	MFPM : Manufacture Française des pneumatiques Michelin	Company-Downstream user	136
Comment received				
<ul style="list-style-type: none"> • Michelin supports the position of the Consortium of Cobalt and CDI. • The Cobalt metal is a pulmonary carcinogen as demonstrated by the NTP's toxicological study with the substance • The unique route of exposure for which the Cobalt metal is carcinogenic is the inhalation route ; among observed effects in in vivo toxicological studies, only lung tumor is relevant for human. • The mechanism of carcinogenicity is based on a treshold mechanism with the release of Co²⁺ ions in situ which involve an oxidative stress. • The methodology used par the Netherlands for the calculation of the LCS (Concentration limit specific) is the methology called T25 ; this one is not dedicated to carcinogenics with threshold mechanism. 				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Germany	TIGRA GmbH	Company-Manufacturer	137
Comment received				
We support the technical position of the Cobalt REACH Consortium Ltd. (CoRC) and the Cobalt Development Institute (CDI).				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Spain	UNESID. Spanish Steel Association	Industry or trade association	138
Comment received				
Source of exposition is almost limited to inhalation in a relevant amount. The existing information shows that other sources of exposition are negligible.				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	139
Comment received				

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam		Individual	140

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Papua New Guinea		Individual	141

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	142

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	143

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	144

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	145

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	India		Individual	146

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	147

Comment received

Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam	Masan Resources	Company-Downstream user	148

Comment received

The Netherlands' final CLH proposal for cobalt metal, is considered to be very stringent, and could consequently pose problems for other metal substances (especially, tungsten) and mixtures that may contain cobalt. Therefore it is important to highlight the potential scope of these CLH implications to you as part of the EU Commission / ECHA / Member States during this public consultation. As an end user I oppose the changes based on cobalt's mechanisms of action which do not support the proposed hazard classifications. Shortly the ITIA will be releasing comments that will mention the soon to be published peer review publications on the hardmetal epidemiological study (conducted by University of Pittsburgh during 2006 to 2016 covering data of more than 30,000 hardmetal workers) looking into the association between cobalt exposure and cancer in the hardmetal industry. The cobalt industry (CDI and CoRC), based on scientific research, have previously decided the following self-classifications for cobalt metal:

- Carc 1B H350i (carcinogenic by inhalation only) for all physical forms (ie powder and massive) at a GCL of 0,1%

Date	Country	Organisation	Type of Organisation	Comment number
16.02.2017	United Kingdom	ICoNiChem Widnes Ltd	Company-Downstream user	149

Comment received

- With respect to carcinogenicity classification we believe that there insufficient quality data to show that the systemic neoplasms seen in F344/NTac rats are as a result of exposure to cobalt. Based on the results of the NTP study we propose a classification of Carc 1B, H350 by inhalation would be appropriate.

- The introduction of a SCL of 0.01% for cobalt would have far reaching consequences. Many alloys contain cobalt as an impurity.

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Canada	Sherritt International Corporation	Company-Manufacturer	150

Comment received

Sherritt International Corporation (Sherritt) strongly supports the Cobalt Development Institute/Cobalt Reach Consortium (CDI/CoRC) technical comments on the overly precautionary Dutch proposal that cobalt metal be classified as Carcinogenic Category 1B via all routes of exposure, and disagrees with the position that a Specific Concentration Limit of 0.01% is justified. Sherritt supports the industry self-classification as Carcinogenic Category 1B via inhalation, which has been in place since December 2013.

A Sherritt mortality study showed statistically significantly lower observed than expected deaths resulting from exposure to nickel containing 0.07% or greater (annual average) cobalt for a cohort of workers employed at the Fort Saskatchewan refinery during the period 1954 to 1978, with a minimum follow-up period of 25 years (i.e. to 2003). Contributing to the decreased overall mortality were significant deficits in deaths due to neoplasms and respiratory disease. Lower observed death rates were also found for respiratory malignancies and cancer of the lung and bronchus. A more detailed summary of the results of the epidemiology studies, and references to the more recent publications, is provided below. On the basis of published scientific reports in the cobalt REACH dossiers, as well as in the public domain, Sherritt believes the proposed SCL of 0.01% is overly precautionary and the potential unintended socioeconomic impacts on the cobalt industry and other concerned industry sectors would be extremely detrimental. Sherritt supports the CDI/CoRC technical arguments against the use of the T25 methodology to calculate the potency of cobalt (non-threshold approach); Sherritt supports the OECD CoCAM (Cooperative Chemicals Assessment Programme) conclusion from the October 2014 meeting that the cobalt soluble salts (highly bioavailable cobalt analogues) are not genotoxic in vivo due to the existence of effective protective processes in vivo that prevent genetic toxicity with relevance for humans from the soluble salts category (Ref <http://webnet.oecd.org/HPV/UI/handler.axd?id=b789fd1c-bab3-433c-9f47-3cbd49042976>). The T25 method is only relevant for non-threshold carcinogens.

Sherritt conducted a mortality study on all workers employed for a minimum of 12 continuous months between January 1954 and December 1978 at the Sherritt Fort Saskatchewan nickel and cobalt refinery. A number of publications reported on this cohort over various follow-up periods (eg. Egedahl R, Carpenter M, and Lundell D. 2001. Mortality experience among employees at a hydrometallurgical nickel refinery and fertiliser complex in Fort Saskatchewan, Alberta (1954--95). *Occup. Environ. Med.* 58(11):711-715 (Reference 1, attached)).

The cohort was eventually followed until 2003, a minimum follow-up period of 25 years. A historical prospective approach was used to compare the mortality rates from various causes of death of cohort members with those of the Canadian general population. Statistics Canada matched the Sherritt employee records to the Canadian historic summary tax file for the years 1984 to 2003 to confirm vital status. Standardized mortality ratios (SMR) were calculated for various causes of death. For all causes, there were 118 observed and 174 expected deaths with an SMR of 68 and 95% Confidence Interval (CI) of 56 to 81. This was a statistically significant lower observed than expected number of deaths in the nickel exposed group. Contributing to the decreased overall mortality were significant deficits in deaths due to neoplasms (SMR 59, 95% CI 40 to 84) and respiratory disease (SMR 26, 95% CI 5 to 75). Lower observed death rates were also found for respiratory malignancies and cancer of the lung and bronchus. No cause of death was significantly increased.

The most recent results of this investigation were published in the proceedings of a Canadian Institute of Mining, Metallurgy and Petroleum Conference (Egedahl RD and Collins MJ. 2009. Vital Status of Sherritt Nickel Refinery Workers (1954-- 2003), *Hydrometallurgy of Nickel and Cobalt*. Budac J, Fraser R, Mihaylov I, Papangelakis V and Robinson D. Eds.,

COM, Montreal, Canada. p. 689–699) (Reference 2, attached).

The focus of the various studies at the time of their publication was exposure to nickel. The cobalt impurity content of the nickel was not reported in the publications. However, Sherritt records indicate that the average cobalt content of the nickel production was about 0.07% for most of the years in question (i.e 1954 to 1978), and was somewhat higher when the refinery first started production and again late in the study period when the Sherritt mine was depleted and the feed mix to the refinery changed. The Sherritt mortality study provides an additional piece of evidence that a 0.01% SCL for Co is overly precautionary, and is relevant to a weight of evidence evaluation of the carcinogenic potency of cobalt. The Sherritt data also corroborate the position that cobalt is not a high potency carcinogen by all routes of exposure, and that its carcinogenic mode of action must have a threshold.

Industrial hygiene monitoring programs began at the Sherritt hydrometallurgical refinery in 1977. Details of the observed nickel exposure levels are reported in the referenced publications, which are also attached to this submission (References 1 and 2). As indicated above, the airborne nickel would typically have contained 0.07% cobalt or higher.

Sherritt is aware of two additional cobalt epidemiological studies currently being undertaken and close to publication. These are highly relevant data that should be taken into account when discussing this CLH proposal.

Sherritt participated in the preparation of the CDI submission to the OECD (CoCAM) and fully supports the OECD conclusion that the Co soluble salts (highly bioavailable cobalt analogues) are not genotoxic in vivo due to the existence of effective protective processes in vivo that prevent genetic toxicity with relevance for humans from the soluble salts category. The studies used to justify the Mutagenic 2 classification proposed by the Dutch authorities had low reliability scores and the conclusion was based on studies of questionable relevance. Sherritt supports the CDI/CoRC technical arguments against the use of the T25 methodology to calculate the potency of cobalt (non-threshold approach), as the T25 methodology is only relevant for non-threshold carcinogens and the CDI/CoRC and OECD CoCAM have concluded that the cobalt ion acts via a threshold mechanism.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment References 1 and 2 Sherritt Epidemiology Reports.7z

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Germany	<confidential>	Company-Manufacturer	151
Comment received				
The now focused limits of the CLH-Proposal are based on animal experimentations which generally can't be directly transformed on human beings. Furthermore the critical point of the metal powder inhalation study (NTP, 2014) is that a much higher dose was used than in the Co sulphate study.				

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Belgium	European Powder Metallurgy Association	Industry or trade association	152
Comment received				
Manufacturers of metal products who use the powder form of metal alloys will be greatly affected by the proposed very low SCL of 0.01% for cobalt. In the manufacture of cobalt-				

based alloys, achieving a concentration of cobalt below 0.01% will be challenging and expensive. Furthermore, the sales of cobalt based alloys will likely reduce significantly due to customer perception. Many manufacturers of metal powder products also produce steels and stainless steels which contain cobalt as an impurity above the proposed SCL of 0.01%. Changes of manufacturing processes, such as increased PPE will also cause considerable cost in producing these alloys. The proposed classification would indeed affect the business during the use of Co containing products in particulate form (e.g. powders, chips) in terms of dust prevention measures like e.g. housing of dust intensive processes, - extraction systems considering CMR requirements in terms of air return, - change of hall concepts in order to prevent contamination of neighbouring working areas, - permanent use of RPE – if inevitable and other PPE. Work place measurements need to be intensified in order to monitor Co dust exposure for the different processes over time with the aim to check and prove compliance with the minimizing principle for CMRs.

Many powder manufacturers also use stainless steel powders that are practically inert. These powders contain around 0.02% cobalt however, and therefore will be classified as Carc 1B should the CLH proposal (for all exposure routes) be implemented. Recycling of cobalt containing products will also undoubtedly be impacted by the CLH. Materials to be recycled that have an SCL of above 0.01% will now be classed as dangerous waste resulting in higher costs for their recycling.

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	United States		Individual	153
Comment received				
<p>I, Gary Marsh, as principal investigator of a large, ongoing, international epidemiology study of hardmetal workers exposed to tungsten carbide with cobalt binder, I believe that the ECHA should be aware of the objectives and design of our study and its anticipated publication dates. The following is a brief overview of the background and features of our study.</p> <p>In 2006, IARC labeled WC with a cobalt binder (WCCo) as a probable human carcinogen based on limited evidence in humans and sufficient evidence in animals that WCCo acted as a lung carcinogen. Metallic Co, with or without WCCo, remains a research priority for IARC for clarifying its potential carcinogenicity in humans (Ward et al. 2010, http://ehp.niehs.nih.gov/0901828/). In 2008, the American Conference of Governmental Industrial Hygienists (ACGIH) classified Co as A3 (confirmed animal carcinogen with unknown relevance to humans), but did not classify WCCo. A review of the scientific basis for the IARC decision revealed significant limitations in the primary occupational epidemiologic studies of French and Swedish workers on which it was based (Hogstedt and Alexandersson 1990, Lasfargues, et al. 1995, Moulin, et al. 1998, Wild, et al. 2000). To address these limitations, the International Tungsten Industry Association (ITIA) initiated an international, occupational epidemiologic investigation of hardmetal workers in 2011. Earlier, the Pennsylvania Department of Health supported preliminary data collection efforts. The study was designed to overcome the methodological limitations of earlier studies by including a comprehensive, quantitative exposure assessment conducted by the University of Illinois at Chicago (UIC), country-specific cohort mortality studies in the US, Austria, Germany, Sweden and UK using both external and internal comparisons, direct (nested case-control study) or indirect statistical methods to adjust lung cancer risk estimates for potential confounding by smoking, and a pooled analysis of the international cohort data. The University of Pittsburgh serves as the coordinating center for the overall international study and is directing the pooled analysis.</p> <p>The study includes 33,393 workers from 3 companies and 17 manufacturing sites (8 U.S., 3 German, 3 Swedish, 2 UK, and 1 Austrian), each independently conducted under the</p>				

direction of country-specific occupational epidemiology experts (Austria-Hanns Moshhammer; Germany: Peter Morfeld and Mei Yong; Sweden: Hakan Westberg and Magnus Svartengren; UK: Damien McElvenny; US: Gary Marsh and Nurtan Esmen). The international study is larger, more robust and more definitive than any hardmetal epidemiology study done to date.

The primary research objectives of the international study are:

1. To investigate the total and cause-specific mortality experience of current and former hardmetal workers potentially exposed to W, Co and/or Ni at multiple US and European (EU) industrial sites that produced WCCo, as compared with the experience of the corresponding national and local populations, with adjustment for potential confounding factors and with emphasis on lung cancer.
2. To characterize the past and current working environment of the study members from the sites relative to process, job title/function and potential for W, Co and/or Ni exposure.
3. To determine the relationship between level and duration of W, Co and/or Ni exposure and mortality from lung cancer with analytic adjustment to the extent possible for potential co-exposures, including tobacco-smoking habits, via direct internal adjustment with a nested case-control study or indirect adjustment using statistical methods.
4. To provide a framework for ongoing mortality surveillance of hardmetal workers.

Scientific articles describing the epidemiological results of the country specific studies, the exposure assessment and results of the pooled cohort data analysis will appear in 2017 as a series of online articles in the Journal of Occupational and Environmental Medicine.

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	Germany	<confidential>	Company-Manufacturer	154
Comment received				
we are concerned about the robustness of actual available results. Studies should be carried out at an relevant industrial concentration level.				

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	Germany		MemberState	155
Comment received				
The German CA agrees to the proposed classification of Cobalt.				

Date	Country	Organisation	Type of Organisation	Comment number
10.02.2017	France	Shepherd Mirecourt S.A.S.	Company-Manufacturer	156
Comment received				
Back in 2013, toxicologists and members of the Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC) self-classified Cobalt metal (all physical forms) as Carc. 1B (H350i), inhalation route only based on the results of a 2-year Co metal powder inhalation study (NTP, 2014).				
The RIVM argumentation for classification as carcinogen by all routes of exposure is based on the lack of additional studies (by oral route for example) and on the fact that systemic tumors are observed in this 2-year Co metal powder inhalation study. We support the technical position of CDI/CoRC toxicologists who question the correlation of the systemic tumors with the levels of Co in the target tissues. On top of that, it appears that systemic tumors only appear in one species and sex. In addition, the type of rats used in the 2-year Co metal powder inhalation study lacks of historical control.				
RIVM also proposes a Specific Concentration Limit (SCL) of 0.01% for this endpoint using				

the T25 methodology. This method is not relevant for threshold carcinogens. The non-threshold approach appears not to be the appropriate one based on recent studies commissioned by CDI and CoRC to strengthen its database and to demonstrate that the carcinogenic mode of action of Cobalt is not via genotoxicity. A SCL of 0.01% will drive classification of all mixtures containing Cobalt at levels $\geq 0.01\%$, all of these mixtures being classified as Carc. 1B by all routes of exposure. It is obvious that at least the alloys' industry will be severely impacted.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	SSAB AB	Company-Downstream user	157

Comment received

Regarding Carcinogenicity

SSAB supports the current industry self-classification as Carc 1B via inhalation route only. SSAB supports the technical and scientific challenge on the proposed NE harmonized classification of Carc 1B, H350 all routes, SCL 0.01% provided by CDI/CoRC.

Cobalt is present in iron ore and carbon steel as an impurity

In the production of steel in Sweden and Finland, SSAB use iron ore as the main source for iron. The iron ore used at SSAB may contain up to 0.1% cobalt probably as oxides. Of course the form in which the cobalt occur in the iron ore needs to be determined, if possible. SSAB will participate in investigating the form of cobalt in the iron ore pellets. Nevertheless the cobalt within the iron ore is added to the blast furnace and follows the iron to the steelworks where it also follows in the steel smelt. We believe most iron ore contain similar amount of cobalt, as it stay in the iron when melted. SSAB intend to participate in the examination of the amounts of cobalt in different iron ores. If most iron ores contain up to 0.1% cobalt, then all carbon steel needs to be classified as Carc 1B; H350 all routes, SCL 0.01% if this proposal become mandatory in CLP.

SSAB also depends on scrap as a source of iron. Probably all scrap known today contains cobalt above 0.1 %. If the proposed classification comes true, all scrap will be classified as dangerous and all carbon steel containing trace element of Co will be classified as Carc 1B, H350 all routes, SCL 0.01%.

Steel is a special type of mixture

All studies referred to in the classification proposal are to very clean cobalt powder or other similarly clean cobalt salts or other clean cobalt compounds. Then these different substances are administered orally, dermally and by inhalation and also by injection route. These substances referred to in the studies are not the least comparable to for example solid steels containing cobalt as an alloying element. The actual form of cobalt tested on the laboratory animals make a big different. Also the route of exposure is critical and depends on how the human body is functioning. For example the vitamin B12 is essential to the human body and is based on cobalt. The scientific evidence for the proposed classification must be understood as weak.

The CLP mixture calculations comply for steels, although they are recognized as special mixtures, as alloys. As you know iron have been used by humans since the iron ages and mined and converted to steels since the middle age. If this production and use have proved to be a major health issue, the world would have known this by now. Therefore the

proposed classification must be regarded not based on the broad scientific ground as it must be, with regard to the consequences.

The handling of steel will be difficult. All steels will be regarded dangerous by both industry and society, because how would you see the difference of steel with 1% cobalt or 0.01% cobalt?

ECHA note – An attachment was submitted with the comment above. Refer to public attachment SSAB STATEMENT DOCUMENT on Cobalt Feb 2017.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	ASD Europe	Industry or trade association	158

Comment received

Having considered the material presented by the Cobalt Development Institute (CDI), ASD notes that this data provides a significant contribution to the Netherlands study on Cobalt classification. We understand that there seems to be a disagreement on potential for carcinogenicity of the substance depending on the various forms of Cobalt (inhalable vs. massive in particular). As an industry which has significant dependence on Cobalt alloys, we note that misclassification could result in application of impractical and unnecessary risk management measures which could have substantial effects on our industry. Consequently we urge that ECHA and member states closely analyse the CDI presented data.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Freeport Cobalt Oy	Company-Manufacturer	159

Comment received

The company support the CDI/CoRC technical comments provided to this consultation. Freeport Cobalt Oy has collected relevant employment and Cobalt exposure data starting from the beginning of Cobalt production in 1968. The information has been given to an study group and the aim is to do an epidemiologic study based on the provided data.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	ACEA	Industry or trade association	160

Comment received

Our comments are attached as below.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170224-Cobalt-CLP_ACEA-final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	EPBA - European Portable Battery Association	Industry or trade association	161

Comment received

See attachment

ECHA note – An attachment was submitted with the comment above. Refer to public

attachment EPBA comments paper_cobalt_24022017.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	CERATIZIT Group	Company-Downstream user	162

Comment received

Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as Carcinogenic Category 1B by the inhalation route based on information about cobalt's carcinogenicity. The other routes of cobalt exposure (oral and dermal) presented in the CLH proposal are not supported by previous and most-current epidemiological studies on hardmetal workers. CERATIZIT Group has participated in an epidemiological study coordinated by the University of Pittsburgh. The study included more than 30,000 hardmetal workers from five different countries (Austria, Germany, Sweden, United Kingdom, and United States). The study is larger than the previous studies together giving it significant statistical power. Study publications are undergoing peer-review and are expected to be available by the end of 2nd Quarter 2017.

The study examines the association between carcinogenicity and cobalt exposure in the hardmetal industry. Because of the scope and the exceptional size of the study it is highly relevant to be included in the RAC assessment of cobalt's carcinogenicity. Based on available scientific data we support the classification of cobalt metal as Carcinogenic Category 1B through inhalation only. CERATIZIT Group supports the technical position of the ITIA and CDI/CoRC (2017), (See Attached)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	France	Alliance des Minerais, Minéraux et Métaux (A3M)	Industry or trade association	163

Comment received

We invite RAC to carefully review the comments issued by CDI and CoRC, notably the conclusions for a classification as carcinogenic 1B via the inhalation route only.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24_A3M_Co consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Agoria	Industry or trade association	164

Comment received

Agoria is supporting the scientific comments of Cobalt Development Institute on the classification proposal. Our members, ranging from producers to users of cobalt, have supported and contributed to the development of the scientific comments prepared by the Cobalt Development Institute. Our comments are more related on the downstream impact of this classification.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170224 PVAN Proposal of classification of Cobalt.pdf

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam		Individual	165
Comment received				
No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam	Masan Resources	Company-Downstream user	166
Comment received				
The cobalt industry (CDI and CoRC), based on scientific research, have previously decided the following self-classifications for cobalt metal:				
<ul style="list-style-type: none"> • Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification 				

Date	Country	Organisation	Type of Organisation	Comment number
16.02.2017	United Kingdom	ICoNiChem Widnes Ltd	Company-Downstream user	167
Comment received				
<ul style="list-style-type: none"> • Mutagenicity should not be classified based on the conclusions by OECD that soluble, highly bioavailable, cobalt salts are non-genotoxic in vivo. 				

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Canada	Sherritt International Corporation	Company-Manufacturer	168
Comment received				
<p>Sherritt International Corporation (Sherritt) strongly supports the Cobalt Development Institute/Cobalt Reach Consortium technical comments. Sherritt participated in the preparation of the CDI submission to the OECD Cooperative Chemicals Assessment Programme (CoCAM) and fully supports the OECD conclusion that the Co soluble salts (highly bioavailable cobalt analogues) are not genotoxic in vivo. The studies used to justify the proposed Mutagenic 2 classification had low reliability scores and the conclusion was based on studies of questionable relevance. Sherritt supports the CDI/CoRC counter-proposal that there should be no classification for mutagenicity.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment References 1 and 2 Sherritt Epidemiology Reports.7z</p>				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	SSAB AB	Company-Downstream user	169

Comment received
<p>Regarding Mutagenicity</p> <p>SSAB supports the technical and scientific challenge on the proposed NE harmonized classification Muta 2, H341, provided by CDI/CoRC.</p> <p>The proposed Muta 2, H341 classification will have an indirect effect leading to extremely low OELs (Occupational Exposure Limits) and restrictive handling through low DMELs , for the whole steel industry and all downstream users of steel.</p> <p>Cobalt is present in iron ore and carbon steel as an impurity</p> <p>In the production of steel in Sweden and Finland, SSAB use iron ore as the main source for iron. The iron ore used at SSAB may contain up to 0.1% cobalt probably as oxides. Of course the form in which the cobalt occur in the iron ore needs to be determined, if possible. SSAB will participate in investigating the form of cobalt in the iron ore pellets. Nevertheless the cobalt within the iron ore is added to the blast furnace and follows the iron to the steelworks where it also follows in the steel smelt. We believe most iron ore contain similar amount of cobalt, as it stay in the iron when melted. SSAB intend to participate in the examination of the amounts of cobalt in different iron ores.</p> <p>SSAB also depends on scrap as a source of iron. Probably all scrap known today contains cobalt above 0.1 %. If the proposed classification comes true, all scrap will be classified as dangerous.</p> <p>Steel is a special type of mixture</p> <p>All studies referred to in the classification proposal are to very clean cobalt powder or other similarly clean cobalt salts or other clean cobalt compounds. Then these different substances are administered orally, dermally and by inhalation and also by injection route. These substances referred to in the studies are not the least comparable to for example solid steels containing cobalt as an alloying element. The actual form of cobalt tested on the laboratory animals make a big different. Also the route of exposure is critical and depends on how the human body is functioning. For example the vitamin B12 is essential to the human body and is based on cobalt. The scientific evidence for the proposed classification must be understood as weak.</p> <p>The CLP mixture calculations comply for steels, although they are recognized as special mixtures, as alloys. As you know iron have been used by humans since the iron ages and mined and converted to steels since the middle age. If this production and use have proved to be a major health issue, the world would have known this by now. Therefore the proposed classification must be regarded not based on the broad scientific ground as it must be, with regard to the consequences.</p> <p>The handling of steel will be difficult. All steels will be regarded dangerous by both industry and society, because how would you see the difference of steel with 1% cobalt or 0.01% cobalt?</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment SSAB STATEMENT DOCUMENT on Cobalt Feb 2017.pdf</p>

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Freeport Cobalt Oy	Company-Manufacturer	170
Comment received				
The company support the CDI/CoRC technical comments provided to this consultation.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	ACEA	Industry or trade association	171
Comment received				
Our comments are attached as below.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170224-Cobalt-CLP_ACEA-final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
10.02.2017	France	Shepherd Mirecourt S.A.S.	Company-Manufacturer	172
Comment received				
Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC) toxicologists and members do not recommend the classification as Muta. Cat. 2 based on very recent negative in vitro and in vivo guideline-compliant studies carried out on Co metal. It appears that RIVM did not take into account the results of these studies and based its argumentation on an old positive in vitro HPRT non-guideline-compliant study.				
The recent conclusion of OECD CoCAM has also to be taken into account. The conclusion of this scientists' group is that Cobalt soluble salts are non-genotoxic in vivo.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	CERATIZIT Group	Company-Downstream user	173
Comment received				
Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as non-mutagenic based on cobalt's absence of chromosome damage in robust GLP studies in vivo, suggesting that effective protective processes are sufficient to prevent oxidative DNA damage in mammals. Overall, there is no evidence of genetic toxicity with relevance for humans caused by cobalt substances and cobalt metal based on an expert peer review (Kirkland et al, 2015) which has been accepted by OECD Cooperative Chemicals Assessment Meeting (CoCAM).				
CERATIZIT Group supports the technical position of the ITIA and CDI/CoRC (2017), (See Attached)				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	France	Alliance des	Industry or trade	174

		Minerais, Minéraux et Métaux (A3M)	association	
Comment received				
We invite RAC to carefully review the comments issued by CDI and CoRC, notably the robust evidence for no classification as Muta.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24_A3M_Co consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Norilsk Nickel Harjavalta Oy	Company-Manufacturer	175
Comment received				
Norilsk Nickel Harjavalta Oy is a member of Cobalt REACH Consortia (CoRC). Norilsk Nickel Harjavalta Oy supports Cobalt REACH Consortia General and Technical comments on Mutagenicity.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	United Kingdom	Covance Laboratories Ltd	Industry or trade association	176
Comment received				
The following comment relates to section 4.9 Germ cell mutagenicity (Mutagenicity), Table 49 (page 81), of the current CLH proposal for cobalt (Co) metal.				
<p>In Table 49, the following test result is reported: "Mammalian cell gene mutation test (hprt locus; Cobalt metal Powder; 30 µg/mL; -S9: negative; +S9: positive (OECD 476; Kirkland 2015)". This test result is cited on page 93 as one of several positive mutagenicity in vitro studies with cobalt itself (... , Hprt mutation assay, ...). This study was carried out at Covance and Covance would like to submit the following comment related to this study. The below comment is also reflected in the publication of this study (Kirkland et al, 2015):</p> <p>In the study on the Cobalt Metal Powder extract (8259038), the test article was incubated with RPMI 1640 culture medium containing 5% v/v horse serum and antibiotics (RPMI 5) for 72 hours at 37°C, followed by filtration to remove the particulate matter. The "extract" was then added to the test system. In the previous study (8232389), Cobalt Metal Powder was formulated in 0.5% w/v methyl cellulose (MC), which was considered acceptable for treatment, but 0.5% MC is a suspending agent (not a solvent/vehicle) therefore the function was to hold the test article in suspension rather than to solubilise it. Solubility trials had indicated that Cobalt Metal Powder was insoluble in all vehicles typically used in our laboratory, which would typically include water, DMSO, DMF, acetone, ethanol and THF, together with an attempt to solubilise the test article directly in RPMI 5.</p> <p>When Cobalt Metal Powder was suspended in 0.5% MC and added to the test system in study 8232389, precipitate and/or undissolved test material was observed by eye at the end of the treatment incubation period in all (or in the large majority of) concentrations tested in the absence and presence of S-9 but all cultures were retained during the 7 day expression period prior to plating out. At the end of the expression period, cultures were selected for plating for viability and mutation based on relative survival, compared to the concurrent vehicle control. There are several things to consider:</p> <p>a. This does not preclude the presence of microprecipitate, which is not readily visible by eye, at any concentration where no apparent post-treatment precipitate was recorded.</p>				

b. The undissolved or precipitated test article may have caused physical damage to the cells resulting in physiological stress.

c. The OECD test guideline indicates that where a test article precipitates at the end of treatment, the highest concentration analysed for mutation should be the lowest at which precipitate is observed at the end of the treatment incubation period but in this study, several concentrations were analysed where post-treatment precipitate was observed. As the mouse lymphoma cells grow in suspension, the test article is removed by centrifugation but as the test article co-precipitates with the cell pellet, there is no guarantee that the test article will be fully removed. As a result the 3 hour test article treatment may have persisted to some extent for some or all of the 7 day expression period, particularly at higher concentrations where there was an increased amount of undissolved test material. Describing this as a 3 hour treatment may therefore be considered inaccurate.

d. The persistence and amount of undissolved and/or precipitated test material raises questions as to the effective concentrations tested.

There was also variable toxicity, particularly in the presence of S-9, between Experiment 1 and Experiments 2 and 3 in study 8232389.

Due to the problems encountered with the testing and the interpretation of the results from study 8232389, the possibility of testing a Cobalt Metal Powder extract was put forward. The rationale for the pre-incubation used in study 8259038 was that in an oxidation reaction, cobalt metal would liberate divalent cobalt cations which would be expected to be the bioavailable cobalt species. Since residual particulate matter might interfere with the cells in culture, a pre-incubation method was used to ensure that a maximum of metal/substance concentration was achieved without interference of particulate matter. Furthermore, after the incubation for 72 hours at 37°C followed by filtration to remove the particulate matter, Tyndall analysis (measuring LASER light scattering) was performed on the formulation sample for 60 minutes at 5 minute intervals in the Range Finder Experiment to ensure the level of any residual particulate matter was at an acceptable level, indicating that the formulation sample was suitable for testing. As the results of the Range-Finder indicated that no undissolved solid was evident in the sample vial at the end of testing and the turbidity reading in the formulation sample was very similar to that for the blank control sample, no further Tyndall analysis was performed in the Mutation Experiments.

The mutation data for the Cobalt Metal Powder extract indicated a negative result in the absence and presence of S-9 over the course of two experiments in study 8259038. Importantly, appropriate levels of test article toxicity (giving 10-20% relative survival) were observed in the absence and presence of S-9 in both experiments and there was a good agreement between both 3 hour experiments performed in the presence of S-9. As the test article had a cobalt content of 99.98%, this indicates that soluble Cobalt cations were liberated from the pure Cobalt sample during the 72 hour incubation in culture medium and the bioavailability of these cations (with no interference from precipitated and/or undissolved test material) should carry greater weight of evidence regarding the mutagenic potential of Cobalt Metal Powder by comparison with the data observed from study 8232389.

It may also be noted that two further Cobalt compounds tested in our laboratory, Cobalt Sulfate (soluble in water: 8232390) and Cobalt Borate Neodeconoate (soluble in THF: 8232392), were not mutagenic in the same test system when tested up to the limit of cytotoxicity.

Date	Country	Organisation	Type of Organisation	Comment number
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24.02.2017	Sweden	Nilar AB	Company-Importer	177
Comment received				
We support the CDI/CoRC technical position.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	RIO TINTO	Company-Manufacturer	178
Comment received				
Our company supports the technical comments made by CDI (Cobalt development institute				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	United Kingdom	UK Steel	Industry or trade association	179
Comment received				
For the classification of Reprotoxic category 1BUK Steel are also in agreement with the CDI, and support the case against these classifications.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment FINAL - UK Steel CLH Cobalt metal response 24 02 17.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Tikomet Oy	Company-Manufacturer	180
Comment received				
The hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as non-mutagenic based on cobalt's absence of chromosome damage in robust GLP studies in vivo. Tikomet Oy supports the technical position of the cobalt industry.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tikomet Oy Response - Co CLH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Finnish Steel and Metal Producers	Industry or trade association	181
Comment received				
Massive metal alloys behave differently than its separate alloying elements (substances in the alloys). And the alloying process in massive metal alloys strongly eliminates the release and exposure to any single alloying element. That's why hazardous classification of single alloying elements of massive metal form should not be used as such for basis of hazardous classification of massive metal alloys. When cobalt is present in the massive metal alloy, the hazardous classification should be based on the measured release and exposure not the concentration of the alloying element cobalt.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment MJ kannanotto_cobalt.docx				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Teknikföretagen	Industry or trade	182

			association	
Comment received				
We support the current industry self-classification as non-mutagenic.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Spain	Spanish Association of Frits, Glazes and Inorganic Pigments	Industry or trade association	183
Comment received				
-				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Letter of support Co- Public Consultation.docx				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	AB Sandvik Materials Technology	Company-Manufacturer	184
Comment received				
AB Sandvik Materials Technology fully supports the comments given by Jernkontoret (Sweden), EUROFER and Team Stainless.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	Wirtschaftsvereinigung Metalle (WVMetalle)	Industry or trade association	185
Comment received				
Wirtschaftsvereinigung Metalle (WVMetalle), the German Non-Ferrous Metals Association, fully supports the technical position of the Cobalt REACH Consortium (CoRC) resp. Cobalt Development Institute (CDI).				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24 WVMetalle commenting on Co CLH proposal.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Wirtschaftskammer Österreich	Please select organisation type..	186
Comment received				
see PDF attached				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_170_StN CLH Cobalt.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	BASF SE	Company-Manufacturer	187
Comment received				
We disagree with the addition of Muta. 2, H341 to the harmonised classification. The				

proposal from the rapporteur for a classification of Muta. 2, H341 is based on in vitro studies showing some weak positive effects without a dose dependency or in the presence of test substance precipitation, and further studies which have low Klimisch ratings. This is problematic, because in order to make this assumption, the rapporteur has ignored or disregarded the extensive work the consortium has done to investigate the mutagenic potential of the test substance according to current OECD guideline studies.

The negative in vitro Ames and HPRT guideline-compliant studies conducted by the consortium without particle precipitation are disregarded, as is an in vivo micronucleus test in mouse normochromatic erythrocytes conducted with the 90-day inhalation study on cobalt metal, which was also negative.

Our concern is that if guideline compliant Klimisch 1 studies are ignored in favour of unreliable non-guideline studies, it reduces trust in the reliability of these classifications.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Sandvik Mining and Rock Technology	Company-Downstream user	188

Comment received

The current self-classification of cobalt metal does not include mutagenicity. That classification is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

IMPACTS of the Muta 2 proposal:

A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Mining and Rock Technology response 20170224].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference x Sandvik Mining and Rock Technology response 20170221 V0 4-CH comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Mining and Steel Association	Please select organisation type..	189

Comment received

Wir unterstützen die wissenschaftlich fundierte Argumentation des Cobalt Development Institutes und des Cobalt REACH Consortium, wonach bei richtiger Anwendung des Beweiskraftansatzes (weight of evidence approach) lösliche Kobaltsalze in vivo nicht genotoxisch sind, und verweisen im übrigen auf die Eingabe dieser Institutionen.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Non Ferrous Metals Association	Industry or trade association	190

Comment received

Wir unterstützen die wissenschaftlich fundierte Argumentation des Cobalt Development Institutes und des Cobalt REACH Consortium, wonach bei richtiger Anwendung des Beweiskraftansatzes (weight of evidence approach) lösliche Kobaltsalze in vivo nicht genotoxisch sind, und verweisen im übrigen auf die Eingabe dieser Institutionen.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Albemarle Europe SPRL	Industry or trade association	191

Comment received

We recognize that there are a huge number of publications and studies on this endpoint that need to be evaluated. However, the CLH report while stating that “the most relevant studies” have been selected, fails to explain how the relevance was determined. The summary of the studies presented also lacks an assessment of reliability, validity, quality and repeatability. In particular crucial information on cytotoxic concentrations and or precipitation in the in vitro studies is missing. The registration dossier and the review article of Kirkland, 2015 contains a lot of this information, but this is only sporadically included in the discussion in the CLH report. Furthermore an important investigation of possible germ cell mutagenicity that was included in the recent 90-day study for cobalt chloride was not considered. This study is included in the respective REACH dossier and summarized in the submission of CDI. We are confident that if a proper weight of evidence analysis of these data that include a big number of studies not considered in the previous classification of soluble Cobalt salts, is performed, one can conclude that Co metal and Co²⁺ ions should not be classified for mutagenicity.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium		MemberState	192

Comment received

BECA agrees that there is an undeniable mutagenic potential of cobalt compounds as seen in in vitro studies in rodents and human (mammalian cell gene mutation test, comet assay) where DNA damages were induced by cobalt metal and related compounds. However, there is a clear lack of consistency and reproducibility between studies. A few cobalt salts are already classified as Cat. 2 this increase the concern and should be taken into account. For these reasons, BECA supports the DS proposal to classify as Muta. 2; H341 because there is strong presumptions of a mutagenic potential.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	FEDIL - The voice of	Industry or trade	193

		Luxembourg's industry	association	
Comment received				
FEDIL entirely supports the technical position of the Cobalt Development Institute (CDI) and the Cobalt Reach Consortium (CoRC).				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170223_ECHA_PC_General_Comments_CLP.docx				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Jernkontoret	Industry or trade association	194

Comment received				
<p>Jernkontoret supports the technical comments from CDI/CoRC, The EUROFER Position Paper on the Harmonized Classification and Labelling Proposal for Cobalt Metal and Team Stainless Position Paper for the Public Submission on the Harmonized Classification of Cobalt Metal. Handling of materials containing cobalt would need to change if cobalt metal had a harmonized classification as Carc 1B (all routes of exposure) or Repro 1B. Carcinogen directive (2004/37/EC) and its implementation in Sweden (AFS 2014:43) require that if the CMR substance cannot be eliminated or handled in a closed system, all exposure should be avoided. Avoiding skin contact with all stainless steel and more than 50 % of carbon steel and other alloyed steels as well as hardmetal would be impossible and a modern society without those materials would not work. The current Cobalt REACH Consortium self-classification of cobalt as Carc 1B through inhalation does not cause those problems, because only exposure via inhalation has to be avoided. Exposure via air is traditionally regulated with OELs and working methods have been designed/optimised to minimise dust exposure.</p> <p>The proposed Muta 2 classification has an indirect effect leading to extremely low OELs (Occupational Exposure Limits) and restrictive handling through low DMELs.</p> <p>Jernkontoret recommends Sweden not to support the proposed classification as long as the scientific support is missing. Jernkontoret also recommends Sweden to carefully consider the scientific background of the proposal and the probable future effects of the proposal. Because the current proposal can have serious consequences for the Swedish industry manufacturing and using several materials containing cobalt for example steel, we think it is extremely important that there is solid data to support the proposed classification.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	EUROBAT	Industry or trade association	195

Comment received				
<p>1. Co metal is mainly used as an intermediate for the manufacturing of other cobalt compounds used as active materials for electrodes manufacturing</p> <p>2. However, Co metal is present as an impurity above the proposed SCL of 0.01% in several metals (nickel, stainless steel, alloys) widely used in the battery manufacturing:</p> <ol style="list-style-type: none"> This impurity is not economically removable Technical feasibility has to be considered <p>3. RECHARGE and EUROBAT support the CDI/CoRC technical comments</p>				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment RECHARGE-EUROBAT input to CLH Cobalt metal consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Cobalt REACH Consortium/Cobalt Development Institute	Industry or trade association	196

Comment received

Please note that the CDI/CoRC have made a separate submission of detailed technical comments on this end-point of the CLH proposal.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Zip of CoRC-CDI Joint Response Comments (3 Documents).zip

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	AB Sandvik Coromant	Company-Downstream user	197

Comment received

The current self-classification of cobalt metal does not include mutagenicity. That classification is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

IMPACTS of the Muta 2 proposal:
 A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires totally new, currently not known techniques.
 B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.
 Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Coromant response 20170223].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Sandvik Coromant response 20170223.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Wirtschaftsvereinigung Stahl e.V. / Stahlinstitut VDEh e.V.	Industry or trade association	198

Comment received

steel in a massive form is not bioavailable, please regards general comments

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Deutsche Edelstahlwerke Specialty Steel GmbH & Co. KG	Company-Manufacturer	199
Comment received				
Cobalt is bound in a matrix. Therefore it is not bioavailable und primarily for human beings unproblematic. In the case of thermal or mechanical processing, work safety measures must be taken anyway, irrespective of cobalt. Please regard general comments.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany		Individual	200
Comment received				
we are in support of the technical position of the CDI-CoRC				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 160608 Original Eng.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Austria	Boehlerit GmbH & co.KG	Company-Manufacturer	201
Comment received				
Again differing sources out of OECD test results have been neglected. Dosage which proves lethal is in itself no confirmation for mutagenicity.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Belgium	The Beryllium Science and Technology Association	Industry or trade association	202
Comment received				
Please see position paper.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Beryllium Science and Technology Association - Cobalt CLH Consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Belgium	EUROFER	Industry or trade association	203
Comment received				
EUROFER supports the scientific arguments against the proposed mutagenic category 2 classification (H341) for cobalt metal as detailed by the Cobalt Industry and supported by Team Stainless.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final EUROFER Carbon Steel Cobalt Input to CLH PC 22.02.17.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Norway	Glencore Nikkelverk AS	Company-Manufacturer	204
Comment received				
Glencore Nikkelverk AS has been appraised of, and supports, the Scientific arguments provided by the Cobalt REACH consortia and the Cobalt Development Institute for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Seco Tools AB	Company-Downstream user	205
Comment received				
<p>The current self-classification of cobalt metal does not include mutagenicity. That classification is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>IMPACTS of the Muta 2 proposal:</p> <p>A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.</p> <p>B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.</p> <p>Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Seco Tools response 20170221].</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Seco Tools response 20170221.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Pramet Tools, s.r.o.	Company-Downstream user	206
Comment received				
<p>The current self-classification of cobalt metal does not include mutagenicity. That classification is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>IMPACTS of the Muta 2 proposal:</p> <p>A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.</p>				

B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Dormer Pramet response 20170221].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 DormerPramet response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Fachverband Pulvermetallurgie e.V. (FPM) / Federation of Powder Metallurgy in Germany (FMP)	Industry or trade association	207

Comment received

The Fachverband Pulvermetallurgie e.V. (Federation of Powder Metallurgy in Germany, FMP) fully supports the technical position of the „Cobalt REACH Consortium Ltd. –CoRC” / „Cobalt Development Institute – CDI”.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Vale Base Metals	Company-Manufacturer	208

Comment received

Vale Base Metals is a member of the Cobalt Development Institute/Cobalt REACH Consortium and Nickel Institute and supports the technical input of these organisations to this public consultation.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of frits (Frit Consortium)	Industry or trade association	209

Comment received

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support FRIT.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of Inorganic Pigments (Inorganic Pigments Consortium)	Industry or trade association	210

Comment received

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support IP.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Walter AG	Company-Downstream user	211

Comment received

The current self-classification of cobalt metal does not include mutagenicity. That classification is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

IMPACTS of the Muta 2 proposal:

A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Walter AG response CLH-Prop_CO_20170222].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Walter AG response CLH-Prop_CO_20170222.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Wolfram Bergbau und Hütten AG	Company-Downstream user	212

Comment received

The current self-classification of cobalt metal does not include mutagenicity. That classification is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

IMPACTS of the Muta 2 proposal:

A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 WBH response 20170221].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 WBH response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	United Kingdom	International Tungsten Industry Association	Industry or trade association	213

Comment received

Proposed Classification from Non-Mutagenic to Mutagenic Category 2

Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as non-mutagenic based on cobalt's absence of chromosome damage in robust GLP studies in vivo, suggesting that effective protective processes are sufficient to prevent oxidative DNA damage in mammals. Overall, there is no evidence of genetic toxicity with relevance for humans caused by cobalt substances and cobalt metal based on an expert peer review (Kirkland et al, 2015) which has been accepted by OECD Cooperative Chemicals Assessment Meeting (CoCAM).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	EBRC	Please select organisation type..	214

Comment received

Lack of evidence of a primary genotoxic mechanism of action for cobalt and soluble cobalt substances

The summary and discussion of the in vitro and in vivo genetic toxicity data rarely provides references to the underlying studies. Without proper referencing, it is difficult to follow the author's discussion and conclusion of the individual studies, e.g. the summary of the in vitro data contains 3 citations (Anard, 1997; NTP, 2014; Kirkland 2015), although 60 in vitro references were cited in Table 49 above.

Section 4.9.1.1, Page 84-85, Germ cell mutagenicity-in vitro data:

The summary does not rate the studies according to their (i) intrinsic reliability and (ii) adequacy for classification purposes, but merely scores the studies according to the assumed result: "4 out of 5 studies were positive", "5 out of 7 assays positive". Such an approach does not adequately evaluate the quality and reliability of the evidence from all sources, as foreseen in the regulation and the guidance (see also comment on lack of quality assessment given in the "General comments").

No differentiation is made between test systems assessing heritable alteration of the DNA (such as in vitro gene mutation in the hprt locus) and systems investigating the induction of unspecific and transient DNA damage, such as comet assays and alkaline sucrose gradient. According to regulation (EC) 1272/2008, Annex I: 3.5.2.3.3 it is stated that "Classification for heritable effects in human germ cells is made on the basis of well conducted, sufficiently validated tests, preferably as described in Regulation (EC) No 440/2008 adopted in

accordance with Article 13(3) of Regulation (EC) No 1907/2006 ('Test Method Regulation') such as those listed in the following paragraphs.". In vitro DNA damage tests are neither validated nor were these tests conducted in accordance with an accepted guideline. The information gained from such systems should therefore be evaluated with great care and regarded to contribute to the overall evidence to a much lesser extent than information gained from tests using standardised, validated and accepted guidelines.

The CLH report briefly summarises the findings of the in vitro studies tabulated in table 49 further above. In the evaluation of the in vitro gene mutation data it is stated that "A HPRT mouse lymphoma assay was weakly positive in the presence of S9, but negative in the absence of S9". The discussion misses the fact that positive findings were solely obtained in the presence of precipitate, and that particulate matter was carried over to the expression period, exceeding the exposure duration so that the exposure conditions become ill-defined. These experimental conditions do not comply with the relevant OECD test guideline (OECD 476) and should be regarded as biologically irrelevant response (see also comment on lack of quality assessment given in the "General comments"). In a repeat experiment using a pre-incubation procedure, a negative finding was received for that substance, using the same test system (Kirkland et al. 2015).

Section 4.9.1.2, Page 85-90, Germ cell mutagenicity-in vivo data:

It appears that the CLH report considers in vivo studies using the intraperitoneal route of administration equally relevant and adequate for classification purposes as studies using a physiological route of exposure. Such an approach is clearly not in-line with (i) the provisions laid down in regulation (EC) 1272/2008 (ii) the test guidelines specified in Article 13(3) of the REACH regulation (iii) ECHA guidance (Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.4):

(i) the CLP regulation states in Annex I: 3.5.2.3.9 "The relevance of the route of exposure used in the study of the substance compared to the most likely route of human exposure shall also be taken into account.". For industrial chemicals, the inhalation, dermal and oral route are considered relevant for human exposure. The intraperitoneal injection may only be relevant for substances used in pharmaceutical applications, which is clearly not the case for cobalt and cobalt substances. Consequently, only studies via physiological routes should be considered relevant as foreseen in the CLP regulation.

(ii) all recent OECD Test Guidelines for in vivo genetic toxicology testing (OECD 474, 475, 483, 488 and 489) state in section "Administration of doses" that "Intraperitoneal injection is generally not recommended since it is not an intended route of human exposure, and should only be used with specific scientific justification.". As stated above, the intraperitoneal route may be relevant for pharmaceutical applications, but not for industrial chemicals. None of the studies using the i.p. route, provides a justification for this route of exposure. Consequently, these studies should be considered non-compliant with the validated and accepted test guidelines.

(iii) the ECHA Guidance on information requirements and chemical safety assessment, Chapter R.4: Evaluation of available information (2011) provides guidance on the reliability rating of studies (Chapter 4.2, page 3). Studies are considered not reliable in case organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application).

In the weight-of-evidence approach studies using a non-physiological route of administration should therefore be considered to contribute to the overall assessment at a

much lesser extent than information obtained respecting the relevant test guidelines and guidance documents.

Section 4.9.3, Page 90-91, Germ cell mutagenicity- Other relevant information:

The CLH report considers the higher K-ras mutation frequency as an indicator for cobalt-induced mutagenicity in normal tissues. However, the presence of oncogene alteration cannot be used as an indicator or proof of a substance-intrinsic mutagenic potential. In consideration of the mode of action analysis for the carcinogenicity of cobalt and cobalt sulfate, a differentiated evaluation for this oncogene alteration is provided:

The studies of the National Toxicology Program have evaluated oncogene alterations in tumours induced by cobalt sulfate (NTP, 1998) and cobalt metal (NTP, 2016). Studies of cobalt sulfate found Kras alterations in nine of 26 pulmonary neoplasms. Five of nine Kras mutations were G to T transversions at codon 12, a lesion associated with damage from oxygen radicals, while the remainder were similar to coding changes in spontaneous lesions. Studies of cobalt metal dust induced lung tumours with Kras alterations in 67% of mouse pulmonary neoplasms and 31% of rat pulmonary neoplasms. Exon 1 codon 12 G to T transversions were the most common mutation observed (80% of mouse Kras alterations and 57% of Kras alterations in the rat).

The majority of the tumours induced by cobalt or cobalt metal dust thus involve mutations that are considered to be the "signature" of reactive oxygen species and suggest that most lesions induced by cobalt sulfate or cobalt metal dust arise via indirect mechanisms associated with treatment-related hypoxia. The overall profile of oncogene changes in tumours arising in rodents treated with cobalt sulfate or cobalt metal dust can largely be attributed to the generation of reactive oxygen species. This in turn indicates that indirect mechanisms mediate the mutations observed in oncogenes and that cobalt metal dust and cobalt sulfate do not directly alter DNA.

Only as exposure levels increase, with the onset of cytotoxicity and potential impairment and/or saturation of protective mechanisms, would oxygen radicals be produced in a quantity sufficient to produce DNA damage. Distinct non-linearity would be expected in the dose response for the production of DNA damage – in essence clearly underpinning a threshold dose-response function.

The reactive nature of oxygen radicals is such that migration from the respiratory tract would not be expected. This in turn indicates that inhalation exposure to cobalt metal or cobalt compounds would not produce systemic neoplastic lesions. Similarly, migration of cobalt from the respiratory tract would not be in quantities sufficient to produce mutagenic events at other tissue sites.

Section 4.9.4, Page 91-92, Germ cell mutagenicity- Summary and discussion of mutagenicity:

The CLH report lists a number of in vitro tests seemingly demonstrating positive clastogenic findings in human cells. However, a large number of these tests were in fact conducted using cobalt substances which were added as suspension (cobalt metal, cobalt oxide). According to OECD recommendations, one should test at least to the solubility limit (hence one concentration exhibiting precipitate at the end of the treatment period) but not go higher, since precipitates could blanket (suffocate) the cells preventing nutrient uptake and gas exchange, and therefore create physiological stress, leading subsequently to DNA

damage, and thereafter chromosomal damage, as a down-stream consequence (Kirkland, 2016). In addition, many of the tests are now done with cells growing in suspension (human lymphocytes, mouse lymphoma cells, TK6 cells) and it is impossible to separate the cells from the precipitate at the end of treatment, leading to a carry-over of the test item to the post-treatment phase; the treatment conditions therefore become ill-defined. Therefore, the findings need to be carefully evaluated whether the positive findings were a true substance-induced effect or rather a biologically irrelevant finding caused by inappropriate test conditions.

The CLH report again considers the higher K-ras mutation frequency as an indicator for cobalt-induced mutagenicity: "However, also the evaluation of lung tumours in the carcinogenicity study shows that cobalt (as cobalt sulphate) is capable of inducing mutations.". This is an incorrect interpretation of the oncogene alterations, as already discussed above.

The CLH report provides a species-specific interpretation of the in vivo studies: "The results of the available in vivo studies could also be split between rats and mice with all rat studies being negative and mice studies positive.". This is an incorrect summary of the data, also summarised in Table 49 of the report, whereby negative results were obtained in the micronucleus assay in mice exposed via inhalation for 13 weeks (NTP, 2014)

Section 4.9.5, Page 92, Germ cell mutagenicity- Comparison with criteria

The CLH report again considers the higher K-ras mutation frequency as an indicator for cobalt-induced mutagenicity: "However, also the evaluation of lung tumours in the carcinogenicity study shows that cobalt (as cobalt sulphate) is capable of inducing mutations.". This is an incorrect interpretation of the oncogene alterations, as already discussed above.

The CLH report states an absence of vivo information on germ cell mutagenicity. Such a statement is most surprising, since the report cites and discusses the in vivo chromosome aberration study in spermatogonia after 28-day oral administration of CoCl₂ (Kirkland et al. 2015) in table 49 and 50 on page 83 and 86 respectively.

The CLH report proposes read-across of the existing Muta cat. 2 classification of 5 soluble cobalt compounds. This approach is questionable, since a large amount of new scientific evidence has been published since the discussion at TC C&L (2003, Document ECBI/65/03), which now allows a more conclusive evaluation of the mutagenic potential of cobalt and cobalt substances. The new database has been considered within the OECD Cooperative Chemicals Assessment Programme, which is aimed to derive OECD-wide agreed hazard assessments of chemicals. The SIAP of the soluble cobalt salts category concludes for the endpoint mutagenicity: "In summary, soluble cobalt salts do not elicit any mutagenic activity either in bacterial or mammalian test systems. However they induce some genotoxic effects in vitro, mainly manifest as DNA strand or chromosome breaks, which are consistent with a reactive oxygen mechanism, as has been proposed by various authors. A weight-of-evidence approach was applied, considering positive as well as negative in vivo clastogenicity studies and the absence of such chromosome damage in humans that are occupationally exposed to inorganic cobalt substances. It was concluded that effective protective processes exist in vivo to prevent genetic toxicity with relevance for humans from the soluble cobalt salts category."

Based on the above comments, a classification of cobalt metal for mutagenic category 2 does not appear justified.

References

ECHA (2011) Guidance on information requirements and chemical safety assessment, Chapter R.4: Evaluation of available information, Version 1.1, December 2011, Reference: ECHA-2011-G-13-EN

ECHA (2014) Guidance on the preparation of dossiers for harmonised classification and labelling, Version 2.0, August 2014, Reference: ECHA-14-G-02-EN

ECHA (2015) Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures, Version 4.1, June 2015, Reference: ECHA-15-G-05-EN

ECHA (2016) Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a: Endpoint specific guidance, Version 5.0, December 2016, Reference: ECHA-16-G-10-EN

Kirkland, D., Brock, T., Haddouk, H., Hargeaves, V., Lloyd, M., McGarry, S., Proudlock, R., Sarlang, S., Sewald, K., Sire, G., Sokolowski, A. and Zieman, C. (2015). New investigations into the genotoxicity of cobalt compounds and their impact on overall assessment of genotoxic risk. *Reg. Tox. Pharmacol.* 73: 311 – 338.

NTP (1998). NTP Technical Report on the Toxicology and Carcinogenesis Studies of Cobalt Sulfate Heptahydrate in F344/N Rats and B6C3F1 Mice. NTP Technical Report 471. National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services.

NTP (2014). NTP Technical Report on the Toxicology Studies of Cobalt Metal in F344/N Rats and B6C3F1/N Mice and Toxicology and Carcinogenesis Studies of Cobalt Metal in F344/NTac Rats and B6C3F1/N Mice. NTP Technical Report 581. National Toxicology Program, National Institutes of Health, U.S. Department of Health and Human Services.

NTP (2016). Report on Carcinogens Monograph on Cobalt and Cobalt Compounds that Release Cobalt Ions In Vivo. Office of the Report on Carcinogens, National Toxicology Program, U.S. Department of Health and Human Services.

OECD (2014) Guideline for the testing of chemicals, No 474: in vivo Mammalian Erythrocyte Micronucleus Test

OECD (2014) Guideline for the testing of chemicals, No 475: in vivo Mammalian Bone Marrow Chromosome Aberration Test

OECD (2015) Guideline for the testing of chemicals, No 476: In vitro mammalian cell gene mutation test

OECD (2015) Guideline for the testing of chemicals, No 483: Mammalian Spermatogonial Chromosomal Aberration Test

OECD (2013) Guideline for the testing of chemicals, No 488: Transgenic Rodent Somatic

and Germ Cell Gene Mutation Assays

OECD (2014) Guideline for the testing of chemicals, No 489: in vivo Mammalian Alkaline Comet Assay

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Hille & Müller Steel, Tata Steel Europe	Company-Downstream user	215

Comment received

TSE supports the scientific arguments against the proposed mutagenic category 2 classification (H341) for cobalt metal as detailed by the Cobalt Industry.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tata Steel Hille and Muller Position paper.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Arno Friedrichs Hartmetall GmbH & Co.KG	Company-Downstream user	216

Comment received

market impact from CMR stigmatization:

- negative impact on supply chains because sales of cobalt based alloys will likely reduce significantly due to customer perception (phasing out without need)
- larger costs in handling cobalt products in downstream sectors (e.g. due to minimize occupational exposure)

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Team Stainless / Eurofer	Industry or trade association	217

Comment received

Team stainless supports the scientific arguments against the proposed mutagenic category 2 classification (H341) for cobalt metal as detailed by the Cobalt Industry.

Although not specifically measured in the epidemiological studies cited in the section on carcinogenicity, given an understanding of the exposures resulting from the unavoidable presence of trace amounts of cobalt in stainless steel in excess of the proposed SCL, and the much higher exposures to cobalt during the manufacture of high alloy materials, evidence of mutagenicity (leading to increased carcinogenicity) would be expected to be evident in the worker and general public exposures. This is especially true in the case of medical implants given the scrutiny for toxicity and adverse health effects given to such applications for many years.

Meanwhile, in their survey of published literature on the toxicity of stainless steel by the Finnish Institute of Occupational Health, no incidence of mutagenicity was reported for stainless steel from a review of in vitro testing. None of the main alloying constituents of stainless steel demonstrate mutagenic properties, in spite of them containing trace amounts of cobalt in excess of the proposed SCL.

References:

"Review on Toxicity of Stainless Steel", T. Santonen, H. Stockmann-Juvala, and A. Zitting. Finnish Institute of Occupational Health, 2010, Helsinki 2010-11-17, ISBN 978-952-261-

039-3.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final - Team Stainless Position Paper for the Cobalt Issue (signed).pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Svemin	Industry or trade association	218

Comment received

We support the technical comments and the position of the REACH Consortium Ltd (CoRC) and the Cobalt Development Institut (CDI)

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Final Slags Task Force of Eurometaux	Industry or trade association	219

Comment received

The members of the Final Slag Taskforce of Eurometaux support the technical position of the CDI/CoRC (Cobalt Development Institute / Cobalt REACH consortium, 2017).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final Slags TF Eurometaux Comments on Co CLH proposal 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	European Copper Institute	Industry or trade association	220

Comment received

The European Copper Institute supports the technical position of the CDI/CoRC (Cobalt Development Institute / Cobalt REACH consortium, 2017), as outlined in the Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal of January 2017.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170222_ECI-PC-Cobalt-CLH_public-attachment.pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Nickel Institute	Industry or trade association	221

Comment received

The NI strongly supports the CoRC comments in opposing the Dutch proposal to classify Co metal as a Germ Cell Mutagen Category 2:

(1) Mutagenicity studies need to be considered in a weight-of-evidence approach (WOE), taking into account the reliability, consistency, relevance, and quality of the studies. This is an absolute requirement to be able to distinguish between the potential of Co ion to directly induce heritable DNA-chromosomal mutations in germ cells, and effects that are only seen in vitro or that indicate cell damage but not heritable changes.

(2)The current studies of Co ion in vivo mutagenicity by relevant routes of exposure include one positive study (Palit, 1991) and four negative studies (reported in Gudi, 1998, NTP 2014, and Kirkland et al., 2015). One of the negative studies directly looked at the induction of chromosomal aberrations in spermatogonial cells after oral exposures of rats to levels of Co chloride (high Co ion bioavailability) that resulted in 17-fold higher Co concentrations in the testes of exposed animals compared to controls. These negative results were observed at oral exposure levels that are 50,000-fold higher than those experienced by humans. Consistent with these results, studies of highly exposed humans (i.e., workers) did not indicate genotoxicity.

(3)Based on a WOE assessment of the current data, the 2014 OECD conclusion that there is no evidence of genetic toxicity for Co salts is warranted. Similarly, a WOE assessment of the current data does not indicate germ cell mutagenicity concerns for Co metal.

A weight of evidence assessment of the current data does not indicate germ cell mutagenicity concerns for Cobalt metal.

Gudi R, Ritter P. 1998. E-5441.01 (Cobalt Chloride Hexahydrate); Cytogenicity Study in Rat Bone Marrow in Vivo. MA Bioservices Inc, Rockville, Maryland, USA. Robust study summary to be published as part of OECD SIDS dossier for Soluble Cobalt Salts.
<http://webnet.oecd.org/HPV/UI/ChemGroup.aspx>

Kirkland D, Brock T, Haddouk H, Hargeaves V, Lloyd M, Garry SM, Proudlock R, Sarlang S, Sewald K, Sire G, Sokolowski A and Ziemann C. 2015. New investigations into the genotoxicity of cobalt compounds and their impact on overall assessment of genotoxic risk. Regul Toxicol Pharmacol 73(1): 311–338.

NTP, 2014. Toxicology Studies of Cobalt Metal (CAS No. 7440-48-4) in F344/N Rats and B6C3F1/N Mice and Toxicology and Carcinogenesis Studies of Cobalt Metal in F344/NTac Rats and B6C3F1/N Mice (Inhalation Studies). Technical Report Series No. 581. NIH Publication No. 14-5932.

Palit S, Sharma A, Talukder G.1991. Cytotoxic effects of cobalt chloride on mouse bone marrow cells in vivo. Cytobios 68(273): 85-89.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170220-Co metal implications for Ni - input in consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	Germany		MemberState	222
Comment received				
The German CA agrees to the proposed classification of Cobalt.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	H.C. Starck	Company-Downstream user	223
Comment received				
H.C. Starck fully supports and subscribes to the comments submitted to this consultation by ITIA and CoRC.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	Kennametal Inc.	Company-Downstream user	224
Comment received				
<p>Based on available scientific data Cobalt metal should not be classified as a mutagen. Following the CLP classification guidelines Kennametal has self-classified powder mixtures of tungsten carbide and cobalt metal as non-mutagenic based on cobalt's absence of chromosome damage in robust GLP studies in vivo. Results from these studies suggest that effective protective processes are sufficient to prevent oxidative DNA damage in mammals. There is no scientific evidence of genetic toxicity with relevance for humans caused by cobalt substances and cobalt metal (Kirkland et al, 2015). Overall, Kennametal supports the CDI/CoRC industry position to not classify cobalt metal as a mutagen.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02 Kennametal Cobalt CLH Response.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Sweden	Outokumpu Oyj	Company-Manufacturer	225
Comment received				
<p>Outokumpu supports support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal, January 2017.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Belgium	Euroalliages	Industry or trade association	226
Comment received				
<p>We support the CDI/CoRC technical response and we refer to it.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	France		MemberState	227
Comment received				
<p>The in vitro database for cobalt compounds reports variable results. However, positive results have been repeatedly observed with cobalt compounds. In particular, the in vitro database for cobalt consistently allows identifying a genotoxic potential of cobalt. The in vivo database of cobalt is reduced to a single study that is negative in bone marrow after inhalation and without evidence of bone marrow toxicity. It therefore does not allow excluding the genotoxicity of cobalt. The in vivo database for other cobalt compounds is mixed; however it is worth to note:</p> <ul style="list-style-type: none"> - A variability in the results based on strain sensitivity of mice compared to rats is difficult to understand considering that rats are not less sensitive than mice to the carcinogenic of cobalt and cobalt compounds (although mutagenicity may not be the driving factor). In vitro, positive results are obtained using mouse, hamster and human cells. In addition, DNA damage was observed in the single study performed on rat (neuronal) cells (Wang 2000). It is also unlikely that metabolic differences can explain species specificity toward Co²⁺ genotoxicity. - The results for all studies performed by IP route consistently display positive results in 				

bone marrow (and testis in one study) and it provides a sufficient basis to justify the classification Muta 2 for cobalt similarly to other classified cobalt compounds as it provides evidence of an in vivo genotoxic effect and raise concern for local genotoxicity.

- Most of the tests performed by oral route are negative but it is worth to note that the mode of administration may also influence the bioavailability for systemic exposure. In particular, the two dominant assay performed in drinking water are positive even at unexcessive dosage (Elbetieha 2008), whereas the other oral negative tests were performed by gavage and as mentioned in the TK part of the dossier, this may limit bioavailability of the cobalt moiety.
- In addition, results of oral studies in local tissues may need to be discussed in more details as there seems to be indications of a genotoxic activity in the gastrointestinal tract in the Kirkland publication (2015) although it is not reported in the summary table.

Overall, the classification Muta 2 is supported on the basis of the largely positive in vitro database for cobalt and the positive results in vivo by IP route for cobalt compounds. Further support for local mutagenicity may be provided in some oral studies. Whereas the database may be too limited for a classification in 1B, it is also noted that a potential for systemic genotoxicity and germ cell genotoxicity is not excluded when the route of exposure allow a sufficient bioavailability of cobalt and cobalt compounds.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	United Kingdom	Outokumpu Stainless Ltd	Company-Manufacturer	228
Comment received				
Outokumpu supports the scientific arguments of CDI/CoRC technical comments.				

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	Germany	The Cobalt Development Institute and Cobalt REACH Consortium	Industry or trade association	229
Comment received				
<p>The CDI/CoRC disagree with the proposed classification as Muta 2, and reason that cobalt (Co) metal should not be classified for this endpoint. CDI/CoRC position: no Muta classification</p> <p>Summary Mutagenicity data on cobalt (Co) metal, in vitro data: All GLP- and guideline compliant bacterial mutagenicity tests for Co metal are negative. An HPRT assay with particulate-free Co metal in solution was unequivocally negative. This test is compliant with the OECD guideline, and is in-line with the read-across principle used by RIVM, stating that the Co cation is the toxicologically relevant species. Although this test result is published (Kirkland, 2015), it is not mentioned or taken into account in the CLH proposal. Mutagenicity data on cobalt (Co) metal, in vivo data: An in vivo micronucleus test in mouse normochromatic erythrocytes following inhalation exposure to Co metal was negative. Significant exposure of the bone marrow was verified by measurements of Co in bone (femur) with marrow. In workers exposed to Co-containing dust, no significant increases of genotoxic effects were detected.</p> <p>Read across of mutagenicity classification from the soluble Co salts Soluble cobalt salts have a harmonised classification as Muta Cat 2. However, read-across can only be applied if there is a structural relationship to known germ cell mutagens</p>				

(Category 1A or 1B mutagens).

There is no basis upon which the soluble Co salts can be interpreted as Category 1A or 1B mutagens, as their classification rests on a mixed dataset that includes many positive studies of low quality, reliability and relevance score, as well as many guideline compliant studies with negative results. The current, complete database was evaluated by the OECD in 2014 in a Weight of Evidence approach, with the application of a quality and reliability scoring of all studies. The OECD determined that the scientific evidence showed the mode of action was not relevant to humans, and agreed on the following conclusion: "Overall, [...] there is no evidence of genetic toxicity with relevance for humans of the soluble Co salts category."

The CoRC proposes that Co metal should not be classified for the endpoint mutagenicity.

DETAILED COMMENTS

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1) Direct evidence: detailed comments on mutagenicity data of Co metal

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- updated mutagenicity database for Co (industry position)
- revised conclusion for the endpoints mutagenicity

2) Weight of evidence considerations: detailed comments on - mutagenicity data of soluble Co salts

- points raised in the CLH report (RIVM position)
- updated mutagenicity database for Co (industry position)
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3) Concluding remarks relevant to Co metal powder and Co soluble salts and less soluble Co compounds

4) Revised proposal for (non-)classification

5) References

1) Direct evidence: detailed comments on mutagenicity data of Co metal

In vitro bacterial mutagenicity

In bacterial mutagenicity assays conducted by the NTP (Behl and Hooth 2014), positive results were seen in *Salmonella typhimurium* strain TA98 without S9, although the responses observed were weak and not well correlated with dose level. Equivocal results were seen in strain TA100 in the absence of S9 metabolising enzymes. In the presence of S9, both strains yielded negative results. The *Escherichia coli* WP2 uvrA/pKM101 strain gave negative results in the absence or presence of S9 mix. The NTP report interprets the mixed results in the bacterial mutagenicity assays as support for the possibility that Co metal induces tumorigenesis by increasing oxidative stress.

In the light of the mixed findings reported by the NTP, and the weakness and lack of dose-response observed in the only positive result (TA98 without S9), the investigations in this strain were repeated by three independent GLP laboratories following the same protocol (OECD 471). All three laboratories obtained negative results for mutagenicity of Co metal powder in TA98 with and without S9.

Thus, the indications of induction of bacterial mutation in the NTP reports have not been substantiated in recent, robust GLP studies. Overall there is no convincing evidence that metallic Co is mutagenic in the Ames test.

In vitro mammalian mutagenicity

A weakly positive HPRT assay in L5178Y cells with Co metal (in the presence of S9) is considered in the Co metal CLH proposal as indicative of mutagenic activity. However, these results were obtained at concentrations with visible test item precipitation, and particulate test material was carried over throughout the entire study, resulting in a non-compliant test result. This issue is described in the publication of this study (Kirkland, Brock et al. 2015). In order to avoid the presence of particulate matter, a so-called pre-incubation method was used in a repetition of the experiment, where the L5178Y cells were incubated with dissolved Co metal (Co cations). Tyndall analysis was used to show that no undissolved particles remained in the supernatant after a 72 h "extraction" and centrifugation of Co metal powder, and cells were incubated with the particle free supernatant. Relative cell survival was reduced to <20% under all treatment conditions, indicating that divalent Co cations were liberated during the extraction process and induced toxic effects in the cells. The repetition of the HPRT assay using the pre-incubation method resulted in a negative result for mutagenicity. This negative finding is in-line with the read-across principle used by RIVM, stating that the Co cation is the toxicologically relevant species.

In summary, the only in vitro mammalian mutagenicity test with Co metal powder conducted to guideline demonstrated that Co ions are not mutagenic in vitro.

In vivo genotoxicity

The present CLH proposal for Co metal considers the detection of "Kras mutations" in lung tumours after chronic inhalation exposure of Co metal as a positive gene mutation assay. This view is, however, not in line with the interpretation of these findings in the NTP report (Behl and Hooth 2014). Also, there is no in vivo genotoxicity test guideline based on the detection of Kras mutations, as this type of lesion is not indicative of mutagenicity. "Kras mutations" are G to T transversions in DNA, and are directly correlated with 8-oxohydroxy guanine (8-OHG) adducts. 8-OHG adducts are used as biomarkers for oxidative stress, but the detection of these adducts is not a suitable assay to measure the direct mutagenicity of chemicals. The NTP report correctly identifies the "Kras mutations" as a result of oxidative stress caused by Co exposure. Whilst oxidative stress is increased by Co, it can also be increased by metabolically active tissue itself, such as fast growing cancer tissue. The measurement of an increase in Kras mutations in cancer tissue at the end of a chronic study is suitable to show that the antioxidative capacity of the tumour tissue was overwhelmed, and that there was an increase of ROS in the tumour tissue. However, the detection of Kras mutations in late-stage tumour tissue is not suitable for a mutagenicity hazard assessment.

On page 93 of the current CLH proposal it is stated that "There are several positive mutagenicity in vitro studies with cobalt itself (DNA strand breaks, comet assay, Hprt mutation assay, micronucleus test) which can be used as supplemental information but no in vivo tests." Indeed, there are no positive in vivo tests for the endpoint mutagenicity with cobalt itself, but there is a negative in vivo mutagenicity test with Co metal, also listed in table 49 (page 84) of the proposal: an in vivo micronucleus test in mouse normochromatic erythrocytes following inhalation exposure to Co metal (OECD 474). The OECD guideline states that this test design is "especially relevant to assessing mutagenic hazard" ... and that it is "useful for further investigation of a mutagenic effect detected by an in vitro system." This test was conducted as part of the 90-day dose-range finding study for the NTP inhalation cancer study with Co metal (Behl and Hooth 2014).

The test was carried out in male and female mice at all six exposure levels of the range finder (control, 0.625, 1.25, 2.5, 5 and 10 mg Co/m³; 5 males and 5 females at each exposure level). Exposure of the bone marrow to Co was confirmed by measurements of Co levels in bone (femur) with marrow. Co concentrations were below the limit of detection (LOD), which was 0.080 µg Co/g tissue in control animals (Co levels in the bone marrow of control animals were reported as ½ LOD), and 1.1 µg Co/g femur (males) and 1.8 µg Co/g

femur (females) in animals exposed to 10 mg Co/m³ for a 2-week exposure (note that the animals of the micronucleus test were exposed for 3 months, so that an even higher increase in Co levels can be assumed). This shows that the Co levels in the target tissue were at least 30-fold higher in the exposed animals, compared to control.

The results for the in vivo micronucleus test were negative in all exposure groups, in both male and female mice, showing that Co metal by a relevant exposure route had no in vivo mutagenic activity.

This negative in vivo finding is supported by a study in workers exposed to Co-containing dust. Systemic exposure of the study participants was confirmed by measuring Co in urine, which was at a mean level of 20 µg Co per gram of creatinine in urine, equivalent to a time weighted average exposure of 20 µg/m³ Co in air. For comparison, background levels of Co in urine, due to its essential occurrence in the diet, are at around 1 µg/g creatinine. Peripheral blood lymphocytes from these workers were investigated by micronucleus and comet assay for the detection of chromosomal damage. As in the mouse micronucleus study by Behl and Hooth (2014), no significant increases of genotoxic effects were detected in relation to inhalation exposure to Co metal (De Boeck, Lardau et al. 2000).

In summary, there is no convincing evidence that Co metal is mutagenic in the Ames test, nor is there evidence for mutagenic activity of Co metal in guideline compliant mammalian mutagenicity tests.

There is evidence that Co metal causes oxidative stress at high doses in vivo.

Findings from two in vivo genotoxicity studies in rats and humans by relevant route of exposure with Co metal were negative.

2) Weight of evidence considerations: detailed comments on mutagenicity data of soluble Co salts

The present CLH proposal states that Co metal should be classified as a Category 2 mutagen based on its "structure activity relationship" with soluble Co salts. Read-across from the soluble Co compounds to Co metal is scientifically correct, since the soluble Co ion is the toxic unit of interest. However, citing from the proposal, it is explained that it is not possible to read-across from Muta Category 2 (5 soluble Co salts) to Muta Category 2 (Co metal). "However, the note to the criteria for category 2 states that read-across can only be applied if there is a structural relationship to known germ cell mutagens which can be interpreted as Category 1A or 1B. Therefore, read-across from the other category 2 classified soluble Co compounds to Co seems to be not in line with the criteria."

The possibility of a read-across of the Muta classification warrants a closer look at the database on mutagenicity for the soluble Co salts:

The classification of the soluble Co salts as Muta 2 rests on a mixed dataset, with

- (i) positive findings by i.p. exposure
- (ii) unreliable studies (with low Klimisch rating) reporting positive in vivo findings after p.o. exposure,
- (iii) a negative GLP and OECD compliant study with Co dichloride by oral exposure
- (iv) a range of mixed in vitro findings
- (v) dominant lethal assays reporting positive findings; however, conducted above the maximum tolerated dose (MTD)

The above points are addressed below, in the context of the CLP Annex I text where it is stated that "3.5.2.3.3. Classification for heritable effects in human germ cells is made on the basis of well conducted, sufficiently validated tests".

(i) i.p. studies

Positive findings from in vivo clastogenicity studies with i.p. route of administration are considered relevant for classification purposes in the current Co metal CLH proposal, which is not in-line with good scientific practice nor with ECHA guidance (Guidance on Information

Requirements and Chemical Safety Assessment, Chapter R.4) or OECD genotoxicity test guidelines. The OECD guidelines specifically state that "intraperitoneal injection is generally not recommended since it is not an intended route of human exposure, and should only be used with specific scientific justification".

(ii) unreliable study by per oral route

A study by Palit, Sharma et al. (1991) is cited in the CLH proposal as a "well conducted" study by oral administration yielding a positive result for chromosomal aberrations. Since this is the only positive study by a physiological route of exposure, a close examination of this study is warranted. Palit et al. report a dose- and time-dependent increase in chromosomal aberrations in mice treated with CoCl₂.

Mutagenic effects by CoCl₂ are reported by Palit, Sharma et al. (1991) from 6 hr of exposure, and with an increasing trend at 12, 18 and 24 hours. This would mean cell DNA was damaged at all phases of the cell cycle, during early cell growth (G1), during DNA replication (S) and during the second growth phase (G2) just before mitosis. Mutagenic damage at all stages of the cell cycle usually prevents division and leads to cell death. Another aspect of this study raises concerns: dose-related increases in numbers of polyploid cells were reported, however, polyploid cells can only be generated after a full cell cycle has been completed, which takes usually 24 hours. The authors report an induction of polyploidy by CoCl₂ as early as 6 or 12 hrs after dosing, which is a biologically implausible finding.

The results of this study (Palit et al, 1991) are incompatible with the overall genotoxic profile of Co dichloride. In the light of the concerns described above, the study by Palit et al. has limited value when rated against other studies, some of which are GLP and guideline compliant.

(iii) negative guideline compliant per oral study with CoCl₂

The statement in the CLH proposal that "There is no in vivo information on germ cells with cobalt" is correct in that there are no studies on Co metal. However, there is one GLP- and guideline compliant study (OECD 483) with CoCl₂-hexahydrate investigating spermatogonial chromosomal aberrations in SD rats. Male rats were exposed per orally for 28-days to doses up to 30 mg CoCl₂/kg bw/day, which represented the maximum tolerated dose (MTD) due to one death at the next highest dose (100 mg/kg bw/day). This study is published (Kirkland, Brock et al. 2015). It is negative for spermatogonial aberrations at all dose levels. In summary, no test item-related increase in the incidence of chromosomal aberrations (excluding gaps) was noted in the cells of the animals treated with 3, 10 or 30 mg test item/kg bw/day. In detail, a mean incidence of chromosomal aberrations (excluding gaps) between 0.7% and of 0.9% was noted for the cells of the animals treated with 3, 10 or 30 mg test item/kg bw/day. These results were within the normal range as no significant difference was observed compared to the cells from the rats of the control group with an incidence rate of 1.1%. The values observed are within the range of the laboratory (LPT) background data and of published historical negative control data (see table "Summary table of chromosomal aberrations" in an appendix to this commenting section; Muta appendix).

The percentage of cells with gaps from the rats treated with 3, 10 or 30 mg test item/kg bw/day was also within the range of the cells from the rats of the control (control group: 1.7%; treatment groups: between 0.6% and 1.5%). The mean mitotic index of the animals treated with 3, 10 or 30 mg test item/kg bw/day (1.11 - 1.48) was also in the range of the mean mitotic index of the animals from the control group (1.00). The mean mitotic index and the mean incidence of cells with aberrations per group are listed in the tables provided in attachment 1 to this commenting section (Muta appendix).

Exposure of the target organ was confirmed by the measurement of Co levels in testes tissue in the 90-day study, which followed this 28-day range finder investigating spermatogonial aberrations. At the end of the 90-day exposure, Co levels in the testes

tissue of 10 control animals and of 10 animals exposed to 30 mg CoCl₂/kg bw/day were measured. Co levels in the testes of control animals were 0.0075 (\pm 0.004) μ g Co/g tissue, and in the animals exposed to 30 mg CoCl₂/kg bw/day Co levels were 0.133 (\pm 0.016) μ g Co/g tissue. The study report with these results is currently in draft, and we herewith notify availability of those data to be reviewed alongside the CLH proposal by the RAC in their deliberations of Co metal classifications. Based on the toxicokinetic data and model discussed by Finley, Monnot et al. (2012), it can be predicted that a steady state of Co levels after oral exposure is achieved within 30 days. It can therefore be inferred that there was significant exposure of the testes to Co in the 28-day study.

(iv) a range of mixed in vitro findings

It is acknowledged that the Co soluble salts have a mixed genotoxicity database, with some studies indicating the potential to induce chromosomal aberrations in vitro. On the other hand, there are 11 GLP and OECD-guideline compliant HPRT assays with 2 highly soluble Co compounds (Co sulfate and Co octoate), and several other Co compounds of varying solubility, all of which release the Co ion to a high or moderate extent. All HPRT assays are unequivocally negative, and all are published (Kirkland, Brock et al. 2015).

(v) two dominant lethal assays above the MTD

Two studies conducting a variation of a Dominant Lethal Assay (DLA) protocol are cited as evidence for mutagenicity of soluble Co salts to germ cells (Pedigo and Vernon 1993, Elbethieha, Al-Thani et al. 2008). Both studies suffer from several problems, mainly a lack of reporting of body weights, animal morbidity, and animal mortality, as well as application of very high doses. Pedigo et al (1993) applied only one treatment dose, 400 ppm Co dichloride. In the Materials and Methods section of this paper it is stated that "Previous studies indicated that reproductive toxicity occurred at this concentration", and it is unclear why such a high dose was chosen for a dominant lethal assay in which, according to the OECD guidance, "the MTD must not adversely affect mating success". The interpretation of these data in the CLH report that "Most tested dose levels were above the MTD for a dominant lethal test defined (amongst others) as not affecting mating success" is in our view correct. The CLH proposal text continues: "However, in the study by Elbetieha (2008) a reduction in viable foetuses was also observed at a dose level (200 ppm) without a significant reduction in pregnant females (75 vs 95%)." At this dose, however, the average epididymal sperm count per mg epididymis was already significantly reduced versus control (193 x 10³ in control versus 167 x 10³ in the 200 ppm animals, $p < 0.05$). This indicates that high-dose male fertility effects were observed in these DLA assays, making the assays unsuitable as evidence for the endpoint germ cell mutagenicity. An interpretation of male reproductive effects at high/excessive Co doses in the absence of records on body weight and animal morbidity and mortality is discussed in detail in the "Reproductive Toxicity" section of this commentary on the CLH proposal for Co metal.

Of further particular interest are the following statements made in the CLH proposal for Co metal:

Page 92 of the CLH proposal text states: "As it is indicated that the mutagenicity of cobalt may be indirect, the local dose level must reach a certain level to induce such effects. This is possibly shown by the strong increase in nuclear anomalies in the gastro-entero tract as shown by Kirkland (2015)." This statement is in line with the view that cobalt can act via a secondary mechanism on DNA (but is not directly mutagenic); and that these effects are only seen at very high doses. The wording in the CLH text strongly implies a threshold mode of action, and is supported by the predominantly negative database on mutagenicity as well as by the recent OECD conclusion that "there is no evidence of genetic toxicity with relevance for humans of the soluble Co salts category" (OECD 2014). The following application of a non-threshold assumption for cancer, the application of the T25 method and the resulting SCL are incompatible with this evidence, and are considered by the CDI/CoRC to be inappropriate.

The proposal states that there is a concern of local mutagenicity at portal-of-entry based on

a “strong increase in nuclear anomalies in the gastro-intestinal tract as shown by Kirkland (2015)”, after single oral administration of Co sulphate (100, 300 and 1000 mg/kg bw/day) to Sprague Dawley (SD) weanling rats. In the methods section of this paper, it is stated that nuclear anomalies are formed by condensation and degradation of the nucleus as a result of single cell necrosis. Single cell necrosis (also referred to as apoptosis) is typically seen in tissues containing actively dividing cells as a response to cytotoxicity. While nuclear anomalies may have other causes, the overall toxicological profile of the soluble Co salts indicates that cytotoxicity at high local doses is the most probable explanation for the observed nuclear anomalies in gastrointestinal tissue. According to the CLP Regulation and ECHA guidance, mutagenicity refers to the induction of permanent transmissible/heritable changes in the amount or structure of the genetic material of cells or organisms. Since the nuclear anomalies were observed in apoptotic cells that can no longer transmit a change in its genetic material, this finding is not relevant for the hazard evaluation of mutagenicity.

The basis for the existing classification of the soluble Co salts, plus a wealth of new scientific evidence for this endpoint has been reviewed in the current proposal. Since the current database is more comprehensive, a read-across from the “old” classification is not appropriate. The current, complete database should be considered in a Weight of Evidence (WoE) approach, and with the application of a quality and reliability scoring of all studies.

A consideration of the same database has led to a recent conclusion by the OECD (OECD 2014) that does not support the existing classification of the soluble Co salts, and certainly does not indicate that this hazard classification can be read-across to Co metal.

In the conclusions adopted by the OECD Cooperative Chemicals Assessment Meeting of October 2014, the properties of the soluble, most bioavailable, Co substances are summarised as follows:

“In summary, soluble Co salts do induce some genotoxic effects in vitro, mainly manifest as DNA strand or chromosome breaks, which are consistent with a reactive oxygen mechanism, as has been proposed by various authors. The absence of such chromosome damage in robust GLP studies in vivo and in humans occupationally exposed to inorganic Co substances, suggests that the more effective protective processes that exist in whole mammals are sufficient to prevent DNA damage resulting from reactive oxygen, even at the high doses tested. Overall, based on the information discussed above, there is no evidence of genetic toxicity with relevance for humans of the soluble Co salts category.”

The scientific evidence thus demonstrates that the mode of action for induction of genotoxic effects in vitro is not relevant to humans, therefore the soluble cobalt salts do not meet the criteria for classification as mutagenic.

3) Concluding remarks relevant to Co metal powder and Co soluble salts and less soluble Co compounds

All Co substances (including Co metal) do not induce:

- gene mutations
- genome mutations (aneugenicity)

Co substances can cause in vitro clastogenicity (chromosome breakage) by inducing oxidative damage, or by other indirect mechanisms such as excessive cytotoxicity or disruption of non-DNA targets. These mechanisms are expected to have a threshold. The clastogenic potential of Co salts in vitro, as seen in chromosomal aberration, micronucleus and tk mutation (small colony mutants) assays, has been satisfactorily addressed by negative in vivo bone marrow micronucleus and chromosomal aberration results with several Co substances of varying solubilities (Co acetyl acetonate, Co resinate, Co sulfate, Co monoxide, tricobalt tetraoxide) (Kirkland, Brock et al. 2015). Further, a

survey in workers occupationally exposed to Co and inorganic Co substances did not detect significant increases of genotoxic effects (micronuclei and DNA damage in peripheral blood), when workers were exposed to Co-containing dust at a mean level of 20 µg Co/m³. Lastly, rats orally exposed to Co dichloride did not show chromosomal aberrations in spermatogonia after 28 days of continuous exposure.

The CDI/CoRC consider it inappropriate to read across to a Category 2 (mutagenicity) for Co metal from the 5 soluble Co salts.

4) Revised proposal for non-classification

The classification criterion for Category 2 mutagens of "chemical structure activity relationship to known germ cell mutagens" is not fulfilled in the case of Co metal, because the Co soluble salts are not "known germ cell mutagens".

Referring back to the criteria for classification, it is the CDI/CoRC opinion that none of the conditions for classification are fulfilled:

- Positive evidence obtained from experiments in mammals and/or in some cases from in vitro experiments, obtained from:
 - Somatic cell mutagenicity tests in vivo, in mammals; Condition not fulfilled. or
 - Other in vivo somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays. Condition not fulfilled.
- Substances which are positive in in vitro mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, shall be considered for classification as Category 2 mutagens. Neither condition is fulfilled.

The CDI/CoRC propose that Co metal should not be classified for the endpoint mutagenicity.

6) References

Behl, M. and M. J. Hooth (2014). Toxicology studies of cobalt metal (CAS NO. 7440-48-4) in F344/N rats and B6C3F1/N mice and toxicology and carcinogenesis studies of cobalt metal in F344/NTac rats and B6C3F1/N mice (inhalation studies), National Toxicology Program. NTP TR 581

De Boeck, M., S. Lardau, J. P. Buchet, M. Kirsch-Volders and D. Lison (2000). "Absence of significant genotoxicity in lymphocytes and urine from workers exposed to moderate levels of cobalt-containing dust: a cross-sectional study." *Environ Mol Mutagen* 36(2): 151-160.

Elbethieha, A., A. S. Al-Thani, R. K. Al-Thani, H. Darmani and W. Owais (2008). "Effects of Chronic Exposure to Cobalt Chloride on the Fertility and Testes in Mice." *Journal of Applied Biological Sciences* 2 1: 2008.

Finley, B. L., A. D. Monnot, S. H. Gaffney and D. J. Paustenbach (2012). "Dose-response relationships for blood cobalt concentrations and health effects: a review of the literature and application of a biokinetic model." *J Toxicol Environ Health B Crit Rev* 15(8): 493-523.

Kirkland, D., T. Brock, H. Haddouk, V. Hargeaves, M. Lloyd, S. M. Garry, R. Proudlock, S. Sarlang, K. Sewald, G. Sire, A. Sokolowski and C. Ziemann (2015). "New investigations into the genotoxicity of cobalt compounds and their impact on overall assessment of genotoxic risk." *Regul Toxicol Pharmacol* 73(1): 311–338.

OECD (2014). "SIDS Initial Assessment Profile Soluble Co salts CoCAM 6."

<http://webnet.oecd.org/hpv/ui/handler.axd?id=e5e60085-1f3f-4df5-92f6-8f32c26c3082>

Palit, S., A. Sharma and G. Talukder (1991). "Cytotoxic effects of cobalt chloride on mouse bone marrow cells in vivo." Cytobios 68(273): 85-89.

Pedigo, N. G. and M. W. Vernon (1993). "Embryonic losses after 10-week administration of cobalt to male mice." Reprod Toxicol 7(2): 111-116.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachmts Co metal PC.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Repr appendix, CONFIDENTIAL.pdf

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	United Kingdom		Individual	230

Comment received

In the discussion of the Ames tests (Section 4.9.1.1) there is no clear comment on the overwhelming weight of negative bacterial mutation studies, or the fact that the positive results in a few strains in some studies were not reproduced in the same strains, often at higher concentrations, under GLP conditions. A conclusion that the weight of evidence indicates that neither cobalt nor soluble cobalt salts demonstrate consistent or reproducible mutagenic activity would be appropriate.

There is no convincing evidence that cobalt metal ions or soluble cobalt salts are able to induce gene mutations in mammalian cells. All of the genotoxic responses in mammalian cells can either be attributed to artefacts of treatment conditions (precipitate), high levels of cytotoxicity, or reactive oxygen species, all of which would exhibit a threshold. There is no evidence that cobalt compounds interact directly with DNA.

The weight of evidence from the in vivo studies indicates that cobalt compounds do not induce genotoxic effects when conventional endpoints (CA and MN) are studied and when administered via a physiologically relevant (oral or inhalation) route. The ip route is not considered superior or physiologically relevant.

The classification of Muta 2 for cobalt metal is to some extent predicated on positive results in vitro, and it appears that the positive in vitro result that is considered relevant for cobalt metal is the positive Hprt mutation test with cobalt metal powder in the presence of particulate matter. This is considered to be an artefact of physiological stress induced by suffocation of the cells where the powder could not be removed from the cultures. Negative results with a cytotoxic extract of cobalt metal and with soluble cobalt salts provide convincing evidence of lack of mutagenic activity. The positive result with insoluble cobalt metal powder should therefore not be used in the context of classification.

There is no evidence of genotoxic effects in vivo when conventional endpoints are measured and when a physiologically relevant route of administration is used. Therefore, the somatic cell in vivo data do not indicate a justification for Muta 2 classification.

Therefore, it is considered that the available relevant data from in vitro and in vivo somatic studies do not support a classification of Muta 2.

Detailed comments have been uploaded.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Kirkland CLH proposal muta and ip 2017Feb15 clean version.doc

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	France	FEPA	Industry or trade association	231

Comment received
 The CDI and CoRC, as the main holders of scientific data on cobalt, have prepared thorough scientific comments on this point. FEPA is supporting these comments.
 ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEPA_Answer to the public consultation cobalt metal_1.pdf

Date	Country	Organisation	Type of Organisation	Comment number
19.02.2017	Vietnam		Individual	232

Comment received
 No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	France	MFPM : Manufacture Française des pneumatiques Michelin	Company-Downstream user	233

Comment received
 • Michelin supports the position of the Consortium of Cobalt and CDI about a threshold mode of action.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Germany	TIGRA GmbH	Company-Manufacturer	234

Comment received
 We support the technical position of the Cobalt REACH Consortium Ltd. (CoRC) and the Cobalt Development Institute (CDI).

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	235

Comment received
 No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam		Individual	236

Comment received
 Mutagenicity (Muta) 2 (H341) at a GCL of $\geq 1\%$ cobalt levels.

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	237
Comment received				
• No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	238
Comment received				
Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	239
Comment received				
No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM)				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	240
Comment received				
• No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam		Individual	241
Comment received				
No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Vietnam	Masan Resources	Company-Downstream user	242
Comment received				
The cobalt industry (CDI and CoRC), based on scientific research, have previously decided the following self-classifications for cobalt metal: No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).				

Date	Country	Organisation	Type of Organisation	Comment number

16.02.2017	United Kingdom	ICoNiChem Widnes Ltd	Company-Downstream user	243
Comment received				
<ul style="list-style-type: none"> • With regards to reprotoxicity, the CHL proposal has ignored negative findings of the OECD studies completed by CoRC. There is also on going testing for reprotoxicity that has not been considered. We believe that the classification should remain Repr 2, H361F as a precautionary statement until this testing is completed. 				

Date	Country	Organisation	Type of Organisation	Comment number
15.02.2017	Canada	Sherritt International Corporation	Company-Manufacturer	244
Comment received				
<p>Sherritt International Corporation (Sherritt) strongly supports the Cobalt Development Institute/Cobalt Reach Consortium (CDI/CoRC) technical comments. Sherritt believes it is highly inappropriate to conclude on a Reprotoxicity category 1B classification prior to the completion of the ECHA MSC mandated testing program (pre-natal development toxicity and extended one generation reproductive toxicity study) and supports the CoRC counter-proposal to remain with an interim self-classification of Reprotoxicity Category 2 until the ECHA mandated testing programme is completed. CoRC would then revisit the need for classification after completion of the testing programme.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment References 1 and 2 Sherritt Epidemiology Reports.7z</p>				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	SSAB AB	Company-Downstream user	245
Comment received				
<p>Regarding Reproductive toxicity</p> <p>SSAB supports the technical and scientific challenge on the proposed NE harmonized classification as Repr 1B provided by CDI/CoRC.</p> <p>The proposed Repr 1B, H360F classification will have an indirect effect leading to extremely low OELs (Occupational Exposure Limits) and restrictive handling through low DMELs for the whole steel industry and all downstream users of steel.</p> <p>Cobalt is present in iron ore and carbon steel as an impurity</p> <p>In the production of steel in Sweden and Finland, SSAB use iron ore as the main source for iron. The iron ore used at SSAB may contain up to 0.1% cobalt probably as oxides. Of course the form in which the cobalt occur in the iron ore needs to be determined, if possible. SSAB will participate in investigating the form of cobalt in the iron ore pellets. Nevertheless the cobalt within the iron ore is added to the blast furnace and follows the iron to the steelworks where it also follows in the steel smelt. We believe most iron ore contain similar amount of cobalt, as it stay in the iron when melted. SSAB intend to participate in the examination of the amounts of cobalt in different iron ores.</p> <p>SSAB also depends on scrap as a source of iron. Probably all scrap known today contains cobalt above 0.1 %. If the proposed classification comes true, all scrap will be classified as dangerous.</p>				

Steel is a special type of mixture

All studies referred to in the classification proposal are to very clean cobalt powder or other similarly clean cobalt salts or other clean cobalt compounds. Then these different substances are administered orally, dermally and by inhalation and also by injection route. These substances referred to in the studies are not the least comparable to for example solid steels containing cobalt as an alloying element. The actual form of cobalt tested on the laboratory animals make a big different. Also the route of exposure is critical and depends on how the human body is functioning. For example the vitamin B12 is essential to the human body and is based on cobalt. The scientific evidence for the proposed classification must be understood as weak.

The CLP mixture calculations comply for steels, although they are recognized as special mixtures, as alloys. As you know iron have been used by humans since the iron ages and mined and converted to steels since the middle age. If this production and use have proved to be a major health issue, the world would have known this by now. Therefore the proposed classification must be regarded not based on the broad scientific ground as it must be, with regard to the consequences.

The handling of steel will be difficult. All steels will be regarded dangerous by both industry and society, because how would you see the difference of steel with 1% cobalt or 0.01% cobalt?

ECHA note – An attachment was submitted with the comment above. Refer to public attachment SSAB STATEMENT DOCUMENT on Cobalt Feb 2017.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Freeport Cobalt Oy	Company-Manufacturer	246
Comment received				
The company support the CDI/CoRC technical comments provided to this consultation.				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	ACEA	Industry or trade association	247
Comment received				
Our comments are attached as below.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170224-Cobalt-CLP_ACEA-final.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
10.02.2017	France	Shepherd Mirecourt S.A.S.	Company-Manufacturer	248
Comment received				
We support the technical position of Cobalt Development Institute (CDI) and the Cobalt REACH Consortium (CoRC) for this endpoint. Interim Repr. 2 classification is recommended based on read-across approach (solubility in gastric fluid is taken into account) proposed by CDI/CoRC toxicologists. There is currently on-going testing program for the Co substances				

covered by CoRC. ECHA decision on testing proposals is not yet known. As a consequence, it appears premature to propose a definitive classification for Co metal for this endpoint.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	CERATIZIT Group	Company-Downstream user	249

Comment received

Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as Reproductive Toxicant Category 2 based on available information about cobalt's reproductive toxicity on experimental animals. This classification can be confirmed or reconsidered after the ongoing tests conducted by the Cobalt REACH Consortium that include a 2nd species pre-natal developmental toxicity (PNDT) study and an EOGRTS (Extended One-Generation Reproductive Toxicity Study) on a cobalt analogue are completed. Based on available scientific data we support the classification of cobalt metal as Reproductive Toxicant Category 2. CERATIZIT Group supports the technical position of the ITIA and CDI/CoRC (2017), (See Attached)

ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	France	Alliance des Minerais, Minéraux et Métaux (A3M)	Industry or trade association	250

Comment received

We invite RAC to carefully review the comments issued by CDI and CoRC, notably the procedural issue created by the anticipation of the results of the REACH testing program for assessing reprotoxic properties (for which a mandate has been delivered).

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24_A3M_Co consultation.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Norilsk Nickel Harjavalta Oy	Company-Manufacturer	251

Comment received

Norilsk Nickel Harjavalta Oy is a member of Cobalt REACH Consortia (CoRC). Norilsk Nickel Harjavalta Oy supports Cobalt REACH Consortia General and Technical comments on Reproductive toxicity.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Nilar AB	Company-Importer	252

Comment received

We support the CDI/CoRC technical position.

Date	Country	Organisation	Type of Organisation	Comment
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				number
24.02.2017	Germany	RIO TINTO	Company-Manufacturer	253
Comment received				
Our company supports the technical comments made by CDI				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	United Kingdom	UK Steel	Industry or trade association	254
Comment received				
For the classification of Reprotoxic category 1B, UK Steel are also in agreement with the CDI, and support the case against these classifications.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment FINAL - UK Steel CLH Cobalt metal response 24 02 17.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Tikomet Oy	Company-Manufacturer	255
Comment received				
Mandated by ECHA, the Cobalt REACH Consortium (CoRC) is conducting tests which include a 2nd species pre-natal developmental toxicity (PNDT) study and an EOGRTS (Extended One-Generation Reproductive Toxicity Study) on a cobalt analogue. The current self-classification of the hardmetal industry of powder mixtures of tungsten carbide and cobalt metal as Reproductive Toxicant Category 2 Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels can be confirmed or reconsidered after these ongoing tests are completed.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tikomet Oy Response - Co CLH.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Finland	Finnish Steel and Metal Producers	Industry or trade association	256
Comment received				
Massive metal alloys behave differently than its separate alloying elements (substances in the alloys). And the alloying process in massive metal alloys strongly eliminates the release and exposure to any single alloying element. That's why hazardous classification of single alloying elements of massive metal form should not be used as such for basis of hazardous classification of massive metal alloys. When cobalt is present in the massive metal alloy, the hazardous classification should be based on the measured release and exposure not the concentration of the alloying element cobalt.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment MJ kannanotto_cobalt.docx				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Teknikföretagen	Industry or trade association	257
Comment received				

We support the current industry self-classification as Repr 2.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Spain	Spanish Association of Frits, Glazes and Inorganic Pigments	Industry or trade association	258

Comment received
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ECHA note – An attachment was submitted with the comment above. Refer to public attachment Letter of support Co- Public Consultation.docx

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	AB Sandvik Materials Technology	Company-Manufacturer	259

Comment received
AB Sandvik Materials Technology fully supports the comments given by Jernkontoret (Sweden), EUROFER and Team Stainless.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	Wirtschaftsvereinigung Metalle (WVMetalle)	Industry or trade association	260

Comment received
Wirtschaftsvereinigung Metalle (WVMetalle), the German Non-Ferrous Metals Association, fully supports the technical position of the Cobalt REACH Consortium (CoRC) resp. Cobalt Development Institute (CDI).
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02-24 WVMetalle commenting on Co CLH proposal.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Wirtschaftskammer Österreich	Please select organisation type..	261

Comment received
see PDF attached
ECHA note – An attachment was submitted with the comment above. Refer to public attachment su_170_StN CLH Cobalt.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Germany	BASF SE	Company-Manufacturer	262

Comment received
We disagree with the addition of Repr. 1B, H360F to the harmonised classification for cobalt. The effects leading to this proposed classification were decreased sperm motility and testes infarction in male rats observed in a range finding study conducted on cobalt metal

under the NTP program in the USA in the presence of significant lung inflammation and haematological effects. Data on CoCl₂ show effects on testes and on fertility. However, these effects were only observed at dose levels causing death and sacrifice of moribund animals.

However, the cobalt consortium has performed extensive studies looking to reproduce effects on the reproductive system, including:

- oral OECD 422 study, in which no effects on male and female fertility were observed at doses not leading to death
- oral OECD 408 study including reproductive parameters on CoCl₂, showing no effects
- Pre-natal developmental toxicity study on CoCl₂, a highly bioavailable analogue, also showing no effects

The weight of evidence shows no consistent results in either sex at lower doses, and some inconsistent effects in doses at which death occurs.

In addition, the cobalt consortium has submitted a testing proposal for an Extended One-Generation Reproductive Toxicity Study (OECD 443) for the group of soluble cobalt substances. A proposal on changing this classification should await the results of those studies. Therefore, given the above evidence, a classification of Repr. 2 H361 as supported by the consortium would be appropriate.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Sandvik Mining and Rock Technology	Company-Downstream user	263

Comment received

The current self-classification of cobalt metal as Reproductive Toxicant Category 2 is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. As pointed out by CDI/CoRC and ITIA further testing related to the reproductive toxicity is ongoing. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

IMPACTS of the Repr 1B proposal:

A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Mining and Rock Technology response 20170224].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference x Sandvik Mining and Rock Technology response 20170221 V0 4-CH comments.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Mining and Steel Association	Please select organisation type..	264

Comment received
Wir unterstützen die wissenschaftlich fundierte Argumentation des Cobalt Development Institutes und des Cobalt REACH Consortium, insbesondere, dass die im Einstufungsvorschlag zitierte NTP Studie kein Beweis für negative Auswirkungen auf die Sexualfunktion oder auf die Fruchtbarkeit ist und dass über eine harmonisierte Einstufung erst zu entscheiden ist, wenn anhängige Testvorschläge für eine Studie der pränatalen Entwicklungstoxizität an einer zweiten Tierart und für eine EOGRTS Studie final abgeschlossen sind.
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Austria	Austrian Non Ferrous Metals Association	Industry or trade association	265

Comment received
Wir unterstützen die wissenschaftlich fundierte Argumentation des Cobalt Development Institutes und des Cobalt REACH Consortium, insbesondere, dass die im Einstufungsvorschlag zitierte NTP Studie kein Beweis für negative Auswirkungen auf die Sexualfunktion oder auf die Fruchtbarkeit ist und dass über eine harmonisierte Einstufung erst zu entscheiden ist, wenn anhängige Testvorschläge für eine Studie der pränatalen Entwicklungstoxizität an einer zweiten Tierart und für eine EOGRTS Studie final abgeschlossen sind.
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	Albemarle Europe SPRL	Industry or trade association	266

Comment received
The CLP report quotes a large number of studies, but fails to sufficiently weigh them in terms of relevance, reliability, validity, and quality. For example in table 71 already 7 studies are mentioned in which effects are only observed at dose levels that already caused mortality. Most recent guideline studies indicate that there is likely no primary effect of Cobalt on male fertility or developmental toxicity. The effects observed in the NTP studies are consistent with hypoxia effects and only occur at dose levels and time points that already show severe respiratory toxicity and/or hypoxia. As the spermatogenesis and testicular tissue is particularly sensitive to hypoxia, it is likely that the effects observed are secondary to this toxicity and thus would not warrant classification. The Cobalt REACH consortium has submitted a further testing proposal under REACH for this endpoint. We therefore propose to not include this endpoint at this point in time into a harmonized classification proposal and wait for the outcome of the proposed studies. Any Risk Management will in any case be triggered by the carcinogenicity classification.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium		MemberState	267
Comment received				

BECA agrees with the DS proposal to classify Cobalt as Repr. 1B H360F, considering the pronounced effects on sperm quality and male reproductive organs integrity. Indeed, cobalt metal administered via inhalation to male rats during 14 weeks induced a decrease in sperm motility at a dose of 0.625 mg/m³. The same effect was observed in mice after 14 weeks of exposure but a dose of 2.5 mg/m³. Above 5 mg/m³, reduced sperm count and a decrease in testis weight was observed, while at 10 mg/m³, a degeneration of testes epithelium, hypospermia, atrophy of the epididymis, ... was caused. Two other studies showed testes infarct and degeneration of germinal epithelium in the testes in rats and mice, respectively, at the same dose level: 5 mg/m³. We consider the developmental effects such as skeletal retardations, decreased number of litters, decreased viability index, increased post-pre implantation losses, decreased live birth index, ... as severe effects but we lack consistency and reproducibility between doses and across species and, considering these uncertainties, it is not possible to classify for developmental toxicity.

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Luxembourg	FEDIL - The voice of Luxembourg's industry	Industry or trade association	268
Comment received				
FEDIL entirely supports the technical position of the Cobalt Development Institute (CDI) and the Cobalt Reach Consortium (CoRC).				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170223_ECHA_PC_General_Comments_CLP.docx				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Sweden	Jernkontoret	Industry or trade association	269
Comment received				
<p>Jernkontoret supports the technical comments from CDI/CoRC, The EUROFER Position Paper on the Harmonized Classification and Labelling Proposal for Cobalt Metal and Team Stainless Position Paper for the Public Submission on the Harmonized Classification of Cobalt Metal. Handling of materials containing cobalt would need to change if cobalt metal had a harmonized classification as Carc 1B (all routes of exposure) or Repro 1B. Carcinogen directive (2004/37/EC) and its implementation in Sweden (AFS 2014:43) require that if the CMR substance cannot be eliminated or handled in a closed system, all exposure should be avoided. Avoiding skin contact with all stainless steel and more than 50 % of carbon steel and other alloyed steels as well as hardmetal would be impossible and a modern society without those materials would not work. The current Cobalt REACH Consortium self-classification of cobalt as Carc 1B through inhalation does not cause those problems, because only exposure via inhalation has to be avoided. Exposure via air is traditionally regulated with OELs and working methods have been designed/optimised to minimise dust exposure.</p> <p>Jernkontoret recommends Sweden not to support the proposed classification as long as the scientific support is missing. Jernkontoret also recommends Sweden to carefully consider the scientific background of the proposal and the probable future effects of the proposal. Because the current proposal can have serious consequences for the Swedish industry manufacturing and using several materials containing cobalt for example steel, we think it is extremely important that there is solid data to support the proposed classification.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
24.02.2017	Belgium	EUROBAT	Industry or trade association	270
Comment received				
<p>1. Co metal is mainly used as an intermediate for the manufacturing of other cobalt compounds used as active materials for electrodes manufacturing</p> <p>2. However, Co metal is present as an impurity above the proposed SCL of 0.01% in several metals (nickel, stainless steel, alloys) widely used in the battery manufacturing:</p> <p>a. This impurity is not economically removable</p> <p>b. Technical feasibility has to be considered</p> <p>3. RECHARGE and EUROBAT support the CDI/CoRC technical comments</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment RECHARGE-EUROBAT input to CLH Cobalt metal consultation.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Cobalt REACH Consortium/Cobalt Development Institute	Industry or trade association	271
Comment received				
<p>Please note that the CDI/CoRC have made a separate submission of detailed technical comments on this end-point of the CLH proposal.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Zip of CoRC-CDI Joint Response Comments (3 Documents).zip</p>				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	AB Sandvik Coromant	Company-Downstream user	272
Comment received				
<p>The current self-classification of cobalt metal as Reproductive Toxicant Category 2 is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. As pointed out by CDI/CoRC and ITIA further testing related to the reproductive toxicity is ongoing. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>IMPACTS of the Repro 1B proposal:</p> <p>A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires totally new, currently not known techniques.</p> <p>B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to</p>				

considering moving production and recycling to regions outside of the EU. Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Sandvik Coromant response 20170223].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Sandvik Coromant response 20170223.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Wirtschaftsvereinigung Stahl e.V. / Stahlinstitut VDEh e.V.	Industry or trade association	273
Comment received				
steel in a massive form is not bioavailable, please regards general comments				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Deutsche Edelstahlwerke Specialty Steel GmbH & Co. KG	Company-Manufacturer	274
Comment received				
Cobalt is bound in a matrix. Therefore it is not bioavailable und primarily for human beings unproblematic. In the case of thermal or mechanical processing, work safety measures must be taken anyway, irrespective of cobalt. Please regard general comments.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany		Individual	275
Comment received				
we are in support of the technical position of the CDI-CoRC				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 160608 Original Eng.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Austria	Boehlerit GmbH & co.KG	Company-Manufacturer	276
Comment received				
According to a report by the Cobalt REACH Consortium using an OECD 422 (28-day) study there are no negative effects by oral administration of cobalt powders. Of course there might be differences to an intake by inhalation, but at least these data should be double checked.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Belgium	The Beryllium Science and	Industry or trade association	277

		Technology Association		
Comment received				
Please see position paper.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Beryllium Science and Technology Association - Cobalt CLH Consultation.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Belgium	EUROFER	Industry or trade association	278
Comment received				
EUROFER supports the scientific arguments against the proposed reprotoxic category 1B classification (H360F) for cobalt metal as detailed by the Cobalt Industry and supported by Team Stainless.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final EUROFER Carbon Steel Cobalt Input to CLH PC 22.02.17.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Norway	Glencore Nikkelverk AS	Company-Manufacturer	279
Comment received				
Glencore Nikkelverk AS has been appraised of, and supports, the Scientific arguments provided by the Cobalt REACH consortia and the Cobalt Development Institute for this endpoint.				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Seco Tools AB	Company-Downstream user	280
Comment received				
<p>The current self-classification of cobalt metal as Reproductive Toxicant Category 2 is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. As pointed out by CDI/CoRC and ITIA further testing related to the reproductive toxicity is ongoing. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>IMPACTS of the Repro 1B proposal:</p> <p>A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.</p> <p>B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.</p> <p>Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Seco Tools response 20170221].</p>				

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Seco Tools response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Sweden	Pramet Tools, s.r.o.	Company-Downstream user	281

Comment received

The current self-classification of cobalt metal as Reproductive Toxicant Category 2 is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. As pointed out by CDI/CoRC and ITIA further testing related to the reproductive toxicity is ongoing. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.

IMPACTS of the Repro 1B proposal:

A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.

B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.

Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Dormer Pramet response 20170221].

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 DormerPramet response 20170221.pdf

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Germany	Fachverband Pulvermetallurgie e.V. (FPM) / Federation of Powder Metallurgy in Germany (FMP)	Industry or trade association	282

Comment received

The Fachverband Pulvermetallurgie e.V. (Federation of Powder Metallurgy in Germany, FMP) fully supports the technical position of the „Cobalt REACH Consortium Ltd. –CoRC“ / „Cobalt Development Institute – CDI“.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	United Kingdom	Vale Base Metals	Company-Manufacturer	283

Comment received

Vale Base Metals is a member of the Cobalt Development Institute/Cobalt REACH

Consortium and Nickel Institute and supports the technical input of these organisations to this public consultation.

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of frits (Frit Consortium)	Industry or trade association	284
Comment received				
-				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support FRIT.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
23.02.2017	Spain	EEIG of Inorganic Pigments (Inorganic Pigments Consortium)	Industry or trade association	285
Comment received				
-				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170220 CLH Cobalt - Letter of Support IP.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Walter AG	Company-Downstream user	286
Comment received				
<p>The current self-classification of cobalt metal as Reproductive Toxicant Category 2 is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. As pointed out by CDI/CoRC and ITIA further testing related to the reproductive toxicity is ongoing. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>IMPACTS of the Repro 1B proposal:</p> <p>A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.</p> <p>B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.</p> <p>Impacts of the CLH proposal are described more closely in the attachment [Reference 1 Walter AG response CLH-Prop_CO_20170222].</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 Walter AG response CLH-Prop_CO_20170222.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Wolfram Bergbau und Hütten AG	Company-Downstream user	287
Comment received				
<p>The current self-classification of cobalt metal as Reproductive Toxicant Category 2 is based on thorough analysis of available data and scientific assessment done by the CoRC following the CLP classification guidance. As pointed out by CDI/CoRC and ITIA further testing related to the reproductive toxicity is ongoing. We support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal. January 2017.</p> <p>IMPACTS of the Repro 1B proposal:</p> <p>A) Overly strict precautionary classification, which is not based on scientific facts, pushes towards totally eliminating exposures and transforming the industry into using closed processes similar to the ones in pharmaceutical industry. Making that kind of changes is very challenging or impossible in the article manufacturing industry like ours. It also requires innovations and totally new techniques.</p> <p>B) Merely increasing the cost of manufacturing and recycling in the EU without a health benefit/improvement has a negative impact on the competitiveness of the EU manufacturing and recycling industry in the extremely competitive global market. It contributes to considering moving production and recycling to regions outside of the EU.</p> <p>Impacts of the CLH proposal are described more closely in the attachment [Reference 1 WBH response 20170221].</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Reference 1 WBH response 20170221.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	United Kingdom	International Tungsten Industry Association	Industry or trade association	288
Comment received				
<p>Proposed Classification from Reproductive Category 2 to Reproductive Category 1</p> <p>Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as Reproductive Toxicant Category 2 Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels based on available information about cobalt's reproductive toxicity on experimental animals. This classification can be confirmed or reconsidered after the ongoing tests conducted by the Cobalt REACH Consortium (CoRC) which include a 2nd species pre-natal developmental toxicity (PNDT) study and an EOGRTS (Extended One-Generation Reproductive Toxicity Study) on a cobalt analogue, are completed.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment ITIA Response - Co CLH 2017_02_22.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
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22.02.2017	Germany	EBRC	Please select organisation type..	289
Comment received				
<p>Inappropriate classification proposal for reproductive toxicity due to pending testing proposal</p> <p>The CLH report proposes to classify cobalt metal as toxic to reproduction (Repr 1B; H360F).</p> <p>In accordance with the Guidance on the preparation of CLH dossiers (Version 2.0 August 2014), section 5.2.7, a proposed harmonised classification shall be carefully considered, in case testing is proposed or ongoing and in case the results are of potential relevance.</p> <p>A testing proposal for a reproductive toxicity study (2-generation or extended one-generation study) has been published on the ECHA website on 2nd September 2011. Since this higher-tier study would represent the most reliable information for reproductive toxicity, the outcome of the testing should be awaited before submission of a proposal for a harmonised classification.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Hille & Müller Steel, Tata Steel Europe	Company-Downstream user	290
Comment received				
<p>TSE supports the scientific arguments against the proposed reprotoxic category 1B classification (H360F) for cobalt metal as detailed by the Cobalt Industry.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Tata Steel Hille and Muller Position paper.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Germany	Arno Friedrichs Hartmetall GmbH & Co.KG	Company-Downstream user	291
Comment received				
<p>market impact from CMR stigmatization:</p> <ul style="list-style-type: none"> - negative impact on supply chains because sales of cobalt based alloys will likely reduce significantly due to customer perception (phasing out without need) - larger costs in handling cobalt products in downstream sectors (e.g. due to minimize occupational exposure) 				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Team Stainless / Eurofer	Industry or trade association	292
Comment received				
<p>Team stainless supports the scientific arguments against the proposed reprotoxic category 1B classification (H360F) for cobalt metal as detailed by the Cobalt Industry.</p> <p>Although not specifically measured in the epidemiological studies cited in the section on</p>				

carcinogenicity, given an understanding of the exposures resulting from the unavoidable presence of trace amounts of cobalt in stainless steel in excess of the proposed SCL, and the much higher exposures to cobalt during the manufacture of high alloy materials, evidence of reprotoxicity would be expected to be evident in the worker and general public exposures. This is especially true in the case of medical implants given the scrutiny for toxicity and adverse health effects given to such applications for many years.

Meanwhile, in their survey of published literature on the toxicity of stainless steel by the Finnish Institute of Occupational Health, no incidence of reprotoxicity was reported. None of the main alloying constituents of stainless steel demonstrate reprotoxic properties, in spite of them containing trace amounts of cobalt in excess of the proposed SCL.

References:

“Review on Toxicity of Stainless Steel”, T. Santonen, H. Stockmann-Juvala, and A. Zitting. Finnish Institute of Occupational Health, 2010, Helsinki 2010-11-17, ISBN 978-952-261-039-3.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final - Team Stainless Position Paper for the Cobalt Issue (signed).pdf

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Sweden	Svemin	Industry or trade association	293
Comment received				
We support the technical comments and the position of the REACH Consortium Ltd (CoRC) and the Cobalt Development Institut (CDI)				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	Final Slags Task Force of Eurometaux	Industry or trade association	294
Comment received				
The members of the Final Slag Taskforce of Eurometaux support the technical position of the CDI/CoRC (Cobalt Development Institute / Cobalt REACH consortium, 2017).				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Final Slags TF Eurometaux Comments on Co CLH proposal 20170221.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
22.02.2017	Belgium	European Copper Institute	Industry or trade association	295
Comment received				
The European Copper Institute supports the technical position of the CDI/CoRC (Cobalt Development Institute / Cobalt REACH consortium, 2017), as outlined in the Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal of January 2017.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment 20170222_ECI-PC-Cobalt-CLH_public-attachment.pdf				

Date	Country	Organisation	Type of Organisation	Comment
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				number
22.02.2017	Belgium	Nickel Institute	Industry or trade association	296
Comment received				
<p>The NI strongly supports the CoRC comments in opposing the Dutch proposal to classify Co metal as a Reprotox Category 1B:</p> <p>(1) Reproductive studies need to be considered in a weight-of-evidence approach (WOE), taking into account the reliability, consistency and quality of the studies. This is an absolute requirement to be able to distinguish between direct Co ion effects on sex organs and fertility, and effects that are secondary to lung or systemic generalized toxicity.</p> <p>(2) The existing combined data for Co metal and soluble Co salts do not support a Category 1B reproductive toxicity classification for Co metal. Effects on sex organs and sperm are only observed at levels above those that cause significant lung toxicity (in inhalation studies) or systemic toxicity (in oral studies), while proper studies that examine fertility and developmental effects are lacking.</p> <p>(3) Definitive studies of fertility and developmental effects of Co ion must be conducted (e.g., EOGRTS) and the reprotoxic potential of Co metal assessed once these studies are completed.</p> <p>(4) In the meantime, it is appropriate to maintain the current self-classification of Co metal as Reprotox Cat 2.</p> <p>The existing data for Cobalt metal and soluble Cobalt salts do not support a Category 1B Reproductive toxicity classification for Cobalt metal.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment 170220-Co metal implications for Ni - input in consultation.pdf</p>				

Date	Country	Organisation	Type of Organisation	Comment number
14.02.2017	Germany		MemberState	297
Comment received				
The German CA agrees to the proposed classification of Cobalt.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	H.C. Starck	Company-Downstream user	298
Comment received				
H.C. Starck fully supports and subscribes to the comments submitted to this consultation by ITIA and CoRC.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Germany	Kennametal Inc.	Company-Downstream user	299
Comment received				
Based on available scientific data cobalt metal should be classified as a Reproductive				

Toxicant Category 2.
 Following the CLP classification guidelines, the hardmetal industry has self-classified powder mixtures of tungsten carbide and cobalt metal as Reproductive Toxicant Category 2 based on available information about cobalt's reproductive toxicity on experimental animals. This classification can be confirmed or reconsidered after the ongoing tests conducted by the Cobalt REACH Consortium are completed. These tests include a 2nd species pre-natal developmental toxicity (PNDT) study and an EOGRTS (Extended One-Generation Reproductive Toxicity Study) on a cobalt analogue.
 Overall, Kennametal supports the CDI/CoRC industry position to classify cobalt metal as a Reproductive Toxicant Category 2.

ECHA note – An attachment was submitted with the comment above. Refer to public attachment 2017-02 Kennametal Cobalt CLH Response.pdf

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Sweden	Outokumpu Oyj	Company-Manufacturer	300
Comment received				
<p>Outokumpu supports support the technical position of the CDI/CoRC (2017), as outlined in: Message to Industry stakeholders regarding the NL CLH proposal on Cobalt Metal, January 2017.</p> <p>The reprotoxicity 1B classification proposed by the Netherlands would affect a significant amount of the stainless steels produced due to residual cobalt in the material. Again this is clearly an over-classification. The epidemiological studies in the stainless steel industry have not indicated reprotoxicity to be a concern. Also, in a 28 days repeated dose inhalation toxicity study with stainless steel powder in rats, no changes in reproductive organ weights were seen.</p> <p>Reference Review on Toxicity of Stainless Steel", T. Santonen, H. Stockmann-Juvala, and A. Zitting. Finnish Institute of Occupational Health, 2010, Helsinki 2010-11-17, ISBN 978-952-261-039-3.</p>				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	Belgium	Euroalliages	Industry or trade association	301
Comment received				
We support the CDI/CoRC technical response and we refer to it.				

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	France		MemberState	302
Comment received				
<p>Fertility Data on soluble cobalt compounds provides evidence that the cobalt ion impairs male fertility through a systemic mode of action (observed by inhalation and oral route). Effects on testis and sperm parameters are also observed with cobalt although only inhalation studies are available. But it confirms the systemic bioavailability of cobalt and the relevance of soluble cobalt findings for cobalt. Overall, classification Repro 1B- H360F is considered</p>				

justified for cobalt.
Development
Although there is no strong evidence of a developmental effect, this endpoint should be evaluated carefully.

Date	Country	Organisation	Type of Organisation	Comment number
21.02.2017	United Kingdom	Outokumpu Stainless Ltd	Company-Manufacturer	303

Comment received

Outokumpu supports the scientific arguments of CDI/CoRC technical comments. The reprotoxicity 1B classification proposed by the Netherlands would affect a significant amount of the stainless steels produced due to residual cobalt in the material. Again this is clearly an over-classification. The epidemiological studies in the stainless steel industry have not indicated reprotoxicity to be a concern. Also, in a 28 days repeated dose inhalation toxicity study with stainless steel powder in rats, no changes in reproductive organ weights were seen.

Reference

Review on Toxicity of Stainless Steel", T. Santonen, H. Stockmann-Juvala, and A. Zitting. Finnish Institute of Occupational Health, 2010, Helsinki 2010-11-17, ISBN 978-952-261-039-3.

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	Germany	The Cobalt Development Institute and Cobalt REACH Consortium	Industry or trade association	304

Comment received

The CDI/CoRC disagree with the proposed classification of Co metal as Repr 1B, and propose to retain the current self-classification as Repr 2 for scientific as well as procedural reasons outlined below.

CDI/CoRC position: classification as Repr 2 for fertility (interim self-classification)

Summary

In order to meet the criteria for classification as Repr Cat 1B, reproductive effects must be "observed in the absence of other toxic effects". Further, if occurring together with other toxic effects, the adverse effect on reproduction needs to be considered "not to be a secondary non-specific consequence of other toxic effects".

Data on cobalt (Co) metal

In the NTP Co metal inhalation study, all effects on testes were observed in the presence of severe lung toxicity, sometimes with haematological effects. The LOAECs for lung impairment and haematological effects were lower than those for effects on testes in each case. There is a plausible mode of action by which the testes effects are secondary to hypoxia. Therefore, these findings do not present sufficient evidence for a classification of Co metal as a Cat 1B reproductive toxicant.

There were no adverse findings on reproduction or development in a p.o. study (OECD 422) with Co metal powder, despite overt toxicity (premature deaths in the high dose group (males), and in all females, except at the lowest dose).

Data on soluble Co salts

Published studies indicate a hazard for male reproduction at very high doses, however, all studies suffer from reporting and quality deficiencies, such that it is impossible to evaluate whether or not the toxicity was secondary to weight reductions, decreased food or water intake, or to overall morbidity. Guideline compliant studies, in which the MTD is not exceeded, do not indicate an effect on reproduction or development. Further testing is warranted for the endpoint reproductive toxicity.

The self-classification as Repr 2 (F) is an interim self-classification to highlight a potential hazard for Co metal, for which currently no sufficiently convincing evidence can be produced. Further testing to address this endpoint is planned, and testing proposals have been submitted to ECHA. The classification of Co metal will be reviewed, and revised as necessary, once those data are available.

DETAILED COMMENTS

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1) Data on Co metal

The current industry Repr self-classification of Co metal is in category 2, not 1, for the reasons and considerations outlined below:

The present CLH proposal is based on effects observed in the NTP inhalation study with Co metal (Behl and Hooth 2014), which resulted in a decrease in sperm motility at doses above 0.625 mg Co/m³ (rats) and above 1.25 mg Co/m³ (mice) in the 13-week studies. Mice were generally less sensitive to this effect. There were effects on male reproductive organs in the chronic inhalation study in rats and mice at 5 mg Co/m³ (testes infarction in rats, effect in mice less severe). The NTP Study did not "provide clear evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects" (CLP Regulation Annex I), as the males were not paired with females to test for fertility or sexual function. Further, other toxic effects were present, as outlined below.

In the current CLH proposal, section 4.11 "Toxicity for reproduction", table 71 "Summary table of relevant repeated dose and reproductive toxicity studies", it is erroneously stated that decreased sperm motility was observed at less than or equal to (\leq) 0.625 mg Co/m³ in the 13-week (3 month) Co metal inhalation study in rats (Behl and Hooth 2014). It is correctly stated in the NTP report that "Sperm motility was significantly decreased in males exposed to 1.25, 2.5, or 5 mg/m³, and the decrease in the 5 mg/m³ group was approximately 8% (Tables 7 and H1)" (page 53, line 1-4 of (Behl and Hooth 2014)). This indicates that 0.625 mg Co/m³ represents the NOAEC for testes effects in male rats, an exposure level which caused toxic effects on haematological parameters and lung. The testes effects occurred after, not before, the onset of a highly significant ($p < 0.01$) increase in haematocrit, packed cell volume, haemoglobin and erythrocytes, as well as a highly significant ($p < 0.01$) chronic active inflammation in the lung and pulmonary alveolar proteinosis in all exposed male rats.

In mice, effects on sperm motility were seen at greater than or equal to (\geq) 2.5 mg Co/m³. Effects on the germinal epithelium and epididymis were seen at 10 mg Co/m³ (the highest dose). In comparison, toxicity in the lung was observed at greater than or equal to (\geq) 0.625 mg Co/m³, manifesting itself as alveolar histiocytic infiltration, cytoplasmic

vacuolisation in the bronchiolar epithelium, and squamous metaplasia (larynx).

The current CLH proposal does not show the original NTP rat and mice data (tables for effects on reproductive parameters and lung pathology) side-by-side. These tables are presented in part A of the appendix to this commenting section (Repr appendix), for a direct comparison of the effects on lung versus male reproductive tissues at the different exposure levels.

The effects on testes were not “observed in the absence of other toxic effects”, which is one of the requirements for classification as a Cat 1B reproductive toxicant (CLP Regulation Annex I). Further, if occurring together with other toxic effects, the adverse effect on reproduction needs to be considered not to be a secondary non-specific consequence of other toxic effects”.

The second condition is reviewed in Bomhard and Gelbke (2013), where it is stated that “The adverse effects of acute, intermittent or chronic hypoxia on male fertility are well known for a long time”, and where the effects of hypoxia from lack of oxygen (such as in high altitude) versus chemical hypoxia (as caused by agents inducing hypoxia response transcription factors and genes) are explored. The testicular interstitium operates on the verge of hypoxia, at oxygen tensions of 12 to 15 mm Hg in liver or 58 mm Hg in intestine (Carreau, El Hafny-Rahbi et al. 2011)), and an oxygen deficit can lead to secondary impairment of testicular function (Reyes, Farias et al. 2012). Because oxygen tension is already very low in testes, this tissue is more sensitive to tissue hypoxia and hypoxaemia (hypoxic conditions in blood). This is well known from healthy mountaineers exposing themselves to high altitude. They experience reduced blood oxygen content that is observed in parallel with impairment of testicular function, but no other adverse effects. Similar findings are described for experimental animals exposed to hypobaric oxygen. It is interesting to note that impairment of testicular function has been observed in spite of a compensatory polycythaemia (Bomhard and Gelbke 2013). It has in fact been demonstrated that “excessive erythrocytosis does not elevate capillary oxygen delivery” (Frietsch, Gassmann et al. 2007). While an increase in erythrocytes does elevate the oxygen tension in the larger blood vessels, the microcirculation and oxygen tension in smaller vessels and tissues is actually decreased due to increased blood viscosity (Frietsch, Gassmann et al. 2007).

Data presented and reviewed by Bomhard and Gelbke (2013) show that chemically induced lung toxicity, if it involves alveolar toxicity such as pulmonary alveolar proteinosis, can lead to systemic hypoxia, which in turn has the same deleterious effect on testes as limited oxygen supply due to high altitude.

In summary, in the NTP Co metal inhalation study (Behl and Hooth 2014), the LOAECs for lung impairment and erythrocytosis are lower than that for effects on testes, and there is a plausible mode of action by which the testes effects are secondary to hypoxia. Therefore, an inhalation toxicity study with testes findings in the presence of lung toxicity does not present sufficient evidence for a classification of Co metal as a Cat 1B reproductive toxicant.

No male reproductive toxicity following Co metal exposure was observed in a per oral (p.o.) study with Co metal powder. In this GLP-compliant OECD 422 study (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats), animals were exposed to 30, 100, 300 and 1000 mg Co/kg bw/day (Hansen 2013). Overt toxicity was observed in this study (premature deaths in the 1000 mg group (males), and in the 100, 300 and 1000 mg groups (females)), and general toxicity, such as piloerection, reduced motility and reduced food consumption, was observed at all doses except the lowest dose. Despite the high doses used, and the clear general toxicity, no reproductive

effects were seen on either males or females.

The applied doses were based on a 14-day range finder, with the identical test item, test item preparation, application and rat strain, carried out immediately before the full OECD 422 study. In the 14-day range finder, all doses, up to 1000 mg Co/kg bw/day, were well tolerated. Based on the lack of effects up to 14 days, the same doses were selected for the full study. However, in the OECD 422 study, the premature deaths occurred from day 15 – 53 (females) and day 18 – 24 (males) indicating delayed toxicity impossible to predict with the range finder. Due to the excessive mortality in this study, the required number of animals per group (10 of each sex) was not achieved to ensure compliance with the OECD guideline. It is, however, a GLP study with sufficient and detailed reporting to draw conclusions from the mid- and low-dose groups.

Male rats tolerated the Co metal p.o. exposure better than the females, and it was possible to examine reproductive parameters in all males from the 30, 100 and 300 mg Co/kg bw/day dose groups (9 of the 10 males in the 1000 mg Co/kg bw/day group deceased prematurely, and no reproductive data were collected from this group).

The number of ultrasound-resistant spermatids per gram testicular tissue was not influenced at any of the tested dose levels of 30, 100 or 300 mg Co powder/ kg b.w./day. No test item-related changes were noted in the percentage of motile spermatozoa in the epididymal cauda for the males treated with either 30, 100 or 300 mg Co powder/kg b.w./day. No test item-related difference was noted for the mean percentage of morphologically normal spermatids in the dosed males compared with the control animals. The only finding was a reduction in weight of the epididymis in the lowest dose group (30 mg/kg bw/kg), which did not occur in the higher dose levels. Due to the lack of dose-response, this was considered a spurious finding by the study director. No other effect was seen on the relative and absolute organ weights of the male rats treated with 30, 100 or 300 mg Co powder/kg b.w./day.

The histopathological examination revealed no test item-related changes in the organs or tissues of male rats after treatment with either 30, 100 or 300 mg Co powder /kg b.w./day.

The female animals did not tolerate the treatment well, and premature deaths occurred in all dose groups, except at 30 mg/kg bw/day. At 1000 mg/kg bw/day, all females deceased prematurely, and at 300 and 100 mg/kg bw/day, 8 of 10 and 5 of 10 females, respectively, deceased prematurely. The fertility of female rats was not influenced at 30 mg Co/kg bw/day, the only dose levels where all animals survived. Fertility effects were observed at 100 and 300 mg Co/kg bw/day, doses which also induced mortality. There was no effect on any parameter of the F1 generation at 30 mg Co/kg bw/day.

The data tables from this study are provided in part B of the appendix to this commenting section (Repr appendix, part B).

The authors of the present CLH proposal state that Co probably did not become bioavailable in this study, because of the lack of haematological effects, a known highly sensitive target of Co. While it is surprising that the expected haematological effects did not occur, it is difficult to explain the non-specific toxicity, if not caused by the test item. The study showed no reproductive effects in males, and in females only at doses causing morbidity and mortality, arguing that Co is not a primary reproductive toxicant.

The inhalation study design (NTP) was not sufficient to study fertility effects. The oral study (OECD 422) confirmed that the testes effects may have been secondary to hypoxia since no fertility effects were observed below the MTD. These studies do not support classification of

Co metal as a reproductive toxicant.

2 - Data on soluble Co salts

The hypothesis that the Co ion causes general or non-reproductive toxicity before affecting the male or female reproductive system is confirmed by several recent studies, which are part of a testing proposal granted under REACH, and in compliance with the ECHA MSC in its 30th meeting in June 2013. A highly bioavailable Co substance, CoCl₂, was tested in a 90-day oral repeated dose toxicity (RDT) study (OECD 408), which included a screening for reproductive endpoints (Hansen 2015). Also, a pre-natal developmental toxicity study (OECD 414) was conducted with the same test item (Hansen 2015).

The 90-day oral toxicity study on CoCl₂ is described in detail in the repeated dose toxicity section of the present CLH proposal, but is only mentioned briefly in the reproductive toxicity section. This study is not considered relevant by the authors of the CLH proposal, as the study dose levels were considered too low. It is stated in the CLH proposal: "the applied dose levels (30 mg CoCl₂ hexahydrate/kg bw/day = 7.4 mg Co/kg bw/day) were below the dose level of approximately 10-20 mg Co/kg bw/day that induces structural and functional effects on male fertility in rats." Such high doses were actually administered in the cobalt metal oral OECD 422 study, but showed no fertility effects.

In the view of the CDI and CoRC, the three GLP-compliant studies on Co metal powder and CoCl₂ are the key studies for the endpoint reproductive toxicity. In the context of a harmonised classification for this endpoint, these studies should be considered as primary evidence.

OECD 408 Repeated dose toxicity: Cobalt dichloride hexahydrate (Hansen 2015)

100 animals (40 male and 40 female rats for the main study and 10 male and 10 female rats for the recovery study) were examined in this study of repeated dose toxicity (with screening for reproductive parameters) from exposure to 0, 3, 10 or 30 mg/kg bw/d CoCl₂ hexahydrate. None of the animals died prematurely. No test item-related changes were noted for neurological screening, behaviour, external appearance, body posture, or movement and coordination capabilities, food and drinking water consumption, faeces, oestrous cycle urinalysis, hormone levels, ophthalmoscopic examination, macroscopic post-mortem findings, or organ weights including testes and prostate.

The body weight of the male and female animals treated with the highest dosage of 30 mg CoCl₂ hexahydrate/kg bw/d was reduced by 5 to 14% from test day 8 onwards and by 5 to 10% from test day 29 onwards, respectively, compared to the control group. The body weight at autopsy was reduced by 11% (males) and 9% (females), respectively. At the end of the recovery period, the body weight of the male and female animals was still reduced by 17% or by 13%, respectively, on test day 118 compared to the control group.

Male animals showed a statistically significant increase in haemoglobin, total red blood cells, and haematocrit at 10 and 30 mg/kg bw/d. Females were noted to have these same changes at the highest tested dose (30 mg/kg bw/d). Males also showed a statistically significant reduction in platelets at 30 mg/kg bw/d (see table in Repr appendix part C). No test item-related influence on haematological parameters was noted for the male and female animals treated with 3 mg CoCl₂ hexahydrate/kg bw/day at the end of the treatment period.

Histopathology revealed a significant and test item-related increase in erythroid hyperplasia in the bone marrow of male and female animals treated with 10 mg or 30 mg CoCl₂ hexahydrate/kg bw/d compared to the controls. All animals dosed at 3 mg CoCl₂ hexahydrate/kg bw/d showed no relevant changes when compared to the controls for both sexes. All changes previously observed in haematological and biochemical parameters and at histological examination after repeated treatment with 30 mg CoCl₂ hexahydrate/kg bw/d were fully reversible after 4 weeks of recovery.

The no observed adverse effect level (NOAEL) for repeated dose toxicity for CoCl₂ hexahydrate was 3 mg/kg bw/day, based on the onset of haematological effects at the intermediate dose (10 mg CoCl₂ hexahydrate/kg bw/d). These changes (an increase in haemoglobin, red blood cells, haematocrit, and a decrease in reticulocytes and platelets) were statistically significant and exceeded a 10% difference from the control. The haematological changes followed a dose-response, as they were more pronounced at the high dose (30 mg CoCl₂ hexahydrate/kg bw/d). The biological relevance of the haematological findings was underlined by the observed erythroid hyperplasia in the bone marrow of the treated animals at 10 and 30 mg CoCl₂ hexahydrate/kg bw/d. The NOAEL for reproductive toxicity in males and females was 30 mg CoCl₂ hexahydrate/kg bw/d, based on the complete absence of findings in any reproductive parameters in the male and female animals at this dose level, including lack of effect on the reproductive organs (males: epididymis, prostate and seminal vesicles with coagulating glands, testicle; females: ovary and oviducts, mammary gland, uterus incl. cervix, vagina), oestrous cycle and blood hormone levels.

The authors of the current CLH proposal dismiss this study for the reason that the doses are "too low", and that "No justification for the test dose levels was provided." The justification for the test dose levels is a dose range finding study, which preceded the 90-day study, but which is not reported as part of the 90-day study (Leuschner 2015). The range finder (28 days) was conducted with 3, 10, 30, 100 and 300 mg CoCl₂-hexahydrate/kg bw/day. The dose groups of 100 and 300 mg CoCl₂/kg bw/day (equals 22 and 74 mg Co/kg bw/day) showed 10% and 50% mortality, respectively. In order to ensure a guideline-compliant conduct of the 90-day study (which was required by November 2015 under a legal ECHA deadline), it was crucial to avoid any loss of study animals due to premature death. Also, in the Co metal study (OECD 422, described above), a delayed effect of Co had been observed, which needed to be factored into the dose selection for the 90-day study. Therefore, the highest dose in the 90-day study was 30 mg/kg bw/day, the dose at which no deaths occurred in the range finder.

Adverse effects (weight reduction and erythrocytosis) were observed in this study, and - to confirm delivery of Co levels to the target organs - Co levels were measured in all tissues (except heart and thyroid) of the high dose animals. Increases of Co concentrations were seen in all tissues when compared to the controls. Co levels were at least 16-fold higher in the high dose animals when compared to the control (exposed to baseline Co levels in the diet). Co levels in the male reproductive organs were 0.13 µg Co/g testes and 0.29 µg Co/g prostate, compared to control levels below 0.008 µg Co/g tissue. Co levels in the female reproductive organs were 0.32 µg Co/g uterus and 0.58 µg Co/g ovary, compared to control levels below 0.03 µg Co/g tissue. These data were generated as part of the 90-day OECD 408 study with CoCl₂, and are reported in a separate study report (Target Organ Study, part of a Toxicokinetic Study currently conducted by the CDI). This study report is currently in draft, and we herewith notify availability of those data to be reviewed alongside the CLH proposal by the RAC in their deliberations of Co metal classifications.

Despite the study having reached the MTD (by reduction in weight of more than 10% versus control), and by adverse effects on bone marrow and haematological parameters) and a 16-fold increase of Co in the target tissues, no adverse effects on fertility were observed.

OECD 414 Prenatal Developmental Toxicity Study: Cobalt dichloride hexahydrate (Hansen 2015)

100 female rats and 80 litters were examined in this study of prenatal developmental toxicity from exposure to 0, 25, 50 or 100 mg CoCl₂ hexahydrate/kg bw/d. None of the animals died prematurely. No test item-related changes were noted for drinking water consumption.

Dams dosed with 25 mg CoCl₂ hexahydrate/kg bw/d showed a 5.3% reduction in net body weight change compared to controls between gestation days 6 and 20 (control: +38.4 g,

low dose: +18.1 g). Carcass weights were reduced in comparison to the control group by 8.7%.

Dams dosed with 50 or 100 mg CoCl₂ hexahydrate/kg bw/d showed statistically significant reduction in body weights in comparison to the control group from gestation day 9 that continued during the further course of the study, leading to body weights on gestation day 20, that were 14.2% (intermediate dose group) or 15.1% (high dose group) below the value of the control group. These dams showed a statistically significantly reduced food intake between gestation days 7 and 20 (44.5% below the control group for the dams of the intermediate dose group and 59.1% below the control group for the dams of the high dose group between gestation days 19 and 20). Gastro-intestinal lesions in form of haemorrhagic foci in the stomach and intestines with a dark content were noted in dams dosed with 50 or 100 mg CoCl₂ hexahydrate/kg bw/d (3 of 20 dams and 9 of 20 dams, respectively). No test item related influence was noted on the gravid uterus weight. The carcass weights were statistically significantly reduced in comparison to the control group by 18.2 and 18.1% for the dams treated with 50 or 100 mg CoCl₂ hexahydrate/kg bw/d.

Statistically significant changes were noted for several haematological parameters for the dams treated with 50 or 100 mg CoCl₂ hexahydrate/kg bw/d (in haemoglobin, total red blood cells, haematocrit and platelets), see table in Repr appendix, part C.

No test item-related changes were noted for the number of resorptions and for the post-implantation loss. No test item-related dead foetuses were noted in the study. There were no noteworthy differences in sex distribution, foetal weights, or placental weights. No test item-related foetal malformations, variations, or skeletal retardations were noted from external, internal, skeletal and soft tissue evaluation.

The maternal NOAEL is 25 mg/kg bw/d, based on the lack of significant general toxicity (body weights, food consumption) and lack of significant haematological changes at this dose level. Further, in this dose group, there was a stable body weight gain throughout the study, whereas body weight development and final body weights were severely affected in the intermediate and high dose groups.

The NOAEL for the foetal organism is 100 mg/kg bw/day, based on the lack of foetal toxicity observed in this study. The reduction of mean foetal weights in the mid and the high dose groups was considered a secondary effect related to the general toxicity and lower body weights and body weight gains in dams of these dose groups. In addition, the weights of foetuses were still within the range of the historical background data of the laboratory (LPT).

In summary the study reached the MTD, resulted in effects linked to high systemic Co delivery but did not show any reproductive effects.

NTP Study: Co sulfate heptahydrate inhalation studies (16 day, 13 week and 2 year) (Bucher 1991, Bucher 1998)

Another highly reliable study is the NTP chronic inhalation study with Co sulfate heptahydrate with its range finder. These studies show that the LOAEC of Co sulfate for inflammatory responses in the lung is equal (male rats in 16-day study) or 10-fold lower (male mice 16-day study) than the LOAEC for testes atrophy, suggesting that the testes effect was secondary to the lung toxicity. In the 13-week exposure study, respiratory metaplasia began at 0.3 mg/m³, and respiratory toxicity became more pronounced at 1 mg/m³, with lung inflammation and alveolar histiocytosis in both male rats and mice. Effects on male reproductive organs begin to set in at 30 mg/m³ in male rats, and at 3 mg/m³ in mice.

The chronic inhalation study with cobalt sulfate heptahydrate did not yield a NOAEC for lung toxicity, and severe lung toxicity was evident at all exposure levels of this study (0.3, 3 and 1 mg/m³, adverse effects included inflammation, metaplasia, hyperplasia and neoplasms). There was however a complete absence of effects on male or female reproductive parameters, even at the highest dose tested. This is consistent with the previous observation that testes effects require exposures that are much higher than those causing

lung toxicity.

In summary, there is no reliable study demonstrating an isolated, primary effect on male or female reproductive parameters by exposure to cobalt (as metal or soluble salt). The five highly reliable studies do demonstrate that under cobalt exposure, effects on male reproductive organs are only observed at the same or higher exposures than those resulting in respiratory toxicity or hypoxia or both. In reliable per oral studies, at doses sufficient to trigger a moderate hypoxic response, no reproductive toxicity was seen.

The remaining 12 studies of lesser reliability (mainly due to reporting deficiencies and non-guideline testing protocols) report effects on male reproductive organs at very high doses. In these studies, some critical observations such as animal morbidity and mortality were not reported, and it is not clear whether the reproductive toxicity was in fact seen in the absence of other toxic effects. It is further unclear whether or not the animals displaying testes effects were still taking in sufficient amounts of feed.

Feed restriction has been shown to lead to male rat reproductive effects in several studies, e.g. Levin, Semler et al. (1993), Rehm, White et al. (2008), or Muzi-Filho, Bezerra et al. (2013), and the severity of reduced feed intake needs to be taken into account when interpreting reproductive toxicity studies (Chapin, Gulati et al. 1993a, Chapin, Gulati et al. 1993b).

Four toxicity studies in mice have shown male reproductive organ damage (Pedigo, George et al. 1988, Anderson, Pedigo et al. 1992, Pedigo and Vernon 1993, Elbethieha, Al-Thani et al. 2008). Each of these studies used animal dosing that resulted in general morbidity or mortality of the test animals. In a study by Pedigo, George et al. (1988), mice were given 100, 200 or 400 ppm CoCl₂ in drinking water. There was no reporting of feed consumption in this study, or of toxic effects other than those observed on the male reproductive tissue, however the high dose animals demonstrating reduction in testes weight also failed to gain body weight from week 5 until the conclusion of the experiment at week 13, and drank 18-26% less water than control or lower dose animals. Decreased testicular weight was first noted at week 9, while reduction in sperm numbers was noted at week 11.

A similar oral over-exposure to cobalt chloride was shown to cause damage to testicular tissue, to sperm number and to sperm motility in male mice (Anderson, Pedigo et al. 1992). Mice were given the same dose that had produced morbidity in the previous study (Pedigo, George et al. 1988) (400 ppm CoCl₂ in drinking water) and again testes effects were reported following 9 weeks of treatment at 400ppm. Unfortunately, weight development, food intake, morbidity and general toxicity were not recorded. It can be assumed that this repeat study design would result in the same general toxicity (reduced body weight gain and reduced water intake) and morbidity seen earlier in the Pedigo 1988 study.

The effect of twelve weeks' ingestion of cobalt chloride (CoCl₂) was investigated on the fertility of adult male Swiss mice (Elbethieha, Al-Thani et al. 2008). Sexually mature male mice were exposed to 200, 400 and 800 ppm cobalt chloride dissolved in drinking water. Absolute epididymal weight, and the relative or absolute testes weights, sperm counts and daily sperm production were significantly reduced in males that ingested cobalt chloride at concentrations of 400 or 800 ppm. There was a statistically significant dose-related reduction in body weight gain by 12 weeks, however food intake was not recorded in this study. Two animals out of 10 and one out of 10 died during the 10th week of the exposure to 800 and 400 ppm cobalt chloride, respectively.

3 – Conclusion

The CDI/CoRC view the overall weight of evidence as follows:

- 3 highly reliable per oral studies (OECD 422, Co metal; OECD 408 and 414, CoCl₂) are negative for fertility and developmental effects
- 2 highly reliable inhalation studies indicate fertility effects only in the presence of severe respiratory toxicity
- Several literature studies (non-guideline testing protocols) indicating effects at very high

doses, but without reporting of morbidity and food intake

Although the weight of evidence from the highly reliable (Klimisch 1) studies would indicate no effect of Co metal on fertility endpoints, this is considered a sufficiently ambiguous database to warrant further testing for this endpoint by conducting an extended one-generation reproductive toxicity study (EOGRTS). The current application of a self-classification of Reproductive Toxicity Cat 2 for Co metal reflects the wording in the classification criteria, according to which Cat 2 may be chosen "where the evidence is not sufficiently convincing to place the substance in Category 1."

It needs to be stressed that the self-classification as Repr 2 (F) is seen as an interim self-classification to highlight a potential hazard, for which currently no sufficiently convincing evidence can be produced. Further testing to address this endpoint is planned, and testing proposals have been submitted to ECHA. The classification of Co metal will be reviewed, and revised as necessary, once those data are available.

In accordance with the ECHA Guidance on the preparation of CLH dossiers (Version 2.0, August 2014), a decision on the classification proposal for fertility impairment of cobalt metal should be postponed, in the light of the fact that a testing proposal for a EOGRTS has been submitted by CoRC for the soluble cobalt substances group, in which cobalt metal is included (cf. chapter 5.2.7, p.29 of the Guidance).

It is therefore proposed to remove the entire section on reproductive toxicity and to re-open the CLH procedure for the endpoint reproductive toxicity, after the proposed experimental testing is final.

4 – Comments related to table 71

Two dominant lethal assays are added to table 71. These studies should not be listed for the reproductive toxicity endpoint, as the study design of these assays is aimed at detecting germ cell mutagenicity, and not fertility effects. The guideline for these assays (OECD/OCDE 478 (Adopted: 29 July 2016) OECD GUIDELINE FOR TESTING OF CHEMICALS Rodent Dominant Lethal Test) states that "the MTD must not adversely affect mating success", indicating that a guideline compliant dominant lethal assay does not affect male fertility.

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment Public attachmts Co metal PC.zip

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Repr appendix, CONFIDENTIAL.pdf

Date	Country	Organisation	Type of Organisation	Comment number
20.02.2017	France	FEPA	Industry or trade association	305
Comment received				
The CDI and CoRC, as the main holders of scientific data on cobalt, have prepared thorough scientific comments on this point. FEPA is supporting these comments.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment FEPA_Answer to the public consultation cobalt metal_1.pdf				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	France	MFPM : Manufacture Française des pneumatiques Michelin	Company-Downstream user	306
Comment received				
• Michelin supports the position of the Consortium of Cobalt and CDI.				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Germany	TIGRA GmbH	Company-Manufacturer	307
Comment received				
We support the technical position of the Cobalt REACH Consortium Ltd. (CoRC) and the Cobalt Development Institute (CDI).				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	308
Comment received				
Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	309
Comment received				

No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	310
Comment received				
Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	311
Comment received				
No classification for mutagenicity based on an expert peer review (which has been accepted by OECD CoCAM).				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	312
Comment received				
Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification				

Date	Country	Organisation	Type of Organisation	Comment number
17.02.2017	Australia		Individual	313
Comment received				
Repr 2 (H361) at a GCL of $\geq 3\%$ cobalt levels as a provisional classification pending the outcome of second phase of long-term reproductive toxicity testing [ie Extended One-Generation Reproductive Toxicity Study (EOGRTS) proposal submitted to ECHA], and noting that the current data set does not support a Repr 1B classification				

PUBLIC ATTACHMENTS

1. SSAB STATEMENT DOCUMENT on Cobalt Feb 2017.pdf [Please refer to comment No. 8, 157, 169, 245]
2. 20170224-Cobalt-CLP_ACEA-final.pdf [Please refer to comment No. 11, 160, 171, 247]
3. EPBA comments paper_cobalt_24022017.pdf [Please refer to comment No. 13, 161]
4. ITIA Response - Co CLH 2017_02_22.pdf [Please refer to comment No. 14, 35, 54, 96, 116, 162, 173, 213, 249, 288]
5. 2017-02-24_A3M_Co consultation.pdf [Please refer to comment No. 15, 163, 174, 250]
6. 20170224 PVAN Proposal of classification of Cobalt.pdf [Please refer to comment No. 16, 164]
7. FINAL - UK Steel CLH Cobalt metal response 24 02 17.pdf [Please refer to comment No. 81, 179, 254]
8. VDA Position on cobalt.zip [Please refer to comment No. 21, 82]
9. Tikomet Oy Response - Co CLH.pdf [Please refer to comment No. 22, 83, 180, 255]
10. MJ kannanotto_cobalt.docx [Please refer to comment No. 23, 84, 181, 256]

11. Letter of support Co- Public Consultation.docx [Please refer to comment No. 25, 86, 183, 258]
12. 2017-02-24 WVMetalle commenting on Co CLH proposal.pdf [Please refer to comment No. 27, 88, 185, 260]
13. su_170_StN CLH Cobalt.pdf [Please refer to comment No. 28, 89, 186, 261]
14. Reference x Sandvik Mining and Rock Technology response 20170221 VO 4-CH comments.pdf [Please refer to comment No. 30, 90, 188, 263]
15. 170223 harmonisierte Einstufung von Kobalt Metall_final.pdf [Please refer to comment No. 31, 32, 91, 92, 189, 190, 264, 265]
16. 20170223_ECHA_PC_General_Comments_CLP.docx [Please refer to comment No. 34, 95, 193, 268]
17. RECHARGE-EUROBAT input to CLH Cobalt metal consultation.pdf [Please refer to comment No. 37, 98, 195, 270]
18. Zip of CoRC-CDI Joint Response Comments (3 Documents).zip [Please refer to comment No. 38, 99, 196, 271]
19. Reference 1 Sandvik Coromant response 20170223.pdf [Please refer to comment No. 39, 100, 197, 272]
20. 160608 Original Eng.pdf [Please refer to comment No. 42, 103, 200, 275]
21. Beryllium Science and Technology Association - Cobalt CLH Consultation.pdf [Please refer to comment No. 105, 202, 277]
22. Final EUROFER Carbon Steel Cobalt Input to CLH PC 22.02.17.pdf [Please refer to comment No. 44, 106, 203, 278]
23. Reference 1 Seco Tools response 20170221.pdf [Please refer to comment No. 46, 108, 205, 280]
24. Reference 1 DormerPramet response 20170221.pdf [Please refer to comment No. 47, 109, 206, 281]
25. 20170220 CLH Cobalt - Letter of Support FRIT.pdf [Please refer to comment No. 50, 112, 209, 284]
26. 20170220 CLH Cobalt - Letter of Support IP.pdf [Please refer to comment No. 51, 113, 210, 285]
27. Reference 1 Walter AG response CLH-Prop_CO_20170222.pdf [Please refer to comment No. 52, 114, 211, 286]
28. Reference 1 WBH response 20170221.pdf [Please refer to comment No. 53, 115, 212, 287]
29. Tata Steel Hille and Muller Position paper.pdf [Please refer to comment No. 56, 118, 215, 290]
30. Final - Team Stainless Position Paper for the Cobalt Issue (signed).pdf [Please refer to comment No. 59, 121, 217, 292]
31. Final Slags TF Eurometaux Comments on Co CLH proposal 20170221.pdf [Please refer to comment No. 61, 123, 219, 294]
32. 20170222_ECI-PC-Cobalt-CLH_public-attachment.pdf [Please refer to comment No. 62, 124, 220, 295]
33. 170220-Co metal implications for Ni - input in consultation.pdf [Please refer to comment No. 63, 125, 221, 296]
34. Gradient_Co_Comments.pdf [Please refer to comment No. 126]
35. 2017-02 Kennametal Cobalt CLH Response.pdf [Please refer to comment No. 65, 128, 224, 299]
36. Public attachmts Co metal PC.zip [Please refer to comment No. 70, 133, 229, 304]
37. Kirkland CLH proposal muta and ip 2017Feb15 clean version.doc [Please refer to comment No. 230]
38. FEPA_Answer to the public consultation cobalt metal_1.pdf [Please refer to comment No. 71, 134, 231, 305]
39. References 1 and 2 Sherritt Epidemiology Reports.7z [Please refer to comment No. 3, 150, 168, 244]

CONFIDENTIAL ATTACHMENTS

1. Repr appendix, CONFIDENTIAL.pdf [Please refer to comment No. 70, 133, 229, 304]