HEALTH RISK ASSESSMENT:
HEAVY METALS (LEAD, CADMIUM AND NICKEL) IN JEWELLERY (ORAL AND DERMAL CONTACT)

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ACRONYMS AND ABBREVIATIONS

ADI	Acceptable daily intake
ATSDR	Agency for Toxic Substances and Disease Registry
BMD	Benchmark dose
bw	Body weight
CIR	Cosmetic Ingredient Review
CSF	Cancer slope factor
ECHA	European Chemicals Agency
ESR	Institute of Environmental Science and Research Limited
EU	European Union
FDA	Food and Drug Administration
IARC	International Agency for Research on Cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LCR	Lifetime cancer risk
LD_{50}	Lethal dose (which causes death in 50% of animals)
LOAEL	Lowest observed adverse effect level
MOS	Margin of safety
NIFDC	China National Institutes for Food and Drug Control
NOAEL	No observed adverse effect level
NZ EPA	New Zealand's Environmental Protection Authority
POD	Point of departure
RfD	Reference dose
SED	Systemic Exposure Dose
SCCP	Scientific Committee on Consumer Products (European)

TGA	Therapeutic Goods Administration
TWA	Time weighted average
US	United States
USEPA	United States Environmental Protection Agency
WHO	World Health Organization

EXECUTIVE SUMMARY

The purpose of this report is to develop a generic health risk assessment for incidental exposure to heavy metals in jewellery by oral and dermal routes of exposure. This report will only consider domestic, non-occupational, routine and incidental exposure to heavy metals in jewellery. While other metals have occasionally been examined in jewellery, three metals [lead (Pb), cadmium (Cd) and Nickel (Ni)] seem to be of consistent concern and the current study is restricted to consideration of these three metals.

Jewellery consists of decorative items worn for personal adornment, such as brooches, rings, necklaces, earrings, pendants, bracelets, and cufflinks. Jewellery may be attached to the body or clothes. Inexpensive jewellery can be made of metals and plastic. It is also reported that they can be made from recycled batteries and may contain high levels of toxic metals such as Pb, Cd and Ni.

Exposure to metals like Pb, Cd and Ni in early life can have deleterious health effects in children. Exposure to Pb causes impairment of cognitive development in children. Cd and Pb may cause neurodevelopment problems and behavioural disorders. Nickel can cause nickel allergic contact dermatitis (NACD) characterised by rash or eczema on the skin of people who are nickel allergic.

The Product Safety Standards (Children's Toys) Regulations 2005 (Regulations) sets a safety standard for children's jewellery in New Zealand.

Jewellery and other items such as toys are reported to contain toxic heavy metals above the acceptable limits in the United States (US) and European Union (EU). This has led to product recalls from the market. In the US, more than 18 million items have been withdrawn from the market due to Pb contamination between 2007 and 2018 via 174 product recalls. In 2010, over 12 million children's products and jewellery items had been recalled in the US via seven recalls due to elevated total Cd concentrations. However, the number of recalls has decreased over time. Recently in Australia, items of children's jewellery were recalled due to the presence of high levels of cadmium. There have been no recalls in New Zealand due to heavy metal contamination of jewellery.

There have been incidents of poisoning and one death of a child reported by the US Centre for Disease Control and Prevention (CDC) due to the presence of high levels of heavy metals in jewellery. The fatality was of a 4 year old boy due to acute lead poisoning following ingestion of a heart-shaped metallic charm containing 99.1% lead. This led to a voluntary recall of 300,000 heart-shaped charm bracelets in 2006. In another incident, a 4-year old boy displayed symptoms of abdominal cramping, vomiting, and diarrhea without fever after ingesting a medallion pendant containing 38.8% lead, 3.6% antimony, and 0.5% tin.

Exposure to heavy metals in jewellery is considered to be incidental to the primary use of the jewellery. Possible routes of exposure to heavy metals in jewellery is either dermal (i.e. direct contact with the skin) or oral (i.e. mouthing the jewellery or accidental ingestion). Inhalation is not considered a relevant route of exposure. Children and women of childbearing age are more vulnerable to the effects of exposure to toxic metals in jewellery because of their behavior and susceptibility. Women are more likely to wear jewellery than men, and therefore are at higher risk of exposure to heavy metals in jewellery, especially through the dermal exposure route. Children are even more vulnerable than adults as they are more likely to mouth jewellery, and therefore are at risk of the metals being extracted by the saliva or swallowing, in addition to dermal exposure.

There are few assessment reports in the scientific literature related to health risks from heavy metals in jewellery. The assessments from the literature show that there may be potential health risk from Cd, Ni and Pb. Overall, the conclusions were largely consistent with the exception of one study where Cd did not pose any risk after dermal exposure in adults. Hence, the contamination of jewellery with heavy metals (specifically Pb, Cd, and Ni), at levels that are currently reported to occur in overseas studies, may present a health risk to children and adults after oral exposure.

1 INTRODUCTION

The purpose of this report is to develop a generic health risk assessment for heavy metals (lead (Pb), nickel (Ni) and cadmium (Cd)) in jewellery. While other metals have occasionally been examined in jewellery, these three metals are of consistent concern and the current study is restricted to consideration of these three metals (Becker *et al.*, 2010; DanishEPA, 2008). This report will only consider domestic, non-occupational, incidental exposure to heavy metals in jewellery. Exposure scenarios will be developed for the most common or likely exposure events.

1.1 CONSUMER PRODUCTS DESCRIPTION – JEWELLERY

Jewellery consists of decorative items worn for personal adornment, such as brooches, rings, necklaces, earrings, pendants, bracelets, and cufflinks. Jewellery may be attached to the body or clothes.

Specific definitions of jewellery have been used in regulations relating to heavy metal content. In the EU, the legal definition of what constitutes 'jewellery' under the REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals) differs slightly for each restricted metal (Annex XVII)[1]:

Cadmium: 'Jewellery articles shall include metal beads and other metal components for jewellery making and metal parts of jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks. Any individual part shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles' (ECHA, 2016).

Lead: 'Jewellery articles shall include jewellery and imitation jewellery articles and hair accessories, including: (a) bracelets, necklaces and rings; (b) piercing jewellery; (c) wrist watches and wrist-wear; (d) brooches and cufflinks. Any individual part shall include the materials from which the jewellery is made, as well as the individual components of the jewellery articles' (ECHA, 2016a).

Nickel: The term jewellery is not explicitly used in the restriction. Based on our understanding, 'jewellery articles shall include jewellery articles intended to come into direct and prolonged contact with the skin such as: (a) earrings; (b) necklaces, bracelets and chains, anklets, finger rings; (c) wrist-watch cases, watch straps and tighteners; (d) rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments' (ECHA, 2016b).

The three definitions are broadly aligned but for nickel include additional items such as tighteners, rivets, zippers.

Canada: Heath Canada makes a distinction between adults and children jewellery, based on definition. Children's Jewellery Regulations define children's jewellery as

[1] https://eur-lex.europa.eu/legal-content/en/TXT/HTML/?uri=CELEX:02006R1907-20220501

'Jewellery that is manufactured, sized, decorated, packaged, advertised or sold in a manner that appeals primarily to children under 15 years of age but does not include merit badges, medals for achievement or other similar objects normally worn only occasionally'. Health Canada has also published examples of jewellery item and rationale for classification (HealthCanada, 2021).

1.2 HEAVY METALS IN JEWELLERY

High levels of toxic heavy metals, particularly Pb, Cd and Ni, are occasionally found in toys and jewellery, particularly in inexpensive jewellery. This has led to product recalls in the US and EU (Becker *et al.*, 2010).

The toxic metals are intentionally added for particular functional purposes. Pb is used as a stabiliser in certain plastics, a paint color enhancer, or an anti-corrosion agent. As restrictions on Pb have increased, Cd has been increasingly substituted, to brighten paint color and stabilise plastics, preventing hydrochloric acid formation that subsequently degrades the polymer (Hillyer *et al.*, 2014). In children's jewellery, Cd can create a lustrous appearance and add mass to make the product more realistic (TheAssociatedPress, 2010).

It has also been reported that metal contamination in toys and jewellery may result from contaminated recycled plastics or metals being used in their production (Guney and Zagury, 2014). Sources of metals used to make low-cost jewellery include recycled lead acid batteries and electronic wastes (Murphy *et al.*, 2016).

There are many studies which have reported the presence of different heavy metals in jewellery. The studies which are used in this assessment are summarised below.

Table 1: Total Pb, Cd, or Ni content and bioaccessible concentrations in metal jewellery

Tested samples	Metals	Analysis	Bioaccessibility	Findings	Reference
Metallic jewellery	Cd, Pb and Ni	Acid digestion ICP-MS	Saliva extraction in 15 mL, 0.07 M HCl extraction	Total Cd: 0.017 - 139 mg/kg Total Pb: 1 mg/kg - 860 g/kg Total Ni: 1.47 - 2894 mg/kg	(Cui *et al.*, 2015)
				Bioaccessible concentrations: **Saliva extraction (µg/kg)** Cd: ND - 927 Pb: ND - 638 Ni: 16 - 261000 **HCl extraction (µg/kg)** Cd: 1 - 410 Pb: ND - 770 Ni: ND - 1039000	

Metallic jewellery	Cd, Pb and Ni	Not tested	Saliva extraction in 15 mL, 0.07 M HCl extraction	Bioaccessible concentrations: **Saliva extraction (mg/kg)** Cd: <0.02 - 22.8 Pb: <0.17 - 0.53 Ni: <0.06 - 2.93 **HCl extraction (mg/kg)** Cd: <0.11 - 80 Pb: <0.90 - 647 Ni: <0.34 - 46	(Guney and Zagury, 2014)
Metallic jewellery	Cd	ED-XRF	Acidic and alkaline sweat 1 mL for each 1 cm^2	Total Cd contents were 13.4 - 44.64% (w/w) **TRA (μg/cm^2/Week)** Acidic: 4.0 - 253 Alkaline: 3.3 - 62	(Pouzar *et al.*, 2017)
Metallic jewellery	Cd, Pb and Ni	FAAS	Not tested	Total Cd: <DL Total Pb: 4.6 - 34.4 mg/kg Total Ni: 5.8 - 17 mg/kg	(Terry *et al.*, 2020)
Metallic jewellery	Cd, Pb and Ni	XRF	Saliva migration	**Total metal content (%)** Cd: 0.03 - 4 Pb: 0.03 - 70 Ni: 0.06 - 70 **Migration (μg/g)** Cd: 0.31 - 16 Pb: 2 - 540 Ni: 0.5 - 210	(DanishEPA, 2008)

Cd: cadmium, Pb: lead, Ni: Nickel, DL: Detection limit; ICP-MS: ED-XRF: Energy dispersive X-ray fluorescence; Inductively coupled plasma mass spectrometry; FAAS: Flame atomic absorption spectroscopy

1.3 RELEVANT LEGISLATION

1.3.1 New Zealand

The Product Safety Standards (Children's Toys) Regulations 2005 sets safety standards for children toys and jewellery (Comcom, 2022). The Regulations specify *AS/NZS ISO 8124.1:2002* Safety of toys – Part 1: Safety aspects related to mechanical and physical properties with amendments as the official product safety standard that suppliers of children's toys must comply with. However, these regulations do not address chemical compositional issues related to children's toys, including jewellery.

The Australian/New Zealand standard *AS/NZS ISO 8124.3:2021 Safety of Toys, Part 3: Migration of certain elements* specifies maximum acceptable levels of certain elements and methods of sampling, extraction, and determination for migration of the elements including antimony, arsenic, barium, Cd, chromium, Pb, mercury and selenium from toy materials and from parts of toys (StandardsNewZealand, 2021). The maximum acceptable levels are also specified for “glass, ceramic and, metallic materials”.

The maximum acceptable element migration from toy materials except modelling clay and finger paint is **Cd: 75 mg/kg** and **Pb: 90 mg/kg**

1.3.2 Canada

Any children's jewellery items manufactured, imported, advertised or sold in Canada are subject to the Canada Consumer Product Safety Act (CCPSA; administered by Health Canada) and Children's Jewellery Regulations. The CCPSA set limits on total Pb and total Cd content to help protect children from toxicity associated with Pb or Cd exposure (HealthCanada, 2021).

Children's jewellery, when tested using good laboratory practices, must not contain more than **90 mg/kg of total Pb and 130 mg/kg of Cd**. These limits apply to all materials, including metallic and non-metallic materials, such as glass and crystal components. The limits apply to any coatings on the jewellery. Children's jewellery items such as beads, chains and clasps, which are available individually or in jewellery-making kits, rather than as a finished jewellery item, must also meet the requirements of the Children's Jewellery Regulations (HealthCanada, 2021).

1.3.3 United States

In the US, consumer products are mainly regulated by the Consumer Safety Product Commission (CPSC), based on the mandatory safety standards including the Consumer Product Safety Act (CPSA) and the Consumer Product Safety Improvement Act (CPSIA).

Children’s jewellery produced or imported to the US must meet the safety requirements of the ASTM standard F2923-14. This standard establishes requirements and test methods for specified elements and certain mechanical hazards in children’s jewellery (ATSM, 2020). Children’s jewellery is a product principally designed and intended as an ornament worn by a child 12 years of age and younger. This includes a product, or a component of the product intended to be removed and worn by a child as an item of ornamentation. The standard includes specification for antimony, arsenic, barium, Cd, chromium, Pb, mercury, Ni and selenium in metal parts or coatings of children’s jewellery. Limits for metals considered in the current study include:

- Pb in accessible components other than paint and surface coatings (≤100 ppm or mg/kg)
- Cd in accessible plastic/polymeric components as small parts (≤300 ppm content and ≤75 ppm extractable)
- Cadmium in accessible metal components as small parts (≤300 ppm content and ≤200 ppm extractable)
- Cadmium in accessible metal or plastic/polymeric components that are not small parts but may be mouthed (≤300 ppm content and ≤18 ppm extractable)
- Ni release – post assemblies inserted into pierced ears and other pierced parts of the human body (≤0.2 $\mu g/cm^2$ per week)
- Ni release – direct and prolonged contact with skin (≤0.5 $\mu g/cm^2$ per week)

Adult jewellery produced or imported to the US must meet the safety requirements of the ASTM standard ASTM F2999-19. Adult jewellery, which is defined as jewellery designed and intended for use primarily by those over age 12 (ATSM, 2019). Limits for metals included in the current study include:

- Pb, in electroplated metal (<6.0%), non-plated metal (<1.5%), plastic/rubber/stone/PVC (<200 mg/kg), paint coatings (<600 mg/kg), other materials (<600 mg/kg)

- Cd, in metal, plastic/polymeric materials (<1.5%)
- Extractable Cd - as for children's jewellery
- Ni release - as for children's jewellery

1.3.4 European Union / European Economic Area

In the EU, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation (No. 1907/2008), establishes maximum concentration limits for heavy metals in consumer products including jewellery. The specific concentration value of heavy metals allowed might vary according to the product and the heavy metal under consideration. Limits for metals considered in the current study include:

- Cd in metal beads and other metal components for jewellery making, metal parts of jewellery and imitation jewellery articles and hair accessories (<0.01%)
- Ni release in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies (<0.2 µg/cm^2 per week)
- Ni release in articles intended to come into direct and prolonged contact with the skin (≤ 0.5 µg/cm^2 per week)
- Pb in any individual part of jewellery articles (<0.05%).

1.3.5 Brazil

On 26 January 2016, the Brazilian National Institute of Metrology, Quality and Technology (Instituto Nacional de Metrologia, Qualidade E Technologia, INMETRO) published Ordinance No. 43 of 22 January, 2016 in the Official Journal of the Federal Government of Brazil (Potario No. 43, de 22 Janeiro de 2016, Diário Oficial da União (DOU).

This Ordinance restricts Pb and Cd in jewellery and components for manufacturing jewellery. "All jewelry and jewellery formulations, intended for use in a condition of skin contact cannot have cadmium and lead concentrations equal or higher, by weight, to 0.01 and 0.03%, respectively of the metal present in the product individually considered, in order to avoid the risk of poisoning by use of the product"(chemycal, 2021).

1.4 PRODUCT RECALLS

Jewellery and other items such as toys may contain toxic heavy metals such as Pb, Ni and Cd above acceptable limits. This has led to product recalls from markets.

1.4.1 New Zealand

There has not been any product recalls due to heavy metal contamination in jewellery.

1.4.2 USA

The US Consumer Product Safety Commission has recalled millions of children's toys and jewellery items due to the presence of toxic elements between 2007 and 2018. A voluntary recall of 300,000 heart-shaped charm bracelets was announced by CPSC in 2006 due to the presence of 99.1% lead. A death of a child was reported due to acute lead poisoning after ingestion of this metallic charm (CDC, 2006).
CPSC also reported that in 2010, over 12 million children's products and jewellery items had been recalled via seven recalls due to elevated total Cd concentrations. Over time, the number of recalled items dropped faster than the number of recalls itself i.e. the general trend showed that the average number of recalled items per recall for Pb decreased over time (e.g. from

177,000 in 2007, no recalls in 2013 and 31,200 in 2018) (Guney *et al.*, 2020). Some examples of jewellery-related recalls from US CPSC website are summarised in Table 2.

Table 2: US recalls of jewellery items due to excessive heavy metal content

Product	Description	Hazard Description	Units	Reference
Reebok Heart-Shaped Charm Bracelets	Jewellery	high levels of Pb, risk of lead poisoning and adverse health effects to young children	About 300,000	(CPSC, 2006)
5-Pack Nose Piercings and Body Bars	Jewellery	Elevated levels of Ni, posing a risk of skin irritation.	5	(CPSC, 2021)
Jewelry-making kit	Children jewellery	Slider bracelet contains high levels of Pb	About 175,000	(CPSC, 2016)
M&M's-Branded Jewelry	Children jewellery	High levels of Pb	About 52,400	(CPSC, 2016a)
"Best Friends" Charm Bracelet Sets	Silver-colored chains with metal pendants	High levels of Cd	About 19,000	(CPSC, 2010a)
Children's Happy Charm Bracelets and Football Rings		High levels of Cd	About 66,200 Charm Bracelets and 2,200 Rings	(CPSC, 2010b)
Metal Necklaces, Bracelets and Earrings	Children jewellery	High levels of Cd	About 137,000	(CPSC, 2010c)

1.4.3 Australia

During 2020-2021 there were two product recalls in Australia related to heavy metals in jewellery. The Australian Competition and Consumer Commission (ACCC) recalled charm bracelets and "Christmas Wishes" children's Jewellery (Figure 1) due to the presence of high levels of Cd (ACCC, 2020; 2021). It is unclear whether these products were also sold in New Zealand.

Figure 1. Children's charm bracelets marketed as "Christmas Wishes" that we recalled in Australia in 2020-2021 due to high levels of Cd

Source: (ACCC, 2020; 2021)

2 HAZARD IDENTIFICATION

2.1 PREVIOUS ASSESSMENTS

No previous health impact assessments for heavy metals in jewellery were found for New Zealand. However, there are some reports and publications from overseas which are summarised in Table 3. These studies will be discussed in detail in sections 4 and 5

Table 3: Summary of risk assessments related to Pb, Cd, or Ni.

Tested samples	Country	Tested HMs	Risk assessment	Reference
Metallic jewellery (n=13)	Czech Republic	Cd	No health risks (non-carcinogenic toxic effects)	(Pouzar *et al.*, 2017)
Children's jewellery	Trinidad and Tobago	Pb, Ni, Cd	No health risks (non-carcinogenic toxic effects)	(Terry *et al.*, 2020)
Children's jewellery (n = 16)	North America	Pb, Ni, Cd	a) Unacceptable risk (HI>1) for ingestion of parts or pieces b) Saliva mobilisation posed less but still significant risk (HI>1) for some samples c) Lowest risk (HI<1) from ingestion from scraped-off toy or jewellery	(Guney and Zagury, 2014)
Metallic jewellery	Denmark	Pb, Ni, Cd	a) Potential health risks related to Cd and Ni after dermal exposure b) Potential health risks related to Cd, Pb and Ni after oral exposure i.e. person sucks the jewelleries for two hours.	(DanishEPA, 2008; EU-SCHER, 2010);
Metallic jewellery	China	Pb, Ni, Cd	a) Potential risk to children in terms of Cd and Ni b) 11 out of 45 samples showed HI >1 for Cd and Ni. c) Pb with the highest total concentration showed HI <1 for all samples while Ni showed the most hazard with HI up to 113.	(Cui *et al.*, 2015)

Cd: cadmium, Pb: lead, Ni: Nickel, HI: hazard index

2.2 HEALTH EFFECTS – HEAVY METALS IN JEWELLERY

2.2.1 Case reports

1) A 4-year old previously healthy boy was taken to a General Physician in Oregon after several days of abdominal cramping, vomiting, and diarrhea without fever. Symptoms were resolved in 1-2 weeks. After that he had another bout of vomiting and abdominal pain and was returned to his physician. His condition was diagnosed as probable viral syndrome and anaemia of undetermined etiology. He was brought to the emergency department after two days with worsening symptoms, including constipation and inability to eat or sleep because of his abdominal pain. An abdominal radiograph

showed a metallic object in the stomach with no evidence of obstruction; repeat laboratory studies showed a persistent normocytic anaemia (CDC, 2004).

Figure 2. **Medallion from recalled toy necklace**

FIGURE. Medallions from recalled toy necklaces that were sold in vending machines in Oregon and linked to lead poisoning

Photo/Oregon Department of Human Services

Source: (CDC, 2004)

Endoscopy was performed, resulting in retrieval of a medallion pendant (along with a quarter) from the boy's stomach. The medallion retrieved from the boy's stomach was reportedly purchased from a toy vending machine, approximately 3 weeks before it was retrieved. The medallion's contents were found to be 38.8% Pb, 3.6% antimony, and 0.5% tin. Similar medallions purchased from toy vending machines in other areas were found to have similar high proportions of lead (44% and 37%). State health officials notified the U.S. Consumer Product Safety Commission; a national voluntary recall was announced on September 10, 2003, of approximately 1.4 million of the metal toy necklaces. The case subsequently received chelation therapy to normalise his blood Pb level (CDC, 2004).

2) In February 2006, death of a child was reported due to acute Pb poisoning caused by encephalopathy after ingestion of a heart-shaped metallic charm containing Pb. The charm had been attached to a metal bracelet provided as a free gift with the purchase of shoes.

Figure 3. Heart-shaped metallic charm containing Pb

FIGURE. Heart-shaped charm bracelet that is the subject of the voluntary recall announced March 23, 2006, by Reebok International Ltd. and the Consumer Product Safety Commission

Photo/Consumer Product Safety Commission

Source: (CDC, 2006)

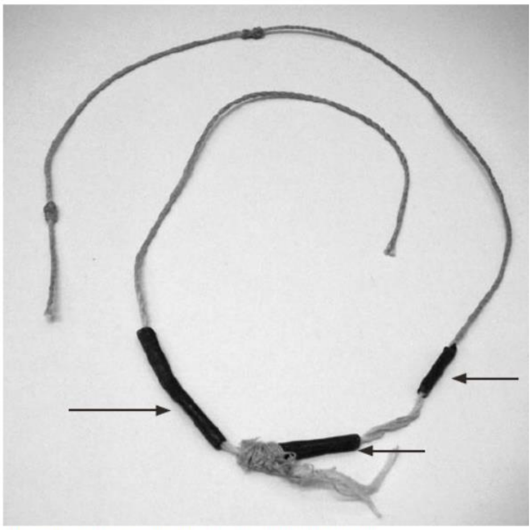
The boy was brought to the hospital pediatric emergency department with complaint of vomiting. He was diagnosed with probable viral gastroenteritis and was treated accordingly. The next day, about 10 hours after admission, the boy became agitated and combative and exhibited possible posturing. During transport to the radiology department, the boy suffered a respiratory arrest associated with seizure-type activity. He was resuscitated and placed on mechanical ventilation. He was administered a computer tomography (CT) scan of his head and of his chest and radiographs of his abdomen. The CT scan revealed diffuse cerebral edema, and the boy underwent emergent ventriculostomy and decompressive craniotomy. A heart-shaped object was observed on his abdominal radiographs, but it was thought to be a radiopaque temperature probe on his body. When the radiographs were examined again, the object was recognised as a foreign body in his stomach, and testing for heavy metal levels was requested (CDC, 2006).

Blood lead level (BLL) of 180 µg/dL was reported; cerebral blood flow studies indicated no flow to the brain, and the boy met clinical brain death criteria. On the fourth day of hospitalisation, the child was removed from life support and died. Upon autopsy, a heart-shaped charm imprinted with "Reebok" was removed from his stomach and analysed. It was determined that the charm consisted of 99.1% lead. CPSC suggested that tests for leaching be conducted on those items containing more than 0.06% lead by weight. A charm similar in size and shape to the one ingested, was obtained by relevant authorities at an athletic shoe store in Minneapolis and tested by the same laboratory using the same method. Results determined that the charm consisted of 67.0% lead by weight. The same staff member purchased another look-alike charm with a pair of athletic shoes from the Reebok Internet site; this charm was tested by the same Minneapolis laboratory using the same testing method and determined to contain only 0.07% lead by weight (CDC, 2006).

The variation in Pb content revealed by the tests was consistent with previous test results for small, inexpensive metallic jewellery. On March 23, a voluntary recall of 300,000 heart-shaped charm bracelets was announced by CPSC and Reebok (CDC, 2006).

3) A case of Pb poisoning in a child aged 1 year was reported and investigated by the New York City Department of Health and Mental Hygiene's (NYC DOHMH) Lead Poisoning Prevention Program in 2009. Routine lead testing showed an elevated BLL of 10 µg/dL. Because the case lived in a household with a cousin who had lead poisoning, he had also been tested at 6 months. His blood lead level was just 1 µg/dL then. Three months later, the boy's blood level doubled to 20 µg/dL. The boy's father again denied that the child wore jewellery or charms, but eventually admitted that the child had worn an amulet acquired at a Cambodian market since he was 3 months old. The amulet, acquired by the boy's mother in a rural Cambodian market, was a knotted string onto which gray metallic beads had been molded. The father reported that the boy had worn the amulet around his neck since age 3 months and had been observed mouthing it (CPSC, 2011).

Figure 4. Amulet worn by the child



Photo/New York City Department of Health and Mental Hygiene

Source: (CPSC, 2011)

A home inspection identified one area of paint with an elevated Pb level, as well as imported spices and rice. Testing revealed that the food products did not have elevated Pb content. The amulet's metal beads had a total Pb content of 450,000 mg/kg (45%). Within 8 days of the amulet being removed from the home, the child's BLL had decreased from 20 µg/dL to 14 µg/dL. Six weeks after the amulet was removed, and 2 days after the lead paint violation was reported as abated, the child's BLL was 10 µg/dL. Five months after the amulet was removed, the boy's BLL was down to 5 µg/dL. Although other factors might have contributed to the child's overall Pb burden, the most likely source identified was the amulet, based on its high Pb content, statements that the child had been observed mouthing it, and the rapid decrease in the child's BLL after its removal (CPSC, 2011).

2.3 TOXICITY OF CADMIUM, LEAD and NICKEL

2.3.1 CADMIUM (Cd)

Acute toxicity data for Cd in humans are very scarce and there are no reliable human studies following acute-duration oral exposure. Acute exposure to high doses of Cd in laboratory animals results in a variety of effects, including altered haematological parameters, focal necrosis and degeneration of the liver, focal necrosis in renal tubular epithelium, necrosis and ulceration in the stomach and intestines, decreased motor activity, and testicular atrophy and necrosis.

Cd is primarily toxic to the kidneys and bones after repeated exposure in animals and humans (EFSA, 2009). Chronic exposure to Cd by the oral or inhalation routes has produced proximal tubule cell damage, proteinuria, glycosuria, amino aciduria, polyuria, decreased absorption of phosphate, and enzymuria in humans and in a number of laboratory animal species. The renal damage produced by Cd is often cumulative and has been related to lifetime Cd dose (Chiyoda *et al.*, 2003; Nogawa *et al.*, 2018). Therefore, episodic exposures at any age contribute to a person’s lifetime accumulated Cd exposure and risk. The clinical symptoms result from the degeneration and atrophy of the proximal tubules, or (in worse cases) interstitial fibrosis of the kidney. After prolonged and/or high exposure the tubular damage may progress to decreased glomerular filtration rate, and eventually to renal failure. Cd can also cause bone demineralisation, either through direct bone damage or indirectly as a result of renal dysfunction. In severe cases this may result in itai itai disease , involving osteomalacia and osteoporosis (JECFA, 2011).

IARC has classified Cd as a human carcinogen (Group 1) on the basis of animal and occupational studies and concluded that “there is sufficient evidence in humans for the carcinogenicity of cadmium and cadmium compounds”. Cadmium and cadmium compounds cause cancer of the lung. Also, positive associations have been observed between exposure to cadmium and cadmium compounds and cancer of the kidney and the prostate (IARC, 1993).

2.3.2 LEAD (Pb)

Studies of Pb exposure in humans as well as laboratory animal studies have reported effects on the nervous system, cardiovascular effects, renal effects, immune system effects, haematologic effects, reproductive and developmental effects and cancer (EFSA, 2010; JECFA, 2011).

The acute toxicity of Pb is low (JECFA, 2011). Ingestion of large amounts of Pb can produce gastrointestinal symptoms, including colic, constipation, abdominal pain, anorexia and vomiting. Exposure to Pb during pregnancy has been associated with toxic effects on the human foetus, including increased risk of preterm delivery, low birthweight, and impaired mental development, including decreased IQ scores (CDC, 2012). Human studies are inconclusive regarding the association between lead exposure and other birth defects, while animal studies have shown a relationship between high lead exposure and birth defects (ATSDR, 2007).

Human studies are inconclusive regarding Pb exposure and an increased cancer risk. Animal studies have reported kidney tumours in rats and mice exposed to lead via the oral route. IARC has classified inorganic Pb compounds as probably carcinogenic to humans (Group 2A) (IARC, 2006).

2.3.3 NICKEL (Ni)

The main human health effects of concern associated with Ni exposure include Ni allergic contact dermatitis, respiratory carcinogenicity, reproductive toxicity, immunotoxicity, and non-cancer respiratory effects. Acute ingestion of Ni compounds may cause nausea, vomiting, diarrhoea, headache, cough and shortness of breath. In severe cases, ingestion of large amounts of a Ni compound may cause death. Chronic oral exposure to Ni or Ni compounds has not been characterised in humans (ATSDR, 2005).

Ni is of low acute toxicity by oral route in animals. The acute LD_{50} is greater than 9000 mg/kg bw. Generally, soluble Ni compounds are more toxic than insoluble compounds: single dose oral lethality studies indicated that soluble Ni compounds are acutely toxic to rats whereas less soluble compounds or insoluble Ni compounds are not acutely toxic to rats (ECHA, 2018). Acute oral LD_{50} values of 46 and 39 mg/kg bw for Ni sulphate were reported in male and female rats, respectively. In rats, the oral LD_{50} values for the less soluble Ni compounds Ni oxide and subsulfide were >3,930 and >3,665 mg/kg bw, respectively.

Some forms of Ni may be acutely toxic to humans in large doses. Acute inhalation exposure of humans to Ni may produce headache, nausea, respiratory disorders, and death. Asthmatic conditions have also been documented for inhalation exposure to Ni.

Ni is a well-known skin sensitiser and allergic contact dermatitis is a commonly reported effect in humans exposed to Ni. Exposure through skin or airways may lead to Ni sensitisation (i.e. the type of sensitisation is associated to the route). A combination of Ni with circulating or tissue protein gives rise to new antigens and acts as a contact allergen and causes sensitisation.

The IARC concluded that there is sufficient evidence in humans for the carcinogenicity of mixtures that include Ni compounds and Ni metal. These agents cause cancers of the lung and of the nasal cavity and paranasal sinuses. Ni compounds are classified as carcinogenic to humans (Group1) by inhalation route. However, the inhalation route of exposure is not relevant to metals in jewellery. In view of the overall findings in animals, there is sufficient evidence in experimental animals for the carcinogenicity of nickel compounds and nickel metal (IARC, 1990) .

3 DOSE-RESPONSE INFORMATION

There are some instances of acute intoxication due to ingestion of jewellery items by children. However, for normal use (wearing as decorative items) of jewellery items concerns associated with oral and dermal exposure to metals in jewellery will be related to chronic exposure events.

3.1 NICKEL

3.1.1 Oral

Non carcinogenic: USEPA has derived an oral reference dose (RfD) for Ni, soluble salts. The RfD was based on a NOAEL of 5 mg/kg/day and a LOAEL of 50 mg/kg/day for decreased body weight and organ weight in rats exposed to dietary Ni for 2 years (Table 4).

In this chronic study, body weights were significantly decreased as compared to controls in high dose male and female rats. The dose of 50 mg Ni/kg bw represents a LOAEL for this study. High mortality occurred in the controls in both sexes (44/50) raising some concern about the interpretation of the results of this study. However, this study was supported by a sub chronic study in which the NOAEL was also 5 mg/kg/day.

EFSA (2020) derived a tolerable daily intake (TDI) of 0.013 mg/kg/day based on reproductive and developmental toxicity observed in rats. Developmental toxicity was also observed in mice (decreased fetal weight, malformations) but at higher doses than for rats suggesting that rats may be more sensitive than mice to developmental toxicity of nickel. Based on the available data, the increased incidence of post-implantation loss in rats was considered a critical effect for the risk characterisation of chronic oral exposure to nickel.

Table 4: Reference dose for nickel

Study / key effect	POD	UF	Reference dose	Reference
Rat Chronic Oral Study/ Decreased body and organ weights	NOAEL: 5 mg/kg/day LOAEL: 50 mg/kg/day	300	0.02 mg/kg bw/day (2.5 µg/kg bw/day)	(IRIS, 1991)
One- and two-generation studies in rats/ increased incidence of post-implantation loss.	$BMDL_{10}$: 1.3 mg Ni/kg	100	TDI: 0.013 mg/kg/day (13 µg/kg bw/day)	(EFSA, 2020)

BMDL: Benchmark dose level, NOAEL: No observed adverse effect level, LOAEL: lowest observed adverse effect level, bw: body weight, TDI: Tolerable daily intake

Carcinogenic: The US EPA has not evaluated soluble salts of Ni, as a class of compounds, for potential human carcinogenicity. However, Ni refinery dust and specific Ni compounds – Ni carbonyl and Ni subsulfide have been evaluated but are not relevant to jewellery.

3.1.2 Dermal

No reference dose for the dermal route of exposure was available at the time of this report.

3.2 CADMIUM

3.2.1 Oral

Non carcinogenic: USEPA has derived an oral RfD for Cd. The RfD was based on an estimated NOAEL of 0.005 mg/kg bw/day for Cd in drinking-water (Table 5). The NOAEL does not reflect the information from any single study. Rather, it reflects the data obtained from many studies on the toxicity of Cd in both humans and animals. These data also permit calculation of pharmacokinetic parameters of Cd absorption, distribution, metabolism and elimination.

The EFSA Panel did not consider the dose-response data for cancer as a sufficient basis for quantitative risk assessment and based their assessment on kidney effects. A meta-analysis was conducted on the relationship between urinary cadmium (a measure of cadmium body burden) and urinary β-2-microglobulin (B2M; a biomarker of renal tubular damage). A urinary reference point of 1 µg cadmium/g creatinine was derived, equating to a tolerable weekly intake (TWI) of 2.5 µg/kg bw per week. Creatinine enters urine at a fairly constant rate and is used to standardise biomarker measurements.

EFSA subsequently reviewed the approach and assumptions used in deriving the TWI and compared them to the approach and assumptions employed by JECFA (see below). The JECFA health-based guidance values (HBGV) is more than twice the EFSA value, when considered in the same time frame.

JECFA published an addendum to their assessment of cadmium in 2011 (JECFA, 2011a). JECFA followed a similar approach to EFSA but concluded that for those aged 50 years or older (a point at which cadmium in the body would have achieved a steady state) there was no evidence of increased B2M urinary excretion at urinary cadmium concentrations less than 5.24 µg/g creatinine. This equates to a provisional tolerable monthly intake (PTMI) of 25 µg/kg bw per month.

Table 5: Reference dose for cadmium

Study / key effect	POD	UF	Reference dose	Reference
Human studies involving chronic exposure/ Significant proteinuria	NOAEL (water): 0.05 mg/kg/day	10	0.005 mg/kg bw/day (5 µg/kg bw/day)	(IRIS, 1989)
Human studies-meta-analysis / urinary cadmium levels and beta-2-microglobulin	1 µg cadmium/g creatinine	Not required	TWI: 0.0025 mg/kg bw (2.5 µg/kg bw)	(EFSA, 2009)

Human studies- meta-analysis / urinary cadmium levels and beta-2-microglobulin	-	-	PTMI: 25 µg/kg bw per month.	(JECFA, 2011a)

NOAEL: No observed adverse effect level, bw: body weight, TWI: tolerable weekly intake, PTMI: provisional tolerable monthly intake

3.2.2 Dermal

No reference dose for the dermal exposure route was available at the time of this report.

3.3 LEAD

According to the USEPA, the degree of uncertainty regarding the health effects of Pb is very low. The critical effects that occur as a result of exposure to Pb (changes in levels of certain blood enzymes, elevation of blood pressure, and neurobehavioral deficits in children) occur at exposure levels (measured as blood lead) so low as to be essentially without a threshold. Therefore, the USEPA's RfD Work Group considered it inappropriate to develop an RfD for inorganic Pb (IRIS, 2004). This is consistent with the conclusions of other evaluations (EFSA, 2010; JECFA, 2011). Consequently, exposure to Pb should be kept as low as reasonably achievable (ALARA). In New Zealand, the health advice is that there is no safe level of lead and lead exposure needs to be avoided as much as possible (Ministry of Health, 2021).

3.4 REFERENCE DOSE AND TDIs USED IN ASSESSMENTS OF HEAVY METALS IN JEWELLERY

Table 6 summarises health based guidance values for Cd, Pb and Ni used in the assessments summarised in subsequent sections of this report.

Table 6: Health guidance values in this assessment

Study	Value	Origin
(DanishEPA, 2008)	**Adjusted TDI (µg/kg bw/day**) **Adults** Pb: 1.48 Ni: 2.6 Cd: 0.03 **Children** Pb: 1.31 Ni: 17.71 Cd: 0.01	**Pb** PTWI: 25 µg/kg bw/week or 3.6 µg/kg bw/day, factor of 2 applied by Danish EPA to convert to 1.8 µg/kg bw/day **Adjusted TDI (µg/kg bw/day)** Adults: 1.8 – 0.317 (Background exposure for food and beverages): **1.48** Children: 1.8 – 0.485 (Background exposure for food and beverages): **1.31** **Ni** TDI (adults, derived by Danish EPA): 4.4 µg/kg bw/day TDI (children, derived by Danish EPA): 22 µg/kg bw/day

		Adjusted TDI (µg/kg bw/day) Adults: 4.4 – 1.81 (Background exposure for food and beverages): **2.6** Children: 22 – 4.28 (Background exposure for food and beverages): **17.71** **Cd** TDI: 1 µg/kg bw/day, factor of 2 applied by Danish EPA to convert to 0.5 µg/kg bw/day **Adjusted TDI (µg/kg bw/day)** Adults: 0.5 – 0.167 (Background exposure for food and beverages) x 8.9% (oral absorption): **0.03** Children: 0.5 – 0.385 (Background exposure for food and beverages) 8.9% (oral absorption): **0.01**
(Pouzar *et al.*, 2017)	Cd RfD (dermal): 0.004 mg/kg bw/day	NOAEL: 0.042 mg/kg bw/day UF: 10
(Cui *et al.*, 2015; Guney and Zagury, 2014)	Pb: 3.6* µg/kg bw/day Ni: 10 µg/kg bw/day Cd: 0.5 µg/kg bw/day	Adopted from JECFA 1993 Derived by (RIVM, 2001) Derived by (RIVM, 2001)

Cd: Cadmium, Ni: Nickel, Pb: Lead, TDI: Tolerable daily intake, PTWI: Provisional tolerable weekly intake, NOAEL: No-observed-adverse-effect level, RfD: Reference dose
*This value has now been withdrawn as Pb has no threshold effect.

The Provisional Tolerable Weekly Intake (PTWI) of 25 µg/kg bw for Pb derived by JECFA was withdrawn in 2011, as it could no longer be considered health protective. Because dose-response analyses do not indicate a threshold for the key effects of lead, JECFA concluded that it was not possible to establish a new PTWI that would be considered health protective. Hence, the concentration of Pb should be as low as possible. The studies summarised in Table 7 either predate the withdrawal of the PTWI or have ignored the withdrawal and continued to use the JECFA PTWI as a basis for risk characterisation.

The unadjusted TDI derived for Cd by Danish EPA (0.5 µg/kg bw/day), the EFSA TWI (2.5 µg/kg bw/week or 0.36 µg/kg bw/day) and the RIVM PTWI (3.5 µg/kg bw/week or 0.5 µg/kg bw/day) are quite similar, but somewhat lower than the JECFA PTMI (25 µg/kg bw/month or 0.83 µg/kg bw/day). The Danish EPA has further adjusted the TDI with oral absorption and background exposure to Cd from food and drinks.

The unadjusted TDI of Ni derived by the Danish EPA for adults (4.4 µg/kg bw/day) is more conservative (lower) than the EFSA TDI (13 µg/kg bw/day) and the RIVM TDI (10 µg/kg bw/day). However, for children, the Danish EPA TDI (22 µg/kg bw/day) is higher than the TDI for adults in the same study or TDIs derived by EFSA or RIVM. The application of different TDIs to different life stages, particularly the application of a higher TDI for characterizing risk to children is highly unusual. A more normal approach would have been to consider the lower TDI to be protective for all life stages.

4 EXPOSURE ASSESSMENT

Jewellery has been used traditionally in almost every culture in the world. Jewellery was made with precious metals such as gold, silver, and platinum, which became very popular due to their lustre and tarnish-free nature. These metals can be worked into ornaments of almost any shape. Jewellery made from these metals is often expensive. In modern days, people have inclined towards fashion or costume jewellery manufactured using various heavy metals, which are cheaper alternatives (Mayildurai *et al.*, 2015). It has been reported that these items may be made from recycled batteries and may contain high levels of toxic metals such as Pb, Cd and Ni.

Children and women are more vulnerable to exposure to toxic metals because of their behaviour and physiological makeup. Women, including pregnant women, are more likely to wear jewellery items than men, and therefore are at higher risk of exposure to components of the jewellery, especially through the skin. Children are even more vulnerable than adults as they may mouth jewellery items, and therefore are at risk of the metals being extracted by the saliva or items being swallowed resulting in aggressive extract by the acid environment of the gut, in addition to dermal exposure (Guney et al., 2020). Children also have greater metabolic rates, rapid growth rates, and a higher body surface area-to-weight ratio which make them more vulnerable to the effects of exposure to these toxic metals (Becker et al., 2010).

Inexpensive jewellery may contain high levels of Cd, Pb and Ni. Exposure to these metals in early life can have deleterious health effects in children. Exposure to Pb causes impairment of cognitive development in children. As and Cd may cause neurodevelopment problems and behavioural disorders (Cui *et al.*, 2015). Nickel can cause rash or eczema on the skin of people who are nickel-allergic. This is also called Nickel allergic contact dermatitis (NACD).

4.1 Relevant Exposure Scenarios

The possible routes of exposure to heavy metals in jewellery in children and adults is either dermal (i.e. through direct contact with the skin) or oral (i.e. through mouthing or swallowing jewellery) (DanishEPA, 2008). Inhalation exposure is not considered a relevant route.

Young children are known to mouth non-food items and the mouthing behaviour frequency peaks at 6-12 months of age with the duration of mouthing in the range 39-66 min/day. Mouthing behaviour therefore plays an important role in children's exposure to metal contamination in toys and jewellery. Farmakakis *et al.* (2007) reported that toys were the most frequent cause of medical emergency situations due to aspiration or ingestion of inedible foreign bodies in Greek children, followed by coins and jewellery. Mouthing contaminated jewellery or toys may cause the release of contaminants via contact with saliva or lead to ingestion of jewellery material. Therefore, there are three main exposure scenarios for children (Guney *et al.*, 2020):

1) ingestion as a whole or partial ingestion resulting in subsequent mobilisation of metals,
2) saliva mobilisation of metals during mouthing,
3) dermal contact and subsequent mobilisation via sweat.

Mouthing behaviours are much less common in adults and this exposure route was considered to be of negligible importance for adults. The exposure routes considered in this study are summarised in Table 7.

Table 7: Exposure routes considered for exposure of adults and children to heavy metals in jewellery

Population	Product type	Exposure pathway		
		Dermal	Oral	Inhalation
Adults	Whole Jewellery or parts	X		
Children		X	X	

4.2 RELEVANT STUDIES

Laboratory assays simulating saliva extraction and gastro-intestinal digestion are employed for detection of contaminant release into digestive fluids. Studies and surveys summarised below have used these methods.

4.2.1 *Danish EPA Survey*

The Danish EPA conducted a survey and health assessment of chemical substances in jewellery. In this study, a number of jewellery items were selected for analysis for content of heavy metals as well as analysis for release of heavy metals. The purpose of the project was to investigate whether heavy metals can be released in an amount that could cause health related problems for humans.

A total of 170 pieces of metal jewellery were purchased from outlets in Copenhagen and were divided between the product types of rings, necklaces, bracelets, earrings, piercing jewellery and ankle chains. All metal jewellery (318 metal parts) were analysed for Pb, mercury (Hg), Cd, selenium (Se), chromium (Cr), antimony (Sb), arsenic (As) and barium (Ba). Based on the screening results, 25 jewellery parts were analysed for release of metals, those included in the initial analysis plus copper (Cu) and Ni. In total, 15 jewellery parts were selected among that contained more than 100 ppm lead and 10 jewellery parts that contained more than 75 ppm cadmium.

Release of metals into artificial sweat was determined. The solution for artificial sweat consisted of 1.0 g urea, 5.0 g NaCl and 0.940 µL lactic acid dissolved in 1 litre of demineralised water. The pH was adjusted to 6.5 and extraction was carried out at 40°C. Inductively-coupled plasma-optical emission spectrometry (ICP-OES) was used to determine the content of emitted metals from samples.

From the results, there was no immediate relationship between the amount of metal released into the artificial sweat and the content of the different metals in the jewellery items. In other words, it was not possible to assume that a high concentration of the metal in jewellery would result in a high level of release. For jewellery where the content of Pb was less than approximately 1% very little release occurred. A similar tendency was not seen for the other metals.

A human health risk assessment was conducted for four metals: Pb, Cd, Ni and Cu. These metals were selected as they released into artificial sweat at concentrations above the detection limit of the analytical method. Release of these metals into saliva was considered to be at the same level as release into sweat. Dermal and oral exposure were calculated for both adults and children. For dermal exposure calculations, two different periods of use were applied (16 and 24 hours respectively) depending on whether the jewellery items are removed during the night or not. The exposure estimates were re-calculated for 24 hour use as these were considered conservative. Exposure estimates were determined for each of the 25 items for which metal release was determined. Exposure estimates for Ni, Cd, and Pb from this study are summarised in Table 8. It should be noted that these are systemic exposures, with the dermal absorbed fraction being included in the calculation.

Table 8: Bioaccessible concentration and exposure estimates (oral & dermal) in adults and children

Metal	bioaccessible concentration (µg/kg)	Dermal exposure (µg/kg bw/day)		Oral exposure (µg/kg bw/day)	
		Adults	Children	Adults	Children
Cd	1.2 – 3.0	0.014 – 0.036	0.043 – 0.072	0.2 – 0.5	0.6 – 1.5
Pb	39 - 210	0.046 - 0.25	0.14 – 0.75	5.6 - 30	0.06 - 105
Ni	13-90	0.5 – 3.6	1.56 – 10.8	2 - 15	6.5 – 4.5

4.2.2 Cui *et al*, 2015

The objective of this study was to assess the health risk of six metals (As, Cd, Cr, Ni, Pb, and Sb) through oral exposure to children's toys and jewellery (Cui *et al.*, 2015). For this, total and bioaccessible metal concentrations were determined in 45 children's toys and jewellery items. Metal bioaccessibility was measured using artificial saliva and extraction with 0.07 M HCl to simulate the mouthing behavior of children and ingestion into the digestive tract of children. Risk assessment was conducted based on bioaccessible metal concentrations and calculating chemical daily intake (CDI) for mouthing (saliva) and ingestion (HCl extraction). A hazard index (HI) for oral exposure to metals in toys and jewellery was calculated, based on reference doses from various sources. The risk is considered unacceptable at HI >1. The reference dose used in the assessment is below:

Total Cd, Pb and Ni concentrations in jewellery items were 0.02-139, 1.0-860,000 and 2.1-2,900 mg/kg, respectively. Bioaccessible metals in jewellery extracted by saliva and 0.07 M HCl was in the range as below in Table 9. As CDI was not reported in the original publication, we calculated the values which are reported in the below table.

Table 9: Bioaccessible concentration and CDI of Cd, Pb, and Ni in children

Metal	Saliva extraction		Gastro-intestinal	
	Bioaccessible concentration (µg/kg)	CDI (µg/kg bw per day)	Bioaccessible Concentration (µg/kg)	CDI (µg/kg bw per day)
Cd	0.96 - 318	0.003 – 1.0	1 - 410	0.001 – 0.44
Pb	100 - 638	0.3 – 2.0	20-770	0.1 – 0.7
Ni	16 – 261,000	0.05 – 800	62 – 1,039,000	0.0002 – 1183

CDI: chemical daily intake

4.2.3 Guney and Zagury, 2014

In this study, risk from oral exposure for children was characterised for highly contaminated metallic toys and jewellery (Guney and Zagury, 2014). The jewellery samples (n = 8) were bought from the North American market: from dollar stores, toy shops, low-cost jewellery stores, retailer chains and from the internet. Three scenarios were considered: ingestion of parts or pieces of a jewellery item or toy, ingestion of scraped-off toy or jewellery material, and mobilisation via saliva following contact with a mouth. Inexpensive jewellery was tested to assess saliva mobilisation and gastro-intestinal bioaccessibility via different *in vitro* protocols. The results were used for risk characterisation of Cd, Cu, Ni, and Pb in the jewellery.

Daily exposure to metals was not reported by the authors in the original publication and could not be recalculated as some of the important parameters essential for calculation were not disclosed by the authors.

For mouthing (solubilisation in saliva), an age-specific exposure duration (minute/day) was calculated for 6–12 months-old infants,1–2 years-old toddlers, and 2–3 years-old toddlers based on their mean play and mouthing times. For the scenario of ingestion of parts or pieces, one-time acute exposure was assumed. For the ingestion of scraped-off material and saliva mobilization scenarios, chronic daily exposure was assumed. The hazard index (HI) for oral exposure to metals in toy and jewellery was calculated. The risk is considered unacceptable at HI >1.

4.2.4 Pouzar *et al*, 2017

Pouzar *et al.* (2017) reported the health risk of Cd released from the surface of 13 samples of low cost jewellery (3 sets of earrings, 6 pendants and 1 ring) in adults. The Cd content in the jewellery was analysed using an energy-dispersive XRF (ED XRF). Acidic and alkaline sweat was used to determine the leaching of jewellery samples and were subsequently analysed by laser-induced breakdown spectrometry (LIBS).

The Cd content in the jewellery surface layer ranged from 13.4 to 44.6% w/w. The total amount of Cd released from a particular piece of jewellery (TRA—Total Released Amount) into acidic or alkaline artificial sweat over one week of leaching and the maximum absorbable daily dose are summarised in Table 10.

Table 10: Total Released Amount of Cd and calculated values for MADD

Sweat type	Cd release (µg/cm^2 per week)	MADD (µg/kg bw/day)
Alkaline	3.2 - 62	3.56×10^{-4} to 4.54×10^{-3}
Acidic	3.5 - 253	2.00×10^{-4} to 1.86×10^{-2}

MADD: maximum absorbed daily dose, bw: body weight

5 RISK CHARACTERISATION

The studies summarised in section 4 all compared estimates of exposure to a tolerable daily intake (TDI) and reference dose (RfD).

5.1 DANISH EPA SURVEY

In this study, a human health risk assessment was carried out for four metals i.e. Pb, Cd, Ni and Cu. Dermal and oral exposure were calculated for both adults and children. For dermal exposure calculations, two different daily periods of jewellery use were applied (16 and 24 hours respectively) depending on whether the jewellery items are removed during the night or not (DanishEPA, 2008).

For risk characterisation, the tolerable daily intake (TDI) was divided by the dermal and oral exposure estimates to give a "Margin to TDI" value. This is the inverse of the more usual hazard index (HI). The TDI was adjusted downwards to account for the exposure to the metals from the diet and from ambient air. Dermal exposure estimates were calculated as internal doses and were converted to external dose equivalents by dividing by the oral absorbed fraction, to allow correct comparison to the TDI, which is an external dose. The TDI for each metal is summarised in table 7.

$$Margin = \frac{TDI}{Exposure}$$

If the exposure value exceeds the adjusted TDI (i.e. the margin to TDI is less than 1 the total exposure (from food, beverages, air and jewellery), then there might be a potential health risk from the additional exposure due to wearing jewellery. The average risk estimates are summarised in Table 11. It should be noted that there might be might difference in the margin to TDI value as compared to the Danish EPA reported. This is because the weight of individual jewellery was not disclosed in the report. We used a default of 40 g in calculation.

Table 11: Risk estimates (margin to TDI) for dermal (24 hour) and oral (2 hour) exposure to heavy metals from jewellery

Metal	Margin to TDI (dermal)[a]		Margin to TDI (oral)[a]	
	Adults	Children	Adults	Children
Cd	0.8 - 3	0.12 – 0.20	0.01 – 0.15	0.016 - 0.015
Pb	5.24 – 32	1.74 – 9.3	0.05 – 0.26	0.012 – 0.67
Ni	0.7 – 5.16	1.6 – 11.8	0.14 – 1.3	0.4 – 2.72

[a] Margins to TDI less than 1 indicate a cause for concern

Metal release from jewellery did not result in exposure to Pb or Ni through skin with Margin to TDI values >1 for adults or children. For children, nearly all jewellery items that released Cd in an amount above the detection limit resulted in Margins to TDI < 1 and constitute a cause for concern. Margins to TDI were as low as 0.1, indicating the adjusted TDI was exceeded by a factor of ten. However, it should be noted that the TDI is a level of exposure

that a person may get daily through an entire lifetime without experiencing health related effects. It is unlikely that wearing low-cost jewellery will be a lifelong activity.
For adults, the dermal Margin to TDI was <1 for two jewellery items but only for 24 hour/day exposure. For Pb and Cd, nearly all jewellery items resulted in oral Margin to TDI values <1, for both children and adults, while one item also had an unacceptable Margin to TDI for Ni.

5.2 CUI *ET AL*, 2015

Health risk through oral exposure to heavy metals from children's toys and jewellery was conducted using a Hazard Index (HI) approach. Risk assessment was conducted based on bioaccessible metal concentrations and calculating chemical daily intake (CDI) for mouthing (saliva) and ingestion (HCl extraction). The HI for oral exposure to metals in toy and jewellery was calculated using the equation below (Cui *et al.*, 2015). The TDI or the RfD for each metal is summarised in table 7.

$$HI = \frac{CDI}{RfD}$$

The risk is considered unacceptable at HI >1. Results from the risk assessment are summarised in Table 12. There might be a minor difference in the HIs calculated here from the ones reported in the publication. However, this does not change in outcome of the assessment.

Table 12: Hazard indices (HI) for exposure to heavy metals from mouthing or swallowing jewellery items, 6-12 month old child

Metal	Saliva extraction	HI_{saliva}	Gastro-intestinal	HI_{gastro}
	CDI (µg/kg bw pr day)		CDI (µg/kg bw pr day)	
Cd	0.003 – 1.0	0.016 - 3.0	0.001 – 0.44	0.021 – 0.89
Pb	0.3 – 5.0	0.08 – 0.5	0.1 – 0.7	(3.0E-05) – 0.19
Ni	0.05 – 800	0.005 - 80	0.0002 – 1183	(2.17E-05) - 118

CDI: chemical daily intake, bw: body weight, HI_{saliva}: hazard index for release of metals from jewellery by saliva, HI_{gastro}: hazard index for release of metals from jewellery by acid

The authors observed high HI values based on bioaccessible metals by saliva for bracelet-chain & pendant for Ni with the HI being 80. Similarly, high HI values were observed for bioaccessible metal concentrations extracted by 0.07M HCl. Abnormally, very high HI values were observed for bracelet w/metal chain for Ni with the HI being at 118.
A high HI (>1) was also observed for bioaccessible metals by saliva for Cd and Pb. No elevated HIs were found for any items due to Pb release.

5.3 GUNEY AND ZAGURY, 2014

In this study, risks from oral exposure (mouthing or swallowing) to heavy metals for children were characterised for highly contaminated metallic toys and jewellery (Guney and Zagury, 2014). The results showed that children’s exposure to eight jewellery items via the ingestion of parts or pieces resulted in unacceptable HIs in terms of Cd, Pb or Ni. The HIs for these items were in the range 1.1 – 75. The HI was calculated for children in three age ranges from 6 months to 3 years. This shows that jewellery samples contaminated with Cd, Pb and Ni may pose risks to children's health if ingested.

The HI values were much lower for the ingestion of scraped-off material scenario as compared to the ingestion of parts or pieces. The Hi values were < 1 for all samples, metals, and age categories. The lower HI values were attributed to the lower ingestion rate (8 mg/day) selected for the exposure assessment. It was concluded that the ingestion of scraped-off material from jewellery did not pose unacceptable risks to children.

HI values for the saliva mobilisation scenario (mouthing) were lower in comparison to the scenario of ingestion of parts or pieces; but higher than the values from the scenario of ingestion of scraped-off material. The HI was >1 for 3 jewellery items (two for Cd and one for Ni) and ranged from 1.1 – 6.1 for Cd and Ni. No HI>1 were calculated for Pb exposure. It was concluded that saliva mobilisation posed less of a risk than swallowing items, but still an unacceptable risk for some samples.

5.4 POUZAR *ET AL*, 2017

Pouzar *et al.* (2017) estimated the health risk of Cd released by acid or alkaline simulated sweat from the surface of 13 items of low cost jewellery (3 pairs of earrings, 6 pendants and 1 ring) for adults. The risk characterisation ratio (RCR) was calculated as the ratio of the maximum absorbable daily dose (MADD) and the reference dose (RfD), expressed as a percentage. The RfD for Cd is summarised in table 7.

$$RCR = \frac{MADD}{RfD}$$

Since, the US EPA has not established a RfD for dermal Cd exposure. The authors performed their own approximation of dermal RfD based on the same toxicokinetic model as by the US EPA. The parameters used to derive oral Rfd were used except for the absorption index, which was set to 0.6%. The calculated value of the NOAEL for dermal exposure was 0.042 mg/kg/day. The resulting dermal RfD using an uncertainty factor (UF) = 10 was 0.004 mg/kg/day. The dermal RfD estimated in such a way represented a worst-case scenario, in as much as the Cd absorption into the plasma could be lower than the absorption into the renal cortex with published data for absorption into the plasma varying between 0.1% and 0.6%.

Results from the study are summarised in Table 13.

Table 13: Risk estimates for release of cadmium by jewellery by acid or alkaline simulated sweat, adults

Sweat type	RCR (%)
Alkaline	7.4×10^{-3} to 1.1×10^{-1}
Acidic	5.0×10^{-3} to 4.64×10^{-1}

The amount of Cd leached into alkaline artificial sweat typically represents about 0.01–0.1% of the safe daily dose (RfD). In the case of acidic artificial sweat, RCR values were higher and more variable (ranging from 0.005% to 0.46%).

It was concluded that the evaluated set of Cd containing jewellery did not pose any serious health risk in terms of systemic non-carcinogenic effects.

5.5 SUMMARY

There were few assessments found in the literature related to health risks from heavy metals in jewellery. In general, oral and dermal exposure were considered the most important exposure pathways in children and adults, respectively.

The assessments from the literature show that there may be potential chronic health risk from Cd, Ni and Pb, particularly for children after oral exposure i.e. when a person mouths or swallows the jewellery. This is consistent with the small number of case reports available. There was potential health risk after dermal exposure to Cd but only from one study. However, a second study did not estimate unacceptable risks due to Cd in jewellery via dermal exposure.

The risk assessment methodology differs among the studies. All the studies that determined the bioaccessible metal concentration employing laboratory assays simulating saliva extraction and/or gastro-intestinal digestion.

Risk characterisation was calculated using health guidance values (TDIs, RfD) and in one study the authors derived their own reference dose for dermal route.

All studies assessed risks by comparison of exposure estimates with TDI or RfD values for the respective metals. The TDI is the amount of a substance that a human can be exposed to on a daily basis (throughout an entire lifetime) without experiencing adverse health effects. Hence, for a shorter period of exposure the TDI value can be exceeded without necessarily causing any adverse effects, particularly if in a corresponding period later in life an equally lesser amount is taken in.

In all studies that assessed risks associated with Pb exposure, the TDIs were derived from a health-based guidance value established by JECFA and subsequently withdrawn, as it has been concluded that there is no threshold to the adverse effect of Pb and the guidance value could no longer be considered health protective. The conclusions regarding Pb exposure from jewellery in these studies should be viewed in this context. That is, no exposure to Pb can be considered acceptable or tolerable and exposure to Pb should be as low as reasonably possible from jewellery. The unadjusted TDI derived by the Danish EPA and by RIVM (0.5 µg/kg bw/day) for Cd is similar to the TWI (2.5 µg/kg bw/week or 0.35 µg/kg bw/day) derived by EFSA. All these health-based guidance values are lower than the PTMI derived by JECFA. Hence, the risk estimates (HI or Margin to TDI) for Cd would not be substantially different if an alternative health-based guidance value had been used for risk characterisation. Similarly, for Ni, all TDIs used are of the same order of magnitude and risk estimates would not have been markedly different if an alternative health-based guidance value had been used.

Overall, the conclusions were largely consistent with the exception of one study where Cd did not pose any risk after dermal exposure in adults. Hence, the contamination of jewellery with heavy metals (specifically Pb, Cd, and Ni), at levels that are currently reported to occur in overseas studies, may present a health risk to children and adults after oral exposure.

6 CONCLUSIONS

The purpose of this report is to develop a generic health risk assessment for incidental exposure to heavy metals in jewellery by oral and dermal routes of exposure. This report only considered domestic, non-occupational, routine and incidental exposure to heavy metals in jewellery.

Jewellery consists of decorative items worn for personal adornment, such as brooches, rings, necklaces, earrings, pendants, bracelets, and cufflinks. Jewellery may be attached to the body or the clothes. Inexpensive jewellery can be made of metals and plastic. It is also reported that they can be made from recycled batteries and may contain high levels of toxic metals such as lead (Pb), cadmium (Cd) and Nickel (Ni).

Exposure to metals like Pb, Cd and Ni in early life can have deleterious health effects in children. Exposure to Pb causes impairment of cognitive development in children. Cd and Pb may cause neurodevelopment problems and behavioural disorders. Cadmium can cause kidney toxicity. Nickel can cause Ni allergic contact dermatitis, characterised by rash or eczema on the skin of people who are Ni allergic.

There are regulatory limits for heavy metals in jewellery overseas and in New Zealand. The Product Safety Standards (Children's Toys) Regulations 2005 (Regulations) sets the safety standard for children's jewellery in New Zealand. However, data are not available about the occurrence or prevalence of these metals in New Zealand jewellery.

Jewellery and other items such as toys are reported to contain toxic heavy metals above the acceptable limits in the US and EU. This has led to product recalls from the market. In the US, more than 18 million items have been withdrawn from the markets due to Pb contamination between 2007 and 2018 via 174 product recalls. In 2010, over 12 million children's products and jewellery items had been recalled via seven recalls due to elevated total Cd concentrations. However, the number of recalls has decreased over time. Recently in Australia, items of children's jewellery were recalled due to the presence of high levels of cadmium.

There have been incidents of poisoning and one death of a child reported by the US CDC due to the presence of high levels of heavy metals in jewellery. The fatality was of a 4 year old boy due to acute lead poisoning following ingestion of a heart-shaped metallic charm containing 99.1% lead. This led to a voluntary recall of 300,000 heart-shaped charm bracelets in 2006. In another incident, a 4-year old boy displayed symptoms of abdominal cramping, vomiting, and diarrhea without fever after ingesting a medallion pendant containing 38.8% lead, 3.6% antimony, and 0.5% tin.

Exposure to heavy metals in jewellery is considered to be incidental to the primary use of the jewellery. Possible routes of exposure to heavy metals in jewellery in children and adults is either dermal (i.e. direct contact with the skin) or oral (i.e. mouthing the jewellery or accidental ingestion). Inhalation exposure is not considered a relevant route of exposure. Children and women are more vulnerable to exposure to toxic metals in jewellery because of their behavior and physiological makeup. Women are more likely to wear jewellery than men, and therefore are at higher risk of exposure to heavy metals in jewellery, especially through the dermal exposure route. Children are even more vulnerable than adults as they are more likely to mouth jewellery, and therefore are at risk of the metals being extracted by the saliva or swallowing, in addition to dermal exposure.

There are few assessment reports in the scientific literature related to health risk from heavy metals in jewellery. The assessments from the literature show that there may be potential health risk from Cd, Ni and Pb. Overall, the conclusions were largely consistent with the exception of one study where Cd did not pose any risk after dermal exposure in adults. Hence, the contamination of jewellery with heavy metals (specifically Pb, Cd, and Ni), at levels that are currently reported to occur in overseas studies, may present a health risk to children and adults after oral exposure.

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