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Environmental Protection Agency

Survey of nickel metal

Part of the LOUS review

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Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011) includes 40 chemical substances and groups of substances which have been classified as dangerous or which have been identified as problematic using computer models or due to other concerns. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and long-term adverse effects on health or the environment, only substances that are used in an industrial context in Denmark in quantities over 100 tonnes per year are included.

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives to the substances, on existing regulation, on monitoring and exposure, and information regarding on going activities under REACH, among others.

On the basis of the surveys, the Danish Environmental Protection Agency (Danish EPA) will assess the need for any further information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns the substance nickel metal, covering both nickel and nickel powder (CAS 7440-02-0).

The main reason for the inclusion in LOUS is the hazardous properties of nickel metal, which is classified Carc 2; H351 (suspected of causing cancer), STOT RE 1; H372 (Causes damage to organs through prolonged or repeated exposure) and Skin sens 1; H317 (May cause and allergic skin reaction). Nickel powder is furthermore classified Aquatic chronic 3; H312 (Harmful to aquatic life with long lasting effects).

The objective of this study is, as mentioned, to provide background for the Danish EPA's consideration regarding the need for further risk management measures.

The process

The survey has been undertaken by DHI from May to October 2014. The work has been followed by an advisory group consisting of:

- Trine Thorup Andersen (Danish Environmental Protection Agency)
- Thilde Fruergaard Astrup (Danish Environmental Protection Agency)
- Lone Schou (Danish Environmental Protection Agency)
- Anne Christine Duer (Danish Nature Agency)
- Charlotte Legind (Danish Veterinary and Food Administration)
- Fatima Øzer Armagan (Danish Working Environment Authority)
- Jacob Zeuthen (Dainsh Chamber of Commerce)
- Nikolai Stubkjær Nielsen (Confederation of Danish Industry)

DHI has acted as secretariate for the group, provided input and participated in the discussions. The DHI team has been represented by:

- Jens Tørsløv (project manager, DHI)
- Frank Leck Fotel (DHI)
- Peter Kortegaard (DHI)

Please note that the report does not necessarily reflect the views of the members of the advisory group.

Data collection

The survey and review is based on the available literature on the substances, information from databases and direct inquiries to industry associations, trade organisations and key market actors.

The data search included (but was not limited to) the following:

- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs website;
- Pre-registered and registered substances from ECHA's website;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from Statistics Denmark, and the Nordic Product Registers as registered in the SPIN database;

Besides, direct enquiries were sent to the European association for nickel producers: the Nickel Institute.
A literature search was performed focussed on the grey literature, with the focus on use patterns, tonnage and material flow.

Summary and conclusions

The scope of the current survey is on nickel metal.

Nickel metal is classified as skin sensitiser (Skin Sens 1), as a suspected carcinogen (Carc 2) by inhalation and causes damage to organs through prolonged or repeated exposure (STOT RE 1). Nickel powder is moreover classified as environmentally hazardous: Aquatic Chronic 3.

Other nickel compounds may have more severe classifications than nickel metal as well as quite different uses and life cycles. Although the aim of this survey is to summarise the uses of metallic nickel and describe its life cycle, information on nickel salts is included where needed to understand the life cycle of metallic nickel.

The regulation of nickel often addresses nickel metal and nickel compounds as a whole. Direct consumer contact with metallic nickel is, however, specifically regulated under REACH, which restricts the release of nickel ions in jewellery and other objects with intended skin contact. Apart from REACH, specific provisions on nickel and nickel compounds apply in the work environment, the water environment, drinking water, air quality and waste incineration as well as content in toys and cosmetics etc.

Exposure to nickel in the work environment is in Denmark regulated by a national Danish OEL for nickel and nickel compounds at 0.05 mg Ni/m^3. The European Commission Scientific Committee on OEL (SCOEL) recommends an 8 hour OEL for the protection against chronic inflammation in the lungs at 0.005 mg Ni/m3 for the respirable fractions of soluble and poorly soluble nickel compounds, including nickel metal. Further a limit at 0.01 mg/m3 is recommended for the inhalable fraction of soluble and poorly soluble nickel to protect against cancer. However, this does not include metallic nickel.

Nickel metal is by far (>95%) the most frequently used form of nickel, due to its use in stainless steel and alloys for special purposes. Stainless steel contains typically with 8 – 12% nickel and special alloys may have higher concentrations. The general worldwide trend is an increased use of nickel metal mainly driven by the construction sector in developing countries (China, Asia).

The import of nickel metal to Denmark is dominated by nickel and nickel alloys in different forms being used in industrial production: nickel powders and flakes, nickel and nickel alloy plates, sheets, foils, tubes, pipes and fittings, alloy bars, rods profiles and wires. The import shows a slight declining trend in tonnage. Production and use of nickel catalysts in Denmark account for a large stable import and export of nickel containing products in the trade statistics. Nickel containing scrap previously constituted a net import (data from 2007) but is today exported and recycled outside Denmark.

The consumption of nickel metal in the EU is approximately 630,000 tonnes/year. Of this, about half is assumed to be new produced nickel and the other half recycled material. In the EU the combined use of nickel metal and nickel compounds in 2010 was: stainless steel (61%); alloy steel and nickel and copper based alloys (22.6%), plating (7%) and foundry use for 4.7 %. The remaining 4.7% was nickel and nickel compounds used in batteries, catalysts, chemicals etc.

In addition to the use in steel and alloys, nickel metal is used for plating and surface treatment in the transport sector as functional plating in cars, trains, airplanes, electronics but is also for decorative purposes on furniture, bathroom fittings, etc. As catalysts nickel metal has an important role in specific chemical manufacturing processes. In battery production nickel metal is used as intermediate and does not appear in the final product.

In waste a content of more than 1 % nickel will lead to a classification as hazardous. Pure non-contaminated alloys will not be regarded as hazardous waste according to the EU regulation from 2015.

In Denmark nickel metal in waste appears in metal scrap, mainly as a component of stainless steel. Metallic waste is mainly treated in shredding facilities where about 95 % is recovered. The recovered nickel containing steel is exported for recycling outside Denmark. The remaining 5 % is about 150.000 tons per year of shredder waste which is mainly deposited in landfills.

A mass balance for End-of-Life Vehicles in Denmark shows that 80.3-262.3 tons Ni/year is recovered in the shredding process and 3.8-13.8 tons Ni/year is contained in shredder waste. As a worst case this can be extrapolated to a total of 138 tons nickel deposited in shredder waste each year. If nickel metal is incinerated it is contained in the bottom ash. Potentially 85% of the nickel can be recovered by new techniques.

Nickel metal is classified as environmentally hazardous in the least severe classification category (Aquatic chronic 3). Investigation of the hazards and risks of nickel in the environment is based on studies of more soluble compounds than nickel metal and the risk assessment of nickel in the environment is therefore less relevant for nickel metal. In the aquatic compartment the nickel-ion is highly toxic, reflected in an EQS for freshwater at 4 µg Ni/L (bioavailable) and for marine water at 8.6 µg Ni/L. In freshwater the bioavailability of nickel dependents on the concentration of dissolved organic carbon, calcium and pH, and user friendly tools have been available for estimation of the bioavailable fraction. The marine environment is less sensitive to nickel and the mechanisms of bioavailability is less intensively studied.

Measured nickel levels, not corrected for bioavailability, in Danish and European freshwater systems are in general below the EQS, but the margin is small and the concentrations often exceed this value. Use of bioavailability corrected values of nickel is therefore highly relevant for a refined assessment of the potential risks.

The observed concentrations of nickel in Danish freshwater sediments are in general below the PNEC value of 47 mg Ni /kg dw. In the EU risk assessment of nickel and nickel compounds it was concluded that risks to sediment organisms was observed only in specific local scenarios, i.e. with releases of nickel. In the marine compartment the EQS at 8.6 µg Ni/L is generally complied with at a regional as well as at local scale near waste water outlets. The risk assessment also concluded that in general there is no risk to terrestrial ecosystem at the observed nickel levels and that assessment of secondary poisoning of predators showed no indication of risk.

Regarding health effects of nickel it need be stressed that nickel metal is less hazardous and has a lower rate of uptake compared to the more soluble forms of nickel. It is classified as a suspected carcinogen (Carc 2) in contrast to several more soluble nickel compounds that are classified as carcinogenic (Carc 1A). Nickel metal is furthermore classified as a skin sensitiser (Skin sens 1) and as toxic to lungs after repeated exposure (STOT RE 1). Exposure to nickel metal in the work environment may lead to inflammatory lesions in the respiratory tract. Nickel metal is, however, not regarded as a carcinogen in humans. Nickel metal is not classified as toxic to reproduction, which is the case for several nickel compounds. Nevertheless it is not possible to separate the exposure to nickel metal from the exposure to other nickel species as nearly all monitoring data are measured as total nickel. In general, however, it can be assumed that nickel in food, drinking water, air and soil is dominated by other nickel species than nickel metal and that the release of nickel ions from nickel metal in stainless steel and nickel containing alloys is low compared to other sources.

Consumer exposure to nickel is mainly via food and drinking water. Dermal exposure to nickel metal by contact to objects like jewellery, watches, buttons and zippers is regulated due to the risk of dermatological effects. It is assessed that dermatological effects to the non-sensitised consumer is not likely to occur.

Due to the observed lung damages the European Commission Scientific Committee on Occupational Exposure Limits (SCOEL) proposed an OEL at 0.005 mg/m3 (respirable fraction) for poorly soluble nickel compounds, and for nickel metal. The recommendation is subject to further evaluation at European level before a possible legal initiative can be decided.

Alternatives to nickel has been evaluated by industry and the overall conclusion is that only in few cases nickel can be phased out and replaced by other materials and techniques. Nickel in stainless steel is generally not a concern, and nickel used for plating can be replaced only where there are no specific technical requirements regarding corrosion, or wear resistance. In functional plating in the car and aerospace industry no alternatives seem to be suitable from a technical perspective and replacement is only possible where less stringent requirements are specified.

In catalysts nickel is used because of its inherent properties as an element. In some cases other elements have similar catalytic effects, with same or lower activity. But the most suitable alternatives are either limited in their availability as resource, or the use entail loss of process efficiency/ capacity as well as significant economic and environmental consequences.

Sammenfatning og konklusion

Det aktuelle projekt omhandler metallisk nikkel. Metallisk nikkel er klassificeret som hudsensibiliserende (Skin Sens 1), mistænkt for at være carcinogent (Carc. 2), og for specifik målorganstoksicitet efter gentagen eksponering (STOR RE 1). Metallisk nikkel på pulverform er desuden klassificeret som farligt for vandmiljøet (Aquatic Chronic 3).

Nikkelforbindelser har ofte mere alvorlige klassificeringer end metallisk nikkel og de har andre anvendelser og dermed andre livscykler. Selvom det aktuelle projekt omhandler metallisk nikkel og dets anvendelser, medtages oplysninger om nikkelforbindelser når det er nødvendigt for forståelsen af livscyklus for metallisk nikkel.

De gældende reguleringer af nikkel i arbejdsmiljø og miljø omhandler oftest nikkel og nikkelforbindelser som samlet gruppe. Eksponering for metallisk nikkel via hudkontakt med smykker og andre objekter med tilsigtet hudkontakt er dog specifikt reguleret i REACH Forordningen, der fastsætter grænser for den maksimale frigivelse af nikkel. Derudover er der lovgivning, der regulerer nikkel og nikkelforbindelser i arbejdsmiljøet, vandmiljøet, drikkevand, luftmiljøet, affaldsforbrænding, legetøj og kosmetik.

I arbejdsmiljøet er der i Danmark fastsat en grænseværdi for nikkel og nikkelforbindelser på 0,05 mg Ni/m^3. Europakommissionens videnskabelige komite for grænseværdier i arbejdsmiljøet (SCOEL) har i 2011 anbefalet en grænseværdi på 0,005 mg Ni/m^3 (for den respirable fraktion) af tungtopløselige nikkelforbindelser, herunder metallisk nikkel, for at beskytte mod kronisk inflammation i lungerne.

Metallisk nikkel er den mest anvendte form for nikkel i samfundet, især fordi nikkel indgår i rustfrit stål. Rustfrit stål indeholder omkring 8 – 12% nikkel, og visse speciallegeringer har endnu højere indhold. Der ses på verdensplan en generelt stigning i anvendelsen af nikkel, primært drevet af den stigende anvendelse af rustfrit stål i byggebranchen i lande som Kina.

Importen af metallisk nikkel til Danmark er domineret af nikkel og nikkellegeringer til industriel brug i forskellig form: nikkelpulver og -flager, plader, ark, rør, barrer, stave og tråd af nikkel og nikkellegeringer. Importen viser en svagt faldende tendens. Produktion og anvendelse af nikkelkatalysatorer udgør en stor og stabil post i statistikken. Nikkelholdigt metalskrot udgjorde tidligere en nettoimport, men eksporteres i dag til genbrug udenfor Danmark.

Forbruget af metallisk nikkel i EU ligger omkring 630.000 tons på årsbasis. Af dette er omkring halvdelen nyt produceret nikkel, mens resten er genvundet nikkel. I 2010 fordelte det samlede forbrug i EU af metallisk nikkel og nikkelforbindelser sig på 61% til rustfrit stål, 22,6% til nikkelholdige legeringer, 7% til overfladebehandling og 4,7% til støberier. De resterende 4,7% omfatter nikkel og nikkelforbindelser anvendt i batterier, kemikalier og i katalysatorer.

Udover rustfrit stål anvendes nikkel også til overfladebehandling. Funktionel overfladebehandling med nikkel bruges i bl.a. biler, fly og tog, men også i vid udstrækning til dekorative formål, f.eks. forkromede vandhaner og udstyr til badeværelser. Nikkel belægninger er desuden meget udbredt i elektronikindustrien. Nikkel har derudover en vigtig anvendelse som katalysator i kemiske processer, bl.a. i raffinaderier, til gødningsfremstilling og i kemisk industri. Endelig anvendes nikkel i batterier.

I affald medfører et nikkelindhold på over 1% en klassificering som farligt affald. Rene legeringer (uden forureninger) bliver dog ikke betragtet som farligt affald fra 2015.

I affald forekommer metallisk nikkel hovedsaligt som rustfrit stål indeholdt i skrot. Metalaffald bliver i Danmark overvejende behandlet i shredder-anlæg, der sikrer at 95% af den behandlede metalmængde kan genanvendes. Det genvundne metal fra disse anlæg eksporteres og genvindes i udlandet. De resterende 5%, svarende til omkring 150.000 tons per år, deponeres.

En massebalance for skrottede biler i Danmark viser at 80,3-262,3 tons nikkel årligt genvindes i shredder-anlæg, og at 3,8-13,8 tons nikkel per år er indeholdt i affald fra shredder processen. I værste tilfælde giver dette 138 tons nikkel, som årligt deponeres med shredderaffald. Fraktionen af nikkel, som indeholdes i affald og forbrændes ender i bundasken. Ved hjælp af nye teknikker kan op til 85% af dette nikkel genvindes.

Metallisk nikkel er klassificeret som miljøfarligt i den mindst alvorlige kategori (Aquatic chronic 3). Undersøgelser af nikkels farlighed i miljøet er oftest baseret på undersøgelser af vandopløselige nikkelforbindelser, og disse undersøgelser er derfor mindre relevante for metallisk nikkel, der er meget tungt opløseligt. Den opløste nikkel-ion er imidlertid meget giftig i vandmiljøet, hvilket reflekteres i det Europæiske miljøkvalitetskriterium for nikkel på 4 µg Ni/L (biotilgængeligt) i ferskvand og 8,6 µg Ni/L i saltvand. Biotilgængeligheden af nikkel-ionen i ferskvand afhænger af de fysisk-kemiske parametre: pH, opløst organisk kulstof og vandets hårdhed (calciumkoncentrationen). Der er udviklet brugervenlige computerværktøjer, som kan anvendes til at beregne den biotilgængelige fraktion. Risikoen for effekter af nikkel i det marine miljø er mindre end i ferskvand, og mekanismerne bag biotilgængeligheden af nikkel i det marine miljø er derfor ikke undersøgt så grundigt.

De målte niveauer af nikkel i danske og europæiske ferskvandssystemer ligger generelt under vandkvalitetskriteriet, men med en lille margin, og de målte koncentrationer overstiger ofte kriteriet. Anvendelse af måledata korrigeret for biotilgængelighed er derfor yderst relevant i situationer, hvor en detaljeret vurdering af risikoen for effekter af nikkel er nødvendig.

De observerede koncentrationer af nikkel i danske ferskvandssedimenter ligger generelt under PNEC værdien på 47 mg Ni/kg (tørvægt). I den Europæiske risikovurdering af nikkel og nikkelforbindelser blev det konkluderet, at der kun sås risiko i specifikke lokale scenarier, dvs. hvor der er udledninger. I det marine miljø overholdes kvalitetskravet for nikkel generelt lokalt såvel som regionalt. Det blev endvidere konkluderet, at der ikke var risiko for effekter i det terrestriske miljø eller hos rovdyr via fødekæden.

Vedrørende sundhedseffekter af nikkel skal det understreges at metallisk nikkel er mindre farligt og optages mindre effektivt end mere vandopløselige former for nikkel. Metallisk nikkel er klassificeret som mistænkt for at være kræftfremkaldende (Carc 2) i modsætning til mere opløselige former, der klassificeret som kræftfremkaldende (Carc 1A). Det skal endvidere bemærkes at metallisk nikkel ikke er klassificeret som skadeligt for reproduktionen i modsætning andre mere vandopløselige former. Det er dog ofte ikke muligt at skelne mellem metallisk nikkel og andre former af nikkel i miljøet og arbejdsmiljøet, da data oftest foreligger for total nikkel. Generelt kan det dog antages, at nikkelindholdet i føde, drikkevand luft og jord primært skyldes andre former end metallisk nikkel, og at afsmitningen af nikkel fra fx produktionsudstyr eller køkkenudstyr af rustfrit stål er lille i sammenligning med andre kilder.

Eksponeringen af forbrugeren sker primært via føde og drikkevand. Eksponering ved optag gennem huden fra smykker mv. er reguleret på et niveau, der vurderes at beskytte mod sensibilisering af ikke-sensibiliserede personer.

Som følge af de observerede lungeskader har den Europæiske Kommissions videnskabelige komité for arbejdsmiljøgrænseværdier (SCOEL) foreslået en arbejdsmiljøgrænseværdi på 0,005 mg/m3 (respirabel fraktion) for tungt opløselige nikkelforbindelser og nikkel metal. Anbefalingen er underlagt nærmere evaluering i EU før der kan tages beslutning om evt. fastsættelse af en bindende grænseværdi.

Den europæiske industri har for de mest relevant sektorer vurderet, om der findes mulige alternativer til nikkel. Den generelle konklusion er, at kun i få tilfælde er det muligt at erstatte nikkel med andre metaller eller teknikker. Metallisk nikkel i rustfrit stål og legeringer er generelt ikke et miljø- og sundhedsmæssigt problem. Nikkel anvendt til overfladebehandling kan kun erstattes, hvor der ikke er specifikke krav til modstandsdygtighed over for korrosion eller slitage. I fly og bilindustri er der ikke fundet teknisk egnede alternativer bortset fra anvendelser, der ikke stiller høje tekniske krav.

Nikkel anvendes i katalysatorer på grund af metallets iboende egenskaber. I visse tilfælde har andre metaller lignende egenskaber og giver samme eller mindre aktivitet. De mest velegnede alternativer er dog enten en begrænset ressource, eller medfører væsentlige tab i proceseffektivitet og/ eller produktionskapacitet. Substitution har derfor signifikante økonomiske og miljømæssige konsekvenser.

1. Introduction to the substance

1.1 Scope of the survey

The scope of the current survey is nickel metal. Other nickel compounds are not included in the LOUS list and are thus not covered by this survey. It is, however, noted that various nickel salts and other nickel compounds have different hazard profiles compared to nickel metal, as well as quite different uses and life cycles.

Although the aim of this survey has been to summarise the uses of metallic nickel and describe its life cycle, information on nickel salts is also included where needed to understand the technical interaction and the life cycle of metallic nickel. The scope of the report is to cover all uses of metallic nickel and also to address the waste life stages and recycling. Based on this the exposure and environmental release is estimated and the possible risks to humans and the environment are identified.

In a regulatory context, nickel metal is mostly discussed together with other nickel substances, e.g. nickel sulphate and nickel chloride. Most reports on nickel cover nickel as well as its compounds. Monitoring data from work places and the environment is mostly based on measurements of total nickel, which includes nickel metal as well as nickel compounds. Nickel is naturally occurring in soil and water mostly as inorganic nickel compounds but also arise from anthropogenic sources e.g. from the production and use of nickel metal and nickel compounds. For the same reason it is difficult to use monitored values as basis for assessing exposure to nickel metal.

Most toxicological and ecotoxicological studies are based on soluble nickel compounds and not nickel metal. The toxicity of nickel substances is connected to the nickel ion, however, the release rate of ions from nickel metal surfaces is very low. Thus the hazard profile and possible concern related to nickel metal is not quite the same as for other nickel substances.

Due to the low rate of uptake of nickel metal in the human body as well as the low rate of release into the environment nickel metal has a less stringent hazard classification compared to other, more soluble nickel compounds. While the main concern of many nickel salts is related to their well-documented carcinogenic and developmental effects in humans, there is no clear evidence for carcinogenic effects of nickel metal in humans. Nickel metal is, however, classified as suspected of causing cancer, i.e. a lower classification category compared to nickel salts.

The continued regulatory focus is primarily on nickel compounds and less on nickel metal.

1.2 Definition of the substance

The substance nickel is an element and registered in REACH as a mono constituent substance. Nickel metal is commercially available as nickel metal powder and nickel metal massive e.g. as pellets, briquettes, chips, granules, shots etc.

TABLE 1.1: SUBSTANCE IDENTITY (ECHA 2014)

EC name	Nickel
EC number	231-111-4
CAS number	7440-02-0
IUPAC name	Nickel
Synonyms	Nickel, metallic
Molecular formula	Ni
Molecular weight	58.6923 g/mol

The following general compositions are summarised from the registration dossier:

TABLE 1.2: GENERAL COMPOSITION (ECHA 2014)

Nickel metal species	Degree of purity %	Impurity	Typical concentrations and range (w/w)
Nickel metal powder Particle diameter < 1mm	>99.0 - <100.0 for pure nickel or ≥79.3-<99 for nickel oxide containing nickel powder[2]		
		Nickel Oxide[1]	>0.0 - ≤0.1 >1.0 - <20
		Carbon	>0.0 - ≤0.35
		Cobalt[1]	>0.0 - ≤0.1 0.1 - <1.0
		Copper	>0.0 – ≤0.001
		Iron	>0.0 - ≤0.05
		Oxygen	>0.0- ≤0.15
		Sulphur	>0.0 - ≤0.2
Nickel metal massive	>97.0 - ≤100.0 for pure nickel metal or >85.0 – ≤99.0 including nickel oxide and/ or cobalt impurities[2]		

Nickel metal species	Degree of purity %	Impurity	Typical concentrations and range (w/w)
		Nickel Oxide[1]	>0.0 - ≤ 0.1 >1.0 - ≤10.0
		Carbon	0.0 – ≤0.03
		Cobalt[1]	>0.0 - ≤0.1 >1 – 1.5
		Copper	>0.0 – ≤0.9
		Iron	>0.0 – ≤0.75
		Silicon dioxide	>0.0 - ≤1.5
		Sulphur	>0.0 – ≤0.14

[1] The impurity varies with different grades. The impurity may have implications on the Classification of the substance.

[2] Nickel oxide and cobalt impurities are included in some qualities of nickel metal. Composition details are confidential and not referred here

1.3 Physico- chemical properties

TABLE 1.3: PHYSICAL-CHEMICAL PROPERTIES (ECHA 2014)

Property	Value
Appearance	Nickel metal is a white shiny metal or grey solid powder.
Physical state at 20°C, 101.3 kPa	Solid
Melting point	1455 °C
Density	8.9 g/cm^3 at 25 °C
Water solubility	Nickel powder: insoluble in cold and hot water Nickel massive metal: not applicable

2. Regulatory framework

2.1 Legislation

This chapter provides an overview of how nickel metal is addressed in the existing legislation in EU and in Denmark. For readers not familiar with legislation issues, Appendix 1 provides a brief overview and connections between legislatives instruments in EU and Denmark. The appendix also gives a brief introduction to chemicals legislation, explanation for lists referred to in chapter 2, as well as a brief introduction to international agreements and relevant eco-labelling schemes

2.1.1 Existing legislation

The current legal status of nickel metal (hereafter named nickel) is summarised in Table 2.1: below.

TABLE 2.1: DANISH AND EU LEGISLATION SPECIFICALLY ADDRESSING NICKEL METAL

Legal instrument	EU/national	Requirements as concerns nickel
General legislation		
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	EU	Registration of production import and uses. Tonnage band registered for nickel: 100,000+ tonnes per year
		Nickel is regulated by restriction No. 27 in REACH Annex XVII: Nickel and its compounds must not be used in piercings and any other articles intended to have direct and prolonged skin contact. Restriction no. 27 specifies limits for the nickel release from piercings (0.2 µg Ni/cm2 /week). For consumer goods that come in contact with human skin (temporarily or longer lasting) the release threshold is 0.5 µg nickel/cm² /week.

Legal instrument	EU/national	Requirements as concerns nickel
REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures	EU	EU harmonised classification. (Classifications are described in section 2.1.3)
Regulation addressing substances and products (consumers)		
Regulation 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys *Implemented in Denmark by Statutory Order No 13; 10 January 2011: "Bekendtgørelse om sikkerhedskrav til legetøjsprodukter".*	EU / DK	The toy safety directive lays down maximum limits for migration of hazardous substances from toys. Upper migration limits depend on the type of material. For nickel limits range from 18.8 mg/kg to 930 mg/kg depending on type of material. Stainless steel is exempted.
REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products	EU	Nickel is prohibited in cosmetics as it is specifically listed in Annex II (entry no. 1093) of the Cosmetics Regulation.
Regulation addressing food and drinking water		
Council Directive 98/83/83/EC on the quality of water intended for human consumption Danish Statutory Order No 292; 26 march 2014 on water quality and monitoring of water supply systems *"Bekendtgørelse nr. 292 af 26/03/2014 om vandkvalitet og tilsyn med vandforsyningsanlæg."*	EU/ DK	A limit value for nickel in drinking water (at entrance to house and at the consumer's tap) has been set at 20 µg/l water.
Danish Statutory Order No 31; 21 January 2013 regarding approvals of drinking water installations amended by Danish Statutory Order No 1259; 5 November 2013: *"Bekendtgørelse nr. 31 af 21/01/2013 om udstedelse af godkendelser for byggevarer i kontakt med drikkevand." ændret ved Bekendtgørelse 1259 af 05/11/2013.*	DK	Special requirements for taps where metal comes into contact with drinking water. There are two test methods of analysis: NKB4: 80 µg. DS/EN 16058: 20 µg For both methods, the requirement applies to the average total amount calculated for at least three products.

Legal instrument	EU/national	Requirements as concerns nickel
REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC	EU/DK	There is no specific regulation of nickel in the Food Contact Materials Regulation. Constituents in food contact materials are not allowed to be able to transfer into food in quantities hazardous to human health. This general provision also applies to nickel. Manufacturers of food contact materials have to prepare a regulatory compliance statement. Normal practice in these statements is to refer to Specific Release Limits (SRL) established in *Metals and alloys used in food contact materials and articles* where SRL for nickel is 0.14 mg/kg food. (EDQM 2013).
Regulation addressing substances and products (workers)		
COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work *Implemented in Denmark by: Statutory Order No. 292; 26. April 2001. "Bekendtgørelse om arbejde med stoffer og materialer (kemiske agenser)"* *Under this Statutory Order Nickel is regulated by an Occupational Exposure limit in Statutory Order No. 507; 17. May 2011. "Bekendtgørelse om grænseværdier for stoffer og materialer"*	EU / DK	The Chemical Agents Directive (CAD) lays down minimum requirements for the protection of workers from risks to their safety and health arising from the use of chemicals in workplaces. The provisions in these directives are the basis for the establishment of Occupational Exposure Limit values (OEL). The Danish OEL for nickel in metallic compounds is set to 0,05 mg/m^3 measured as Ni. For soluble non-metallic nickel compounds the DK-OEL-list defines an even more restrict level of 0.01 mg/m^3 measured as Ni.

Legal instrument	EU/national	Requirements as concerns nickel
DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. *Implemented in Denmark by Statutory Order No 908; 27 September 2005: "Bekendtgørelse om foranstaltninger til forebyggelse af kræftrisikoen ved arbejde med stoffer og materialer".*	EU / DK	Because of the carcinogenic properties of nickel, the substance is covered by this Danish statutory order if the concentration of nickel in chemical preparations is 0.1% or higher. Special provisions are valid for nickel
Regulation addressing waste		
DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives. *Implemented in Denmark by Statutory Order No 1309/18/12: "Bekendtgørelse om affald"*	EU / DK	No special regulation on nickel, but based on their classification nickel metal and mixtures with nickel metal will be regarded as hazardous waste. The European Waste Catalogue has no categories specifically mentioning nickel. Nickel metal is however indirectly regulated in the catalogue based on impurities of heavy metals. The European Waste Catalogue is implemented in the Danish Statutory Order as Annex II.
Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000, on the incineration of waste (*Waste incineration Directive*)	EU	An air emission limit value for nickel at either 0.5 mg/m^3 or 1 mg/m^3 applies dependent on NOx emission level and type of facility.
REGULATION (EC) No 1013/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 June 2006 on shipments of waste	EU	Regulates shipment of various types of hazardous waste. Nickel metal is included based on it classification. The annex's from the Basel Convention form the basis of the regulation e.g. as nickel scrap in *Metal and metal bearings waste.*
DIRECTIVE 2006/66/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 September 2006 on batteries and accumulators and waste batteries and accumulators	EU	Recycling processes shall result in recycling of minimum 75 % by average weight of nickel-cadmium batteries. For other batteries (a.o. NiMH-batteries) minimum 50 %

Legal instrument	EU/national	Requirements as concerns nickel
		recycling is required.
Regulation addressing emissions to the environment		
DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy (*Water Framework Directive*)	EU	The current EQS for nickel is 4 µg Ni/L in inland water, and 8.6 µg Ni/L in other surface waters. Both values are referring to the bioavailable fraction as indicated in the latest amendment of the directive - DIRECTIVE 2013/39/EU of 12 August 2013.
Directive on Ambient Air Quality 2008/50/EC and specific regulation of a.o. nickel in Directive 2004/107/EC	EU	A target value for nickel at 20 ng Ni/m³ has been set. The Ambient air directive contains specific target values specifically for arsenic, cadmium, nickel and benzene. The Directive contains provisions for monitoring of the air quality with respect to these substances and set target values for the individual substances. Where target values are exceeded measures such as those in the IPPC /IED directive on use of BAT should be used to reduce the levels in air.
Danish Statutory Order no. 669 of 18/06/2014: *"Bekendtgørelse om godkendelse af listevirksomheder. BEK nr 669 af 18/06/2014"*	DK	Sets out criteria for the authorisation of industrial facilities handling substances that may pose a risk when emitted into the environment. If substances on the "List of unwanted substances" are used it shall be justified why substitution is not possible.

In 2011 the EU Scientific Committee on Occupational Exposure Limits (SCOEL) submitted a recommendation on an 8 hour OEL for the protection against chronic inflammation and carcinogenic effects of the lungs at 0.01 mg Ni/m3 for the inhalable fractions of soluble and poorly soluble nickel compounds, and at 0.005 mg/m3 for the respirable fraction of poorly soluble nickel compounds. Nickel metal is regarded poorly soluble. This recommendation is being further discussed and the values are not adopted as Community OELs.

2.1.2 Risk Assessment according to Council Regulation (ECC) 793/931

Nickel and nickel compounds, were subject to a risk assessment under the Council Regulation (EEC) 793/931, submitted in May 2008 (European Commission. 2008 (EU RAR)). The risk assessment conclusions have shown that it is the nickel ion rather than the individual nickel compounds that have effect on the risk to human health and environment.

The extensive toxicological and ecotoxicological data base created during the EU RAR was used as background for the preparation of the registration dossiers on nickel. Thus in many ways the REACH registration dossiers represent an update and refinement of the work done in the risk assessment.

2.1.3 Classification and labelling

Nickel metal is included in the list of harmonised classifications in Annex VI of the CLP regulation (EC no. 1272/2008).

2.1.3.1 Harmonised classification in the EU

The harmonised classification of nickel metal is summarised in Table 2.2 below. Nickel is listed in two entries: One for nickel metal and one for nickel powder.

TABLE 2.2: HARMONISED CLASSIFICATION ACOORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International chemical identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
028-002-01-4	nickel powder [particle diameter < 1 mm]	7440-02-0	Skin Sens. 1	H317[1]
			Carc. 2	H351[2]
			STOT RE 1	H372[3]
			Aquatic Chronic 3	H412[4]
028-002-00-7	nickel	7440-02-0	Skin Sens. 1	H317
			Carc. 2	H351
			STOT RE 1	H372

Further, nickel shall be labelled with the signal word “Danger” and the pictograms:

GHS07

GHS08

According to the registration dossier nickel metal and nickel metal powder may contain impurities of other metals including nickel oxide and cobalt. The registration dossier includes nickel metal grades of different impurities and different resulting classifications. Nickel oxide has a harmonised classification as Carc 1A and if present in concentrations higher than 0.1 % (w/w) the nickel metal is classified Carc 1A.

[1] H317: May cause an allergic skin reaction
[2] H351: Suspected of causing cancer by inhalation
[3] H372: Causes damage to organs through prolonged or repeated exposure
[4] H412: Harmful to aquatic life with long lasting effects

ECHAs Classification and Labelling Inventory (C&L Inventory) has 3,130 entries in a combined record for both nickel and nickel powder. Nearly all entries follow the harmonised Annex VI classification for either nickel or nickel powder and only a few single entries deviate from this. It is important to note that submissions to C&L Inventory have not undergone any quality control.

2.2 Summary and conclusions

Nickel metal is classified as skin sensitiser, as causing damage to the lungs through prolonged and repeated exposure and as a suspected carcinogen by inhalation. Additionally nickel powder is classified as environmentally hazardous although not in the most severe classification category. A classification as Carc 1A can be triggered by impurities - e.g. nickel oxide - available in some grades of nickel in concentrations higher than 0.1 %.

The direct exposure of consumers to products containing nickel and nickel compounds is regulated by REACH, by more specific community legislation as well as by national Danish legislation. REACH restricts the release of nickel ions in jewellery and other objects with skin contact. Moreover specific provisions relevant for nickel and nickel substances apply in the work environment, the water environment, drinking water, ambient air, waste incineration, toys and cosmetics.

Exposure to nickel in the work environment is in Denmark regulated by a national Danish OEL for nickel and nickel compounds at 0.05 mg Ni/m^3. The European Commission Scientific Committee on OEL (SCOEL) recommends an 8 hour OEL for the protection against chronic inflammation and carcinogenic effects of the lungs at 0.01 mg Ni/m3 for the inhalable fractions of soluble and poorly soluble nickel compounds including nickel metal, and at 0.005 mg/m3 for the respirable fraction.

3. Manufacture and uses

3.1 The nickel life cycle

Nickel metal is widely used in the society, mainly as a component in stainless steel, steel and alloys where it contributes by increasing the resistance to wear and corrosion as well as other properties. In terms of volume stainless steel is the most important use of nickel accounting for 61 % of the use in the EU in 2011. Stainless steel is used widely in construction and process industry, where the resistance to corrosion and wear is needed. In EU approx. 70 % of the use of nickel (mainly on metal form) lies in the sectors: building and infrastructure, transportation and industrial machinery (Reck et al. 2008).

An important use of metallic nickel is in functional plating of machine parts and in engineering. Nickel plated items are for example used in cars, aeroplanes and trains in places where there are specific requirements to wear (e.g. landing gear in airplanes) and corrosion resistance parts (cars). Nickel plating is used to substitute cadmium in electronic equipment, which has been phased out according to EU legislation. In electronics nickel plating ensures corrosion free contacts and prevents formation of so called ‘whiskers’ that may short circuit electronic devises. Nickel metal is moreover used in a range of downstream industries such as catalyst production, decorative plating and production of batteries. The different uses of nickel metal are discussed in further details in this chapter.

The anthropogenic life cycle of nickel can be presented graphically as shown in Figure 3.1:

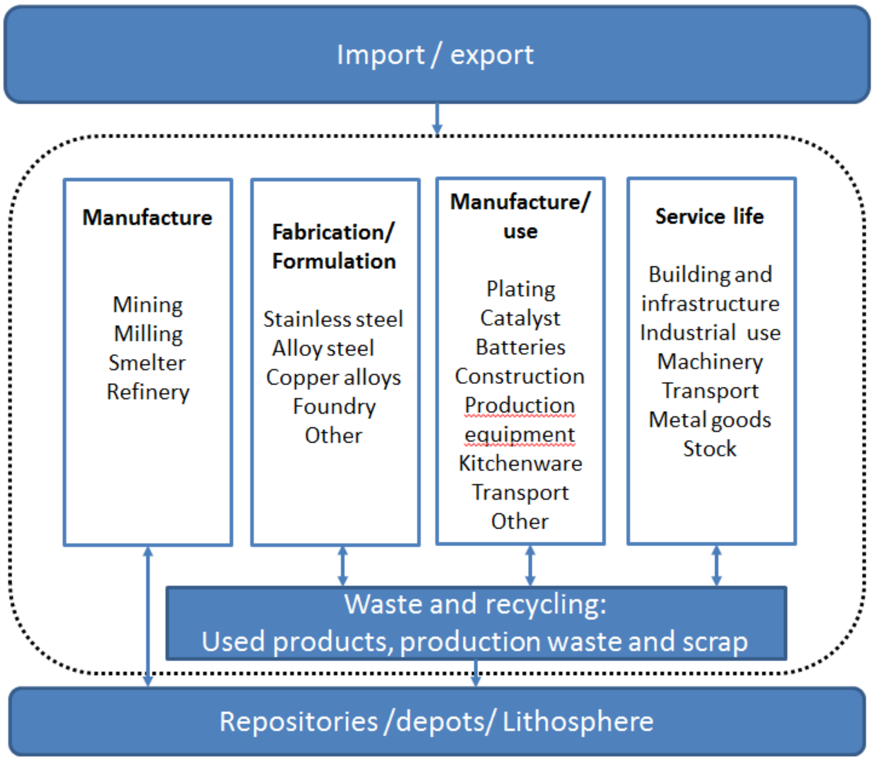

FIGURE 3.1: THE ANTHROPOGENIC LIFE CYCLE OF NICKEL CAN BE PRESENTED GRAPHICALLY (BASED ON RECK 2007)

Figure 3.1 shows the steps in the life cycle of nickel metal from the mining of ore and smelting into the intermediate product nickel 'matte' and further refining to primary (new) nickel metal (Manufacture). In the formulation step primary and secondary nickel (from scrap and recycled production waste) is used in the production of different metal alloys such as stainless steel and nickel containing steel alloys, copper alloys and foundry. The metal nickel or alloys are used in the production of steel equipment, batteries, plating, construction materials, machinery etc. The service life phase includes metal nickel in steel and alloys used in constructions, machinery etc. This is by volume far the largest pool or standing stock of nickel metal in the society and has a long turn-over time. Waste and recycling is characterised by recycling companies specialised in separating and recycling of metals, including nickel containing steel. In addition 'internal' recycling at the individual production sites is common in manufacture and fabrication. Recycling is integrated in the product life cycle of e.g. catalysts, batteries and electronics.

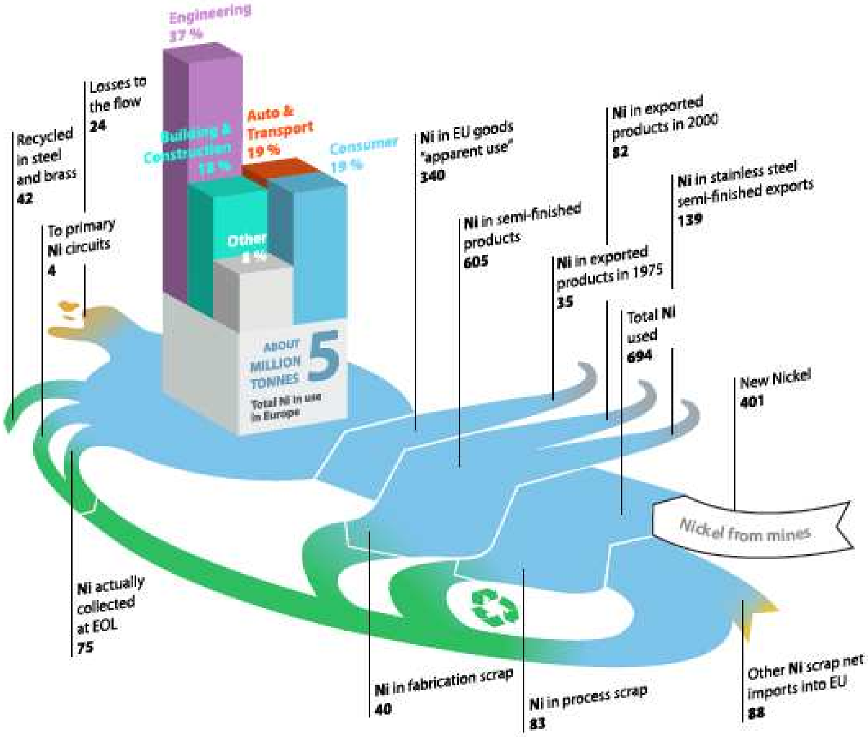

FIGURE 3.2: NICKEL MASS-FLOW IN EUROPE. THE FIGURES ARE IN THOUSAND TONNES PER YEAR AND REPRESENTATIVE OF ANNUAL FLOWS IN THE PERIOD 2005 – 2010, BASED ON AN ASSUMED AVERAGE 25 YEAR LIFE CYCLE (NICKEL INSTITUTE 2013)

Figure 3.2 from the Nickel Institute illustrates that the fraction of 'new produced nickel' entering the life cycle is only a little higher than the recycled fraction of nickel. New nickel at 401,000 tonnes/ year accounts for 55% of the use whereas recycled nickel accounts for 332,000 tonnes/year, or 45%. New nickel is mainly new produced nickel metal but includes also nickel salts used in manufacture of nickel metal, and in plating, battery and catalysts sectors. A second important observation is the large fraction of nickel in use (service life stage) which is estimated at 5 mill tonnes included in constructions, auto and transport equipment and consumer products.

3.2 Manufacturing

Nickel is a naturally occurring, lustrous, silvery-white metallic element. It is the fifth most common element on earth and occurs everywhere in the earth's crust. The nickel containing mineral ore is in the first step refined into nickel matte (nickel oxide or nickel sulphide matte). The further processing into nickel metal takes place by one of the following processes:

a) From NiO matte via reduction and activation in rotary kilns.
b) From NiS sulphide matte by leaching with chlorine gas into iron or cobalt nickel containing chloride solution followed by electrowinning to give nickel metal.
c) By leaching of NiS matte with sulphuric acid to give nickel sulphate followed by electrowinning to give nickel metal.
d) By leaching of NiS matte to give nickel sulphate followed chemical reduction with hydrogen gas to nickel powder and briquettes.
e) By precipitation of nickel sulphate solution followed by pyrolysis to form nickel powder.
f) Heat treatment of lateritic ore (specific for FeNi production) in rotary kilns, further refining in furnace and quenching in water to give nickel metal granules.
g) Production of nickel powder from hydroxycarbonate by hydrogen reduction.

Nickel metal is commercially available as nickel metal powder and nickel metal massive (pellets, briquettes, chips, granules, shots etc.)

3.2.1 Manufacturing sites

The largest mining countries in the EU are Finland, Greece, Spain and France. France is mining nickel in New Caledonia in the southwest Pacific Ocean. Sweden is in the process of exploiting the possibilities of nickel mining in the future. On the global scale, the largest mining countries are Russia, Indonesia, Canada, Australia and New Caledonia.

The map below show the main sites of mining, smelting, refining and use if chemicals for nickel in Europe.

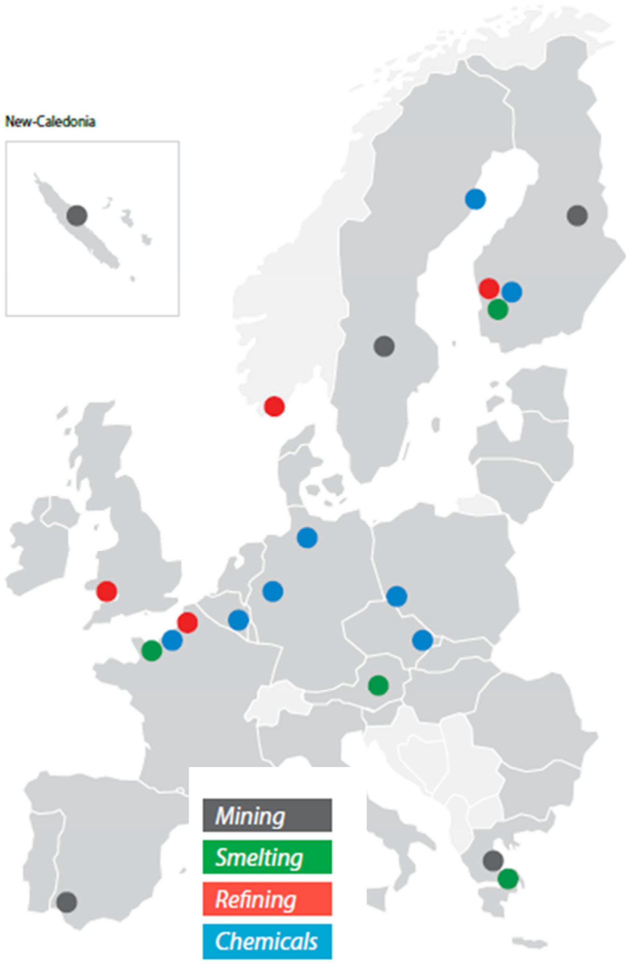

FIGURE 3.3: MAIN SITES IN EUROPE OF MINING, SMELTING, REFINING AND USE OF NICKEL IN CHEMICALS (NICKEL INSTITUTE 2013)

3.3 Import and export

3.3.1 Import and export of nickel metal in Denmark

The import and export for nickel metal containing SITC (Standard International Trade Classification) product groups are presented in Table 3.1. Nickel as ore, matte and ferronickel play an insignificant role in the Danish nickel cycle. The nickel import to Denmark is dominated by nickel and nickel alloys in different forms being used in industrial production, e.g. nickel powders and flakes, nickel and nickel alloy plates, sheets, foils, tubes, pipes and fittings, alloy bars, rods profiles and wires. The import/ export data also reflect that an important producer of catalysts and a major refinery using nickel catalysts (in Kalundborg) are located in Denmark, with a large import and export of nickel containing catalysts. There is a declining trend for the import of some the product groups. However this is not the case for supported catalysts, and nickel unwrought (pure nickel).

Supported catalysts are the most important route for import of nickel into Denmark as well as the most important export route. Previously nickel waste and scrap has been imported in significant amounts, but this seems to have decreased significantly probably because the main steel manufacturer in Denmark (DanSteel, Frederikssund) does not use scrap any more. Waste and scrap seem now to be exported to a higher degree than previously. For some of the product groups, the high yearly variation in import of nickel can be explained partly by import of large scale construction works such as the Great Belt Bridge or the Copenhagen Metro, where huge amounts of steel as rods and wire are needed.

According to the Danish Statistics the reported data have some uncertainties, primarily because only industries with more than 50 employees are required to report import and export data. Moreover nickel products may be imported and stocked for later use, thereby leading to fluctuations in the general trend.

The average import of products containing nickel for the years 2007 to 2013 was approximately 1330 tonnes. In the same time the export of nickel containing products approximated 5430 tonnes per year. The reason for this apparent in-balance is that the import is registered in tonnes of product not considering the nickel content. Thus import of unwrought nickel and nickel as powders and flakes with a purity of close to 100% has a higher weight in the nickel balance than the main export item catalysts, which has a much lower nickel content.

TABLE 3.1: INFORMATION FROM STATISTICS DENMARK REGARDING IMPORT, EXPORT AND NET-FLOW OF NICKEL CONTAINING PRODUCTS, FOR THE YEARS 2007 TO 2013. NUMBERS ARE GIVEN IN TONNES OF NICKEL CONTAINING PRODUCT

Import		2007	2008	2009	2010	2011	2012	2013
28410 Nickel Ores And Concentrates	imp	0.7	0.3	0.2	0.0	116.0	116.8	1.0
	exp	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	net	0.7	0.3	0.2	0.0	116.0	116.8	1.0
28421 Nickel Matte	imp	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	exp	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	net	0.0	0.0	0.0	0.0	0.0	0.0	0.0
28422 Nickel Oxide Sinters And Other Intermediate Products Of Nickel	imp	0.0	0.5	25.6	0.0	0.0	0.0	0.0
	exp	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	net	0.0	0.5	25.6	0.0	0.0	0.0	0.0

Import		2007	2008	2009	2010	2011	2012	2013
Metallurgy								
28822 Nickel Waste And Scrap	imp	561.7	47.4	0.0	0.0	4.4	28.9	79.9
	exp	491.2	781.1	907.0	1291.6	858.7	440.7	92.5
	net	70.4	-733.7	-907.0	-1291.5	-854.3	-411.8	-12.6
59881 Supported Catalysts With Nickel Or Nickel Compounds As Active Substances	imp	309.6	310.2	680.3	477.3	349.6	1265.6	754.1
	exp	2227.6	6009.7	6387.1	nd	4375.0	6297.5	6929.7
	net	- 1918.0	- 5699.5	- 5706.8	nd	- 4025.4	- 5031.9	-6175.6
67155 Ferronickel	imp	0.0	0.0	1.0	0.5	0.1	0.1	0.0
	exp	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	net	0.0	0.0	1.0	0.5	0.1	0.1	0.0
68311 Nickel. Unwrought (Not Alloyed)	imp	60.9	53.8	30.5	34.0	56.4	65.1	65.8
	exp	10.4	3.4	0.7	0.0	0.9	0.1	0.0
	net	50.5	50.4	29.8	34.0	55.5	65.0	65.7
68321 Nickel And Nickel Alloy Bars. Rods. Profiles And Wire	imp	163.3	98.9	417.5	28.7	32.5	26.7	32.2
	exp	10.9	4.3	28.6	4.4	3.6	2.8	2.0
	net	152.3	94.6	388.9	24.2	28.8	23.9	30.2
68322 Nickel And Nickel Alloy Tubes. Pipes And Tube Or Pipe Fittings	imp	50.0	42.7	44.6	24.4	15.7	36.5	23.1
	exp	17.2	9.9	7.0	3.8	7.7	364.1	17.1
	net	32.8	32.8	37.6	20.6	8.0	-327.6	6.0
68323 Nickel Powders And Flakes. Including Nickel Alloy Powders And Flakes	imp	377.3	459.3	549.7	374.8	0.9	131.7	10.3
	exp	0.0	0.0	0.0	0.0	0.0	7.9	0.0
	net	377.3	459.3	549.7	374.8	0.9	123.9	10.3
68324 Nickel And Nickel Alloy Plates. Sheets. Strip And Foil	imp	250.2	100.3	67.3	46.1	84.9	82.9	106.9
	exp	3.1	6.5	3.6	26.8	12.9	9.8	13.4
	net	247.1	93.9	63.7	19.4	72.0	73.1	93.5
69975 Articles Of Nickel. N.E.S.	imp	19.9	25.3	7.9	28.9	11.6	26.1	7.7
	exp	45.3	116.0	15.8	10.9	8.3	11.6	127.5
	net	-25.3	-90.6	-7.8	18.0	3.3	14.4	-119.8

3.3.2 Import and export of nickel metal in EU

Reck (2008) studied the material flow in nickel and stainless steel for the years 2000 and 2005 on a global scale. According to the study the import of nickel into EU was in the form of refined nickel, nickel matte, scrap and concentrate, in decreasing order. The export of nickel from EU was mainly as intermediate and final products. However, large variations between countries can be observed.

Norway for example, refines nickel matte to nickel. Germany imported roughly 100 Gg (100,000 tonnes nickel metal) refined nickel and the resulting export was intermediate nickel compounds, final products and scrap (Reck 2008).

Regarding nickel scrap the general picture is that Germany, France and Holland seem to export the highest amounts of scrap, whereas the European importers are mainly Belgium, Finland and Spain. The data for Denmark show a similar overall picture: nickel is imported as semi-finished products, and exported as final products and scrap.

TABLE 3.2: DATA FOR NET IMPORT OF NICKEL FOR SELECTED EUROPEAN COUNTRIES, FOR THE YEARS 2000 AND 2005. NUMBERS ARE GIVEN AS GIGAGRAM NICKEL/YEAR. DATA OBTAINED FROM BACKGROUND DATA FOR THE STUDY BY RECK (2008)

	Be-Lu	Dk	Fin	Fr	De	Gr	It	Ne	No	Es	Se	UK	Eu
2000													
Ni concentrate	0	0	40	0	0	0	0	0	-3	0	0	0	37
Ni matte	0	0	16	9	0	0	0	0	58	0	0	25	108
Refined Ni	28	0	-12	39	105	-20	51	43	-59	40	38	-4	259
Ni semis	-29	6	-30	4	-10	2	3	12	2	-37	-30	15	-64
Final products	4	-3	-3	-4	-14	7	-27	7	5	-3	-4	2	-36
Scrap	45	0	8	0	-30	0	11	0	0	29	20	13	95
2005													
Ni concentrate	0	0	20	0	0	1	0	0	0	-1	0	0	20
Ni matte	0	0	14	15	0	0	0	0	84	0	0	27	140
Refined Ni	43	0	28	20	101	-21	72	-2	-82	43	33	-15	227
Ni semis	-57	6	-60	-12	-19	4	0	8	1	-30	-33	-3	-164
Final products	3	0	-4	3	-18	1	-29	2	2	0	-1	10	-36
Scrap	54	-2	38	-16	-19	0	13	-13	-1	26	9	-9	74

According to the Nickel Institute, the nickel mass flow in the EU presented in figure 3.2 indicates a total average use of nickel in the period from 2005 – 2010 of 694.000 tonnes per year. Of this over 95%, or 659.000 tonnes, is nickel metal, of which 61%, or 401.000 tonnes, is 'new nickel', and the remaining comes from recycled material. About 88.000 tonnes of nickel scrap is imported into EU per year (Nickel Institute, 2013).

The International Nickel Study Group, INSG, documents that the production of primary nickel in Europe(27) has been relatively stable, around, 120.000 tonnes per year, during the years 2007 to 2012, but with a decrease in 2009 and 2010. **Fejl! Henvisningskilde ikke fundet.** shows the production of primary nickel in the different regions of the world, according INSG. In Table 3.4 the data for use of primary nickel in the different regions of the world is presented (INSG 2014).

TABLE 3.3: PRODUCTION OF PRIMARY (NEW) NICKEL IN THE YEARS 2007 TO 2012, DATA OBTAINED FROM INSG, 2014

Primary nickel production in 1000 tonnes	2007	2008	2009	2010	2011	2012
Africa	43.0	36.6	36.3	36.0	36.5	41.1
America	317.2	299.4	234.1	223.1	272.7	300.7
Asia	379.4	378.6	432.3	538.0	628.5	730.3
Europe	513.7	510.2	444.4	501.6	521.7	514.3
EU27	121.8	122.8	81.5	108.7	118.6	117.2
Oceania	156.2	141.9	167.6	141.4	150.7	174.5
world total	1409.5	1366.7	1314.7	1440.1	1610.1	1760.9

TABLE 3.4: PRIMARY NICKEL USAGE IN THE YEARS 2007 TO 2012, DATA OBTAINED FROM INSG, 2014

Primary nickel usage in 1000 tonnes	2007	2008	2009	2010	2011	2012
Africa	33.6	27.0	31.7	24.0	21.8	24.8
America	171.4	160.5	121.8	153.2	163.9	169.9
Asia	690.9	688.3	760.4	929.4	1026.4	1099.2
Europe	423.9	407.5	317.7	355.9	365.5	361.6
EU27	381.4	365.1	279.9	317.4	336.4	333.0
Oceania	2.9	2.9	2.7	2.7	2.8	2.8
world total	1322.7	1286.1	1234.3	1465.2	1580.4	1658.3
EU27 import	259.6	242.3	198.4	208.7	217.8	215.8

From the tables above it is clear that the production of primary (new) nickel in the EU accounts for approximately 1/3 of the total use. During the economic crises the EU production and use declined from 2009 to 2012. Asia is the main global driver for nickel consumption especially due to the increase in construction activities in China (Reck 2008).

3.4 Use

3.4.1 Use of nickel metal in Denmark

The use of nickel metal in Denmark was estimated for the years 1992-1993 (Danish EPA, 1996). Although these data are rather old they show a similar pattern as reported for Europe, with the main use being stainless steel and alloys. The consumption of nickel for stainless steel was estimated at 4.600-6.000 tonnes Ni/year, corresponding to 80% of the total Danish consumption of nickel metal. Other uses included other steel types (70-300 tonnes), nickel plating (70-130 tonnes), nickel-copper alloys (220-300 tonnes), and other uses of nickel as metal (86-330 tonnes).

Since 1992 – 1993 it is assumed that the Danish consumption of nickel in primary production like plating industry and foundry industry has declined. It is a general trend in EU that plating industry has moved from high cost countries in the northern Europe to e.g. Italy or countries outside the EU. Also the number of Danish foundries is reduced since the early 1990'es.

According to the most recent figures from the SPIN database, the use of nickel (as nickel and nickel compounds) in Denmark is primarily in the use categories process regulators and welding and soldering. However the relevance of data from the SPIN database, in the case of nickel, is most likely low, because the use accounted for in SPIN is limited to the use of substances in chemical products and preparations.

3.4.2 Use of nickel metal in the EU

According to the Nickel Institute, the main use of nickel metal in Europe is for the production of stainless steel, which accounts for 61% of the total nickel consumption. The majority of stainless steel alloys contains between 8 and 12 % nickel. Figure 3.4 presents the main uses of nickel and nickel compounds in Europe.

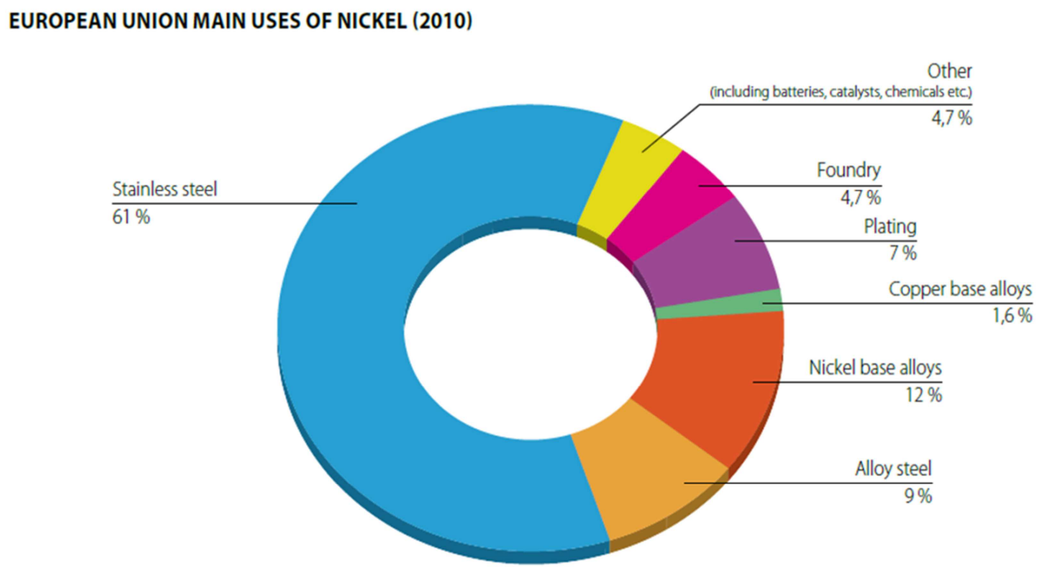

FIGURE 3.4: MAIN USES OF NICKEL AND NICKEL COMPOUNDS IN EUROPE, OBTAINED FROM THE PUBLICATION "NICKEL IN THE EUROPEAN UNION" (NICKEL INSTITUTE 2013)

Provided the tonnage of nickel metal used in 2008 is 630,000, the approximate tonnage for different purposes can be estimated as shown in Table 3.5.

TABLE 3.5: TONNAGE DATA FROM 2008 DISTRIBUTED ON THE MAIN USES OF NICKEL METAL IN EU FOR 2010. BASED ON DATA FROM THE NICKEL INSTITUTE (2013)

Use category	Estimated tonnage
Stainless steel	386862
Alloy steel	57078
Nickel base alloys	76104
Copper base alloys	10147
Plating	44394

Foundry	29807

The Nickel Metal registration dossier identifies the following uses of nickel metal:

Manufacture of nickel:
- Carbonyl refining of nickel matte (Nickel carbonyl process)
- Electrolytic refining of nickel matte via nickel sulphate solution (Hydrometallurgical process)
- Leaching and hydrogen (H2) reduction of Ni sulphide (NiS) matte
- Thermal decomposition of complexed nickel into nickel powder
- Production of FeNi for use in stainless steel
- Production of Nickel metal powder from Nickel Hydroxycarbonate
- Production of nickel-containing alloy powders from nickel oxide
- Production of nickel metal
- Leaching and hydrogen reduction of nickel sulphide matte
- Production of nickel containing alloys

Manufacture of catalysts
- Production of catalyst
- Manufacture of Ni-containing catalysts from NiO-containing catalyst precursors
- Ni catalyst production from NiO-containing catalyst precursor
- Use as Raney nickel (catalyst)
- Use of homogeneous catalyst

Downstream uses of nickel metal
- Stainless, special steels and special alloys manufacturing
- Integrated steel and iron manufacturing
- EAF carbon steel manufacturing
- Powder metallurgy
- Metal surface treatment – nickel electroplating and nickel electroforming
- Production of Ni salts from Ni metal
- Manufacturing of batteries using positive nickel electrodes
- Use of pre-reduced Ni-containing catalysts
- Production of magnets (powder use)
- Production of nickel-containing products (electronics).
- Production of brazing alloys.
- Use of brazing alloys.
- Production of silver-nickel contact material.
- Use of silver-nickel contact material.
- Sputter deposition.
- Thin film deposition by evaporation technique.
- Machining of nickel alloys and nickel-coated metal objects.
- Use of Ni metal for Thermal Spraying.
- Use of nickel metal for the production of steel and other alloys powder by atomisation.
- Use of Ni-containing alloys for blasting.
- Use of nickel metal in formulating surface treatment products.

3.5 Summary and conclusions

Nickel metal is by far the main form of nickel in the society, due to use in stainless steel for construction, in machinery and production equipment as well as special alloys. The general worldwide trend is an increased use of nickel metal, mainly driven by the construction sector in developing countries (China, Asia).

The largest pool of nickel metal is the fraction in use (Service Life) in constructions, industry and transport equipment and machinery and the turnover of this pool is slow. The recirculation is relatively high and the amount of recycled nickel metal is about the same size as the new produced (primary) nickel.

The nickel import to Denmark is dominated by nickel and nickel alloys in different forms being used in industrial production with a slight declining trend: nickel powders and flakes, nickel and nickel alloy plates, sheets, foils, tubes, pipes and fittings, alloy bars, rods profiles and wires. Due Danish nickel catalysts production and use nickel catalysts is responsible for a large stable net import and export of nickel in the trade statistics. Nickel containing scrap constituted earlier (2007) a net large net import but is today exported and recycled outside Denmark.

The consumption of nickel metal in the EU is approximately 630,000 tonnes/year. Of this, about half is assumed to be new produced nickel and the other half recycled material. In the EU the combined use of nickel metal and nickel compounds in 2010 was: stainless steel (61%); alloy steel and nickel and copper based alloys (22.6%), plating (7%) and foundry use for 4.7 %. The remaining 4.7% was nickel and nickel compounds used in batteries, catalysts, chemicals etc.

In addition to the use in steel and alloys, nickel metal is used for plating and surface treatment in the transport sector as functional plating in cars, trains, airplanes, electronics but is also for decorative purposes on furniture, bathroom fittings, etc. As catalysts nickel metal has an important role in specific chemical manufacturing processes. In battery production it is used as intermediate and does not appear in the final product.

4. Waste management

Nickel is present in many forms in waste, mostly as a nickel compounds – e.g. nickel oxide or nickel hydroxide. This report focusses, however, on nickel metal which is present mainly in metal scrap, electronic waste and slags from foundries.

4.1 Regulatory practices

In Denmark waste treatment is regulated by the statutory order on waste (Danish Ministry of the Environment, 2012), which includes waste streams where nickel typically may occur. In addition other regulations may cover more specific fractions of the waste stream e.g. sludge from STPs. There are no waste categories in the European Waste Catalogue specifically mentioning nickel. Nickel metal is however indirectly included in several wastes defined as hazardous triggered by their content of heavy metals. Nickel metal is defined as a heavy metal in the Catalogue.
As an overall rule all waste fractions containing hazardous compounds at a concentration level that, according to the classification rules for chemical compounds and preparations would require classification as hazardous, should be considered and treated as hazardous waste.
The limit for the classification of a mixture for the nickel classification as Carc 2; STOR RE 1 and Skin sens. 1 is the general value in CLP at 1 % (w/w).

Until 2015 waste is classified based on the classification rules in the Dangerous Preparation Directive[5] (DPD). Similar to CLP, mixtures containing nickel will also according to DPD be classified as hazardous from 1 % (w/w). Hence according to current regulation, waste containing nickel metal is considered as hazardous waste if the content of nickel metal exceeds 1%.
Pure uncontaminated metal alloys will not be regarded as hazardous waste when the new classification criteria for waste (aligning waste classification with the principles in the CLP Regulation) will enter into force from June 1st 2015. E.g. uncontaminated stainless steel with more than 1 % nickel will not become hazardous waste based on the nickel content alone.

4.2 Import and export of metal waste in Denmark

Statistics for Denmark show an increase in the export of metal waste from 2009 to 2011. The increase is mainly caused by an increase in export of the “iron and metal” fraction. It is estimated that 95 % of the exported fraction is recycled. It should be noted that due to a recent implementation of a new data collection system on waste in Denmark these statistics are subject to great uncertainty and the numbers have not undergone any quality control (Danish EPA, June 2013).
Accordingly nickel contained in metal waste will be recycled and integrated in new products. It needs to be mentioned that normally it is not possible to separate nickel from other metals in the scrap, and that nickel will be contained in the recycled fractions of stainless steel, nickel containing alloys and steel.

4.3 Waste from manufacture and use of nickel metal

Metallic nickel waste is generated in several steps in the lifecycle of nickel. Primary waste is waste from manufacture and fabrication of semi-finished and finished products.

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5 Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

Metallic nickel in End-of-Life-products from industry and consumers ends up in the general waste stream and is either separated and recycled, incinerated or deposited in landfills.

In Denmark nickel metal will most likely end up as part of the metal scrap fraction collected either directly at the source, or (especially for waste from consumers) through municipal waste collections of metal fractions. It is assumed that all recyclable metal scrap fractions are exported for treatment outside Denmark.
Despite a large fraction of metal is collected separately and recycled, the incinerated waste will still contain a significant amount of metal – including nickel.

4.3.1 Shredder waste

Normally the collected metal waste fractions are treated in highly specialized sorting and shredding facilities where the valuable metal fractions are extracted through various processes e.g. magnetic separation, cyclone separation, manually, and sold to recycling companies. The remaining fraction after sorting is referred to as shredder waste. The shredder waste consists of foam, rubber, plastic, iron and metals, and has high energy content. In Denmark approximately 150.000 tons of shredder waste is generated each year but significant variations in tonnage may occur (Danish EPA, 2013a). Until recently most shredder waste was deposited in landfills. This may have changed as a result of change in taxation of shredder waste, but no newer data can confirm this. Some of the shredder waste is incinerated at approved incineration facilities as it is considered hazardous waste.
The estimated amount of nickel in shredder waste is 15-50 tons Ni/year as reported in 1996 (Danish EPA, 1996). The Danish Government's waste-as-resource strategy aims at 70 % recovery (including at least 10 % recycling) of all generated shredder waste in 2018 compared to today, where almost all shredder waste is landfilled.

4.3.2 Residual products from waste incineration/Energy production

Waste treated by incineration include small fractions of metal, including nickel e.g. in stainless steel. In Denmark bottom ash – a residual product generated in waste incineration - represents 15-30 % of the incinerated tonnage (Allegrini, E., et al.). A Danish company has specialised in recovery of metals e.g. stainless steel from bottom ash. Stainless steel scrap in bottom ash accounts for approximately 0.29 %. Currently this company experience efficiency up to 85 % in the recovery of metals (Allegrini, E., et al.), (Personal communication, Allegrini, E.).

4.3.3 Waste production in EU

The available data for waste production from the manufacture and use of nickel metal are from 2000 (European Commission 2008) where questionnaires were sent to individual industries in the different sectors using nickel metal. The volume and disposal method is summarised in Table 4.1. It need be noted that the data represent only the manufacturing and use sites that did reply to the questionnaire. It need also be noted that the figures in Table 4.1 are from 2000 and that production and waste volumes may have changed significantly since then.

TABLE 4.1: WASTE GENERATION FROM INDUSTRIAL USES OF NICKEL METAL (EU RAR 2008)

Sector	Tonnes per year (2000) [1]	Waste type and recycling disposal
Stainless steel production	1,536,234 (22 of 24 sites)	Recycled, reused or disposed to landfill
Multiple steel production	152,849 (2 of 3 sites)	Recycled
Nickel alloy production	5568 (7 of 10 sites)	Recycled or disposed to landfill
Steel production and foundry	129,839 (6 of 9 sites)	Recycled, disposed to landfill or incinerated
Metal products manufacturers	2025 (4 of 5 sites)	Recycled or disposed to landfill
Recyclers	310 (5 of 7 sites)	Recycled or disposed to landfill

[1] Numbers in parenthesis indicate the responding sites out of total number of sites

More recent data on nickel in metal scrap has not been found, but one of the significant contributors to nickel in waste is stainless steel in End-of-Life Vehicles (ELV). As it has not been possible to generate data on nickel content in collected scrap, an example based on End-of-life Vehicles (ELVs) in Denmark is here presented as an example.

4.4 Nickel in stainless steel waste in End-of-Life Vehicles

From statistics (http://bilordning.dk/Statistikker) it is seen that 125,505 vehicles received car scrapping payment in 2013. 91 % of these vehicles were 11-20 years old. Vehicles from 1990-1995 contains typically 63 % steel (Gradin et al., 2013). A minor part of this steel is stainless steel of various types typically containing nickel. According to Snelgrove, 2001 a passenger vehicle contains 15-22 kg of stainless steel mostly found in the exhaust parts. Assuming half the stainless steel is austenitic steel (9-20 % nickel) a passenger vehicle typically contains 0.7-2.2 kg of nickel as steel alloys.

The shredding process recovers approx. 95 % of the steel from ELVs (Eurofer, 2013). Applied to the above calculation for stainless steel this means that 0.64-2.09 kg nickel metal per vehicle is recovered and 0.03-0.11 kg nickel will end up in the shredder waste.
It is estimated that 20 % of the input to shredding facilities ends up as shredder waste (Danish EPA, 2013a). For an average vehicle of 1200 kg this represents 240 kg. With the above assumptions this leads to an estimated concentration of nickel in shredder waste (from vehicles) at 130-460 mg/kg. Based on a number of references Danish EPA, 2013a estimates a nickel content of 178-3400 mg Ni/kg in shredder waste.
Another project explored landfilled shredder waste in two locations in Denmark and found a nickel content of 178-538 mg/kg (Danish EPA, 2012).
There are, however, other sources of nickel in shredder waste than vehicles. Vehicles are estimated to account for 10-50 % of the input to shredding facilities (Personal communication, shredding facilities). Besides nickel metal shredder waste also contains other nickel compounds.

There seem to be a general agreement between the observations above and the mass balance calculations for stainless steel from vehicles. However, in these calculations it is not possible to

discriminate between nickel from vehicles and other sources. Hence nickel in shredder waste include both metal nickel and nickel compounds.
Chemical speciation modelling on shredder waste performed by DHI indicate that at least a part of the nickel content in shredder waste is present as nickel-metal and nickel alloy.

It should moreover be noted that of the 125,505 vehicles receiving car scrapping payment in 2013 it is not known if all are treated by Danish shredding facilities. Some may be exported and treated e.g. in Sweden or Germany.
Assuming all vehicles are treated by Danish shredding facilities the following estimates on recovered nickel can be made:

Nickel recovered from ELVs as part of stainless steel:
Minimum: 125,505 x 0.64 kg = 80.3 tons Ni/year
Maximum: 125,505 x 2.09 kg = 262.3 tons Ni/year

Nickel from ELVs leaving the shredding facilities as part of the shredder waste:
Minimum: 125,505 x 0.03 kg = 3.8 tons Ni/year
Maximum: 125,505 x 0.11 kg = 13.8 tons Ni/year

Stainless steel (containing nickel) and other valuable metal fractions recovered through the shredding process are exported for further processing outside Denmark.

Based on the example on ELVs in Denmark the fraction of not recovered nickel is 3.8-13.8 tons Ni/year. Considering ELVs account for 10-50 % of the input to shredding facilities the total tonnage of nickel metal and nickel compounds not recovered in the shredding process is:
Minimum: If input is 50 % ELV and the lowest concentration of 3.8 tons Ni/year = 7.6 tons Ni/year
Maximum: If input is only 10 % ELV and the highest concentration of 13.8 tons Ni/year = 138 tons Ni/year.

4.5 Nickel in other waste fractions

It is the high market value of metals, including nickel, which is driving the recycling of scrap. Besides metal scrap other waste fractions may contain non-metallic nickel. Such fractions, which are outside the scope of this survey include:

4.5.1 Waste water/sewage treatment plants

Sewage sludge contains traces of non-metallic nickel from various sources. The recycling of sludge as fertiliser in agricultural soil is regulated by the sewage Sludge Directive and in Denmark by the related Statutory Order, which include cut-off values for nickel in the sludge.

4.5.2 Batteries

Nickel metal is used as intermediate in the manufacturing of nickel-cadmium batteries. The different types of nickel containing batteries including NiCd, NiMH, Li-ion and NiFe do not contain nickel metal but nickel oxides and hydroxides. Treatment and recycling of batteries is regulated by the Battery Directive (European Commission 2006b). Though this regulation mainly concerns cadmium in NiCd-batteries, a derived effect of this is the requirement of minimum 75 % recycling of NiCd-batteries and 50 % of other waste batteries/accumulators among these also NiMH-batteries. Despite the intentions to regulate recycling of batteries, a significant amount of batteries still ends up in other waste streams e.g. house hold waste and is as such potentially incinerated. It is assessed that actually less than 50 % of portable NiCd-batteries are collected for recycling (Danish EPA 2013b).

4.5.3 Electronics

Electrical and electronics equipment that has become waste (WEEE) are required to be collected, pre-treated to remove hazardous substances and recycled/recovered according to EU legislation (WEEE directive, European Commission 2012). These requirements are not because of the nickel content but other substances of concern e.g. mercury cadmium, lead and PCB, which are likely to be present in electronic equipment for many years ahead. Nickel metal used in electronic equipment covered by the WEEE directive will as a consequence of this also be recycled. The level of recovery of WEEE in the EU is currently around 50 % but the EU requirement is by 2015 a level of recycling at 50-70 % and a recovery efficiency at 70-80 % (Danish EPA, 2013a). According to statistics for Denmark the collection rate of WEEE were approx. 50 % based on an average of 2010-2012 with recovery levels at 68-97 % dependent on product types (DPA-System, 2014). The uncollected WEEE possibly ends up in waste fractions that are incinerated. The unrecovered fraction is contained in shredder waste and potentially incinerated or landfilled. No data on nickel content in shredded WEEE has been found.

4.5.4 Catalysts:

Catalysts contain nickel metal or nickel compounds e.g. nickel metal or nickel oxide. Nickel catalysts are recycled by dedicated professional companies.

4.6 Summary and conclusions

A content of more than 1 % nickel in waste will lead to classification as hazardous waste. Pure non-contaminated alloys will not be regarded as hazardous waste when the new classification criteria for waste enter into force from June 2015.

In Denmark nickel metal in waste mostly appears as part of metal scrap. A large nickel-contributor to this fraction is stainless steel. The main waste treatment routes for metals are either shredding facilities or incineration.
Approximately 95 % of steel that enters shredding facilities is recovered. The recovered nickel containing steel is mainly exported for recycling outside Denmark. The remaining 5 % becomes part of the shredder waste, and has until recent been landfilled. 150.000 tons of shredder waste is generated each year. A recent change in taxation will potentially lower the yearly tonnage of landfilled shredder waste.

Based on a mass balance for End-of-Life Vehicles in Denmark it is estimated that 80.3-262.3 tons Ni/year from ELVs is recovered in the shredding process. 3.8-13.8 tons Ni/year may be found in the shredder waste. In the scenario where ELVs account for only 10 % of input to shredding facilities this can be extrapolated to a maximum of 138 tons nickel landfilled as part of shredder waste each year.

If nickel metal is incinerated it can be found in the bottom ash. A Danish company has succeeded in recovering up to 85 % of the steel contained in bottom ash. This recovery technology has potential of being applied to larger volumes of bottom ash.

Increase in recovered nickel from fractions like shredder waste and bottom ash seems to have a high potential for increasing the recycling of nickel metal.

5. Environmental effects and exposure

5.1 Environmental hazard

The environmental hazard of nickel metal is limited by the low solubility in water. Nickel metal powder bears a harmonised classification as Aquatic Chronic 3 (Harmful to aquatic life with long lasting effects), whereas nickel metal is not classified as environmentally toxic. Most studies of the toxicity of nickel in the environment are based on the nickel ion and without considering the solubility of the parent substance. Nickel metal is poorly soluble in water and the studies of the ecotoxicity of nickel are therefore less relevant to nickel metal. Nevertheless discussions of the environmental hazard and the effects of nickel are included.

5.1.1 Aquatic ecotoxicity, freshwater

The data on the aquatic toxicity of nickel is one of the largest data sets available with more than 230 chronic data points for 31 species, which represents a high number of families at all trophic levels relevant for the aquatic environment. Many of the chronic toxicity data were developed for the purpose of the EU RAR and are therefore recent and of high quality. The data set can therefore be considered as very extensive and robust. Table 6.1 presents geometric mean values of No Observed Effect Concentration (NOEC) or 10% Effect Concentration (EC10) values for different aquatic species. The most sensitive endpoint per species is used for the derivation of the Predicted No Effect Concentration (PNEC) for surface waters using a Species Sensitivity Distribution approach (SSD)[6].

TABLE 5.1: SUMMARY OF NOEC OR EC10 VALUES IN µG NICKEL/L (WITH MOST SENSITIVE ENDPOINT) (EUROPEAN COMMISSION 2008)

Taxonomic group	Species	Most sensitive endpoint	NOEC/EC10 (µg Ni/l)
Algae	Scenedesmus accuminatus	Growth rate	12.3
	Desmodesmus spinosus	Growth rate	22.5
	Pediastrum duplex	Growth rate	23.8
	Chlamydomonas sp	Growth rate	27.9
	Ankistodesmus falcatus	Growth rate	28.4
	Chlorella sp	Growth rate	42.0
	Coelastrum microporum	Growth rate	46.2
	Pseudokirchneriella subcapitata	Growth rate	92.7

[6] SSD or species sensitivity distribution defines the Hazard Concentration used for WQS setting as the HC5 corresponding with the 5 % limit using a 50 % confidence interval.

Taxonomic group	Species	Most sensitive endpoint	NOEC/EC10 (µg Ni/l)
Higher plants	Lemna minor Lemna gibba	Growth Growth rate	27.9 50.0
Rotifer	Brachionus calyciflorus	Intrinsic rate of growth	633.2
Molluscs	Lymnea stagnalis Juga plicifera	Growth mortality	6.8 124.0
Cladocerans	Ceriodaphnia dubia Ceriodaphnia quadragula Peracantha truncata Simocephalus vetulus Ceriodaphnia pulchella Alona affinis Daphnia longispina Daphnia magna	Reproduction Mortality Reproduction Reproduction & mortality Reproduction & mortality Mortality Mortality Reproduction	6.9 7.4 8.0 16.3 16.7 25.0 27.8 35.6
Insects	Clistoronia magnifica Chironomus tentans	Mortality Biomass	66.0 458.9
Hydrozoans	Hydra littoralis	Growth	60.0
Amphipods	Hyalella Azteca	Mortality	29.0
Fish	Brachydanio rerio Pimephales promelas Oncorhynchus mykiss	Hatchability Growth Growth	40.0 57.0 134.0
Amphibians	Xenopus laevis Gastrophryne carolensis Bufo terrestris	Malformation Mortality Growth	171.6 184.9 640.0

Based on data from the EU RAR the rapporteur country (Denmark) prepared a dossier with the purpose to revise the quality standard under the Water Framework Directive. In 2012 a revised Environmental Quality Standard (EQS) was adopted for nickel at 4.0 µg Ni/L for freshwater and 8.6 µg Ni/L for marine water. The values refer to the bioavailable fraction.

The nickel registration dossier (publicly available from the ECHA public database) refer to a PNEC value in freshwater at 7.1 of µg Ni/L based on the HC5(50%) and an application factor of 1.

5.1.2 Bioavailability in the freshwater environment

It is generally accepted that it is the nickel ion that is responsible for the toxic action of nickel in the environment. The actual toxicity of a nickel compound therefore depends on the solubility of the nickel substance and the bioavailability of the nickel ion in the environment. Investigations have shown that the bioavailability and toxicity of nickel in freshwater depends strongly on the local physical- chemical conditions such as the pH, concentration of dissolved organic carbon (DOC) the hardness of the water (measured as the concentration of Ca_2CO_3). In general it is the DOC which is the most important determinant for the bioavailability (DHI 2014). Within the normal range of DOC concentrations in the Danish and European freshwater systems increasing DOC levels reduces the bioavailability of nickel.

Consequently the chemical physical conditions need be taken into account in assessment of the risks of nickel in aquatic ecosystems. In the EU RAR local PNEC values were derived for different types of freshwater ecosystems (Tables 5.2 and 5.3).

TABLE 5.2: COMPARISON OF THE PHYS.-CHEM. CONDITIONS IN DIFFERENT TYPES OF EU FRESHWATER ENVIRONMENTS (EUROPEAN COMMISSION 2008)

	Type	Name	Country	Scenario[7]		
				pH	H (mg/l $CaCO_3$)	DOC (mg/l)
Rivers	Small (ditches with flow rate of ± 1,000 m^3/d)	/	The Netherlands	Low	High	High
	Medium (rivers with flow rate of ± 200,000 m^3/d)	River Otter River Teme	United Kingdom	High Medium	Medium Medium	Low Medium
	Large (rivers with flow rate of ± 1,000,000 m^3/d)	River Rhine	The Netherlands	Medium	High	Low
	Mediterranean river	River Ebro	Spain	High	High	Low
Lakes	Oligotrophic systems	Lake Monate	Italy	Medium	Low	Low
	Neutral acidic system	/	Sweden	Low	Low	Low

[7] Low (L): when the phys.-chem. in the system ≈ 90^{th} % of abiotic factor in EU surface waters: pH= 7.1; DOC= 5.8 mg/L; Ca= 35 mg/L)
Medium (M): when the phys.-chem. in the system ≈ 50^{th} % of abiotic factor in EU surface waters: pH= 7.6; DOC= 7.5 mg/L; Ca= 50 mg/L
High (H): when the phys.-chem. in the system ≈ 10^{th} % of abiotic factor in EU surface waters: pH= 8.0; DOC= 10.3 mg/L; Ca= 62 mg/L).

TABLE 5.3: SUMMARY OF THE HC5 FOR THE BEST FITTING AND LOG-NORMAL DISTRIBUTIONS DERIVED FOR THE DIFFERENT SELECTED SCENARIOS (EUROPEAN COMMISSION 2008)

Scenario	HC_5 (µg Ni/l) based on Log-normal distribution	PNEC (µg Ni/l) using an assessment factor of 2
Ditch in The Netherlands	43.6	21.8
River Otter in the United Kingdom	8.3	4.4
River Teme in the United Kingdom	19.4	9.7
River Rhine in The Netherlands	11.0	5.5
River Ebro in Spain	8.9	4.5
Lake Monate in Italy	7.3	3.7
Acidic lake in Sweden	12.3	6.2

In practise the oligotrophic Lake Monate with a derived PNEC at 3.7 µg Ni/L was used as a reasonable worst case for predicting the risk of effects in the freshwater compartment (European Commission 2008).

Two tools for simplified assessment of the bioavailability of copper, zinc and nickel were evaluated for use in Danish freshwater systems in a study by DHI (DHI 2014). The two models are based on extensive data on chronic toxicity of the metals to a range of different types of freshwater organisms and under different physical-chemical conditions. The Biotic Ligand Models (BLM) are predictive tools that can account for variations in metal toxicity using information on the chemistry of local water sources. The main conclusion of this study was that the tools are applicable also under the conditions in Danish freshwaters and that the vast majority of the 374 evaluated surface water samples were within the validity ranges of pH, $CaCO_3$ and DOC. The correction for bioavailability had a significant effect on the assessment of the measured nickel concentrations. The number of samples where the nickel concentration exceeded the EQS at 4 µg Ni/L were 23 out of 264 samples without correction for bioavailability, whereas only 5 and 6 samples, respectively, exceeded the bioavailability corrected PNEC with the two tools.

5.1.3 Marine environment

The database on marine species compiled during the execution of the EU RAR includes a broad range of temperate marine organisms. The data base used for calculating the PNEC value include 15 different organisms representing 6 taxonomic groups (algae, crustaceans, echinoderms, molluscs, annelids and fish) and covering a range of different life forms , feeding strategies and trophic levels (European Commission 2008).

A PNEC for the marine environment was derived at 8.6 µg Ni/L by use of an application factor of 2 on the statistically derived HC5 value (European Commission 2008).

In 2012 the Environmental Quality Standard (EQS) for nickel in marine surface water was updated according to the findings in the EU RAR and EQS for nickel in the marine surface water is set at 8.6 µg Ni/L. The value is identical to the PNEC value applied in the nickel registration dossier (ECHA 2014).

5.1.4 Sediments

The outcome of the EU RAR with respect to sediment toxicity was that it was not possible on the basis of available data to draw any conclusion regarding the risk to sediments organisms, mainly because the experimental studies were too few and did not correspond to the most recent knowledge regarding exposure of sediment organisms. It was therefore concluded that further information was needed (European Commission 2008).

The Nickel Institute initiated therefore additional long term toxicity studies with sediment organisms as well as field validation studies. The programme was followed by independent experts as well as the Danish EPA. Based on these additional studies the it was recommended to apply an application factor of 2 for derivation of a generic $PNEC_{sediment}$ of 47 mg Ni/kg sediment dw. This was based on the HC5 (50%)-value of 97 mg Ni/kg sediment dw.

The nickel registration dossier (ECHA public website) use a PNEC value for freshwater sediments at 136 mg Ni/kg dw based on an application factor of 1. The reason for the difference between the $PNEC_{sediment}$ values is that the registration dossier uses a bioavailability corrected HC5 (50%)-value of 136 mg Ni/kg sediment dw and a lower application factor.

5.1.5 Terrestrial environment

The availability and the toxicity of nickel in the soil depends strongly on the physical-chemical characteristics, e.g. the pH, organic matter content, the cation exchange capacity (CEC), clay content. Because of the variability in sensitivity to nickel a hazard characterisation was made for different soil types in the EU RAR in order to take into account the bioavailability in different soil types. The results are summarised in Table 5.4.

TABLE 5.4: PNEC VALUES OF NICKEL IN SOIL EXPRESSED AS HC5 (50%)[8] IN MG/KG SOIL (EUROPEAN COMMISSION 2008)

Scenario	HC5 at 50% confidence limits (5^{th} – 95^{th}%) mg/kg
Agricultural acid sandy soil	8.5 (5.5 – 11.8)
Agricultural loamy soil	99.2 (67.7-133.6)
Agricultural peaty soil	186.3 (128.1-249.5)
Natural acid sandy soil	25.0 (16.7-34.3)
Natural clay soil	192.3 (132.2-257.4)
Natural agricultural soil	47.1 (31.8-64.0)

PNECs for these soil types were estimated at 4.3 – 96.2 mg Ni/kg derived on basis of the HC5 value using an application factor of 2 (European Commission 2008).

5.1.6 Toxicity to sewage treatment plants

The nickel registration dossier uses a PNEC at 0.33 mg Ni /L based on tests of the toxicity to microorganisms (ECHA 2014).

5.1.7 Conclusion on toxicity in the environment

In the discussion of the toxicity of nickel metal in the environment it need be stressed that measured and calculated concentrations of nickel in the environment as well as the ecotoxicological studies are referring to the total nickel concentration in the water, sediment or soil environment. Total nickel includes all nickel species including inorganic and organic nickel compounds and nickel metal. In addition the bioavailability of nickel is not taken into account as this requires data on the

[8] Based on uncertainty assessments it has been recommended to apply an assessment factor on the 50% confidence value of the 5th percentile value, i.e. the HC5 (50%), thus PNEC = HC5(50%) / AF.

local physical-chemical conditions, i.e. in the case of freshwater environment, measurements of DOC, pH and the calcium concentration.

The nickel ion is highly toxic in the environment. Nickel metal (solid) is, however, not classified for aquatic toxicity due to the low solubility of the substance as well as the low release rate of nickel ions to the environment. Nickel powder has a harmonised classification Aquatic Chronic 3. An environmental quality standards (EQS) for nickel in freshwater at 4 µg Ni /L (bioavailable) and the marine water 8.6 µg Ni /L was adopted recently.

It has been demonstrated that the physical-chemical conditions in the environment has a significant impact on the bioavailability of the nickel ion and thus the toxicity of the nickel. In the freshwater environment it is mainly the parameters Dissolved Organic Carbon, pH and hardness that are determining the bioavailability, while in soil it is the organic carbon content, pH, Cation Exchange Capacity (CEC) and clay content that are the main determinants of bioavailability. In sediments the bioavailability is strongly correlated to the sulphide content measured as AVS.
Bio-ligand modelling (BLM) tools are available for estimating of the bioavailable fraction of nickel in freshwater. A Danish study on the applicability of two user friendly tools for estimation of bioavailability corrected concentrations of nickel concluded that the tools are useful under the prevailing conditions in Danish freshwater environment and that estimation of the bioavailability of nickel significantly changes the indication of risks compared to an assessment based on the total nickel content in the water. The report recommends applying BLM in a regulatory context.

In the sediment compartment a generic $PNEC_{sediment}$ of 47 mg Ni/kg sediment dw was derived based on a number of experimental long term toxicity studies carried out based on recommendation from the EU RAR.

In soil the PNEC value for nickel is determined to the soil characteristics and PNEC values for different types of soil range from 4.25 mg Ni/kg dw in acid sandy soil (i.e. HC5 (50%) at 8.5 mg Ni/kg dw divided by an application factor of 2) to 96.1 mg Ni/kg dw for a natural clay soil.

5.2 Exposure assessment and monitoring data

Freshwater environment
Nickel is a natural occurring element and is found in all environmental compartments. The natural background levels of nickel vary across Europe and reflect the geological and local physical – chemical conditions. According to the FOREGS database, the nickel concentration in European freshwater streams, ranges from a minimum value of 0.03 µg/l to a maximum value of 24.6 µg/l, with a mean value of 2.43µg/l (FOREGS, 2005). The nickel concentrations in Danish freshwater streams are reported to be 0.2 to 2.3 µg/l in the database (only 5 data).

The concentrations of dissolved nickel in Danish freshwater systems are reported in the NOVANA survey 2011 and 2012. The values range from below the detection limit (around 0.07 µg Ni/L), and up to 17 µg Ni/L. The highest concentrations are reported from Damhus Å, which runs through the western suburbs of Copenhagen. This stream could be influenced by high levels in groundwater in the Copenhagen area where the nickel levels are influenced by the dissolution of nickel compounds in the soil because of the lowered groundwater levels in the area (Municipality of Copenhagen 2014). In general the measured values seem high compared to the PNEC values for freshwater (EU RAR, PNEC at 2.74 µg Ni/L; EU EQS at 4 µg Ni/L (bioavailable)).

TABLE 5.5: CONCENTRATION OF NICKEL IN DANISH FRESHWATER STREAMS. DATA ARE OBTAINED FROM THE NOVANA SURVEY DURING 2011 AND 2012.(DANISH NATURE AGENCY, 2014)

Stream	Minimum µg/l	Maximum µg/l	Average
Brende å	<0.067	2.3	1.65
Guden å	0.9	1.9	1.43
Højen å	0.51	2.3	1.27
Følstrup bæk	<0.067	0.7	0.63
Skjern å	2.9	3.7	3.33
Gerå	0.9	1.9	1.51
Solkær å	1.1	1.9	1.53
Ejstrup Bæk	0.39	2.2	1.6
Damhus å	0.4	17	6.23

Estimated concentrations of nickel based on worst case scenarios in European freshwater systems were in the range 1.1 – 5.2 µg Ni/L with an average at 2.9 µg Ni/L (European Commission 2008). Measured values (FOREGS data) ranged from 0.6 – 2.9 µg Ni/L with an average at 1.8 µg Ni/L. The EU RAR notes that the estimated background average value exceeds the PNEC at 2.74 µg Ni/L and that the average measured concentration at 1.8 µg Ni/L is close to this level (European Commission 2008).

Effluents from sewage treatment plants were reported to contain an average nickel concentration at 4.4 µg Ni/L with a maximum value of 29 µg Ni/L (Jensen et al, 2013).

Sediments
Nickel concentration in Danish stream sediments were monitored in 2011 and 2012 in the NOVANA survey. The levels were between 4.7 and 74.4 mg Ni/kg dw, with an median value of 22.7 mg Ni/kg dw (Danish Nature Agency, 2014). Values of nickel concentrations in Danish sediments reported in the FOREGS database are in the range 4 – 33 mg Ni/kg dw (FOREGS 2005).

The levels of nickel in European stream sediments are highly variable and covers a range from 1-1406 mg/kg dw with an average concentration of 35 mg/kg (FOREGS, 2005).

Terrestrial compartment
The content of nickel in European soil is highly variable with concentration ranging from < 2.0 to 2690 mg Ni/kg dw. The median for topsoil is 37.3 mg Ni/kg dw. The reported Danish values in FOREGS lie from 1.0 – 7.41 mg Ni/ kg d.w. (FOREGS 2005).

5.3 Environmental impact and risk charcacterisation

5.3.1 Freshwater systems
A series of local exposure assessment pertaining to various industrial sectors were carried out in the EU RAR. In several cases this led to the conclusion that risks were identified. It should be noted,

however, that these assessment are outdated since many of the production and downstream user sites are not active any more. Moreover reduction measures as treatment techniques and cleaner production measures have been implemented since the data used in the EU RAR were collected. More recent data were collected and analysed as basis for the REACH registration dossier submitted in 2010 and since updated (Nickel Consortium 2013). The detailed discussion of the risk characterisation for the freshwater environment is found in the confidential annex to this report.

In Denmark the reported values of nickel in freshwater systems indicate that the levels are in general below the EQS. Concentrations of nickel that exceeds the EQS are, however, not uncommon and the margin between the EQS and the measured average concentration is low. A recent study on Danish monitoring data showed that it is important to consider the bioavailability of nickel in the assessment of monitoring data on nickel (DHI 2014).

The EU RAR included an assessment of regional scenarios. The overall conclusion was that in 6 out of 7 ecoregions, no risk was indicated at the regional level. However in one type of river with high pH and low levels of dissolved organic carbon (DOC) a risk was indicated. It was recommended that member states should intensify the monitoring in sensitive areas and that local and more specific risk characterisations should be carried out (European Commission 2008).

The conclusion is that the general average level of the total nickel concentrations in freshwater systems in Denmark and in the EU is below the EQS, but that the margin is narrow and values higher than the EQS are not uncommon. It should be considered to use bioavailability corrected data for compliance evaluations and risk assessment.

5.3.2 Sediments

The EU RAR concluded that further studies were needed in order to assess the risk to this compartment. Based on additional testing a reasonable worst case PNEC at 47 mg Ni /kg dw was derived using an application factor of 2.
The refined assessment included a correction for the bioavailability of nickel in the sediment, which is correlated to the sulphur content measures as acid volatile sulphide (AVS). The overall conclusion was that after correction for bioavailability the number of sites where a risk was identified based on a local exposure scenario was reduced by 40% at average AVS levels. However in some sectors there were still sites where a risk to the sediment environment was identified (DHI 2012). None of these sites were placed in Denmark.

The levels of nickel in Danish freshwater sediments are in general below the PNEC at 47 mg Ni /kg dw, however, the highest end of the reported range lies above this value. It should be noted that this does not take the bioavailability in sediments into account.

The risk assessment of sediments exposed by industrial sites has been updated with more recent data in the REACH registration dossier (Nickel Consortium 2013).

5.3.3 Marine environments

The concentrations of total nickel in European marine environments were reported to be in the range 0.26-3.75 µg Ni/L for estuarine and estuarine influenced coastal water. In open marine waters the reported range lies 0.14 – 3.75 µg Ni/L and for semi closed brackish water (The Baltic Sea) the levels were in the range 0.64 – 0.81 µg Ni/L. As the derived marine PNEC is 8.6 µg Ni/L the overall conclusion was that at a regional scale no risk is indicated.

5.3.4 Terrestrial compartment

The EU RAR concluded based on different scenarios covering the variation of conditions in EU that there is in general no risk of effects of nickel at the observed levels in soil (European Commission 2008).

5.3.5 Secondary poisoning

With respect to the possible secondary poisoning the EU RAR concluded that there is no indication of risk to aquatic mammals or birds exposed via the freshwater and marine aquatic food chain. Regarding the terrestrial food-chain it was concluded that for all but one site (a nickel production site) there was no indication of risks to terrestrial birds or mammals (European Commission 2008).

5.4 Summary and conclusions

Investigation of the hazards and risks of nickel in the environment is normally based on the nickel ion, which is the biological active form of nickel. In the aquatic freshwater compartment the nickel ion is highly toxic, which if reflected by an EQS at 4 µg Ni/L (bioavailable). The bioavailability of nickel highly dependent on the physical chemical conditions: DOC, pH and Calcium concentration. User friendly tools have been developed that allow estimation of the bioavailable fraction. The tools are applicable also under the prevailing conditions in Denmark and a preliminary evaluation shows that considering the bioavailability is important in risk assessment of nickel in freshwater.

Measured levels of the total nickel concentrations in Danish and European freshwater systems show that the levels in general are below but close to the EQS, and sometimes exceed this value. A refined risks assessment considering the bioavailability of nickel is relevant for these environments but requires data on the relevant physical-chemicals parameters.

The observed concentrations of nickel in Danish freshwater sediments are in general below the PNEC value of 47 mg Ni /kg dw, but the high end of observed concentration range lie above the PNEC value and indicate a risk. It should be noted, however, that this is without considering the bioavailability.

The risk of effect was investigated for the sediment compartment in the EU RAR. Initially a high number of scenarios indicated a risk, but after refining the assessment by considering the bioavailability of nickel, it was concluded that there was risk only in specific local scenarios, and that this should be dealt with on a local basis.

The EQS for the marine compartment is 8.6 µg Ni/L. The EQS is generally complied at a regional as well as at local scale including where industry release waste water directly or via a public waste water treatment facility.

It was concluded in the EU RAR that in general there is no risk to terrestrial ecosystem at the observed nickel levels in soil. Moreover there no indication of risk was observed via secondary poisoning of predators in the aquatic system.

6. Human health effects and exposure

6.1 Human health hazard

Under the CLP regulation, Nickel Metal has the following harmonised classification:

- Skin Sens. 1. H 317 (May cause an allergic skin reaction)
- Carc. 2. H351 (Suspected of causing cancer)
- STOT RE. 1. H372 (May cause damage to organs through prolonged or repeated exposure)

Different grades of nickel metal may contain impurities that are classified as Carc. 1A. e.g. nickel oxide or cobalt at concentrations higher than 0.1 % (w/w) triggering a classification of the nickel metal as Carc. 1A.

6.2 Toxicity to humans

6.2.1 Absorption

The absorption of nickel compounds in general depends strongly on the solubility of the substances. Insoluble nickel substances such as nickel oxide and metallic nickel are relatively poorly absorbed. The absorbed fraction of nickel following oral administration of nickel metal in 5% starch saline solution by gavage was about 0.09% in a study in rats. No human data were available (OECD 2008).

Dermal absorption of nickel metal is very limited. An in vivo study with humans exposed to nickel powder showed that a large part of dermally applied dose remained on the skin and only a minor part (0.2%) penetrated into the upper part of the skin (stratum corneum). In artificial sweat nickel metal, however, release nickel ion, which is more easily absorbed by skin (European Commission 2008).

The exposure by inhalation depends on the particle size, where particle with an aerodynamic diameter over 1 – 5 µm have the greatest probability of settling in the nasopharyngeal regions (inhalable fraction) and particles with aerodynamic diameters below 1 – 5 µm are most likely to settle in the tracheobronchial and pulmonary regions.

Rats exposed by inhalation to metallic nickel powder showed accumulation of nickel particles in the lungs and increased nickel blood levels. It was estimated that approximately 6% of the inhaled fraction was absorbed (OECD 2008).

Absorbed nickel is widely distributed in the body and may penetrate the placenta. Tissue levels are generally below 1 ppm; elevated tissue levels of nickel have been observed in the kidney, liver and lung. Generally, nickel tends to deposit in the lungs of workers occupationally exposed to nickel compounds and in experimental animals following inhalation or intratracheal instillation OECD (2008).

Absorbed nickel is excreted in the urine, regardless of the route of exposure; the half-life for urinary excretion in humans has been reported to range from 17 – 29 hours. An elimination half-life of 30-60 days has been estimated for metallic nickel particles accumulated in lung tissue. The elimination is dependent on dissolution of the accumulated nickel particles followed by absorption and elimination of nickel from the blood (OECD 2008).

6.2.2 Acute toxicity

Nickel metal has a relatively low acute toxicity by inhalation and concentrations up to 24 mg/m^3 6h per day, 5 days a week for 4 weeks did not result in increased mortality among the exposed animals. Similar experiments with nickel compounds with low solubility showed similar results. By oral intake metallic nickel as well as other nickel compounds with a low solubility also showed very low acute toxicity: iron nickel powder LD50 >1475 mg Ni/kg (European Commission 2008). The low oral toxicity of nickel is confirmed by a study from 1983 referred in the registration dossier where the LD50 was reported to be > 9000 mg/kg bw (Nickel Consortium 2013).

6.2.3 Irritation/corrosiveness

Nickel metal has been reported as not causing skin irritation (European Commission 2008). The registration dossier refers to a key study on acute irritation/corrosion (OECD 404) of nickel powder where rabbits were exposed dermally. Based on the negative results in the test nickel metal is not classified as an irritant (Nickel Consortium 2013).

6.2.4 Sensitisation

There are extensive experimental data and documentation based on clinical data on humans regarding skin sensitisation of nickel metal and nickel compounds supporting the classification of nickel metal as a skin sensitiser (Skin Sens 1).

Metallic nickel is the main cause of contact allergy in Denmark. Among a population in the period of 2006-2008 in the Copenhagen area 10 % of women and 1% of men were sensitised to nickel. Jewellery and buckles are considered the primary causes for developing contact allergy accounting for about 41% of all cases. However the prevalence of nickel sensitisation has declined especially among women as the prevalence in 1990 was at about 20%. This is most probably due to a strict migration limit that was introduced into the Danish regulation as well as in REACH (NARC 2014).

Thus, the cutoff release rate of 0.5 µg Ni/cm2/week from nickel containing surfaces is considered sufficient to protect against sensitisation of non-sensitised individuals in a substantial part of the population exposed to direct and prolonged contact with nickel and nickel alloys. The release rate of 0.5 µg Ni/cm2/week after direct and prolonged contact is also considered sufficient to protect against elicitation in a significant proportion of nickel sensitized individuals (European Commission 2008).

Respiratory sensitisation is documented for nickel sulphate. It is considered that it is the nickel ion which is responsible for the immunological effect. Metallic nickel has also been reported to cause respiratory sensitisation, but the data was not considered adequate to justify a classification (European Commission 2008).

6.2.5 Repeated dose toxicity

The target organ for long term exposure to metallic nickel is the respiratory tract with effects seen in both the lungs and nose. Inflammatory lesions have been reported in studies with rat and mice following subchronic and chronic inhalation exposure (SCOEL 2011).

It is documented that inhalation of nickel metal powder results in lung inflammation and fibrosis in a 13 days inhalation study with rats. A LOAEC at 1 mg/m^3 was derived from this study (European Commission 2008).

In a 2 year inhalation study with rats exposed to metallic nickel powder at 0, 0.1, 0.4 and 1.0 mg/m3 6 hours/day, 5 days/week. Adverse effects were seen down to the lowest dose level of 0.1 mg/m3. At 0.1 mg/m3 changes in blood parameters were seen, and microscopic changes were noted in lymph nodes, kidney, spleen, and bone marrow. Further increased lung weights and histopathological alterations (alveolar proteinosis, alveolar histiocytosis, chronic or chronic active inflammation, and bronchiolo-alveolar hyperplasia) were seen. At 0.4 mg/m3 increased mortality among the animals was observed. Overall, no NOAEC could be found in this study. The lowest exposure level of 0.1 mg/m3, is therefore a LOAEC. The effects seen fulfil the criteria for the current classification as T; R48/23 (STOT RE Category 1 H372).

With the LOAEC of 0.1 mg/m3 as a starting point and using an overall assessment factor of 50 the Danish EPA concluded on a DNEL for workers of 0.002 mg Ni /m3 (Danish EPA 2009).

SCOEL however, in 2011 recommended an OEL of 0.005 mg/m3 based on the severe lung damages observed at the lowest tested concentration (at 0.1 mg/m3). This value applies for the respirable fraction for poorly soluble nickel compounds and nickel metal (SCOEL 2011).

6.2.6 Mutagenicity

There is considerable evidence for the *in vitro* genotoxicity of nickel compounds, while the interpretation of the available in vivo studies is more complicated. There is, however, very limited information on the genotoxicity on sparingly soluble nickel compounds, including nickel metal (European Commission 2008). SCOEL (2011) concludes from a review of the available literature that nickel and nickel compounds are not directly mutagenic. Investigations at cellular level indicate that nickel ions do not interact directly with the DNA but rather exert indirect genotoxic effects such as interference with the DNA repair system. OECD (2008) considered the available data on nickel metal were inadequate in order to draw any direct conclusion on the in vivo genotoxicity of nickel metal.

6.2.7 Carcinogenicity

The carcinogenic properties of soluble and insoluble nickel compounds are widely accepted, while carcinogenic effects of metallic nickel cannot clearly be supported by experimental animal data. Recently a 2-year carcinogenicity inhalation study with nickel metal has been conducted (described in section 6.1.5) and no carcinogenic effects were observed in the respiratory organs at any dose levels.

However, differences may exist in the carcinogenic response between experimental animals and humans as soluble nickel compounds proven to be human carcinogens were not found to be positive in inhalational animal carcinogenicity testing.

Whereas SCOEL (2011) in connection with their OEL derivation did not find carcinogenic potential of metallic nickel, the International Agency on Research on Cancer (IARC) on the other hand concluded that nickel metal is carcinogenic to humans (group1) based on sufficient evidence in humans as well as in experimental animals (IARC 2012). It has to be noted that IARC also considered animal experimental data where carcinogenic responses were found in studies where nickel metal powder was introduced directly to the animals by intratrachael administration or intrapleural, subcuraneous, intramuscular or intraperitoneal injections of metallic nickel.

According to CLP metallic nickel is classified as Carc. 2 (Suspected of causing cancer).

6.2.8 Toxicity for reproduction

There are no studies on the toxicity to reproduction of nickel metal mentioned in the available reviews (European Commission 2008, SCOEL 2011). Water soluble nickel compounds are classified as Repr. Cat 1B due to developmental toxicity. However, due to the much lower degree of bioavailability a considerable lower potential for developmental effects may be anticipated for metallic nickel.

No experimental data with metallic nickel is available. However, based on a recent oral OECD TG 416 two-generation study in rats with nickel sulphate, a NOAEL of 2.2 mg Ni/kg bw/day is determined for effects on fertility and on male reproductive organs and a NOAEL of 1.1 mg Ni/kg bw/day for developmental toxicity following oral ingestion of nickel sulphate, nickel chloride, nickel dinitrate, nickel carbonate as well as for nickel metal. It should be noted that the NOAEL for fertility is possibly higher. When applying this oral NOAEL for nickel metal, consideration should be given to the lower bioavailability of metal compared to nickel sulphate (OECD 2008).

6.2.9 Conclusion on toxicity to humans

Metallic nickel is a well-known human allergen in connection to dermal exposure and although the problem seems to be decreasing metallic nickel is still believed to be the main cause of the induction of dermal contact allergy in Denmark. About 10% of young women suffer from contact allergy towards nickel. However, the current legislation restricts the liberation of nickel –ions from metallic surfaces to below 0.5 µg Ni/cm2/week. The provision to a great extent protects against sensitisation of non-sensitised individuals.
Inhalation of metallic nickel powder may induce severe inflammatory responses in the lung including lung fibrosis. This has been found down to a dose level in rats at 0.1 mg/m3 of metallic nickel powder.

Due to the observed lung damages the European Commission Scientific Committee on Occupational Exposure Limits (SCOEL) proposed an OEL at 0.005 mg/m3 (respirable fraction) for poorly soluble nickel compounds, and for nickel metal. It has to be noted that the OEL proposed by SCOEL is subject to further discussion in the European Commission Advisory Committee on Safety and Health at Work before a possible OEL value can formally enter into a legislative procedure.

The carcinogenic properties of metallic nickel are debated and different interpretations exist for both the epidemiological data and the experimental animal data. SCOEL (2011) does not consider the evidence for metallic nickel as sufficient to conclude a carcinogenic potential of the substance, whereas IARC (2012) find that both the epidemiological and the experimental animal data as sufficient to conclude that metallic nickel has to be considered as a human carcinogen. In EU metallic nickel has a harmonised classification as a suspected carcinogen unlike many nickel compounds that are classified as human carcinogens.

In relation to soluble nickel compounds a NOAEL of 1.1 mg Ni/kg bw/day for developmental toxicity following oral ingestion has been observed in experimental animal studies. When applying this oral NOAEL for nickel metal in connection with a risk assessment, consideration should be given to the considerable lower bioavailability of metal compared to nickel sulfate.

6.1 Exposure assessment and monitoring data

6.1.1 Consumer exposure

Exposure of the consumer to nickel was evaluated in details in the EU RAR (European Commission 2008). The exposure via non-occupational pathways are summarised in the Figure below.

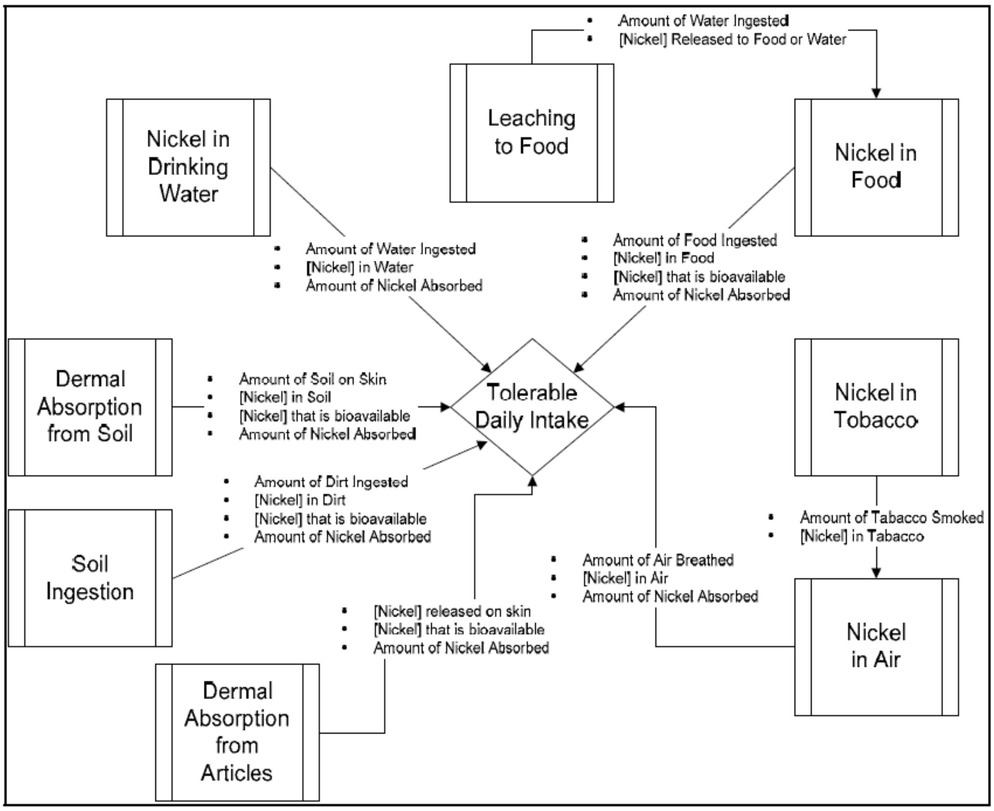

FIGURE 6.1: OVERVIEW OF DIFFERENT EXPOSURE PATHWAYS OF NICKEL TO HUMANS (EUROPEAN COMMISSION 2008)

The figure indicates the exposure routes 'via environment', i.e. via food, drinking water, air and via dermal absorption and oral intake of soil.

When discussing the exposure to nickel via the environment the differentiation between different types of nickel compounds becomes difficult, if not impossible. Nickel is a naturally occurring element in soil, surface water and groundwater and it is not possible to discriminate the contribution from anthropogenic sources from the background exposure. The vast majority of the nickel species found in the environment are inorganic or organic compounds. Nickel metal contributes to a relatively small fraction of the measured total nickel (see section on ambient air below).

The methodology for assessment of exposure via the environment is to estimate the general regional exposure and absorption of nickel for each route of exposure and add these contributions together. At a local scale the exposure is evaluated in specific scenarios since the exposure could be higher due to local pollution sources and industrial activities e.g. refining of nickel, steel production etc. The exposure from such industrial sites is mainly due to nickel emitted to the air and from food grown in the vicinity of the site.

6.1.1.1 Dermal exposure

Consumers may be exposed directly to nickel by skin contact with surfaces where nickel metal forms the outer layer, e.g. nickel plated objects or nickel alloys. A specific concern is related to prolonged exposure due to contact with jewellery, piercings, wrist watches, mobile phones etc. Exposure to nickel via prolonged dermal contacts is regulated by REACH; Annex XVII (27) specifying a migration limit for jewellery, including earrings, used as piercings at 0.2 µg/cm²/week, and for earrings, necklaces, wrist watch cases, mobile phones at 0.5 µg/cm²/week (European

Commission 2006). The regulation covers all items where normal use may involve prolonged dermal contact.

The dermal exposure to nickel and possible effects (dermatitis) by direct contact to items containing nickel metal is due to the release of nickel ions from the surface. The exposure thus depends on the ability of the surface to release nickel ions, which is related also to the ability of the surface to corrode in presence of sweat and saliva. A test according to the European standard method (CEN; EN 1811) is used to test the release under conditions similar to sweat, saliva and other body fluids.

Due to restriction in REACH Annex XVII, pure nickel or nickel plated items are not used where prolonged dermal contact is intended. Stainless steel may, however, be used for such purposes. Measurements of release of nickel ion in artificial sweat according to CEN; EN 1811 of 7 different grades of stainless steel indicate that the migration limit at 0.5 $\mu g/cm^2$/week was complied with by all grades, including for stainless steel grades with a high sulphur content. The highest observed value was 0.3 $\mu g/cm^2$/week obtained with a stainless steel type containing 0.3% sulphur (compared with < 0.03% in other grades). The releases from other steel types were in the range 0.0005 to 0.0015 $\mu g/cm^2$/week (European Commission 2008).

Releases of nickel from metal surfaces can be enhanced by bimetallic corrosion e.g. where nickel or a nickel alloy is in contact or used as undercoat for another more noble metal such as platinum or gold (European Commission 2008).

6.1.1.2 Food

Consumers are exposed to nickel via food and drinking water that contain a natural background level of nickel as well as small contributions released from nickel containing surfaces. Nickel metal is not found in food. Nickel in food is complex bound nickel–ions found generally in levels from 0.001-0.01 mg/kg and up to 0.8 mg/kg in foodstuffs such as grains, nuts, cocoa and seeds. The French Authorities for food (ANSES) has estimated a mean daily intake at 2.33 µg/kg bw in adults and 3.83 µg/kg bw in children (Council of Europe 2013). WHO has derived a The Tolerable Daily Intake for nickel at 12 µg/kg bw (WHO 2005).

The dietary intake of nickel by Danish adults was 167 µg Ni/day on average (97.5th percentile: 278 µg Ni/day) in the period 1993-1997. The corresponding total diet study in period of 1983-1988 and 1988-1992 did not show a significant increase or decrease in function of time (mean intake in 1983-1988: 157 µg Ni/day and in 1988-1992: 199 µg Ni/day) (Larsen et al., 2002). An older Danish study (Flyvholm et al., 1984) reported an average daily intake of 147 µg Ni/day (European Commission 2008).

The EU risk assessment report made a detailed analysis of regional exposure to humans from food:

Adults

For adult the an average exposure, 95-percentile and 99-percentil exposure from *food* of *115 µg Ni/d; 239 µg Ni/d, and 352 µg Ni/d* was estimated

Children (1-2 years old)

For children an average exposure and 95-percentile exposure from *food* of *63 µg/d and 107 µg Ni/d* was estimated.

At a regional level the dietary intake of nickel is the most important pathway of human exposure and is responsible for over 95% of the external nickel dose. Even higher contributions via food are estimated in local exposure scenarios where food is grown near industrial sites. In such scenarios higher contributions via food is estimated for the nickel refining sector (direct air deposition) and for the stainless steel and battery sector (soil to plant uptake) (European Commission 2008).

Nickel containing stainless steel is strongly corrosive resistant and can resist the aggressive cleaning methods needed in food production. Stainless steel is therefore an important food contact material and used e.g. for storage, transportation, processing equipment in slaughterhouses and fish industry and kitchen utensils. It has, however been shown that only a minor part of the nickel content in food can be explained by use of stainless steel kitchenware (Council of Europe 2013)

6.1.1.3 Drinking water

Nickel in drinking water comes from the natural content in groundwater, mostly as nickel oxides and hydroxides. Groundwater accounts for more than 50% of the water supply in Europe and in some countries 100%, e.g. in Denmark and Austria. In addition nickel ions may be released to drinking water from nickel containing taps, tubes and fittings. The release depends on the material, bimetallic or galvanic effects, surface finish, and the age of the installation since precipitation on the inside of the tubes/ fittings reduces the release. Similarly the water pH, conductivity, content of oxygen, carbon dioxide and minerals may also influence the release of nickel (European Commission 2008).

The EU risk assessment report made a detailed analysis of regional exposure to humans from drinking water:

Adults
From drinking water a nickel exposure in the range of *2.0 – 20 µg Ni/d* were estimated

Children (1-2 years old)
From drinking water a nickel exposure in the range of *0.8 –8.8 µg Ni/d* were estimated

The typical value for tap water is around 1.5 µg Ni/L and with a Reasonable Worst Case scenario at 8.8 µg Ni/L (European Commission 2008). The Drinking Water Directive (Directive 98/83/EC) sets a limit value for nickel at 20 µg Ni/L (see section 2.1).

Recently the Danish EPA made an update of the health based quality criterion of nickel in drinking water. This assessment confirmed that a value of 20 µg Ni/L is protective for the population both in relation to protection of sensitised people towards worsening of symptoms from nickel allergy and for protecting against the developmental toxicity of the nickel ion Danish EPA (2013).

6.1.1.4 Ambient air

According to data from 2012 from the Danish Nature Agency surveillance program, NOVANA, the yearly deposition of total nickel to the terrestrial and aquatic environment is 210 and 180 µg Ni/m2, respectively. In Denmark the yearly emissions of nickel to air was reduced from 26479 kg Ni/year in 1990 to 18910 kg/year in 1998. A possible reason for this reduction could be a change of energy sources from oil/coal to natural gas with a lower nickel content and/or more efficient treatment of air emissions from power plants. The levels of nickel in ambient air in the EU are: Rural areas: 0.1-0.7 ng Ni/m^3; urban areas 3–100 ng Ni/m^3 and in industrial areas 8-200 ng Ni/m^3 (Danish health and Medicines Authority 2000). This should be compared to the Quality Standard for ambient air at 20 ng Ni/m^3 (section 2.1.1 of this report).

An investigation of the nickel speciation in ambient show that in urban air samples 19% of the measured nickel content is on metal form. The fraction of nickel metal is, however, lower in air samples from industrial areas where only 7.4% was nickel metal (European Commission 2008).

6.1.1.5 Soil/dust

Data on nickel content in soil and dust show typical concentration of 16 mg Ni/kg and 49 mg Ni/kg (European Commission 2008). Realistic worse case concentrations were estimated to 26 mg Ni/kg and 255 mg Ni/kg in soil and dust, respectively.

Based on this a daily average and worst case exposure to children of 4.8 µg Ni/d and 21 µg Ni/d was estimated (European Commission 2008).

6.1.1.6 Conclusion of consumer exposure

In the EU RAR it is estimated that at regional level the contribution from food is 86-89% of the total absorbed dose of nickel, drinking water contributes with 9 – 11.7%, soil/ dust with 1.3 – 1.4%, and air with 0.7%. In a worst case scenario with high nickel from the diet the contribution from food was estimated to be as high as 99%. It should be noted that these values are for total nickel and that metallic nickel only contributes to a small fraction of this.

6.1.2 Occupational exposure

The EU RAR (European Commission 2008) contains a detailed and thorough description of the occupational exposure to nickel metal covering all steps of the life cycle of nickel metal:
a) Mining, smelting and refining.
b) Alloy and powder production and plating and
c) Downstream uses including battery production, catalysts production and production of other nickel compounds.

In the work environment high exposure levels of nickel metal may be seen by dusting processes, e.g. manufacture of nickel powder (i.e. not relevant in Denmark) or where nickel powder is handled by downstream users. The risk reduction measures used in such places include enclosing of the processes equipment, integrated or Local Exhaust Ventilation as well as respiratory protection equipment for short term exposure operations such as cleaning and maintenance.

All exposure scenarios were updated in the nickel registration dossier reflecting the currently identified uses of nickel metal and contain an updated risk characterisation for all uses. The occupational exposure and risk assessment is discussed in detail only in the confidential annex to this report. All exposure scenarios in the registration dossier indicate adequate control of exposures in the workplace (Nickel Consortium 2013).

6.2 Human health impact

6.2.1 Consumers

Dermal exposure of consumers to nickel was assessed in the EU RAR. Exposure due to prolonged skin contact with jewellery watches, buttons, mobile phones etc. is as mentioned, regulated by the REACH regulation. Other possible exposure could be from kitchenware, door handles, furniture and tools that are nickel plated or made of stainless steel. Coins are often made of nickel containing alloys and handling of coins is also a possible route of exposure. In general, however, these exposures are limited in time and it is concluded that risks of dermatological effects to the non-sensitised consumer due to nickel released by skin contact is not likely to occur (European Commission 2008).

It was further concluded in the European Risk Assessment on nickel metal, that the contribution of nickel from kitchenware made of stainless steel into the daily diet is insignificant compared to the natural content of nickel in the food (European Commission 2008).

The EU RAR concludes further that in general there is no risk of effects in the general population, i.e. local toxic effects: respiratory toxicity and carcinogenicity, and systemic toxic effects: oral elicitation of dermatitis, repeated dose toxicity and developmental toxicity. Only in cases of high nickel intake where 99% comes from food and beverages there is a risk for severely nickel sensitised persons of worsening of their nickel eczema. For the reasonable worst case scenarios, assumed to be a borderline case, developmental toxicity is identified as a possible risk (European Commission 2008).

It need be noted that these conclusions concern the combined exposure to nickel and nickel compounds and that metallic nickel are considered less hazardous than the water soluble nickel compounds. Also it should be noted that inhalation of metallic nickel as powder is not a relevant exposure route for consumers and therefore hazards in relation to this exposure can be ignored. Moreover nickel metal is poorly water soluble and not classified for developmental toxicity because the absorption of nickel metal via oral route (and inhalational route) is less than for the soluble nickel compounds.

As described above consumers are exposed to nickel via food, beverages, consumer products and via the environment. The EU RAR included two exposure scenarios where the combined exposure of consumers to nickel metal was assessed (European Commission 2008):

- Combined consumers scenario 1: exposure to nickel released to the water from kettles where the heating coils were nickel plated coils combined with the regional exposure via the environment.
- Combined consumers scenario 2: exposure to nickel released from pipe fittings combined with the regional exposure via the environment.

The scenario 1 indicated that the overall nickel dose was clearly dominated by the intake of nickel ions released from the kettle. It was concluded that there is a need for limiting the exposure due to risks of toxic effects to the consumer.

The results from the scenario 2 were similar. The nickel dose was clearly dominated by the release from pipe fittings (80%) and the combined scenario indicated a risk.

The conclusions from these scenarios were taken forward in the risk reduction strategy which followed up on the conclusion in the EU RAR and agreed by the EU member states and the Commission. In order to reduce the transfer of nickel through the human food chain it was recommended in the strategy to discourage the inappropriate use of nickel plated heating elements in water kettles. This recommendation was later taken up by industry in the REACH registration dossier that specifically advice against the use of nickel plated heating coils. Furthermore it was recommended that the member states should brief nickel hypersensitive persons about which food materials has high nickel content and the need to flush stagnant water from first water tap use.

6.2.2 Workers

The main conclusions in the EU RAR concerning the risk assessment from occupational exposure scenarios were, for the majority of the uses involving exposure of workers by inhalation, that no further information was needed and no risk was identified related to repeated dose toxicity, carcinogenicity or developmental toxicity. Moreover for all scenarios on dermal exposure in the work environment sufficient information was available, and no risk was indicated in relation to repeated dose toxicity, irritation, sensitisation, carcinogenicity and reproductive toxicity (European Commission 2008). It should be noted that these conclusions were made for nickel and nickel compounds as a group. Nickel metal is not classified as developmental toxic and bears a Carc 2 classification unlike many nickel substances that are classified as Carc 1A.

In some specific exposure scenarios with workers, however, risks were identified mainly in relation to realistic worst case exposure, and it was concluded that further reduction measures were needed. These included nickel refining (scenario A4 and A5); nickel alloy production (scenario B1 and B2 melting and foundry techniques, powder metallurgy B3); battery production (scenario C1 and C2 nickel metal as feedstock and unknown nickel species as feed stock); nickel catalysts production (scenario C3 and C4: nickel metal as feedstock and unknown nickel species as feed stock); and production of nickel containing chemicals (scenario C5). Of these scenarios only catalyst production takes place in Denmark and it is not likely that workers at the Danish site are exposed to nickel in concentrations that entail health risks. The Danish OEL is set at 0.01 mg Ni/m^3, i.e. lower than in most EU countries and at the same level as recommended by SCOEL.

In the preparation of the REACH registration dossier all scenarios on occupational exposure to nickel metal were reviewed and updated. The conclusion of this work was that adequate control of risks was documented in the exposure scenarios for all identified uses of nickel metal. This was based on a refinement of the exposure assessments and recommendation on appropriate risk management measures. The risk characterisation is discussed further in the confidential annex to this report.

6.3 Summary of health effects

Metallic nickel is a well-known human allergen in connection to dermal exposure. Although declining metallic nickel is the main cause of the induction of dermal contact allergy in Denmark. About 10% of young women suffer from contact allergy towards nickel. However, if liberation of nickel –ions from metallic surfaces is controlled down below 0.5 µg Ni/cm_2/week this to a great extent may protect against sensitisation of non-sensitised individuals.
In connection with inhalation of metallic nickel powder this may induce severe inflammatory responses in the lung including lung fibrosis. This has been found down to a dose level in rats at 0.1 mg/m3 of metallic nickel powder.

The carcinogenic properties of metallic nickel are debated as different interpretations exist for both the epidemiological data and the experimental animal data.
SCOEL (2011) does not consider the evidence for metallic nickel as sufficient to conclude a carcinogenic potential of the substance, whereas IARC (2012) find that both the epidemiological and the experimental animal data as sufficient to conclude that metallic nickel has to be considered as a human carcinogen. In EU metallic nickel has a harmonised classification as a suspected carcinogen.

In relation to soluble nickel compounds a NOAEL of 1.1 mg Ni/kg bw/day for developmental toxicity following oral ingestion has been observed in experimental animal studies. When applying this oral NOAEL for nickel metal in connection with a risk assessment, consideration should be given to the considerable lower bioavailability of metal compared to nickel sulfate.

Most measurements and assessment of the exposure of consumers and workers to nickel refer to total nickel and it is not possible to separate the exposure to nickel metal from the exposure to other nickel species. In general, however, it can be assumed that nickel in food, drinking water, air and soil is dominated by other nickel species than nickel metal and that the release of nickel ions from nickel metal in stainless steel and nickel containing alloys is low compared to other sources.

Oral consumer exposure to nickel takes place primarily via food and drinking water. Direct exposure to nickel metal is by dermal contact to nickel containing objects like jewellery, watches, buttons, zippers, etc. The release of nickel from such articles is regulated by REACH due to the risk of dermatological effects and consequently pure nickel or nickel plated items are not used where prolonged dermal contact is intended. Thus it is to be expected that the prevalence of nickel contact allergy will further decline in future.

In a worst case scenario it was shown that the exposure via food and water may lead to a risk for nickel sensitised consumers due to high releases from water kettles with nickel plated heating coil and pipe fittings in domestic water installations. The general scenarios for combined exposure do not indicate a risk to the consumer.

Exposure to nickel metal in the work environment may lead to inflammatory lesions in the respiratory tract and may possibly be carcinogenic as well. Due to the observed lung damages the European Commission Scientific Committee on Occupational Exposure Limits (SCOEL) proposed an OEL of 0.005 mg/m3 (respirable fraction) for poorly soluble nickel compounds and for nickel metal. SCOEL furthermore suggested an OEL at 0.01 mg/m^3 to protect against nickel induced carcinogenicity of soluble as well as poorly water soluble nickel compounds (excluding nickel metal). The OELs proposed by SCOEL is subject to further discussion in the European Commission Advisory Committee on Safety and Health at Work before a possible OEL value can formally enter into a legislative procedure.

7. Information on alternatives

7.1 Identification of possible alternatives

Alternatives to nickel and nickel substances in different sectors have been investigated by the Nickel Institute through several reports covering uses of a range of nickel substances (DHI 2013). The Assessment of alternatives have included use of nickel as plating material for decorative and functional purposes e.g. in cars and in the aerospace industry. Furthermore, alternatives to nickel have been identified and evaluated in electronics and catalysts sectors.

7.1.1 Alternatives to nickel in steel and alloys

Stainless steel is the generic name for a number of different steels characterised by their corrosion resistance. The main uses of stainless steel are within the industrial sector where is it used e.g. in production equipment, piping systems and tanks. Other main uses are in consumer products, for construction purposes and in the transport sector, mainly in the automotive industry and aerospace, but also in rail cars and special transport vehicles.

All stainless steels share a minimum percentage of about 10% chromium, but the content of nickel varies in different grades of stainless steel. Where the most commonly used grades contain 8-10% nickel, there are grades with lower nickel contents, for example chromium-manganese stainless steel which contains 3.5-6% nickel. Some chromium – manganese grades contain as little as 1% nickel and the lower cost manganese is usually used to replace nickel in these grades. The low-nickel stainless grades are generally less expensive to produce but are also less corrosion resistant and more difficult to form and weld. They are also considered more difficult to recycle. Thus, for certain applications where highly corrosion resistant steel is needed there are no alternatives to nickel. Nevertheless, the global use of these steel grades is significantly increasing. Alloys with a higher percentage of nickel are often applied where high corrosion resistance is required (DHI & RPA 2008).

The high nickel price is driving the market towards materials with lower content of nickel. These alternatives include ferritic stainless steel, manganese with low nickel grades of steel and other materials such as composites and coated carbon steels. The tendency is reflected in the steel mills increased production of corrosion resistant steel with higher chromium and manganese content and lower nickel content, or stainless steel without any nickel (DHI & RPA 2008).

5.1 Nickel Alloys

Apart from the use of nickel in commonly used grades of stainless steel it is used in a number of alloys applied in harsh environments where specific properties are required. Nickel-chromium alloys (alloys that contain more than about 15% Cr and with 50% or higher nickel content) are used to provide oxidation resistance at temperatures exceeding 760°C with high strength and without embrittlement. Other elements such as cobalt, aluminium, niobium or rare earth metals can be also added to improve properties further. Similar grades with high molybdenum content are used where high corrosion resistance is required. There are nickel alloys with lower nickel contents (~33-50%) which are used for less aggressive conditions. Applications where high corrosion and heat resistance is required include:

- aircraft gas turbines;
- steam turbine power plants;
- medical applications;
- nuclear power systems;
- oil and gas production and refining;
- chemical and petrochemical industries; and
- pharmaceutical industry.

A number of other applications for nickel alloys benefit from the physical properties of special-purpose nickel-base or high-nickel alloys. These include:

- low-expansion alloys;
- electrical resistance alloys;
- soft magnetic alloys; and
- shape memory alloys.

The nickel content in alloy steel and non-ferrous alloys varies significantly and the nickel content is mainly determined by the specific technical requirements (DHI & RPA 2008).

In conclusion nickel is used mainly to provide special qualities to alloys e.g. corrosion resistance in very aggressive environments. The driver for use of nickel in alloys and steel are specific technical requirements, which are difficult or even impossible to achieve without nickel.

7.1.2 Alternatives to nickel in plating

Nickel is used widely in industrial surface treatment for both decorative and functional purposes. Sectors that apply nickel in surface treatment include:

- Automotive industry
- Aerospace industry
- Electronic industry
- Nickel plating used for decorative purposes

Nickel plating is widely used to improve the wear and corrosion resistance of mechanical parts in e.g. car and aerospace industry, but is also used for decorative purposes, e.g. on plastic items, to give a glossy shiny surface either alone or as under-layer for a chromium finish (DHI 2013).

<u>Car industry</u>

The car industry has a very high focus on coatings and the competition and marketing of coating solutions to this sector are very aggressive. The main plating techniques used are electrolytic zinc-nickel and electroless nickel coating (DHI 2013).

In many cases, zinc-nickel plating with chromate free passivation has replaced zinc plating with chromium free or hexavalent chromium passivation. Zinc-nickel coatings are very corrosion resistant in salt spray and do not form heavy corrosion products. Therefore, the technique is very useful for fasteners (screws) in cars. The coating will be difficult to replace in the automotive industry due to the high demands of corrosion protection (DHI 2013).

Possible alternatives to nickel plating in car industry includes zinc and tin-zinc plating zinc-iron alloy coating (sherardizing) and non-electrolytic zinc-aluminum coating (dip-spin coating). However, none of these methods provide the same level of protection to corrosion as zinc-nickel and can only replace nickel where there are less strict technical demands (DHI 2013).

<u>Aerospace industry</u>

Within the aerospace industry, zinc-nickel plating is used increasingly as replacement for cadmium. Furthermore, hard chromium has been widely replaced by a range of alternatives, including electroless nickel and nickel composite. Specialised nickel plating is also used in the maintenance of landing gear. Introducing new coatings in the aircraft industry is complicated and requires a wide range of long-term tests. The combination of the specific functional properties of nickel coatings, i.e. excellent adhesion, corrosion protection, hardness, wear and erosion resistance as well as uniform thickness on complex components, is a technical barrier to substitution of nickel. The general trend is an increased use of zinc-nickel within the aerospace industry (DHI 2013).

Decorative plating

Nickel plating is widely used as decorative coating alone or in combination with other coatings, e.g. bright chromium. Nickel plating has the property of being protective against corrosion and wear of the plated item and providing a strong adhesion to the base material. This is used for example in the plating of items used in the bathroom and kitchen where wear and corrosion resistance is required.

Alternatives do exist, e.g. white bronze, zinc or tin-zinc plating with trivalent chromium passivation, but none of these solutions provide the same combination of wear and corrosion resistance (DHI 2013).

Electronic industry

Nickel plating is used widely in electronic industry where it contributes to secure the functioning and reliability of e.g. connectors, contacts, microprocessors and integrated circuits. Electronic industry is characterized by a rapid development and miniaturization of components and devises. Intensive R&D is critical and the global market is competitive.

In terms of tonnage the use of nickel for plating of components used in the electronic industry is by far less than in other areas using nickel plating, but the importance and value of nickel plating in electronics is high.

The general conclusion of the Assessment of Alternatives is that there is currently no alternative that provide an overall substitution possibility to nickel in electronics. For some specific uses alternatives do exists, e.g. noble metals. These are, however, more expensive than nickel and the economic feasibility of thus depends also on the implication the plating cost has to the overall cost of the product (DHI 2013).

7.1.3 Alternatives to nickel in catalysts

Nickel metal is used in manufacture of catalysts where it is applied in the production of other nickel salts used in the production.

For the two main applications of nickel catalysts: steam reforming and hydrotreating, no viable alternatives exist. In steam reforming catalysts nickel could technically be replaced by ruthenium, and possibly by other platinum group metals (pgm) like platinum or palladium. However, the increased demand will strongly influence the market price of these metals and catalysts will become too expensive for a cost-effective operation. More seriously, world metal production would only allow a tiny fraction (<1%) of current approximately 1400 steam reforming plants to switch over.

Overall possibilities for large-scale substitution of nickel in catalysts are limited. Substitution generally leads to increased capital and process costs and/or inferior products, or, if substitution is technically feasible, this would lead to a rapid depletion of world resources of certain metals (DHI 2013).

The overall conclusion is that although alternatives do exist for some applications of nickel as catalyst a full substitution seem not possible without major economic and environmental consequences (DHI 2014b).

7.2 Summary and conclusions

The overall conclusion on the assessment of alternatives to nickel is that there are only a few applications where nickel can be phased out and replaced by other materials and techniques. As contact to, or release of nickel ion from, stainless steel does not seem to be a concern no assessment on alternatives to nickel in stainless steel has been conducted.

Nickel used for plating can be replaced only in areas where there are no specific technical requirements regarding corrosion, or wear resistance. In functional plating in the car and aerospace industry no alternatives seem to be able to compete with nickel. Only where less stringent requirements are specified e.g. for decorative plating on indoor other surface treatments or technical solutions would be suitable.

The use of nickel used as catalyst is based on its inherent properties as an element. In some processes other elements have similar catalytic effects, with same or lower activity. Due to market process and limited availability of some of the most suitable alternatives it seems to be very difficult to find technically suitable alternatives without loss of efficiency/ capacity as well as significant economic and environmental consequences.

8. Abbreviations and acronyms

CLP	Classification, Labelling and Packaging Regulation
DOC	Dissolved Organic Carbon
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EU	European Union
EU RAR	European Commission Risk Assessment Report
LOUS	List of Undesirable Substances (of the Danish EPA)
NOEC	No observable effect concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PNEC	Predicted no effect concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
STP	Sewage treatment plant

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Appendix A: Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in chapter 3. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 3.

EU and Danish legislation

Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvring as to the form and means of implementation. However, there are great differences in the space for manoeuvring between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently and to further strengthen a level playing field within the internal market; the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: bekendtgørelser).

- The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set-out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive, even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a so-called comitology procedure involving Member State representatives. Decisions are also used under the EU ecolabelling Regulation in relation to establishing ecolabel criteria for specific product groups.

- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, Danish legislation regulates to some extent chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation

REACH and CLP

The REACH Regulation[9] and the CLP Regulation[10] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration

All manufacturers and importers of chemical substances > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered dead-lines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation

A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation

Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction

If the authorities assess that that there is a risks to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling

The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

Two classification and labelling provisions are:

1. **Harmonised classification and labelling** for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.

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[9] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[10] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

2. **Classification and labelling inventory**. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publish the classification and labelling inventory based on all notifications received. There is no tonnage trigger for this obligation. For the purpose of this report, self-classifications are summarised in Appendix 2 to the main report.

Ongoing activities - pipeline

In addition to listing substance already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA web-site also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

Community Rolling Action Plan (CoRAP)

The EU member states have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating by who and when a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV

Before a substance is included in REACH Annex XIV and thus being subject to Authorisation, it has to go through the following steps:

1. It has to be identified as a SVHC leading to inclusion in the candidate list[11]
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions

When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.

This is done as a REACH Annex XV proposal.

The 'registry of intentions' gives an overview of intensions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions
- for the three types of Annex XV dossiers.

[11] It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Article 7.2 ff).

International agreements

OSPAR Convention

OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- issues of importance
- agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out.
- guidelines or guidance setting out the way that any programme or measure should be implemented
- actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which is works as:

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention

The objectives of the Rotterdam Convention are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;

- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:
- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels
Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the ecolabelling criteria for that type of product. An EU scheme (the flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

EU flower
The EU eco-labelling Regulation lays out the general rules and conditions for the EU eco-label, the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

Nordic Swan
The Nordic Swan is cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Eco-labelling Board consists of members from each national Eco-labelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Eco-labelling Denmark "Miljømærkning Danmark" (http://www.ecolabel.dk/). New criteria are applicable in Denmark when they are published on the Eco-labelling Denmark’s website (according to Statutory Order no. 447 of 23/04/2010).

Blue Angel (Blauer Engel)

The Blue Angel is a national German eco-label. More information can be found on: http://www.blauer-engel.de/en.

Appendix B: Confidential information - separate report

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