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Survey and analyses of consumer products with non-nickel coatings

Survey of chemical substances in consumer products No. 189

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Preface

The project “Survey and analyses of consumer products with non-nickel coatings” was carried out from April to November 2021 by Help2comply and ChemAgenda. The chemical analyses were performed in August 2021 by Modern Testing Services (Global) Ltd. UK.

This report describes the project and its results. The aim of the project was to assess if common consumer products which may come into contact with the skin and which are equipped with non-nickel surface coatings may potentially still be a source of consumers’ exposure to nickel. In addition, the project included chemical analyses on coated products to assess their compliance with the rules for nickel as laid out in the EU REACH Regulation (REACH, 2006).

The project was financed by the Danish Environmental Protection Agency as part of a wider program to conduct surveys on chemicals in consumer products.

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We wish to thank the Nickel Institute –and the US National Association for Surface Finishing for providing much useful basic information about the use of different coatings. In addition, we wish to thank a wide group of stakeholders in different supply chains, industry organisations, and other actors for providing information about the use of nickel and coatings in consumer products. Finally, the MTS laboratory has provided much useful information for the project.

Summary and conclusions

Background and scope
Nickel is used in many consumer products, and it is well-known that this substance is a frequent cause of skin allergy. A study in five EU countries in the period from 2008 to 2011 found that 22,2 % of women and 5,2% of men suffered from nickel allergy (Diegpen et al., 2016). In Denmark, a study on grown-ups in the city of Glostrup in the period from 2006 to 2008 showed that 10% of women and 1% of men suffered from nickel allergy (Danish National Allergy Research Centre, DNARC, 2021).

Consumer products may be equipped with surface coatings to provide certain colour or texture, but the coating may also protect consumers from being exposed to underlying layers with nickel. The aims of this project was to gather information about the types, uses, and durability of nickel-free coating on consumer products intended for prolonged and direct skin contact and to select two or three product categories for chemical analysis to control compliance related to the EU REACH Regulation article 67 (1) and corresponding Annex XVII, entry 27, restricting the release of nickel from consumer products and finally to assess whether products with protective coatings may still potentially be a source of consumers' exposure, e.g. if the coating is insufficient in preventing release, particularly after being worn during use.

Survey
A survey to gather information about the use of nickel as base material or in coatings of consumer product was carried out. The survey included literature search as well as reach-out to a large group of relevant stakeholders to ask about their experience with non-nickel coatings. The stakeholders approached included retailers and their supply chains, industry organisations, laboratories, and knowledge-based institutions. Inquiries were made related to the use of coatings and their durability as well as on the expected service life of products and any particular market developments.

A secondary aim of the survey was to provide a basis for selecting product categories for further chemical analysis to test compliance with the nickel restriction. It was decided from the start, that the study should focus on products fulfilling the four basic criteria shown below, and the survey aimed at identifying such product categories:

- Product categories that often cause nickel allergy due to skin contact
- Product categories frequently shown to be in non-compliance in earlier enforcement campaigns
- Product categories that may contain nickel covered by a non-nickel coating
- Product categories with a service life of more than 2 years which could potentially still release nickel.

The survey identified the following product categories as to a high degree fulfilling the four criteria:

- Jewellery, particularly earrings and body piercing products
- Clothing accessories
- Toys
- Wrist watches
- Spectacle frames

Among these categories low-price products may be considered the most problematic as these are often insufficiently coated.

Publicly available information focused on coatings preventing nickel release is scarce, and the information received during this study has shown that most retailers are not able to identify the specific type of coating on their products.

At the same time, the survey revealed that it is common that major manufacturers, and brands provide very clear specifications to their surface coating providers.

Finally, the survey revealed that surface coatings may be the result of highly sophisticated processes with several different layers of coatings, some of which may intentionally contain nickel.

Chemical analyses

Based on the information obtained during the survey, products from the categories toys, body piercings and earrings/studs were selected for chemical analyses. The selected categories were chosen because body piercing jewellery, including earrings, is recognised as a major culprit in the prevalence of nickel allergies among consumers, and toys has been highlighted as a product category that may be an overlooked source of nickel exposure. Moreover, quite many cases of non-compliance have been reported for these categories.

A total of 63 products were purchased for chemical analysis: 22 toys, 14 body piercings, and 27 earrings/studs. Products which were claimed at the website to be coated or plated, or which had an obvious colour, silver, or gold coating were prioritised. Products were purchased from Danish, EU, or non-EU based shops.

Some of the products were comprised of several individual parts, so the study included a total number of 73 samples. All samples were subject to a screening procedure using XRF and DMG screening methods to determine if nickel was present in the surface or the outer layer of the products. The initial tests were used only as a qualitative screening test, and only samples which showed positive results in either of the two selected tests (XRF and DMG) were chosen for further chemical analyses.

In the screening tests, nickel was detected in 47 individual samples from 38 products, and those samples were selected for further chemical analysis. The 38 products were 12 toys, 12 body piercings, and 14 earrings/studs, which gives a distribution of approximately 1/3 for each product category.

For the toy products the chemical analyses were performed according to standard methods for simulation of wear and corrosion (CEN, 2020) and for nickel release (CEN, 2015). The earrings and body piercing products were tested for nickel release both with and without an initial simulation test for wear and corrosion (CEN, 2015) even though these products are not formally within the scope of the standard for wear and corrosion (CEN, 2020).

Results and conclusion

The study has shown that the composition of coatings and the related manufacturing processes may play a significant role in causing or preventing nickel release from consumer products and that this is a complex issue that could not be fully clarified in this project.

A relatively high frequency of non-compliance (5%, 21% and 15% for toys, body piercing and earrings respectively) was found among the purchased products in this project. Particularly for the body piercing products, which have not often been included in earlier enforcement projects.

Moreover, looking selectively at the 38 products containing nickel selected for chemical analysis, the frequency of non-compliance among these products were 8% for toy products, 25% for body piercing products, and 28% for earrings/studs.

These results indicate that the use of nickel in consumer products constitutes a risk of nickel release as the nickel is not always firmly bound in the material. The results also indicate that the presence of a coating on a product is in itself not sufficient to prevent nickel release. This can be due to ineffective coatings covering a base material with nickel, or it can be due to release of nickel from a product where the coating itself contains nickel.

Relatively to the number of products purchased in a particular market, the frequency of non-compliance for products purchased from web-shops outside the EU is about twice that for products purchased in Denmark.

Higher as well as and lower values for nickel release after the simulation for wear and corrosion was found. Comparing nickel release rates for untreated samples and samples exposed to simulated wear and corrosion could – in principle – indicate the effect of the wear and corrosion: An increase could indicate that a non-nickel coating was damaged exposing a nickel containing layer below, and a decrease could indicate that a nickel containing coating was removed. Each test for nickel release after the simulation for wear and corrosion was conducted in triplicate. An increase in nickel release were concluded for four products and a decrease in nickel release were concluded for four other products.

Finally, the study highlighted a possible problem related to the current standard for simulating wear and corrosion. This standard is not applicable for products where nickel is used in the coating, which may constitute a general problem for testing laboratories, as obtaining information about the coatings nickel content may be a complicated task.

1. Introduction

1.1 Background

Nickel is used in many consumer products, and it is well-known that the substance is a frequent cause of skin allergy. The allergy is experienced as an itchy rash, redness and swelling of the skin and is caused by prolonged or repetitive contact between human skin and items that release nickel.

The migration of nickel from consumer products is regulated in the EU through the REACH regulation, however, a large number of individuals are still suffering from reduced quality of life due to the adverse effects of the use of nickel in consumer products.

On a global scale 12-15% of all women and 1-2% of all men suffer from nickel allergy (Kate Heim, 2021).

A study in five EU countries in the period from 2008 to 2011 found that 22,2% of women and 5,2% of men suffered from nickel allergy (Diegpen et al., 2016).

In Denmark, a study on grown-ups in the city of Glostrup in the period from 2006 to 2008 showed that 10% of women and 1% of men suffered from nickel allergy (DNARC, 2021).

A study from 2009 (Thyssen et al., 2009) showed a significant decline in nickel allergy among younger women from 20% in 1990 to 10% in 2006 indicating that legal provisions introduced in the 1990's has had an effect on the prevalence of nickel allergy.

According to a Danish study (DEPA, 2016) the single most important reason for allergic reactions to nickel among women was earrings, followed by buttons on clothing, wrist watches, jewellery other than earrings, zippers, and belt buckles. Among men, wrist watches and belt buckles were the most important causes of first-time rash, followed by spectacles, jewellery other than earrings, earrings, buttons on clothing, and keys.

It is well known that products may be plated or otherwise coated with surfaces for the purpose of decoration or resistance against abrasion and corrosion. Coatings may also be applied to protect the consumer against nickel in the base material. However, such coatings may deteriorate during service life thus exposing a layer of nickel underneath. The current REACH restriction takes this into account by requiring a minimum durability of any such coatings on consumer products. However, there is not much public information available about what kinds of coatings are used on different products, neither on their durability or efficiency in protecting the consumer.

1.2 Aim and scope of the study

The initial aim of this project was to:

- Gather information about the types, uses, and durability of nickel-free coating on consumer products that would otherwise release nickel above the limit value set out by the REACH regulation article 67 (1) and corresponding annex XVII, entry 27 (The nickel restriction).
- Analyse approximately 40 consumer products for compliance with the legal provisions related to release of nickel from consumer products.
- Assess whether products equipped with nickel-free surface coatings covering a base material which contains nickel are potentially a significant source of consumers' exposure to nickel.

Consequently, the focus of this report is consumer products covered by the restriction in the EU REACH regulation that may be equipped with a non-nickel coating covering a subsurface or base

material that contain nickel. Examples of such products could be commonly used consumer items such as jewellery, watches, spectacle frames, buttons, and zippers as well as toys or electronics.

1.3 Use and properties of nickel

Nickel (Ni) (CAS-no. 7440-02-0) is a transition metal with the atomic number 28. It is the sixth most common element on earth, a naturally occurring, lustrous, silvery-white, hard metallic element with properties that makes it very suitable for alloys. It increases strength, hardness, and corrosion resistance over a wide temperature span. Nickel is ubiquitous, inexpensive, and used in a wide range of applications with stainless steel, other alloys, and plating as the most common uses. Consumer applications cover a wide range of articles to which consumers can be exposed.

Figure 1 shows that about 70% of the nickel which is produced is used to manufacture stainless steels. Another 15-20% is used in alloys, including for highly specialised non-consumer applications such as aerospace, transport, and electronic devices. About 7% is used in plating and 1% in other uses, including consumer products.

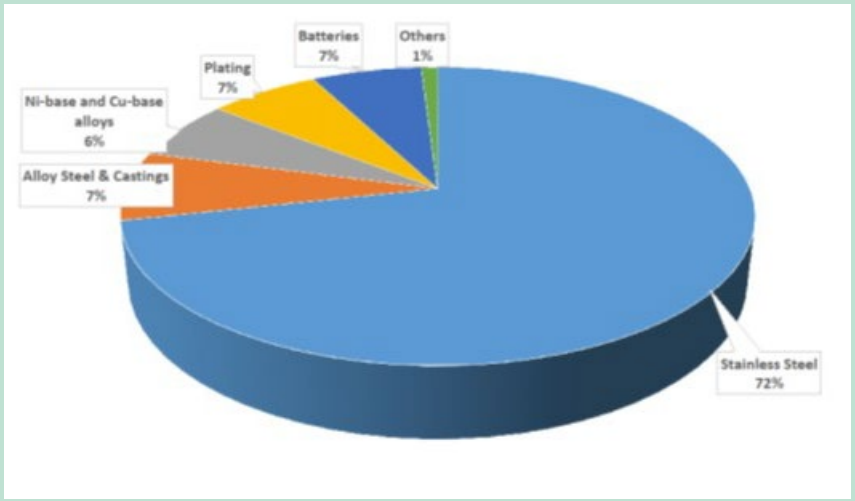

FIGURE 1. Overview of use of global use of Nickel (Roskill, 2021)

The widespread use of nickel is based on a unique combination of physical and chemical properties, which makes this metal very attractive in a number of end-use products:

- High melting point, 1.453º
- It alloys with most other metals
- High resistance to corrosion and oxidation
- Enhances strength in alloys
- Ductile
- Magnetic at room temperature
- Deposits with electroplating
- Catalytic properties in a large number of industrial processes and in organic synthesis.
- Electrochemical properties, such as high active surface area and chemical stability.

Unfortunately, the metal is also a frequent cause of nickel allergy, which makes it less attractive in many consumer applications unless the release of nickel onto the skin during use can be avoided.

1.4 Causes of nickel allergy

Nickel Allergy Contact Dermatitis was first described in nickel-platers in the late 19th century and for many years nickel has been recognised as an element that can cause a variety of allergic reactions in the skin ranging from mild irritation to severe eczema (LGC Limited, 2003).

In short, nickel allergy starts with **sensitisation,** which is caused by exposure to nickel above a threshold which is different from person to person. There is no cure for nickel allergy, and once sensitised, subsequent direct and prolonged contact with items that release nickel – even at lower concentrations - can elicit an allergic reaction (**elicitation**).

It is the migration of nickel onto the skin that is relevant for the risk of an allergic reaction rather than the content of nickel in the product (DNARC, 2021; Basketter, 2021; Ahlstrøm et al. 2019, Ringborg et al., 2016). Factors such as the time length of skin contact, friction and pressure may affect the nickel migration. It is also well-known that the presence of sweat or other body fluids, such as blood, can enhance nickel migration by causing corrosion of the surface of a product (DEPA, 2016; LGC Limited, 2003). This means that products used in pierced skin or in areas with more perspiration, such as belt buckles worn under the clothes are generally more likely to cause allergy.

In order to provide a specific colour or texture and /or to protect the consumer, products made from materials that contain nickel may be equipped with a protective non-nickel coating which can prevent nickel release. These coated products are in focus in this report.

2. Legislation

EU rules to protect consumers from allergic contact dermatitis caused by nickel have been in place since 1994 according to a Directive, which was inspired by Danish national legislation from 1989 (Statutory Order no. 47 June 27, 1989). The reason for the original EU Directive (Nickel Directive, 1994) was given in the recitals, which stated that "*whereas the presence of nickel in certain objects coming into direct and prolonged contact with the skin may cause sensitisation of humans to nickel and may lead to allergic reactions; whereas for these reasons the use of nickel in such objects should be limited".*

The limits of the original Directive were not all the same as the rules in place today. For piercing post assemblies, the Directive from 1994 addressed the concentration of nickel in such post assemblies rather than the migration from these items, and the limit was related to the period of recovery. The Directive restricted nickel *"in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelization of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogeneous and the concentration of nickel - expressed as mass of nickel to total mass - is less than 0,05%"*

In 2004, the Directive was amended to replace this provision regarding total concentration with a limit on the release of nickel from post assemblies. This change may have been based on the findings of the UK based consultants LGC Limited (2003), who argued that it is the migration, not the content, of nickel in a material that determines the potential to cause allergy, particularly highlighting products made from stainless steel.

The amended Directive was later subsumed into the EU Commission's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), which entered into force in 2007.

2.1 Restriction on nickel release in the EU

Today, legal provisions that affect the content and migration of nickel from different products are found in different legal acts. With regard to consumer products, the most significant legal provision is the REACH regulation (REACH, 2006) which restricts the release of nickel (CAS-no. 7440-02-0) from consumer products during use. The release is restricted according to the Regulation's article 67(1), as specified in the regulation's annex XVII, entry 27 (hereinafter referred to as the nickel restriction).

The specific restriction addresses the main groups of products that may cause sensitisation or allergic reactions as follows:

1) Nickel and its compounds shall not be used:

(a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm²/week.

(b) in articles intended to come into direct and prolonged contact with the skin such as:

earrings, necklaces, bracelets and chains, anklets, finger rings, wrist-watch cases, watch straps and tighteners, rivet buttons, tighteners, rivets, zippers, and metal marks, when these are used in

garments, if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week.

(c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm²/week for a period of at least two years of normal use of the article.

The **"**post assemblies" (or the "piercing parts") mentioned in point a) is the part of an earring or another piercing jewellery, that is intended for insertion into the hole in the skin caused by piercing either during or after the period of healing of the wound. Thus, the current legislation recognises a higher risk related to nickel release from piercing jewellery (Section 1.4) by setting a lower migration limit for those parts of any piercing jewellery, which are intended for insertion into the hole in the skin. However, contrary to the case for other articles, the restriction does not include demands related to the durability of the coating for these post assemblies intended for piercing purposes. The post assembly must always comply with the (comparably lower) migration limit.

2.2 Harmonised standards for analytical tests

The REACH restriction further provides that the following standards, adopted by the European Committee for Standardization, CEN, shall be used as analytical test methods for demonstrating conformity:

EN 1811:2011+A1:2015: Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin (CEN, 2015).

EN 12472:2020: Method for the simulation of wear and corrosion for the detection of nickel release from coated items (CEN, 2020).
The standard specifies a method for the simulation of accelerated wear and corrosion, to be used prior to the detection of nickel release from coated articles that come into direct and prolonged contact with the skin.

EN 16128:2015: **Ophthalmic optics, Reference method for the testing of spectacle frames and sunglasses for nickel release:** Reference method for testing of spectacle frames, sunglasses and other items for eye and face protection for nickel release.
The standard applies to those parts of metal spectacle frames that are intended to come into direct and prolonged contact with the skin (CEN, 2015-2).

2.3 Definition of prolonged or repetitive contact with skin

Point (b) in the nickel restriction (Section 2.1) concerns articles, which are intended to come into direct and prolonged contact with the skin. However, the point only presents a non-exhaustive list of products that are covered by the restriction, and the legal text does not define the term "prolonged contact with the skin". This has created uncertainty about whether a number of different products should be considered within the scope of the restriction and after request by the Commission, a more detailed definition has been provided and justified by ECHA (ECHA, 2014):

Prolonged contact with the skin is defined as contact with the skin of nickel of potentially more than:

- 10 minutes on three or more occasions within two weeks, or
- 30 minutes on one or more occasions within two weeks.

2.4 The scope of the restriction

As a follow up action to the publication of the above interpretation related to the definition of prolonged, and repetitive, skin contact, Member States and stakeholders also requested a more practical guideline with a non-exhaustive list of product categories that could be considered to be within or outside the scope of the restriction. As response to this ECHA produced a first draft guideline (ECHA, 2017) based on a mandate from the European Commission. After publication of this guidance more than 80 comments were received from interested parties. ECHA announced at the time that they would revise the guidance based on those comments. However, this has still not happened and thus we consider the draft from 2017 as the best point of departure when seeking to determine if a given product is within the scope of the legislation (see Appendix 2).

3. Survey and criteria for selection of products

A dedicated survey to gather information about nickel and its use as base material or coatings of in consumer products was conducted in April 2021.

It was initially decided that the survey should take departure in a number of specific criteria, which were developed as a first step to identify the most important product categories and to prioritise the selection of product categories for further chemical analysis to check the frequency of compliance with the nickel restriction. These criteria are presented in the following sections together with a summary of the sources of information for the survey.

3.1 Selection criteria

In cooperation with the Danish Environmental Protection Agency (Danish EPA, DEPA), it was initially decided that the decision as to what product categories should be chosen for further analysis should be based on the following criteria:

The product categories should be covered by the restriction on release of nickel as specified in the REACH regulation. In addition, the following product categories should be in focus:

- Product categories that often cause nickel allergy due to skin contact
- Product categories frequently shown to be in non-compliance in earlier enforcement campaigns
- Product categories that may contain nickel covered by a non-nickel coating
- Product categories with a service life of more than 2 years

Product categories within the scope of the restriction

As outlined in Section 2.4, the European Chemicals Agency has published a guidance with a list of product categories considered to be within the scope of the REACH restriction (ECHA, 2017). This list (Reproduced in Appendix 2) was described as “indicative” and “non-exhaustive”, but it is the most comprehensive description available.

Product categories that often cause nickel allergy due to skin contact

The second criteria for prioritising products for chemical analyses was the frequency or recurrence by which different categories have been reported as causes of nickel allergies. Information about this was obtained mainly from recent reports from the Danish EPA as well as other relevant literature. More information is provided in Section 3.3.

Product categories frequently shown to be in non-compliance in earlier enforcement campaigns

Information about the frequency of non-compliance found in recent enforcement campaigns in DK and EU was retrieved from reports from ECHA and the Danish Chemical Inspection Service (DCIS) as well from a targeted RAPEX search. Section 3.4 provides a summary of the information retrieved.

Product categories, that may contain nickel covered by a non-nickel coating

Information on the various surface coatings, which may be applied to products to protect the consumer from migration of nickel and the expected durability of such coatings was obtained from a

variety of sources in the relevant supply chains (see Appendix 1). The information retrieved is provided in Chapter 4.

Product categories with a service life of more than 2 years

Information about the expected service life for different categories of consumer products was sought from the same sources as those approached in the search for information on surface coatings. Section 4.3 describes considerations on this issue among various stakeholders.

3.2 Information sources

A large number of relevant stakeholders, including retailers, laboratories, industry organisations and knowledge-based institutions was approached via e-mail and/or telephone asking for information on surface coatings.

It was considered that the initial reach-out to stakeholders to ask for information should be broad and wide-reaching as a high degree of response was not expected, and it was not possible to predict which individual stakeholders would be willing to contribute to the study.

Appendix 1 provides examples of standard questions developed for the initial approach to stakeholders. Based on this effort information was received from the following sources, which were mainly medium to large companies:

- 2 major retailers
- 4 distributors of DIY products
- 3 suppliers to the clothing industry
- 3 suppliers of spectacles
- 2 suppliers of toys
- 2 suppliers of jewellery
- 4 laboratories based in Asia
- 2 retailers organisations
- 3 knowledge-based institutions

Particularly detailed information came via a few Danish retailers who offered to pass on our questions to their product suppliers. This effort provided more than 10 individual answers which were passed on to us directly from their supply chain.

In total 25 responses were received based on our broad reach out to approximately 100 individual stakeholders. In addition to these responses, crucial basic information about coatings was obtained from web-meetings and e-mail exchange with representatives from the Nickel Institute (Nickel Institute, 2021). This institute is part of a global association of primary nickel producers with the aim to “promote and support the proper use of nickel in appropriate applications”. The institute also provided contact to the US based National Association for Surface Finishing (NASF, 2021).

The contacts approached were asked about the use of nickel and non-nickel surface coating in their sector and also about information related to the durability of coatings, expected service life and market developments. Many sources from individual companies required that their information could be provided anonymously. This was accepted as otherwise the information would not be made available, and although much of the information retrieved from many stakeholders was primarily in the form of personal experience rather than general overviews, it was considered useful for establishing the overall picture of the current situation and for confirming the basic information on coatings etc. received from the Nickel Institute.

The REACH helpdesks of all EU member states were approached, but none were able to provide information on this issue.

3.3 Product categories identified as causes of nickel allergy

A survey by the Danish EPA (DEPA, 2016) identified the following five product categories as the most reported causes of sensitisation and first-time nickel allergic contact dermatitis:

- Earrings, followed by
- Buttons on clothing
- Wrist watches
- Other jewellery
- Zippers

The study provides information from 314 women and 24 men about what product was the cause of sensitisation (the first rash) from shiny metal items. Among women, the single most important reason for first-time rash was earrings, followed by buttons on clothing, wrist watches, jewellery other than earrings, zippers, and belt buckles. Few women reported tools, computers, mobile phones, or lighters as causes of their initial rash. Among other items, four persons mentioned hooks on clothing as a cause.

The study further highlighted, that earrings still seem to play a major role in nickel sensitisation when they are non-compliant.

Among men, wrist watches and belt buckles were the most important causes of first-time rash, followed by spectacles, jewellery, earrings, buttons on clothing, and keys. However, as only few men participated in the study, the results are less robust.

Women were median 16 years old, and men were 18 years old when experiencing first-time rash, which is consistent with common knowledge that nickel allergy mostly affects women, in particular young women, often as a result of wearing jewellery.

A workshop in 2015 following up on the ECHA guidance provided consensus that body piercings and low-quality products continue to be a significant source (Nickel Institute, 2017).

Recent research has suggested tattoo needles as a possible cause of nickel allergic reactions (Schreiver et al., 2019).

A recent Danish study on earrings (Wennervaldt et al., 2021) confirms that this product category is still a significant problem as 14,8% of the tested products showed non-compliance.

3.4 Product categories in focus in earlier enforcement activities

This section provides a summary of findings from recent Danish, and EU-wide enforcement activities related to the release of nickel from consumer products. These findings provide insight into whether some product categories are more often found to be in non-compliance than others.

As a first step, a targeted search was performed by the Danish Chemical Inspection Service (DCIS) in their internal database. The Authority looked into which product categories had in the period from 2011 to 2021 been reported to them as being non-compliant by private consumers and companies. Examples were electronic products such as smart watches, portable PCs, cell phones and headphones as well as jewellery such as necklaces and rings, and hair accessories, spectacle frames, massage gloves, musical instruments, and second-hand products. The DCIS emphasized that product categories such as toys, electronics, jewellery, and cosmetics are reported quite frequently, while products such as tools and building materials are seldomly reported (DCIS, 2021).

To support these findings, two additionally targeted information searches were conducted as described in the following sections.

3.4.1 Key enforcement campaigns

Information from a number of key enforcement campaigns conducted during recent years was gathered from DCIS, as well as from reports on joint enforcement campaigns conducted by the European Chemical Agencies' network of enforcement authorities, the so-called REF projects (ECHA, 2021). A summary of these findings is presented in Appendix 3, and these results indicate that jewellery and wrist watches are examples of product categories in which significant non-compliance have been found.

3.4.2 RAPEX Notifications

The Rapid Alert System (RAPEX) is a database created to ensure that information about dangerous non-food products withdrawn from the market and/or recalled anywhere in Europe is quickly circulated between Member States and the European Commission. This way, appropriate follow-up action can be taken in all Member States. In principle only dangerous products should be reported to RAPEX, but some MS also report products which are non-compliant but does not necessarily constitute a risk for human health or the environment.

The RAPEX System is connected to a public website 'the Safety Gate' (https://ec.europa.eu/safety-gate-alerts/screen/webReport) where the Commission provides access to weekly updates of alerts submitted by national authorities. A dedicated search into RAPEX weekly newsletters performed as part of this study showed that in the period from 2011 until 2020 there have been 225 notifications to RAPEX relating to consumer products that do not comply with the nickel restriction in REACH. The notifications cover a wide range of product categories. Table 1 provides an overview.

TABLE 1. Summary of RAPEX notifications related to nickel in the last 10 years

Year	Jewellery	Clothing, textile, and fashion	Stationary	sun-glasses	Toys	Gadget	Hobby	Other	Sum
2011	8	3							11
2012	8	2	1	1					12
2013	11	4			2	1			18
2014	18	1	3		3				25
2015	21	1			4				26
2016	9	1			3				13
2017	12	1			1				14
2018	19	2			4		1		26
2019	21	2	1		1				25
2020	29	8			1			1	39
sum	156	25	5	1	18	1	1	1	209

Besides the RAPEX database, there is also another Information exchange database, which is a part of the ICSMS-system (https://webgate.ec.europa.eu/icsms/public/consumer.jsp?locale=en). A system that provides a mechanism for exchange of information related to market surveillance between authorities. This platform also has a publicly available search function, but as the search criteria are mainly related to brand names and barcodes, it was considered of limited use for this survey.

Table 1 shows that “jewellery” is by far the product category most often reported to RAPEX, followed by “clothing, textile, and fashion items”. The number of toys reported to RAPEX due to nickel release is also noticeable. Comparing these results with the summary of recent enforcement projects shown in Appendix 3 (which show that jewellery and wrist watches seem to be problematic) and the national experience of DCIS (which highlighted toys, electronics, and jewellery) results in the following indicative list of product categories often seen to be in non-compliance:

- Jewellery
- Clothing, textile, and fashion items
- Toys
- Wrist watches
- Electronics

Comparing these categories with the list of product categories that are often reported as cause of nickel allergy (Section 3.3) shows that there is a significant overlap. This is not surprising as authorities would tend to focus on problematic product categories in their control activities.
These categories are thus examples of categories, which can be highlighted as frequent causes of nickel allergy and/or as often non-compliant and for which it could be particularly relevant to assess the use of non-nickel surface coatings.

The use of coatings is described in Chapter 4 and the list of products to be in focus is further discussed according to these findings.

4. Information on surface coatings and nickel content

Surface coatings are applied to many different consumer products for protection against abrasion and corrosion or to obtain an attractive colour or finish. For example, chromium- and nickel plating are well-known and widely used coatings in many sectors including transport, furniture, machine parts, and electronics (DEPA, 2015).

This survey aimed to gather information specifically about the use of protective non-nickel surface coatings on products that are considered problematic due to their potential for causing nickel allergy. In order to do so we have reviewed information on surface coatings provided mainly by representatives from the Nickel Institute and supplemented with information received from a number of Danish manufacturers, importers, and distributors in different sectors (Annex 1).

This chapter presents the results from the search for information about the use of coatings in different sectors.

Publicly available information on surface coatings is scattered and scarce, and the information received during this study has shown that most retailers are not able to identify the coating on their products. One respondent to the study summarised the situation in certain supply chains quite well by referring to their product as coated with "*God knows what*".

At the same time, however, the survey revealed that it is not uncommon that manufacturers and major brands provide very clear specifications to their surface coating providers.

Finally, this chapter will clarify that surface coatings may be the result of highly sophisticated processes and that several different layers of coatings, some of which may contain nickel and some not, may be in place between the surface finish and the base material of an article.

4.1 Common protective coatings

Non-nickel surface coatings which can prevent the release of nickel from different consumer products are in common use on the market today (Nickel Institute, 2021; Lo, 2021). Such coatings can be divided into the following four categories based on their material's nature rather than the process:

- Organic coating – polymers including powder coating.
- Inorganic compounds such as silicon dioxide or titanium nitride.
- Precious metals – e.g., gold, silver, or palladium, which can be applied by electroplating, Physical Vapor Deposition (PVD) etc.
- Corrosion resistant alloys - e.g., copper-tin alloy, or cobalt-tin alloy, which can be applied by electroplating.

The base materials may be plastics, metals such as chromium, cobalt, zinc, iron, titanium, or manganese, or alloys such as monel, steel, or brass, that may contain a various amount of nickel.

The following information relates to the different coating methods:

Organic coatings can be applied using several approaches, including sol–gel coating, painting, powder coating which lets the paint melt on the surface, electrophoretic coating (e-coating), which

is the application of organic coatings to electrically conductive materials, such as metal jewellery. Products can also be immersed into an organic lacquer creating a surface film on the product (NASF, 2021)

Inorganic coatings can be plating with different metals, such as copper, tin, zinc, chromium, and alloys. This can be done mechanically or electrolytically. Plating can also be done with precious metals such as silver, gold, rhodium, and palladium, and finally, corrosion resistant alloys can also be applied with the use of plating.

A special but well-known coating method is PVD, a batch process where there is a controlled explosion, and the target compound, such as e.g., TiN compounds to provide a gold-coloured coating, is vaporized and transferred to the surface of the product. This is often used on top of a nickel or chromium substrate but can also be deposited directly onto stainless steel (NASF, 2021).

Table 2 provides a list of examples of various protective coatings that can be applied on top of nickel base materials to prevent abrasion and corrosion as well as nickel release and examples of product categories where such coatings are used. Information was provided by the Nickel Institute (2021) and supplemented with further information as shown in footnotes.

Table 2: Examples of protective coatings that can be used on top of nickel base materials on different products.

Type of coating	Examples of coating materials	Examples of products	Function of the coating layer
Organic	Electrophoretic coating (E-coating)	Spectacle frame, costume jewellery.	Top layer for abrasion/corrosion resistance and colour
	clear coating/lacquer/varnish	Spectacle frames, buttons (in clothing, jeans studs, metal snaps), buckles (in belts, bras buckle/hooks, suspender clips), zippers in clothing.	Top layer for abrasion/corrosion resistance and colour
	powder coating/paints	Buttons (buttons in clothing, jeans studs, metal snaps), buckles (in belts, bras buckle/hooks), metals parts in hair pins/clips, zippers in clothing.	Top layer for abrasion/corrosion resistance and colour
Inorganic coating – inorganic compounds such as silicon dioxide, titanium nitride (TiN)	Silicon dioxide / ceramic in hybrid E-coating	Costume jewellery.	Silicon dioxide /ceramic enhanced abrasion resistance of rather soft E-coating
	PVD ceramic coating (including TiN, TiC, TiCN, TiAlCN, DLC)	Watches, costume jewellery, cutting tools[1].	Top layer for extremely high abrasion resistance

[1] Cutting tools mentioned by NASF (2021).

		spectacle frames, including luxury items[2], piercing jewellery[2].	and colour, corrosion resistance may not be as good as other coatings
Precious metals – e.g., golds, silver, palladium which can be applied by electroplating, PVD etc.	Precious metals topcoats, gold, silver, and rhodium plating etc.	Jewellery products, buttons (buttons in clothing, jeans studs, metal snaps), buckles (in belts, bras buckle/hooks, suspender clips), spectacle frames[2].	Precious metals in top layer serve to provide the abrasion and corrosion resistance required in preventing nickel release
	Diffusion barrier layers such as palladium plating for nickel plating	Costume jewellery, spectacle frames, buckles (in belts, bras buckle/hooks, suspender clips).	Palladium plating provide the diffusion barrier layer cover the nickel plating or nickel containing alloys
Corrosion resistance alloys/layers - e.g., chromium, copper tin alloy, tin cobalt alloy etc. which can be applied by electroplating	Tin cobalt	Metal parts.	Top layer for abrasion/corrosion resistance and colour
	Copper-tin, tin-copper, tin iron, brass, zinc[3]	Costume jewellery, buttons (buttons in clothing, jeans studs, metal snaps), buckles (in belts, bras buckle/hooks, suspender clips), zippers in clothing.	Inter-layer/ top layer for abrasion/corrosion resistance and colour
	Nickel phosphorus	Metals parts.	Inter-layer abrasion/corrosion resistance
	Chromium	Plastic plated parts in old flip phones, metals parts in hair pins/clips.	Chromium provides both high abrasion/corrosion resistance of the underneath nickel plating layers and prevent the nickel release

4.1.1 Nickel coatings and multiple layer coatings

When studying the relation between surface coatings and nickel release, it is important to be aware that for many products made of metals, alloys, or plastic, it is in fact the coating process itself that introduces the nickel – or layers of higher nickel content than the base material - onto the product.

Nickel is widely used in sublayers or substates for many coatings. For instance, electroplating is often done on a nickel sublayer, and a chromium surface cannot be applied on a steel surface unless nickel is applied first (Nickel Institute, 2021).

[2] Supply chain contact.

[3] Danish Retail Brand.

A full surface coating solution may require many layers of coatings between the surface and the base material of an article, and some of these layers may contain nickel. An example of such sophisticated coatings is shown in Figure 2. In this example, three layers of coating are used, but advanced surface coatings can be made up by even more layers, typically metal alloys.

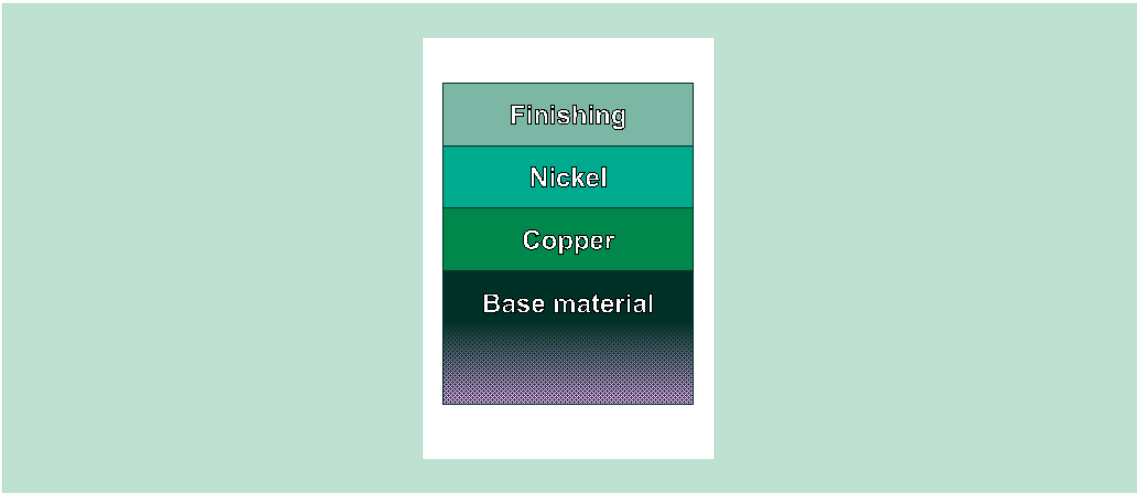

FIGURE 2. Example of a multiple surface coating solution where one layer contains nickel (Redrawn after figure from Coventya, 2021)

4.2 Factors affecting the durability of coatings

For the purpose of this survey, we asked a number of importers and retailers in different sectors (Appendix 1) if they had discussed the use of non-nickel coatings in their sector, and if so, how they handle the issue of durability. This section summarises the most important points received from different information sources sorted by the three most important – and also interlinked - factors affecting durability of surface coatings: Abrasion, Corrosion, and Quality.

4.2.1 Abrasion

If coated products are further treated through welding, brazing, soldering or other heat treatment this may damage the coating. Any degreasing, grinding or polishing operation that modifies the surface or damage the surface in the course of assembly may also be problematic.

The handling of a product during use may also cause cracks in surface coatings. This was specifically mentioned by suppliers of spectacle frames and earrings. It is not uncommon that the surface layer of consumer products is worn during service life and all consumers have probably experienced how coatings of costume jewellery, spectacle frames, and other metal coated items may become scratched and worn during use. In addition to such tear and wear expose to a sublayer containing nickel may also happen from products with microscopic pores in the surface layer (Nickel Institute, 2021).

4.2.2 Corrosion

Corrosion is the gradual deterioration of a metallic material that, together with metal release, takes place at the surface of a material. Corrosion of alloys containing nickel leads to the release of nickel ions which may induce an allergic reaction.

As mentioned above, nickel is mostly used in combination with other metallic elements in numerous different alloys with different properties that influence their durability, including resistance to corrosion. Nickel can be present in the “finish”, the outer surface layer, as well as in any subsurface coating, or in the base material of products. Corrosion may be a factor affecting a nickel surface layer and moreover, if abrasion, wear, or cracks damage one or more surface layers this

may result in the exposure of a new layer, which contain nickel and subsequently, corrosion of this layer may lead to nickel release.

The metal release onto skin from a given product is much dependent on the corrosion resistance of the (surface) material, and as mentioned in Section 1.4 corrosion is enhanced by perspiration, and even more by the presence of blood.

4.2.3 Quality

The quality of a coating is linked to its resistance to corrosion and abrasion. Several stakeholders with particular expertise as related to nickel and coatings (e.g., Lo, 2020; NASF 2021) highlight that if a protective coating is properly designed, the product should meet relevant requirements including protection against nickel migration.

The durability of protective or decorative organic or inorganic coating over nickel plated or nickel containing alloys generally depends on the thickness of the coating layers and the deposition process (Nickel Institute, 2021). As illustrated in Figure 2 as well Figure 3, Section 4.5, the design of a surface coating can be a highly sophisticated process and involve an intricate puzzle of several layers consisting of different chemicals. The application of durable coating to a material may be seen as a process requiring both technical skills and in-depth knowledge of chemical reactions as there are often requirements related to the visible appearance and other technical functions apart from protection against migration of nickel. Good coatings can be quite expensive which may explain why low-price materials are often insufficiently coated. (Heim, 2021; NASF 2021).

The Nickel Institute (2021) mentioned electroplating as an example of a process which can be of higher or lower quality. Basically, it is a simple process, which is done both by large companies with ready access to professional resources as well as by smaller, more inexperienced producers. However, it is crucial for the protective capacity of the surface that the plating process is conducted carefully. For instance, any debris must be carefully removed from the subsurface before plating. Otherwise, the process may result in damaged coatings with cracks already from the production process. This means that poor quality products with insufficient coating are likely to be found in flea markets, street vendors and other places selling cheaper products, but according to experience from the US, poor-quality coatings can also be sold by more high-prised retailers such as gift-shops selling products from small-scale individual designers and artisans (Heim, 2021).

4.3 Considerations in the supply chains related to coatings and their durability

Most medium to large distributors and importers approached for this survey respond that they have different quality management procedures in place to ensure compliance with the nickel restriction. These procedures may include demands to avoid nickel in products and/or other measures such as for instance requirements for adequate test reports to show that products are compliant, spot tests on products from different suppliers, and subscription to targeted alerts about non-compliant products from the Commission's Safety Gate (European Commission, 2021-2). Some importers and distributors were able to provide general information about what coatings could be used on different products. But it was clear that detailed knowledge about coatings could generally only be retrieved by contacting the producers further up the supply chains.

Most respondents had not encountered any specific discussions in their sector related to problems with durability of coatings, but many stated that it is well-known that there is much variability in the quality of surface coatings.

A supplier of zippers for use in consumer clothing as well as professional uses informed us that information on the nickel content is given for all relevant products in their B2B catalogue. Moreover, the Nickel Institute (2021) explained how OEMs (Original Equipment Manufacturers) i.e.,

brands providing apparel, accessories, jewellery, spectacle frames, and other products may specify grades of coatings to be delivered such as "*nickel free*" or "*hypoallergenic*". Product specifications may also be more targeted, e.g., demanding a certain thickness of surface layers and may include several other technical specifications as well as specifications for colour and surface finish.

The standard test for compliance with the nickel restriction (Section 2.1) requires that the testing laboratory shall always initially assess whether a product is coated or not. If the product is coated, the laboratory shall perform the standard procedure to simulate two years' tear and wear (CEN, 2020) before performing the nickel release test [4]. In many supply chains this is considered an approach, which sufficiently covers the issue of whether a coating is sufficiently durable.

In spite of these procedures reported from different supplier, the frequency of non-compliance as reported in Section 3.4 suggest that some producers and distributors are either consciously accepting nickel release from their products or lack sufficient knowledge about the problem. Several respondents associated non-compliant nickel release with costume jewellery and other low-price products and clearly smaller independent stores may not be aware of the nickel restriction or able to place demands on their suppliers in the same manner as bigger brands and OEMs.

Finally, one contact in the DIY jewellery and sewing kit sector mentioned that it is easier to obtain information from suppliers in the EU and parts of Asia than from suppliers in the US. The reason for this could be that there are no legal nickel migration limits for consumer products in place in the US.

4.3.1 Suppliers' expectations about service life

Manufacturer's and retailer's expectations regarding service life and the frequency of use of a given product varies significantly. Even within the same product category, such as clothing, producers have very different expectations. Some clothes are fashion and in principle only relevant for one season. Likewise, low-price garments may not be expected to be used for long, while other attire may be used for many years but infrequently. In the case of jewellery, the general trend would be that the more expensive the jewellery, the longer the expected service life. Precious stones and pearls may be made to be passed on for generations, while producers of cheap jewellery would have expectations in line with low-price clothing. This may, however, be a mistake as some consumers, including teens, might well keep such products for quite a while.

Product categories such as tools, toys, electronics, wrist watches and jewellery including piercings are all categories, which include products with short as well as long expected service life. As a general rule, there are cheap products which may only last for a few months while other more costly products are designed to last longer.

The REACH regulation requires that the coating of products shall be durable for two years, and the standard to simulate wear and corrosion has been designed according to this demand (CEN, 2020). However, in principle the rules of the General Product Safety Directive (GPSD, 2001) demands that any product must be safe to use during its lifetime and contacts to this study (Lo, 2021; NASF 2021) have explained how specific requirements for the durability of coatings may come from customers (OEMs) for products for which longer service life is expected. Moreover, it has been argued that if a surface coating is viable for two years (i.e., compliant with the nickel restriction), then it is also likely to be viable (compliant and protective) for much longer (Nickel Institute, 2017).

[4] However, if the surface coating contains nickel, the laboratory shall not perform the simulation. See chapter 6.

A special consideration regarding service life of products is related to the second-hand market. At flea markets and second-hand shops, including on-line shops for used products, products such as clothes, including children's clothes, jewellery, including earrings and spectacles are sold. The durability of a non-nickel coating may certainly not be suited for such a second service life, which is an issue that has not been looked much into. It was not mentioned by the retailers or other companies approached in this study.

4.4 Specific features for selected product categories

The frequency of nickel allergy has declined in the EU in recent decades (Thyssen et al., 2009; DEPA, 2016; 2021; ECHA, 2017; Garg et al., 2013) which could indicate that producers, and surface coaters have been able to adapt to the restriction. Moreover, within different sectors there have also been different trends in the last 20 years, which may be relevant for the overall risk of consumers developing nickel allergy. This section presents key considerations related to the specific features for different product categories.

Precious metal jewellery

An organisation for jewellers and watchmakers responded to this study claiming that the use of nickel in relation to precious metal (silver and gold) in their view is virtually non-existent. This contact explained how in earlier days nickel was widely used in alloys with white gold but today such use it limited. Nickel has also been used as subsurface coating on gold plated silver jewellery as this would provide a good finish, but this use has ceased today.

Costume Jewellery and apparel

Although the nickel restriction has been in place for many years (Section 2), and well-known brands place clear demands for surface coating and nickel content on the producers (Section 4.3) there is still a high frequency of non-compliance in this product category.

According to Wittington and Lo (2019) costume jewellery is usually made from cheaper metals and plated with nickel. Therefore, there is a need for efficient surface coatings to prevent nickel release from these decorative items.

Section 4.1.1 described how several layers of coating can be applied to these materials. According to the Nickel Institute (2021) gold- or silver-plated materials frequently have a nickel base, especially if they are relatively inexpensive. If such layers are damaged, this may cause nickel migration, particularly in piercing jewellery such as earrings. The Nickel Institute also noticed that items marketed to children and teens are likely to be less expensive and thus plated in a process involving nickel.

Whittington and Lo (2019) tested several protective surface coatings and found many efficient in preventing nickel release. However, a thin, porous flash surface coating of gold applied over costume jewellery failed the tests, particularly since the thin coating of gold significantly accelerated the release of nickel, a phenomenon also reported by others (LGC Limited, 2003). On the other hand, an uncoated gold alloy containing 6% nickel passed the test indicating that it is possible to prevent nickel release even when nickel and gold is used together.

Body piercing jewellery

Body piercing is the practice of puncturing or cutting a part of the human body, creating an opening in which different kinds of jewellery may be worn. Earrings and -studs can be seen as the most common kind of body piercing, while other piercings have become increasing popular in the last decades where piercings of the nose, eyebrow, lip, tongue, as well as naval, nipple and genital piercings have become well known. The jewellery used may be rings, barbells, clickers, or tunnels.

Body piercing is an invasive procedure and the risk of nickel release from the piercing jewellery used in ear or body piercing "posts" when in contact with broken skin, blood and sweat, i.e., during the period of epithelisation is assumed significantly higher than the risk of contact with intact skin (DEPA, 2016). It has been shown that the release rate to blood plasma resulted in the release of twice as much nickel from stainless steel compared to artificial sweat (LGC Limited, 2003). Consequently, as seen in Chapter 2, the legal limit of migration from the post assembly is significantly lower (0,2 µg/cm²/week) than the limit that apply to other products in contact with skin (0,5 µg/cm²/week).

For many years, earrings have clearly been the most important cause of allergy and in a new study (Wennervaldt et al., 2021) 304 earrings bought on the Danish market were tested using DMG and the standard test method for nickel migration (CEN, 2015). Nickel migration above the legal limit was found for 14,8% of tested earrings indicating that this product category is still problematic.

Some consumers are well aware that body piercings jewellery – including earrings and studs - imply an allergy risk and consequently products made from surgical steel, or metals such as gold, niobium, platinum, palladium, or titanium may be marketed as "nickel-free". However, many body piercings come with colours or with a silver and gold finish, which would imply that some kind of coating has been applied. A random search of 16 websites for piercing jewellery conducted as part of this study showed that 10 suppliers allow for choice of material, while only 3 provides an explanation for the importance of that choice.

The durability of coatings seems particularly relevant for this product group. Concerns have been reported by e.g., DEPA (2016) that coatings on earring piercings and earring studs can be very thin and thus might crack or break during use. Moreover, ear studs are equipped with a lock which may be frequently handled increasing the risk of abrasion causing (more or less invisible) cracks close to the skin.

Spectacle frames

Spectacle frames are often made from materials that contain nickel. According to contacts to this study (Section 3.2) low-price metal spectacles are often made from monel, a nickel-cobber alloy, and even frames made of stainless steel or titanium, which would be the choice for sensitive consumers, may be equipped with screws and hinges made from nickel alloys. If the latter is the case and there is the likelihood of skin contact, the standard EN 16128 for testing spectacle frames (CEN, 2015-2) requires the hinges and screws to be tested. Spectacles frames are also often coloured with lacquer, which could have a nickel sub-surface layer for better adhesion. If so, the standard EN 16128 requires the simulation of wear and corrosion prior to migration testing.

One contact to this survey claimed that their spectacle frames are coated for protection against nickel release but did not know what type of coating. When the frame is adjusted to the user, such lacquers may crack and expose the nickel alloy, and moreover, it was mentioned by one respondent that coatings on spectacle frames are often affected by the cleaning solution uses for the daily cleaning of the lenses. Spectacle frames displaying these characteristics would not meet the requirements of the EU General Product Safety Directive (GPSD, 2001) and, therefore, they should not be placed on the market.

Wrist Watches

Watches can be made from stainless steel, and if this is of good quality, it should not release nickel in quantities to cause elicitation (Nickel Institute, 2021; LCG limited, 2003). However, one of the most famous cases of stainless steel causing a nickel allergy was the Disney Light-up Watch Recall in 2011 (US Consumer Product Safety Commission, 2011). Disney had to recall over 1,200 watches after children's wrists became red and irritated where the metal touched their skin. A few

kids even developed blisters. The watches' battery current interacted with nickel in the stainless steel back, causing the irritation.

Wrist watches have recently been reported as one of the most frequent causes of allergy (DEPA, 2016) and a market survey in 2012/2013 covering the low-to middle price range found 8% non-compliance. In 2020 two non-compliant children's watches were detected in a market survey (Appendix 3) indicating that watches are still a problematic product category in which there is a correlation between price, quality, and risk of nickel migration.

Tattoo needles
Although not included in ECHA's draft guidance (ECHA, 2017) needles used for tattooing purposes could be considered to be within the scope of the restriction. The machine used for tattooing 'shoots' the needle up to 3000 times per minute onto the skin (DEPA, 2017), which could be regarded similar to continuous contact rather than short term or repetitive. The tube/tip where tattooing needles are installed, and the tattoo gun (held by the tattoo artist) are also in prolonged contact with the skin and could thus be within the scope of the nickel restriction which could be relevant if they contain nickel.

Toys
The importance of toys as a cause on nickel allergy has been much debated. Some stakeholders have claimed that the duration of skin contact with toys is often not very long (Nickel Institute, 2017). However, according to ECHA (2017), the nickel restriction in REACH applies to toys as long as the toy can be seen as intended to come into direct and prolonged contact with skin.

The Toys Safety Directive (2009) restricts the use of nickel and many other substances through the general restriction on CMR-substances[5] for accessible parts, such as screws and other metal parts. The Directive also includes migration limits for nickel expressed as mg/kg:

- 75 mg/kg in dry, brittle, powder-like or pliable toy material.
- 18,8 mg/kg in liquid or sticky toy material.
- 930 mg/kg in scraped-off toy material.

These limits do not apply to stainless steel in toys, but otherwise they apply side by side with the nickel restriction in REACH.

Metal parts of toys, such as small
cars, can contain nickel at the surface, which can migrate to the skin of a child during play. A study from 2014 (Jensen et al., 2014) looked at 149 toys from DK and 63 from the US and found that among these 34,4% (73) had metal parts which could have skin contact and nickel migration. The study concluded that toys may be an overlooked source of nickel exposure. A later study of three of these toys showed that after 30 seconds of play, nickel could be detected on the skin of the hands in volumes that could entail a risk.

Based on the above-mentioned and other studies the Danish National Allergy Research Centre has suggested that children's toys as a cause of nickel allergy should be explored because even if the frequency of nickel allergy has declined after the restriction, the number of cases among children is still surprisingly high (DNARC, 2017).

Electronics
In 2008, The Danish EPA suggested the REACH restriction should cover cell phones after the Danish National Allergy Research Centre reported elicitation caused by these products (DEPA,

[5] CMR: carcinogenic, mutagenic, or toxic to reproduction.

2021). However, according to information from the Nickel Institute and NASF (2021), skin contact with nickel surfaces in electronics is mainly a problem of the past. The institute claims that even if nickel is still in use in decorative surface coatings, e.g., of cell phones, the main use is not on those parts of consumer electronic products which could have skin contact although nickel is essential for use in electronics in many of the inner components. In line with this view, a study on nickel under the LOUS programme (DEPA, 2015) reports that nickel plating is used widely in the electronic industry, where it contributes to secure the functioning and reliability, e.g., of connectors, contacts, microprocessors, and integrated circuits. However, the report does not mention any use of nickel in surface parts that could come into skin contact during use.

During their early years, cell phones had metallic components that, when held against the face for a period of time, could result in allergic contact dermatitis. As nickel was the metal most frequently used, cell phone dermatitis to nickel became well known. Today, with the new habits among many consumers of not holding the cell phone to the chin as often as in earlier days, this problem may have receded (although a cell phone is still also held by the hand and thus skin contact is still normal during use).

During this survey, we received only few feedbacks related to electronics from suppliers to a large retailer. These feedbacks confirmed the suggestion that at least some suppliers are able to provide cell phones and portable computers without nickel, while products, like notebooks, desktops, and “all-in-one” computers may use aluminium cases finished with a nickel containing compound to prevent fingerprinting and to increase the robustness of the surface. The amount of nickel was claimed by these suppliers to be small and fully compliant with restrictions around the world with regard to nickel release, including REACH.

Moreover, a targeted internet search - performed as a part of this study - revealed that in recent years the number of individual reports or studies about nickel migrating from electronics have been limited. This supports the impression that nickel in consumer electronics is a significantly smaller problem today than it has been previously.

Tools

Tools constitute a broad product category, and some tools are used in such a way that prolonged skin contact to the bare hand can be expected. This can happen both during occupational and private use. According to ECHA’s first draft guidance (see Appendix 2), tools are within the scope of the nickel restriction.

A comprehensive cross-sectional study was conducted by Lidén et al., (1998) on nickel release from unused (new) hand-held non-powered tools on the Swedish market. The study focused on occupational use and showed that some tools released nickel in amounts greater than the limit value. There was no direct evidence of nickel allergy associated with use of these tools, but the authors pointed out that there was a possibility of eliciting allergic contact dermatitis in people already nickel sensitive as well as a risk for sensitisation.

Today, many common tools used by private consumers such as saws, hammers, screwdrivers, and drills are equipped with plastic handles. There are only relatively few types of handheld tools, such as spanners, where the user is in contact with a metallic surface. This may explain why tools are not that often reported as a cause of nickel allergy (Section 3.3).

Trendy products

In some situations, when a new product trend occurs, new products are brought to the market in large quantities during a very short time period. This may result in a low degree of communication with the supplier or preventive compliance testing, and non-compliance has been shown in products such as fidget spinners. The problem was, however, lead rather than nickel (Appendix 3).

4.5 Substitution possibilities to avoiding nickel release

Many consumers are well aware of the need for avoiding nickel in products and this has led to a demand for nickel free products. Together with the legal provisions, this has created a need for substitution in multiple sectors.

Options for substitution are completely nickel free non-coated products such as titanium or alternatively non-coated products made from metal alloys where the nickel may be bound firmly in the alloy, e.g., stainless steel. Stainless steel is used in spectacle frames including in the screws, jewellery, electronics, and watches, etc. both uncoated and coated. There are multiple types and grades available on the market and many of these have been shown to release nickel (LGC Limited, 2003). However, there are also grades of stainless steel available, such as surgical steel, which is by some stakeholders claimed to be safe including in post assembly piercings (LGC Limited, 2003) and according to the Danish National Allergy Research Centre stainless steel will often not cause allergy (DNARC, 2021-3).

Surface coatings are considered attractive or even necessary to obtain certain technical or decorative properties. Thus, the surface coating industry has a challenge in developing cost-effective alternative nickel free coatings including substitution of nickel-based intermediate layers. As seen in Figure 3 examples of such alternatives could be a layer of bronze alloy. Another solution has been a Palladium-Nickel alloy, which can be used when some leaching below the migration limit values is accepted (Coventya, 2021).

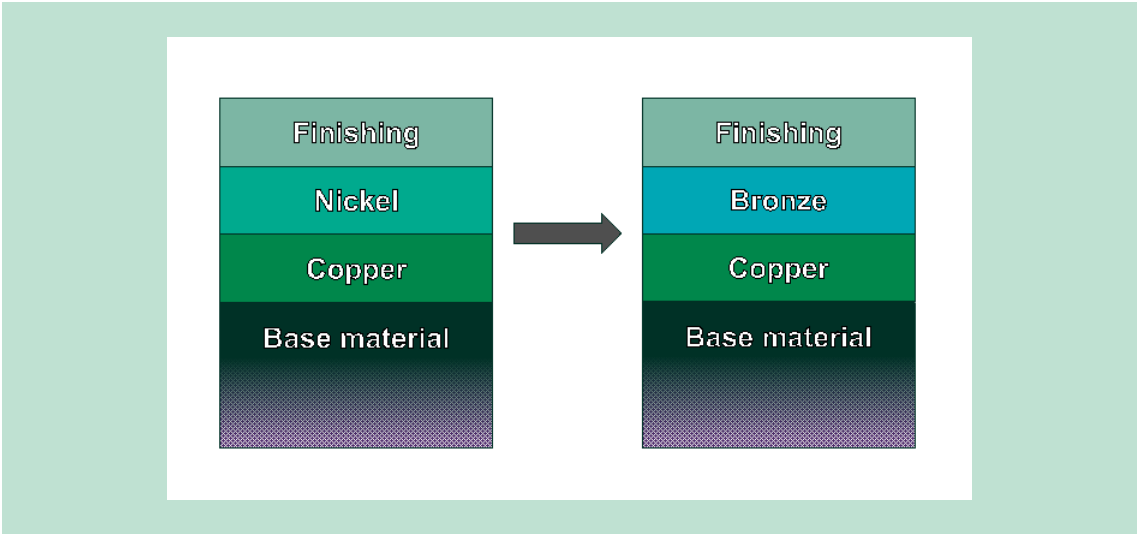

FIGURE 3. Example of how a coating sequence used in the fashion industry was redesigned in order to provide a compliant product (Redrawn after Coventya, 2021)

Whittington and Lo (2019) evaluated several non-nickel surface coatings which should enable nickel-containing consumer products to be safely placed on the market without concern for nickel release. The results from these tests showed that most of the tested coatings were effective in preventing nickel release above the limits. The study found that different colours without nickel could be applied to topcoats to give the effects needed. For example, organic non-nickel topcoats may be dyed to produce a variety of colours in the surface finish of the item.

In summary, the findings from this chapter confirms that products such as jewellery, particularly low-price products may contain nickel and may be insufficiently coated.

Piercing products including earrings may be particularly problematic due to their widespread use and the contact to broken skin which may increase corrosion of any surface coating.

Spectacle frames, clothing accessories and wrist watches are other examples of products which may be coated, and these are also products which may have a longer service life than expected by the producer.

Toys may be coated, and studies have indicated that these may be an overlooked source of children's nickel exposure.

It is possible to provide these products without nickel at the surface and/or with durable protective coatings, but this is not always prioritised by the producers, and finally sometimes the nickel in a product is added as part of the coating rather than as part of the base material.

5. Chemical analyses

The aim of the chemical analyses was to analyse coated consumer products for compliance with the legal provisions related to release of nickel from consumer products and to obtain information about their coatings' resistance to wear and corrosion.

5.1 Selection of products for purchase and analyses

Based on the information obtained during the initial survey, the following product categories were selected for chemical analyses:

- Earrings/studs
- Body piercings
- Toys

These categories were chosen because body piercing jewellery, including earrings, were recognised as a major culprit in the prevalence of nickel allergies among consumers, and toys has been highlighted as a product category that may be an overlooked source of nickel exposure. Moreover, quite many cases of non-compliance have been reported for these categories (Section 3.4 and Appendix 3).

A total of 63 products were purchased for the test programme: 22 toys, 14 body piercings, and 27 earrings/studs. The purchase and initial screening processes to select products for quantitative chemical analysis (Section 5.3) were carried out in two phases to ensure an equal distribution of products among the product categories. In a first phase, a set of products were purchased and screened, but the products selected for chemical analyses turned out to be non-evenly distributed amongst the three product categories. Hence, additional products from the product categories piercing and earrings/studs were purchased and screened in a second phase.

5.1.1 Distribution of place of purchase

In order to gain information about possible differences in the frequency of non-compliance depending on country/region of sale it was aimed to distribute the products to be purchased as 50% from web shops or physical shops in Denmark, 25% from web shops in the EU and 25% from web shops outside the EU (Section 5.4).

5.1.2 Assessment of coatings on products from web shops

A key aim of this project was to gather information about products equipped with non-nickel surface coatings. Products which were claimed at the website to be coated or plated or which had an obvious colour, silver, or gold coating were thus prioritised. For example, inexpensive products claiming "gold" would indicate that it is coated with a thin layer of gold (Whittington and Lo, 2019, Nickel institute, 2020). Other examples of products chosen for this project were products with claims such as "Gold plated jewellery does not have a lasting surface". In addition, products made from plastic/steel was chosen as it could indicate a plastic coating on steel, and a foam-covered metal handle on a toy scooter was also regarded as a coated product for the purpose of this study.

However, for some of the products bought from web shops, it was not possible to verify if the product was coated prior to purchase.

5.2 Screening of products

The further selection of products for quantitative chemical analyses was done using a stepwise approach. As a first step a detailed visual inspection of the product's surfaces was conducted to determine if the presence of a coating could be excluded. It was found that some coatings are obvious. However, for other products it was concluded that visual inspection was not sufficient to determine if the product was coated and was therefore insufficient for this purpose. It was concluded that absence of coating could not be determined with certainty for any of the purchased products and all products were thus included in the following screening test. A more detailed discussion on the possibilities for determining if a product is coated is presented in Chapter 6.

As a second step, two simple screening tests for nickel: a DMG spot test (Section 5.2.1) and a XRF screening test (Section 5.2.2) was performed on each product. These tests are common test methods used widely by companies, scientists, and inspection authorities to provide indications about whether nickel is released from the surface or present in the product.

Some of the 63 purchased products were comprised of several different parts and/or colours which were considered relevant for further chemical analyses. Thus, a total of 73 individual product parts – equal to 73 individual samples - were selected for the screening using DMG and XRF.

Only samples which showed positive results in either of the two screening tests were chosen for further chemical analyses.

5.2.1 DMG spot testing (dimethylglyoxime test)

The DMG spot test is a widely used qualitative screening test which can indicate release of nickel from a material. Positive results suggest that nickel is released, but due to the relatively low sensitivity (DNARC, 2010) further tests are needed to quantify the release rate.

The testing kit consists of two bottles, one with 10 ml of ammonia water 5 M, and one with 10 ml of dimethylglyoxime 1% in ethanol. Two drops of each solution are added to a cotton-tipped applicator. The moistened tip is firmly rubbed on the sample to be tested in a circular motion for 30 seconds. The swab will turn pink if nickel is present.

Doubtful reaction was defined as reactions with a discoloration other than pink and in those cases, retesting was done. The validity of this simple test has been disputed as the sensibility is quite low and there may be many false negative results. But since the specificity is high, a positive test is reliable, which is why it fulfil an important function for screening purposes. (Wennervaldt et al., 2021; Thyssen et al., 2009-2). Most products chosen for analysis showed negative results in the DMG screening and positive results in the XRF test (Section 5.2.2).

A positive DMG spot test indicates presence of nickel at the surface - either in a coating or a non-coated material. It could also indicate that if a non-nickel coating had been applied, this was not sufficient to prevent release of nickel.

For enforcement purposes, all products which showed positive results in the DMG spot test were selected for further chemical analysis.

The tests were performed at Help2Comply's office in Århus, and at DCIS in Slagelse.

5.2.2 X-ray fluorescence spectroscopy (XRF)

X-ray fluorescence spectroscopy (XRF) is a non-destructive analytical technique used for elemental analysis. The fluorescent (or secondary) X-rays emitted from a sample, when excited by a primary X-ray source, are measured. Each of the elements present in a sample produces a set of characteristic fluorescent X-rays or "unique fingerprints".

The XRF method can provide a non-destructive measure of elemental content of nickel in the material. Different XRF instruments have different penetration range into the material. For metals it is generally around 100-300 microns, which means that for some products the x-ray may not penetrate fully into the bulk of the material and thus, there may be base material and/or sub layers with nickel, which are not detected. However, the test provides a reasonable indication of presence of nickel at the outer layer. A negative result indicate that the outer layer of the product is nickel free. A positive result, on the other hand, indicates that nickel is present in the outer layer (Figure 2) or in the base material. Further chemical analysis (Section 5.5) is necessary to determine if nickel is released from the product and to quantify the rate of the release.

All samples were individually examined by a handheld X-ray fluorescence analyser to determine if nickel was present in the samples. XRF screening does provide a value for nickel content, expressed as mg/kg or %. However, for the purpose of this project the XRF test was only used as a screening to determine if nickel could be detected. Thus, the numerical values for the nickel content are not reported.

The XRF tests were performed by DCIS in Slagelse, DK or at the Modern Testing Services' laboratory, Leeds, UK.

5.3 Result from the screening tests

Nickel was detected in 47 individual parts (samples) from 38 products in either of the screening tests. These samples were selected for further chemical analysis. Both screening test were negative for 26 parts (samples) from 25 products, and these 26 parts (samples) were not included in the further chemical analyses.

The 47 samples from the 38 products included 19 samples from 12 toys products, 14 samples from 12 body piercings, and 14 samples from 14 earrings/studs. It should be noted that a product part (sample) can be a distinct part of a product, such as the chest piece of a toy stethoscope or an individual item from a package of several items, e.g., an individual ring in a collection of several rings.

The distribution of purchased and selected products as well as the number of individual product parts is summarised in Table 3. In addition, Tables 5, 6, and 7 provide more information about the specific products and the parts chosen for analysis.

TABLE 3. The distribution of purchased products, and parts (samples) chosen for screening and chemical analysis respectively

	No. of purchased products	No. of screened individual parts of products	No. of products in chemical analyses	No. of individual parts analysed
Toys	22	30	12	19
Body piercings	14	16	12	14
Earrings/studs	27	27	14	14
Total	63	73	38	47

It should be noted that for both the DMG and XRF screening that the small areas of earring and piercing components make it difficult to test the post assembly separately without interference from other parts.

5.4 Place of purchase for products selected for chemical analysis

The final distribution of place of purchase for the 38 products selected for chemical analysis were: 47% from retailers in Denmark, 18% from web shops based in other EU Member States, and 34% from web shops based outside the EU. This distribution came about as a result of the screening tests as a higher proportion of the products purchased from Non-EU countries were found to contain nickel in the XRF screening test.

Table 4 provide a summary of place of purchase for the products selected for chemical analysis as well as the distribution related to categories.

TABLE 4. Place of purchase for the 63 purchased products and the 38 products chosen for chemical analysis

	No. of purchased products				No. of product selected for chemical analysis			
	DK	EU	Non-EU	Total	DK	EU	Non-EU	Total
Toys	10	5	7	22	5	3	4	**12**
Body piercings	8	2	4	14	6	2	4	**12**
Ear-rings/studs	16	4	7	27	7	2	5	**14**
Total	**34**	**11**	**18**	**63**	**18 (47%)**	**7 (18%)**	**13(34%)**	**38**

5.5 Chemical analyses

The chemical analyses were performed according to standard methods for simulation of wear and corrosion (CEN, 2020) and for nickel release (CEN, 2015) (Section 2.2).

5.5.1 Simulation of wear and corrosion

The standard EN 12472:2020 (CEN, 2020) is a test method for the simulation of accelerated wear and corrosion for the detection of nickel release from coated items.

The standard specifies a method to be used prior to the detection of nickel release from coated articles that come into direct and prolonged contact with the skin.

This testing method was applied to the toy samples.

This method was also applied to the piercing products, although this product category is outside the scope of the standard. The reason for applying this method is discussed in Section 5.5.4 and Chapter 6.

5.5.2 Nickel release test

The nickel release from new samples as well as samples that has been exposed to wear and corrosion simulation were analysed according to the standard EN 1811:2011 + A1:2015 (CEN, 2015).

This standard specifies a test method for measuring the release of nickel from articles intended to come into direct and prolonged contact with the skin, including post assemblies, which are inserted into pierced parts of the human body.

The limit values for nickel release of the nickel restriction in REACH is 0,2 µg/cm^2/week for post assemblies and 0,5 µg/cm^2/week for other products. The uncertainty given in the standard for the nickel release test is 46% and according to the methodology of the standard EN1811 (CEN, 2015)

all values below 0,35 µg/cm^2/week for post items and 0,88 µg/cm^2/week for other articles shall be deemed compliant with the limit value set out by the REACH regulation article 67 (1) and corresponding annex XVII, entry 27 (The nickel restriction).

5.5.3 Analyses of toys

Four identical copies of each product were purchased for all products in the toy category. Three to be used for testing, and one as reference product for the Inspection Service, DCIS.

After visual inspection and initial screening of the 22 purchased toy products, 12 toy products were selected for further testing for nickel release.

As a part of a standard procedure to determine if a standard simulation for exposure for wear and corrosion should be performed, a visual inspection for coating was also performed at the testing laboratory on the 12 toy products. This inspection confirmed that all 12 toy products seemed to be coated.

To assess whether the products were compliant with the nickel restriction in REACH, (Section 2.1) all toy products were exposed to simulated wear and corrosion according to the standard test methodology (CEN, 2020; Section 5.5.1) followed by analyses for nickel release according to the standard test method (CEN, 2015; Section 5.5.2).

5.5.4 Analyses of body piercing jewellery including earrings/studs

It was from the outset of the project decided that any chemical analysis for piercing products should include a normal standard test for nickel release (CEN, 2015), as well as a test for nickel release performed after a simulation of wear and corrosion of the piercing items similar to the standard procedure to simulate wear and corrosion on other product types (CEN, 2020). This approach was chosen even though the standard procedure to simulate wear and corrosion is neither recommended nor normally performed for piercing products. However, it was considered that the best way to simulate wear and corrosion on the piercing products would be to use the same procedure as described in the standard method for other products. The only difference from the standard test method was that the items were placed loosely in the barrel. This is a procedure used for small products and may perhaps influence the wear rate.

The use of this procedure is further discussed in Chapter 6.

To be able to perform these additional tests on the piercing products, at least 7 identical copies of each product were purchased in order to ensure sufficient sample material as well as a reference item.

The visual inspection for coating was also performed at the testing laboratory on the 12 body piercing products and the 14 earrings/studs, and this inspection confirmed that all piercing products seemed to be coated.

5.6 Results including frequency of non-compliance

This section summarise the test results and the findings related to compliance as well as differences in nickel release with or without the simulated wear and corrosion.

For each of the categories, Tables 5, 6, and 7 respectively provide an overview of the results from the initial screening for all purchased products and from the chemicals analyses for all selected products.

As described in Sections 5.2.1 and 5.2.2, the DMG and XRF screening tests were used only as a qualitative screening test. The presence of nickel is in Tables 5, 6, and 7 marked with a “+” for

samples that showed positive results in the screening, whereas samples that did not show presence of nickel are marked with "-". As mentioned in Section 5.3, 26 samples taken from 25 products did not show presence of nickel for either of the two screening tests and these were not selected for further testing.

5.6.1 Toys

Table 5 provides a summary of the results obtained for the 22 purchased toy products. The table presents the place of purchase of the products and the results from the DMG, the XRF, as well as the wear and nickel release tests for all individual samples. Samples where the chemical analysis show that the product is not compliant with the nickel restriction in the REACH regulation are marked in bold.

According to the screening tests 12 out of the 22 purchased toy products (54%) contained nickel.

Assuming that the negative results in both screening tests for 10 of the purchased products were sufficient to conclude that the product would not release nickel, Table 5 shows that only one sample (Acupressure Massage Rings, silver) out of the 22 purchased toy products (equal to 5%) did not comply with the nickel restriction. The test indicates that the product's coating is not sufficiently durable as it does not pass the simulation for wear and corrosion. The non-compliant product was purchased from a web shop outside EU.

In addition to the non-compliant product, 5 other products (23%) were shown to release nickel in a detectable quantity, but below the limit value of the nickel restriction.

TABLE 5: Summary of results of screening test and chemical analyses for the 22 toy products. Each product part was identified with a sample ID. Results showing non-compliance are marked in bold

Product Description	Country of purchase	Sample ID	DMG	XRF	Wear and Nickel release (µg/cm²/week)
Kazoo, whistle	Non-EU	1	-	-	
Handcuffs "silver metal"	Non-EU	2-A1	-	+	< 0,1
Handcuff key "silver metal"	Non-EU	2-A2	-	+	< 0,1
Acupressure Massage Rings, red	Non-EU	3-A1	-	+	0,13
Acupressure Massage Rings, blue	Non-EU	3-A3	-	+	0,11
Acupressure Massage Rings, green	Non-EU	3-A2	-	+	0,11
Acupressure Massage Rings, silver	Non-EU	3-A4	-	+	**2,9**
Acupressure Massage Rings, gold	Non-EU	3	-	-	
Acupressure Massage Rings, gold	Non-EU	4-A1	-	+	< 0,1
Acupressure Massage Rings, silver	Non-EU	4-A2	-	+	< 0,1
Small neo cube	Non-EU	5	-	-	
Carabiners, simple dimple	Non-EU	6	-	-	
Fidget toy (silver metal ring)	Non-EU	7	+	+	0,37
Referee Whistle	EU	26	-	-	
Scooter, metal handle (foam coated)	EU	27	+	+	< 0,1
Harmonica (silver metal)	EU	28	-	+	< 0,1
Grey car	EU	29	-	-	
Stethoscope (silver metal chest piece)	EU	30-A1	+	+	< 0,1
Stethoscope (ear tube spring)	EU	30-A2	-	+	< 0,1
Scooter, metal handle (foam coated)	DK	70	-	+	< 0,1
Car w. metal part	DK	71	-	-	
Wireless microphone	DK	72	-	+	< 0,1
Stethoscope (silver metal chest piece)	DK	73-A1	-	+	< 0,1
Stethoscope (ear tube spring)	DK	73-A2	-	+	0,10
Wooden car w. metal wheels	DK	74	-	-	
Fidget spinner	DK	75	-	-	
"Dimples" (silver metal carabiner attached)	DK	76	-	+	< 0,1
Harmonica (silver metal)	DK	77	-	+	< 0,1
Key chain	DK	78	-	-	
Suitcase (cardboard)	DK	79	-	-	

5.6.2 Body Piercings

Table 6 provides a summary of the results obtained for the 14 purchased body piercing products. The table presents the place of purchase and the results of the DMG, XRF and nickel release test with and without a preceding simulation of wear and corrosion.

According to the screening tests 12 out of 14 purchased body piercing products (86%) contained nickel.

Assuming that the negative results in both screening tests for two of the purchased products were sufficient to conclude that the product would not release nickel, Table 6 shows that 3 products out

of 14 body piercing products (21%) did not comply with the nickel restriction in the REACH regulation according to the standard test for nickel release. Two of these products (no. 22 and 24) were purchased outside EU, and one (no. 84) was purchased in Denmark.

In addition to the non-compliant products, 4 products (29%) released nickel in a detectable quantity, but below the limit value of the nickel restriction.

In Table 6, the results for nickel release after simulation of wear and corrosion are not marked as non-compliant as this test is not a common standardised procedure for compliance testing. Even though the nickel restriction in REACH states that piercing products must always be compliant, it could still be disputed if this analysis would be sufficient for enforcement purposes.

The results obtained after the simulated wear is discussed in section 5.7.

TABLE 6: Summary of results from screening test and chemical analyses for the 14 body piercing products. Each product part was identified with a sample ID. Results indicating non-compliance according to the standard test are marked in bold

Product Description	Country of purchase	Sample ID	DMG	XRF	Nickel release (µg/cm²/week)*	Wear and Nickel release (µg/cm²/week)
Nose piercing, rose gold/copper	EU	20	-	+	< 0,1	< 0,1
Piercing multi-coloured oil slick	EU	21-A1	-	+	< 0,1	< 0,1
Piercing, blue	EU	21-A2	-	+	< 0,1	< 0,1
Piercing, Black	EU	21-A3	-	+	< 0,1	< 0,1
Piercing jewellery w. stop balls, black-brown	Non-EU	22	+	+	**0,35**	0,48
Piercing, oil slick	Non-EU	23	-	+	< 0,1	< 0,1
Piercing w. stop ball, rose gold	Non-EU	24	-	+	**6,49**	0,1
Piercing "teapot", blue and gold	Non-EU	25	-	+	< 0,1	< 0,1
Piercing rod	DK	84	-	+	**2,44**	2,53
Piercing ring, purple	DK	85	-	+	< 0,1	< 0,1
Piercing ring large	DK	86	-	+	0,12	0,14
Nose stud	DK	88	-	-		
Body piercing, blue	DK	90	-	-		
Piercing, gold	DK	92	-	+	0,34	0,16
Piercing w. ring, gold	DK	93	+	+	0,11	< 0,1
Labrets	DK	94	-	+	0,21	< 0,1

*As mentioned in Section 5.5.2 due to the uncertainty of the method results below 0,35 µg/cm2/week shall be deemed compliant, so this value has been used as reference.

5.6.3 Earrings/studs

Table 7 presents a summary of the results obtained for the 27 purchased earrings/studs. The table presents the products analysed, the place of purchase and the results of the DMG, XRF, and nickel release test with and without a preceding simulation of wear and corrosion.

According to the screening tests 14 out of 27 purchased earrings (52%) contained nickel.

Assuming that the negative results in both screening tests for 13 of the purchased products were sufficient to conclude that the product would not release nickel and looking only at the results for

nickel release before the simulation for wear and corrosion, Table 7 shows that 4 out of 27 purchased earrings (15%) did not comply with the nickel restriction. Three of these products (no. 67, 68, 69) were purchased in Denmark and 1 (no. 19) was purchased outside EU.

In addition to this 1 product (no. 83) released nickel above the limit value of the nickel restriction only when tested with initial simulation for wear and corrosion.

TABLE 7: Summary of results from screening test and chemical analyses for the 27 purchased earrings/studs. Each product part was identified with a Sample ID. Results indicating non-compliance according to the standard test are marked in bold

Product Description	Country of purchase	Sample ID	DMG	XRF	Nickel release (µg/cm²/week)*	Wear and Nickel release (µg/cm²/week)
DIY ear studs, rose gold/brass	Non-EU	9	-	-		
Ear studs with cherries, golden	Non-EU	10	-	-		
Ear studs, black flower	Non-EU	11	-	+	< 0,1	< 0,1
Ear studs w. berries, pink	Non-EU	12	-	+	< 0,1	< 0,1
Piercing, black metal assortment	Non-EU	13	-	+	< 0,1	< 0,1
Ear studs assortment (heart shaped box)	EU	14	-	-		
Ear studs, silver with glass	EU	15	-	+	< 0,1	< 0,1
DIY ear studs, rose gold	Non-EU	16	-	+	< 0,1	< 0,1
DIY ear studs, silver coloured	EU	17	-	+	< 0,1	0,12
DIY ear studs, gold plated, back lock	EU	18	-	-		
DIY ear studs, gold	Non-EU	19	-	+	**5,08**	3,53
Ear studs, triangle, gold	DK	63	-	+	< 0,1	< 0,1
Ear studs, elephant	DK	64	-	-		
Ear studs, coin with hole	DK	65	-	-		
Ear studs, plate	DK	66	-	-		
Ear studs with stone, blue	DK	67	-	+	**0,43**	0,46
Ear studs with stone, black	DK	68	-	+	**0,80**	0,88
Ear studs with stone, gold	DK	69	-	+	**1,64**	1,62
DIY ear studs	DK	80	-	-		
DIY ear hooks	DK	81	-	-		
Ear hoops	DK	82	-	-		
Ear studs (different styles)	DK	83	-	+	0,31	0,51
Ear studs	DK	87	-	+	< 0,1	< 0,1
Ear studs	DK	89	-	-		
Ear studs (round)	DK	91	-	-		
Ear studs	DK	95	-	+	< 0,1	< 0,1
DIY ear studs	DK	96	-	-		

*As mentioned in Section 5.5.2 due to the uncertainty of the method results below 0,35 µg/cm2/week shall be deemed compliant, so this value has been used as reference.

5.7 The effects of simulated wear and corrosion

As described above, the product categories body piercing, and earrings/studs were tested and the reported levels for nickel release with and without simulated wear and corrosion have been recorded and compared.

The uncertainty of measurement of 46% as set out in EN 1811+A1 factors in a number of different parameters, including within lab variability (repeatability) and between lab variability (reproducibility) as well as factors accounting for the test equipment, etc. and is designed solely for the purpose of establishing compliance or non-compliance.
However, each test was conducted in triplicate and the individual measurements were found not to vary by more than 1 unit in the least significant digit of the reported mean result, suggesting that regardless of the uncertainty of measurement, the samples were producing consistent results either before or after the wear and corrosion treatment. This criterion will thus be used to determine if a change in nickel release rate has been induced by the simulated wear and corrosion.

Nominally, an increase in nickel release was found after simulated wear and corrosion for 7 of the tested body piercing and earrings/studs and nominally a decrease was found after simulated wear for 6 of the tested body piercing and earrings/studs. An increase could be due to removal of a surface coating containing less nickel than the base materials, whereas a decrease could indicate the removal of a surface coating containing nickel.

Products no. 17, 22, 67, 68, 83, 84 and 86 showed a nominal increase in nickel release after the simulation of wear and corrosion, and applying the criterion described above, an increase can be concluded for products no. 22, 68, 83 and 84.
Product no. 19, 24, 69, 92, 93 and 94 showed a nominal decrease in nickel release after the simulation of wear and corrosion, and applying the criterion described above, a decrease can be concluded for products no. 19, 24, 92 and 94.

Wear and corrosion was simulated as described in standard (CEN, 2020). The method had remarkably little effect on the level of nickel release from the analysed products and most of the products (9 out of 13) that released nickel showed comparable levels of nickel release before and after the simulation of wear and corrosion. This could indicate that the coating was not sufficient to prevent the release of nickel from a base material in the first place, or that the surface coating contained nickel. Finally, some products could be uncoated despite the assessment that a coating was present.

Product no. 17 showed release only after the simulation of wear and corrosion indicating a possible removal of a non-nickel surface coating,

Product no. 24, 93, and 94 only released nickel before the simulation of wear and corrosion indicating a possible removal of a nickel-containing surface coating, in which case the standard for wear and corrosion would not be applicable (CEN, 2020).

According to standard test methodology for coated products, the product category “toys” were only tested for nickel release after simulation of wear and corrosion. As it had been estimated that all tested toys were coated and as all had shown positive results for nickel content in the XRF screening, these results could indicate the presence of a durable non-nickel coating or that nickel was firmly bound in the material.

5.8 Summary of the findings in the chemical analyses

The initial screening tests confirmed that nickel is commonly used in the production of consumer products within the three selected product categories. The XRF screening showed that a large proportion (86%) of the purchased body piercing products contained nickel, while fewer earrings did (52%). In the toy category the use of nickel also seems to be common as 54% of the purchased products contained nickel.

The initial screenings also showed that a higher proportion of the products purchased from non-EU countries contained nickel (72%) compared to products purchased in EU (64%) and Denmark (53%).

Looking at nickel release form the nickel-containing products showed that: For the toy category, 12 products contained nickel, and 6 (50%) of those also released nickel. For the body piercing category, 12 products contained nickel and 7 (58%) of these released nickel before simulated wear and corrosion and 4 (33%) released nickel after the simulation. For the earrings/studs category, 14 products contained nickel and 5 (36%) of these released nickel without the simulation for wear and corrosion while 6 (43%) released nickel after the simulation.

Absence of nickel release can be due to the nickel being bound in the material e.g., in stainless steel or the product could be equipped with a surface coating with sufficient durability to pass the test even after simulation of wear and corrosion.

Finally, the results show that non-compliance may still be a significant problem in particular for the product categories piercing and earrings/studs.

In total 8 out of 63 purchased products showed non-compliance with the REACH Regulation's nickel restriction according to standard test methodology (see Table 8). 1 out of 22 (5%) of all the purchased toy products, 3 out of 14 (21%) of purchased body piercing products, and 4 out of 27 (15%) purchased earrings/studs showed non-compliance. These results are based on quantitative chemical analysis for 38 products, which were selected for analysis combined with lack of detection of nickel during the screening tests for 25 products. These are relatively high frequencies compared to the results from other inspection campaigns, which found frequencies of non-compliance between 5-12% for jewellery products (Appendix 3).

Moreover, when looking selectively at the 38 products containing nickel (detected by a positive result in the XRF screening), the levels of non-compliance increase to 8% for toy products (1 out of 12), 25% for body piercing products (3 out of 12), and 28% for earrings/studs (4 out of 14). However, it is recognized that care must be exercised when drawing conclusions from small quantities of samples that may not be fully representative of the large number of these types of articles on the market.

In conclusion, these results indicate that the use of nickel in consumer products still constitutes a risk of nickel release to a level, which entails non-compliance.

As seen from Chapter 4, nickel is used both in coatings and in base materials, and the results of the chemical analyses clearly indicate, that the presence of a coating on a product is in itself not sufficient to prevent nickel release. This can be due to ineffective coatings covering a base material containing nickel, or it can be due to release of nickel from a product where the coating itself contains nickel.

TABLE 8. Overview of the distribution of purchased products, products selected for chemical analyses based on positive results in the screening test, and non-compliant products

	Purchased products				**Products selected for chemical analysis**				**Non-compliant products**			
	DK	EU	Non-EU	To-tal	DK	EU	Non-EU	Total	DK	EU	Non-EU	Total (% of puchased products / % of nickel con-taining prod-ucts)
Toys	10	5	7	22	5	3	4	12	0	0	1	1 (5% / 8%)
Body Pier-cings	8	2	4	14	6	2	4	12	1	0	2	3 (21% / 25%)
Ear-rings/studs	16	4	7	27	7	2	5	14	3	0	1	4 (15% / 28%)
Total	34	11	18	63	18	7	13	38	4 (12%)	0	4 (22%)	8 (13% / 21%)

Half of the non-compliant products were purchased in Denmark and half were purchased in web shops outside the EU. Relatively to the number of products purchased in a particular market, the frequency of non-compliance for products purchased from web-shops outside the EU is about twice that for products purchased in Denmark.

No non-compliant products purchased in EU based web-shops was found which may be due to the fact that web shops from relatively large companies had been chosen.

Information on non-compliant products have been passed on to the Danish Chemical Inspection Service in September 2021.

6. Discussion and conclusions

The current EU legislation takes a pragmatic approach towards protecting the general population from nickel allergy. As the risk of allergy is individual, the current restriction does not aim to protect all consumers against nickel allergy, but it aims to protect all people from sensitisation and the majority of sensitised consumers from allergic reactions (Heim, 2021).

Sensitisation often happens when the consumer is quite young. This means that the success of the legislation can be assessed by comparing the frequency of sensitisation in people born before and after the implementation of the EU nickel restriction. Thyssen et. al., (2019) showed that there has been a decline in the prevalence of nickel allergy, indicating that the legislation has had some positive effect. It is clear, however, that the current legislation has not been sufficient to eliminate nickel allergy as a widespread problem.

In this study we have focused mainly on identifying the most problematic product categories and on gathering information about the role of surface coatings in preventing consumers' exposure to nickel.

As a first step in this survey, it was decided to use four specific criteria to prioritise which product categories should be chosen for further chemical analysis. The aim of this approach was to identify those product categories which would be most important causes of nickel allergy in the general population. The aim of the chemical analyses was to test the selected product categories for compliance with the nickel restriction and to assess the effect of performing an initial simulation for wear and corrosion of the product's surface coating.

The four selected criteria were:

- Product categories that often cause nickel allergy due to skin contact
- Product categories which have been shown to be in non-compliance in earlier enforcement campaigns
- Product categories that may contain nickel covered by a non-nickel coating
- Product categories with a service life of more than 2 years

The survey gathered information about which product categories would fulfil the different criteria and found the criteria to be clearly interlinked. Products categories which are often made with nickel in the (base) material, and which may have long service life, and which may even often be non-compliant would by logic also frequently be a cause of nickel allergy, and thus important in contributing to the high prevalence of nickel allergy.

The most important product categories fulfilling these criteria were found to be:

- Body piercing jewellery, including earrings
- Other jewellery
- Clothing accessories
- Wrist watches
- Spectacles
- Toys

Results from the chemical analysis
Earrings/studs, body piercings, and toys were selected for further chemical analyses. The XRF

screening showed that a large proportion (86%) of the purchased body piercing products contained nickel, while fewer earrings did (52%). In the toy category the use of nickel also seems to be common as 54% of the purchased products contained nickel.

For all three product categories, the subsequent chemical analysis detected nickel release from some products and non-compliant products were also found on the market within all the selected product categories. 1 out of 22 (5%) of all the purchased toy products, 3 out of 14 (21%) of purchased body piercing products, and 4 out of 27 (15%) purchased earrings/studs showed non-compliance (Section 5.8).

Moreover, looking selectively at the 38 products containing nickel, the frequencies of non-compliance were 8% for the toy products (1 out of 12), 25% for body piercing products (3 out of 12), and 28% for earrings/studs (4 out of 14).

Thus, one reason for the limited success of the nickel restriction in preventing nickel allergy may be the continued widespread use of nickel in consumer products and the large amount of non-compliant products on the market, which reflect that nickel is not always firmly bound in the products' material but may be released during use (See also Section 3.4).

In addition to the non-compliant products the chemical analyses also showed that a proportion of the products release nickel below the limit value of the nickel restriction. These lower release rates may also play a role for sensitive consumers.

In conclusion, the use of nickel in these product categories still seem to represent a possible risk for the consumers.

The importance of surface coatings

Information provided by expert stakeholders for the purpose of this study has provided insight into the extremely complex area of manufacturing surface coatings. By using different coating techniques there are numerous possibilities for designing a sequence of multiple surface layers made from different materials (Chapter 4).

Several combinations of base material and coatings are used for the product categories covered by this report. Products can be made from base material with or without nickel and covered with surface coatings with or without nickel. Moreover, individual coating solutions can consist of several layers of which some may contain nickel and some not (Figure 2 and 3).

In this study, the focus was on assessing how well non-nickel surface coatings provide protection against nickel release. The results from the chemical analyses showed relatively high frequencies of non-compliance compared to the results from other inspection campaigns where frequencies of non-compliance of between 5-12% were found for jewellery products (Appendix 3). This indicates that the presence of a coating on a product is in itself not sufficient to prevent that nickel is released. This may be due to abrasion, corrosion, and general low quality of the coating (Chapter 4) or the fact that coatings may contribute to the overall nickel content of the product i.e., when the coating itself contains nickel. However, the limited information on the coatings and the unknown coating status of some of the tested articles are indeed a challenge for drawing definite conclusion.

Moreover, this study has revealed some possible general concerns related to standards developed to assess compliance with the nickel restriction. These are described below.

Assessment of coatings before performing the test for wear

The current standard for simulated wear and corrosion (CEN, 2020) states that the method is not applicable to products with nickel-containing surface coating. This requirement seems logical as

the wear and corrosion simulation could remove the outer nickel surface coating and therefore remove the nickel, affecting the results. This was also discussed in Section 5.7 as a possible explanation for results where the detected nickel release was lower with simulated wear and corrosion testing than without.

As we have experienced in this study, it is often quite difficult to determine whether a given product is coated or not (Section 5.2). Some coatings are obvious. However, due to the way in which different metals and alloys are produced, the same material can have different appearances, e.g., polished or brushed aluminium. Coatings can similarly have different appearances. Physical appearance can thus not be relied upon to determine whether a material has a coating, and simple visual inspection is thus insufficient for this purpose.

According to the laboratory performing the tests in this study (MTS, 2021), a simple method can be to scrape the surface and see if the layer underneath is different. If a non-silver-coloured (or metal coloured) metal was chromium plated, for example, it would be easy to see that scraping the surface revealed a different coloured metal underneath. However, sometimes the base metal and plating may be of the same colour, so scraping alone may not suffice to distinguish them from each other. Moreover, this approach would not reveal whether the coating contained nickel. However, some provision for this eventuality is made in the standard (CEN, 2015) as it indicates that X-Ray fluorescence spectrometry, microscopic techniques or other suitable methods should be used in deciding whether an article has a non-nickel containing coating.

The standard tests (CEN, 2020; CEN, 2015) are widely used by producers, scientists and authorities and it could be interesting to look further into how the different laboratories determine if a product is coated and not least how they determine if that coating contains nickel or not before deciding if the simulation for wear and corrosion shall be carried out. Our understanding, which is based on the input from a few stakeholders, is that in many cases the laboratories do not assess if a coating contains nickel. The simulation for wear and corrosion is simply carried out as part of the test if it is assumed that the product is coated. Thus, there may be two general concerns related to current testing methodology. One problem is the erroneous results that would be obtained if laboratories simulate wear and corrosion on products, which contain nickel at the surface and thereby remove nickel before testing the release. The second problem is that if it is acknowledged by the testing laboratory that the standard for wear and corrosion cannot be used then it is not possible to determine compliance with the nickel restrictions point 1(c) i.e., that the coating shall be durable for 2 years (Section 2).

Assessing the durability of coatings on piercing jewellery

As described in Section 5.5.4, the piercing products were analysed both with a standard test for nickel release (CEN, 2015), and with an identical test performed after a simulation of wear and corrosion of the piercing items similar to the standard procedure to simulate wear and corrosion on other product types with direct and prolonged skin contact (CEN, 2020). The rationale for including this additional approach in the testing program was an assumption that insight into the presence of any non-nickel coating on the piercing products could be obtained by comparing the nickel release from the product with and without the simulation of wear and corrosion.

One argument in favour of this approach is that it is not clear why the current standard excludes the piercing products (Nickel Institute, 2021). It could simply be because the legislation does not specify requirements to coatings on piercing jewellery. It could also be that the method is less suitable for these products if e.g., the daily wear happens in a different way than it does for other products due to the different conditions within the skin and the exposure to body fluids.
Each test was conducted in triplicate and the individual measurements were found not to vary by more than 1 unit in the least significant digit of the reported mean result, suggesting that regardless of the uncertainty of the measurements, the samples were producing consistent results either before or after the wear and corrosion treatment.

Based on the above, an increase in nickel release after the simulation of wear and corrosion were thus concluded for four products and a decrease in nickel release after the simulation of wear and corrosion were concluded for four other products.

In summary, this study has shown that there is still a significant amount of non-compliant articles on the market, in particular for items purchased from online shops outside of the EU. Coatings on consumer products may play a significant role in both causing and preventing consumer exposure to nickel as coatings may prevent nickel release as well as being a source of nickel release. The complexity of coatings is an issue that could not be completely elucidated within the scope of this project. However, the finding of this survey could be used as a starting point for further assessment of how well the nickel restrictions´ provisions related to coatings work in practice, and for further evaluation of the practical implementation of the standard for accelerated wear and corrosion.

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Appendix 1. Information sources

A number of relevant stakeholders were approached to gather information for this survey. These included producers and distributors in relevant sectors such as jewellery, electronics, watches, clothing and accessories, DIY- products, tattoo equipment, and spectacles. Relevant national and international industry organisations were also approached. In addition, laboratories and a few knowledge-based institutions with knowledge of allergy or surface treatment were contacted to gain further information.

The exchange of information with most contacts was initiated using e-mail templates with standard questions developed for this study, but naturally the following exchange was unique for each contact. Particularly, a good source of information came from a few Danish retailers who offered to pass on our questions to their suppliers.

Standard questions for retailers and industry organisations

- What kind of products would typically contain nickel under a non-nickel surface coating?
- Which types of coatings do you find on different types of products (gold, silver, varnish etc.)?
- What information about non-nickel surface coating is typically passed on in the supply chain?

Standard questions for laboratories

- Do you assess whether products have such coatings before performing a Nickel-test (EN 1811:2011 + A1:2015 and EN12472:2020) and if so, do you often find, that such coatings are used?
- What kind of products would typically contain nickel under a non-nickel surface coating?
- Which types of coatings do you find on different types of products (gold, silver, lacquer etc.)?

Appendix 2. Indicative list of products covered by the nickel restriction

The table in this appendix provides an indicative list of products (articles) covered by REACH article 67(1), as specified in the regulation's annex XVII, entry 27.
The table is reproduced from ECHA's draft guidance document about the scope of the restriction (ECHA, 2017). The top rows in the table are articles, which are considered to resemble those that are listed in the legal text. The second part of the table are additional examples of products provided by the draft guidance.

Examples of articles similar to those described in the legal text and in ECHAs original Q and A no 663

Article described in entry	Similar types of articles	Part of the article that come in direct contact with the skin
Earrings (non-piercing)	Earphones, headsets, hearing aid.	Earphones, headsets, hearing aids: external part.
Necklaces, bracelets and chains, anklets, finger rings.	Hair slides, hairgrips, hair clasps, pendants, toe rings, spectacle frames, sunglasses.	Whole article except hinge mechanism of spectacle frame and sunglasses. Hinges on the bridge (over the nose) and temples (side pieces) of foldable spectacles.
Wrist-watch cases, watch straps and tighteners.	Activity trackers, their straps, and tighteners.	The whole of each article composing the listed items.
Rivet buttons, tighteners, rivets, zippers, and metal marks when these are used in garments.	Belts and belt buckles, decorative parts of garments and sandals, other buttons, buckles for handbags, clothing hooks (such as bra hooks), lace suspenders, suspenders holding the stockings (garters) and suspenders holding mittens (suspenders holding trousers and skirts outside the scope), pins, clasps.	The whole of each article composing the listed items.
Mobile phones	Smart phones, tablets, portable computers, e-readers, computer mice or other pointing devices (trackballs, joysticks, touchpads, laser pointers) for computers, laptops etc.	External parts, excluding keys[6] of portable computers and laptops and the underside of computer mice.

[6] Keys were considered a borderline case by ECHA

Examples of additional articles or parts of articles which are expected to result in prolonged contact with the skin

Articles /parts of articles	Non exhaustive list of examples where these articles or parts are considered to be intended for prolonged skin contact
Grips.	
Handles.	Pram handles, handles of golf clubs, handles of garden equipment (e.g., lawnmower, trimmer), handles of home equipment (e.g., vacuum cleaner), shower-head handles.
Rudders, tillers, steering wheels.	Rudders, wheels and gear sticks for boats, ships, cars, and other vehicles.
Seat back armrest.	Seats/backs/armrests of chairs or similar furniture.
Tools, utensils, and other articles used by hand.	Articles: Needles, pins, thimbles, knitting needles, knitting hoods, manicure/pedicure tools like nail-files, tweezers, pencil sharpener, other office equipment. Holding area: Combs, hairbrushes, writing instruments/mechanical pencils/ball point pencils, mugs (including thermos mugs), tools like pocketknives, knives, hammer, spanners, pliers, screwdrivers, chisels, wrenches. Outer case: Snuff boxes, cigarette cases, cosmetic and powder boxes (powder compacts) and cases (e.g., lipstick holders), pencil cases and similar pocket articles.
Hand-held equipment and devices.	Outer case or holding area: Cameras, calculators, dictation machines, electric razors, cigarette lighters, flashlights, compasses, hair dryers, straighteners, curlers, other handheld equipment. Holding area: Fishing and hunting equipment.
Additional products mentioned in the ECHA guidance.	Electronic cigarettes trumpets, trombones, guitar strings, Key fobs Metal toy cars, Slinky toys, Toy keys, Eyelash curlers.

Appendix 3. Results from selected key chemical inspection campaigns

This table provides results from the most important inspection campaigns related to nickel release in DK and the EU in recent years.

Year	Campaign	Products included in campaign	Tests included in campaign	Products with non-compliant nickel release	Non-compliance rate	Comments	Reference
2012-2013	Danish wristwatch campaign	39 men's, women's, and children's watches from grocery stores, watch and jewellery stores and importers of watches in the low and middle price range	Heavy metal content and release of nickel	Watches	8%		https://mst.dk/kemi/tilsyn-og-haandhaevelse/tilsynskampagner/kampagner-2012/tungmetaller-i-ure-2012/
2013-2016	Danish National Children's Chemistry project	Textiles, toys, cosmetics, and electronics marketed for children		None	None	A subsequent border control of 66 products found a single infringement related to nickel, as nickel was released from a button.	Danish Chemical Inspection Service, 2017
2016-2017	Danish contribution to Ref 4 Campaign	88 different kinds of jewellery, including piercings items.	metal	jewellery	5%		https://mst.dk/kemi/tilsyn-og-haandhaevelse/tilsynskampagner/kampagner-2017/ref-4-smykker/

Year	Campaign	Products included in campaign	Tests included in campaign	Products with non-compliant nickel release	Non-compliance rate	Comments	Reference
2016-2017	Ref 4 Campaign	5.625 products in 29 EU/EEA countries including jewellery, buttons, and clothing zippers	14 different REACH restrictions	Jewellery, buttons, and clothing zippers	8% of 888 tested jewellery. 11% of 72 buttons on clothing and zippers.		ECHA, 2018
2017	Danish Chemical Inspection Service own campaign	33 Fidget spinners from six major store chains, a toy retailer and one online store	Lead and nickel	none	none	Non-compliance was only found as related to lead The Danish Consumer Council (2017) also tested fidget spinners and found excess nickel migration in 3 out of 12 tested products	https://mst.dk/kemi/tilsyn-og-haandhaevelse/tilsynskampagner/kampagner-2017/kontrol-af-bly-og-nikkel-i-fidgetspinnere/
2019	Joint compliance project with customs on imported products performed by 16 MS in 2019 as follow up to Ref 4	Mostly jewelleries and metal articles, followed by a small number of plastic and leather articles	Different restricted substances were checked. 622 checks for nickel, and 95% of these in jewellery		5%	Metal parts of clothes were all compliant	ECHA, 2020
2020	Danish activities under the Coordinated Activities for Safety of Products, Ref 8.	26 jewellery products bought from Danish and international web shops and e-commerce platforms. Necklaces with pendants, DIY-products, watches, and earrings. Mainly low-price products for children and young people	Content of Cd and Pb + migration of Ni	2 children's watches and one set of children's jewelleries.	12%	No surface coating detected on the products	European Commission, 2021. p.c. Hanne Thygesen, DCIS

Survey and analyses of consumer products with non-nickel coatings

Nickel is used in many consumer products and it is well known that the substance is a frequent cause of skin allergies. The release of nickel from consumer products is regulated in the EU through the REACH regulation. Nickel release can be limited by applying nickel-free coatings to nickel-containing products. REACH requires a certain durability of such coatings.

The purpose of this project was to collect information on the types, use and durability of nickel-free coatings on consumer products intended for long-lasting and direct skin contact. In addition, products were purchased within three product categories (ear studs, piercing jewellery and toys) for analysis of nickel content and nickel release.

The surveys showed that a large proportion (86%) of the purchased piercing jewellery contained nickel, while the proportion was lower for earstuds (52%). In the toy category, the use of nickel also appears to be common, as 54% of purchased products contained nickel.

The results also showed that violations of current legislation can still be a significant problem, especially for earstuds and other piercing jewellery. 8 non-compliant products were found among the 63 products purchased: 1 in 22 (5%) toy products, 3 in 14 (21%) body piercing jewellery and 4 in 27 (15%) earstuds.

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