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15-16 November 2017

Concerns:

Commission's request to ECHA for the development of a guideline on articles intended to come into direct and prolonged contact with the skin in relation to restriction of nickel and its compounds (entry 27 of Annex XVII)

Agenda Point:

Point 9.3

Action requested:

Member State Competent authorities and observers are invited to discuss the content of the draft guideline

Written comments on this document should be sent to Kirsi.sihvonen@echa.europa.eu and restriction@echa.europa.eu by 15 December 2017.

Draft guideline on articles intended to come into direct and prolonged contact with the skin in relation to restriction entry 27 of Annex XVII to REACH on: Nickel and nickel compounds

This document aims to assist producers, importers and distributors of articles, as well as Member States' authorities, in understanding and complying with their obligations under the REACH Regulation (EU) No 1907/2006. However, readers are reminded that only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

1. Introduction

The nickel restriction (Ni and its compounds: entry 27, paragraph 1 (b) and 2 of Annex XVII to REACH Regulation) restricts the use and placing on the market of nickel and nickel compounds in articles intended to come into direct and prolonged contact with the skin 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 Ni/cm²/week. The restriction entry does not define the term "prolonged contact with the skin", but does include a non-exhaustive list of example articles falling within the scope of the entry, as follows:

- 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.

When the original restriction was adopted in 1994 (Directive 94/27/EC)¹ the aim was to improve the quality of life, to protect health and to ensure consumer safety. The above list of items contains articles that are placed on the market and typically used by consumers.

Paragraph 2 of the entry restricts the placing on the market of articles falling under the scope of the restriction unless they conform to the requirements defined in paragraph 1. All articles intended to come into direct and prolonged contact with the skin, whether placed on the market for workers, professionals or consumers are covered by this restriction. The restriction covers articles made of different materials, not only metal alloys, if these materials release nickel and its compounds.

The entry does not exclude second hand articles (e.g. vintage accessories). In addition to the non-exhaustive list of articles included in paragraph (b), a Question and Answer (Q&A) on ECHA's website states that the use in mobile phones fulfils the conditions of direct and prolonged contact with the skin and thus are covered by the

¹ The Directive was reviewed by Directive 2004/96/EC and the change related to the paragraph 1(a) restricting nickel and nickel compounds in post assemblies, i.e. the content limit was removed and release limit of 0,2 µg/cm²/week was adopted for post assemblies. Further changes were technical nature; inclusion as entry 27 in Annex XVII to the REACH Regulation and changing the term 'products' to 'articles' by Regulation (EC) No 552/2009.

restriction (see No 663: [Q&As - ECHA](#)).

It should be noted that sub-paragraph 1(c) of entry 27 restricts also articles covered by paragraph (b) (articles intended to come into direct and prolonged contact with the skin) even though they have a non-nickel coating, unless such coating is sufficient to ensure that the rate of nickel release will not exceed the given release rate for a period of at least two years of normal use of the article.²

At the request of the Commission (February 2011), ECHA developed an interpretation of what can be considered as "prolonged contact with the skin" in the context of the nickel restriction. This interpretation was endorsed in the CARACAL³ meeting of 2-3 April 2014. It was published on ECHA's website as a Q&A No 935 (see [Q&As - ECHA](#)).

As a follow up action to the publication of that interpretation, Member States and stakeholders requested a more practical guideline with a non-exhaustive list of article types and sub-types that could be considered to be within or outside the scope of the restriction. As a response to this request, the Commission asked ECHA on 13 October 2014 to develop such a guideline.

In order to prepare the guideline ECHA launched targeted consultations from February to April 2015 where relevant stakeholders, including industry associations and healthcare institutions, were contacted and requested to respond to a survey regarding types and sub-types of articles that may fall within the scope of the restriction. In addition, respondents were asked about any known allergic contact dermatitis cases due to nickel and its compounds and which articles may have caused the cases. Responses were received from three healthcare institutions and 13 industry associations and other stakeholders.

A call for comments was organised on the draft guideline from January to April 2017. Comments were received from industry organisations, companies, Member States, regional authorities, health care institutions, academic institutions and individuals.

Taking into account the comments received through the public consultation, the guideline was updated and ECHA sent a draft of this guideline to the Commission, Member State Competent Authorities and stakeholders for discussions at the xx Meeting of Competent Authorities for REACH and CLP (CARACAL) in xxx. The MSCAs were requested to provide their views on the draft guideline. ECHA received comments from MSCAs and stakeholders and the updated final draft was discussed at CARACAL xxx, which agreed on the guideline.

The aim of this guideline is to give to stakeholders and enforcement authorities examples of articles that are covered by (or are out of) the scope of the restriction entry 27 on nickel and nickel compounds, beyond those already provided in entry 27. These articles need to fulfil the requirements in the entry, thus not exceeding the rate of nickel release defined therein. The guideline does not provide an exhaustive list of all the potential articles that could be in the scope of the restriction but rather gives an indicative list of concrete examples that have been identified during the preparation of the guideline. The purpose is to ensure a common understanding of the scope and an effective implementation of the restriction.

² Standard EN 12472:2005+A1:2009 – Method for the simulation of wear and corrosion for the detection of nickel release from coated items.

³ CARACAL is the expert group advising the European Commission and ECHA on questions related to REACH and CLP, composed of representatives of Member States and EEA-EFTA Competent Authorities, as well as observers from non-EU countries, industry and trade associations, NGOs, and trade unions.

2. Scope

Paragraph 1(a) restricts the use of nickel and its compounds 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. This is a strict liability restriction, assuming that any post assembly produced or sold will come into contact with the skin.

Regarding other articles, paragraph 1(b) restricts articles *intended to come into direct and prolonged contact with the skin* 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.

An article is any object that fulfils the criteria of REACH article 3(3), which is explained in the Guidance on Substances in Articles.⁴

2.1. Articles "intended to" come into direct and prolonged contact with the skin

The restriction targets articles "*intended to come into direct and prolonged contact with the skin*" (emphasis added). Thus, the restriction covers articles that come into direct and prolonged contact with the skin when used for their intended purpose.

For the purposes of establishing what, on a balance of probabilities, is the intended use of an article, the use to which such an article is generally put may be adduced in evidence.

The ECHA Guidance on Requirements for Substances in Articles, notes the following when explaining "normal conditions of use", which is relevant in considering what "intended to" means:

"Normal conditions of use" means the conditions of use associated with the main function of an article. They are frequently documented in the form of user manuals or instructions for use. Normal conditions of use for articles used by industrial or professional users may differ significantly from conditions that are "normal" for consumers. This may particularly be true for the frequency and duration of normal use as well as temperature, air exchange rates or conditions related to water contact. It is explicitly not a "normal condition of use" if the user of an article uses an article in a situation or manner that the supplier of the article has clearly recommended to avoid in writing, e.g. in the instructions or on the label of the article⁵.

The aim of the restriction is to protect the majority of individuals, including those already sensitised to nickel, from contact dermatitis resulting from dermal exposures which are of a sufficiently long duration as to elicit those reactions. The intention of the producer of the finished article that will come into direct and prolonged contact with skin can be inferred directly (where there is evidence that the producer meant this to happen) or indirectly (where it is a virtual certainty that such contact would occur if he places those products on the market and people use them). From the point of view of the protection of human health, an article can be considered as "intended to come into direct and prolonged contact with the skin", even if the uses

⁴ ECHA Guidance on Requirements for Substances in Articles (2017)
https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

⁵ Examples of the exclusion of specific conditions of use are warning statements such as "keep out of children's reach" or "do not expose to high temperatures".

are not "typical" conditions of use, i.e. when the intended use of an article can lead to patterns of exposure that fulfil the definition of "direct and prolonged contact". Such an example could be an electronic cigarette. Smoking a cigarette normally takes less than 10 minutes, however, when used for its intended purpose, it is almost certain that the electronic cigarette will be held for longer than 10 minutes. Therefore electronic cigarettes are within the scope of the restriction.

2.2 Direct contact with the skin

Articles or parts of articles come into direct contact with human skin where the surfaces of the article (or parts of article) are touched or are in touch with the skin.

2.3 Prolonged contact with the skin

The interpretation of "prolonged contact with the skin" in relation to the nickel restriction as endorsed by CARACAL is as follows:

Prolonged contact with the skin is interpreted as contact with the skin of potentially more than either

10 minutes on three or more occasions within two weeks, or

30 minutes on one or more occasions within two weeks.

The skin contact time of 10 minutes applies when there are three or more occasions of skin contacts within a two-week time period. The skin contact time of 30 minutes applies when there is at least one occasion within a two-week time period.

To further clarify this interpretation, the contact of more than 10 or 30 minutes need to be continuous and not consisting of several short discontinuous periods of contacts.

From a practical point of view, the prolonged contact within that interpretation normally occurs, when carrying an article, sitting on it, leaning on it, holding on to it or wearing it for a prolonged period of time in direct skin contact.

The contact time in the interpretation of "prolonged contact with the skin" is for intact skin, without damage of the skin barrier and without contact with body fluids.

The interpretation of "prolonged contact with the skin" was based on the available scientific information on nickel. The background information for the interpretation is available at the ECHA website⁶

2.4 Rate of nickel release

The restriction entry provides the rate of nickel release limit from articles covered by the entry. For post assemblies the rate of nickel release must be less than 0.2 µg/cm²/week (migration limit) and for articles intended to come into direct and prolonged contact with the skin the rate of nickel release from the parts of these articles must be equal to or less than 0.5 µg/cm²/week. In case articles intended to come into direct and prolonged contact with the skin have a non-nickel coating the rate of nickel release cannot exceed 0.5 µg/cm²/week for a period of at least two

⁶ See: https://echa.europa.eu/documents/10162/13641/nickel_restriction_prolonged_contact_skin_en.pdf/b6f35357-da40-4a04-8085-fe42f6f543ab. Note that the interpretation is only for nickel restriction and is not as such applicable to other restrictions where "prolonged contact of the skin" is mentioned.

years of normal use of the article.

The standard methods to be used for demonstrating the conformity of the articles are:

- 1) 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;
- 2) EN 12472:2005+A1:2009: Method for the simulation of wear and corrosion for the detection of nickel release from coated items and
- 3) EN 16128:2015: Reference method for the testing of spectacle frames and sunglasses for nickel release.⁷

3. Indicative lists of article types and subtypes under the scope of the restriction entry (Annex 1)

To base the guideline on a precise contact time of an article with the skin, based on its use, is not possible. This information is not normally available in the scientific literature and the information received through the targeted consultation did not provide clear justification of the use times of articles, if any was given. During the call for comments some detailed information on contact times associated to the use of some articles was provided and the information has been taken into account. The following sections base the division of articles falling or not falling under the scope of the restriction mainly on reasonable assumptions of the likely contact time, taking also into account information from case studies in open literature. The rationale behind the segmentation used is given. It is noted that there seems to be a misunderstanding in some of the scientific publications on nickel allergy in the sense that they quote as restricted the items listed in the entry and not other items. Information received through the targeted consultation, call for comments and relevant information from scientific publications are summarised in the background report to this guideline [separate link provided when published, see background document currently attached to this guideline].

The following chapters provide a rationale for two categories of articles falling under the scope of the restriction entry 27 on nickel and its compounds. It is to be emphasised that the lists of articles and subtypes of articles annexed to these chapters are non-exhaustive.

The methodology used to categorise the articles potentially falling into the scope of the restriction is the following: 1) identifying similar types of articles to those listed in the entry and the Q&A and 2) identifying articles or parts of articles which according to their pattern of use can be considered to meet the interpretation of prolonged contact with the skin. Case reports as described in the background report to this guideline [link provided when published] are used as a supporting source of information.

The following figure presents a "stepwise approach" for assessing whether an article is within or outside the scope of the restriction on a case-by-case basis.

⁷ Dimethylglyoxime (DMG) test is used for screening (CEN report - CR 12471: Screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin).

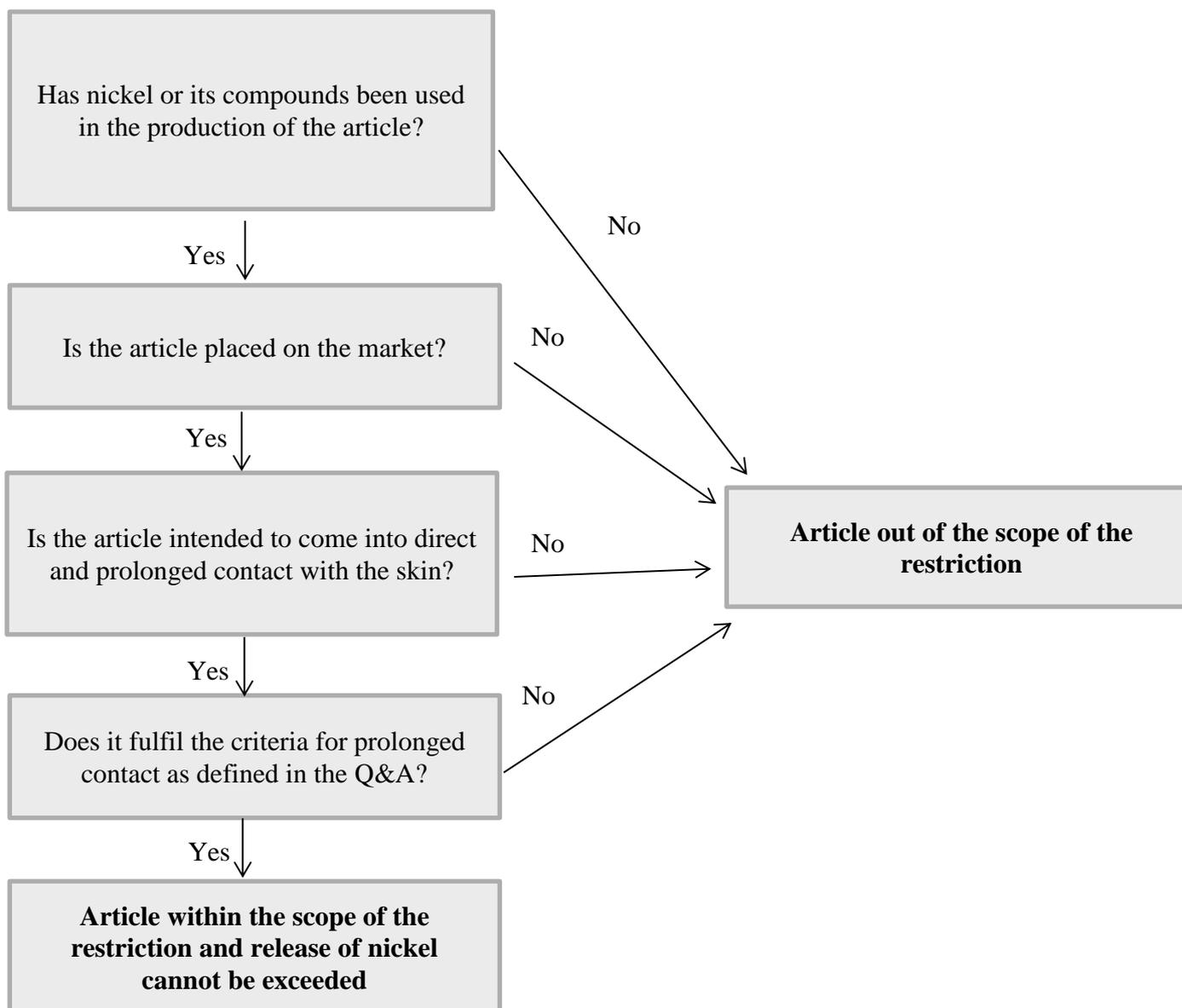


Figure 1. Steps to assess whether articles are within the scope of the restriction

3.1. Similar types of articles to those listed in the entry and in the Q&A

As indicated by the wording of the entry, other articles than those in the non-exhaustive list of articles that fulfil the criteria for direct and prolonged contact with the skin and fulfil the rest of the conditions in the entry are covered by the restriction. Therefore, if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than $0.5 \mu\text{g}/\text{cm}^2/\text{week}$ the article is subject to the restriction. This is exemplified by the clarification regarding the inclusion of mobile phones under the scope of the restriction in the ECHA's Questions and Answers⁸.

Table 1 of Annex 1 describes articles which are similar to the articles described in the entry and in the referred Question and Answer. It also explains the subtypes of articles that are already mentioned in the entry and parts in direct and prolonged contact with the skin.

⁸ See: Q&A No 935 on ECHA's website: [Q&As - ECHA](#)

3.2. Articles which according to their pattern of use can be considered to meet the condition of being intended to come into direct and prolonged contact with the skin

Certain articles and parts of articles are designed to be, in their normal use, in direct contact with the skin. Some of them might be also in prolonged contact with the skin.

Typically these articles are those which are expected to be manually handled such as grips, handles, steering wheels, rudder tillers, tools and utensils used primarily with the hands. Seats, backs and arm-rests of chairs are other examples of articles which can be in direct and prolonged contact with the skin. As an example, during summer, when lighter clothes are worn, when sitting on a metallic chair prolonged contact is possible. In some cases the duration of the contact is shorter than the one referred to in Section 2.3, such as when opening a door (door handle), but in some other cases it can be longer, e.g. when steering a boat using a rudder. In many cases direct contact is possible, even though gloves could be sometimes used thus avoiding direct skin contact. It should be noted also that handles and grips of many products are made with materials not containing nickel or its compounds.

In general, tools are a very broad category and some tools are used in such a way that prolonged contact is expected (e.g. screwdrivers used for model constructions, knives and chisels used for carving). Therefore if the nickel rate release from the parts coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm²/week, they fall under the scope of the restriction.

Table 2 of Annex 1 provides examples of articles falling under this category. Based on the comments received during the call for comments further consideration has been given to the possible contact time with the article.

4. Articles which are considered not to be in prolonged contact with the skin (Annex 2)

Articles in contact with the skin for short periods

Articles which are considered to be in contact with the skin for only a short time, even though repetitive contact may exist, are outside the scope of the restriction. Taking into account the interpretation of "prolonged contact with the skin" explained in Section 2.3, articles that are in contact with the skin for less than 10 minutes, or 10 to 30 minutes, but on less than three occasions within two weeks, or less than 30 minutes within two weeks, do not fall under the scope of the restriction.

Many articles at home (such as rails/handrails, door handles), even though direct contacts are to be expected, can be regarded such that the skin contact will not foreseeably take place with the duration required by the interpretation of "prolonged contact with the skin". In addition, articles, if covered e.g. by certain material or located 'underside' of the whole item may be considered to be in contact with the skin for only a short time, if any.

Coins are regarded to be outside the scope of the entry. Handling of the coins can be repetitive, but typically contact with the coins is not prolonged.

Inaccessible internal articles

Inaccessible⁹ internal articles which cannot be accessed during normal use of a product, or which only become accessible as a result of its dismantling or destruction, can be considered to be excluded from the scope of the restriction as they would clearly not be "intended to come into direct contact with the skin".

Examples of this are inner components of items, like the inner parts of watches, or inaccessible mechanical components inside of writing instruments.

Annex 2 provides examples of articles and types of articles not falling under the scope of the entry.

⁹ In relation to toys and childcare articles EN 71 (European Standard on the safety of toys) provides a definition to accessible.

ANNEXES

ANNEX 1 Indicative list of examples of articles¹⁰ within the scope of the restriction

Table 1 - Examples of articles similar to the articles described in the entry and in the Q&A No 663		
<i>Articles described in the entry</i>	<i>Similar types of articles</i>	<i>Parts of the articles which come into direct and prolonged contact with the skin¹¹</i>
Earrings (non-piercing)	Earphones, headsets, hearing aids	Earphones, headsets, hearing aids: external parts.
Necklaces, bracelets and chains, anklets, finger rings	Hairslides, hairgrips, hair clasps, pendants, toe rings, spectacle frames and sunglasses	Whole articles, except hinge mechanism of spectacle frames 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 hand bags, 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 – see Annex 2), pins, clasps	The whole of each article composing the listed items
<i>Articles described in the Q&A</i>	<i>Similar types of articles</i>	<i>Parts of the article which come into direct and prolonged contact</i>

¹⁰ Taking into account the definition of Article in Article 3(3) of REACH and the ruling of the CJ in case C-106/14, some items listed in the Annex under the title of 'Article' may be in fact complex products composed of several articles (e.g. necklaces are often composed of several articles such as beads, chain links, etc.). The conditions of the restriction should be assessed for each of the components of the listed item which fulfil the REACH definition of article. Where one of those component articles is under the scope of the restriction, the complex product can only be placed on the market if that article is removed or replaced.

¹¹ Conditions in the standards referred to in section 2.4 to be followed. Guidance related to the parts of the articles provided only for some cases.

		<i>with the skin</i>
Mobile phones	Smart phones, tablets, portable computers , e-readers, mice or other pointing devices (trackballs, joysticks, touchpads, laser pointers) for computers, laptops etc.	External parts, excluding keys ¹² of portable computers and laptops the underside of mice

¹² Computers and laptops can be used for hours. During that time, the keys of these devices are in contact with the skin, for example, when the fingers are pressing the keys or resting over the keys. However, the position of the hands and fingers need to be constantly changed while writing/playing. ECHA considers this example as a borderline case and seeks CARACAL's advice on whether the contact time exceeds the time in the interpretation in Section 2.3. ***[To be removed from the final public version]***

Table 2 - Examples of articles¹³ or parts of articles which are expected to result in prolonged contact with the skin (excluding articles described already in Tables 1)	
<i>Article/Part of article</i>	<i>Non-exhaustive list of examples where these articles/parts of articles are considered to be intended to be in prolonged contact with the skin</i>
Grips	Grips of umbrellas, scissors, garden (e.g. spades, shovels, rakes) and gym (e.g. dumbbell/kettlebell) tools and equipment, bikes and kick scooters.
Handles	Pram handles, handles of golf clubs, handles of garden equipment (e.g. lawnmower, trimmer), handles of home equipment (e.g. vacuum cleaner).
Rudder tillers, steering wheels	Rudder tillers and steering wheels for boats, ships, cars and other vehicles.
Seats/back/arm-rests	Seats/back/arm-rests of chairs or similar furniture.
Tools, utensils and other articles used by hand	Articles: Needles ¹⁴ , pins, thimbles, knitting needles, crochet hooks, manicure/pedicure tools like nail-files, tweezers, pencil sharpener ¹⁵ , keychains, key rings, key fobs ¹⁶ , trays. Model accessories (e.g. kits for the assembly of detailed scale models). Mugs (including thermos mugs). Accessible parts of toys ¹⁷ : toy cars, trains ¹⁸ , generic slinky and other toys

¹³ Taking into account the definition of Article in Article 3(3) of REACH and the ruling of the CJ in case C-106/14, some items listed in the Annex under the title of 'Article' may be in fact complex products composed of several articles. The conditions of the restriction should be assessed for each of the components of the listed item which fulfil the REACH definition of article. Where one of those component articles is under the scope of the restriction, the complex product can only be placed on the market if that article is removed or replaced.

¹⁴ Needles used for tattooing purposes can be considered also to be within the scope. The machine used for tattooing 'shoots' the needle up to 5000 times per minute on the skin, which can be regarded similar to continuous contact and not short term and repetitive. The tube/tip where tattooing needles are installed and the tattoo gun (holding area) are also in prolonged contact with the skin and thus within the scope. Needles used for piercing purposes (which are not intended to stay within the piercing) are not in prolonged contact with the skin.

¹⁵ If a sharpener is in a case which does not contain nickel and nickel compounds, the sharpener is outside the scope.

¹⁶ A key fob is a generally decorative and at times useful item many people often carry with their keys, on a ring or a chain, for ease of tactile identification, to provide a better grip, or to make a personal statement.

¹⁷ An internal or recessed component (e.g. recessed metallic screw fixing) that is accessible by the finger probes is not regarded to be in direct and prolonged contact with the skin.

¹⁸ Railroad tracks are outside the scope as they are not expected to be in prolonged contact with the skin.

	<p>used by hand.</p> <p>Holding area: Writing instruments/mechanical pencils/ball point pencils (holding area, tip excluded), manual razors for shaving, tattoo guns (including nose of the tattoo gun), tools like pocketknives, knives, hammer, spanners, pliers, screwdrivers, chisels, wrenches.</p>
Hand-held equipment and devices	<p>Outer case or holding area: Cameras, calculators, dictation machines, electric razors, flashlights, compasses, hair dryers, straighteners, curlers, electronic cigarettes, cigarette mouthpieces, whistles, other handheld equipment.</p> <p>Holding area: Fishing and hunting equipment (including sports weapons).</p> <p>Mouth pieces, strings, keys¹⁹ and parts of the body of the instrument from which it is held or which rests on the body: musical instruments/parts of instruments in direct and prolonged contact with the skin.</p>

¹⁹ Musical instruments can be played for hours. During that time, mouth pieces, strings and keys of musical instruments are in contact with the skin, for example when the fingers are pressing the part or resting over the keys. However, the position of the hands and fingers need to be constantly changed while playing. ECHA considers these examples as borderline cases and seeks CARACAL advice whether the contact time exceeds the time in the interpretation in Section 2.3. **[To be removed from the final public version]**

ANNEX 2 Indicative list of examples of articles²⁰ outside the scope of the restriction

Examples of articles in direct but not prolonged contact with the skin	
<i>Article/subtype of article</i>	<i>Remarks</i>
Household fittings, like door and window handles, handrails	Contact time expected to be shorter than the time in the interpretation in Section 2.3.
Kitchen and bathroom fixtures, like towel rails, water taps, shower-head handles ²¹	Contact time expected to be shorter than the time in the interpretation in Section 2.3.
Kitchen tools and utensils, like kettles, pans, citrus squeezers and cutlery	Contact time expected to be shorter than the time in the interpretation in Section 2.3 (except trays).
Shaver foils and razor blades	Contact time expected to be shorter than the time in the interpretation in Section 2.3.
Suspenders holding trousers, skirts	Contact time expected to be shorter than the time in the interpretation in Section 2.3. Shirt is normally expected to be between the part of the article and the skin.
Coins	Contact time expected to be shorter than the time in the interpretation in Section 2.3.
Medals (from sport)	Contact time can be rather long on the day of award, but not expected to be repeated many times.
Decorative items at home, public areas, offices	Contact time expected to be shorter than the time in the interpretation in Section 2.3.
Certain articles in vehicles like door handles, luggage racks, gear sticks, trims (e.g. bumpers, headlight bezels etc.)	Contact time expected to be shorter than the time in the interpretation in Section 2.3 (except steering wheels etc.).

²⁰ Taking into account the definition of Article in Article 3(3) of REACH and the ruling of the CJ in case C-106/14, some items listed in the Annex under the title of 'Article' may be in fact complex products composed of several articles. The conditions of the restriction should be assessed for each of the components of the listed item which fulfil the REACH definition of article. The fact that one of those component articles is not under the scope of the restriction, does not exclude that other articles components of the complex product may be subject to the restriction.

²¹ According to MEERP Preparatory Study on Taps and Showers (JRC, 2014) the average shower time is 7 minutes.

ANNEX 3 Pictures²² of certain articles that fall in the scope of the restriction

- (a) Picture of keys, key ring and key fob (individual articles)



- (b) Picture of the rudder (grip area)



- (c) Picture of wrist watch (external parts)



- (d) Picture of spectacle frames (whole articles, except hinges²³)

²² Images were provided by the following source: Fotolia (2015)

²³ Hinges on the bridge (over the nose) and temples (side pieces) of foldable spectacles are within the scope.



(e) Picture of a fishing equipment (handle, grip area)



(f) Picture of writing instrument (holding area, tip excluded)



Change history

Revision	Comment	Date
Original document		

BACKGROUND REPORT TO THE GUIDELINE ON ARTICLES INTENDED TO COME INTO DIRECT AND PROLONGED CONTACT WITH THE SKIN IN RELATION TO RESTRICTION ENTRY 27 OF ANNEX XVII TO REACH ON: NICKEL AND NICKEL COMPOUNDS (To be published simultaneously with the guideline)

Information from scientific literature, case reports, obtained from the stakeholder survey and received through the call for comments

1. General trends in prevalence of nickel allergy

According to the European Society of Contact Dermatitis (ESCD) and Karolinska Institutet there is no international, national, regional or clinic-based registry identified for occupational versus consumer cases of allergic contact dermatitis (ESCD and Karolinska Institutet, replies to ECHA during the targeted consultation in 2015).

Several studies investigating trends in nickel allergy after the nickel restrictions were adopted (Directives 94/27/EC and 2004/94/EC) have been published (e.g. Garg et al., 2013, Schnuch. et al. 2011, Fall et al., 2015 and Garcia-Gavin, J., 2011). When analysing information from Denmark, Germany, Italy and the UK, the conclusion drawn was that there has been a reduction in the prevalence of nickel allergy in young women, contemporaneous with the introduction of the nickel restriction. A reduction in the prevalence of nickel allergy is also suggested in men in Germany and the UK, with the regulatory intervention considered to be the most likely explanation (Garg et al., 2013). However, based on data from Germany (Schnuch. et al. 2011), nickel allergy is still frequent in young females (the vast majority of which came into contact with nickel after the nickel restriction was adopted). This was considered by the authors to be as a result of: 1) articles not complying with nickel restriction, 2) different limits [for post assemblies and other articles] were or are still too high, 3) the application of the adjustment factor of 0.1 (EN 1811:1998) led to a large number of 'compliant' samples, although in reality the levels resulted in an allergic reaction in consumers and 4) other sources of cutaneous nickel exposure that were not covered by the EU regulation are (partly) responsible.

Trends in Sweden show significant decreases in rates of skin sensitisation to nickel sulphate using patch test data from 1992, 2000 and 2009 (Fall et al., 2015). However, the study shows that nickel is still the allergen with the highest sensitisation rates in Sweden.

In Spain, the high overall prevalence of nickel sensitisation in Spanish patients, especially in young women but even up to 60 years of age is still found (Garcia-Gavin, J., et al., 2011).

The European Surveillance System on Contact Allergies (ESSCA) provides results from several European countries on the prevalence of contact sensitisation to allergens tested with dermatitis patients. The first survey was done in 2002/2003 with nine European countries (Uter et al., 2005) and the most recent published data is from 10 European countries during 2007 and 2008 (Uter et al., 2012). The surveillance is based on patch test results. The results presented in the latest report (2012) shows, that nickel is still by far the most common allergen in all countries involved in the survey, although there is a greater than two-fold variation between countries (e.g. in Denmark the percentage of positive reaction to nickel is 11.9 %

and in Italy 27.4%). The low frequency observed in Denmark is explained to show the longstanding nickel restriction established there, and that high prevalence may indicate later implementation of the restriction, different fashion habits or insufficient control of exposure.

2. Case reports, release information and information from occupational contact dermatitis

Despite nickel being the most common cause of contact dermatitis, only a few case reports describing the articles causing nickel allergy have been published.

Jensen et al. (2012) described a patient with contact dermatitis which was located on skin areas which had been in prolonged contact with metal parts of the frame of a computer keyboard. The patient experienced complete symptom relief after she stopped using the keyboard. The patient reacted to nickel sulphate in a patch test. Nickel release was tested with both a dimethylglyoxime (DMG) test²⁴ and with the standard EN 1811 (release rate below the limit value with the standard test). In a further example (Thomas et al., 2000), a male patient with itching, dryness and sometimes scaling of the lips (lip eczema) experienced complete healing following the use of a gold mouthpiece of his trumpet. Reactions to nickel sulphate and fragrance mix were found with a patch test.

Maridet et al. (2015) reported a case of allergic contact dermatitis caused by nickel resulting from the use of an electronic cigarette. The patient had erythematous, scaly dermatitis, slightly lichenified, which was limited to the right thumb and index finger. The electronic cigarette the patient used gave strong positive result with DMG nickel test.

One schoolboy had vesicular hand dermatitis that developed two months after he started playing the trombone. A patch test showed reaction to nickel and palladium. Dimethylglyoxime-ammonia testing demonstrated intense nickel release from the instrument (Jacob and Herro, 2012).

One case report describes a man with no history of atopic dermatitis who developed eczema located on the fingertips of the left hand. The subject was a manufacturer of electric guitars and also played the guitar professionally. The results from a release test done according to EN 1811 were negative. However, with more aggressive testing excessive nickel release from guitar strings was measured (Friis et al., 2012).

In one nickel release study Jensen et al. (2014) referred to three cases seen and treated at the Contact Dermatitis Clinic, University of Miami by S.E.J. (Society of Environmental Journalists): contact dermatitis of a one-year-old boy caused by his parents' key fob as a 'favourite toy', contact dermatitis of a three-year-old boy caused by metallic toys (namely metal cars and a generic slinky), and contact dermatitis of a two-year-old boy caused by toy keys.

In addition, case reports cast doubts that eyelash curlers may cause contact dermatitis (Romaguera and Grimalt, 1985; Henke and Boehncke, 2005).

Far more release studies than case reports have been published. The release studies are not cited in this guideline in detail, as they were taken into account when the interpretation of "prolonged contact with the skin" was provided. One release study however described a case report on acute dermatitis from a fitness wristband, referred to by Gumulka et al. (2015). The causative substance was not identified,

²⁴ Dimethylglyoxime (DMG) test is used for screening (CEN report - CR 12471: Screening tests for nickel release from alloys and coatings in items that come into direct and prolonged contact with the skin)

but stainless steel or plastic chemical was suspected. Due to this case report Gumulka et al. (2015) evaluated nickel deposition on the hands after one hour of training with different equipment in the gym. Relatively high nickel doses on the skin were noticed.

Another release study describes the items that were used by the nickel allergic patients and from which the nickel release was examined with a DMG method by experienced nurses (Thyssen et al., 2010). The type of metallic items that resulted in positive DMG test reactions were: mobile phones, spectacle frames, hair clasps, watches, keys, necklaces, knitting needles, work tools, scissors, belt buckles, key chains, ear rings and pens. The same scientific paper also includes a list of items self-reported from nickel allergic patients and the list is very similar to the one tested by nurses. A positive DMG test result provides an indication that the articles may release nickel and it is therefore a commonly used and inexpensive screening test. Whether these articles are regarded to be in prolonged contact with the skin or not is described in this guideline and whether they fall under the scope of the restriction or not can only be determined as a function of the results of the corresponding EN standard test.

One recent study investigated releases of nickel with DMG test from different types of articles which could meet the conditions of "prolonged contact with the skin" (Ringborg et al. (2016)). Different accessories (bags, wallets, and umbrellas), electronic devices (laptop computers, activity bracelets and computer mice) and utensils for needlework, painting and writing were chosen for the test, and parts of those objects were tested. In total, 44 % of the tested items (141 items tested) released nickel by using the DMG test.

The EU Risk Assessment Report (2008) on nickel and its compounds summarises information on nickel release rates for some nickel alloys and coatings. However, it is not clear if the release rates are in compliance with the EU restriction because either the reference method was not mentioned or it was not the standard method. Based on this information no solid conclusion can be drawn if for some nickel alloys the release rate is always below the migration limit given in the restriction entry.

Some indications of which types of articles could be considered to fall under the scope of the entry can be drawn from studies where the incidence of nickel related occupational contact dermatitis has been investigated. One needs to bear in mind that the duration and frequency of exposures is expected to be much higher for workers than for consumers or general public. Shum. et al. (2003), based on occupational surveillance reporting data, concludes that the highest incidence rates were seen in hairdressers, bar staff, chefs and cooks, retail cash and checkout operators and catering assistants. It can be considered that these occupations require the use of articles that can result in contact dermatitis. The percentage of cases among women by occupation (July 1997 – January 1999) in which nickel was the sole suspected agent were the following: secretarial personnel 94%, counter clerks/cashiers 86%, cash/checkout operators 83%, cleaners/domestics 63%, catering assistants 27%, chefs/cooks 11%, nurses 10%, hairdressers 4% and beauticians 4%.

Bauer et al. (2002) found out that there were significant higher sensitisation rates in employees in the food processing industry, (22.4%) compared to the total test population, (17.2%) for nickel sulphate. The study states that the impact of occupationally acquired nickel sulphate sensitisations is debatable. But it also states that there is some evidence that sensitisation to nickel, independently of whether it was acquired in leisure time or under occupational conditions, plays a role in occupational settings, especially in employees involved in wet work.

3. Information from stakeholders

Targeted consultation in 2015 – information from industrial stakeholders'

According to the Nickel Institute about 65% of the nickel which is produced is used to manufacture stainless steels. Another 20% is used in other steel and non-ferrous alloys, often for highly specialised industrial, aerospace and military applications. About 9% is used in plating and 6% in other uses, including consumer products.

ECHA received several comments from the manufacturers of writing instruments in addition to those from the European Writing Instruments Manufacturer's Association (EWIMA). Most of the comments claim that none of the writing instruments come into "prolonged contact with the skin" and that direct contact with some parts of the products is only brief. The manufacturers and EWIMA also state that writing instruments were never involved in dermatological findings related to nickel release. However, one manufacturer considered that certain parts of mechanical pencils and ball point pens (nickel plated barrel, nickel-plated ornamental ring at the grip area of hands) fall under the interpretation. Two manufacturers initiated in 2014 dermatological evaluations of their products. The persons used the writing instruments under dermatological and clinical observation without development of any pathological disorder, even though the release rates of the specific parts of the instruments were above the limit value tested with the standard methods. Daily use was instructed but no observation of the subjects and patterns of exposure were done.

The European Tool Committee (CEO – Comité Européen de l'Outillage) provided information on hand tools. Nickel is a key substance for high quality hand tools and is used as an ingredient of alloys and in coatings. According to the CEO, the duration of each single contact with the surface of a hand tool during use, e.g. when fastening of a screw with a wrench or a screwdriver, is too short to enable a migration of nickel into the skin. Moreover, CEO is not aware of any case reports of allergic reactions caused by the use of hand tools, neither from private users nor from professionals. CEO provided information from its member companies that migration rates are above the (regulatory) limits for some type of pliers and wrenches, but did not know the exact values. According to CEO the contact zones of hand tools like pliers are usually coated with plastic handles.

A manufacturer of shaver foils stated that shaving always takes less than 10 minutes per occasion and locally less than seconds. In addition, it provided information on the nickel release from shaver foils, which show release rates below the limit in the restriction (Test reports from 2011, with standard EN 1811, issued June 2008, including correction 1, issued September 2008).

The European Federation of Precision, Mechanical and Optical Industries (EUROM) provided metal frames and metal sunglasses (temples, rims, bridge, brace bar and trims) as examples of articles in prolonged contact with the skin. EUROM stated however, that the skin is protected by an organic coating barrier. Moreover, the spectacle frames and sunglasses are designed with plastic nose pads and end covers on the sides so that metal components should not come into direct and prolonged contact with the skin.

Toy Industries of Europe (TIE) informed that their members produce toys and that some of them may contain nickel. TIE referred to the Toy Safety Directive-TSD (2009/48/EC) which prevents substances classified as carcinogenic, mutagenic or toxic to reproduction (CMRs) categories 1A, 1B and 2 to be used in toys, in components of toys or in micro-structurally distinct parts of toys. The TSD has foreseen derogations for nickel in toys and toy components made of stainless steel

and in toy components which are intended to conduct an electric current (Directive 2014/84/EU). However, as entry 27 to Annex XVII is intended to protect from skin sensitisation (different endpoint than CMR), the restriction under REACH applies to toys, even made of stainless steel, if the toy is intended to come into direct and prolonged contact with the skin. This is also stated in the recitals of the Directive 2014/84/EU and emphasised by the Scientific Committee on Health and Environmental Risks (SCHER) in its opinion on 25 September 2012 on Assessment of the Health Risks from the Use of Metallic nickel in Toys. SCHER states that intake of nickel by oral or skin contact with nickel containing parts of toys is also expected to be very limited due to the restrictions on nickel release applicable to metal containing parts in toys.

Some stakeholder organisations wished to also have clarification that the continuous contact needs to be with the same part of the article and with the same part of the skin. This strict interpretation is not in line with the restriction entry as the articles already listed in the entry are not always in contact with exactly the same part of the skin (even though very close). Where an item is a complex product composed of several articles (e.g. a bicycle), direct and prolonged contact has to be assessed independently for each of the articles that is a component of the complex product.

Call for comments in 2017 – summary of comments received

ECHA launched a call for comments on the draft guideline in January 2017 until April 2017. More than 80 comments were received by the deadline. In addition several comments were submitted to ECHA after the public consultation. The comments have been taken into account, where relevant and some further explanations how they have been taken into account are provided in the guideline. This section summarises the comments received.

Comments were received from industry organisations, companies, Member States, regional authorities, health care institutions, academic institutions and individual citizens.

Health care institutions that submitted comments supported the proposals in the guideline, stating that it is a much wanted step in the direction of preventing disease. One organisation stated that the examples of articles are well justified and relevant. In addition, health care institutions reminded about the concerns related to the short term and repetitive contact with articles, which in their view should be considered in any future restriction related to nickel.

Member States and regional authorities provided also specific comments on certain articles.

Most of the comments received were from individual companies and industry associations. Many of them welcomed the guideline to clarify the scope of the restriction but had concerns related to the general principles expressed in the guideline as well as concerns related to the inclusion of some specific articles within the scope of the restriction.

Concerning the general principles, some of the comments stated that there was no robust scientific evidence supporting the interpretation for “prolonged contact with the skin”. Concern was raised that the guideline extended the scope of the original restriction to articles that were not meant to be covered by the restriction, and to articles that are not relevant causes of nickel dermatitis to a significant number of nickel sensitised individuals, let alone a potential cause for becoming allergic to nickel. From the stakeholders’ point of view such alleged widening the scope would require a new restriction.

Moreover, according to the comments, the articles listed in the current restriction should be enforced more efficiently. The comments referred to the conclusions of the Danish EPA study, i.e. that earrings especially and similar items listed already in the entry seem to be the most important reasons for first-time rash²⁵.

Stakeholders also claimed that as the restriction is covering articles "intended" to come in prolonged contact with the skin, it is not possible to interpret this to cover also "reasonably foreseeable conditions of use".

Most of the article-specific comments that argued that these articles were outside the scope of the restriction concerned shower head handles, keys, key rings and key fobs and musical instruments.

²⁵ An investigation of causes of nickel allergy. Environmental Project No 1869, 2016. Danish Environmental Protection Agency. Note that in addition to the items already listed in the restriction entry, few women reported also tools, computers, mobile phones and lighters as causes of their initial rash. Men reported also keys as the cause of their initial rash (results less robust due to few men with nickel allergy, who responded).

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