Nickel allergy and EU nickel restriction

articles in direct and prolonged contact with skin

State of play and challenges ahead

BRUSSELS, JUNE 2017
WORKSHOP REPORT

Nickel INSTITUTE
knowledge for a brighter future

All presentations made at the workshop can be downloaded at https://www.nickelinstitute.org/KnowledgeBase/Events/20170627-NACDWS.aspx
This link will also allow you to download speakers' biographies and information packs about NACD.

Executive Summary

Representatives of the European Commission, ECHA, national authorities as well as dermatologists, experts from standards bodies and other stakeholders gathered in Brussels for the Nickel Institute's second workshop on 'Nickel allergy and EU nickel restriction'. The event was a follow-up to a 2015 event and it again provided an excellent opportunity for participants to exchange their views on topics related to nickel allergy and the implementation of the EU restriction on articles in 'prolonged skin contact'. The event was chaired by independent toxicology consultant **David Basketter.**

At the end of the day there was a consensus that preventing nickel sensitisation remained the most important measure in avoiding nickel allergic contact dermatitis (NACD) and that body piercings and low-quality products continue to be a significant source.

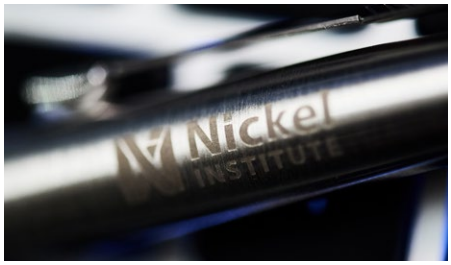
SENSITISATION VS. ELICITATION

- Nickel sensitisation: The process of becoming allergic to nickel
- Nickel elicitation: Nickel Allergic Contact Dermatitis (NACD) – the skin reaction of a nickel-allergic person

NICKEL SENSITIZED = NICKEL ALLERGIC


DAVID BASKETTER


TONY NEWSON




KIRSI SIHVONEN

Since the Nickel Institute's first workshop on the topic in 2015, there have been two important developments which were discussed at the workshop:

- ECHA has issued new draft guidelines concerning the EU REACH nickel restriction (at the request of the European Commission);
- The Nickel Institute has conducted further research with the aim of supporting a more scientifically accurate and robust definition of 'prolonged contact'.

Welcoming participants to the event, Nickel Institute President, **David Butler** explained that NACD was a crucial issue for the nickel industry as its negative connotations meant that the many positive and beneficial aspects of nickel were often overshadowed.

First on the agenda was **Tony Newson** (metallurgist and consultant to the Nickel Institute) who gave an overview of the properties and uses of nickel, a naturally occurring metallic element with a large number and variety of uses. On the subject of ECHA's guidelines, Newson commented that the extension of the number of articles considered as falling within the scope of the restriction was "stretching a point", as many articles listed were unlikely to elicit an allergic reaction because of the way they are used in practice.

> PREVENTING NICKEL SENSITISATION REMAINS THE MOST IMPORTANT ISSUE IN AVOIDING NICKEL ALLERGIC CONTACT DERMATITIS

ECHA's **Kirsi Sihvonen** briefly explained the history of the nickel restriction, dating back to the initial Nickel Directive in 1994, which introduced a 'non-exhaustive list of articles' falling under the restriction. ECHA issued a guidance definition of 'prolonged contact' in 2014 and the latest proposed draft guideline of articles that would fall under the definition 'prolonged contact with the skin' was issued for public consultation in January 2017. Sihvonen said the draft guideline included examples of articles that were to be considered within the scope of the restriction. She described the process and timing for decision making as regards the guideline.

The European Commission's **André Berends** gave an overview of the EU RAPEX system, explaining its role in the EU market surveillance framework, and giving a brief update on examples of RAPEX notifications involving non-compliance with the EU restriction on nickel release. He informed the audience about new user-friendly features of the RAPEX website.

Kate Heim (NiPERA) stressed the point that NACD was preventable by avoiding direct and prolonged contact with items that could potentially release a sufficient amount of nickel to cause an individual to become allergic to nickel, or to cause a nickel-allergic reaction in individuals already sensitised to nickel.


KATE HEIM

ANDRÉ BERENDS


DAVID BUTLER

Heim explained that nickel is considered to be a weak skin sensitiser as the prevalence of nickel allergy in general population is due to frequency and type of exposure to nickel-releasing materials (e.g. jewellery) and not to the high strength of nickel as an allergen.

> BODY PIERCINGS AND LOW-QUALITY PRODUCTS CONTINUE TO BE A SIGNIFICANT SOURCE OF NICKEL SENSITISATION

She presented the results of NiPERA's scientific project on 'prolonged skin contact'. The study found no consistent reactions in any of the nickel sensitive individuals subject to the testing, at any of the shorter times of exposure included in the ECHA definition of 'prolonged contact'. Therefore, further testing is needed for longer time periods to determine a clinically relevant definition. Heim informed the workshop participants that initial discussions regarding a third phase of the project were ongoing.

Speaking from a market perspective, **Holger Fehrholz** (CEIR) said that while his organisation supported the legislation on nickel restriction, it felt that the "vast extension" to the list of articles in the new draft guidelines was not justified. He commented that there was a lack of scientific evidence supporting the list and more work was required on an analysis of usage patterns together with an impact assessment.

Jacob Thyssen (Gentofte University Hospital) argued that the focus of the debate should be on overall prevention of nickel sensitisation and not elicitation in just a few individuals. He remained convinced that some of the main threats as a cause of nickel allergy were body piercings and low-quality products. Thyssen felt that nickel allergy was preventable by regulation but emphasised the need for much stronger enforcement of the existing legislation.


DIPPAL MANCHANDA


DURK J. SCHAKEL


HOLGER FEHRHOLZ


MALIN AHLSTRÖM


JACOB THYSSEN

Malin Ahlström, from the Danish Allergy Research Centre (Gentofte University Hospital), introduced the results of a study carried out on behalf of the Danish Environmental Protection Agency (EPA) to investigate the causes of nickel allergy. The report highlighted the positive preventative effects of the nickel regulation. However, it also showed that young women were still being sensitised and that the prevalence of NACD in Europe remained high, in particular in Southern European countries.

As several speakers were of the opinion that further enforcement of the existing nickel restriction was required, it was interesting to hear the views of the Netherlands Consumer Product Safety Authority's **Durk J. Schakel.** Describing a recent market surveillance study on restricted metals in jewellery (nickel, lead, cadmium), he highlighted the challenges of compliance checks, noting that the nickel restriction compliance testing process based on the EN 1811 standard on nickel release was both complex and time-consuming.

The final speaker of the day, **Dippal Manchanda** (Birmingham Assay Office (AnchorCert Group) presented results of a 2005 study that compared two testing methodologies: EN 1811 and the DMG test. Overall, Manchanda argued that the results showed that the latter test was not reliable (giving both false positive and false negative results) and that EN 1811 had been proven to be accurate as long as laboratories followed the correct procedures. According to Manchanda, the DMG can be seen as a screening and qualitative test, rather than a definitive test to assess compliance with the nickel release limits.

> IMPROVE COMPLIANCE WITH THE EXISTING RESTRICTION RATHER THAN BROADENING ITS SCOPE TO ARTICLES THAT ARE NOT CLINICALLY RELEVANT CAUSES OF NICKEL ALLERGY

Wrapping up, Butler echoed the concern of many that the draft guidance lists had been expanded without sufficient scientific backing. We need to improve compliance with the existing restriction rather than broadening its scope to articles that are not clinically relevant causes of nickel allergy. Indeed, there is a risk that attention is diverted from the most relevant causes of nickel sensitisation: non-compliant piercing items. At the same time, there would be an unnecessary stigmatising impact on a whole range of articles, with a corresponding impact on industry and the need for excessive testing. Butler said a pause for reflection was necessary. The Nickel Institute, for its part, would continue with scientific research and discussions with regulators to further address the important issue of nickel allergy.

01
Setting the scene


DAVID BASKETTER

The Nickel Institute's President **David Butler** opened the workshop by emphasising the Institute's mission: to promote and support the use of nickel in appropriate applications. He also stressed the importance of communicating the value and benefits of nickel, and nickel-containing products, underpinned by science via the work of NiPERA[1].


DAVID BUTLER

Butler acknowledged that Nickel Allergic Contact Dermatitis (NACD)[2] is a crucial issue for the nickel industry as it is visible to many downstream users who are concerned about the resulting negative connotations. These often undermine the many positive and beneficial aspects of the metal.

Referring to the Nickel Institute's 2015 workshop on nickel allergy, also held in Brussels, Butler described

> NOTICEABLE EFFORTS HAVE BEEN MADE BY THE NICKEL INDUSTRY SINCE 2015 TO RAISE AWARENESS AND FOSTER THE DEBATE

the main developments since that date: innovative scientific research, new reports from the regulators and proposed draft guidelines issued by the European Chemicals Agency (ECHA) on the nickel restriction and articles in prolonged contact.

There has been much progress since 2015, and noticeable efforts by the nickel industry: more research on the issue of 'prolonged contact'; intensive work on the technical side vis-a-vis solutions regarding nickel release; and a concerted effort to convey the right message to the appropriate stakeholders to raise awareness and foster the debate.

AIMS OF THE DAY

1. To pull together the current thinking
2. To examine the potential implications of regulatory action
3. To share views on the implementation of the Nickel restriction.

Moderated by **Dr. David Basketter** (independent toxicology consultant), the speakers at the workshop were

- **Tony Newson,** consultant to the Nickel Institute
- **Kirsi Sihvonen,** European Chemicals Agency
- **André Berends,** European Commission
- **Dr. Kate Heim,** NiPERA
- **Holger Fehrholz,** European Association for the Taps and Valves Industry -CEIR
- **Dr. Jacob Thyssen,** Gentofte University Hospital, Denmark
- **Dr. Malin Ahlström,** Allergy Research Centre, Gentofte University Hospital, Denmark
- **Durk J. Schakel,** Consumer Product Safety Authority, The Netherlands
- **Dippal Manchanda,** Birmingham Assay Office

David Basketter opened the proceedings by reminding the audience that the Nickel Institute and its stakeholders were continually searching for solutions. Looking forward to the day's proceedings, he called for a robust discussion and introduced the day's first speaker.

1. The major goal of NiPERA Inc. is to promote the health and safety of those exposed to nickel or nickel-containing products in the workplace and general environment. (http://www.nipera.org/)
2. For a fact sheet on NACD – see http://www.nipera.org/HumanHealthScience/FS1-AllergicContactDermatitis.aspx.

02

Properties and uses of nickel

Tony Newson (Nickel Institute consultant) gave an overview of nickel – its uses and its properties. Stressing that nickel was a naturally occurring metallic element, Newson explained that it is present in air, soil, water and food, and is essential to plants and some animals. Looking at its most significant characteristics, Newson noted nickel's high melting point (1453°C), its resistance to corrosion and oxidation, and its ductility. In addition, nickel is fully recyclable. Explaining nickel's practicality, Newson stated it is used in over 300,000 products in a wide-range of innovative applications, from industry and transport to marine engineering and architecture. He added that in many of those applications, there is no substitute for nickel without a resulting reduction in performance and/or increase in cost.

TONY NEWSON

Newson explained that nickel is mostly used in combination with other metallic elements in alloys. Focusing on alloys[3], he emphasised that they rarely behaved as simple mixtures, and that the chemical properties were not proportional to the amount of each constituent element. Noting that alloying was the biggest use of nickel, especially in stainless steels (around 68%), he explained that the mechanical and thermal history of an alloy influences its properties (corrosion, hardness, resistance, strength and toughness). Regarding corrosion, Newson described it as the gradual deterioration of a metallic material that, together with metal release, took place at the surface of the material in question. As for nickel and skin contact, Newson stated that

> THERE IS NO SUBSTITUTE FOR NICKEL WITHOUT A RESULTING REDUCTION IN PERFORMANCE AND/ OR INCREASE IN COST

following corrosion, released nickel ions could enter the skin. In large enough quantities, that may induce sensitisation in non-nickel allergic individuals or lead to elicitation of dermatitis reactions in nickel-sensitised individuals.

Newson explained that nickel had to be present on the skin in the form of nickel ions in a solution (such as sweat) to enable absorption into the skin. A nickel allergic reaction could be caused if sufficient nickel ions (from corrosion of a nickel-containing material) are absorbed by the skin.

Newson concluded that the two main factors affecting metal release[4] were corrosion resistance of the material and the time of contact with the skin. Release could occur if non-metallic intrusions on the surface allowed leaching through the passive film on the surface of the item. Newson added that the release of the nickel, rather than the nickel content, was the key factor in determining the potential of a material to cause NACD. He concluded his presentation by stating that most uses of nickel did not result in prolonged skin contact.

3. "An alloy is a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot readily be separated by mechanical means". (United Nations Globally Harmonized System -UN GHS- definition).
4. European nickel release standard, EN 1811:2011+A1:2015, defined the test method and criteria for compliance with the REACH Annex XVII requirements for nickel release.

QUESTIONS FOR NEWSON

Martin Baker (AGOSI and convenor CEN TC 347 WG1) asked if the products listed in the new ECHA guidelines all contained nickel, and if so, what kind of alloys or coatings could be involved.

Tony Newson stated that many would contain nickel but added that the real question was whether such articles would be in prolonged contact with the skin. The Nickel Institute supported the original Nickel Directive (94/27/EC) that had listed examples of articles intended to come into direct and prolonged skin contact, such as jewellery items, which have been shown to be clinically relevant causes of NACD. However, there was a feeling that the proposed draft ECHA guidance lists broadened the scope of the nickel restriction unnecessarily. Many articles listed are unlikely to give such a reaction (e.g. tiller handles for boat rudders) and not all were uses intended for prolonged contact. Newson added that the Nickel Institute had submitted comments on the draft lists of articles through the public consultation to ECHA and the European Commission.

David Basketter asked if alloy production was similar to that of polymers, where some constituents are not bound in the final product and are still bioavailable. Newson said there was no 'free nickel', as all of the metal was bonded into the alloy structure.

03

EU nickel restriction: Background and ECHA activities

KIRSI SIHVONEN

ECHA's **Kirsi Sihvonen** briefly explained the history of nickel restriction, which had been in place since the adoption of the nickel Directive in 1994[5] and introduced a "non-exhaustive list of articles" falling in the scope of the restriction. Later the Member States agreed that mobile phones should be covered by the restriction. Amendment to the nickel restriction was introduced in 2004 (the use of migration limit value for post assemblies instead of nickel content). In 2009, the restriction was incorporated into entry 27, Annex XVII, REACH Regulation[6] that set the migration limits[7] for nickel from piercings and articles intended to come into direct and prolonged skin contact (see last Appendix).

In 2014, ECHA produced a guidance definition of prolonged skin contact, which was endorsed by REACH and CLP Competent Authorities (CARACAL). However, EU Member States wanted further practical guidelines on what articles should be considered as being in prolonged contact with the skin i.e. within the scope of the EU REACH

WHY WAS THE NICKEL DIRECTIVE PUT IN PLACE?

Original directive 94/27/EC

"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"

> EU MEMBER STATES WANTED FURTHER PRACTICAL GUIDELINES ON WHAT ARTICLES SHOULD BE CONSIDERED AS BEING IN PROLONGED CONTACT WITH THE SKIN

nickel restriction.
In January 2017, following a mandate from the European Commission, ECHA issued a draft guideline on "articles intended to come into direct and prolonged skin contact", including a non-exhaustive list of articles considered in "prolonged skin contact" and hence as falling in the scope of the restriction.

The draft guideline was subject to a call for comments until April 2017. Sihvonen said that the proposed guideline had been produced in a practical fashion, rather than being based on scientific results. She added that more than 80 comments had been received from interested parties and that a revision of the draft was ongoing.

ECHA'S GUIDANCE DEFINITION OF PROLONGED CONTACT WITH THE SKIN (2014)

Prolonged contact of nickel with the skin is when it is potentially more than

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

Sihvonen gave an overview of the rationale behind the criteria for listing an article in the draft guideline. An item would be on the list if e.g.:

- surfaces of articles (or parts) are touched or are in touch with the skin;
- carrying an article, sitting on an article, leaning or holding on to it, or wearing it for a prolonged period may occur; and/or
- cases of contact dermatitis had been reported from its use and/or
- it was considered to be in direct and prolonged contact with the skin (see box).

Articles where contact would be for short discontinuous periods, e.g. door handles, or where articles were internal and inaccessible inner components of products, were considered outside the scope of the restriction[8].

As would be expected, both positive and negative comments about the draft guideline were received by ECHA.

Those in favour felt that the proposed guideline would help to prevent nickel allergy, would give much-needed clarification and inclusion of articles were well-founded. It was also suggested that articles coming into short-and repetitive contact could be considered at a later stage.

5. This directive (94/27/EC) had established nickel release limits for articles 'intended to come into direct and prolonged contact with the skin' and content limit for items used in body piercings (latter part amended in 2014 to introduce the release limit).
6. REACH (EC 1907/2006) aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. (http://ec.europa.eu/environment/chemicals/reach/reach_en.htm)
7. The restriction states that the rate of nickel release is not permitted to exceed 0.5 micrograms/cm^2/week in articles such as watches and jewellery that are intended to come into "direct and prolonged contact" with the skin.
8. ECHA 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

However, most comments were "negative" and expressed disagreement. Amongst others, these comments argued that:

- There was minimal scientific basis for the ECHA guidance definition of 'prolonged contact'
- Some articles did not have sufficient justification for their inclusion on the list of articles included under the nickel restriction
- The availability of alternative products and materials had not been discussed
- An impact assessment should have been performed
- There should have been greater emphasis on the enforcement of the existing restriction.

Concluding her presentation, Sihvonen said that ECHA would continue to work on the proposed guideline lists and revise the draft. CARACAL[9] members would be consulted in the autumn for discussion and possible endorsement at their meeting in November 2017.

9. CARACAL is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP. http://ec.europa.eu/environment/chemicals/reach/competent_authorities_en.htm

QUESTIONS FOR SIHVONEN

Speaking on behalf of the French Union of Musical Instruments Manufacturers (CSFI), **Coraline Baroux-Desvignes** was concerned that musical instruments were included in the draft ECHA list even though there was not continuous contact, e.g. guitar strings, and questioned the rationale behind their inclusion. **Kirsi Sihvonen** agreed that in the case of some musical instruments, if the hands were moving, it would not be a continuous contact. Baroux-Desvignes expressed concerns and pointed out that musical instruments should be excluded from the list, as no alternative metals existed for some instruments. In her view, it was very positive to have an opportunity to debate the issue and the matter should be further discussed.

Ansgar Wennemer (TÜV Rheinland) stressed that, to be relevant, continuous contact had to be with the same part of the skin and that this would not be the case, for example, when shaving with a razor. **David Basketter** felt that the target had to be a continuous contact with the same lymph node. **Kate Heim** (NiPERA) explained that the threshold for nickel-allergic reactions was based on a per cm^2 area of skin and this had to be taken into account if a larger area was involved, i.e.; more nickel had to be released to cause a dermatitis reaction.

Wennemer wanted to know if the inclusion of products in the proposed guideline was scientifically-based and if examples could be given. Sihvonen explained that the definition of prolonged contact was based on scientific literature. Inclusion of articles as described in the draft guideline was rather based on practical consideration. Heim commented that she thought the ECHA guidance definition of 'prolonged contact' was science-based, but based only on the very limited relevant information that had been available at the time, which was not sufficient to develop a robust and scientifically justified definition.

EXAMPLES OF ARTICLES PROPOSED TO BE WITHIN THE SCOPE OF RESTRICTION

GRIPS: umbrellas, scissors, garden (e.g. spades, shovels, rakes) and gym (e.g. dumbbell/kettlebell) tools and equipment, bikes and kick scooters.

HANDLES: prams, golf clubs, garden equipment (e.g. lawnmower, trimmer) handles of home equipment (e.g. vacuum cleaner), shower-head handles.

SEATS/ BACKS/ ARM RESTS: of chairs or similar furniture

RUDDERS, WHEELS, GEAR STICKS: for boats, ships, cars and other vehicles

TOOLS AND UTENSILS USED BY HAND:

ARTICLES: needles, pins, thimbles, knitting needles, knitting hoods, manicure/pedicure tools (e.g. nail files), tweezers, pencil sharpeners, other office equipment

HOLDING AREA: combs, hair brushes, writing instruments/mechanical pencil/ball point pens; mugs (including thermos mugs), tools (e.g. pocket knives, knives, hammers, 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.

04

EU RAPEX system and notifications: an overview and update

André Berends (European Commission) gave an overview of the Commission's Rapid Alert system for dangerous non-food products: RAPEX[10].

He explained the principles of EU Product Safety legislation that obliges producers to only place safe products on the market and authorities to ensure this rule is respected. He gave an overview of added value the Rapid Alert System provides to enforce these rules and the functionalities of the system. Berends said that notifications submitted in RAPEX must be accompanied by a risk assessment. The risk assessment is performed by the national authority and notifications are reviewed by the Commission before they are validated in the system.

> INFORMATION ON NEWLY REGISTERED ALERTS ARE PUBLISHED WEEKLY ON THE RAPEX WEBSITE TO INFORM CONSUMERS AND OTHER INTERESTED STAKEHOLDERS


ANDRÉ BERENDS

Explaining that the legal basis of RAPEX dated back to 2001 (General Product Safety Directive), Berends said there were currently 31 RAPEX members (the 28 EU Member States and the three EFTA/EEA countries). Berends noted that 'access' to RAPEX can be opened to other countries according to arrangements defined in agreements with those countries. Work is ongoing in this respect with Canada. The Commission is also working with China on product safety related issues based on a Memorandum of Understanding.

10. RAPEX is a mechanism for the rapid exchange of information if there is a concern (of a serious risk to the health of consumers).


MARTIN BAKER

NICKEL-RELATED NOTIFICATIONS IN RAPEX

- Between 2016-2017, 800 notifications concerned chemical risks
- 50 notifications concerned nickel
- The vast majority of nickel-related notifications referred to jewellery items and non-compliance with the nickel release limit; other notifications concerned products in the toy, cosmetics and clothing categories.

Describing the system's operation, which is managed by the Commission, Berends stated that if a measure was taken against a dangerous product, then the country would submit a notification in RAPEX through the national contact point. Notifications validated by the Commission would be circulated in the system and would be picked up by the market surveillance authorities of the other countries participating in the Rapid alert system, for follow up and action where necessary.

Information on newly registered alerts are published weekly on the RAPEX website to inform consumers and other interested stakeholders. Berends explained that it is now also possible to make personalised subscriptions to weekly 'alerts', based on a combination of specific key words chosen by the subscriber, such as "nickel" + a specific country + a specific product category.

https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.listNotifications:

The information meeting the criteria would be distributed by email to the subscribers providing timely and tailored updates. He also stated that companies such as Amazon use the system for getting information – about products and safety – to their supply chain.

QUESTIONS FOR BERENDS

Referring to the General Product Safety Directive, **Martin Baker** (AGOSI and convenor CEN TC 347 WG1) noted that it specified that a product had to be safe for its lifetime. He was concerned about the timeframe mentioned in the Nickel Directive for coated items, i.e. two years, and asked if consumers would be safe after this period.

André Berends felt the harmonised legislation was specific enough and that compliance with product safety is required for the entire life-time of a product. He referred to examples of cases notified in the Rapid Alert System that relate to safety issues identified on products that were placed on the market several years before. **David Basketter** added that if the surface coating was viable (i.e. compliant with the nickel release limit) for two years, then it was likely to be viable (compliant and protective) for much longer.

Kate Heim was interested in the example shown of a wooden toy car that had been notified in RAPEX due to an excessive amount of nickel being released by the tyre rivets (2.63 µg/cm^2/week). Heim argued that it was unlikely that any child would have prolonged contact with that part of such a toy.

Berends explained that the responsibility for a notification lay with the Member States as they flagged such items based on the outcome of their risk assessment, which may involve different use scenarios. The Commission evaluates whether the correct risk assessment principles have been applied. If there are concerns, the Commission can ask for clarification and get in touch with the relevant national authority to then decide whether to validate the notification.

05

Nickel dermatitis and NiPERA scientific research on “prolonged contact”

KATE HEIM

The focus of the presentation by **Dr. Kate Heim** (NiPERA) was on characteristics of nickel allergy and ongoing scientific research on ‘prolonged skin contact’. Stating that 12-15% of women and 1-2% of men were sensitised to nickel, Heim emphasised that although the problem was common, NACD was not life threatening. An important focus for the Nickel Institute, she added, was effective communication about nickel sensitisation (nickel allergy) across stakeholders and consumers, as this would help prevent nickel allergy and NACD.

Heim argued that nickel allergy could be prevented by avoiding direct and prolonged contact with items that could potentially release an amount of nickel above the defined threshold (the amount above which an allergic reaction could be caused).

CONDITIONS FOR NACD TO OCCUR

Direct skin contact with nickel-releasing items
+ Prolonged skin exposure to nickel
+ an amount of nickel – above the threshold - being released.

Heim stressed that time was a fundamental factor, as it was required for:

1. corrosion to occur and nickel ions to be released, via a liquid medium such as sweat, and
2. sufficient nickel ions to be released and absorbed by the skin.

Heim also explained that nickel was a weak sensitiser. She clarified that very low levels of nickel would not lead to sensitisation – measured by patch testing – and that the prevalence of nickel allergy could be attributed to the amount of exposure to nickel due to its many uses. Nickel allergy and NACD can result when high

> IT IS ESSENTIAL TO DEFINE THE CLINICALLY RELEVANT TIME FOR A NACD REACTION TO OCCUR IN ORDER TO PROVIDE AN ADEQUATE BASIS FOR THE NICKEL RESTRICTION AND ARTICLES INCLUDED WITHIN ITS SCOPE (...)

NIPERA'S SCIENTIFIC RESEARCH PROJECT

Heim explained that NiPERA was supporting an ongoing scientific project to generate data to determine a more robust definition of the 'prolonged contact' necessary to have an allergic reaction. She noted that the 2014 ECHA guidance definition of prolonged contact was based on information available at the time, which was not sufficient to derive a scientifically accurate definition of prolonged contact. The lack of available relevant data resulted in overly conservative assumptions. Therefore, new research was necessary to support a clinically relevant definition of prolonged contact and determine the amount of time needed to elicit NACD reactions.

This research project was started in 2015, with patch-testing of nickel-sensitive individuals for various times, using nickel metal discs. Phase 1 was completed in 2016 and the results were presented by the researcher (Dr. Rosemary Nixon) at the European Society of Contact Dermatitis meeting in September 2016. Results showed only one reaction in any of the test subjects, at times tested shorter than 48 hours (maximum 3x60 minutes or 1x2 hours). However, reactivity in only one of 20 individuals is not sufficient to define prolonged contact under the nickel restriction since it is meant to protect most nickel-allergic people from having a NACD reaction and all non-allergic people from becoming allergic.

Phase 2 was conducted with the same testing protocol but with nickel-plated brass discs as these have a higher nickel-release rate and would be more representative of materials used in the products in the marketplace that caused NACD. This phase was started in autumn 2016 and preliminary results were available in May 2017. As in Phase 1, only one person reacted at times tested shorter than 48 hours, so no definition of prolonged contact could be derived.

The overall conclusion was that the ECHA guidance definition of prolonged contact was much shorter than the time taken for any nickel-sensitised individuals to react, and that more testing is needed to accurately define prolonged skin contact. Heim noted that it is essential to define the clinically relevant time for a NACD reaction to occur in order to provide an adequate basis for the nickel restriction and articles included within its scope, since current tests did not show sufficient reactions.

There is a need to test for longer time periods – this could logically be a third phase. This next phase could possibly test, in parallel, different parts of the body (i.e. sites of previous NACD reactions or initial sensitisation) or areas of the body that were thought to be more sensitive (i.e. ear lobes, forearms). Additionally, tests on soluble nickel could be undertaken as this would bring interesting information to the table as 'worst-case' for nickel release.

nickel-releasing materials are used inappropriately and come into direct and prolonged skin contact.

Heim stated that the prevalence of nickel allergy in the general population was primarily due to such inappropriate uses, and especially the popularity of piercing (e.g. with high nickel-releasing jewellery) among both men and women. Heim stressed that it is nickel release, and not nickel content, which is the critical factor in assessing risk of nickel allergy or NACD. This was indicated by the change to the Nickel Directive in 2004, to restrict the release rather than the content of nickel for all uses. Previously, the Directive restricted nickel content in piercing materials. Heim also pointed out that some nickel-containing materials – as wrist watches made from stainless steel containing 9-28% of nickel – had not been reported to cause nickel allergic reactions.

OVERALL RESULTS OF THE RESEARCH PROJECT (PHASES 1 AND 2)

- Results showed that the ECHA guidance definition of prolonged contact was not consistent with the clinical reactivity for pure nickel metal or Ni-plated brass
- DMG test results were not consistent with EN1811 test results for nickel metal
- Insufficient reactions were seen at times tested to accurately define prolonged contact- longer times need to be tested (Phase 3)

QUESTIONS FOR HEIM

David Basketter found Heim's test results to be interesting and commented that he had heard of a Swedish paper that had concluded that testing in nickel sulphate (soluble nickel) required at least five hours to cause nickel allergic reactions.

Martin Baker (AGOSI and convenor CEN TC 347 WG1), wanted to know if patch tests could be conducted regarding piercings, as in these cases the skin would be broken. Heim said surface patch testing could be carried out but it would be hard to test internally. Basketter added that scarified skin testing was a possibility but it might be hard to find volunteers.

Dippal Manchanda (the Birmingham Assay Office, AnchorCert Group, UK), asked why pure nickel metal discs had been used. Heim said the tests had been an attempt to have high nickel releasing material, that was representative of fashion jewellery. However, realising that nickel metal discs may not have fulfilled those criteria, Phase 2 of the project was launched to carry out patch testing using nickel-plated brass discs.

Manchanda argued that rather than pure nickel metal, if German Silver, for example, had been used, then the results would have been different. He suggested testing other alloys for comparative purposes. Heim stated that there might have been more reactions but she was not sure of the relevance of these materials for articles used in direct and prolonged skin contact, which is important in deriving a relevant definition of prolonged contact for NACD.

> IT IS NICKEL RELEASE, AND NOT NICKEL CONTENT, WHICH IS THE CRITICAL FACTOR IN ASSESSING RISK OF NICKEL ALLERGY OR NACD

06
Market perspective

Speaking on behalf of the CEIR[11], the European Taps and Valves industry association, **Holger Fehrholz** (Similor AG) opened his presentation by explaining that industry supported the legislation restricting the use of nickel in articles in prolonged skin contact (entry 27, Annex XVII, REACH Regulation). This is important as nickel allergy was widespread in the EU.

However, he noted that the sanitary industry does not consider that it produces articles intended to come into prolonged contact, such as those items listed as examples in the nickel restriction (e.g. jewellery, wrist watches, etc.). Fehrholz explained that manufacturers in the sector were using nickel plating to make articles resistant to corrosion, which is necessary as these products need to withstand corrosive chemical agents used for bathroom cleaning.

Fehrholz reviewed the proposed ECHA guideline draft list(s) of articles to be considered in the scope of the nickel restriction, which includes mobile phones, grips, handles etc., (based on the ECHA guidance definition of prolonged contact) and musical instruments (based on reported cases of NACD). He also examined items in the draft list of articles considered outside of the scope: household fittings, kitchen tools, coins etc. Overall, Fehrholz expressed surprise and concern about the proposed


HOLGER FEHRHOLZ


MARCEL DUTRIEUX


MARKKU PAVELA

11. CEIR is the European Association for the Taps and Valves Industry - https://www.ceir.eu/

guideline lists of articles issued by ECHA in January 2017. He felt that the definition of 'prolonged contact' gave a rather short timeframe and that there was insufficient detail as to why some articles were included in the non-exhaustive list, e.g. professional tools, and some excluded, e.g. domestic use of tools.

Fehrholz said that CEIR had contributed to the ECHA public consultation on the draft guideline lists and, although the association generally supported the objectives, it had strong concerns about the broad extension of the scope of the nickel restriction.

CEIR's opinion was that there had been a vast extension of the scope of the restriction and that this could not be justified, due to a lack of scientific evidence. The industry was also concerned that there had been no analysis of usage patterns and no impact assessment.

For CEIR, the inclusion of articles such as shower-head handles would lead to higher prices and increased costs for the manufacturers, with no obvious improvement in the health of consumers and prevention of nickel allergy.

THE CASE OF HAND-SHOWERS

- User behaviour not properly studied
- According to a JRC report, EU average shower time, 7 minutes/day – hand shower held for 30% of that time. This is below the ECHA 10 minutes prolonged contact guidance definition
- 400 million shower outlets in Europe – no case of NACD reported
- CEIR wants hand-showers taken out of scope as their inclusion is not justified

In conclusion, Fehrholz highlighted that CEIR called for a revision of the ECHA proposed guideline lists and the removal of shower-head handles and other products from the draft list of articles, stressing that their inclusion should be justified based on data and user patterns, not assumptions.

QUESTIONS FOR FEHRHOLZ

Markku Pavela, occupational physician at Boliden Harjavalta, agreed with Fehrholz's remarks and noted that, over the last ten years, he had not seen any new NACD reactions at their plant. This viewpoint was shared by The Toro Company's **Marcel Dutrieux** who also urged for more scientific assessment before items were placed on the list of articles, in or out of the scope.

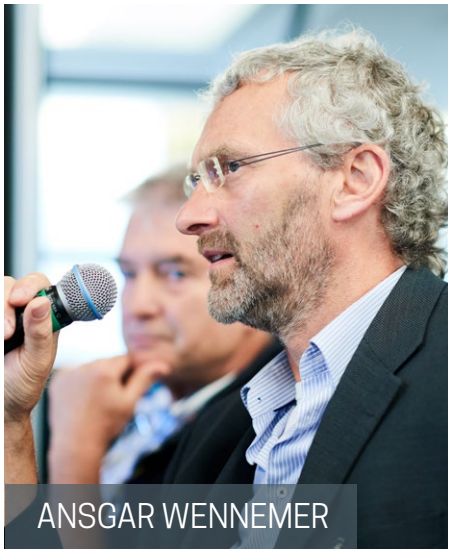
David Butler, Nickel Institute, felt that the presentation and the subsequent comments had come as a breath of fresh air as they were based on practical knowledge. He did acknowledge that real problems existed, such as in the realm of costume jewellery and piercings. However, Butler felt that by broadly extending the guidance list of articles, ECHA was diverting the focus away from the real problems and the articles that are the main causes of nickel sensitisation.

07

Dermatology clinic perspective

JACOB THYSSEN

Coming to the podium, Gentofte University Hospital's **Professor Dr. Jacob Thyssen** said he agreed with **Butler** that the discussion about nickel exposure had sometimes been derailed. He argued that the primary point of examination should be sensitisation and that the main problem remained 'piercing'. Thyssen stressed the importance of also involving patients in the debate.



ANSGAR WENNEMER

Thyssen was of the opinion that there was too much discussion about items where there could be brief contact with the skin, such as door handles, and this was reducing the focus on the main issue, i.e. nickel sensitisation and how to prevent it.

Thyssen acknowledged that nickel allergic dermatitis is ubiquitous and nickel is consistently the number one allergen in patch test populations. Indeed, some individuals – once sensitised - reacted to very low concentrations. However, Thyssen stressed that nickel allergy is preventable. It has decreased, thanks to the regulation, or an increased sense of responsibility by manufacturers. However, there are still persistently high prevalence rates, particularly in some countries (e.g. Spain, Lithuania). On the other hand, in some countries progress has been made and nickel allergy prevalence has been reduced significantly.

Thyssen gave several reasons for the persistence of nickel allergy, such as

regulations not being complied with. He emphasised the lack of sufficient enforcement by national authorities.

While there are generally fewer problems with items sold in well-known chains or high street shops, there is the presence on e.g. street markets of articles such as jewellery items that are not compliant with the regulation and have nickel release rates which are too high. This was because of the lack of control on items sold in street markets. There should be more focus on better enforcement. Thyssen also stressed that some populations can be more vulnerable to nickel allergy, for example, children. Nickel allergy is also more prevalent amongst persons affected by atopic contact dermatitis. In addition, Thyssen noted that there are periodically new devices developed and put on the market, which can involve prolonged skin contact.

Thyssen concluded with a reference to a new electro-chemical detection method for nickel release, currently under development, that could replace the traditional DMG screening test. This had been proven in tests on products from Japan, the UK and Poland. He claimed that sensitivity could be improved.

REASONS FOR THE PERSISTENCE OF NICKEL ALLERGY

- Sensitisation before regulation - older individuals
- The regulation was too weak
- Violation of the regulation
- Lack of control by authorities
- New items cause nickel allergy – e.g. laptops, phones
- Other sources not covered by regulation: toys, medical devices, coins, occupational

QUESTIONS FOR THYSSEN

Ansgar Wennemer (TÜV Rheinland) expressed interest in the new electro-chemical detection method for nickel release. He asked for clarification about its efficiency, wondering if corrosion and nickel release was not accelerated by electricity and the process itself. Wennemer said they had tried a similar electro-chemical test method a few years ago with spectacle frames and they had some difficulties as they found the method was accelerating corrosion and tests had shown an incorrect range of nickel release.

Jacob Thyssen acknowledged that the process does accelerate corrosion to some extent, and it is intended to do so, to measure the nickel release. However, the real question is whether the device is over-releasing nickel, to a point that is not clinically relevant. This aspect has still to be investigated. He also added that the sensitivity could increase but not dramatically.

08

Survey of nickel metal - investigation of causes of nickel allergy

MALIN AHSTRÖM

Dr. Malin Ahlström (Allergy Research Centre, Gentofte University Hospital, Denmark) introduced the results of a study conducted by the University Hospital's National Allergy Research Centre on behalf of the Danish Environmental Protection Agency (EPA)[13].

The aim was to investigate the causes of nickel allergy and to assess if citizens were being sufficiently protected by the EU nickel legislation. As part of the study, the team reviewed literature (published between 2005-2015) regarding the prevalence of nickel allergy in EU countries, since the implementation of the nickel regulation. The results showed that there was a preventative effect of the nickel regulation, with a decrease of NACD e.g. for young women in Denmark and for dermatitis patients under the age of 16 in some EU countries.

However, it could be concluded that young women were still becoming sensitised to nickel. There was a persistent high prevalence of nickel allergy across Europe. There were geographical differences, with a higher prevalence in southern European countries than those in the north for all age groups combined.

> EARRINGS ARE THE LEADING CAUSE OF ALLERGIC NICKEL DERMATITIS

Within the general population, prevalence ranged from 8% in Sweden to 18% in Portugal. Among dermatitis patients, the prevalence ranged from 11.9% in Germany to 26.4 % in Spain. A second phase of the study involved a questionnaire survey addressed to 541

13. "An investigation of causes of nickel allergy", a LOUS follow-up project, Danish Environmental Protection Agency, 2016

nickel allergic patients in Denmark, who reacted positively to a patch test (nickel sulphate). The response rate to the questionnaire was 63.2% (318 women, 24 men).

These responses showed that earrings were the leading cause of allergic nickel dermatitis, followed by other jewellery, buttons on clothing, wrist watches, belt buckles and zips. They also found that a significant number of patients reported dermatitis within a few minutes of contact with a metallic item: 26% within 30 minutes.

MAIN CONCLUSIONS OF THE STUDY

- Substantial decrease in nickel allergy in young women following nickel regulation introduction
- Decreases more prominent in northern Europe than in the south
- Persistent high prevalence among young women
- Earrings represent a particular problem as skin pierced
- Length of contact for a reaction to occur is in good agreement with recent definition of 'prolonged contact'.

QUESTIONS FOR AHLSTRÖM

In response to a question about the north-south divide in terms of the prevalence of NACD, **Ahlström** acknowledged that this could be due to a lack of enforcement and perhaps the more likelihood of sweat being an issue in southern European countries. This is because sweat would increase corrosion of the material, resulting in higher release rates for nickel. However, she acknowledged that there had been relatively few studies conducted in southern Europe.

Workshop moderator, **David Basketter** felt that the results of Danish EPA study were interesting and commented that regulations had been put in place but there seemed to be reliance on ad-hoc studies rather than on a formal system of monitoring post-legislation.

09

Implementation and enforcement: update on national activities

DURK J. SCHAKEL

With enforcement as an important item on the agenda, the Netherlands Consumer Product Safety Authority's **Durk J. Schakel** gave an overview of his organisation's work and the emphasis on consumer safety. He explained that authorities have to focus their compliance checks and enforcement efforts on key priorities, as it is not possible to check all the articles and products on the market.
Schakel reported that in 2015, the Dutch Consumer Product Safety Authority conducted a market surveillance study on the compliance of imported jewellery with the existing restrictions on lead and cadmium, but not nickel. This included a review of the cheaper end of the jewellery market (with prices from five to 40 euros). The 2015 study found that seven out of ten importers were not in compliance with the restrictions on cadmium and lead. In 2016, the market surveillance investigation on jewellery was conducted again but the scope of the testing was extended to nickel release. The focus was on earrings and necklaces, not made exclusively of silver, gold and platinum, available in department stores, fashion and jewellery shops.

The testing in their 2016 study included screening for the presence of nickel with testing on the part of the article where the skin was pierced. Tests were restricted to the area where the skin was penetrated. Testing to assess if a coating was present was then done. If a coating existed, then a corrosion test was then carried out

according to EN 12472[14].
Schakel explained that six separate sub-samples were taken for each type of earring. The migration tests were conducted according to EN 1811:2011. He emphasised that the process – including taking measurements using a micrometre – was extremely time-consuming. An average of three (nickel) migration results was taken for each sample. As an aside, Schakel noted that there were many difficulties for an enforcement laboratory in dealing with EN 1811.

The results, which were published on the website[15] of the Dutch authorities, indicated that out of 56 samples (earrings), four were not compliant with the nickel release limit. In particular, three samples had a significant nickel release rate, resulting in risk in terms of nickel sensitisation and NACD reactions.

MAIN CONCLUSIONS OF THE STUDY

- Of the 56 earrings tested, four were non-compliant with the nickel release limit
- EN 1811 testing is very time consuming
- Further clarity needed as to how to deal with results in triplicate
- Measurement of uncertainty methodology is questionable.

> “OF THE 56 EARRINGS TESTED, FOUR WERE NON-COMPLIANT WITH THE NICKEL RELEASE LIMIT”

14. European standard, EN 12472:2005+A1:2009 “Method for the simulation of wear and corrosion for the detection of nickel release from coated items”
15. https://www.nvwa.nl/nieuws-en-media/nieuws/2017/05/23/nvwa-een-vijfde-van-onderzochte-sieraden-bevat-te-veel-cadmium-lood-of-nikkel

QUESTIONS FOR SCHAKEL

Martin Baker (AGOSI and convenor CEN TC 347 WG1) was interested to hear that Schakel had mentioned that the EN 1811 testing was difficult, as this was not widely understood. He noted that in Germany the assessment of compliance is not based on the mean of three testing results, as taking an average would lead to distortion. Schakel felt it all depended on the quality of the batch in question.

Ansgar Wennemer (TÜV Rheinland) said there was a need to go back to the manufacturer if the results were not homogeneous. Schakel agreed but added that the manufacturer could be lucky if all three were below the limit or unlucky if only one was above the limit.

10

The perspective of standardisation and testing experts


DIPPAL MANCHANDA

> EVEN IF THE DMG TEST IS PROVEN TO BE NOT RELIABLE, ECHA STILL RELY ON DMG TEST DATA TO MAKE IMPORTANT DECISIONS

Dippal Manchanda, Technical Director at AnchorCert Analytical (Birmingham Assay Office), presented the results of a study that compared two nickel release testing methods – PD CR 12471:2002[16] (DMG test) and EN 1811:1998. This study had been conducted in 2006 at the request of NiPERA. Four leading laboratories took part in the project and 11 homogeneous materials were tested. Manchanda explained that it was expected that all the laboratories would give similar results concerning nickel release but this was not the case.

Prior to the tests being conducted, Manchanda said that precautions were taken to ensure that there were no surface impurities. Looking at the results in total, he said it had been difficult to reach conclusions especially as there was little consistency, i.e. the materials had passed on one occasion and then subsequently failed, furthermore, different laboratories gave different results.

Summing up, Manchanda said that if only the DMG test (PD CR 12471:2002) was used to assess compliance, 17% of items tested would have gone to the marketplace despite being non-compliant using EN 1811 (DMG false negatives) while 35% would have been excluded from the marketplace despite being compliant using EN 1811 (DMG false positives). Overall, the results had confirmed that PD CR 12471:2002 itself was not sufficiently accurate to be used as an alternative to EN 1811.

Given that the current compliance limit with the new EN 1811 was 18 times lower than before, Manchanda asked if a DMG-based test is still relevant and could accurately detect such a low level of nickel. He concluded that the DMG test was not reliable. However, he noted that some, including ECHA, still rely on DMG test data to make important decisions.

16. Dimethylglyoxime (DMG) nickel-screening test.

TEST MATERIALS USED IN THE COMPARATIVE STUDY

- Metallic nickel
- Cupro nickel
- German silver
- Monel nickel
- Carbon steel
- 304 stainless steel
- 316 stainless steel
- 430 stainless steel
- Nitinol
- 303 stainless steel
- 18 carat white gold

QUESTIONS FOR MANCHANDA

Martin Baker (AGOSI and convenor CEN TC 347 WG1) looked to the future and thought it highly likely that they would have to test articles that have 30 minutes' contact with the skin over two weeks. He wanted to know if the current EN 1811 was suitable for such testing.
Dippal Manchanda said there was nothing wrong with EN 1811 as long as all laboratories followed the same procedure for longer time frames.
David Basketter felt that Baker had asked a valid question as EN 1811 had been developed to test articles that had been designed for continuous contact for several hours e.g. pierced earrings. Was the EN 1811 the right tool for testing material that might be hand-held only three times in two weeks?
Subsequent comments from the floor indicated that it may be necessary to look at replacing or adjusting EN 1811 for articles that had occasional contact with the skin.

Kate Heim suggested that a shortened EN 1811 test for, say, 30 minutes, might be needed but would have to be validated with clinical data of similar time frames. Baker confirmed that the EN 1811 test was designed for longer skin contact and it was not relevant for testing the types of articles that had been included in the draft ECHA guideline list, where the contact with the skin was not continuous. He argued that manufacturers would be asking the testing bodies what the procedures are for testing the products added to the scope of the restriction. Baker felt that the testing bodies were not adequately equipped for appropriate testing of the newer types of contact being included under the EU nickel restriction. Heim proposed going back to the original study[17] to address the modifications in time of exposure and associated nickel release limits associated with clinical reactivity.

Summing up, Basketter said that EN 1811 had been designed for prolonged contact, e.g. jewellery. He suggested that a future project could be to look at new testing methods, for articles that had occasional contact with the skin.

17. Menné T, Brandup F, Thestrup-Pedersen K, Veien NK, Andersen JR, Yding F, Valeur G. Patch test reactivity to nickel alloys. Contact Dermatitis. 1987; 16:255-9.

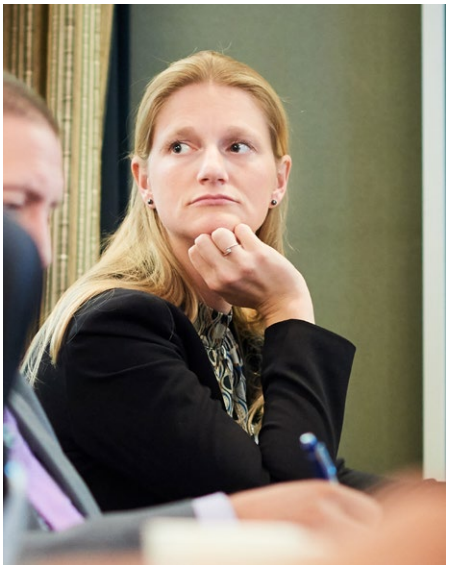
11 Q&As

David Basketter invited further questions.

Coraline Baroux-Desvignes (CSFI - French Union of Musical Instruments Manufacturers) said that a dermatologist study had shown that there were some musicians who had developed NACD from jewellery but were now allergic to instruments. She asked if a warning label system could be developed so that consumers could be warned against products that contained nickel.

Ansgar Wennemer (TÜV Rheinland) pointed out that, in his opinion, it is always possible to have a label on a product, as according to product safety legislation, manufacturers have to inform consumers about any risks from the product.

Kirsi Sihvonen (ECHA) explained that under current EU legislation (i.e. CLP Regulation 1272/2008) there are labelling requirements for substances and mixtures but not articles. If it was to be pursued, then the relevant regulation and the current restriction would need to be amended. Basketter noted, that warning labels have been in place for fragrance allergens already for ten years, but fragrance allergy prevalence has increased.



A participant asked if Manchanda was certain that EN 1811 was useful and reliable given the discrepancy in the results that were shown earlier. Manchanda reiterated that, in his opinion, the test had no flaws but the results could differ due to irregularities in the surface properties of standard discs. The questioner was confused as Manchanda had said that all the discs were the same. Manchanda insisted that even if there just a small discrepancy, corrosion could kick in – it was a material problem.

An Hagenaars (Umicore) asked when the final ECHA guidelines would be issued. Sihvonen said the current aim was to update the draft guideline based on comments received in the consultation period and during this workshop. The issue would be discussed at a CARACAL meeting later in the year and the Member States would also have their say. If new studies were to be undertaken, this could change the timing of agreement on the draft guidance lists of articles.

12 Conclusions

David Butler started his closing statements by saying that the Nickel Institute acknowledged NACD was a serious issue. It was a tragedy for anyone affected but it had to be remembered that it was not life-threatening. He felt that the day's workshop had confirmed that it is essential to pay attention to the leading causes of contact dermatitis and not to lose sight of the main issue, which is sensitisation, with ear piercing being the main problem. Butler insisted that NACD is preventable. Regulations seem to have had a positive impact but is regulation the right solution to achieve the objective to further reduce the prevalence of nickel allergy?

Butler noted that the colleagues of other industries were quite clear in saying that they did not hear of any complaints from their workforce or their customers, which is very positive. At the same time, for those suffering from nickel allergy, the issue remained serious. **Durk Schakel** had explained about the complexity of testing and the challenges of enforcement authorities. This led Butler to ask if an extension to the list of examples of articles currently in the nickel restriction would potentially improve the situation, as this would lead to more EN 1811 testing and additional costs, or rather should the focus be on the real problem, allowing valuable regulatory resources to be invested where better compliance can bring the solution.

> IT IS ESSENTIAL TO PAY ATTENTION TO THE LEADING CAUSES OF CONTACT DERMATITIS AND NOT TO LOSE SIGHT OF THE MAIN ISSUE, WHICH IS SENSITISATION, WITH EAR PIERCING BEING THE MAIN PROBLEM

Butler concluded by arguing that the answer was not to increase the need to test more articles and that it was not necessary to add items that were used on a more short-term basis. This would result in potential stigmatization of many products, for which there is no apparent evidence that they contribute to the nickel allergy problem.

Butler summed up by saying a pause was necessary to step back and look at the whole issue. The Nickel Institute would continue to conduct research projects, contribute to scientific literature and pursue its dialogue with regulatory authorities and stakeholders.

The workshop wrapped up with appreciation shown for the chairperson, speakers, and attendees.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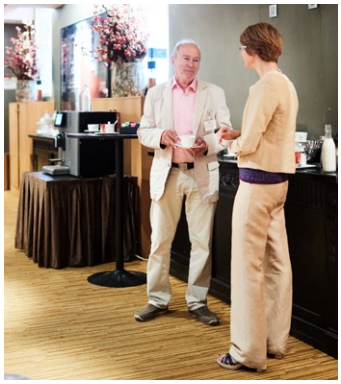

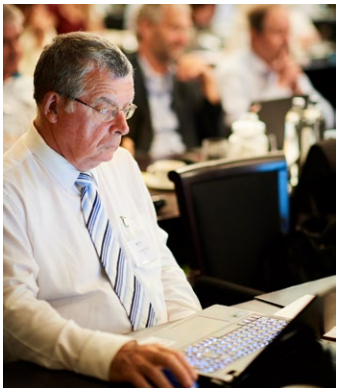


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Appendices

AGENDA

9.30 **Welcome and introduction**
Mr. D. Butler, President, Nickel Institute

Properties and uses of nickel: an overview
Mr. T. Newson, Consultant to Nickel Institute

EU nickel restriction: background and ECHA activities
Ms. K. Sihvonen, Scientific Officer, European Chemicals Agency

EU RAPEX system and notifications: an overview and update
Mr. A. Berends, RAPEX Team Leader, DG JUST, European Commission

11.00-11.30 Coffee break

Nickel dermatitis and NiPERA scientific research on "prolonged contact"
Dr. K. Heim, Senior Human Health Toxicologist, NiPERA

Market perspective
Mr. H. Fehrholz, European Association for the Taps and Valves Industry (CEIR), Similor AG

Dermatology clinic perspective
Prof. Dr. J.P. Thyssen, Gentofte University Hospital, Denmark

12.45-13.45 Lunch

Survey of nickel metal – investigation of causes of nickel allergy
Dr. M. G. Ahlström, Gentofte University Hospital, Allergy Research Center, Denmark

Implementation and enforcement: update on national activities
Mr. D.J. Schakel, Researcher, Consumer Product Safety Authority, The Netherlands

The perspective of standardisation and testing experts
Dr. D. Manchanda, Technical Director, Birmingham Assay Office, UK

Discussion - Q&As

15.45-16.00 **Conclusions**

REGISTERED PARTICIPANTS

AGOSI	Martin Baker
Allergy Research Center, Gentofte University Hospital	Malin Ahlström
Beama	Adrian Regueira Lopez
BeCOH	Steven Verpaele
BIC	Aurelie Pagniez
BIC	Aline Usson
Birmingham Assay Office	Dippal Manchanda
Boliden Harjavalta	Markku Pavela
CEIR - PROFLUID	Julien Chalet
CEIR / (Taps and Valves Industry), Similor AG	Holger Fehrholz
Certottica	Giuseppe Da Cortà
CETS	Malte-Matthias Zimmer
CSFI - Chambre Syndicale de la Facture Instrumentale	Coraline Baroux-Desvignes
Danish EPA	Trine Thorup Andersen
DIGITALEUROPE	Sarah Wagner
Dutch Consumer Product Safety Authority	Durk Schakel
ECI - European Copper Institute	Katia Lacasse
ECHA	Kirsi Sihvonen
EUROFER	Anna-Maria Kaczmarek
EUROFER	Hans Regtuit
Eurometaux	Lorenzo Zullo
European Commission - DG GROW	Enrique Garcia John
European Commission - DG JUST	André Berends
FEC (European Federation of Cutlery , Flatware, etc.)	Gustaaf Bos
Forschungsgemeinschaft Werkzeuge und Werkstoffe e.V.	Samuel Zind
Gentofte University Hospital	Jacob Thyssen
Grohe AG	Norbert Lange
Hansgrohe SE	Werner Heinzelmann
Hansgrohe SE	Christoph Tschaar
Mission of Canada to the EU	Nicola Waterfield
Moderator	David Basketter
Nickel Institute Consultant	Tony Newson
Nickel Institute	David Butler
Nickel Institute	David Chen
Nickel Institute	Christian Richter
Nickel Institute	Isaline de Baré
Nickel Institute	Clare Richardson
Nickel Institute	Veronique Steukers
Nickel Institute	Marco Vallini
NiPERA	Katherine Heim
Philips	Claudia Albuquerque
Premec SA	Fausto Conti
Rapporteur	John Chapman
Staedtler Mars GmbH & Co. KG	Alexander Vyhnal
Surface Engineering Association	David Elliott
The Toro Company / EGMF	Marcel Dutrieux
TIE - Toy Industries of Europe	Lars Vogt
TÜV Rheinland	Ansgar Wennemer
Umicore	An Hagenaars
Vale	Michael Shepherd
VDMA	Sylvi Claussnitzer
Wieland-Werke AG	Birgit Twrdek

ENTRY 27, ANNEX XVII, REACH REGULATION:

Nickel CAS No 7440-02-0 EC No 231-111-4 and its compounds

1. 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/ cm 2 /week (migration limit);

(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,

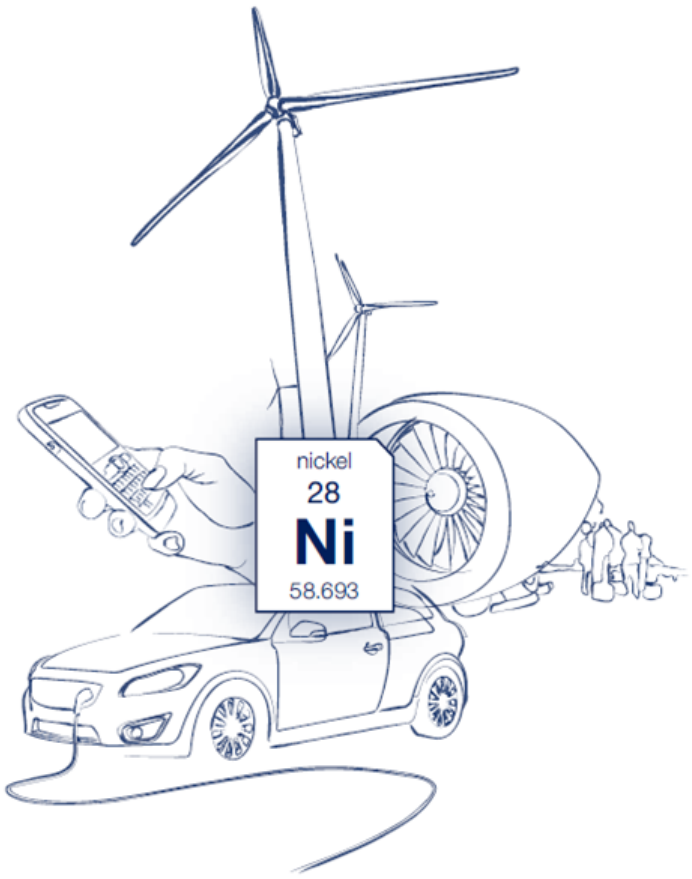
if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm^2/week.

2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.

3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.

28
Ni
Nickel

The Nickel Institute is the global association of leading primary nickel producers. Our mission is to promote and support the use of nickel in appropriate applications. NI grows and supports markets for new and existing nickel applications including stainless steel; and promotes sound science, risk management, and socio-economic benefit as the basis for public policy and regulation. Through our science division NiPERA Inc. (www.nipera.org), we also undertake leading edge scientific research relevant to human health and the environment. NI is the centre of excellence for information on nickel and nickel-containing materials and has offices in Asia, Europe and North America.



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