

Revision of the European standard for control of the EU nickel restriction – a probable improvement for European citizens

doi:10.1111/j.1600-0536.2011.01928.x

Dear Sir,

EU member states began regulating consumer nickel exposure in 1994, when the EU Nickel Directive was passed (1). Entry into force in 2000 was linked to the publication of the reference test methods for control of compliance with the regulation developed by CEN (2), namely, EN 1811, EN 1810, and EN 12472. The Nickel Directive has been in Annex XVII of REACH since 2009, and it was amended in 2005 in terms of replacing the nickel content limit for piercing posts by a release limit (Table 1). Consumer items such as jewellery, buttons, zippers, hair clasps, mobile phones and belt buckles should not release more than 0.5 µg nickel/cm²/week, and piercing posts not more than 0.2 µg nickel/cm²/week. EN 1811 states how the item under investigation is placed in artificial sweat for 1 week before nickel in the solution is analysed and the release rate calculated (3). As we recently described, the initial version of EN 1811:1998 had a major weak point, as it allowed multiplication of

the measured nickel release value by 0.1 ('adjustment factor') before interpretation of compliance (Table 1) (1). Thus, in theory and practice, items such as jewellery, hair clasps, buttons and zippers that released up to 5 µg nickel/cm²/week and piercing posts that released up to 2 µg nickel/cm²/week were considered to comply with the restriction, despite the fact that they would cause nickel allergy and dermatitis (4). The 'adjustment factor' was introduced in the first version of the standard to compensate for difficulties in calculating complicated area sizes, inter-laboratory variations, and the limited experience with the method. Hence, instead of nickel release being limited to the intended 0.5 and 0.2 µg nickel/cm²/week, it was, in reality, limited to 5 and 2 µg nickel/cm²/week.

Despite a marked decrease in nickel allergy and nickel dermatitis in young women after the nickel regulation came into force (5–8), the prevalence of nickel allergy remains very high, and seems to have stabilized at a high level, for instance in young female German dermatitis patients (9). There may be several explanations for this finding (1), but it is generally accepted that excessive nickel release from consumer items is one of the most important single factors. By using the dimethylglyoxime (DMG) test, a simple and rapid spot test in which a pink

Table 1. Interpretation of conformity with the EU nickel restrictions in REACH (former Nickel Directive)

Articles and limit value for nickel release	Interpretation of measurement results regarding conformity with the nickel restriction	
	Old EN 1811:1998 + A1:2008, multiplication of analytical result by 0.1 ('adjustment factor')	New EN 1811:2011, 'uncertainty interval'
Post assemblies inserted into pierced ears and other pierced parts of the body, <0.2 µg/cm ² /week	Items with nickel release <2 µg/cm ² /week are considered to comply	Non-compliant, ≥0.35 µg/cm ² /week Compliant, ≤0.11 µg/cm ² /week No clear decision, >0.11 and <0.35 µg/cm ² /week*
Articles intended to come into direct and prolonged contact with the skin, <0.5 µg/cm ² /week	Items with nickel release <5 µg/cm ² /week are considered to comply	Non-compliant, ≥0.88 µg/cm ² /week Compliant, ≤0.28 µg/cm ² /week No clear decision, >0.28 and <0.88 µg/cm ² /week*

*It is important to understand that, for articles that fall in the 'no clear decision' categories, there is not sufficient probability for enforcement or test laboratories to justify a result of non-compliance. Further guidance on the interpretation of measurement uncertainty is detailed in annex A of EN 1811:2011. Comparison between the old and the new revised European reference test method EN 1811.

colour indicates release of $>0.5 \mu\text{g nickel}/\text{cm}^2/\text{week}$, investigators have shown that 20–25% of mobile phones (10, 11), 10–15% of earrings (12, 13) and up to 80% of hair clasps intended for children (14) purchased in EU countries are DMG test-positive, and hence release nickel in concentrations that may cause nickel allergy and dermatitis. It is of particular importance that the DMG test has high specificity and moderate sensitivity in relation to the $0.5 \mu\text{g nickel}/\text{cm}^2/\text{week}$ limit value (3). This means that it does not detect all items with nickel release $>0.5 \mu\text{g}/\text{cm}^2/\text{week}$. Despite this, the DMG test is considered to be very useful for screening purposes, and we recommend it for monitoring individual exposure and surveys of the market.

We have long argued that the 'adjustment factor' of 0.1 should be removed or at least replaced, to protect consumers as intended. An EC mandate 2007 to CEN for revision of EN 1811:1998 did ask for a revised standard without an adjustment factor, or with a smaller adjustment factor, if appropriate. In January 2011, CEN adopted the revised EN 1811. The most important amendment is that the 'adjustment factor' has been replaced by 'uncertainty intervals', so that items with nickel release $\geq 0.88 \mu\text{g}/\text{cm}^2/\text{week}$ (articles intended to come into direct and prolonged contact with the skin) and $\geq 0.35 \mu\text{g}/\text{cm}^2/\text{week}$ (post assemblies inserted into pierced ears and other pierced parts of the body), will be deemed to be non-compliant (Table 1). Additionally, a

new annex has been included to give practical guidance about enforcement, and information to test laboratories about how to test for nickel release from a variety of consumer articles. EN 1811:2011 was published by CEN in February 2011 (personal communication by M. Baker, convenor of CEN/TC 347/WG 1, 16 March 2011). The adopted standard shall then immediately be used as the test method for demonstrating conformity of articles with the nickel restriction of REACH (personal communication by S. Pickering, European Commission, 23 March 2011).

We welcome this revision of EN 1811, and estimate that it will result in further decreases in nickel allergy and dermatitis in Europe. Nevertheless, continuous epidemiological monitoring of contact allergy and nickel exposure is still necessary to determine the effectiveness of the regulation, which may still need future amendment to reduce nickel allergy further.

Jacob P. Thyssen¹, Wolfgang Uter², Torkil Menné¹ and Carola Lidén³

¹Department of Dermato-Allergology, National Allergy Research Centre, Copenhagen University Hospital Gentofte, DK-2900 Hellerup, Denmark, ²Department of Medical Informatics, Biometry and Epidemiology, Friedrich Alexander University, Erlangen-Nürnberg, 91054 Erlangen, Germany, and ³Institute of Environmental Medicine, Karolinska Institutet, 10005 Stockholm, Sweden

Conflicts of interest: The authors have declared no conflicts.

References

- 1 Thyssen J P, Uter W, McFadden J et al. The EU Nickel Directive revisited – future steps towards better protection against nickel allergy. *Contact Dermatitis* 2011; **64**: 121–125.
- 2 Lidén C, Johnsson S. Nickel on the Swedish market before the Nickel Directive. *Contact Dermatitis* 2001; **44**: 7–12.
- 3 Thyssen J P, Skare L, Lundgren L et al. Sensitivity and specificity of the nickel spot (dimethylglyoxime) test. *Contact Dermatitis* 2010; **62**: 279–288.
- 4 Menné T, Brandup F, Thestrup-Pedersen K et al. Patch test reactivity to nickel alloys. *Contact Dermatitis* 1987; **16**: 255–259.
- 5 Schnuch A, Uter W. Decrease in nickel allergy in Germany and regulatory interventions. *Contact Dermatitis* 2003; **49**: 107–108.
- 6 Thyssen J P, Johansen J D, Menné T, Nielsen N H, Linneberg A. Nickel allergy in Danish women before and after nickel regulation. *N Engl J Med* 2009; **360**: 2259–2260.
- 7 Thyssen J P, Hald M, Avnstrøm C et al. Characteristics of nickel-allergic dermatitis patients seen in private dermatology clinics in Denmark: a questionnaire study. *Acta Derm Venereol* 2009; **89**: 384–388.
- 8 Thyssen J P, Linneberg A, Menné T, Nielsen N H, Johansen J D. The association between hand eczema and nickel allergy has weakened among young women in the general population following the Danish nickel regulation: results from two cross-sectional studies. *Contact Dermatitis* 2009; **61**: 342–348.
- 9 Schnuch A, Wolter J, Geier J, Uter W. Nickel allergy is still frequent in young German females – probably because of insufficient protection from nickel-releasing objects. *Contact Dermatitis* 2011; **64**: 142–150.
- 10 Thyssen J P, Johansen J D. Mobile phones are now covered by the European Union Nickel Directive. *Contact Dermatitis* 2009; **61**: 56–57.
- 11 Thyssen J P, Johansen J D, Zachariae C, Menné T. The outcome of dimethylglyoxime testing in a sample of cell phones in Denmark. *Contact Dermatitis* 2008; **59**: 38–42.
- 12 Biesterbos J, Yazar K, Lidén C. Nickel on the Swedish market: follow-up 10 years after entry into force of the EU Nickel Directive. *Contact Dermatitis* 2010; **63**: 333–339.
- 13 Thyssen J, Menné T, Lidén C et al. Excessive nickel release from earrings purchased from independent shops and street markets – a field study from Warsaw and London. *J Eur Acad Dermatol Venereol* 2010 November 25. doi: 10.1111/j.1468-3083.2010.03909.x. [Epub ahead of print].
- 14 Thyssen J P, Menné T, Johansen J D. Nickel release from inexpensive jewelry and hair clasps purchased in an EU country – are consumers sufficiently protected from nickel exposure? *Sci Total Environ* 2009; **407**: 5315–5318.