Don't let nickel get under your skin – the European experience!*

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Introduction

Nickel has a long history of usage in both precious metal and fashion, non-precious, jewellery. It is used in carat gold jewellery alloys as a whitener and hardener in contents ranging between 1 and 15 percent. It is also present in fashion jewellery products and watches where surgical/stainless steels are used; typical applications are posts in earrings/other piercing products, watch cases, backs, straps and buckles. Some fashion jewellery is produced using cupro-nickel alloys. Nickel is also used as an under- and finish-plate where articles are electro-plated and is included in many proprietary gold electro-plating solutions to improve the hardness and durability of the coating.

Surprisingly, nickel has also long been recognised as an element that can, when in direct contact with the skin, cause a wide variety of allergenic reactions ranging from mild irritation to severe eczema. However, its usage and presence in articles of jewellery has generally been unrestrained, with only a few countries, mainly within Europe, having any form of controlling legislation. Among these countries with some form of "anti-nickel" legislation are Denmark, Germany and Sweden. Generally, consumers outside these countries have had to fend for themselves, finding out by reaction whether they were, were not or were becoming sensitised to nickel. Further, the incidence of sensitisation among consumers has increased over the last twenty years or so as piercing, not just of ears but a wide variety of other parts of the body, has become very fashionable. As a result many consumers, particularly females, have suffered reactions when coming into contact with nickel-containing jewellery. Now, finally, the European Community has acted decisively in taking the first steps to reduce the risks associated with wearing jewellery, thereby relieving the consumer of learning by painful experience that she or he is sensitised to nickel.

This Paper reviews the effects of nickel sensitisation and allergy, the requirements of the Directive and the development of the supporting test procedures. In addition our experiences with these test procedures are discussed and the performance of various materials that conform discussed.

The medical evidence

While this paper is not intended to be medical in nature, it is worth reviewing the relevant statistics and type of effects noted on sensitised people that have been variously documented over the last few years. There are many papers that have been published detailing the results of a variety of tests and discussing the various aspects of nickel sensitivity; some of these are listed in this paper's reference list.

These studies, completed by many experts in many countries, show that more than 10 percent of all women and more than 1 percent of men suffer from nickel allergy. It is claimed that 20 percent of all individuals with pierced ears who wear nickel-containing earrings will become nickel sensitive. Swedish Dermatologist Alexander Fisher reported that, in one study, 95 percent of nickel-sensitised women had pierced ears; he also claimed that nickel caused more dermatitis problems than all other metals in total and that women were more sensitised than men. In one study, covering 111 sensitised people in three European countries, Denmark, Sweden and Great Britain, a number of facts emerged. People of all ages can be affected, although this study shows that sensitisation is more prevalent in the age group 10 to 30 years, Figure 1.

This same study indicated that the majority became sensitised after ear piercing, or within a year of being pierced, Table 1.

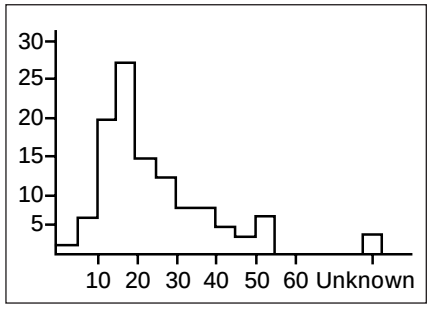

Figure 1 - Sensitisation to nickel in relation to age – 111 patients were surveyed.

Table 1. Time elapsed to suspected sensitisation following ear piercing

Time of suspected nickel sensitisation following ear piercing	No of patients
Not pierced	13
Before piercing	12
Shortly after piercing	60
Within 1 year of piercing	22
Not known	4

* This paper is based on one given at the Santa Fe Symposium, May 1999.
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Table 2. Items causing dermatitis in sensitised patients

Item	Patient Reports of Dermatitis
Earring	84
Wrist Watch	74
Button	54
Necklace	47
Finger Ring	45
Zipper	45
Bracelet	31
Spectacles	13

Further, as one would expect, earrings appeared to be the prime cause of dermatitis in these sensitised people, with watches a close second and, surprisingly, buttons also featuring, Table 2.

Probably the following three statements summarise general opinion:

'*There is a clear link between ear piercing and the onset of nickel allergy.*'
B Larsson-Stymne & L Widstrom, Contact Dermatitis, 1985 – 13: 289-293

'No one is born with nickel allergy; it is something that you develop through short or long term contact with materials containing nickel. Nickel-containing skin piercing needles are particularly dangerous.'
L Widstrom, MD, Registrar at the Dermatological Clinic, Eskilstuna, Sweden.

'Hand dermatitis occurs in up to 50 percent of nickel sensitive women and can be severe enough to result in incapacity and prolonged absence from work'.
A McDonaugh, A Wright, M Cook & D Gawkrodger, British Journal of Dermatology, 1992 – 126: 16-18

Unfortunately, once developed, as far as we know, nickel allergy is with you for life! The consequences of a sensitised person coming into contact with nickel or nickel containing alloys varies:

i) Local or limited dermatitis which will affect most nickel sensitive people. The reaction is confined to the general area of contact with rings, chains, watches, spectacles and zippers.
ii) Chronic eczema/severe dermatitis which can, in highly sensitised people, be caused by contact with low concentrations of nickel. Such people and their reaction can be affected by the intake of nickel in food.
iii) Hand eczema generally noted where there is frequent contact with nickel-containing objects such as coins, cutlery and tools. About forty percent of nickel-sensitised people develop hand eczema, often recurrent and sometimes chronic.

These effects are graphically illustrated in the next several figures. Figure 2 shows the short term – approximately 30 minutes – effects of a sensitised lady wearing a nickel–containing chain. Predictably, more prolonged contact exacerbates this reaction severely, Figure 3. However, as one would expect, reaction to nickel-containing ear posts will be more severe, particularly during the period of epithelisation, i.e. the "healing" period post-piercing, Figure 4. Unfortunately, once a person is sensitised, reaction is not confined only to the original point of contact with nickel. The lady shown in Figure 5 illustrates the severe effects of wearing nickel-containing earrings and chain.

Figure 2 - Skin reaction following approximately 30 minutes contact with a nickel-containing chain

Figure 3 - Severe skin reaction after more prolonged contact with a nickel-containing chain.

Figure 4 - Severe reaction in an ear piercing following contact with a nickel-containing post

Figure 5 - Severe reaction on both ear lobe and neck following contact with nickel-containing jewellery

The wearing of jeans is not usually associated with any particular reaction and many of us virtually live in denims once out of the office. However, given extreme sensitisation, contact with a nickel-containing zipper of the type usually sewn into jeans can be horrendous for the sensitised person, Figure 6.

In addition, as if these effects are not sufficiently devastating to those affected, direct contact with nickel is not always essential for reaction. The sensitised person can react after handling nickel-containing articles by transfer from the hands to more sensitive parts of the body, such as the face and eyelids, as illustrated in Figure 7.

Figure 6 - Severe eczema and blistering on the stomach caused by contact with a nickel-containing zipper.

Figure 7 - The effects of transfer from the less sensitive skin of the hands to the more delicate areas of the face

The European approach

In 1991 Carola Liden, eminent dermatologist of Sweden, and her colleagues attended a Plenary Meeting of the CEN – European Standards Body – Technical Committee, responsible for standardisation with the jewellery and associated products industry. This Committee was already addressing issues of fineness of precious metal jewellery alloys, methods of assay, precious metal coatings and so on. The Swedish team presented evidence regarding the potential effects of nickel-containing jewellery on the wearer. Their presentation was sufficiently forceful to cause the Technical Committee to set up a Working Group to establish the appropriate actions in order to "counter" the proliferation of nickel allergy and sensitisation.

It became clear, as this Working Group reviewed and collated the evidence, that the basic mechanism of "contamination" of the body with nickel involved dissolution of nickel from the article in contact with the skin in "sweat"; this would then be re-absorbed into the skin and underlying tissue. Subsequent sensitisation could then follow depending on a variety of biological and physiological conditions specific to the individual. This basic sensitisation mechanism has become key in the European approach to controlling the types of materials that are allowed to be used for piercing or come into contact with our skin.

As a result of the recommendations of the Working Group, a Directive was formulated and proposed to the European Parliament, finally being accepted in June 1994. Once this Directive was written and accepted, alternative considerations that might preclude the use of any materials that contained more than very low concentrations of nickel were not applicable. However, its implementation by Member States was delayed pending the development of suitable supporting test procedures, to be published as European – EN – Standards. Unfortunately, this became extremely problematical to the technical experts nominated by CEN to address this. In fact, it has taken these experts and the various Member States Standards Organisation Technical Advisors over four years to agree the precise details of the supporting test procedures. In that time, the original test procedures have been substantially modified and, *in my view*, do not necessarily facilitate a clear and unequivocal definition of conforming and non-conforming materials and coatings.

The European Directive

This Directive, 94/27/EC, presented at the Fourteenth Amendment of Directive 76/769/EEC supplemented as Annex 1, seeks to restrict the use of nickel in certain objects coming into direct and prolonged contact with the skin. The European Parliament and Council, in accepting the Directive, noted that one Member State already had legislation restricting the use of nickel and a second was preparing to introduce a different set of control measures; the promulgation of a Directive was seen as essential to prevent each Member State having different controls that might jeopardise free trade. The Directive addressed the three main groups of products that might lead to nickel sensitisation. It stated that Nickel and its compounds may not be used:

i) *in post assemblies which are inserted into pierced ears and other pierced parts of the human body during epithelization of the wound caused by piercing, whether subsequently removed or not, unless such post assemblies are homogeneous and the concentration of nickel – expressed as mass of nickel to total mass – is less than 0.05%;*

The requirement for control of content in the materials used for such products simplifies the test procedure as there are several reliable and accurate methods available. It is vague regarding the precise definition of a post assembly, i.e. does this include the front and back parts or refer only to the post itself. We, in advising our customers, have taken the view that all parts of the assembly that are likely to come into contact with an epithelizing wound should conform to this requirement. Further, this requirement does not eliminate the potential for ear wires that conform to subsequent sections of the Directive, therefore, to be free

to contain several percent of nickel, being used after epithelization. This could be dangerous for the sensitised person if the piercing is damaged by "normal wear and tear" at some point.

ii) *in products 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, zippers and metal marks, when these are used in garments*

if the rate of nickel release from the parts of these products coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm²/week;

This introduces a new concept, that of measurement of nickel release, which is an attempt to control the amount of nickel that might dissolve into surface body fluid, i.e. sweat, and be absorbed back through the skin into the underlying tissue. Therefore, nickel content is not relevant and not necessarily indicative of the release performance of a material. It also implies that some earrings, whether for pierced ears or not, will be acceptable, irrespective of nickel content, once any piercing has epithelized. Furthermore, it requires identification of those parts of an item that are in direct and prolonged contact with the skin for test purposes, a potentially difficult task with complex products such as metal watch cases/straps, chains and bracelets. Even measuring the surface area of relatively simple articles such as earrings provided a challenge as the results provided by 4 Test Houses shows, Table 3.

The test procedures for measuring nickel release were and remain controversial; they were modified several times in the light of technical trials and comments, all of which significantly contributed to the delay in the implementation of the Directive.

iii) *in products listed in point ii) above, where these have a non-nickel coating, unless such a coating is sufficient to ensure that the rate of nickel release from those parts of such products coming into direct and prolonged contact with the skin will not exceed 0.5 µg/cm²/week for a period of at least two years of normal use of the product.*

This addresses those products that are covered with a non-nickel coating (e.g. gold-plated) to ensure that any nickel present in the undercoats or substrate is not released at a rate greater than that specified. It also specifies that this rate is not exceeded for a period of at least 2 years of "normal use", the definition of this being left to the technologists of the Member States to establish; implicit in this is a requirement that the product does not release nickel above the rate specified throughout the two year period. The test can only be applied to new and simulated wear treated product, i.e. before and after the 2 year simulation; this does not establish that the article will not release nickel above the limiting rate at some time between 0 and 2 years. Consequently, this also became another area of controversy, resulting in several significant modifications to the original test procedures, yet again contributing to the delay in implementing the Directive. I suspect that the final procedures were accepted more on the basis of having a test at all, than any relation to "two years of normal use".

The test procedures

The CEN Working Group 4, tasked with devising/agreeing the test procedures and establishing them as EN Standards, have worked very hard to meet their objectives. However, the terms of the Directive, particularly with respect to the release test and "two years of normal use", made their task very difficult and probably impossible with respect to devising technically competent tests. There was always resistance to a general content limitation other than for piercing materials, probably on both commercial and biological grounds; control of nickel sensitisation from all types of products by content remains would involve technically the easiest and least disputed test. The three main test procedures were agreed in September 1998 by a majority of the Member States Standards Committees. In addition, two simple screening tests are being prepared under prEN 12471:1998. It is not my intention to include the precise details of these but to refer to the technique in general terms, commenting where relevant.

Table 3. Comparison of surface area measurements by 4 Test Houses

Test House	Surface Area of Product, cm²	
	Earring	Stud earring
1	6.35	1.25
2	10.24	1.34
3	9.86	-
4	8.40	1.40

i) The Content Test

The relatively speedy agreement on the methodology for measuring nickel content as required by *Part 1* of the Annex, described in EN 1810:1998, confirms that control of nickel in product by content would have been far less problematical for the technical experts. The method is based on an atomic absorption spectrometric (AAS) determination, easily within the capability of any competent analyst, being very reliable, reproducible and accurate.

ii) The Release Test

I believe that the measurement of release is far more complex than the – now agreed – simple one week immersion test would suggest. These procedures, described in EN 1811:1999, require the article, or those parts likely to come into direct and prolonged contact with the skin to be placed in a specified "artificial sweat" solution to be held at 30°C for 168 hours, i.e. one week. Those parts not deemed to be in direct contact should be protected by an effective stopping-off agent. The nickel content of the resultant solution is determined by atomic absorption spectrometry, in a similar method to that used for the nickel content determination above; this nickel content is then converted to a release rate based on the unprotected surface area of the product and the one week test time. The methodology of this test has been adjusted only slightly over the 4 years; the calculation to establish the release rate – once the solution content and item surface area have been measured – has been changed significantly. Initially, the result as calculated was reported; then, in acknowledging a variety of technical points, including the significant variations in results that occurred when several Test Houses tested items from the same batch, a factor of 0.4 was applied to the calculation. So, for example, a real result of 1.0 µg/cm^2/week was quoted as 0.4 µg/cm^2/week, i.e. an item originally failing became acceptable.

Following further trials and representations, particularly from the UK Technical Committee, this factor of 0.4 became 0.1. Therefore, in the final Release Test Standard an adjustment factor of 0.1 is included, so that items releasing at 5 µg/cm^2/week will now conform at a quoted release rate of 0.5 µg/cm^2/week.

In the course of setting the final details of this test, the UK Laboratory of the Government Chemist organised a series of tests completed by 4 UK independent reputable Test Houses. These involved release testing of earrings, stud earrings and reference discs. The results reported by each are shown in Tables 4 and 5, noted **without** applying any correction factor. Even with the "correction" factor, the variations in results across Test Houses and items ostensibly from the same batch could be embarrassing. The effects of build-up of dissolved nickel adjacent to the surface of the test article, variations in convection conditions in the test liquid, the presence of a protective/passivating film on the surface of the material and other subtle conditions must contribute to these variations.

The Working Group also identified an alloy that released at about 0.5 µg/cm^2/week, uncorrected, and recommended that this be used as a reference in the testing procedures. Unfortunately, this is not a commercially available alloy and, even when obtained, does not necessarily perform as predicted. The results of release tests on identical reference discs completed by 4 independent and reputable Test Houses, shown in Table 6, confirms this view. The use of these for reference purposes is therefore suspect.

The results from Tables 4 and 5 suggest that it is far easier to test products with very low release rates than those that release extravagantly. Even with the application of the 0.1 correction factor, one Test House could fail a product that another might just pass.

Table 4. Comparison of nickel release test results, uncorrected, on 5 batches of different earrings. Standard surface areas were used to calculate the release rate

Test House	Release rate of earring, µg/cm^2/week				
	Batch 1	Batch 2	Batch 3	Batch 4	Batch 5
1	-	6.4; 2.4	<0.05; 0.15	<0.05	<0.05
2	5.09	9.14; 3.32	<0.05	<0.05	<0.05
3	-	1.03	<0.05	<0.05	<0.05
4	3.8	7.7; 4.95	<0.05	<0.05	<0.05

Table 5. Comparison of the nickel release results from 4 Test Houses, uncorrected, each testing 25 identical stud earrings

Test House	Nickel release, µg/cm^2/week		
	Range	Mean	Std. Dev.
1	704 – 1745	941	247
2	285 – 919	641	143
3	500 – 847	672	418
4	201 – 582	418	134

Table 6. Nickel Release results on reference alloy discs after testing by 4 Test Houses

Test House	Nickel release, µg/cm²/week		
	Range	Mean	Std. Dev.
1	0.05 – 0.20	0.098	0.06
2	0.02 – 0.46	0.16	0.053
3	0.23 – 0.90	0.40	0.28
4	0.06 – 0.08	0.066	0.011

iii) The Corrosion/Wear Test

This was the most difficult procedure to devise as it had to represent "two years of normal use", whatever that is. Again, a number of variations were proposed and evaluated before the basic combination of a corrosive element followed by a wear test were agreed in principle, in order to test the durability of a coating. Initially, this test specified that the articles were suspended above a specified solution in a controlled environment for 16 hours; the articles were then tumbled with a given amount of specified media under specific conditions for 48 hours. Unfortunately, this resulted in smaller articles such as earrings being totally destroyed by the action of the media in the tumbling barrel. Following a reduction in tumbling time to 16 hours, further testing proved that this was also unsatisfactory. Results indicated that the performance of articles plated with a non-nickel top coat, covering a nickel undercoat with a nickel-free substrate was dependent on the thickness of the two plated layers, but not quite as predicted. Thin coatings would be worn away, leaving non-nickel surfaces for release testing, whereas thicker top coatings could be worn away, exposing the nickel undercoat which would then cause the article to fail the release test.

The result – some manufacturers' top quality items were failing the release test while their lower grade products conformed! Also, the Directive requires that products conform for a period of two years; clearly, the lower grade articles would have released nickel at some point during their life as the protective top coat was worn away.

Further procedural modifications were made which resulted in a 2 hour corrosion test followed by 4 hours tumbling in the barrel. It is probable that the effect of this on most products is minimal and very unlikely to represent "two years of normal use". These procedures are now encompassed in EN 12472:1999.

iv) The Screening Tests

These are not designed to replace the reference tests which should be used as the "definitive" methods but are available for spot checks "in the field". These tests are based on the reaction between nickel and dimethylglioxime to produce a distinct pink/red coloration. Clearly, the results of these are subject to a wide variety of conditions and probably the optimum approach is to accept a pink/red colour response as an indication of a non-conforming item. A negative result, i.e. no pink/red response to the test, could indicate a conforming item or one that is plated/protected/lacquered etc. Such items will require full testing to the appropriate Standard for confirmation. These screening tests are, therefore, useful in assisting buyers visiting manufacturers abroad or locally, to complete an initial test that should eliminate the worst "nickel emitters". These tests are described in prEN 12471:1998 but these procedures will be changed before being accepted.

The logistics

The sequence of events following the acceptance of the Directive are as follows:

i) Publication of the titles of the supporting test procedures as Standards in the *Journal of the European Commission*.

ii) Member State legislation – within 6 months.

iii) Six months after ii) – No manufacturer or importer may place products that fail to conform on the market.

iv) Eighteen months after ii) – Products that fail to comply cannot be sold or made available to the consumer unless they have been placed on the market before the expiry of their six month period, e.g. six months manufacturer/importer, six months wholesaler, six months retailer.

The test procedures, having not yet been issued as Standards in all Member States throughout the Community, have not been recorded in the Journal of the Commission.* Once completed, all Member States will have a maximum of 6 months to enact the appropriate legislation. In the UK a discussion document has already been in circulation for some time in order to obtain comments on the form of the legislation. It is clear that it will almost – word for word – reflect the terms of the Directive.

* This has since been done on 20th July 1999.

The experience to date

First, we should be clear that this is probably the "first bite" at constraining not just nickel but any element proven to harm us. The resultant Directive and Test Procedures, therefore, are not ideal but will at least reduce the numbers of people who will become sensitised in future. However, in the UK, there is already evidence that our local Trading Standards Officers will enforce this Directive. We have seen – and been involved in – a number of attempted prosecutions, not on the basis of the Directive but against retailers claiming that their products were "nickel free", "nickel safe" or "nickel conforming". "Nickel free" claims are particularly contentious as they were being applied to product that conformed to the Directive, although not enacted at the time, irrespective of nickel content, i.e. products that contained several percent of nickel but passed the latest version of the release test would be described thus. Our Trading Standards and Consumer Organisation, LACOTS, reacted quickly to these claims by specifying that any product, claimed to be nickel free, should not contain more than 0.01% nickel. This is a local requirement and is not included in the Directive. Prosecutions against such claimants who cannot substantiate their claim are now rare and not controversial as content determination is clear and unequivocal. However, attempts to prosecute retailers claiming "safe" or "conforming" products have mostly been unsuccessful as the case rests on the results of the release test. Ultimately, a set of supporting guidelines will be required to clarify some of these issues and ensure that all Member States apply the same descriptions and criteria.

Material selection

The delays in enacting this Directive have at least allowed considerable time for manufacturers to commence addressing the materials used to produce their products. This has been relatively simple for those in the precious metal business through adjustments to compositions of those alloys, mainly white golds, that contained nickel and did not meet the relevant test requirements. Typically, nickel has been reduced/removed and more palladium added, with shifts in the silver content accordingly. This has had an impact on cost as palladium is much more expensive than nickel. I am assured by the reputable producers, that those alloys containing significant amounts of nickel will now meet the requirements of the release test.

However, the manufacturers of non-precious jewellery have not had it so easy. "Surgical" or stainless steels, traditionally used extensively for posts and watch cases/straps, not only could not meet the nickel content requirement for piercing alloys but also failed the release test. Our own release testing confirmed that copper-based alloys containing quite low deliberate additions of nickel could not comply and certainly could not be used for ear posts or for cast items that might come into direct and prolonged contact with the skin.

Further, the extensive use of nickel in plated products also became problematical; it's use both as a universal "underplate" and also a hardener in gold plating baths could cause failure of the item. The use of plated articles has been constrained by the terms of the Directive. Now articles plated with a nickel "underplate" have to be covered with a sufficiently thick non-nickel releasing top coating to resist the corrosion/wear two year normal usage simulation.

Alternative materials have been evaluated: initially, for instance, titanium was used as a post material, replacing so-called surgical steel, as it was considered to be "nickel free". However, there was a problem with high surface concentrations of nickel being detected at the surface of titanium wire, probably "picked up" from tools and dies during production. Some samples that we evaluated contained up to 600 ppm nickel. The accidental introduction of nickel into titanium wire now appears to have been reduced and, more recently, titanium is accepted as an alternative post material.

The watch industry faced even more devastating problems as millions of watches were sold with cases, backs and straps manufactured in a stainless steel, probably the conventional 18/8 type, that actually failed the release test. Testing of other compositions then established that some stainless steels, such as the 316L type, although still containing 6 to 10 percent nickel, have a very low release rate. More recently, the Ugine-Savole Research Centre in France has identified that nickel release rates in stainless steels are high only where the sulphur content exceeds 0.15%. This precludes the use of types 303, 416 and 316, if re-sulphurised. They claim that all low sulphur grades, less than 0.03%, can be used without restriction. Therefore, other grades such as 304L, 304 Cu and normal 316L will comply and are suitable for replacing non-conforming steels in most applications.

Table 7. Content and release test performances of non-conforming materials

Material	Content test, 0.05% max.	Release test, 0.5 µg/cm^2/week max.
18/8 stainless/surgical steel	Fail	Fail
Cupro-nickel alloys	Fail	Fail
Low gold, high nickel alloys	Fail	Fail
Gold-nickel electroplates	Fail	?
Nickel undercoats	Fail	Depends on cover layer

Table 8. Content and release test performances of conforming materials

Material	Content test, 0.05% max.	Release Test, 0.5 µg/cm²/week max.
Titanium & Niobium	Pass *	Pass
'Nickel-free' stainless steels	Pass	Pass
High carat golds, nickel-containing	Fail	Pass?
304L/304Cu/316L stainless steels	Fail	Pass
'Nickel-free' gold electroplates	Pass	Pass
Palladium-nickel electroplates	Pass	Pass
Titanium based (CVD) coatings	Pass	Pass

* Avoid nickel pick-up during manufacture

So far so good – but most fashion jewellery is plated, quite often with gold electro-plates containing sufficient nickel to cause failure in the release test. The development of alternative electro-plating technology has not been easy and some further developments are probable. It does appear that systems based on palladium-nickel do conform and meet most of the operational requirements. They are not ideal and are more expensive. The traditional gold electro-plating systems were and remain free of significant contents of nickel. The "trick" here to satisfy the Directive is to cover any underlayers or substrates that contain nickel with a sufficiently thick non-nickel containing layer to resist the corrosion/wear simulation that is supposed to equate to two years of normal use. Conforming and non-conforming materials are summarised in Tables 7 and 8.

Future Developments

This is, as far as I am aware, the first concerted effort to address the nickel issue across a major trading area. It has clearly had its problems but at last the European Community have a set of regulations operating to reduce the incidence of nickel sensitivity. Initially, there will be difficulties associated with the uniform enforcement of the Directive throughout all the Member States, particularly in the area of consistent test results and descriptions of products. The issuing of agreed guidelines should be a priority to ensure consistency across the Community.

Given a reasonable operating period with this legislation, with its current set of testing parameters, and clinical assessments of its effects in limiting the numbers of newly sensitised men and women, one would expect further – possibly more stringent – regulations to appear, if shown to be required. Certainly, the CEN Technical Committee and its Working Group should be monitoring the performance of the current test procedures so that, while the terms of the Directive might remain, more reliable tests for release and wear are devised.

This Directive specifically excludes coinage at this time. However, as I showed earlier in this paper, it is possible, even with relatively limited contact with nickel-containing objects, to transfer it and hence it's effect to the very sensitive areas of the body. Those who have to routinely handle coinage through their employment, e.g. shop assistants, bank tellers, should establish their sensitivity to nickel and take appropriate precautions. In the meantime, certainly in Europe, the use of non– or low–nickel-containing alloys is being actively pursued with respect to new issues of coinage including the Euro.

While nickel does appear to be the "bad boy" among metals, there is already evidence to suggest that palladium, both in an oral and contact environment, can cause an allergic reaction in some people. What price, then, a Palladium Directive in the future?

Conclusions

It is clear that the extent of nickel sensitisation is far wider than many perceive and that the effects of it can be devastating and unpleasant. The European Community, with the Nickel Directive, has taken the first steps to reduce the potential for people to become sensitised through piercing and the wearing of jewellery, watches and spectacles. The efficacy of the test procedures, particularly those for determining release and simulating wear, has yet to be proved, with evidence already that they might produce inconsistent results and effects not intended originally. This might result in contention among experts involved in any prosecutions brought under Directive-based local legislation; this could seriously reduce the effectiveness of enforcement and even discredit the Directive.

One final point: there is direct cost implication of this legislation; the changes necessary to the materials used for products and the test work essential to complete "due diligence". The cost of these is significant, particularly for the lower priced end of the fashion jewellery/watch trade. The new conforming materials are generally more expensive; in addition, the test work is arduous and time consuming requiring equipment and expertise not always available to manufacturers located, quite often, in the Far East and Asia. Typically, in the UK, a release test on the three or four components of a cheap quartz watch that might be in direct and prolonged contact with the skin will cost at least two or three times its retail price. These increased costs, which are causing concern among suppliers, will have to be passed to the "beneficiaries" of the legislation – that is, the consumer, many of whom are not aware of nickel allergy, are unaffected by it and who might not appreciate paying the extra costs associated with controlling it.

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