TO ALL EU MEMBERS AND OBSERVERS OF THE INTERNATIONAL HALLMARKING CONVENTION

Dear Colleagues,

WHITE NICKEL/GOLD ALLOYS in THE EU.

A Cause for Great Concern and a Call for Action.

I have recently become aware of a very significant problem for gold jewellery manufacturers and suppliers worldwide in relation to some new EU proposals which will have very serious implications for all Convention countries operating or trading in the EU. I hope you can help to overcome the problem.

You will all be aware that in 1999, for health and safety reasons, the EU introduced a Directive to limit the amount of nickel that could be released from any item which is intended to come into prolonged and direct contact with the skin, which clearly includes jewellery. For the precious metal jewellery industry the main impact was on white nickel/gold alloys which are considerably less expensive than white palladium/gold alloys. After a spate of failures when nickel release testing was first introduced the industry adjusted its procedures and established that white nickel/gold alloys can be made perfectly safely when in the correct proportions and with the correct manufacturing processes.

Research suggests that the Directive has been effective, and that the incidence of nickel allergies in the EU population has been falling.

The test method (EN 1811) for determining the release rates of nickel is not ideal and the EU Commission asked the relevant working group (CEN TC 347 WG 1) to revise the method and parameters going forward.

No changes to the Directive itself are proposed and the revised method was still intended to demonstrate whether items comply with the current maximum release limit of 0.5 or 0.2µg/cm²/week, depending upon the type of article.

The CEN working group particularly wanted to remove a ‘correction factor’ of 0.1 applied to the results of the existing method. This correction factor was originally introduced due to the wide range of variables impacting on the results and was intended to make results more consistent. The proposed revision replaces the correction factor with a ‘measurement of uncertainty’ calculation. Unfortunately the revised parameters and method of calculation that has been recommended mean that in effect the level of nickel release which will “pass” the test has been significantly reduced. As a result the majority of white nickel/gold alloys will fail to meet the new requirements, and therefore will technically be considered unsafe to sell on the EU market, although there is currently no evidence to show they are causing a problem.

This is a potential disaster for the gold jewellery trade and the watch and costume jewellery industry in the EU, while conferring no consumer benefit.
I must make it clear that I support the proposal to replace the current 0.1 correction factor with a more scientifically based alternative and agree that the use of measurement uncertainty is more in keeping with current thinking. However, the approach used by the working group did not fully incorporate all aspects of the test procedures, specifically the uncertainty associated with testing actual white gold jewellery articles, and the variability between what ostensibly appear to be the same items was not included in the uncertainty budget, thereby from our experience understating the uncertainty of measurement considerably.

Furthermore, the new draft proposes three categories of results, ‘Pass’, ‘Undecided’ and ‘Fail’, unlike the existing standard which has Pass and Fail parameters. This is a ridiculous and unsustainable position. Suppliers could spend a considerable amount of money testing items only to be told “no decision” can be made as to whether the product complies or not. All this at a higher price as the new test requires the testing of minimum three samples wherever possible, plus a duplicate blank for each sample. The three samples will all be rendered un-saleable, instead of one currently, thereby incurring higher testing costs and sample wastage.

The UK Working Group identified these flaws in the proposed revisions to this method early on and consequently challenged the proposed revisions. However, the voting at the inquiry stage in January 2010 went against the UK with 18 countries saying “yes”, 7 abstentions and only the UK and France saying “No”. The French rejected the proposed revision for completely different reasons from the UK.

Inevitably there are mixed agendas. The Italian and French delegations had particular interest in the revision as the existing standard includes spectacle frames and sunglasses. These have now been reclassified as medical devices and P.P.E (Personal Protective Equipment) respectively and excluded from the standard, so these two Member States have achieved their aim and are less interested in other details. Some members of the UK Working Group are concerned that the proposed revisions may have been accepted by member states that do not fully understand the implications of the amendments, or have no direct interest in the standard itself, as it may be of little importance to them.

The final draft of the proposed revision is almost complete and will be circulated to all Member States for voting once approved by the CEN Working group.

I propose that all Convention countries urgently contact their own national leading National Standards authority which represents their country on the European Working Group CEN TC 347 WG 1 to insist that nominated representatives reconsider their position and vote against the new proposals.

Representatives are urged to demand that:

1. The proposed changes to EN1811 be abandoned forthwith, other than the reclassification of spectacle frames and sunglasses.

2. The proposed revision to EN1811, as currently drafted is rejected

3. New research is put in place to establish a definitive ruling from medical experts on a safe level for nickel release

4. Relevant chemists and metallurgists research and develop a new test with reliability and repeatability to identify whether products comply with the safety levels imposed.
I urge you to also contact your national standards bodies and trade organisations and lobby them vigorously to ensure they fully understand the implications of the proposed revisions to EN1811. The UK trade are currently working closely with their national standards body (BSI) and, with their committee representative’s support, intend to lodge a formal appeal with CEN to prevent the revision progressing to the next formal voting stage, pending a new validation trial being undertaken with the involvement and support of other countries. This would encompass all areas of uncertainty associated with the test procedure and jewellery samples in order to arrive at a more realistic, practical, scientifically justified basis of uncertainty of measurement with which to replace the current correction factor, to enable a definite ‘pass or fail’ decision (ideally excluding the proposed ‘no decision’ category) to be reached as is the case currently.

Yours sincerely,

Michael Allchin
Chief Executive and Assay Master
The Birmingham Assay Office, UK
Background

EN 1811 is the "Reference test method for release of nickel from post assemblies which are inserted into pierced parts of the human body and products intended to come into direct and prolonged contact with the skin."

CEN’s original mandate tasked the European Working Group CEN TC 347 WG 1 with improving the test procedure in order that the 0.1 adjustment factor in this method could be removed or reduced. This adjustment factor was introduced at the outset to compensate for the wide inconsistency of results. No evidence has been presented to indicate that the current Nickel Directive is failing to protect consumers from the dangers of nickel sensitisation and subsequent allergy. Therefore no intention to reduce the level of nickel release was declared; the requirements of the European Nickel Directive 1999 remain unchanged.

Current Criteria

The products tested for nickel compliance are usually produced in large volumes and therefore inherently variable to some degree. The test procedure itself is subject to a considerable amount of variability and uncertainty and in recognition of this the existing standard requires the test result to be multiplied by an ‘adjustment factor’ of 0.1 in order to obtain suitably realistic figures to compare with the pass levels. Effectively this means that the actual pass level in the existing standard is 5.0µg/cm²/week for most articles intended to come into prolonged and direct contact with the skin and 2.0µg/cm²/week for post assemblies intended for insertion into a body piercing.

Proposed Revision to method:

The proposed method in the revised standard is to replace the adjustment factor above with a measurement of uncertainty of 46%. The introduction of the measurement of uncertainty is yet one more complication in a standard which is already difficult to practically apply.

The proposed level of uncertainty is based on research which has been carried out as a “Round Robin” between 14 laboratories, including some in the UK. Precious metal alloys samples were not included in this study.

Analysis of the results of the experiments conducted by participating laboratories showed that the replacement of the current adjustment factor of 0.1 is not justified. The measurement of uncertainty has been based on a statistical interpretation of a set of round robin test results conducted by testing solid, homogeneous samples of very simple geometry (not a selection of actual items from the market) and laboratory data that was not sufficiently close to the average was excluded from the statistics. In addition, many articles submitted for testing are coated and therefore subject to corrosion and wear (EN 12472 in order to simulate 2 years wear of articles). The uncertainty associated with this process has not been included in the above measurement of uncertainty.

Research by The Birmingham Assay Office has indicated that the proposed overall measurement of uncertainty of 46% in the revised standard is considerably understated, possibly by a factor of at least 5 times and therefore is not a true reflection of the uncertainty of measurement known to occur when testing real samples from the market place.

To make matters worse, the revised standard proposed that if a laboratory can show that the measure of uncertainty of its own results is different from those obtained by the round robin trial then it is permitted to set its own values for non-compliance, compliance and values where no decision is possible.
Proposed changes to interpretation of results
The changes proposed for the interpretation of results are as follows:

For items that must comply with the 0.5 µg/cm²/week limit there will be 3 possible outcomes:

Noncompliant (when nickel release, µg/cm²/week is >5.00 (existing), ≥0.88 (proposed.))
Compliant (when nickel release, µg/cm²/week is ≤ 5.00 (existing), ≤ 0.28 (proposed).
‘No decision’ (when nickel release, µg/cm²/week is Not Applicable (existing), >0.28 or <0.88 (proposed).)

For items that must comply with the 0.2 µg/cm²/week limit (i.e. those intended to be inserted into body piercings) there will be 3 possible outcomes:

Noncompliant (when nickel release, µg/cm²/week is >2.00 (existing), ≥0.35 (proposed).
Compliant (when nickel release, µg/cm²/week is ≤ 2.00 (existing), ≤ 0.11 (proposed)).
No decision (when nickel release, µg/cm²/week is Not Applicable (existing), >0.11 or <0.35 (proposed))

The UK has serious concerns about this proposed revision:

There are two immediate effects which are detrimental to the consumer and to the industry:

1. To lower the effective pass limit by a factor of on average 18 times (5.00/0.28=17.9 for items in direct and prolonged contact with the skin or 2.00/0.11=18.2 for piercing post assemblies).

   The effect is that many commonly used materials that previously passed the existing standard requirement, such as many nickel containing white gold alloys, would now fail the proposed revised standard and their use would therefore no longer be permissible in such products.

In the absence of any data in the public domain concerning nickel release from precious metal jewellery articles The Birmingham Assay Office carried out some comparisons to understand the potential impact of this change.

The Birmingham Assay Office compared 27 individual nickel release results for precious metal jewellery articles intended to come into direct and prolonged contact with the skin such as rings, bracelets and pendants (existing 0.5 release limit) received over a four month period with the following observations:

Implications of changing from a 0.1 adjustment factor to the proposed uncertainty limits:
Change from 68% compliant to 0% compliant = 100% reduction – i.e. all failed and therefore could not legally be sold in the EU under the proposed revision.

Change from 32% non-compliant to 100% definitely non-compliant = 313% increase like for like – i.e. all failed and therefore could not legally be sold in the EU under the proposed revision.

In addition, the Birmingham Assay Office compared 5 individual nickel release results for precious metal jewellery articles intended to be used as piercing products (existing 0.2 release limit) with the following observations:
Change from 40% compliant to 0% compliant =100% reduction – i.e. all failed and therefore could not legally be sold in the EU under the proposed revision.
Change from 60% non-compliant to 80% definitely non-compliant = 33% increase like for like.
Change to uncertain (including definitely non-compliant) 60% to 100% = 66% increase.
20% uncertain samples now require further surface area evaluation to assess if may become compliant or not.

2. A new area of uncertainty has now been created that did not exist before regarding the interpretation of test results. A ‘no decision’ result will mean that even after testing according to the revised standard the laboratory carrying out the tests cannot make a definitive statement as to whether or not the article is compliant with the standard.

The effect is that because suppliers cannot assure retailers that the product is ‘safe’, they will be withdrawn from the market completely, even though they would go on to the market today.

The proposed revisions will cause consternation in the manufacturing and retail sectors, as well as introducing difficulties for enforcement authorities where testing multiple samples is the norm and a clear cut decision is required if enforcement is to be fair and effective.

To summarise, the proposed revision will generate variable results and will undermine the credibility of EN1811 even further and introduce even more uncertainty to the compliance decision process for testing houses, laboratories, Customers and enforcement authorities alike. The inevitable result is that suppliers of those items which are intended to come into direct and prolonged contact with the skin will be less inclined to test items for nickel compliance. This will ultimately be detrimental to the consumer and the fine jewellery industries across the EU.

Following the required majority vote at the inquiry stage by CEN TC 347 WG 1, this revision is progressing to the next stage. After some technical amendments the final draft will soon be circulated to CEN TC 347 WG 1 for approval. The UK is committed to protecting the consumer, supporting the jewellery industry in its widest sense, and providing expert and accurate results using internationally accepted standards. This revision is a serious obstacle to each of those objectives and should be reviewed urgently.

Michael Allchin
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The Birmingham Assay Office

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