

**Comments by ZVO  
on ECHA's derivation „prolonged contact“  
for Nickel  
(10.08.2017)**

With the entry of Nickel into Annex XVII of REACH (Entry 27) it got restricted for articles. But to take effect section 1(b) of the restriction defines three conditions that have to occur in combination for general articles:

*„(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<sup>2</sup>/week.“*

1. Condition: Direct contact (with the skin)
2. Condition: Prolonged contact (with the skin)
3. Condition: A certain release rate

While the condition of release rate has not been challenged too much, the term „prolonged contact“ has been discussed intensively. ECHA derived a definition mainly based on a literature study which was published on 2014-04-02<sup>1</sup>. Its conclusion was the following definition for „prolonged contact“ in the case of Nickel as a metal:

*„Prolonged contact with the skin is defined as contact with the skin of nickel of potentially more than 10 minutes on three or more occasions within two weeks, or 30 minutes on one or more occasions within two weeks.“*

In its (draft) guideline<sup>2</sup> published 2017-01-27 ECHA is giving examples for parts that are considered to fulfil the conditions of Entry 27 in general. At this moment the discussion of these examples is very intense and controversial as there is much doubt about the applicability of the definition.

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<sup>1</sup> [https://echa.europa.eu/documents/10162/13641/nickel\\_restriction\\_prolonged\\_contact\\_skin\\_en.pdf](https://echa.europa.eu/documents/10162/13641/nickel_restriction_prolonged_contact_skin_en.pdf)

<sup>2</sup> <https://echa.europa.eu/documents/10162/5dea96fd-1db4-4b64-1572-19858939d8fd>

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It is therefore legitimate and worth checking if the derivation of the definition of „prolonged contact“ is well-founded and scientifically proven, as claimed by ECHA<sup>3</sup>.

### Conclusions

The study of the definition building by ECHA<sup>1</sup> reveals a number of weaknesses that contest the entire meaning of the derivation. The weaknesses will be summarized here, while the indication(s) for each will be given in the following passages:

1. The definition building does not deal with the content of Entry 27 of REACH Annex XVII;
2. The scientific approach is flawed; common rules of sound science are broken.

The definition is not applicable to the case of Entry 27.

### Justification of the Conclusions

The following reasons are based on the definition building document of ECHA only; it does not discuss the original studies cited. This does not seem to be necessary as the conclusions and arguments in ECHA's definition building clearly indicate evidence for the conclusions.

#### 1 The definition building does not deal with the content of Entry 27 of REACH Annex XVII

In the underlying document ECHA is drawing a conclusion. In that passage it becomes clear, that the definition is not referred to the topic and goal of Entry 27:

*„... it was estimated which contact time would sufficiently protect Ni-sensitised and not yet sensitised subjects from contact dermatitis. (...) A contact time of 30 minutes of an alloy releasing Ni at the rate of the legal threshold should be adequately protective towards skin reactions of the Ni-sensitised individuals. (...)“ (emphasis added)*

All the studies of Ni-induced skin dermatitis have been processed with pre-sensitised people („subjects“)<sup>4</sup>.

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<sup>3</sup> K. Shivonen, „EU nickel restriction: background and ECHA's activities – guideline“, Workshop on EU nickel restriction, 2017-06-27, Brussels

<sup>4</sup> [https://echa.europa.eu/documents/10162/13641/nickel\\_restriction\\_prolonged\\_contact\\_skin\\_en.pdf](https://echa.europa.eu/documents/10162/13641/nickel_restriction_prolonged_contact_skin_en.pdf), pages 3-5, 9,10

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**This means, while the restriction of Nickel in Entry 27 is covering all possible skin contacts ECHA's definition assures the protection of a minority of pre-sensitised persons.**

Adopting this approach to other areas of regulation or human protection this approach will and in absurd results:

- a. All regulations concerning air quality would have to be based on the allergic reaction of asthmatics. It will be rather difficult then to find enough areas to live in;
- b. Due to the existence of bee allergy we have to protect all people against such insects! Which measures could be feasible (actually the bees are in danger of extinction)? What side effects would have to be faced?

One correct or feasible approach would possibly have consisted of two steps:

1. Determination of conditions for sensitising people and their avoiding;
2. Protection of sensitised people

Obviously the definition of „prolonged contact“ for Nickel will overestimate and overemphasize the risk of dermal adverse effect for non-sensitised people by far. It has not even been proven that the prolonged contact as defined here is able to cause sensitisation itself to non-sensitised people.

The result is an over-regulation that should be avoided, in particular as there has not been any impact assessment of it.

**2 The scientific approach is flawed; common rules of sound science are broken**  
Several references for this conclusion can be verified in the document:

- a. ECHA is using unpublished results and information for its argumentation  
The fact that ECHA is basing its argumentation on unpublished scientific work (pages 4, 6, 7, 10) is unacceptable. The premise of sound science is the assessment of any scientific work by the scientific community. There has to be the opportunity to check those results for correctness and reproducibility. Using unassessed claims without giving detailed facts and without publishing it to the scientific community is making all its conclusions useless. Additionally it may be doubted, if all relevant information has been considered.
- b. Unexpected results are neither investigated nor implemented correctly  
There is a rather uncommon chemical behaviour in the results concerning the release rates. Figure 1 (page 6) is interpreted as a decreasing release rate over time. Apparently the release rate is much higher in the first 30 to 60min

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than later. This is rather surprising as normally the rate of dissolution will increase as long as the concentration of the solving acid is constant and no passivation effect will occur. The reason is that the active surface will increase during the acid attack. There may be differences between metal and alloys, but ECHA does not discuss this uncommon behaviour and there is no further investigation of the mechanism.

On the other hand, if this effect is in fact true, it should have been reflected in cases of repetitive contact. Later repetitions should result in lower released amount of Nickel and with that reduce the adverse effects. But ECHA is drawing a different conclusion (page 10); the possible contrariety remains untouched.

Obviously even the experimental facts cited do not seem to be lighted from all sides and interpreted in a comprehensible way.

c. The study does not discuss any conflicting practical experiences

The main reference to this is the absence of a detailed discussion of the main contact with Nickel for people in general: Coins.  
ECHA indicates correctly that coins are out of scope of the restriction, but

*„... even though the information on coins has been used as supporting evidence.“*

If this was true, the use as evidence should not only be supportive to the definition's approach. The obvious main question should have been: Why are not many more people affected by Nickel-dermatitis, although many of them get in repeated, sometimes (e.g. cashiers) prolonged contact for years.  
The only comment ECHA is giving in its „study“ was:

*„Furthermore the European Union Risk Assessment Report on Nickel (2008) did not find concern from coins or other nickel releasing objects e.g. tools for workers or consumers, even though addressed uncertainties in its assessment.“*

To summarise this: There is a major source for all people in Europe (coins), the restriction is dealing with general protection of people and there is indication, that no adverse effect has to be expected (stated by an European authority). It is rejected in general by ECHA because of „uncertainties“. On the other hand ECHA does not discuss any uncertainties in its own study (see below).

This can be called dubious, at least.

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d. The definition building does not check for uncertainties

In this definition building many aspects seem to be questionable and the experimental results are showing great variances. But ECHA does not discuss any possible uncertainties in its approach and conclusions.

Looking at the final result this becomes obvious. The result defines two different kinds of „prolonged contact“:

- 10 minutes on three or more occasions within two weeks, or
  - 30 minutes on one or more occasions within two weeks.
- (assuming the maximum release rate is not exceeded)

Comparing these strict definitions with the uncertainty and variance of the underlying data (e.g. pages 5, 9) they can hardly be justified.

Just to put it into a practical view:

- 3 x 10 mins is not acceptable, but 5 x 9 mins is OK?
- 30 mins once is risky, but 3 x 25 mins in two weeks is OK?

Both examples are not even covered by the definition building itself, as the document clearly states, that a number of short contacts are of more risk than a single longer one (step 5, page 10).

The definition of prolonged contact in the way it is done is obviously not applicable.

#### Further requirements

It has become obvious that this definition of „prolonged contact“ can only be applied to pre-sensitised people; therefore it is a protective approach for people suffering from a specific disease or defect. This is highly appreciated. But stretching the meaning to the general public is inappropriate. Such a broad approach should only be chosen when there will be no other effect from the regulation – which has not been discussed and which is not true, obviously.

ECHA has to clarify this before such an overregulation may be accepted!

There have to be defined, consistent, objective, and commonly agreed criteria for the preparation of such scientifically based decisions or deductions. Sound science has to be respected and met. Otherwise regulation decisions take the risk of arbitrariness and inner inconsistency.