ZVO Position paper
Nickel restriction, entry 27 in Annex XVII of REACH
(21.08.2017)

The ECHA's clarifications regarding entry 27, nickel restriction[1] have caused a great deal of uncertainty in the industry. Particularly the examples for "prolonged contact" have been hotly discussed and in many cases appeared doubtful also to ZVO.
With this position paper ZVO clarifies its interpretation of entry 27 based on the original text[2] .
The definition of prolonged skin contact is stated separately by the ECHA[3]. It is the subject of scientific discussion. ZVO currently considers this definition to be insufficiently scientifically justified and will address this aspect separately. A statement may be made on this in a paper devoted to the subject.

Key formulations of entry 27 (see appendix 1)

In section 1(a) initially piercings are explicitly restricted – this aspect will not play any part in the rest of this paper.
In section 1(b) the key formulations:

"in articles intended to come into direct and prolonged contact…" and

"… if the rate of nickel release from parts of these articles coming into direct and prolonged contact with the skin is greater than 0.5µg/cm^2/week."

1(c) indicates that the use of articles which are specified in 1(b) and have a coating containing nickel which does not ensure that the nickel release value of 0.5 µg/cm²/week is not exceeded is not permitted.

The relevant articles must therefore be explicitly intended to have prolonged direct (skin) contact and in addition exceed a certain limit of nickel release in order to be subject to the restriction.

[1] https://echa.europa.eu/documents/10162/5dea96fd-1db4-4b64-1572-19858939d8fd
[2] https://echa.europa.eu/documents/10162/7851171d-53e9-455a-8bb8-7ca22e89ad87
[3] https://echa.europa.eu/documents/10162/13641/nickel_restriction_prolonged_contact_skin_en.pdf

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Clarification of prolonged (skin) contact

According to the definition of the ECHA[3], prolonged skin contact should be understood as follows:

"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."

With this definition, the ECHA departs from the basis for the original, binding restriction, because it uses the word "potentially", while the restriction unequivocally refers to "intended". The choice of the term "potentially" leads to a lack of clarity. How can a manufacturer of an article specified in 1(b) gauge or make a binding judgement as to whether the users of its article use it once per week for more than 30 minutes or twice per week for more than 10 minutes on each occasion and thus actual skin contact occurs, even though this is not envisaged where the item is used as intended?

Interpretation, consequences

Because the restriction has a legally binding effect and expresses the will of the Commission, it must be taken as the basis for any assessment of articles, particularly in the event of contradictions vis-à-vis clarifying official documents. The ECHA's clarifications are merely an interpretation and are not legally binding.

In ZVO's view, the intended function of an article is decisive because it is assumed by the restriction, and not the theoretical possibility of prolonged contact occurring. For example, use other than as intended need not be taken into account by the manufacturer or distributor. An appropriate description of the use or a declaration of ingredients by the manufacturer (e.g. analogously to the provisions of the German Product Safety Act (*Produktsicherheitsgesetz*)) should provide sufficient safety here and be the basis for any evaluation. Such an approach enables the consumer to make his/her own decision. In the jewellery trade, inscriptions such as "nickel-free" etc. are already common practice. In the food sector too this approach is accepted and effective (e.g. in the case of lactose intolerance).

Furthermore, in ZVO's view providing proof that the release of nickel is less than 0.5µg/cm^2/week for each article would be tantamount to the invalidity of the

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restriction, irrespective of the possibility of “prolonged skin contact”, because the restriction inseparably links the two conditions in 1(b) with each other.

Summary

In ZVO’s view, the individual specification of articles in an ECHA guideline is not helpful and gives rise to uncertainty. It is to be expected that due to the unclear situation alone changes will be made which could have other negative consequences (e.g. shortened lifetime, risk-risk trade-offs, etc.).

The ECHA should limit itself to unequivocally clarifying the criteria which are clearly defined in the restriction, particularly in the languages of the EU countries. Those criteria are:

a. the intended use also includes prolonged skin contact according to the definition from “PROLONGED CONTACT WITH THE SKIN - DEFINITION BUILDING FOR NICKEL”;
b. the nickel release exceeds a value of 0.5µg/cm^2/week;
c. the same ancillary conditions apply for articles containing or made of nickel with non-nickel coatings.

If there is a clear definition of the use of the articles showing an intended use with non-prolonged skin contact together with proof that the nickel release limit is not exceeded, an article is not subject to the restriction.
All further Interpretations and requirements depart from the scope of the restriction under No. 27 in Annex XVII to REACH and only create uncertainty and confusion.

Furthermore, ZVO urgently points out that phenomena occurring in individual cases (as quoted in the guideline) cannot be a basis for a restriction founded on principle. This requires a causal link, to the exclusion of other effects, for example medical history, additional exposures, hereditary disposition, etc. Serious science requires unequivocal verification of cause-and-effect relationships.

ZVO considers that it would be beneficial and helpful if the EU Commission and the ECHA were to ensure clarity in this matter. In particular, ZVO considers that ECHA should specifically apply the legally prescribed basis of entry 27 in REACH Annex XVII and refrain from adding extensions.