Comments by ZVO
on the revised Guideline of ECHA, Nickel restriction, Entry 27 of Annex XVII to REACH, 26.10.2017, 25. CARACAL Meeting (18.12.2017)

Through the REACH Regulation (EU) No 1907/2006, the European Commission called on the EU Member States to protect the population from allergies caused by Nickel (Entry 27 of Annex XVII). With its new Guideline concerning Entry 27, ECHA aims to support the Member States' authorities with the interpretation of these parameters. Overall, the ZVO views this Guideline positively, but would like to contribute with the following comments.

The ZVO welcomes the fact that ECHA, in its revised draft Guideline on entry 27 of Annex XVII to REACH, is making efforts to take into account the key conditions concerning this restriction. As already stated by the ZVO in its position paper on the first draft Guideline, the key formulations of restriction entry 27 are as follows:

- *„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/cm²/week."*
- *Section 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.*

It is to be welcomed that ECHA now expressly specifies that if the maximum nickel release rate is not reached, the article is automatically excluded from the restriction.

The ZVO agrees with ECHA that in order to be subject to the restriction, articles must explicitly be intended to have a prolonged direct (skin) contact and, in addition, exceed a certain nickel release rate. An unintended use of the article by consumers should not need to be taken into account by the manufacturer or distributor. An appropriate description of the use or a declaration on the content by the manufacturer (e.g. similarly to the provisions of the German Product Safety Act) should provide sufficient safety and should be used as a basis for any kind of assessment.

The ZVO also welcomes the fact that ECHA has in its revised draft Guideline:

(i) taken up the industry's advice on the intended uses of articles and any associated risk of prolonged skin contact;

(ii) reviewed its previous assessments; and

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(iii) deleted the concerned articles from the list. This especially applies to some articles used in the automotive industry (e.g. the lever to shift gears), the sanitary industry (e.g. the handle of a shower head) and household supplies (e.g. frying pans).

However, the ZVO remains critical of the further development of the non-exhaustive list. The selection of articles is inevitably arbitrary and bears the risk to create insecurity and stigmatization amongst consumers.

The ZVO would welcome, if ECHA would limit its Guideline to explaining the clearly defined criteria of the restriction. An official translation of these final explanations into all EU languages would be very helpful, notably for SMEs.

The requirement for the manufacturer/distributor to provide an explicit definition on the intended use of the articles would clarify that an article is not intended for prolonged skin contact and would make it easy to judge for consumers whether an article is subject to the restriction or not. Alternatively, or in addition, a requirement for the manufacturer / distributor could be introduced in order to provide proof that the maximum release rate of nickel is not surpassed.

In this context, the ZVO points out that according to many experts from the industry, the suitability of the method to measure the nickel release rate (EN 12472:2005+A1:2009) has not yet been clearly established. The first step of the method entails an artificial acceleration of the aging process, which was developed to simulate the erosion of jewelry, wrist watches, and glasses and its effects on the skin when used more than 10 hours a day. It is not intended to simulate a few hours of use every month. In the view of the ZVO there is an urgent need to develop a testing method that is adapted to the relevant requirements. It needs to achieve a high reproducibility and comparability. In addition, measurement and detection thresholds are urgently needed.

The ZVO continues to express doubts about the scientific value of the definition of “prolonged skin-contact”. In the view of the ZVO the following provision is scientifically speaking not plausible and is difficult to apply:

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— *"Prolonged contact with the skin is interpreted as contact with the skin of potentially more than either 10 minutes on three or more occasions within two weeks, or 30 minutes on one or more occasions within two weeks".*

This definition would infer that a skin-contact of e.g. 9 minutes, repeated on four occasions within two weeks would be acceptable.

The ZVO does not agree that the protection of the general population can only be achieved by applying the same restrictions to the non-sensitized as to the sensitized part of the population. The restriction Entry 27 (Annex XVII to REACh) does not foresee this as a requirement. Such an over-regulation results in the freedom of the non-sensitized population to be severely restricted. Instead, to protect people with allergies, there should be a clear warning on products intended to come into prolonged contact with the skin. This approach is already common practice in the food sector (e.g. warnings that products may contain nuts).

The ZVO continues to urgently point out that individual cases (as mentioned in the background document[1]) should not be a basis for a general restriction. Rather, there would need to be a causal link that allows the exclusion of other effects (e.g. medical history, additional exposure through other sources, hereditary predispositions etc.). The principle of sound science requires an indisputable verification of cause-and-effect relationships. This includes establishing a causal relationship and thereby ensuring the reproducibility of results.

[1] BACKGROUND REPORT TO THE GUIDELINE ON ARTICLES INTENDED TO COME INTO DIRECT AND PROLONGED CONTACT WITH THE SKIN IN RELATION TO RESTRICTION ENTRY 27 OF ANNEX XVII TO REACH ON: NICKEL AND NICKEL COMPOUNDS (To be published simultaneously with the guideline)

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