



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
REACH

ENVIRONMENT DIRECTORATE-GENERAL
Green Economy
Chemicals

Brussels,
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European Chemicals Agency
Attn. Mr. Jack de Bruijn
Director of Risk Management
Annankatu 18, P.O. Box 400
F-00121 Helsinki, Finland

Ref: Request made to ECHA for the elaboration of guidelines in support to the implementation of existing restrictions on Nickel (entry 27), Polycyclic Aromatic Hydrocarbons in consumer articles (entry 50) and of the upcoming restriction of lead in consumer articles.

Dear Mr. de Bruijn, *Dear Jack*

A certain number of restrictions already included in Annex XVII to REACH, or currently in preparation, concern substances in articles. Due to the nature of these existing or forthcoming restrictions, a problem may arise for enforcement authorities and stakeholders alike in determining which articles are within the scope of a restriction, and which are not. This problem often results from the difficulty in giving a precise meaning to narrative descriptors that define the articles concerned by the restrictions.

As requested repeatedly by stakeholders and a number of Member States, the Commission would like to address this complex issue by developing practical guidelines, for which ECHA's support is necessary.

1. Nickel articles intended to come in "direct and prolonged" contact with the skin [Entry 27, subparagraphs b and c)]

After the endorsement in the CARACAL meeting of 2-3 April 2014 of the recommendation made by ECHA on the interpretation of "prolonged contact with the skin" in the context of the nickel restriction, this interpretation, together with the supporting technical analysis performed by ECHA, was made available via the Q&A section of ECHA's website as Q&A ID No. 0935¹.

¹ How to clarify the "prolonged contact with the skin" in relation to the nickel restriction entry 27?
<http://echa.europa.eu/support/qas-support/search-qas>

As a follow-up action to the publication of the definition, and in view of the requests from Member State Competent Authorities and stakeholders during CARACAL, it was agreed that a more practical guide with a non-exhaustive list of article types and subtypes within the scope of the restriction would be elaborated. This non-exhaustive list of articles is meant to complement the limited list already included in the text of entry 27 to Annex XVII and the example provided in Q&A ID No 663 (mobile phones) and should assist enforcement authorities and stakeholders in determining the obligations imposed by the restriction with respect to different types of articles.

Consequently, the Commission requests ECHA to prepare a guideline document containing a non-exhaustive list of article types and subtypes covered by the provisions in sub-paragraph (1)(b) of entry 27, as well as the rationale used in elaborating such a list.

We expect that the starting point for this assessment will be the definition of "prolonged contact with the skin" developed by ECHA but consider that this could be further complemented by other relevant sources such as inquiries to a broad range of stakeholders in order to obtain information on patterns of use of articles containing nickel and other information useful in determining if a given article falls under the scope of the restriction. This will be complemented with other information sources, e.g. other restriction proposals with similar narrative descriptors (e.g. prolonged contact with skin) and open literature. ECHA should also consider case-reports or research studies relative to allergic contact dermatitis caused by nickel in articles. This could be done by contacting some of the health-care institutions and dermatological associations in Europe.

2. Articles containing polycyclic aromatic hydrocarbons (PAHs) coming into "direct as well as prolonged or short-term repetitive contact with the skin or the oral cavity" [Entry 50 paragraphs 5 and 6]

Recital 9 of Regulation (EU) 1272/2013 commits the Commission to the development of further guidance in relation to articles which "*come into direct as well as prolonged or short-term repetitive contact with the skin or the oral cavity under normal or reasonably foreseeable conditions of use*". It is further specified that "*articles or parts thereof which are only in short and infrequent contact with the skin or oral cavity should not be included within the scope of the restriction as the resulting exposure to PAHs would be insignificant*".

ECHA is requested to carry out a qualitative assessment, based on the narrative descriptors² that define the article types and subtypes within the scope of the restriction, mainly on the information in the Annex XV dossier prepared by Germany, of articles

² Those that define the scope of the restriction. In this case: "rubber or plastic components which come into direct as well as prolonged or short-term repetitive contact with the human skin...", "under normal or reasonably foreseeable conditions of use", etc.

potentially within the scope of the restriction. Work with other guidelines need to be taken into account (e.g. lead – under normal or reasonable conditions of use). ECHA may consider contacting Germany who prepared the Annex XV dossier as well as a broad range of stakeholders for further information on article types which might contain PAHs. A quantitative risk-based approach based on the migration behaviour of PAHs in different plastic and rubber materials and on the exposure resulting from different use patterns for different article types is not required in the justification of the article types recommended for inclusion, as detailed information on exposure conditions and migration of PAHs for each of these articles / materials may not always be available to sustain such an approach.

The assessment should result in a list that complements and expands the existing list of article types defined in paragraphs 5 and 6 of entry 50 to Annex XVII. Such a list, as well as a rationale for its development should be incorporated in a guideline document.

Lead in consumer articles

Following from the opinion received from ECHA on 7 April 2014 on an Annex XV dossier prepared by Sweden, to restrict the presence of lead and its compounds in articles intended for consumer use, the Commission has had a first discussion with Member States on a draft Commission Regulation setting out the restriction in the REACH Committee of 23 September and expects to submit a proposal for a vote before the end of 2014.

In order to support regulators and stakeholders in the implementation of this restriction the Commission requests ECHA to develop guidelines so as to (i) clarify certain aspects of terms that define the scope of the restriction (e.g. “accessibility”, “normal/reasonably foreseeable conditions of use” (ii) provide a non-exhaustive list of article types (and examples of sub-types) which fall within (or out of) the scope of the restriction. The current draft text of the proposed measure, as submitted to the Committee and notified to WTO is attached for your reference.

In principle we would expect the elaboration of such a guideline (+list of examples) to build upon the work already done by RAC and SEAC during the opinion making process in analysing different article types and which resulted in the generic identification of article groups included and excluded from scope, as described (i) in pages 17 – 20, and in the more detailed list provided in Annex 1, of the RAC/SEAC compiled opinion and (ii) in section B.2 and in appendix 7 of the background document. It should be noted that in this case the focus should be placed on whether article types and subtypes meet the criteria for inclusion in the scope (whereas the list of "ins" and "outs" in the previously mentioned Annex 1, currently refers to the inclusion of a given category in the cost calculation of the socio-economic assessment (SEA). As a minimum the guidelines should contain a description of the scope of the restriction and

its associated inclusion / exclusion criteria as well as a detailed list of article types and subtypes which would typically meet them.

3. General approach

For the sake of reference, the three guideline documents requested could resemble in their approach the "*Guideline on the interpretation of the concept "which can be placed in the mouth" as laid down in the entry 52 of Annex XVII to REACH Regulation 1907/2006*". If considered useful, in each of the cases, ECHA might complement the list elaborated with a 2nd one with examples of articles that are clearly not within the scope of the restriction.

As customary for the development of such guidelines, ECHA might wish to conduct a public consultation on draft versions of the guidelines.

Our services are available for further detailed discussion on the approach and methodology to be followed, and on the particular content and structure of the guideline documents to be elaborated by ECHA. The officials responsible for this activity are Enrique.Garcia-John@ec.europa.eu and Christian.Heidorn@ec.europa.eu.

We foresee that a draft of each of these guideline documents will be distributed for consultation and further inputs by Member States and stakeholders in the framework of CARACAL before final endorsement.



Klaus Berend
DG Enterprise and
Industry



Bjorn Hansen
DG Environment

Attachments: Draft Commission Regulation on Lead (Act + Annex)

Cc.: Giuseppina Luvarà, Enrique Garcia-John (DG ENTR, unit F1)
Sylvain Bintein, Christian Heidorn (DG ENV, unit A3)
Matti Vainio, Kirsi Sihvonen, Sotirios Kiokias (ECHA)