Call for Evidence on skin sensitising substances in consumer mixtures

Background note

Introduction

Allergic contact dermatitis (ACD) is a widespread skin disease with significant health implications for the individuals concerned, which also has a significant social and economic impact. Contact allergy (CA) is caused by contact with a specific allergen and can result in ACD after repeated contact with the allergen. The German Information Network of Departments of Dermatology (IVDK) estimates the prevalence of CA to be about 20 %, and the yearly incidence of the occurrence of ACD to be about 7 % in the German general population[1]. Similar estimations are available from other sources[2].

Although a high proportion of cases is caused by nickel and its compounds, many other sensitising substances can trigger ACD. Skin sensitisation is a health effect that can lead to lifelong sensitivity to a specific allergen, to which people who are sensitised must avoid exposure. This may not always be possible, for instance, when the allergen has not been identified in a patch test, the source of exposure is not known, or when other substances cause cross-reactivity. Chemicals that can induce an allergic skin reaction are referred to as skin sensitisers. 'Skin sensitisation' is a toxicological endpoint under the CLP Regulation and more than 1 200 chemicals have a harmonised classification as skin sensitisers. In addition, REACH registrants or other notifiers have self-classified an even greater number of substances as skin sensitisers.

Given the high prevalence and incidence of the disease and considering the high number of substances with allergenic properties, an assessment of the need for regulatory action on skin sensitisers in consumer mixtures is considered necessary.

The Competent Authorities of France, Germany, and Ireland are issuing this call for evidence (CfE) regarding the uses of skin sensitising substances in consumer mixtures[3] in order to assess (i) whether risks are adequately controlled under specific conditions, and (ii) which impact additional regulatory risk management would have on society.

In case inadequately controlled risks are identified, the Competent Authorities of France, Germany, and Ireland may decide to address them by proposing a restriction according to REACH Art. 68 (1).

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[1] https://ivdk.org/ivdk_broschuere.pdf (in German language)

[2] Diepgen et al. 2016 doi: 10.1111/bjd.14167, Alinaghi et al. 2019 doi: 10.1111/cod.13119, Hermann-Kunz 2000 doi: 10.1007/s001030070045

[3] https://echa.europa.eu/support/substance-identification/what-is-not-a-substance and Regulation (EC) 1907/2006, Art.3

Call for Evidence (CfE)

This CfE is an opportunity for all sectors to provide information on the use of skin sensitising substances in consumer mixtures, but also to provide information on known safe uses. In addition, epidemiological data on allergic contact dermatitis or information on health costs are requested. It will also be an opportunity for the Competent Authorities of France, Germany, and Ireland to identify relevant stakeholders and contact points within the sectors.

This CfE and subsequent consultations will help the competent authorities to frame potential future work on skin sensitisers.

The scope of the investigations comprises substances fulfilling the criteria for classification as skin sensitisers in accordance with the CLP criteria (Regulation (EC) 1272/2008)

i. in mixtures marketed or available for uses by consumers in the EU/EEA,
   AND
ii. to which skin contact is possible during reasonably foreseeable use.

Cosmetic products, as defined by Directive 76/768/EEC are outside the scope of the investigation (as per REACH Article 67).

The objective of this CfE is to gather information on skin sensitising substances in consumer mixtures, e.g.:

- information on the sectors, and type of uses/applications,
- measures in place (e.g. changed formulation, reduction of concentration, specific packaging, conditions of use) to minimise consumer exposure,
- experience regarding substitution efforts, availability of alternatives or reasons for non-substitution,
- data on the skin sensitising potency of substances,
- data on the technical functions of skin sensitisers in mixtures and/or on the safe use in consumer products,
- epidemiological data on allergic contact dermatitis and other health-related information including health costs.

Interested parties such as:

- companies (manufacturers, formulators, suppliers, distributors, importers etc.) and their associations,
- trade associations,
- scientific bodies (including dermatology clinics and dermatologists),
- Member State Authorities and any other stakeholders (including consumer associations, health insurance organisations) holding relevant information

are invited to submit information. The information gathered will provide valuable input to the assessment of regulatory actions on skin sensitisers in consumer mixtures.

Information can be submitted confidentially and will be treated as such by the involved authorities of the Member States.

Germany, France, and Ireland invite interested parties to respond to the CfE by 30 September 2022.
For any clarifications, please contact the German Competent Authority: chemg@baua.bund.de