

Hexavalent chromium in leather is now regulated in European Union member states to limit chromium allergy and dermatitis

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Metals have for more than a century played important roles in allergic contact dermatitis epidemics. While nickel exposure in consumers has been limited by the 1994 EU Nickel Regulation, now part of the REACH agreement, occupational nickel exposure is still not regulated. Nonetheless, nickel allergy prevalences have decreased significantly in European populations as opposed to the increasing trends in unregulated American and Chinese populations. The nickel regulation must therefore be considered successful as it shows that regulation can indeed alter the epidemiology of metal allergy. A cobalt regulation has not yet been formally discussed despite cobalt allergy remains prevalent in patch tested dermatitis patients. Notably, market surveys are now being conducted to identify sources of cobalt exposure which may provide the basis for future regulations.

Chromium exposure has also resulted in a severe contact allergy epidemic. Historically, allergic chromium dermatitis was mainly observed on the hands of construction workers resulting in occupational disability. In 1983 in Denmark and in 2005 in the European Union member states, the addition of ferrous sulphate to cement became compulsory to reduce the water soluble hexavalent chromium content to no more than 2 ppm (parts per million). Following this intervention, the prevalence of chromium allergy decreased significantly in Denmark and Germany among construction workers, again showing the potential benefits of a regulatory intervention on metal exposure.

In recent years, an increase of allergic chromium dermatitis due to skin contact with leather products has been observed (1). Trivalent chromium is used in leather tanning to obtain softness, durability, and flexibility following binding to collagen fibres, whereas hexavalent chromium is mainly an impurity or appears following oxidation of trivalent chromium during manufacturing, and perhaps even following normal wear (2, 3). While free trivalent chromium can indeed be found in leather and result in chromium allergy and dermatitis, the free pool of water-soluble hexavalent chromium appears to be the main hazard since its bioavailability is much higher. A German survey on 850 leather items conducted between 2000 and 2006 by the regulatory authorities of the federal states showed that half released more than

3 ppm hexavalent chromium and 1/6 more than 10 ppm (<http://www.bfr.bund.de/cd/9575>). Of 197 patients with chromium dermatitis seen in our clinic between 1995 and 2007, 55% had relevant exposure to leather products and a significant increase of chromium allergy was observed after 1999 (1). Pertinently, nearly half of our chromium allergic patients had foot dermatitis. Moreover, Danish patients with chromium allergy had a much worse clinical course of their hand dermatitis than patients with other allergies (4), and a Danish survey from 2009 showed that chromium was identified in nearly all of 60 randomly evaluated leather footwear and that the median chromium content was 1.7% (5). Notably, hexavalent chromium was released from 44% of 18 products evaluated with the ISO 17075 standard method. This test determines the mass fraction expressed in milligrams per kilogram of soluble hexavalent chromium in leather and has an analytical determination limit of 3 ppm by weight. Three items released more than 10 ppm and one shoe released 62 ppm hexavalent chromium. The chromium release rates should be interpreted together with elicitation threshold levels. Reactivity to hexavalent chromium differs slightly with a significant proportion of patients reacting to 7–10 ppm and with some reacting down to 1 ppm when the skin is irritated (6). Trivalent chromium elicitation concentrations are generally much higher.

In January 2012, the Danish government submitted a dossier with information about the chromium leather problem to the European Chemicals Agency. It was proposed that no more than 3 ppm hexavalent chromium should be released from leather products sold in European Union member states. In November 2012, the Committee for Risk Assessment adopted by consensus the opinion on the restriction proposed in the Danish dossier, although the restriction was modified by deleting a notion of 'direct and prolonged contact with the skin'. The restriction covers leather articles and articles containing leather parts used by consumers or workers that under normal or reasonably foreseeable conditions of use come into contact with the skin. The ISO 17075 Standard was chosen as the analytical method that should be utilized to test for compliance with the regulation. According to the opinion of the Committee for Risk Assessment, that threshold is expected to be 80% effective in reducing the occurrence

of new hexavalent chromium-related allergic dermatitis cases due to hexavalent chromium in leather articles. Manufacturers were given a 12-month period before entry in to force of this regulation to take appropriate measures.

This regulation on chromium release from leather products is a very positive and important step towards better prevention of allergic chromium dermatitis in Europe. There will be a continuous requirement for

dermatologists and epidemiologists to monitor the effect of the regulation. Also, the European Union needs to allocate resources to enforce the regulation. As a warning, there seems to be severe weaknesses in the enforcements of the nickel regulation in parts of Europe. We therefore hope that the good intentions based on solid science should not be put aside by a lack of enforcement.

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