

Restriction of the chromium VI in leather under REACH Regulation

On the 26th of March 2014 the COMMISSION REGULATION (EU) No 301 of 25 March 2014 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards chromium VI compounds, was published on the Official Journal of the European Union.

On the 19th January 2012 the Kingdom of Denmark submitted to ECHA a dossier pursuant article 69(4) of REACH Regulation for the amendment of annex XVII according to article 68(1). It followed RAC opinion (28th November 2012) and SEAC opinion (6th March 2013) besides public consultation. Eventually ECHA submitted the final opinions at issue to the Commission (8th April 2013) triggering the bases for the present Regulation.

The mechanisms of the formation of chromium (VI) in the leather are today well known. All tanning within the EU is carried out using basic trivalent chromium (III) sulphate, but chromium (VI) may be formed by oxidation of the chromium (III) within the leather. The main mechanism of the formation of chromium (VI) in the leather seems to be the oxidation of the chromium (III) by oxidizing fatty acids. A considerable influence on the formation of chromium (VI) in leather could be attributed to ageing and UV irradiation. Some pigments contain chromium (VI) too.

The restriction of chromium (VI) in leather and leather articles is not limited to direct and prolonged contact with skin, which is instead peculiar of nickel restriction where the definition "prolonged contact"¹, is based on specific information on nickel allergy. In fact, sensitised individuals may react to the low levels of chromium (VI) that might migrate from leather articles eliciting an allergic response to chromium (VI), a potent allergen. Paragraphs 5 and 6 of entry 47 of the new Regulation emphasises that prolonged skin contact with a leather article is not necessarily required and therefore **the presence** of the chromium (VI) ion in concentrations equal or greater than 3 p.p.m. is sufficient for non-compliance with REACH regulation. The "coming into contact with skin" seems to exclude for instance shoes wore with socks but this is not the case as chromium (VI) can migrate through the socks.

The restriction is valid for both consumers and professional users once the article is placed on the market.

All the following conditions and provisions shall apply:

1. restriction shall apply to both **leather articles** and **articles containing leather parts, and**
2. restriction shall apply to both leather articles and articles containing leather parts coming into **contact with skin, and**
3. restriction shall apply where either leather articles or articles containing leather parts or both are **placed on the market and**
4. restriction shall apply when **chromium (VI) \geq 3 mg/kg.**

It must be noted that the concentration limit fixed to be < 3 mg/kg measured on the total dry weight of the leather (part), is the quantification limit of EN ISO 17075², the only internationally recognized analytical standard method currently available to detect chromium (VI).

¹ "prolonged contact" should be understood as covering a daily overall contact with skin of more than 30 minutes continuously or 1 hour discontinuously.

² Leather – Chemical tests -Determination of chromium (VI) content" published in 2007

In paragraphs 5 and 6 of entry 47 it appears the regulation applies only when the leather comes into **direct contact** with the skin. It wouldn't be possible to come into contact with skin indirectly. But, poring over the wording (considerandum 4) and the preliminary works previous to the adoption of Regulation 301/2014, one can assume that the Regulation at issue applies also when the leather comes into **indirect contact** with skin when considering the risk of induction of skin sensitisation related to indirect contact. For instance, in already sensitised people, indirect contact with leather may also elicit allergic responses. The loophole is quite evident. Therefore, it can be argued that the Regulation does not apply if there is no direct contact with leather. Notwithstanding, I would like to emphasize that it is the chromium (VI) ion coming into contact with skin the driving factor regardless leather being into contact or not. It is chromium (VI) the strong allergenic and not the leather itself. Indirect contact of leather is deemed to be important once chromium (VI) can migrate through e.g. textile fabrics or any other lining.

The loophole stands in the "coming into contact" wording and shall be closed in order to avoid misinterpretations or illicit behaviours.

Then, for the application of the Regulation the time contact is not important. It applies even following one short exposure!

Paragraph 6 of entry 47 is also important in regard to the ongoing and old discussions on the definition of article. The restriction applies to the "leather part" of an article and therefore, in application of the "once an article always an article" interpretation for SVHC, the "leather part" is an article. If we apply the ECHA (mis)interpretation of article definition, the limit of 3 p.p.m. should be applied to the "assembled article" for instance to the whole weight of a wool coat which has some leather parts. It is now clear that the part of an article is an article when the part is already an article before being assembled.

The restriction shall not apply to any **second-hand** article, which was in **end-use** before 1 May 2015. This means that second-hand leather articles or articles containing leather parts even if stocked before 1 May 2015 cannot benefit from this provision because they are not in end-use.

The regulation shall apply from 1 May 2015.