

Restricted substances in leather

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Managing restricted substances policies and getting the best out of testing budgets is becoming an increasingly important factor for footwear retailers, manufacturers and material suppliers as the range of chemical restrictions increases. As part of this process, it is important to focus testing on the appropriate substances and materials, for example, the testing for azo dyes on dyed linings. It is also important to understand which restricted substances relate to the specific materials involved and how to focus testing on realistic risks.

LEGISLATION

Many countries around the world have legislation in place to restrict the use of certain chemicals and materials that are considered to cause harm to humans, animals or the environment. The European REACH Directive 1907/2006 is probably the most comprehensive of global restricted substances legislation and, as such, is complex and far-reaching.

'REACH' is an acronym for the Registration, Evaluation, Authorisation (and restriction) of Chemicals. The legislation is designed to improve the protection of human health and the environment by ensuring that exposure to potentially harmful chemicals is kept to a minimum. Each identified chemical is assessed and, over time, the most harmful

chemicals will be removed from use. In addition, members of the supply chain are provided with more information on how to use chemicals safely and minimise exposure when necessary.

There are two distinct sets of requirements within REACH that are relevant to those who are manufacturing goods in or importing finished goods into the European Union. This includes components, footwear and other consumer goods, which are covered by Annex XIV and Annex XVII. It is important to remember that there are also additional requirements to consider within other European legislation (such as the General Product Safety Regulation) and also country-specific legislation.

Where decisions taken by the European Commission will restrict the use and presence of certain chemicals in consumer products, these substances will be listed in Annex XVII of REACH. These decisions are often applicable to specific materials or processes. Products which do not meet the requirements in Annex XVII should not be placed on the market in the European Union. The relevant substances associated with leather are as follows.

AZO DYES

Leathers that are dyed and will be in direct and prolonged contact with the skin should be assessed for the presence of certain restricted carcinogenic

aromatic amines, which can form from the breakdown of certain azo dyes. For footwear, the most obvious area for skin contact will be unlined uppers, linings and insoles. Other less obvious areas to consider are any decorative trims such as on women's or children's footwear which may come in direct contact with the foot.

European legislation views 22 aromatic amines as being problematic. These must not be present in concentrations over 30 parts per million (ppm), as specified in REACH 1907/2006 Annex XVII Entry Number 43. The primary method for analysis is EN ISO 17234-1:2010. Each coloured leather in contact with the skin should be assessed separately; undyed leathers should not require testing.

PENTACHLOROPHENOL (PCP)

Pentachlorophenol is a bioaccumulative anti-fungal agent that has been restricted for sale in preparations since 1991. The requirements in REACH 1907/2006 Annex XVII Entry Number 22 state that mixtures shall not be placed on the market which contain equal to or greater than 0.1 per cent (1,000ppm) of PCP. National legislation in some countries, as for example Germany, restricts the use of pentachlorophenol in leathers to a maximum limit of 5ppm. Many brand or retailer specifications use this lower limit as a basis for their requirement.

ORGANOTINS

Organotins have had a wide range of uses, including as stabilisers, catalysts and anti-microbial additives. Four of these organotin compounds have been restricted in articles under EU Commission Decision 2009/425/EC and phasing dates for these restrictions were introduced in 2010. The restricted organotin compounds concerned are Tributyltin (TBT), Triphenyltin (TPT), Dibutyltin (DBT) and, for certain articles including footwear, Dioctyltin (DOT). These compounds shall not be present in leather greater than 0.1 per cent (1,000ppm) by weight of tin.

DIMETHYLFUMARATE

Dimethylfumarate (DMFu) is a biocide that has been included in footwear packaging to prevent mould growth during transit. This chemical was restricted in the European Union by an emergency ban (Commission Decision 2009/251/EC) in 2009. However, during 2012 a permanent ban was placed on the chemical under REACH 1907/2006 Annex XVII Entry Number 61. This chemical has been linked to a number of serious skin reactions, including that due to contact with leather furniture which contained sachets of DMFu. Sachets of DMFu have also been found in footwear packaging.

The DMFu in sachets can sublime (change from a solid to vapour state and condense back to solid state) during transport allowing the chemical to migrate into the consumer product it is intended to protect, in our case footwear. REACH Annex XVII Entry Number 61 restricts the maximum amount of DMFu in consumer products to 0.1mg/kg (0.1ppm). DMFu should not be confused with silica gel, a desiccant that is often found in sachets within footwear packaging.

CHROMIUM VI

On 25th March 2014, the European Commission published regulation 301/2014 to extend the REACH Annex XVII restriction on chromium VI to include leather articles and other articles containing leather parts which will come into contact with the skin. This regulation amends entry 47 of Annex XVII of the REACH regulation (1907/2006) by the addition of the following paragraphs:

5. *Leather articles coming into contact with the skin shall not be placed on the market where they contain chromium VI in concentrations equal to or greater than 3mg/kg (0,0003% by weight) of the total dry weight of the leather.*

6. *Articles containing leather parts coming into contact with the skin shall not be placed on the market where any of those leather parts contains chromium VI in concentrations equal to or greater than 3mg/kg (0,0003% by weight) of the total dry weight of that leather part.*

7. *Paragraphs 5 and 6 shall not apply to the placing on the market of second-hand articles which were in end-use in the Union before 1 May 2015.*

These additional requirements will apply to all products within the scope placed on the market from 1st May 2015.

The regulation cites EN ISO 17075 as the reference test method to be used with 3mg/kg being the determination limit of this method and the basis for monitoring and enforcing these requirements. However, this limit is higher than the 'lowest-observed adverse effect' level quoted in the Committee for Risk Assessment (RAC) opinion. Therefore, there is pressure for a more sensitive test method to be developed in order to allow this level to be determined accurately.

The regulation is aimed at reducing the occurrence of chromium VI related allergic dermatitis from leathergoods, and it has been claimed that the instance of such reactions will drop by 80% when the regulation is in place.

If it does not bring about the required reduction in incidents of allergic dermatitis or a more sensitive method becomes available, this regulation will be reviewed.

FORMALDEHYDE

Manufacturers and suppliers should also include chemicals which are known irritants such as formaldehyde in their restricted substance policies.

In leathers, formaldehyde may be present in some synthetic tannages, dyeing auxiliaries, fatliquors or finishes. Exposure to formaldehyde may result in irritation to the skin, eyes and respiratory tract. Even a low level of formaldehyde can cause an allergic

reaction in people who are sensitive to this chemical. Although not necessarily restricted in all national legislation, formaldehyde is included in the European Eco-label standard and SATRA's Restricted Substances List.

Formaldehyde in leather is measured using the EN ISO 17726 method, which uses a colourimetric method to determine any formaldehyde present in the leather.

TOTAL LEAD

The use of lead and other heavy metals is restricted in many countries. For instance, in the USA, the Consumer Product Safety Improvement Act (CPSIA) of 2008 has specified stringent requirements for the total amount of lead in products for children up to the age of 12. This includes footwear. Third-party laboratory testing is required to confirm that products do not contain lead that exceeds the specified levels. Lead has been linked to irreversible brain damage in children and, in extreme cases, fatalities.

The maximum requirements set by the CPSIA are 100ppm for lead in products intended for children 12 years old or younger and 90ppm for lead in paint or similar surface coatings. An accredited third-party laboratory must carry out this testing, and certificates are required to prove safety compliance.

THE FUTURE

It is anticipated that the number of substances being restricted will increase in the future. For example, the REACH Candidate List to Annex XIV known as the 'Substances of Very High Concern' (SVHC) list has expanded from the first version (which contained 15 substances in 2009) to a current total of 151. No doubt, some of these will become subject to increased restrictions at some stage. It must be noted, however, that many of the substances on the SVHC list are not used in the production of leather and so manufacturers need only concern themselves with a smaller group of chemicals.

Although not necessarily bound up in one piece of all-encompassing legislation, many other parts of the world have statutes that restrict the use of certain substances. Suppliers will therefore need to take care that they are aware of all the requirements which apply in each of their markets. 