

New Legal Provisions of Relevance for Footwear and Leather Production

In addition to the regular update of the SVHC candidate list in January 2019, October and December 2018 saw two new entries in Annex XVII of the REACH Regulation regarding 33 CMR compounds and four phthalate plasticisers of relevance for materials widely used in footwear and clothing. They include, among others, formaldehyde and quinoline as well as a number of substances belonging to the phthalates, soluble heavy metals, organochlorine carriers, and disperse dyes. Although the legal amendments do not come into force until July and November 2020, respectively, REACH-compliant manufacturing of goods and materials needs a certain lead time. It is therefore advisable to consider the new regulatory limits immediately, particularly in the case of raw materials and components.

Phthalates: Entry in Annex XVII of the REACH Regulation

On 18 December 2018 the European Commission published a new regulation modifying Entry 51 of Annex XVII of Regulation (EC) 1907/2006 (REACH). This modification concerns four phthalates (DIBP, DBP, BBP, DEHP) which are present in a wide range of plasticiser-containing materials and pose an unacceptable risk for human health in the opinion of the commission.

Uptake of phthalates can take place through contaminated foodstuffs, through inhalation of indoor air contaminated with phthalate-containing dust, as well as through direct contact of the skin or mucous membranes with contaminated objects.

The new regulation will come into force on 7 July 2020. It applies to materials consisting of poly(vinyl chloride) (PVC), poly(vinylidene chloride) (PVDC), poly(vinyl acetate) (PVA), polyurethane (PU), as well as all other polymers (including polymer foam and rubber, apart from silicone rubber and natural latex coatings), surface coatings, non-slip coatings, panelling, adhesive coatings, printed patterns, adhesives, sealing compounds, inks, and paints. Moreover, the ban has been extended to toys and baby articles. In fact, the use of DEHP, DBP, or BBP in such products was already regulated, and now DIBP has also been banned.



Phthalate plasticisers: Limits for articles and materials as of 7 July 2020	
DIBP - Diisobutyl phthalate DBP - Dibutyl phthalate BBP - Benzyl butyl phthalate DEHP - Diethylhexyl phthalate	0.1 % = 1000 mg/kg for each substance or for the sum thereof Restrictions for products, which are - intended for outdoor use - intended exclusively for industrial or agricultural use The regulation applies only if the products come into contact with human mucous membranes or for longer periods with the skin.

Products placed on the market after 7 July 2020 and which exceed the limits for the phthalates listed in the table have to be withdrawn from the market.

Exceptions to this ban are encountered in the areas of aircraft, motor vehicles, laboratory measuring instruments, and products for which specific regulations already exist, such as materials coming into

contact with foodstuffs or pharmaceutical and cosmetic products, as well as electrical and electronic equipment, the last-mentioned articles being covered by Directive 2011/65/EU.

33 CMR Substances: Entry in Annex XVII of the REACH Regulation

The commission's regulation (EU) 2018/1513 of 10 October 2018 amending Annex XVII of regulation (EC) No. 1907/2006 regulates the limitation and use of 33 CMR substances (CMR = carcinogenic, germ-cell mutagenic, or reprotoxic), to which consumers are exposed by skin contact and inhalation. In order to keep exposure as low as possible, it bans placing on the market of the CMR substances in clothing, footwear, bags, and other textiles, which come into contact with human skin to a similar extent to clothing (for example, bed linen). The substances to which the restrictions apply are used in various processes in the textile and footwear industries and by their suppliers.

The following products are given high priority for regulation of the 33 CMR substances:

- Clothing or related accessories
- other textiles, which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing
- footwear



The new regulations for the 33 CMR substances come into force on 1 November 2020 for textiles worn close to the body.

33 CMR substances: Limits for articles and materials placed on the market after 11 November 2020	
Heavy metals, soluble cadmium, arsenic, lead, chromium VI	1 mg/kg per substance
VOC Benzene	5 mg/kg
EU-PAH Benz[a]anthracene, benz[e]acephenanthrylene, benzo[a]pyrene, benzo[e]pyrene, benzo[j]fluoranthene, benzo[k]fluoranthene, chrysene, dibenz[a,h]anthracene	1 mg/kg per substance
Chlorinated benzenes and toluenes (organochlorine carriers) Tetrachlorotoluene, trichlorotoluene, chlorotoluene	1 mg/kg per substance
Formaldehyde	75 mg/kg*
Phthalates DIHP, DMEP, DIPP, DPP, DnHP	1000 mg/kg per substance
Solvents NMP, DMAC, DMFA	3000 mg/kg per substance
Disperse dyes Disperse Blue 1, Basic Red 9, Basic Violet 3	50 mg/kg per substance
Salts of regulated azo dyes 4-Chloro-o-toluidine chloride; 2-naphthylammonium acetate; 4-Methoxy-m-phenylenediammonium sulphate; 2,4-diaminoanisole sulphate; 2,4,5-trimethylaniline hydrochloride	30 mg/kg per substance
Quinoline	50 mg/kg

* Transition period with 300 mg/kg for jackets, coats, and upholstery until 1 November 2023

Most of the 33 CMR substances are already included in the existing lists of limit values compiled by the footwear and leather industries. It should be noted, however, that legal limits have now been established for parameters encountered very frequently in footwear materials, such as soluble heavy metals, formaldehyde, and the phthalates DIHP, DMEP, DIPP, DPP, and DnHP.

Excluded from the new restriction on the 33 CMR substances are clothing, footwear, or parts and accessories that are made entirely out of natural leather, fur, or hide as well as non-textile fasteners and decorative attachments, wall-to-wall carpets and textile floor coverings for indoor use, second-hand clothing and footwear and related accessories, personal protective equipment, and medical devices.

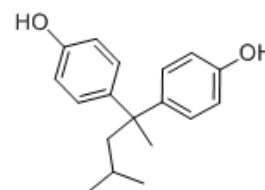
Extension of the SVHC Candidate List

On 15.01 2019 the ECHA added six new substances of very high concern (SVHCs) to the REACH candidate list, which now contains 197 chemicals.

Bisphenol derivative:

BisP-MIBK or 2,2-Bis (4'-hydroxyphenyl)-4-methylpentane
(CAS 6807-17-6)

Reason for inclusion: reprotoxic

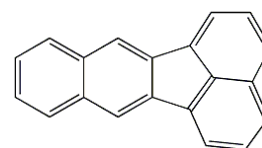


In addition to Bisphenol A, BisP-MIBK is another member of the bisphenol group to be put on the SVHC list. Like Bisphenol A, BisP-MIBK is also used in plastics, thermopaper, coatings, and epoxy resins. It is rather unlikely that the concentration limit will be exceeded in footwear material, but this cannot be entirely excluded in individual cases.

Polycyclic aromatic hydrocarbons (PAH):

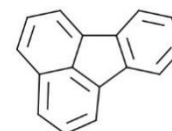
Benzo[k]fluoranthene (CAS 207-08-9)

Reason for inclusion: carcinogenic, persistent (P), bioaccumulative (B), and toxic (T)



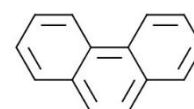
Fluoranthene (CAS 206-44-0; 93951-69-0)

Reason for inclusion: persistent (P), bioaccumulative (B), and toxic (T)



Phenanthrene (CAS 85-01-8)

Reason for inclusion: persistent (P) and bioaccumulative (B)



Pyrene (CAS 129-00-0; 1718-52-1)

Reason for inclusion: persistent (P), bioaccumulative (B), and toxic (T)



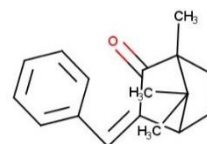
Benzo[k]fluoranthene belongs to the group of polycyclic aromatic hydrocarbons (PAH) which, as so-called EU-PAH, are subject to a limit of 1.0 mg/kg, or 0.5 mg/kg for children's articles, in plastics coming

into frequent contact with the skin. As SVHC candidates, benzo[k]fluoranthene, fluoranthene, phenanthrene, and pyrene are, with immediate effect, subject to a duty to notify if their content in a material exceeds 0.1 % (= 1000 mg/kg), regardless of whether skin contact is expected. PAH are not added intentionally; they originate either from contaminated raw materials or as a result of the production process. PAH are found mainly in rubber, plastics, coatings, paints, or adhesives. Their content in a finished product hardly ever exceeds the 0.1% limit.

UV Filters:

**3-BC or 3-benzylidene camphor or
1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one**
(CAS 15087-24-8)

Reason for inclusion: endocrine disruptor, environmentally hazardous for aquatic ecosystems



The compound was formerly used as a UV filter in cosmetic products. However, such use has been forbidden since 2016. Use of 3-BC in footwear materials is not to be expected.

A complete list of SVHC Candidates with reference to their relevance for footwear and footwear materials will be found on the [PFI Web Site](#).

Further questions will be gladly answered by:

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