

LETTER TO THE EDITOR

Commission Regulation (EU) No. 412/2012: is dimethyl fumarate still present in products imported from countries outside the European Union?

Editor

Dimethyl fumarate (DMF), the methyl ester form of fumaric acid (DMF) is an effective mould-growth inhibitor. It has a wide-spectrum biocide activity and has been used to protect leather during storage and transport. DMF was first identified as a potent contact sensitizer during a contact dermatitis outbreak that occurred because of its use in Chinese manufactured furniture.^{1,2} In the United Kingdom, this led to the largest consumer group action ever recorded, with an estimated compensation of £ 20 000 000 being paid to 1650 claimants.¹ DMF was most often contained in little pouches fixed inside the furniture or added to the footwear boxes; numerous studies have documented DMF as an allergen in shoe dermatitis, furniture and clothes.^{1,2} The marketing and use of DMF in biocidal products has not been permitted in the European Union since 1998 and articles produced in the Union may not be treated with DMF.² However, Directive 98/8/EC did not foresee restricting measures regarding imported articles into the European Union without being treated with such biocides. In March 2009, the European Commission adopted the decision 2009/251/EC and banned goods contaminated with DMF from being marketed in or imported into the EU. This prohibition was subsequently prolonged on 2010, 2011 and 2012.^{3,4} The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (EC) No 412/2012 have added the following communication in the Annex XVII: 'Dimethylfumarate (DMF) shall not be used in articles or any parts thereof in concentrations >0.1 mg/kg. Articles or any parts thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market'.⁴ Countries outside the European Union, China and USA do not have mandatory parameters about concentration of DMF; accordingly, the importers based in an EU country are responsible for ensuring the REACH compliance of their products. Despite the implementation of a ban on the use of DMF as a fungicide in consumer products in the EU, allergy to DMF continues to be reported¹ and several authors yet recommend considering DMF as a possible allergen.^{5–7} The aim of this study was to evaluate if European preventive measures could be considered completely

Table 1 Results of chemical analysis

Year	Analysed samples	Articles containing DMF	Concentration of DMF	Material
2013	58	1	6.64 mg/Kg	Leather footwear
2014	83	0	—	—
2015	67	1	0.4 mg/Kg	Leather article

accepted and practised; to do this we evaluated the presence of DMF in samples of textiles, footwear and leather imported into Italy, from countries outside the European Union. The presence and concentration of DMF in textiles, footwear and leather was determined by gas chromatography/mass spectrometry at the chemical laboratory, Buzzi Spa located in Prato, Italy. The requests for inspections came from manufacturing and shipping companies that are required to be REACH compliant. The analysis to detect any critical substances potentially present in footwear and footwear components was performed in accordance with the International Organization for Standardization (ISO) prepared by the European Committee for Standardization (CEN). The ISO/TS 16186:2012 was chosen as the analytical method that should be utilized to test for compliance with the regulation. This Technical Specification gives a test method for determining the amounts of dimethyl fumarate (DMF) in footwear materials, desiccant sachets and other commodities. Chemical analysis verified the presence of DMF in two out of 208 samples during a 3-year period from July 2013 to July 2015 (Table 1). The results of our study suggest that almost all suppliers are capable of complying with the REACH directive and the Regulation No. 412/2012 is effective in reducing the presence of products contaminated with DMF in Europe. However, there are still isolated cases^{5–8} due to illegal importation or sale of merchandise imported prior to 2009.

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DOI: 10.1111/jdv.14008
