Commission Regulation (EU) No 412/2012 of 15 May 2012 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) (Text with EEA relevance)

COMMISSION REGULATION (EU) No 412/2012

of 15 May 2012

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)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[(1)], and in particular Article 68(1) and Article 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 provides that, if a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall prepare a dossier after notifying that intention to the European Chemicals Agency (the Agency).

(2) France has prepared a dossier concerning the substance dimethylfumarate (DMF) which demonstrates that DMF contained in articles or parts thereof, in concentrations greater than 0,1 mg/kg, poses a risk to human health and that action on a Union-wide basis, beyond any measures already in place, is necessary. That dossier was submitted to the Agency in order to initiate the restriction process.

(3) Furniture and footwear available on the market in several Member States have been identified as the cause of damage to the health of consumers in France, Poland, Finland, Sweden and the United Kingdom.

(4) It was recognised that the health damage was caused by DMF, which is a biocide that prevents moulds that may deteriorate leather furniture or footwear during storage or transport in a humid climate. DMF was most often contained in little pouches fixed inside the furniture or added to the footwear boxes. It evaporated and impregnated the

product, protecting it from moulds. However, it also affected consumers who were in contact with those products. DMF came into contact with consumers' skin where it caused a number of cases of sensitisation (contact dermatitis), resulting in a painful condition. In some cases, acute respiratory troubles were also reported. Dermatitis is particularly difficult to treat and the sensitisation is irreversible. Because of its potential for sensitisation, exposure to DMF can elicit adverse reactions at very low concentrations in sensitised subjects.

(5) The marketing and use of DMF in biocidal products is not permitted in the Union, according to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[(2)] and to Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market[(3)]. Therefore, articles produced in the Union may not be treated with DMF. However, Directive 98/8/EC does not foresee restricting the import into the Union of articles treated with biocides.

(6) On the basis of Article 13 of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[(4)], the Commission has adopted Decision 2009/251/EC of 17 March 2009 requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market[(5)], which restricts the placing on the market of products containing DMF, as an emergency measure until the situation of DMF could be evaluated under Regulation (EC) No 1907/2006.

(7) The prohibition provided by Decision 2009/251/EC was subsequently prolonged by Commission Decision 2010/153/EU[(6)], Commission Decision 2011/135/EU[(7)] and Commission Implementing Decision 2012/48/EU[(8)] and is applicable until the entry into force of this Regulation or 15 March 2013, whichever is the earlier.

(8) In its opinion of 8 March 2011, the Committee for Risk Assessment of the Agency considers that prohibiting the use of DMF in articles or parts thereof at a concentration higher than 0,1 mg/kg, and the placing on the market of articles or parts thereof containing DMF at a concentration greater than 0,1 mg/kg, is the most appropriate Union-wide measure to address the identified risks in terms of the effectiveness in reducing the risks.

(9) In its opinion of 14 June 2011, the Committee for Socioeconomic Analysis considers that the proposed measure regarding DMF is the most appropriate Union-wide measure to address the identified risks in terms of the proportionality of its socioeconomic benefits to its socioeconomic costs.

(10) The Agency has submitted to the Commission the opinions of the Committees for Risk Assessment and Socioeconomic Analysis.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 15 May 2012.

For the Commission

The President

José Manuel BARROSO

ANNEX

In the table of Annex XVII to Regulation (EC) No 1907/2006, the following entry 61 is added:

61.	Dimethylfumarate (DMF) CAS No 624-49-7 EC 210-849-0	Shall not be used in articles or any parts thereof in concentrations greater than 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.

(**1**) OJ L 396, 30.12.2006, p 1.

(**2**) OJ L 123, 24.4.1998, p. 1.

(**3**) OJ L 325, 11.12.2007, p. 3.

(**4**) OJ L 11, 15.1.2002, p. 4.

(**5**) OJ L 74, 20.3.2009, p. 32.

(**6**) OJ L 63, 12.3.2010, p. 21.

(**7**) OJ L 57, 2.3.2011, p. 43.

(**8**) OJ L 26, 28.1.2012, p. 35.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) No 412/2012.