

The EU Bans Dimethylfumarate (DMFu) in Consumer Products

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The Challenge

May 15, 2012, the Official Journal of the European Union (OJ) published Regulations (EU) No 412/2012, formally adding Dimethylfumarate (DMFu) into the REACH regulations, which becomes the 61st permanently restricted substance in Appendix XVII. Thereafter, the EU's temporary ban on dimethylfumarate (DMFu) becomes permanent now. The Regulation had been put into execution in 20 days after releasing.

Background: 3 years ago (March 17, 2009), the Commission of EU Community published a 1-year temporary Decision 2009/251/EC on 17 March 2009 requiring as of 1 May 2009 Member States shall ensure that products containing DMFu (maximum limit value: 0.1 mg/kg) are prohibited from being placed or made available on the market, and products containing DMFu and already placed or made available on the market are withdrawn from the market and recalled from consumers. The validity period of the Decision was extended on March 7, 2010 and March 2, 2012 respectively.

By the end of 2008, there had been many reports in the Europe about DMFu causing skin contact dermatitis to consumers. Many European countries have reacted to this:

- **France:** An act was issued on Dec 12, 2008 banning import of footwear and sofa / chairs containing DMFu for at least one year and requiring all products containing DMFu to be withdrawn from the market and not to be sold in France.
- **Belgium:** Measures have been taken to ban import and sale of footwear and chairs containing DMFu.
- **Spain:** Prohibits skin contacting products containing DMFu.
- **Italy:** The government recently issued an order requiring all products using DMFu as mildew-proof agent to be confiscated and undergo testing.

So far, member states of EU have initiated many product recalls due to the DMFu exceeding limit value. Among these products, shoes account for more than 90%. Besides, it also involves gloves, bags and clothing. The most representative cases are:

Year -Month	Notifying country	Product	Danger	Measures adopted by notifying country
August, 2012	Germany	 Category: Protective Equipment Product: Gloves Country of origin: India	The product poses a chemical risk due to the presence of 0.49 - 0.13 mg/kg of dimethylfumarate (DMF) in the leather.	Withdrawal of the product from the market.



Year -Month	Notifying country	Product	Danger	Measures adopted by notifying country
August, 2012	Estonia	 <p>Category: Clothing, textiles and fashion items</p> <p>Product: Children's shoes</p> <p>Country of origin: China</p>	The product poses a chemical risk due to the presence of 0.17 mg/kg of dimethylfumarate (DMF) in the footwear.	Withdrawal of the product from the market.
October, 2012	Bulgaria	 <p>Category: Clothing, textiles and fashion items</p> <p>Product: Girls' shoes</p> <p>Country of origin: China</p>	The product poses a chemical risk because it contains 5.93 mg/kg by weight dimethylfumarate (DMF).	Withdrawal of the product from the market.

What is DMFu?

DMFu is widely used in products manufactured in China. It is a stable compound classified as strongly irritating and even harmful to the skin, eyes, mucous membranes and upper respiratory tracts, by simple contact, inhalation or ingestion. This substance which is volatile can be found in the conservation and transportation process of leather, shoes, textile and products made of wood or bamboo to keep the products dry and prevent moulds.

Our Solution

Through global network and close relationship with regulation authorities worldwide, Intertek delivers the latest national and international regulatory standards on all industries and provides services including testing, inspection and consultation to ensure that your process and products comply with various quality and safety requirements to avoid product return, recall and claim due to violation of the regulations, and protect the company's reputation and benefits.

August 15, 2012, ISO issued DMFu detection method ISO/TS 16186:2012 for footwear material, making a breakthrough to the situation that DMFu can only be detected with laboratory's internal method. Intertek provides complete testing solution to identify the presence of DMFu in your anti-humidity sachets or your products, ensures your products conforming to the requirements of EU.

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欧盟禁止在消费品中 使用富马酸二甲酯(DMFu)

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挑战


2012年5月15日，欧盟官方公报 (OJ) 上发布条例 (EU) No 412/2012，正式将富马酸二甲酯并入REACH法规，成为附录XVII中第61项永久限用物质。因此，欧盟之前有关含富马酸二甲酯(DMFu)的产品的临时禁令将成为永久禁令。该条例已于发布之日起20天后执行。

背景信息：三年前（2009年3月17日），欧盟委员会通过了为期一年的临时决议2009/251/EC，即《要求各成员国保证不将含有生物杀灭剂富马酸二甲酯 (DMFu) 的产品投放市场或销售该产品的决定》，要求自2009年5月1日起，欧盟各成员国禁止将DMFu含量超过0.1 mg/kg的消费品投放或在市场上销售，已投放市场或在市场上销售的含有DMFu的产品应从市场上和消费者处回收。此决议分别于2010年3月7日和2012年3月2日延长了有效期。

2008年年底，媒体报道欧洲各地涌现多起富马酸二甲酯 (DMFu) 引起消费者皮肤过敏和丘疹的事件，欧洲多国纷纷做出响应：

- ▶ **法国：** 于2008年12月5日发布法令，在至少一年的时间内停止进口含有富马酸二甲酯的鞋类产品 and 沙发/扶手椅，并要求所有含有DMFu的产品撤架，不得在法国市场上销售。
- ▶ **比利时：** 禁止进口和销售含富马酸二甲酯(DMFu)的鞋和座椅。
- ▶ **西班牙：** 禁止任何接触到皮肤的产品含有富马酸二甲酯(DMFu)。
- ▶ **意大利：** 意大利卫生部发布部令，要求对意大利市场上使用DMFu做防霉剂的产品进行没收和检测。

迄今为止，欧盟各国已发起了多次由于产品中富马酸二甲酯(DMFu)超标而引起的召回。其中，九成以上为鞋类产品；除此以外，召回还涉及到手套、箱包、服饰等产品。较典型的案例如：

召回日期	通报国	产品信息	通报原因	通报国所采取的措施
2012年8月	德国	 产品类别：防护装备 产品：手套 原产国：印度	该产品中因富马酸二甲酯超标而存在化学风险	强制要求将该产品撤出市场



召回日期	通报国	产品信息	通报原因	通报国所采取的措施
2012年 8月	爱沙尼亚	 <p>产品类别： 服装、 纺织及时尚产品</p> <p>产品：童鞋</p> <p>原产国：中国</p>	该产品中因富马酸二甲酯超标而存在化学风险	自愿将该产品撤出市场
2012年 10月	保加利亚	 <p>产品类别： 服装、 纺织及时尚产品</p> <p>产品：女童鞋</p> <p>原产国：中国</p>	该产品中因富马酸二甲酯超标而存在化学风险	强制要求将该产品撤出市场

什么是富马酸二甲酯(DMFu)?

DMFu在国内产品中的应用非常广泛，是一种稳定的化合物，易挥发，常用于皮革、鞋类、纺织品、木竹制品等保存、运输过程中的杀菌、防霉、防腐和防虫处理。人体接触、吸入或摄取后会对皮肤、眼睛、粘膜和上呼吸道产生强烈刺激甚至伤害。

我们的解决方案

通过遍布全球的网络和与世界各国的法规机构密切合作，Intertek天祥集团随时为客户传递各行业的最新国际国内法规和标准，提供相关的专业测试、检验和咨询服务，帮助客户确保其产品符合各类法规和标准的要求，有效避免因违规而引起的退货、召回和索赔，保护企业的商业声誉和经济利益。

2012年8月15日，ISO针对鞋材中DMFu 的检测方法 ISO/TS 16186:2012 发布，突破了DMFu只有实验室内部分方法检测的局面。短期内即受到众多买家、品牌的关注，纷纷将其纳入RSL管控体系。针对近期欧洲备受关注的富马酸二甲酯(DMFu)，Intertek天祥集团提供全套专业的测试方法，帮助您检测防潮袋或产品中是否含有DMFu，确保符合欧洲各国的相关要求。



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