



25.3.2010

NOTICE TO MEMBERS

Subject: **Petition 1476/2009 by Marga Santamaría (Spanish), on behalf of of ANDAFED (National Association for those affected by dimethylfumarate), on the harmful effects of DMF where used for the manufacture of various consumer articles**

1. Summary of petition

The petitioner expresses concern at the inadmissible use of dimethylfumarate (DMF) by a number of footwear, sofa and leatherwear manufacturers, indicating that the product is harmful to health causing contact dermatitis and asthma. Although this substance is prohibited under a Commission decision of 17 March 2009 (OJ L 74, 20.3.2009, p. 32) the association is still receiving complaints from those affected by it. The petitioner is accordingly seeking the removal from the Community market of products containing this dangerous substance, the use of which constitutes an infringement of Directive 2001/95/EC on general product safety.

2. Admissibility

Declared admissible on 25 January 2010. Information requested from Commission under Rule 202(6).

3. Commission reply, received on 25 March 2010.

‘The petitioner, in her function as president of the Spanish National Association for those affected by dimethylfumarate (ANDAFED), complains about the use of dimethylfumarate (DMF) in sofas, footwear, clothing and other items and the health damage that it has caused to many consumers. She claims that several EU countries have identified numerous cases of contact dermatitis and asthma, caused by DMF, and adds that despite the DMF ban in

consumer products, provided for in the relevant Commission Decision¹, ANDAFED is still receiving reports from people being newly affected by DMF, such as when having purchased footwear. She reports that ANDAFED has asked the Spanish courts to conduct an exhaustive investigation into the matter.

ANDAFED therefore submits a petition to the European Parliament to:

- Totally prohibit DMF in all items that may come into contact with skin, and in all types of packaging for these items;
- Regulate the materials used to manufacture leather items, such as adhesives and dyes;
- Include and specify the item's composition on the label;
- Create a European list of people affected.

Indeed DMF has been found in a range of (imported) consumer products such as furniture, footwear, textiles and others. It protects consumer products from moulds, such as during transport in a humid climate. DMF possesses strong sensitising properties and has caused, through its presence in consumer products, severe skin reactions to hundreds, if not thousands of consumers in the EU.

DMF is an anti-mould biocide which is not authorised in the EU. Due to the number and severity of skin problems in consumers the Commission adopted, within only 3 months, the above-mentioned Decision under Article 13 of the General Product Safety Directive (GPSD), following the favourable opinion of the Member States. The Decision requires Member States to ensure, as of 1 May 2009, that consumer products containing DMF are not placed on the market or made available to consumers, that such products are recalled from consumers (even when provided before the entry into force of the Decision), and have to inform consumers about the risk from DMF. Thus, DMF is entirely banned in consumer products.

In 2009 Member State authorities notified to the Commission almost 120 cases of consumer products containing DMF, which they banned from the market in accordance with the Decision. Spain championed these efforts with 69 cases, which included sandals, slippers, sports footwear, ladies shoes and boots as well as children's shoes.

Regarding the petitioner's requests:

- Prohibit dimethylfumarate ... :
DMF is indeed banned in all consumer products according to the above-mentioned Decision, including in the packaging because the packaging is an integral part of the product;
- Regulate materials to manufacture leather items ... :
There are several bans for chemicals, including dyes, which may no longer be used in the manufacture of leather products, such as

¹ Commission 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. OJ L 74, 20.3.2009, p. 32.

- Short-chained chlorinated paraffin for the fat liquoring of leather¹;
- Azocolourants and azodyes in leather articles which may come into direct and prolonged contact with the human skin or oral cavity, including leather toys²;
- Nonylphenol and nonylphenol ethoxylates in the leather processing (unless there is no release into the environment)³;

In addition, there are a number of standards concerning tests on chemicals in leather, aiming at ensuring the quality and safety of the related leather products. These include tests on:

- Chromium⁴, chromic oxide⁵, chromium(VI)⁶, formaldehyde⁷, pentachlorophenol⁸;
- Colour fastness to perspiration⁹.

Furthermore, Commission Decision 2002/231/EC on the eco-label to footwear¹⁰ aims to limit the levels of toxic residues in and the emissions of volatile organic compounds from footwear, including substances like chromium (VI), arsenic, cadmium, lead and formaldehyde. It also lists substances which should not be used during the production of material and of the product itself.

Other chemicals, in particular solvents, are banned from adhesives and have been notified through the RAPEX system. These include chloroform and other chlorinated solvents¹¹, toluene¹² and benzene¹³.

- Include and specify the item's composition on the label:

There is no general requirement to specify certain chemicals or even the entire composition on the packaging of consumer products, with the exception of cosmetic products which come regularly into contact with the skin, possibly for many hours. However, if consumer products can be flammable (such as certain sprays) or corrosive (such as sewage water tube cleaners) due to their chemical content, this has to be labelled in accordance with European legislation¹⁴.

¹ REACH Annex XVII, entry 42. See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:164:0007:0031:EN:PDF>.

² REACH Annex XVII, entry 43. Web address: see above.

³ REACH Annex XVII, entry 46. Web address: see above.

⁴ EN ISO 4045:1998 Leather - Chemical test - Part 4.

⁵ prEN ISO 5398.

⁶ CEN/TS 14495:2003.

⁷ CEN ISO/TS 17226:2003.

⁸ CEN/TS 14494:2003.

⁹ EN ISO 11641:2003.

¹⁰ Commission Decision 2002/231/EC of 18 March 2002 establishing revised ecological criteria for the award of the Community eco-label to footwear and amending Decision 1999/179/EC; OJ L 77, 20.3.2002, p. 50.

¹¹ REACH Annex XVII, entries 32 - 38. Web address: see above.

¹² REACH Annex XVII, entry 48. Web address: see above.

¹³ REACH Annex XVII, entry 5. Web address: see above.

¹⁴ See Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives

- Create a European list of people affected:

The Commission is aware that hundreds, if not thousands of consumers have encountered skin reddening, rashes, burns and other serious health problems from the presence of DMF in consumer products, which were sometimes very difficult to heal. Consumers have been joining to request compensation through national courts, for example in the largest class action in the UK. Also in France consumers were reported to join in a joint action before the courts.

However, the Commission is not aware of a list that would include all consumers in the EU with health problems from DMF. At EU level, there is no database that would collect such cases.

It may be of interest in this context that in 2008 the Commission initiated a study "The collection and evaluation of data on incidence and severity of skin and respiratory allergy related to exposure of chemicals from non-food sources", in order to gather more information on human sensitizers and to identify a way forward on data collection and dissemination. The final report of the study is currently still under preparation, but it can be said already now that various patient databases exist at national or regional levels in several European Union countries, and that they contain many pieces of information on chemical sensitizers and individuals allergic to them. However, such database is not available at European Union level.

The main request of the petitioner, namely to prohibit DMF, has been satisfied by a ban of DMF in the EU, which the Commission established for all consumer products as soon as sufficient evidence for a rapid action was available. The ban has to be enforced by the Member States as of 1 May 2009, and almost 120 notifications in 2009 and 13 notifications in January 2010 show that enforcement is indeed being undertaken.

The petitioner's request to regulate the manufacture of leather items has been satisfied by restrictions of chemicals in EU legislation to the extent that risks from such chemicals have become evident. Leather products should therefore be safe when in compliance with EU legislation, and the petitioner's request for a label displaying the composition of leather products, such as required for cosmetics, does not appear proportionate.

The Commission is not aware of a list of people affected by DMF in consumer products.

67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1.
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF>