BIS | Department for Business Innovation & Skills

DIMETHYLFUMARATE DIRECTION 2012

DMF Guidance

MARCH 2012

Contents

GENERAL PRODUCT SAFETY REGULATIONS 2005

Direction of the Secretary of State under regulation 35(2) of the Regulations

Recitals

1. On 17 March 2009 the Commission of the European Communities adopted a Decision requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market[1] ("the Decision"). The Decision is attached as Annex 1 to this Direction.

2. The Decision was adopted under Article 13 of Directive 2001/95/EC of the European Parliament and of the Council on general product safety[2]. The UK implemented Directive 2001/95/EC by the General Product Safety Regulations 2005[3] ("the Regulations"). Regulation 35(2) gives the Secretary of State the power to take action under the Regulations to comply with a Commission decision.

3. On 26 March 2009 the Secretary of State made a Direction under regulation 35(2) requiring local authorities to take action to comply with the Decision. This Direction came into force on 1 May 2009 and expired on 15 March 2010.

4. On 11 March 2010 the Commission adopted a further Decision[4] amending and prolonging the validity of the Decision for a further twelve months. This Decision is attached as Annex 2 to this Direction.

5. On 5 May 2010 the Secretary of State made a second Direction under regulation 35(2) requiring local authorities to take action to comply with the Decision as amended.

6. On 1 March 2011 the Commission adopted a further Decision[5] amending and prolonging the validity of the Decision for a further twelve months. This Decision is attached as Annex 3 to this Direction.

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[1] 2009/251/EC (OJ L74, 20.3.2009, p.32)
[2] OJ L 11, 15.1.2002, p. 4
[3] SI 2005/1803
[4] OJ L 63, 12.3.2010, p21
[5] OJ L57, 2.3.2011, p43

7. On 24 March 2011 the Secretary of State made a third Direction under regulation 35(2) requiring local authorities to take action to comply with the Decision as amended.

8. On 26 January 2012 the Commission adopted a further Decision amending and prolonging the validity of the Decision for a further twelve months or until the entry into force of the Commission Regulation amending Annex XVII to Regulation (EC) No 1907/2006 concerning the biocide dimethylfumarate, whichever is the earlier. This Decision is attached as Annex 4 to this Direction.

Direction

1. This Direction is addressed to each authority referred to in regulation 10(4) of the Regulations (each a "Local Authority").

2. It is made in accordance with regulation 35(2) and comes into force on 15 March 2012 and unless renewed, expires on 15 March 2013 or earlier on the entry into force of the Commission Regulation amending Annex XVIII to Regulation (EC) No 1970/2006 concerning DMF. It replaces the Direction of 24 March 2011.

3. In this Direction:

"DMF" means the chemical dimethylfumarate, with the IUPAC name Dimethyl (E)-butenedioate, the CAS number 624-49-7 and the EINECS number 210-849-0;

"product containing DMF" means any product or any part of a product where either:

(i) the presence of DMF is declared, such as on one or more pouches; or

(ii) the concentration of DMF is greater than 0.1 mg/kg of the weight of the product or part of the product;

"placing on the market" means the first making available of a product on the Community market;

"made available on the market" means supplied for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge.

4. Terms used in this Direction which are defined in the Regulations shall have the same meaning in this Direction.

5. In this Direction a reference to a regulation means a regulation in the Regulations.

6. The Secretary of State directs each Local Authority to take action under the Regulations to ensure that:

(a) no products containing DMF are placed on the market;

(b) products containing DMF and already placed on the market are withdrawn from the market;

(c) no products containing DMF are made available on the market;

(d) products containing DMF and already made available on the market are recalled from consumers; and

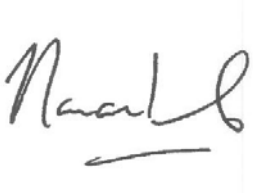
(e) consumers are adequately informed of the risk posed by products containing DMF.

7. The Secretary of State directs each Local Authority to take action under the Regulations as necessary to comply with paragraph 6 including:

(a) the issue of withdrawal notices in accordance with regulation 14.

(b) the issue of recall notices in accordance with regulation 15.

(c) supplementary action as provided for under regulation 16.



Made by Norman Lamb,

Minister for Employment Relations, Consumer and Postal Affairs,

Department for Business, Innovation & Skills.

Date: 14 March 2012

COMMISSION

COMMISSION DECISION

of 17 March 2009

requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

(notified under document number C(2009) 1723)

(Text with EEA relevance)

(2009/251/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [1], and in particular Article 13 thereof,

Having consulted the Member States,

Whereas:

(1) Pursuant to Directive 2001/95/EC producers are obliged to place only safe consumer products on the market.

(2) 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 UK.

(3) According to clinical tests the health damage was caused by the chemical dimethylfumarate (DMF), a biocide preventing moulds that may deteriorate leather furniture or footwear during storage or transport in a humid climate.

(4) DMF was most often contained in little pouches fixed inside the furniture or added to the footwear boxes. It thus evaporated and impregnated the product, protecting it from moulds. However, it then also affected consumers who were in contact with the products. DMF penetrated through the clothes onto consumers' skin [2] where it caused painful skin contact dermatitis, including itching, irritation, redness, and burns; in some cases, acute respiratory troubles were reported. The dermatitis was particularly difficult to treat. The presence of DMF is thus a serious risk.

(5) Under Article 13 of Directive 2001/95/EC, if the European Commission becomes aware that certain products present a serious risk to the health and safety of consumers, it may, subject to certain conditions, adopt a decision requiring Member States to take measures intended in particular to restrict or make subject to specific conditions the availability on the market of such products.

(6) Such a decision may be adopted if (a) Member States differ significantly on the approach adopted or to be adopted to deal with the risk concerned; (b) the risk cannot, in view of the nature of the safety issue, be dealt with in a manner compatible with the degree of urgency of the case under other procedures laid down by the specific Community legislation applicable to the product concerned; and (c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.

[1] OJ L 11, 15.1.2002, p. 4.

[2] Williams J.D.L., et al. (2008), 'An outbreak of furniture dermatitis in the UK', *British Journal of Dermatology* 159: p. 233-234.

(7) A clinical study on humans [1] (patch tests) with leather furniture and patches of pure DMF showed strong reactions in the most severe case down to 1 mg/kg. On the basis of this study, France adopted a decree [2] which bans the importation and placing on the market of seating and footwear containing DMF. The French decree also requires the recall of all seating and footwear which visibly contains, or the packaging of which visibly contains, DMF. The duration of the decree is limited to 1 year. Belgium issued a decree [3], on the basis of the same study, which bans the placing on the market of all articles and products containing DMF. Spain issued measures [4] banning DMF in all consumer products coming into contact with the skin.

(8) Belgium, Spain and France are the only Member States having adopted specific regulatory measures to address the serious risk to consumer health from the biocide DMF.

(9) Under Article 2(1)(a) of 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 (the Biocides Directive) [5], biocidal products are defined as active substances and preparations containing one or more active substances, which are intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. Article 3(1) of the Biocides Directive requires Member States to prescribe that a biocidal product shall not be placed on the market and used in their territory unless it has been authorised in accordance with the Directive; and Article 5(1)(b)(iii) of the Directive provides that Member States shall authorise a biocidal product only if, amongst other things, it has no unacceptable effects itself or as a result of its residues, on human health, directly or indirectly. Thus, very high safety standards have to be fulfilled before a biocidal product can be authorised.

(10) Biocidal products containing DMF are not authorised in the Community in accordance with the Biocides Directive. Thus, biocidal products containing DMF are not legally available in the Community for the treatment of products against moulds, and thus no product manufactured in the EU can legally contain DMF. However, there is no restriction when DMF is present in products (or raw materials of products) that are imported into the Community.

(11) Any restriction of DMF to be put in place under 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 [6] would be impossible in the short term and would thus not suffice with regard to the urgency of the present risk management need.

(12) In these circumstances, Member States should be required to ensure that no products containing DMF are placed or made available on the market, in order to prevent the serious risk posed by these products to consumers, until a permanent solution becomes available.

(13) The presence of DMF in products should be determined against the maximum limit of 0,1 mg DMF per kg of product or part of the product. This is considered to be sufficiently below the concentration of 1 mg/kg which showed a strong reaction in the patch tests mentioned above. The maximum limit of 0,1 mg/kg thus appropriately addresses the serious risk from DMF in products.

(14) Accordingly, the analytical method employed should be able to reliably quantify 0,1 mg DMF per kg of product or part of the product. This means that the method's quantification limit should be 0,1 mg/kg or less.

(15) Member States must carry out market surveillance and enforcement activities to prevent risks posed by unsafe products to the health and safety of consumers.

[1] Rantanen T. (2008), 'The cause of the Chinese sofa/chair dermatitis epidemic is likely to be contact allergy to dimethylfumarate, a novel potent contact sensitizer.' Concise communication, *British Journal of Dermatology* 159: p. 218-221.

[2] Ministry for the Economy, Industry and Employment, Decree of 4 December 2008 suspending the placing on the market of seats and footwear containing DMF from the market. JORF (French Official Journal), 10 December 2008, Text 17 of 108.

[3] The Minister for Public Health and the Minister for Consumer Protection, Ministerial Decree concerning the prohibition of placing articles and products containing DMF on the market. *Belgisch Staatsblad/Moniteur belge* (Belgian Official Journal), 12 January 2009.

[4] Resolution of 22 December 2008 of the National Consumer Institute BOE (Spanish Official Journal) No 18, 21 January 2009, Sec. V-B, p. 5474.

[5] OJ L 123, 24.4.1998, p. 1.

[6] OJ L 396, 30.12.2006, p. 1, as corrected by OJ L 136, 29.5.2007, p. 3.

(16) A short transition period is necessary in the interests of both the Member States, who must ensure that this Decision will be applied, and producers and distributors who are subject to the obligation to make available on the market only safe products. The shortest possible transition period is appropriate, consistent with the need to prevent further incidents of serious damage to the health and safety of consumers and to ensure proportionality.

(17) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 15 of Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision the following definitions shall apply:

(a) 'DMF' means the chemical dimethylfumarate, with the IUPAC name Dimethyl (E)-butenedioate, the CAS No 624-49-7 and the Einecs No 210-849-0;

(b) 'product' means any product as defined in Article 2(a) of Directive 2001/95/EC;

(c) 'product containing DMF' means any product or any part of a product where either:

(i) the presence of DMF is declared, such as on one or more pouches; or

(ii) the concentration of DMF is greater than 0,1 mg/kg of the weight of the product or part of the product;

(d) 'placing on the market' means the first making available of a product on the Community market;

(e) 'made available on the market' means supplied for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge.

Article 2

Implementation

1. As of 1 May 2009 Member States shall ensure that products containing DMF are prohibited from being placed or made available on the market.

2. As of 1 May 2009 Member States shall ensure that products containing DMF and already placed or made available on the market are withdrawn from the market and recalled from consumers, and that consumers are adequately informed of the risk posed by such products.

3. Member States shall inform the Commission without delay of the measures taken under this Article in accordance with Article 12 of Directive 2001/95/EC.

Article 3

Information

Member States shall take the necessary measures to comply with this Decision, publish those measures and inform the Commission thereof accordingly.

Article 4

Period of application

This Decision shall be applicable until 15 March 2010.

Article 5

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 17 March 2009.

For the Commission

Meglena KUNEVA

Member of the Commission

COMMISSION DECISION

of 11 March 2010

prolonging the validity of Decision 2009/251/EC requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

(notified under document C(2010) 1337)

(Text with EEA relevance)

(2010/153/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [1], and in particular Article 13 thereof,

Whereas:

(1) Commission Decision 2009/251/EC [2] requires Member States to ensure that products containing the biocide dimethylfumarate (DMF) are not placed or made available on the market.

(2) Decision 2009/251/EC was adopted in accordance with the provisions of Article 13 of Directive 2001/95/EC, which restricts the validity of the Decision to a period not exceeding 1 year, but allows it to be confirmed for additional periods none of which shall exceed 1 year.

(3) In the light of the experience acquired so far and the absence of a permanent measure addressing consumer products containing DMF, it is necessary to prolong the validity of Decision 2009/251/EC for 12 months and to amend it accordingly.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

The text of Article 4 of Decision 2009/251/EC is replaced by the following:

'This Decision shall be applicable until 15 March 2011.'

Article 2

Member States shall take the necessary measures to comply with this Decision by 15 March 2010 at the latest and shall publish those measures. They shall forthwith inform the Commission thereof.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 11 March 2010.

For the Commission
John DALLI
Member of the Commission

[1] OJ L 11, 15.1.2002, p. 4.
[2] OJ L 74, 20.3.2009, p. 32.

COMMISSION DECISION

of 1 March 2011

extending the validity of Decision 2009/251/EC requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

(notified under document C(2011) 1174)

(Text with EEA relevance)

(2011/135/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [1], and in particular Article 13 thereof,

Whereas:

(1) Commission Decision 2009/251/EC [2] requires Member States to ensure that products containing the biocide dimethylfumarate (DMF) are not placed or made available on the market.

(2) Decision 2009/251/EC was adopted in accordance with the provisions of Article 13 of Directive 2001/95/EC, which restricts the validity of the Decision to a period not exceeding 1 year, but allows it to be confirmed for additional periods none of which shall exceed 1 year.

(3) The validity of Decision 2009/251/EC was extended by Commission Decision 2010/153/EU [3] for an additional period of 1 year. In the light of the experience acquired so far and the absence of a permanent measure addressing consumer products containing DMF, it is necessary to extend the validity of Decision 2009/251/EC for a further 12 months.

(4) Decision 2009/251/EC should be amended accordingly.

(5) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 15 of Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

Article 4 of Decision 2009/251/EC is replaced by the following:

'*Article 4*

Period of application

This Decision shall apply until 15 March 2012.'

Article 2

Member States shall take the necessary measures to comply with this Decision by 15 March 2011 at the latest and shall publish those measures. They shall forthwith inform the Commission thereof.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 1 March 2011.

For the Commission

John DALLI

Member of the Commission

[1] OJ L 11, 15.1.2002, p. 4.
[2] OJ L 74, 20.3.2009, p. 32.
[3] OJ L 63, 12.3.2010, p. 21.

COMMISSION IMPLEMENTING DECISION

of 26 January 2012

extending the validity of Decision 2009/251/EC requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market

(notified under document C(2012) 321)

(Text with EEA relevance)

(2012/48/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [1], and in particular Article 13 thereof,

Whereas:

(1) Commission Decision 2009/251/EC [2] requires Member States to ensure that products containing the biocide dimethylfumarate (DMF) are not placed or made available on the market.

(2) Decision 2009/251/EC was adopted in accordance with the provisions of Article 13 of Directive 2001/95/EC, which restricts the validity of the Decision to a period not exceeding 1 year, but allows it to be confirmed for additional periods none of which shall exceed 1 year.

(3) The validity of Decision 2009/251/EC was extended by Commission Decisions 2010/153/EU [3] and 2011/135/EU [4] for additional periods of 1 year each. A permanent restriction on DMF in articles is currently being considered to be incorporated in Regulation (EC) No 1907/2006 of the European Parliament and of the Council [5]. As that measure will address the same concerns as Decision 2009/251/EC, for legal certainty, Decision 2009/251/EC should apply until the permanent restriction under Regulation (EC) No 1907/2006 enters into force.

(4) In the light of the experience acquired so far and the absence of a permanent measure addressing consumer products containing DMF, it is necessary to extend the validity of Decision 2009/251/EC for a further 12 months.

(5) Decision 2009/251/EC should be amended accordingly.

(6) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 15 of Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

Article 4 of Decision 2009/251/EC is replaced by the following:

'*Article 4*

Period of application

This Decision shall apply until entry into force of the Commission Regulation amending Annex XVII to Regulation (EC) No 1907/2006 concerning DMF or 15 March 2013, whichever is the earlier.'

Article 2

Member States shall take the necessary measures to comply with this Decision by 15 March 2012 at the latest and shall publish those measures. They shall forthwith inform the Commission thereof.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 January 2012.

For the Commission

John DALLI

Member of the Commission

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[1] OJ L 11, 15.1.2002, p. 4.
[2] OJ L 74, 20.3.2009, p. 32.
[3] OJ L 63, 12.3.2010, p. 21.
[4] OJ L 57, 2.3.2011, p. 43.
[5] OJ L 396, 30.12.2006, p. 1.

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