Commission Directive 2008/47/EC of 8 April 2008 amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers (Text with EEA relevance)

## COMMISSION DIRECTIVE 2008/47/EC

## of 8 April 2008

amending, for the purposes of adapting to technical progress, Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers

(Text with EEA relevance)

## THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers<sup>(1)</sup>, and in particular Articles 5 and 10(3) thereof,

Whereas:

- (1) Technical progress and innovation have made possible the placing on the market of an increasing number of aerosol dispensers with a complex technical design and characteristics different from the traditional ones. However, the provisions of Directive 75/324/EEC are not sufficient to guarantee a high level of safety for such non-traditional aerosol dispensers. The individual design of non-traditional aerosols may create safety hazards that are not addressed by the safety provisions of the Directive, which are adapted to the known design of traditional aerosols. Therefore, a hazard analysis is necessary to be performed by the manufacturer in order to cover all safety aspects adequately.
- (2) Where appropriate the hazard analysis must address the risk resulting from the inhalation of the spray ejected by the aerosol dispenser under normal or reasonably foreseeable conditions of use, taking into account droplet size and size distribution in conjunction with physical and chemical properties of the contents, as the inhalation of small aerosol droplets may give rise to adverse health effects for the user under such conditions of use, even if the aerosol dispenser is properly classified and labelled according to the provisions of Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations<sup>(2)</sup>.
- (3) The safeguard clause provided for in Article 10 of Directive 75/324/EEC has been applied by one Member State. The safeguard measure adopted is justified in view of

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the risk of flammability raised, under normal or reasonably foreseeable conditions of use, by the substances contained in the aerosol dispenser.

- (4) The current definition of flammable contents is not sufficient to guarantee a high level of safety in all cases. In particular, although some contents dispersed by aerosol dispensers are not defined as 'flammable' according to the criteria listed in Annex VI to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances<sup>(3)</sup>, they may lead to ignition under normal or reasonably foreseeable conditions of use of the aerosol dispenser. Furthermore, the current criteria for flammability only address chemical substances and preparations and do not take properly into account special physical conditions of an aerosol spray or specific conditions of use.
- (5) In order to achieve the optimal level of safety and considering the specificities of aerosol dispensers, the new criteria for the classification of the flammability of aerosol dispensers should also address the hazards relating to the dispersion of the contents of aerosol dispensers and the specific conditions of use of the aerosol dispensers rather than only the physical and chemical properties of the contents themselves.
- (6) The provisions of Directive 75/324/EEC currently in force require that each filled aerosol dispenser be immersed in a bath of hot water in order to assess its leak tightness and burst resistance. However, heat sensitive aerosol dispensers cannot withstand this test. Technological progress has made possible alternative test methods for the final assessment of aerosol dispensers for burst resistance and leak tightness, which guarantee the same level of safety.
- (7) The provisions of Directive 75/324/EEC currently in force provide for the possibility to use a test system enabling a result equivalent to that of the water bath method, subject to the agreement of the Committee referred to in Article 6. However, this procedure appears to be extremely heavy to be implemented in practice, and therefore, it has never been used. Therefore, in order to enable economic operators to benefit from technological progress without compromising the current level of safety by guaranteeing the appropriate technical expertise, it is necessary that the alternative test methods are approved, instead of the Committee referred to in Article 6 of the Directive, by the relevant competent authorities designated by Member States under Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road<sup>(4)</sup>.
- (8) Safety concerns have been raised following the burst and leak of metal aerosol dispensers heated to high temperatures, as is the case in cars exposed to solar radiation. It is therefore necessary to limit the maximum filling level to the same value for all types of aerosol dispensers.
- (9) Most environmentally friendly and non-flammable propellants are compressed gases. However, the loss of pressure of aerosol dispensers using compressed gas propellants at the end of their life-time typically leads to a less efficient yield of contents. Consequently, the use of compressed gases as propellants should be encouraged by

increasing the maximum internal pressure of aerosol dispensers, to the extent that it is safe for the consumer.

- (10) Directive 75/324/EEC should therefore be amended accordingly.
- (11) The measures provided for in this Directive are in accordance with the opinion of the Committee on the adaptation to Technical Progress of the Directive on aerosol dispensers,

HAS ADOPTED THIS DIRECTIVE:

- (1) OJ L 147, 9.6.1975, p. 40. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
- (2) OJ L 200, 30.7.1999, p. 1. Directive as last amended by Regulation (EC) No 1907/2006 (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3).
- (3) OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850, corrected by OJ L 136, 29.5.2007, p. 281).
- (4) OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2006/89/EC (OJ L 305, 4.11.2006, p. 4).