

Commission Decision of 16 March 2006 on the publication of the references of standard EN 143:2000 ‘Respiratory Devices — Particle filters — Requirements, testing, marking’ in accordance with Council Directive 89/686/EEC (personal protective equipment) (notified under document number C(2006) 777) (Text with EEA relevance) (2006/216/EC)

COMMISSION DECISION

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(2006/216/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment⁽¹⁾, and in particular Article 6(1) thereof,

Having regard to the opinion of the Standing Committee set up pursuant to Article 5 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations⁽²⁾,

Whereas:

- (1) Directive 89/686/EEC provides that personal protective equipment may be placed on the market and brought into service only if it preserves the health and ensures the safety of users without prejudice to the health or safety of other individuals, domestic animals or goods, when properly maintained and used for its intended purpose.
- (2) Pursuant to Article 5 of Directive 89/686/EEC, personal protective equipment bearing the CE marking and with respect to which the manufacturer is able to produce the declaration of conformity and the EC type-examination certificate issued by a notified body attesting to its conformity to the relevant national standards transposing the harmonised standards, the references of which have been published in the *Official Journal of the European Union* by the Commission, is to be presumed to satisfy the basic health and safety requirements referred to in Article 3 of Directive 89/686/EEC and set out in Annex II thereto. Member States are required to publish the references of the national standards transposing the harmonised standards.

- (3) Pursuant to Article 6(1) of Directive 89/686/EEC, the Commission and France have lodged a formal objection to the effect that standard EN 143:2000 ‘Respiratory Devices — Particle filters — Requirements, testing, marking’, approved by the European Committee for Standardisation (CEN) on 7 January 2000 and the references of which were first published in the Official Journal on 24 January 2001⁽³⁾, does not completely satisfy the basic health and safety requirements referred to in Article 3 of Directive 89/686/EEC with respect to particle filters, the filtering efficiency of which is exclusively or partially achieved by the use of materials based on non-woven electrically-charged fibres, hereinafter referred to as ‘electrostatic filters’.
- (4) On the basis of the results of tests on the filtering efficiency of the various types of particle filters, there is substantive evidence that the test procedure for the measuring of filter penetration as set out in clauses 8.7.2.4, last sentence, and 8.7.3.4, last sentence, of standard EN 143:2000, according to which the measurement of penetration is taken three minutes after the start of the aerosol test, fails to ensure compliance with basic health and safety requirement 3.10.1 (Respiratory protection) of Annex II to Directive 89/686/EEC with respect to electrostatic filters.
- (5) Specifically, it has been observed that the filtering efficiency of this type of filter can deteriorate rapidly during use. The filtering efficiency as determined according to the standardised test procedure — three minutes after the start of the test — can become meaningless at any instance beyond these three minutes. The filtering efficiency drop can be drastic and therefore compromise the efficiency class allocated to an electrostatic filter and the information related to it. When the allocation to an efficiency class is deemed not correct during the period of use, the resulting potential exposure to dangerous airborne particulates can seriously harm the health and safety of the user. Test results point to a loss of filter efficiency of electrostatic filters also when used intermittently.
- (6) In view of these findings, clauses 8.7.2.4, last sentence, and 8.7.3.4, last sentence, of standard EN 143:2000 also fail to ensure compliance with basic health and safety requirements 1.1.1 (Ergonomics), 1.1.2.1 (Highest level of protection possible) and 1.1.2.2 (Classes of protection appropriate to different levels of risk) of Annex II to Directive 89/686/EEC with respect to electrostatic filters. In addition, clause 10 of the standard fails to ensure compliance with basic health and safety requirement 1.4(b) (Information supplied by the manufacturer), since no warning of the deterioration of the filtering efficiency of electrostatic filters over time is required.
- (7) Accordingly, other related harmonised standards, which either provide that testing is to be done in accordance with standard EN 143:2000 or provide for a test measurement procedure identical to that set out in standard EN 143:2000, also fail to ensure compliance with the basic health and safety requirements of Directive 89/686/EEC referred to above with respect to electrostatic filters.
- (8) At the request of the Commission the European Standardisation Organisation — CEN, Technical Committee CEN/TC 79 ‘Respiratory protective devices’, has started the revision of standard EN 143:2000 in order to address the described shortcomings. Pending this revision, in the interest of safety and legal certainty, the publication of the

references of standard EN 143:2000 should be accompanied by an appropriate warning which should also be taken into account as regards the related harmonised standards. Member States should add an identical warning in their national standards transposing that harmonised standard.

- (9) The references of harmonised standard EN 143:2000 should therefore be republished accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The references of harmonised standard EN 143:2000 are replaced by the text set out in the Annex.

Article 2

Where, pursuant to Article 5(4) of Directive 89/686/EEC, Member States publish the references of the national standards transposing the harmonised standard referred to in Article 1, they shall add to that publication a warning identical to that provided for in the text set out in the Annex to this Decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 16 March 2006.

For the Commission

Günter VERHEUGEN

Vice-President

Status: This is the original version (as it was originally adopted).

ANNEX

Publication of references of European harmonised standards in accordance with Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment

ESO^a	Reference and title of the harmonised standard (and reference document)	First publication in OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard^b
CEN	EN 143:2000 Respiratory protective devices — Particle filters — Requirements, testing, marking	24.1.2001	EN 143:1990	Date expired (31.8.2000)

- a** ESO: European Standardisation Organisation:
 — CEN: rue de Stassart/Stassartstraat 36, B-1050 Brussels, Tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (<http://www.cenorm.be>)
 — CENELEC: rue de Stassart/Stassartstraat 35, B-1050 Brussels, Tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (<http://www.cenelec.org>)
 — ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel. (33) 492 94 42 00; fax (33) 493 65 47 16 (<http://www.etsi.org>)

- b** Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Warning: As regards particle filters the filtering efficiency of which is exclusively or partially achieved by the use of materials based on non-woven electrically-charged fibres, this publication does not concern clauses 8.7.2.4, last sentence, 8.7.3.4, last sentence, and 10 of the standard, in respect of which there shall be no presumption of conformity with the basic health and safety requirements of Directive 89/686/EEC. This warning shall also be taken into account in the application of the following harmonised standards: EN 149:2001; EN 405:2001; EN 1827:1999; EN 12083:1998; EN 12941:1998; EN 12941:1998/A1:2003; EN 12942:1998; EN 12942:1998/A1:2002; EN 13274-7:2002.

NOTE:

- Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to the Directive 98/34/EC.
- Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.
- This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

More information about harmonised standards on the Internet at <http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/>

Status: This is the original version (as it was originally adopted).

- (1) [OJ L 399, 30.12.1989, p. 18](#). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (2) [OJ L 204, 21.7.1998, p. 37](#). Directive as last amended by the 2003 Act of Accession.
- (3) [OJ C 21, 24.1.2001, p. 2](#).