

Directive 2001/95/EC of the European Parliament and of the Council of  
3 December 2001 on general product safety (Text with EEA relevance)

CHAPTER II

**General safety requirement, conformity assessment criteria and European standards**

*Article 3*

1 Producers shall be obliged to place only safe products on the market.

2 A product shall be deemed safe, as far as the aspects covered by the relevant national legislation are concerned, when, in the absence of specific Community provisions governing the safety of the product in question, it conforms to the specific rules of national law of the Member State in whose territory the product is marketed, such rules being drawn up in conformity with the Treaty, and in particular Articles 28 and 30 thereof, and laying down the health and safety requirements which the product must satisfy in order to be marketed.

A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the *Official Journal of the European Communities* in accordance with Article 4. The Member States shall publish the references of such national standards.

3 In circumstances other than those referred to in paragraph 2, the conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:

- a voluntary national standards transposing relevant European standards other than those referred to in paragraph 2;
- b the standards drawn up in the Member State in which the product is marketed;
- c Commission recommendations setting guidelines on product safety assessment;
- d product safety codes of good practice in force in the sector concerned;
- e the state of the art and technology;
- f reasonable consumer expectations concerning safety.

4 Conformity of a product with the criteria designed to ensure the general safety requirement, in particular the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or recall where there is evidence that, despite such conformity, it is dangerous.

*Article 4*

1 For the purposes of this Directive, the European standards referred to in the second subparagraph of Article 3(2) shall be drawn up as follows:

- [<sup>F1</sup>a the requirements intended to ensure that products which conform to those standards satisfy the general safety requirement shall be determined by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 15(4);]

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- b on the basis of those requirements, the Commission shall, in accordance with 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 and of rules on information society services<sup>(1)</sup> call on the European standardisation bodies to draw up standards which satisfy these requirements;
- c on the basis of those mandates, the European standardisation bodies shall adopt the standards in accordance with the principles contained in the general guidelines for cooperation between the Commission and those bodies;
- d the Commission shall report every three years to the European Parliament and the Council, within the framework of the report referred to in Article 19(2), on its programmes for setting the requirements and the mandates for standardisation provided for in subparagraphs (a) and (b) above. This report will, in particular, include an analysis of the decisions taken regarding requirements and mandates for standardisation referred to in subparagraphs (a) and (b) and regarding the standards referred to in subparagraph (c). It will also include information on the products for which the Commission intends to set the requirements and the mandates in question, the product risks to be considered and the results of any preparatory work launched in this area.

2 The Commission shall publish in the *Official Journal of the European Communities* the references of the European standards adopted in this way and drawn up in accordance with the requirements referred to in paragraph 1.

If a standard adopted by the European standardisation bodies before the entry into force of this Directive ensures compliance with the general safety requirement, the Commission shall decide to publish its references in the *Official Journal of the European Communities*.

If a standard does not ensure compliance with the general safety requirement, the Commission shall withdraw reference to the standard from publication in whole or in part.

In the cases referred to in the second and third subparagraphs, the Commission shall, on its own initiative or at the request of a Member State, decide in accordance with the procedure laid down in Article 15(2) whether the standard in question meets the general safety requirement. The Commission shall decide to publish or withdraw after consulting the Committee established by Article 5 of Directive 98/34/EC. The Commission shall notify the Member States of its decision.

#### Textual Amendments

- F1** Substituted by [Regulation \(EC\) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny](#)  
Adaptation to the regulatory procedure with scrutiny — Part Four.

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- (1) [OJ L 204, 21.7.1998, p. 37](#). Directive amended by Directive 98/48/EC ([OJ L 217, 5.8.1998, p. 18](#)).