



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2008)

final

Draft

COMMISSION DECISION

of

requiring Member States to ensure that magnetic toys placed or made available on the market display a warning about the health and safety risks they pose

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(Text with EEA relevance)

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 safety¹, and in particular Article 13 thereof,

Having consulted the Member States,

Whereas:

- (1) Pursuant to Directive 2001/95/EC and Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys², as amended by Council Directive 93/68/EEC, producers are obliged to place only safe toys on the market.
- (2) Directive 88/378/EEC lays down the essential safety requirements that toys must meet to ensure the safety objectives of the Directive. In addition, the Directive provides that, in order to facilitate the proof of conformity with the essential safety requirements, European standards concerning the design and composition of toys should be drawn up by the standardisation bodies. Currently the risk posed by magnets is covered by the general safety requirement of Directive 88/378/EEC, but the Directive does not lay down particular safety requirements dealing with the risk posed by magnets.
- (3) The European Committee for Standardisation (CEN) issued European standard EN 71-1:2005 "Safety of toys – Part I: mechanical and physical properties" which is a consolidated version of harmonised standard EN 71-1:1998 and its 11 amendments. Toys complying with the standard are presumed to be in conformity with the essential requirements of Directive 88/378/EEC, as far as the specific requirements covered by the standard are concerned. The standard does not currently contain technical requirements for magnetic toys. In accordance with Article 8(2)(a) of Directive 88/378/EEC, producers must have recourse to EC type-examination when a harmonised standard does not cover all the risks that a toy may present.

¹ OJ L 11, 15.1.2002, p. 4.

² OJ L 187, 18.7.1998, p. 1. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

- (4) In order to address the specific risks of magnetic toys, on 25 May 2007 the Commission gave a mandate to CEN³, 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 regulations⁴, to revise the European standard EN 71-1:2005 within 24 months. Pending the drawing up and entry into force of the revised standard, it is necessary to address immediately the risks posed by magnetic toys in order to minimise further accidents to children caused by these toys by improving the knowledge of the risks.
- (5) In addition to Directive 88/378/EEC, the safety of toys is covered by Directive 2001/95/EC which sets out the market surveillance framework for consumer products. According to 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, under certain conditions, adopt a decision requiring Member States to take temporary measures intended in particular to restrict or make subject to specific conditions the placing and making available 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.
- (7) A serious risk has recently emerged concerning magnets in toys. Even though magnets have been used in toys for a long time, in the last few years they have become increasingly powerful and they can become detached more easily if attached using the same techniques as those employed in the past. Moreover, given their increased strength, loose magnets or magnetic parts used in toys now pose a higher risk of serious accidents than in the past.
- (8) This serious risk has been established by a number of accidents that were reported worldwide in the course of 2006 and 2007 where children had swallowed magnets detached from toys or small parts of toys containing magnets. When more than one magnet is swallowed, the magnets can attract each other and may cause intestinal perforation, infection or blockage, which can be fatal. Inhalation of those magnets has also caused serious injuries, and aspiration into the lungs requires immediate surgery.
- (9) Besides one fatal accident reported in the United States, several occurrences of children swallowing at least two magnets or a magnet and a metal object, and requiring major surgery, have been reported worldwide since 2006. These incidents have involved children aged between 10 months and 12 years.

³ Standardisation mandate to CEN of 25 May 2007 to draw up standard for magnetic toy (M/410).

⁴ OJ L 204, 21.7.1998, p. 37.

- (10) In 2006 and 2007, several toy producers launched major recalls of magnetic toys. In particular, over 18 million magnetic toys were recalled worldwide during the summer of 2007, and a significant proportion of these toys were on the European market. As a result of the accidents and the recent recalls, many producers have realised the risk and modified the design of the toys concerned, encapsulating or collaring the magnets in the parts containing them.
- (11) Some countries have already adopted measures to deal with the risk. In particular, the United States Consumer Product Safety Commission (CPSC) released, on 19 April 2007, a warning to parents concerning the health and safety risks posed by magnetic toys. The CPSC has also participated in the revision of ASTM F963-2007 'Standard Consumer Safety Specification for Toys' created under the auspices of the standardisation body, ASTM International, to deal with magnets in toys. In Europe, both France and Germany have informed the Commission of national measures.
- (12) In its resolution of 26 September 2007 on the safety of products and particularly toys⁵, the European Parliament urged the Commission to use its powers to take restrictive measures, including bans, if consumer goods placed on the Community market are found to be unsafe.
- (13) Consultation of the Member States in the Committee set up by Article 15 of Directive 2001/95/EC has established that Member States differ significantly on the approach to deal with the risk posed by magnetic toys.
- (14) In the absence of Community rules, some Member States have adopted or are about to adopt divergent national measures to manage the risk posed by magnetic toys. The introduction of such national measures will inevitably result in an uneven level of protection and in intra-Community barriers to trade in magnetic toys. Several Member States have called for a Community measure.
- (15) There is Community legislation on small parts in toys meant for small children⁶, but that legislation does not deal specifically and sufficiently with risks from magnetic toys to children who are over three years of age. In view of the nature of the hazard, the risk posed by magnetic toys cannot be dealt with effectively under other procedures laid down in specific rules of Community law in a manner compatible with the degree of urgency of the case. It is therefore necessary to have recourse to a temporary decision under Article 13 of Directive 2001/95/EC until the revised European standard EN 71-1:2005 provides a comprehensive solution to the problem identified. The targeted measure introduced by this Decision offers only a partial, temporary, short-term solution. The Commission has already clearly recognised the need for constructional requirements to deal adequately with the risks posed by magnetic toys when issuing the standardisation mandate to CEN to revise EN 71-1:2005.

⁵ Texts Adopted, P6_TA(2007)0412.

⁶ In accordance with Directive 88/378/EEC, toys, and their component parts, and any detachable parts of toys which are clearly intended for use by children under 36 months must be of such dimensions as to prevent their being swallowed and/or inhaled. This means that toys intended for children under 36 months must not contain any element liable to be swallowed or inhaled, whether magnets or not.

- (16) In view of the serious risk from magnetic toys, and in order to ensure a consistent and high level of consumer health and safety protection throughout the EU as well as to avoid barriers to trade, it is urgent that a temporary decision pursuant to Article 13 of Directive 2001/95/EC be adopted. Such a decision should rapidly make the placing and making available on the market of magnetic toys subject to the condition that they are marked with an adequate warning of the risks linked to the presence of powerful magnets or magnetic components of ingestible shape and size that are accessible to children. Such a decision should contribute to the prevention of further deaths and injuries.
- (17) In the light of the accident and hazard data and the pending permanent measure in the form of the revision of standard EN 71-1:2005, the scope of this Decision should cover magnetic toys.
- (18) Magnets or magnetic components whose flux index is less than $50 \text{ kG}^2 \text{ mm}^2$ are considered as not capable of exerting attraction through the intestinal walls. Furthermore, the revision of the ASTM F-963-2007 standard identifies as unsafe only those magnets whose magnetic flux exceeds $50 \text{ kG}^2 \text{ mm}^2$. Additionally, some production processes can lead to a weak magnetisation of certain metallic objects or parts due to exposure to magnetic sources. It is therefore necessary to distinguish between weak and powerful magnets and magnetic components by setting a threshold and excluding from the scope of this Decision magnets and magnetic components whose flux index is below a threshold of $50 \text{ kG}^2 \text{ mm}^2$.
- (19) This Decision is without prejudice to Articles 3(4) and 6 to 8 of Directive 2001/95/EC, and thus does not bar Member States from taking appropriate measures where there is evidence that a magnetic toy is dangerous, regardless of the conformity with the requirements in this Decision and other criteria designed to ensure the general safety requirement. Member States must carry out market surveillance and enforcement activities to prevent risks posed by unsafe products to the health and safety of consumers.
- (20) On the basis of the progress made with the revision of the European standard EN 71-1:2005 and with regard to the completeness of the revised standard and its adequacy to address fully the risks posed by magnetic toys, the Commission will decide whether to extend the validity of this Decision for additional periods and whether the Decision should be amended. In particular, the Commission will decide whether to introduce constructional requirements to supplement the warning required in this Decision.

- (21) A short transition period is necessary in the interests of both the Member States who must ensure that the Decision will be applied efficiently and also of the producers and distributors of magnetic toys who are subject to the obligation to place or make available on the market only magnetic toys that bear the appropriate warning. In this case, the shortest possible transition period should be laid down, consistent with the need to prevent further accidents and to ensure proportionality, taking into account that the measure consists of a marking only and does not require changes to the product design itself. Therefore, the requirement for a warning to be affixed to magnetic toys should apply shortly after the adoption of this Decision by the Commission.
- (22) 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:

- (1) “magnetic toy” means a toy that contains or consists of one or more magnets or one or more magnetic components that are of ingestible shape and size, are accessible to children, and whose flux index is $50 \text{ kG}^2 \text{ mm}^2$ or more;
- (2) “toy” means any product or material designed or clearly intended for use in play by children of less than 14 years of age;
- (3) “of ingestible shape and size” means fitting entirely into the small-parts cylinder defined in the standard EN 71-1:2005;
- (4) “accessible to children” means loose or able of becoming detached from the toy under normal or reasonably foreseeable conditions of use by children, even if originally contained, encapsulated, recessed or collared in the toy;
- (5) “making available on the market” means any supply of a magnetic toy 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;
- (6) “placing on the market” means the first making available of a magnetic toy on the Community market;
- (7) “withdrawal” means any measure aimed at preventing the distribution, display and offer.

Article 2

Warning

1. Member States shall ensure that magnetic toys which are placed or made available on the Community market display a warning :
 - (a) with the following wording: “Warning! This toy contains magnets or magnetic components. Magnets sticking together or becoming attached to a metallic object inside the human body can cause serious or fatal injury. Seek immediate medical help if magnets are swallowed or inhaled.”;
 - (b) or with an equivalent easily understandable wording that clearly conveys the same content.
2. The warning shall appear in a clearly visible and legible manner, conspicuously displayed on the packaging or otherwise attached to the magnetic toy in such a way as to be visible to the consumer at the point of purchase.
3. The warning shall appear in the official languages of the Member State in which the product is placed or made available on the market.

Article 3

Implementation

1. As of [Insert fixed day! two months from the date of adoption of this Decision by the Commission], Member States shall ensure that magnetic toys which do not display the required warning are prohibited from being placed or made available on the market.
2. As of [Insert fixed day! two months from the date of adoption of this Decision by the Commission], Member States shall ensure that magnetic toys which do not display the required warning and are placed or made available on the market are withdrawn from the market, and that consumers are adequately informed of the risk.
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 4

Information

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

Article 5

Period of application

This Decision shall be applicable until [Insert fixed day! twelve months from the date of adoption of this Decision by the Commission].

Article 6

Addressees

This Decision is addressed to the Member States.

Done at Brussels, [...] 2008

For the Commission
Meglana KUNEVA
Member of the Commission