

## COMMISSION DECISION (EU) 2015/1603

of 13 August 2015

**on a measure taken by Spain in accordance with Article 7 of Council Directive 89/686/EEC withdrawing from the market a type of buoyant aids for swimming instructions**

THE EUROPEAN COMMISSION,

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

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 <sup>(1)</sup>, and in particular Article 7 thereof,

Whereas:

- (1) The Spanish authorities notified to the Commission and to the other Member States a measure of withdrawal from the market relating to buoyant aids for swimming instructions type *Delphin Schwimmscheiben- Typ Super*, manufactured by Delphin Vertriebs- und Service GmbH, D-61192 Niddatal, Germany. The product bore the CE marking in accordance with Directive 89/686/EEC, having been tested and type-examined in accordance with the harmonised standard EN 13138-1:2008 *Buoyant aids for swimming instruction — Part 1: Safety requirements and test methods for buoyant aids to be worn* by the German Notified Body TÜV Rheinland LGA Products GmbH (NB 0197). The product is considered personal protective equipment classified in category II.
- (2) The notification followed an accident report: after a swimming session, when parents were gathering their belongings before going home, a child bit one of the discs, detaching and swallowing a small piece of it, being necessary medical assistance and hospitalisation.
- (3) The Spanish authorities ordered the withdrawal of the product from the market. The measure was motivated by the unsatisfactory application of the standards referred to in Article 5 of Directive 89/686/EEC, in particular the harmonised standard EN 13138-1:2008 *Buoyant aids for swimming instruction — Part 1: Safety requirements and test methods for buoyant aids to be worn*, clause 5.4.2 *Small parts*, related to the basic health and safety requirement of point 1.2.1 of Annex II to Directive 89/686/EEC, *Absence of risks and other 'inherent' nuisance factors*. Clause 5.4.2 of standard EN 13138-1 requires that attached small parts withstand a pull of  $(90 \pm 2)$  N in the direction most likely to cause failure without becoming detached from the device. Parts which can become detached should not fit wholly into the small parts cylinder, the testing of which is to be in accordance with standard EN 71-1.
- (4) The Spanish authorities indicated that, after carrying out tensile tests in accordance with the harmonised standard EN 13138-1:2008, it was revealed that small parts can be detached from the product, and swallowed by small children for which the product is intended. The level of pull where such small parts were detached resulted always less than 90 N and fit wholly into the small parts cylinder. The Spanish authorities considered that clause 5.4.2 of that standard is not limited to test only attached small parts, but small parts in general. They used a 'bite tester' equipment according to the tests defined in standards EN 12227:2010 *Playpens for domestic use — Safety requirements and test methods* and EN 716-2:2008 *Furniture — Children's cots and folding cots for domestic use — Part 2: Test methods*.
- (5) The German authorities did not agree with the risk assessment carried out by the Spanish authorities, considering that the test method used was not compatible with the practical use of the equipment. In their opinion, clause 5.4.2 of standard EN 13138-1 only covers attached small parts. The German authorities argued that the product does not present any serious risk, since it is not a toy and the risk scenario, as described by the Spanish authorities, would be unrealistic.
- (6) The manufacturer also questioned the test method used by the Spanish authorities. In the EC type-examination of the product, the notified body did not perform a test in accordance with clause 5.4.2 of standard EN 13138-1 with the remark that the product does not have any attached small parts.
- (7) After the notification, the manufacturer asked the notified body to perform an additional tensile test in accordance with clause 8.5.2.2 of standard EN 1888:2012 *Child care articles — Wheeled child conveyances — Safety requirements and test methods*, using the 'bite tester' described in clause 5.7 of that standard, identical to the 'bite

<sup>(1)</sup> OJ L 399, 30.12.1989, p. 18.

tester' described in standards EN 716-2 and EN 12227. No small parts could be generated from the body of the product. Furthermore, the Notified Body carried out a follow-up test which showed that no parts came loose when the device was subjected to a tensile force of 90N, a test resembling the test method for small parts in standard EN 71-1 *Safety of toys — Part 1: Mechanical and physical properties*.

- (8) The Commission sought expert technical assistance in order to assess the main questions involved in the case. An external study was carried out by technical experts which concluded that testing with only attached small parts is enough to demonstrate compliance with the basic health and safety requirement set out in point 1.2.1 of Annex II to Directive 89/686/EEC.
- (9) The standard EN 13138-1 does not provide for a clear test method for testing attached small parts. In view of this ambiguity, a choice had to be made amongst appropriate available test method, taking into consideration the nature of the product. The Spanish authorities applied the test method they found the most appropriate to assess the risks posed the product. The technical experts, nevertheless, concluded that the test method applied by the Spanish authorities was not appropriate.
- (10) The tensile test carried out by the German notified body can be considered as the only relevant test method in the present case. Therefore, the EC-type examination test method is valid and the EC-type examination assessment granted by the notified body was made correctly.
- (11) According to the available statistics on inherent swimming aids on the market and accidents, the conclusion can be drawn that swimming aids made of inherent material do not pose any particular risks of choking when used in accordance with their intended purpose and under their foreseeable conditions of use. These products are meant to be used only in the water,

HAS ADOPTED THIS DECISION:

#### *Article 1*

The measure taken by the Spanish authorities withdrawing from the market the buoyant aids for swimming instructions type *Delphin Schwimmscheiben- Typ Super*, manufactured by Delphin Vertriebs- und Service GmbH, D-61192 Niddatal, Germany, is not justified.

#### *Article 2*

This Decision is addressed to the Member States.

Done at Brussels, 13 August 2015.

*For the Commission*  
Elżbieta BIENKOWSKA  
*Member of the Commission*

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