

Commission Decision of 2 July 2010 on the safety requirements  
to be met by European standards for certain products in the  
sleep environment of children pursuant to Directive 2001/95/  
EC of the European Parliament and of the Council (2010/376/EU)

COMMISSION DECISION

of 2 July 2010

on the safety requirements to be met by European standards for  
certain products in the sleep environment of children pursuant to  
Directive 2001/95/EC of the European Parliament and of the Council

(2010/376/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety<sup>(1)</sup>, and in particular Article 4(1)(a) thereof,

Whereas:

- (1) Directive 2001/95/EC provides for European standards to be established by European standardisation bodies. These standards should ensure that products satisfy the general safety requirement of the Directive.
- (2) Under Directive 2001/95/EC a product is presumed safe, as far as the risks and risk categories covered by national standards are concerned, when it complies with voluntary national standards transposing European standards.
- (3) In 2006 the European Commission commissioned a study<sup>(2)</sup> to assess the safety of several child-care articles commonly used to care for babies and young children from 0 until 5 years of age. The study was carried out in cooperation with national authorities, national standardisation bodies, consumer associations, product safety organisations, economic operators and testing laboratories.
- (4) For these products, the study compiled statistics on accidents and injuries in the Union and worldwide and carried out a complete risk assessment, based on an identification of the main hazards and an assessment of exposure scenarios.
- (5) Five types of products assessed by the study, which are regularly found in the sleep environment of newborns and young children, were identified for follow-up to the study. These are cot mattresses, cot bumpers, suspended baby beds, children's duvets and children's sleep bags.
- (6) Every day, newborns sleep for on average at least 16 hours, and at 3-5 years children still sleep for 11-13 hours a day. Including awake periods, babies and young children spend at least half of the day in a sleep environment during their first five years of life.

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Decision of 2 July 2010 on the safety requirements to be met by European standards for certain products in the sleep environment of children pursuant to Directive 2001/95/EC of the European Parliament and of the Council (2010/376/EU), Introductory Text. (See end of Document for details)

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- Products in the sleep environment must be safe, because that is where babies and young children are commonly left unattended for longer periods during the day and the night.
- (7) According to the European Injury Database IDB, between 2005 and 2007, 17 000 accidents involving children from 0 to 4 years happened in the cot in the European Union<sup>(3)</sup>. According to the US Consumer Product Safety Commission (CPSC), every year more babies die in incidents involving cots and cot-related products than with any other child-care product<sup>(4)</sup>.
  - (8) Some models of cot bumpers and children's sleep bags have been notified through the European rapid alert system RAPEX as posing risks of suffocation and choking and consequently withdrawn from the market or recalled. In 1992, the French Consumer Safety Commission recommended action to inform consumers and improve the safety of children's duvets, due to risks of flammability, overheating and suffocation.<sup>(5)</sup> In 2002, 2007 and 2008 the US CPSC ordered the recall of some models of mattresses for cots due to entrapment hazards and unfounded claims<sup>(6)</sup>.
  - (9) Cot bumpers, mattresses, and children's duvets, if unsafe or supplied without essential safety warnings, may increase the incidence of Sudden Infant Death Syndrome (SIDS) due to the risk of overheating and asphyxia<sup>(7)</sup>.
  - (10) At the same time, research has found that children's sleep bags may have a protective effect against SIDS<sup>(8)</sup>, since they reduce the incidence of turning to a prone position and prevent bedding from coming up over the face and the head during sleep. If their use is to be encouraged for these reasons, it is necessary to ensure their safety against other risks, such as choking on small parts and entrapment.
  - (11) No European standards exist for the abovementioned five types of products. It is therefore necessary to determine specific requirements pursuant to Article 4(1)(a) of Directive 2001/95/EC, with the view to requesting the standardisation bodies to develop standards to reduce the risks associated with the use of those products.
  - (12) These standards should be developed according to the procedure laid down in 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>(9)</sup>. The reference of the standard adopted should be published in the *Official Journal of the European Union*, in accordance with Article 4(2) of Directive 2001/95/EC.
  - (13) Once the relevant standards are available, and provided that the Commission decides to publish their reference in the Official Journal, according to the procedure laid down in Article 4(2) of Directive 2001/95/EC, cot mattresses, cot bumpers, suspended baby beds, children's duvets and children's sleep bags manufactured in compliance with such standards should be presumed to comply with the general safety requirement of Directive 2001/95/EC, as far as the safety requirements covered by the standards are concerned.
  - (14) This Decision is in accordance with the opinion of the Committee set up pursuant to Article 15 of Directive 2001/95/EC,

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HAS ADOPTED THIS DECISION:

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- (1) [OJ L 11, 15.1.2002, p. 4.](#)
- (2) [http://ec.europa.eu/consumers/safety/projects/ongoing-projects\\_en.htm#project\\_results](http://ec.europa.eu/consumers/safety/projects/ongoing-projects_en.htm#project_results)
- (3) IDB All Injury Data, 2005-2007.
- (4) 'Nursery product-related injuries and deaths among children under the age of five', in CPSC, February 2009.
- (5) <http://www.securiteconso.org/Article195.html>
- (6) <http://www.cpsc.gov/cgi-bin/prod.aspx>
- (7) 'Environment of infants during sleep and risk of sudden infant death', *British Medical Journal*, 1996,  
'Changing concepts of SIDS: implications for infant sleeping environment and sleep position', *American Academy of Paediatrics*, March 2000,  
'Sleep Environment and the risk of sudden Infant death in an urban population', *American Academy of Paediatrics*, May 2003,  
<http://www.hc-sc.gc.ca/cps-spc/legislation/pol/bumper-bordure-eng.php>
- (8) 'Risk and preventive factors for cot death in The Netherlands, a low-incidence country', *European Journal of Paediatrics*, July 1998.
- (9) [OJ L 204, 21.7.1998, p. 37.](#)

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