

COMMISSION DECISION

of 6 January 2010

on the safety requirements to be met by European standards for bath rings, bathing aids and bath tubs and stands for infants and young children pursuant to Directive 2001/95/EC of the European Parliament and of the Council

(notified under document C(2009) 10290)

(Text with EEA relevance)

(2010/9/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⁽¹⁾, 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 conforms to voluntary national standards transposing European standards.
- (3) In 2006 the Commission commissioned a study⁽²⁾ to assess the safety of several child-care articles which are commonly used for the care of infants and young children from 0 until 5 years of age, in cooperation with national authorities, national standardisation bodies, consumer associations, product safety organisations, economic operators and testing laboratories.
- (4) For these products, the study collected relevant statistics on accidents and injuries in the EU and worldwide and carried out a complete risk assessment, based on identification of the main hazards and assessment of exposure scenarios.
- (5) Bath rings, bathing aids and bath tubs, whether or not combined with stands, are amongst the products assessed by the study. These products are used to bath babies and young children and have been identified as posing

serious risks, mainly of drowning accidents which have often resulted in fatalities, due to the young age of the users.

- (6) Evidence and statistics gathered from accidents consistently show that the risk of drowning is due to insufficient, inconclusive and inconspicuous warnings and instructions on the safe use of products and to their poor structural integrity and resistance. Accidents and statistics have also revealed risks of falling, injury and ingestion of small parts associated with the use of these products and inadequate supervision on the part of the carer.
- (7) Although there is extensive information worldwide on bath-drowning accidents and injuries in early childhood, a direct correlation between the use of bath-assisting devices and fatalities or accidents in the bath is unconfirmed. Researchers and scientific literature worldwide concur that there is no decisive evidence demonstrating a link between the increase in the number of accidents and the use of bath-assisting devices⁽³⁾. Some researchers, observing latest trends of the increase in the sales of bath rings and the decrease in bath-related accidents and drowning, have even claimed a 'small protective effect' due the use of bath rings⁽⁴⁾.
- (8) No European standards exist for these three types of products. It is therefore necessary to determine specific requirements under 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 bath rings, bath aids and bath tubs (whether or not combined with stands) while bathing babies or young children. 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⁽⁵⁾. 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.

⁽¹⁾ OJ L 11, 15.1.2002, p. 4.

⁽²⁾ http://ec.europa.eu/consumers/safety/projects/ongoing-projects_en.htm#project_results

⁽³⁾ 'Drowning of babies in bath seats: do they provide false reassurance?' in Royal Society for the Prevention of Accidents (UK). February 2005. http://www.rospe.com/productsafety/info/bathseats_drowning.pdf

⁽⁴⁾ Comments to CPSC on Advance Notice of Proposed Rulemaking on baths seats and rings by Harvard School of Public Health — Department of Health Policy and Management. May 2001. <http://www.cpsc.gov/LIBRARY/FOIA/foia01/pubcom/commenta.pdf>

⁽⁵⁾ OJ L 204, 21.7.1998, p. 37.

- (9) 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, bath rings, bathing aids and bath tubs (whether or not combined with stands) manufactured in compliance with such standards should be presumed to conform to the general safety requirement of Directive 2001/95/EC, as far as the safety requirements covered by the standards are concerned.
- (10) To improve the current safety levels while using these products, it is necessary to both take action on standards and provide parents and adult caregivers with information on the purpose and safe use of these products.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Article 15 of Directive 2001/95/EC,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision:

- ‘bath rings for babies’ (‘bath seat’) means products allowing to keep a child in a seated position during bathing. These products are intended for use only with a child who is able to sit upright unassisted and should not be used when the child begins pulling up to a standing position.

- ‘bathing aids for babies’ means products allowing to keep a child in a reclined or lying position during bathing. These products are intended for use from birth and until the child is able to sit upright unassisted.
- ‘bath tubs for babies and young children’ means products designed for bathing children from birth up to 12 months. These products can be used as stand-alone products, placed in or on the rim of a regular bathtub or on the floor, or combined with stands.

Article 2

Requirements

The specific safety requirements for the products referred to in Article 1 to be met by European standards pursuant to Article 4 of Directive 2001/95/EC shall be set out in the Annex to this Decision.

Article 3

Publication

This Decision shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Done at Brussels, 6 January 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

Specific safety requirements for bath rings

RISKS: The main risk associated with the product is drowning.

1. SAFETY REQUIREMENTS

(1) **General safety requirements**

Articles shall not jeopardise the safety or health of children and carers when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children. The ability of the child and their carers shall be taken into account, in particular, for articles which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 10 months. Labels on articles or on their packaging and accompanying instructions for use shall draw the attention of users or carers to the hazards and risks of harms inherent in using the articles and to the way of avoiding them.

(2) **Specific safety requirements***Chemical requirements*

Bath rings shall comply with relevant EU legislation.

Fire and thermal properties

To prevent the risk of scalding from hot water pouring from the tap, instructions shall be given to carers to pay attention to the temperature of the water and to prevent the child from gaining access to the tap.

Physical and mechanical properties

Entrapment hazards from gaps and openings

Articles shall be designed and manufactured in order to prevent:

- Entrapment of fingers as far as possible.
- Entrapment of legs maintaining the child submerged in an opening through which the child was able to slip.

Hazards from moving parts

Articles designed to fold shall have a folding mechanism that cannot be activated by a child or by inadvertent action on the part of the carers. It shall not be possible to erect the product without activating the locking mechanism. Changes in the spacing due to the movement of the child, in particular when his/her weight shifts (between the seat base and the bath tub) shall be prevented and shall not cause severe crushing. Rotating seat bases shall be designed as far as possible in order to prevent lacerations and crushing of the child when they are operated.

Falling hazards

To reduce the risk of falling that could result in drowning; the article and its attachment to the bath tub shall be able to withstand internal and external forces applied by the child that could cause it to tip over. In particular, the article shall not tip over when a child leans in any direction, tries to stand up or pushes the seat over.

Choking hazards

To reduce the risk of choking, the article shall not comprise small parts which are detachable by the force a child can apply and which can fit completely into a child's mouth. To reduce the risk of choking, filling materials that constitute choking hazards shall not become accessible when submitted to the force a child can apply, in particular by biting.

Suffocation hazards

The article shall not comprise plastic decals which are detachable by the force a child can apply or any other impermeable sheeting of the bath ring which can cover both the mouth and the nose and constitute a suffocation hazard. The packaging in which the articles are contained must not constitute a risk of suffocation by obstructing the mouth and nose airways.

Ingestion hazards

To reduce the risk of ingestion, the article shall not comprise separate or small parts which are detachable by the force a child can apply and which can pass into the oesophagus.

Hazardous edges

Accessible edges shall be designed to prevent lacerations and wounds, especially edges in direct contact with the skin of the child.

Structural integrity

Securing devices (suction cups or other means) that are essential to attach the product shall maintain performance during the lifetime of the product.

To prevent breaking of components likely to cause physical injury, articles shall be able to withstand mechanical stress to which they are subjected during use.

Protective function

To prevent suffocation by drowning, articles shall be designed to accommodate the child in a sitting position only. The design shall take into account relevant anthropometric data relevant to the age range. The protective function must enable the child to be removed easily in an emergency situation

Hazards resulting from action of the child on the securing device of the articles

To prevent drowning hazards, the securing device shall not be able to be activated by a child or by inadvertent action on the part of the carers.

Specific warnings for the article

Warnings and instructions for use shall clearly state that

- the carer shall at all times be in contact with the child
- drowning can occur in a very short time and in very shallow water (± 2 cm)
- the article does not provide any additional safety related to water hazards and drowning has occurred with bath rings.

Warnings and information should be conspicuously displayed on the packaging, on the product and at the point of sale and should be complemented with pictograms.

The warning label shall be durable and should remain visible when the child is in the bath ring.

Information on the vulnerable age range of children (5 to 10 months) shall be provided to carers.

Hygiene

Bath rings shall be designed to be washable and capable of being dried.

Specific safety requirements for bathing aids

RISKS: The main risk associated with the product is drowning.

2. SAFETY REQUIREMENTS

(1) General safety requirements

Articles shall not jeopardise the safety or health of children and carers when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children. The ability of the child and their carers shall be taken into account, in particular for articles which, by virtue of their functions, dimensions and characteristics, are intended for use by children under 9 months. Labels on articles or on their packaging and accompanying instructions for use shall draw the attention of users or carers to the hazards and risks of harm inherent in using the articles and to the way of avoiding them.

(2) Specific safety requirements

Chemical requirements

Bathing aids for babies shall comply with relevant EU legislation.

Fire and thermal properties

To prevent the risk of scalding from hot water running from the tap, instructions shall be given to the carers to pay attention to the temperature of the water and to prevent the child from gaining access to the tap.

Physical and mechanical properties

Entrapment hazards from gaps and openings

Articles shall be designed and manufactured in order to prevent entrapment of fingers as far as possible.

Strangulation

Articles shall be designed and manufactured to prevent strangulation.

Falling hazards

To reduce the risk of falling that could result in drowning, the article and its attachment to the bath tub shall be able to withstand internal and external forces applied by the child that could cause it to tip over. In particular the article shall not tip over when a child leans in any direction, tries to stand up or pushes the seat over.

Choking hazards

To reduce the risk of choking, the article shall not comprise small parts which are detachable by the force a child can apply and which can fit completely into a child's mouth. To reduce the risk of choking, filling materials that constitute a choking hazard shall not become accessible when submitted to the force a child can apply, in particular by biting.

Suffocation hazards

The article shall not comprise plastic decals which are detachable by the force a child can apply, or other impermeable sheeting of the bathing aid which can cover both the mouth and the nose and constitute a suffocation hazard. The packaging in which the articles are contained must not constitute a risk of suffocation by obstructing the mouth and nose airways.

Ingestion hazards

To reduce the risk of ingestion, the article shall not comprise separate or small parts which are detachable by the force a child can apply and which can pass into the oesophagus.

Hazardous edges

Accessible edges shall be designed to prevent lacerations and wounds, especially edges in direct contact with the skin of the child.

Structural integrity

To prevent breaking of components likely to cause physical injury, articles shall be able to withstand mechanical stresses to which they are subjected to during use.

Specific warnings for the article

Warnings and instructions for use shall clearly state that:

- the carer shall at all times be in contact with the child,
- drowning can occur in a very short time and in very shallow water (± 2 cm),
- the maximum level of water to prevent water entering into the child's mouth,
- the article does not provide any additional safety related to water hazards and drowning has occurred with bathing aids.

Warnings and information should be conspicuously displayed on the packaging, on the product and at the point of sale and should be complemented with pictograms.

The warning label shall be durable and should remain visible when the child is in the bathing aid.

Information on the vulnerable age range of children (from birth up to 9 months) shall be provided to carers

Hygiene

The articles shall be designed to be easily cleanable and dried.

Specific safety requirements for bath tubs for babies and bath stands

RISKS: The main risks associated with the product are drowning and falling when the baby bath tub falls from its stand or support.

3. SAFETY REQUIREMENTS

(1) General safety requirements

Articles shall not jeopardise the safety or health of children and carers when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children. The ability of the child and their carers shall be taken into account, in particular, for articles which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 12 months. Labels on articles or on their packaging and accompanying instructions for use shall draw the attention of users or carers to the hazards and risks of harm inherent in using the articles and to the way of avoiding them.

(2) Specific safety requirements

Chemical requirements

Baby bath tubs and stands for baths shall comply with relevant EU legislation.

Fire and thermal properties

To prevent the risk of scalding from hot water pouring from the tap, instructions shall be given to the carers to pay attention to the temperature of the water and to prevent the child from gaining access to the tap.

Physical and mechanical properties

Entrapment hazards from gaps and openings

Articles shall be designed and manufactured in order to prevent entrapment of fingers as far as possible.

Strangulation

Articles shall be designed and manufactured to prevent strangulation.

Hazards from moving parts

Articles designed to fold shall have a folding mechanism that cannot be activated by a child or by inadvertent action on the part of the carer. It shall not be possible to erect the product without activating the locking mechanism. Changes to the spacing due to movement of the child, in particular when his/her weight shifts shall be forbidden to prevent crushing.

Falling hazards

To prevent inadequate stability, the bath and its stand shall be designed and manufactured to withstand both the weight of the child and the bath water. The bath and its stand shall not tip over under stress due to movement of the child or inadvertent movement of the carer. In particular, the article shall not tip over when a child leans in any direction or tries to stand up.

Choking hazards

To reduce the risk of choking, the article shall not comprise small parts which are detachable by the force that a child can apply and which can fit completely into a child's mouth. To reduce the risk of choking, filling materials that constitute choking hazards shall not become accessible when submitted to the force a child can apply, in particular by biting.

Suffocation hazards

The article shall not comprise plastic decals which are detachable by the force a child can apply or other impermeable sheeting of the bath tub which can cover both the mouth and the nose and constitute a suffocation hazard. The packaging in which the articles are contained must not constitute a risk of suffocation by obstructing the mouth and nose airways.

Ingestion hazards

To reduce the risk of ingestion, the article shall not comprise separate or small parts which are detachable by the force a child can apply and which can pass into the oesophagus.

Hazardous edges

Accessible edges shall be designed to prevent lacerations and wounds, especially edges in direct contact with the skin of the child.

Structural integrity

To prevent collapsing or breaking of components likely to cause physical injury, the article shall be able to withstand mechanical stress to which they are subjected during use. To prevent degradation of components likely to cause injury, material used to manufacture bath tubs and stands shall have characteristics that maintain performance during the lifetime of the product, in particular taking into account thermal changes.

Hazards due to the combination of two separate items

Device attaching the tub to the stand shall be able to withstand mechanical stress to which they are subjected during use. For stands and bath tubs sold separately, warnings and instructions for use shall indicate the references of products that can be safely used together.

Specific warnings for the article

Warnings and instructions for use shall clearly state that:

- the carer shall at all times be in contact with the child,
- drowning can occur in a very short time and in very shallow water (± 2 cm), the articles do not provide any additional safety related to water hazards and that drowning has occurred with bath tubs.

Warnings and information should be conspicuously displayed on the packaging, on the product and at the point of sale and should be complemented with pictograms.

The warning label shall be durable and should remain visible when the child is in the bath tub.

Information on the vulnerable age range of children (less than 12 months) shall be provided to carers.

Bath tubs shall have a warning to prevent carers from installing tubs on an elevated position in combination with articles such as tables.

Hygiene

The articles shall be designed to be easily washable and dried.
