STANDARDISATION MANDATE TO CEN ON THE SAFETY OF CHILD-CARE ARTICLES:

CLUSTER 1 (DROWNING RISKS)

BATH RINGS, BATHING AIDS, BATH TUBS AND STANDS

I. Background

Accidents and injuries involving pre-school children (0-5 years) happen more frequently in a domestic environment, as children in this age group spend most of their time at home\(^1\). For the same reason, accidents in this age group are also often related to a child-use or nursery product.

In the US 62,500 child care product-related injuries among children under the age of five were treated in hospital emergency departments in 2007. In Australia, 2,300 child-care product-related injuries were treated in emergency departments in the period 2003-2007, an average of 455 cases per year.

The situation in Europe echoes statistics worldwide: in France, between 2004 and 2005, 1,238 accidents involved a child-use product or furniture. According to the IDB database injuries with child-care articles and child use product account for 133,000 cases of injuries in the EU 27 involving children.

Most of these accidents, and the resulting injuries, are preventable by, e.g., setting safer standards for these products, and by providing better and clearer information and warnings to adults and caregivers\(^2\).

Between 2007 and 2008 the Commission investigated the safety of several child care and child use products sold in Europe, with the assistance of an external consultant. Further to this investigation, a first list of 20 products for which there are no European standards, or the existing standard does not cover all the risks, was drawn up. For each product, a risk

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\(^1\) In Canada, more than 75% of injury-related emergency room visits among children from birth to 4 years are for injuries occurring at home.

assessment was carried out and preliminary safety requirements were identified. The results of this investigation are publicly available\(^3\).

Three of the products identified have in common a high risk of drowning: bath seats (or bath rings), bathing aids, bath tubs combined or not with stands.

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety\(^4\) (GPSD) aims at ensuring that only safe products are placed on the EU market. To that end, it establishes a general safety requirement for consumer products, supported by a definition of “safe” product.

Products that conform to European standards, which are drawn up and published in the Official Journal according to the procedure described in Article 4 of the GPSD, are presumed to be safe.

The Commission adopted Decision 2010/9/EU on 6 January 2010 setting the safety requirements for bath seats, bathing aids and bath tubs and stands, with the view to requesting the European Committee for Standardisation (CEN) to develop European standards for these products. Commission Decision 2010/9/EU is annexed to this Mandate and forms an integral part of it.

II. Bath time: a hazardous activity.

Drowning is the second leading cause of unintentional injury-related deaths and accidents worldwide involving children, and the single leading cause of deaths amongst children in Europe\(^5\).

In the age interval 6-12 months, drowning and near-drowning occur usually in the bathtub\(^6\). Young children and babies can drown in as little as 5 cm of water. Childhood drowning occurs usually silently and quickly, in just a matter of seconds. Even a brief lapse of adult's supervision can be fatal.

Bath seats (or rings), bathing aids and bath tubs (with or without stands) have become very popular amongst consumers\(^7\). Parents and caregivers find that these products help them to hold the baby steadily in the water, without too much strain on their backs. Also, having both arms free is considered as an additional benefit (e.g. for playing with the child while in the bath).

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\(^5\) WHO- Regional Office for Europe; Eurosafe-Child Safety Alliance

\(^6\) "Rates of Paediatrics Injuries by 3-Month Intervals for Children 0 to 3 years of age", American Academy of Paediatrics, June 203

\(^7\) In 2005, a US survey indicated annual sales of bath seats of about 1.5 million, while about 1.7 million bath seats were in use. According to information released by a French manufacturer, annual sales of bathing aids are estimated at 90.000 in France and 90.00 in Europe, and sales of bath rings are estimated at 80.00 in France and 140.000 in Europe.
Figures from the US Consumer Product Safety Commission CPSC (USA) released in February 2009\(^8\), indicate that, between 2003 and 2005, 90 young children died while using baby baths or bath rings. In France, 112 accidents while using a bath assisting device were registered between 1996 and 2000. The average age of the victims is between 5 and 11 months.

Parents and adult caregivers are generally misled into thinking that bath rings, seats or tubs are safety devices. Most of the accident data referred to above report that fatalities have occurred when parents and caregivers, reassured by a false sense of security, left the unattended in a bath for a very short time, even seconds, or in the care of an older child.

Data also report that accidents have occurred while the parent was present, as the suction cups, which should firmly fasten the device to the surface of the bath tub, suddenly detached and the child tipped over. In other cases, the infant managed to release the bath ring or to climb out of the bath tub. For bath tubs resting on special stands, falling represents a major risk, as the bath tub and the stand can collapse even in the presence of an adult.

Although there is extensive information worldwide on bath-drowning fatalities 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 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\(^9\). Some researchers, observing recent trends in increased sales of bath rings and a decrease in bath-related accidents and drowning, have even claimed a ‘small protective effect’ due the use of bath rings\(^10\).

Against this background, a ban of these articles under Directive 2001/95 does not have, at present, a solid scientific justification. The best option is to produce European safety standards to improve the overall safety of the products and inform parents and adults on their safe use and, in general, on the risks which babies and young children.

III. Existing standards, regulations and ongoing work

- FRANCE

Norme expérimentale XP S54-048 (Dispositifs d'aide au bain à usage domestique-Exigences et méthodes d'essai")

Norme expérimentale XP S54-044 (Baignoires pour enfants- Exigences de sécurité et méthodes d'essai)

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\(^8\) "Nursery Product-Related Injuries and Deaths Among Children under 5". US CPSC, February 2009


USA

The Consumer Product Safety Improvement Act of 2008 ("CPSIA,"') entered into force on 14 August 2008. Section 104(b) of the CPSIA requires the CPSC to promulgate consumer product safety standards for "durable infant or toddler products". These standards are to be "substantially the same as" voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the use of the product. In the case of bath seats, in September 2009, CPSC notified to the WTO some amendments to the relevant ASTM F 1967-08a.11.

For bath tubs and stands, the relevant standard is ASTM F 2670-09.

AUSTRALIA

The law requires that bath seats supplied from 1 August 2004 must have a prescribed warning notice permanently attached in a prominent position.

EUROPE

Standardisation process at European level was initiated under Mandate M/264 issued in 1997. The work was discontinued (prEN 13822). Mandate M/264 was a "bulk" mandate for child care articles and did not contain specific risk assessment and safety requirements for drowning risks in general, and for the products concerned by the present mandate, in particular.

IV Description of the mandated work

The essential requirements attached to this mandate, and which form an integral part of it, aim at making warnings and instructions to adult users clearer, permanent and visible, at improving the stability and structural integrity of the products, and at minimising the risks due to accidental openings of mobile parts.

For the development of the standard, attention should be paid to:

• the child’s stage of development (ability, weight, age, etc.);

• the intended or foreseeable use of the product, bearing in mind a child’s unpredictable behaviour. Such unpredictable behaviour exposes children to injury in ways that differ from those of adults, making children a particularly vulnerable group in society;

• the hazard presented by the product in the environmental circumstances under which the product and the child come into contact with each other.

The standards should include safety requirements and test methods. Although the essential requirements attached to this mandate have been developed to address mainly conditions of use of the products mostly in a domestic environment, consideration should be given to

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a foreseeable use in some professional or public environments (e.g. hotels, child-care centres, nursery schools).

In carrying out the mandated work, CEN is requested to consider existing standard(s) in this area as well as general guidelines on child safety, such as CEN guide 12 ("Child safety- Guidance for its inclusion in standards") and CEN TR 13387.

IV. Execution of the mandate

The European standard(s) shall be delivered within **three** years of acceptance of the mandate at the latest. At this time the text of the standard in the three working languages of CEN (DE, EN, FR) shall be available, as well as the correct titles in the other official European Union languages.

CEN shall inform the Commission of the arrangements to be adopted for the execution of the work within **three months** of acceptance of this mandate. CEN will submit progress reports to the Commission every six months.

CEN shall develop the draft standard in close consultation with the European Commission.

In carrying out the mandate, appropriate co-ordination and liaison with relevant activities and organisations shall be established at international, national and European level to ensure coherence. In particular, the work should be coordinated with ongoing activities in ASTM and CPSC at international level.


V. Bodies to be associated

ANEC (European association for the co-ordination of consumer representation in standardisation), ECOS, NORMAPME (European Office of Crafts, trades and Small and Medium-sized Enterprises for Standardisation) and ETUI-REHS (European Trade Union Institute – Research, Education, Health and Safety) should be invited to take part in the mandated work.
Draft

COMMISSION DECISION

of [...] 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

(Text with EEA relevance)

EN
COMMISSION DECISION

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

(TEXT WITH EEA RELEVANCE)

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, 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 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.


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.

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. 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.

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. 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.

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.

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.


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 twentieth day following that of its publication in the Official Journal of the European Union.

Done at Brussels,


For the Commission
José Manuel BARROSO
The President
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 (± 2cm)
- 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.

1. SAFETY REQUIREMENTS:

(3) 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.

(4) 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.

- 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 (± 2cm)
- 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.

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 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 with 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 (± 2cm)
- 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.

Background documents: