

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)

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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 complies with voluntary national standards transposing European standards.
- (3) In 2006 the European Commission commissioned a study⁽²⁾ 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.

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⁽³⁾. 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⁽⁴⁾.
- (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.⁽⁵⁾ 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⁽⁶⁾.
- (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⁽⁷⁾.
- (10) At the same time, research has found that children's sleep bags may have a protective effect against SIDS⁽⁸⁾, 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⁽⁹⁾. 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,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision:

- ‘*cot mattress*’ means a product providing support for newborns and children sleeping in a cot. It usually measures 60 × 120 cm or 70 × 140 cm and varies in thickness between 6 and 15 cm. It can also be foldable,
- ‘*cot bumper*’ means an upholstered accessory for a cot attached to the inner part of it, generally used to improve the comfort of the child. It can cover at least one side of the cot,
- ‘*suspended baby bed*’ means a cot or a crib, often with a non-rigid or other flat surface suspended with cords, straps or slings from one or more anchorage points. It is used to lay down a young baby who cannot kneel or sit up unaided,
- ‘*duvet for children*’ means a fabric bag containing a soft filling for use in the cot to increase comfort when sleeping and prevent hypothermia,
- ‘*children’s sleep bag*’ means a warmly lined or padded body-length bag, in which the baby is placed and designed to prevent hypothermia and suffocation while sleeping or lying in a cot.

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 are set out in the Annex to this Decision.

Article 3

Entry into force

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

Done at Brussels, 2 July 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

SPECIFIC SAFETY REQUIREMENTS FOR COT MATTRESSES

RISKS: The main risks associated with the product are entrapment and flammability.

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 users 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 five years. Labels on articles or on their packaging and accompanying instructions for use shall draw the attention of carers to the hazards and risks posed by using the articles and to the way of avoiding them.

2. Specific safety requirements

Chemical requirements

Cot mattresses shall comply with EU legislation.

Fire and thermal properties

Cot mattresses shall not constitute a dangerous flammable object in the child's environment. Therefore they must be composed of materials which fulfil at least one of the following conditions:

- they do not burn if directly exposed to a flame or spark,
- if they do ignite, they shall burn slowly with a low rate of spread of the flame.

In addition, combustible materials shall not release toxic fumes during combustion.

The use of chemical flame retardant substances should be kept to the minimum. If chemical flame retardant substances are used, their toxicity during use and end-of-life disposal should not endanger the health of the users, carers and the environment.

Physical and mechanical properties

Entrapment hazards from gaps and openings

To prevent entrapment of the torso, head and neck in the bed base, cot mattresses shall completely cover the bed base and withstand stress induced by the child by standing on the mattress or walking in the cot.

The child should not be able to lift the parts of the foldable mattress, which could give him/her access to the bed base and thus increase the risk of entrapment.

Articles shall be designed and manufactured as far as possible in order to prevent entrapment of limbs, feet and hands in spaces between the mattress and the sides of the cot.

To prevent asphyxia of the child whose head or torso is entrapped between the mattress and the sides of the cot, the space between the mattress and the sides of the cot must be limited, taking into account the most onerous position of the mattress on the cot base.

Entanglement hazards

The length of cords, ribbons and parts used as ties and the size of the loops must be limited to prevent the risk of entanglement.

External suffocation hazards

Cot mattresses shall not comprise plastic decals which can be detached by the child or other impermeable layers of the mattress which can cover both the mouth and the nose.

The packaging in which the articles are contained must not constitute a risk of suffocation caused by airway obstruction.

To prevent the risk of suffocation, the product shall not comprise a soft mattress filling which could mould to the child's face or produce indentations which could obstruct the airways.

Choking and internal suffocation hazards

Cot mattresses shall not contain separate or small parts which can be detached by the child, fit completely into a child's mouth and swallowed.

Cot mattresses shall not contain small parts which can be detached by the child and which can remain stuck in the pharynx or at the back of the oral cavity. The filling material shall not be accessible, especially by biting off and shall withstand stress from foreseeable use by the child, taking into account the possibility of fibres passing through the seams and the strength of the seams.

Hazardous edges

Cot mattresses shall not have sharp edges or points. Springs wires shall not have hazardous points and shall not protrude through the surface of the mattress.

Structural integrity

The material of the mattress shall have physical properties such that the mattress does not constitute an entrapment hazard. There shall be no permanent deformation of the filling resulting in a loose cover.

Specific warnings for the article

Warnings and instructions for use shall indicate to the carers the thickness of the mattress to prevent falling from the cot, and the appropriate size (length and width) for it to fit in the cot and avoid entrapment.

To prevent suffocation, instructions shall draw the attention of carers to the dangers posed by piling up two or more mattresses to improve the comfort of the child.

Warnings against possible scenarios that could cause a fire (e.g. smoking in proximity of the cot) should be included.

Hygiene

Cot mattresses should be designed in such a way as to meet hygiene and cleanliness requirements to avoid the risk of infection or contamination.

SPECIFIC SAFETY REQUIREMENTS FOR COT BUMPERS

RISKS: The main risks associated with the product are strangulation, internal and external suffocation and choking.

Safety requirements

1. General safety requirements

Articles shall not jeopardise the safety or health of children when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The ability of the users 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 from six up to 18 months.

Labels on articles or on their packaging and the instructions for use which accompany them shall draw the attention of carers to the inherent hazards and risks of harm involved in using the articles and to the way of avoiding them.

2. Specific safety requirements

Chemical requirements

Cot bumpers shall comply with EU legislation.

Fire and thermal properties

Cot bumpers shall not pose flammability risks in the child's environment. They shall be composed of materials which fulfil at least one of the following conditions:

- they do not burn if directly exposed to a flame or spark,
- if they do ignite, they shall burn slowly with a low rate of spread of the flame.

In addition, combustible materials shall not release toxic fumes during combustion.

The use of chemical flame retardant substances should be kept to the minimum. If chemical flame retardant substances are used, their toxicity during use and end-of-life disposal should not endanger the health of the users, carers and the environment.

Physical and mechanical properties

Microbiological hazards

Cot bumpers shall not pose microbiological hazards from insufficient hygiene from material of animal origin.

Entrapment hazards from gaps and openings

Cot bumpers shall not constitute a risk of entrapment of the head and neck of the child in loops or cords or other attachment devices. Stitching and decorative parts on the bumper shall not become loose when submitted to mechanical stress from foreseeable use by children so as not to pose an additional risk of entrapment of limbs, head and fingers or make the filling accessible (see choking hazards).

Entanglement hazards

There shall be no cords or loops on the cot bumpers that could entangle a child's neck. Loops where a child's fingers or toes could be trapped should be avoided.

Choking and internal suffocation hazards

Cot bumpers shall not contain separate or small parts which can be detached by the child, fit completely into a child's mouth and swallowed.

Cot bumpers shall not contain small parts which can be detached by the child and can remain stuck in the pharynx or at the back of the oral cavity. The filling material shall not be accessible, especially by biting off, and shall withstand stress from foreseeable use by the child, taking into account the possibility of fibres passing through the seams and the strength of the seams. The filling material shall not contain any hard or sharp contaminants, such as metal particles, nails, needles or splinters.

External suffocation hazards

The product shall not comprise plastic decals which could be detached by the child or other impermeable coverings of the cot bumper which could cover both the mouth and the nose.

The packaging in which the articles are contained shall not constitute a risk of suffocation due to obstruction of the external airways.

To prevent suffocation, the product shall not comprise soft materials which could mould to the child's face or produce indentations which could obstruct the airways.

Hazardous edges

Cot bumpers shall not have sharp edges and points. They shall not comprise points or protruding surfaces that could constitute a puncture hazard.

Protective function

Cot bumpers shall be designed and manufactured in such a way as to avoid the presence of parts likely to be used as footholds enabling children to climb on the product.

Hazards due to the combination of two separate items

Cot bumpers shall not pose an additional entrapment or asphyxiation hazard if the child manages to put his/her head between the cot bumper and the side of the cot.

Specific warnings for the article

Adequate information shall be given for the correct fitting of the cot bumper to the side of the cot. The warning shall indicate that the cot bumper shall be fitted correctly so that the attachment device shall not comprise cords and loops that could entrap the head and neck of the child. Warnings shall draw the attention of carers to the risks posed by cot bumpers which are not compatible (due to the size or model) with the cot and by cot bumpers which are not correctly attached to the cot.

Hygiene

Cot bumpers shall be designed and manufactured in such a way as to be easily and thoroughly cleaned, to avoid the risk of infection or contamination. The product shall fulfil this condition also after washing according to the manufacturer's instructions and should not stain when in contact with the child.

SPECIFIC SAFETY REQUIREMENTS FOR SUSPENDED BABY BEDS

RISKS: The main risks associated with the product are entrapment, suffocation and injury due to structural failure and instability.

Safety requirements

1. General safety requirements

Articles shall not jeopardise the safety or health of children when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The ability of the users 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 below 12 months.

Labels on articles or on their packaging and the instructions for use which accompany them shall draw the attention of carers to the inherent hazards and risks of harm involved in using the articles and to the way of avoiding them.

2. Specific safety requirements

Chemical requirements

Suspended baby beds shall comply with EU legislation.

Fire and thermal properties

Suspended baby beds shall not pose flammability risks in the child's environment. They shall be composed of materials which fulfil at least one of the following conditions:

- they do not burn if directly exposed to a flame or spark,
- if they do ignite, they shall burn slowly with a low rate of spread of the flame,
- if they do ignite, they shall burn slowly and shall not produce flaming debris or melting drops.

In addition, combustible materials shall not release toxic fumes during combustion.

The use of chemical flame retardant substances should be kept to the minimum. If chemical flame retardant substances are used, their toxicity during use and end-of-life disposal should not endanger the health of the users, carers and the environment.

Physical and mechanical properties

Entrapment hazards from gaps and openings

Suspended baby beds shall be designed and manufactured in order to prevent any entrapment of the child's head, fingers, limbs, hands and feet in all type of openings.

Hazards from moving parts

Suspended beds shall be designed to prevent impacts of the child in the bed against the frame or other furniture in the room due to sideway movement.

Suspended beds shall be designed to limit rotation of the bed, for instance when twisted.

Suspended beds shall not constitute a hazard (e.g. entrapment) to other children (e.g. siblings) who may come in contact with the bed.

Falling hazards

The stand and the bed shall be sufficiently stable to prevent accidental tipping over of the suspended bed which could cause the child to fall. Baby beds should remain stable when the child moves in the bed or when the bed swings along the amplitude permitted by the suspension device.

The attachment device shall not become detached from the supporting beam or similar device.

The suspension device including its components shall withstand the movement of the child during use.

Entanglement hazards

There shall be no cords or ribbons in the suspended baby bed that could entangle the child's neck. The child in the suspended bed shall not be susceptible to becoming entangled in cords and straps from the suspension device and the adjustment device.

Choking and internal suffocation hazards

Suspended beds shall not contain separate or small parts which can be detached by the child, fit completely into a child's mouth and swallowed.

Suspended beds shall not contain small parts which can be detached by the child and can remain stuck in the pharynx or at the back of the oral cavity. The filling material shall not be accessible and shall withstand stress from foreseeable use by the child (including biting off).

External suffocation hazards

The product shall not comprise plastic decals which could be detached by the child and other impermeable coverings which can cover both the mouth and the nose.

The packaging in which the articles are contained shall not constitute a risk of suffocation caused by obstruction of the external airways. To prevent the risk of suffocation, the product shall not comprise soft materials which can mould to the child's face or produce indentations which could obstruct the airways.

Hazardous edges

Suspended beds shall not have sharp edges and points. Accessible edges and corners shall be rounded and chamfered.

The product shall not comprise protruding parts on which a child could fall and be injured.

The product shall not comprise points or protruding surfaces that can constitute a puncture hazard.

Structural integrity

Deformation of the suspension device and slipping in the adjustment device shall be limited to prevent falls or impacts from the bed.

Stitching and decorative parts on the suspended baby bed shall not become loose when submitted to mechanical stress from foreseeable use by children and pose a risk of entrapment of limbs, head and fingers.

Movement of the child's body weight shall not create gaps or modify existing gaps leading to entrapment of the fingers, hands and feet.

To prevent collapse of the suspended baby bed and breaking of components (from stands, attachment device or suspension device) likely to cause physical injury, suspended beds shall withstand the mechanical stress to which they are subject during use for the lifetime of the product.

Specific warnings for the article

Warnings and instructions for use shall draw the attention of carers to the fact that mounting and adjusting the bed safely requires skill. Warnings should also convey the following messages:

- the child may get injured if the amplitude of the swing is excessive (e.g. the child may hit the bed frame, or the bed may hit other furniture),
- suspended beds may pose risks to other children,
- other children may pose additional risks (e.g. by trying to bend over the bed),
- suspended beds should be installed on flat surfaces,
- the use of suspended beds as night-time beds should be discouraged,
- suspended beds should not be used when the child is able to kneel or sit up unaided. The age group suitable for this product (not beyond 12 months) should be clearly indicated.

Hygiene

Suspended beds shall be designed and manufactured in such a way as to be easily and thoroughly cleaned to avoid the risk of infection or contamination.

SPECIFIC SAFETY REQUIREMENTS FOR DUVETS FOR CHILDREN

RISKS: The main risks associated with the product are suffocation and hyperthermia, frequently associated with Sudden Infant Death Syndrome.

Safety requirements

1. General safety requirements

Articles shall not jeopardise the safety or health of children when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

Labels on articles or on their packaging and the instructions for use which accompany them shall draw the attention of carers to the inherent hazards and risks of harm involved in using the articles and to the way of avoiding them.

2. Specific safety requirements

Chemical requirements

Duvets for children shall comply with EU legislation.

Fire and thermal properties

Children's duvets shall not pose flammability risks in the child's environment.

They shall be composed of materials which fulfil at least one of the following conditions:

- they do not burn if directly exposed to a flame or spark,
- if they do ignite, they shall burn slowly with a low rate of spread of the flame.

In addition, combustible materials shall not release toxic fumes during combustion.

The use of chemical flame retardant substances should be kept to the minimum. If chemical flame retardant substances are used, their toxicity during use and end-of-life disposal should not endanger the health of the users, carers and the environment.

Hyperthermia hazard

Warnings and instructions shall draw carers' attention to the temperature in the room where the product is used, to prevent hyperthermia.

Physical and mechanical properties

Microbiological hazards

Children's duvets shall not pose microbiological hazards from insufficient hygiene from material of animal origin.

Entrapment hazards from gaps and openings

Stitching and decorative parts on duvets shall not become loose when subject to mechanical stress from foreseeable use and thus pose a risk of entrapment (especially of fingers).

Entanglement hazards

Duvets for children shall not comprise cords or loops that could entangle the child's neck.

Choking and internal suffocation hazards

Duvets for children shall not contain separate or small parts which can be detached by the child, fit completely into a child's mouth and swallowed. Duvets for children shall not contain small parts which can be detached by the child and can remain stuck in the pharynx or at the back of the oral cavity. The filling material shall not be accessible, and shall not contain any hard or sharp contaminants, such as metal particles, nails, needles or splinters. The filling shall also withstand stress from foreseeable use by the child (including biting off), taking into account the possibility of fibres passing through the seams and the strength of the seams.

External suffocation hazards

Duvets for children shall not comprise plastic decals which could be detached by the child and other impermeable coverings which can cover both the mouth and the nose.

The packaging in which the product is contained shall not constitute a risk of suffocation caused by obstruction of the external airways.

The baby shall be able to breathe and get sufficient airflow when the duvet covers his/her face while sleeping.

Specific warnings for the article

Warnings and instructions for use shall draw carers' attention to the serious risks of suffocation if duvets are used with children under four months.

The minimum age recommended for use is nine months.

Information concerning the size of the cot in which the duvet is to be used shall also be provided.

Warnings about the room temperature shall also be provided (see hyper thermal hazards).

Hygiene

Duvets for children shall be designed and manufactured in such a way as to be easily and thoroughly cleaned to avoid the risk of infection or contamination. The product shall fulfil this condition also after washing according to the manufacturer's instructions and should not stain when in contact with the child.

SPECIFIC SAFETY REQUIREMENTS FOR CHILDREN'S SLEEP BAGS

RISKS: The main risk associated with the product is choking on small parts and entrapment inside the bag

Safety requirements

1. General safety requirements

Articles shall not jeopardise the safety or health of children when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

Labels on articles or on their packaging and accompanying instructions for use shall draw the attention of carers to the inherent hazards and risks of harm involved in using the articles and to the way of avoiding them.

2. Specific safety requirements

Chemical requirements

Children's sleep bags shall comply with EU legislation.

Fire and thermal properties

Children's sleep bags shall not pose flammability risks to the child environment.

They shall be composed of materials which fulfil at least one of the following conditions:

- they do not burn if directly exposed to a flame or spark,
- if they do ignite, they shall burn slowly with a low rate of spread of the flame.

In addition combustible materials shall not release toxic fumes during combustion.

The use of chemical flame retardant substances should be kept to the minimum. If chemical flame retardant substances are used, their toxicity during use and end-of-life disposal should not endanger the health of the users, carers and the environment.

Hyperthermia hazard

Warnings and instructions shall draw carers' attention to the temperature in the room where the product is used, to prevent hyperthermia.

Physical and mechanical properties

Entrapment hazards from gaps and openings

Stitching and decorative parts on the sleeping bag shall not become loose when subject to mechanical stress from foreseeable use and thus pose a risk of entrapment (especially of fingers). Also the size of the neck and arms openings should prevent the child slipping down into the bag.

Structural integrity

Fastenings shall be secure to prevent the child slipping down into the bag. Seams and fastenings shall remain stable after washing according to the manufacturers' instructions.

Entanglement hazards

There shall be no cords or loops on the sleeping bags that could entangle the child's neck.

Choking and internal suffocation hazards

Children's sleep bags shall not contain separate or small parts which can be detached by the child, fit completely into a child's mouth and swallowed. Sleeping bags shall not contain small

parts which can be detached by the child and can remain stuck in the pharynx or at the back of the oral cavity. The filling material shall not be accessible and shall withstand stress from foreseeable use by the child (including biting off), taking into account the possibility of fibres passing through the seams and the strength of the seams.

External suffocation hazards

Children's sleep bags shall not comprise plastic decals which could be detached by the child or other impermeable coverings or fabrics which can cover both the mouth and the nose.

The packaging in which the product is contained shall not constitute a risk of suffocation caused by obstruction of the external airways.

The baby shall be able to breathe if the sleeping bag covers his/her face while sleeping.

Hazardous edges

Children's sleep bags shall not have sharp edges and points.

Specific warnings for the article

Warnings and instructions shall instruct carers to choose the sleeping bag recommended for the age and height of the child.

Warnings about the room temperature shall also be provided (see hyper thermal hazards).

Hygiene

Children's sleep bags shall be designed and manufactured in such a way as to be easily and thoroughly cleaned to avoid the risk of infection or contamination. The product shall fulfil this condition also after washing according to the manufacturer's instructions and should not stain when in contact with the child.

- (1) [OJ L 11, 15.1.2002, p. 4.](#)
- (2) 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.](#)