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Directorate B – Consumer Affairs

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STANDARDISATION MANDATE TO CEN, CENELEC AND ETSI ON THE SAFETY OF CHILD-CARE ARTICLES

CLUSTER 2 - RISKS IN THE SLEEPING ENVIRONMENT

MATTRESSES FOR COTS, COT BUMPERS, SUSPENDED BEDS FOR CHILDREN, DUVETS FOR CHILDREN, SLEEP BAGS FOR CHILDREN

1. 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 home¹. 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, 2300 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, 1238 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 caregivers².

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

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.

² WHO – World Report on Child Injury Prevention, December 2008 -<u>http://www.who.int/mediacentre/news/releases/2008/pr46/en/index.html</u>

risk assessment was carried out and preliminary safety requirements were identified. The results of this investigation are publicly available³.

Five of the products identified in the study carry high risks and they are all present in the sleeping environment of babies and young children:

- 1) Mattresses for cots
- 2) Cot bumpers
- 3) Suspended baby beds
- 4) Duvets for cots
- 5) Sleep bags for children

The photos below provide a generic illustration of these products:

Mattresses for cots	
Cot Bumpers	
Suspended baby beds	

³ http://ec.europa.eu/consumers/safety/projects/docs/report_20products.zip



Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety⁴ (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.

On 2 July 2010 the Commission adopted **Decision 2010/376/EU** setting the safety requirements for products in the sleep environment (mattresses for cots, cot bumpers, suspended baby beds, duvets for children, and sleep bags for children) with the view to requesting the European Committee for Standardisation (CEN) to develop European standards for these products. Commission Decision 2010/376/EU is published on the OJEU⁵ and constitutes an integral part of this mandate.

2. A SAFE SLEEP ENVIRONMENT FOR BABIES AND YOUNG CHILDREN

Sleeping is the primary activity of the brain during early development and it is particularly important for children, as it directly impacts mental and physical development. By the age of two, most children have spent more time asleep than awake and overall, a child will spend 40% of his or her childhood asleep. As children spend so much time sleeping, they need a safe environment and safe products when they do.

⁴ OJ L11, 15.1.2002, p.4.

⁵ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:170:0039:0048:EN:PDF

The sleep environment is also where parents and caregivers leave their babies and young children unattended for longer periods during the day and the night. This factor, combined with the young age of the children, contribute to making accidents and injuries involving cots and cots-related products very common, and often resulting in fatalities or severe injuries.

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 Union⁶. 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 product⁷.

The main risks posed by products in the sleep environment of babies and young children are:

- ➤ strangulation;
- internal asphyxiation (choking/ingestion of small parts);
- external asphyxiation (suffocation);
- ➢ flammability;
- ➢ injuries due to falls and entrapment;
- hyperthermia (overheating);

More specifically, 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.⁸ In 2002, 2007 and 2008 the US CPSC ordered the recall of some models of **mattresses for cots**⁹.

Cot bumpers, mattresses, and children's duvets, if unsafe or supplied without essential safety warnings, could be a contributing factor of the Sudden Infant Death Syndrome (SIDS).-^{10.}

⁶ IDB All Injury Data, 2005-2007.

⁷ "Nursery product-related injuries and deaths among children under the age of five", in CPSC, February 2009

⁸ <u>http://www.securiteconso.org/article195.html</u>

⁹ <u>http://www.cpsc.gov/cgi-bin/prod.aspx</u>

 [&]quot;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

[&]quot;Sleep Environment and the risk of sudden Infant death in an urban population", American Academy of Paediatrics, May 2003

[&]quot;Foam Mattress linked to cot death" - http://news.bbc.co.uk/2/hi/health/1935034.stm

[&]quot;Antimony, cot mattresses and SIDS"- http://www.ploetzlicher-kindstod.org/literatur/kloesterl/19-Taylor.Lancet-1996.pdf

http://www.hc-sc.gc.ca/cps-spc/legislation/pol/bumper-bordure-eng.php

At the same time, research has suggested that **children's sleep bags** may have a protective effect against $SIDS^{11}$, 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.

Suspended baby beds pose suffocation and entrapment hazards. In 2009^{12} and 2010^{13} , the US CPSC announced the recalls of some models.

As there are no European standards for the five products referred to above, it is therefore necessary to request the development of safety standards to reduce or eliminate the risks associated with the use of these products.

3. EXISTING STANDARDS, REGULATIONS, GUIDELINES AND ONGOING WORK

For the development of the relevant standards, attention should be paid to existing legislation and standards, such as:

- EN ISO 12952-1 Textiles Assessment of the ignitability of bedding items Part 1: Ignition source: smouldering cigarette (ISO 12952-1:2010)
- EN ISO 12952-2 Textiles Assessment of the ignitability of bedding items Part 2: Ignition source: match-flame equivalent (ISO 12952-2:2010)
- EN 1725 Domestic furniture Beds and mattresses Safety requirements and test methods
- EN 14976 Textiles Mattress ticking Specifications and test methods
- EN 14533 Textiles and textile products Burning behaviour of bedding items Classification scheme

MATTRESSES FOR COTS

EN 597 concern flammability of mattresses and upholstered bed bases (ignition sources: smouldering cigarette and match equivalent).

EN 716 on children's cots and folding cots contains labelling requirements for the mattress of the cot. According to Commission Decision 2010/376/EU, also **foldable mattresses** shall be included in the scope of this work.

In **France**, the "norme expérimentale **XP D 64-011** mai 2004 - Meubles à usage domestique et de collectivité-Matelas pour lits d'enfants-Exigences et méthodes d'essai" lays down performance and labelling requirements.

In the **United Kingdom**, standard **BS 1877-10** "Domestic bedding- Specification for mattresses and bumpers for children's cots, perambulators and similar domestic articles" lays down requirements both for **cot mattresses and cot bumpers**. Nursery furniture in the UK has also to conform to the Furniture and Furnishing Fire Safety Regulations and relevant standards supported by this legislation (e.g. in the case of mattresses BS 7177).

¹¹ "*Risk and preventive factors for cot death in The Netherlands, a low-incidence country*", European Journal of Paediatrics, July 1998.

¹² http://www.cpsc.gov/cpscpub/prerel/prhtml10/10056.html

¹³ <u>http://www.cpsc.gov/cpscpub/prerel/prhtml10/10324.html</u>

In Australia, standard AS/NZS 3744 parts 1 to 3 contain specifications on the ignitability of mattresses and upholstered furniture.

In the US, standard ASTM E 1590-07 contains test methods for determining the burning behaviour of mattresses used in public occupancies. ASTM F 406-08a contains also requirements for mattresses for non-full size cribs and play yards.

COT BUMPERS

In **France**, there is a *"norme expérimentale* **NF XP G 30-106 février 2009 -** *Exigences de sécurité relatives aux articles de couchage en textile pour jeunes enfants"* dealing with bedding articles for children, including cot bumpers.

In the United Kingdom, standard BS 1877-10 (see above section on mattresses).

In the US, standard ASTM F 1917-08 sets safety requirements for infant beddings and related products, including provisions for ties, ribbons, strings for cot bumpers.

SUSPENDED BABY BEDS

These products include any suspended flat sleeping surface for babies or young children (such as, for example, a crib, a cot or a hammock), regardless of the anchorage system (such as ropes, cords, straps etc...).

Currently, there are no specific European standard or legislation applicable to these products. The listing below contains references to standards and regulations applying to infant beds.

EN 716 and EN 1130 set safety requirements for cribs and cradles (infant beds with an internal length up to 900 mm) and cots (internal length from 900mm up to 1400mm).

In the US, part 1500 of code of Federal Regulations¹⁴ is dedicated to full size and non full size cribs. Standards ASTM F 406-07, ASTM 966-00, ASTM F 1169-07 contain safety specifications for full and non full size cribs.

In Australia, the Fair Trading Amendment (Children Portable Folding Cots) Regulation was adopted in 2009¹⁵ and makes mandatory certain provisions of the Australian/New Zealand Standard AS/NZS 2195:1999- Folding cots - safety requirements as the product safety standard for children's portable folding cots. These provisions complement the Consumer Product Safety Standard for Children's Portable Folding Cots introduced under the Trade Practices Act 1974 on 19 February 2008. Other relevant standards are AS/NZS 2172:2003 "Cots for household-Safety requirements" and AS/NZS 4395:1996 "Infant's rocking cradles- Safety requirements".

¹⁴ <u>http://www.cpsc.gov/info/cribs/regulations.html</u>

¹⁵ <u>http://www.legislation.nsw.gov.au/sessionalview/sessional/SRTITLE/Fair%20Trading%20Act%201987%20-%20Fair%20Trading%20Amendment%20(Children's%20Portable%20Folding%20Cots)%20Regulation%202009%2 0(2009-92)%20LW%2013%20March%202009.pdf</u>

Canada announced new **Regulations** on Cribs, Cradles and Bassinets on 1^{st} December 2010^{16} .

CHILDREN'S DUVETS

EN 12935:2001 "Feather and down- Hygiene and cleanliness requirements".

In **France**, the "fascicule de documentation **FD D90-217** mai 2007- Couettes ou articles assimilés pour lit d'enfants - Recommandations pour la conception et l'utilisation" adresses performance and labelling requirements for this product.

In the **UK**, standard **BS 4578:1970** contains specification for test methods for hardness and air permeability for infants' pillows.

CHILDREN'S SLEEP BAGS

This product shall not be confused with sleep suits (or blanket sleepers¹⁷ or, in general, with any other night garment featuring sleeves and legs, and sometimes bootees to enclose the wearer's feet).

EN 13537 contains requirements for sleeping bags for adults.

In the UK, standard **BS 8510:2009** "Child use and care articles-Safety of children's sleep bags- Safety requirements and test methods".

In **France**, the "norme expérimentale **NF XP G 30-106 février 2009 -** *Exigences de sécurité relatives aux articles de couchage en textile pour jeunes enfants*" also deals with sleep bags for children.

ADDITIONAL REFERENCES

Attention should also be paid to ongoing work in TC 248 (WG 20) on the safety of children clothing, with particular reference to mechanical risks posed by buttons, press fasteners, sequins and other small parts.

EN 71-1 shall be considered when toys or other decorative items presenting a play value are present.

Finally, EN 14682:2007 shall also be used as a reference when considering the safety of cords and drawstrings.

4. **DESCRIPTION OF THE MANDATED WORK**

The essential requirements are laid down in the Commission Decision on the safety requirements to be met by European standards for certain products in the sleep

¹⁶ http://gazette.gc.ca/rp-pr/p2/2010/2010-12-08/html/sor-dors261-eng.html

¹⁷ <u>http://en.wikipedia.org/wiki/Blanket_sleeper</u>

environment of children pursuant to Directive 2001/95/EC of the European Parliament and of the Council (2010/376/EU) of 2 July 2010¹⁸ which is part of the present mandate, address the risks inherent to the five products identified, make warnings and instructions to adult users clearer and more visible and aim at minimising the risks arsing to poor hygiene.

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

- the child's stages of development (age, height, weight, ability, etc.). The five products can be used by children in the age range from birth to 3 and ½ years (for some of them), therefore the foreseeable users are very vulnerable children.
- the intended or foreseeable use of the product, bearing in mind a child's behaviour. Such 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 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 conditions of use primarily in a domestic environment, consideration should also be given to a foreseeable use in some professional or public environments (e.g. hotels, child-care centres, hospitals, nurseries etc...), at least for some of these products.

In carrying out the mandated work, CEN, CENELEC and ETSI are requested to consider existing legislation, guidelines, code of practices and standard(s) in this area, ongoing standardisation works at international, European and national level, as well as general guidelines on child safety, such as, for example, CEN guide 12 ("Child safety- Guidance for its inclusion in standards") and CEN TR 13387.

5. 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, CENELEC and ETSI (DE, EN, FR) shall be available, as well as the correct titles in the other official European Union languages.

CEN, CENELEC and ETSI 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, CENELEC and ETSI will submit progress reports to the Commission every six months.

CEN, CENELEC and ETSI shall develop the draft standard in close consultation with the European Commission.

In carrying out the mandate, appropriate co-ordination and liaison with relevant regulatory or standardisation organisations (e.g. CPSC, ISO etc) shall be established at international, national and European level to ensure coherence.

¹⁸ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:170:0039:0048:EN:PDF

Acceptance by CEN, CENELEC and ETSI of this mandate starts the standstill period referred to in Article 7 of the Directive 98/34/EEC of 22 June 1998 (OJ L 204, 21 July 1998, p. 37).

6. 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 (European Trade Union Institute) should be invited to take part in the mandated work.

CEN, CENELEC and ETSI are also requested to consult with the European Commission Directorate-General Joint Research Centre in order to explore if the Commission's research institutes dispose of specific competence to support the standardisation work.