Investigating Safe Sleeping Conditions for Children

December 2018



S2E4



Investigating Safe Sleeping Conditions for children – Final Report for the ANEC Child Safety Working Group – December 2018

The purpose of this report is to ensure that young children can sleep in a safe condition and that this is reflected within the relevant current European Standards and/or incorporated into new standards. Ultimately, to provide ANEC with proposals for the improvement and/or development of applicable standards and to review current best practice for sleeping.

Commissioned by:

ANEC, the European consumer voice in standardisation, AISBL, Avenue de Tervueren 32, box 27, B-1040 Brussels, Belgium

Prepared by:

S2E4

Margaret Powell House, 401 Midsummer Boulevard, Milton Keynes, MK9 3BN, UK
E enquiries@s2e4.com
M (+44) 07788 715733
W s2e4.com

DISCLAIMER:

The views and/or guidance expressed in this report are not necessarily those of ANEC. The views relating to Task 1 are not necessarily the views of the authors, as this section was a summary of another contract.

Contents

Contents	3
0.0 EXECUTIVE SUMMARY	1
0.1 Introduction	
sleep products	2
0.3 Task 2 - Appraisal of product-related safe sleep evidence	
0.4 Task 3 - Appraisal of the product standards	3
0.5 Task 4 - Detailed analysis of products without standards and recommendations for actions	5
0.6 Conclusions and recommendations	7
1.0 SUMMARY OF CONTRACT TASK 1 REPORT: RESEARCH INTO REPORTED ACCIDENTS SINCE 2007	
4.4.Courses of information	0
1.1 Sources of information	
1.1.1 Fatalities and other cases described in public media	
1.1.3 USA fatality and injury databases	
1.1.4 Consumer safety complaints in the UK	
1.1.5 Products recalled or withdrawn in Europe	
1.1.6 Academic review articles and reports	.10
1.2 Summary observations relevant to standards in the scope of the CRL study	. 10
baskets, baby boxes	
1.2.2 Cots	
1.2.3 Cot-beds and child beds	
1.2.5 Mattresses, bedding, bumpers, baby nests, sleep positioners	
1.2.6 Adult beds and other sleeping environments	
1.3 Comments on the contribution of Task 1 to Tasks 3 and 4	
2.0 TASK 2 - APPRAISAL OF PRODUCT-RELATED SAFE SLEEP EVIDENCE	
2.1 Introduction	
2.2 Deaths in infancy	
2.3 Definitions	
2.4 Sources of information	
2.5 Guidance on the prevention of SIDS and other sleep-related infant deaths	
2.6 Sleep product guidance	.20
2.6.1 Mattresses	
2.6.2 Nests (baby nests)	
2.6.3 Cot bumpers (bumper pads)	
2.6.5 Pods	

2.6.6 Hammocks	26
2.6.7 Bunk/high and cabin beds	26
2.6.8 Baby boxes	27
2.7 References	27
3.0 TASK 3 - APPRAISAL OF THE PRODUCT STANDARDS	29
4.0 TASK 4 - DETAILED ANALYSIS OF PRODUCTS WITHOUT STANDARDS AND	
RECOMMENDATIONS FOR ACTIONS	35
4.1 Framework for analysis	35
4.2 Analysis of products without standards	35
4.3 Conclusions and recommendations from the product analyses	36
4.3.1 Baby nests	36
4.3.2 Cot beds	37
4.3.3 Cots and travel cots supplied with accessories such as changing tables and	
bassinets	37
4.3.4 Baby boxes	38
4.3.5 Bedside sleepers	39
4.3.6 Pop up travel cots and UV tents	39
4.3.7 Sleep positioners	40
5.0 CONCLUSIONS AND RECOMMENDATIONS	41
5.1 Deciding on what products to standardise	41
5.2 The practicality of moving the recommendations forward	42
ANNEX 1 RECOMMENDATIONS FROM APPRAISAL OF STANDARDS	
ANNEX 2 RESULTS OF PRODUCT ANALYSES FROM TASK 4	48

0.0 EXECUTIVE SUMMARY

0.1 Introduction

The aim of the project was to examine whether specific standards for the sleep products listed below, mainly for children aged under one year, facilitated safe sleeping practices. The project involved reviewing

- death and injury data (through a separate contract);
- the best evidence on safe sleeping practices, primarily relating to products as opposed to parental behaviours;
- relevant product standards for content and consistency.

It also contributes to the requirements of <u>Commission Mandate M/497 EN</u>
'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' and <u>Commission Decision</u> 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'. In particular, the Commission Decision requires that "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."

This report outlines the work undertaken, presents the results of the analysis of the standards mentioned above focussing on whether or not they facilitate safe sleeping practices, contains a structured analysis of the potential hazards associated with other sleep-related products and, based on this analysis, makes recommendations on whether or not ANEC should promote that standards should be developed for these products.

The work comprised four tasks, one undertaken under a separate contract by Consumer Risk Ltd (Task 1), summarised in section 1 of this report. The other three tasks were carried out by S2E4 Ltd:

- Task 2 Appraisal of safe sleep evidence (section 2)
- Task 3 Appraisal of the product standards (section 3)
- Task 4 Detailed analysis of products without standards and recommendations for actions (section 4)

0.2 Task 1 - Results of the collection and analysis of deaths and injuries associated with sleep products

This work was undertaken by Consumer Risk Ltd (under a separate contract). It involved searching multiple sources covering a ten-year period – death and injury databases in Europe and the USA, press reports, consumer safety complaints in the UK, information on products recalled or withdrawn from the market in Europe, and academic papers. The outcome of the research is briefly summarised in section 1.

The research produced some valuable information but also demonstrated the problems of accessing useful data and the limited availability of sufficiently detailed information to contribute significantly to the revision of existing and the drafting of new standards.

0.3 Task 2 - Appraisal of product-related safe sleep evidence

Multiple sources of information were used to identify what is regarded as best practice to promote the safety of children under one year whilst using those products identified for this study (other than bunk and high beds) sleep safely, along with the characteristics of products needed to support this situation.

The sleep product-related guidance from the different sources was largely consistent, although it should be recognised that some products are more common in some parts of the world than others. The most comprehensive primary source of guidance are technical and policy documents from the American Academy of Pediatrics (AAP).

Overall, the product-related safe sleeping guidance highlighted that:

- mattresses should be firm, flat (i.e. horizontal), fit closely into the cot, crib, etc and be waterproof or have a waterproof cover;
- products such as baby nests and padded cot bumpers that can place soft padding close to the baby's face should be avoided as they can present suffocation and overheating hazards;
- sleep positioners and wedges increase risks to the baby;
- a study from New Zealand reports that there is some evidence that the
 Wahakura (a woven flax portable sleeping basket used in some communities in

New Zealand) can be promoted as a safe alternative to infant-adult bedsharing;

- an extension of the New Zealand study suggests that the Pēpi-Pod®, a
 recently-developed rigid-sided plastic equivalent of the Wahakura, may be a
 safer and more convenient alternative to the "baby box" (of cardboard
 construction);
- products such as hammocks that do not meet that above mattress criteria should be avoided;
- there is variation on the age guidance for the non-use of the upper bunk of bunk and high beds ranging from under six years to under nine years.
 However, there is a lack of clarity on whether the age guidance relates to use of the upper bed for sleep or play;
- there is some controversy over the contribution that "baby boxes" (made of cardboard) have made to the reduction in Sudden Infant Death Syndrome (SIDS).

While relatively little of this guidance related to potential product modification through standards, it should be remembered that standards can provide an opportunity through the consumer information to promote safe sleep practices.

0.4 Task 3 - Appraisal of the product standards

As required in the contract, the sleep products and standards studied under this Task were:

- EN 716-1 and EN 716-2:2017 Furniture Cots and folding cots for domestic use
- prEN 1466 *Child use and care articles. Carry cots and stands. Safety requirements and test methods* (currently under revision)
- prEN 1130 *Furniture. Cribs and cradles for domestic use* (currently under revision)
- EN 747:2012+A1:2015 Furniture Bunk beds and high beds
- EN 16890:2017 Children's furniture Mattresses for cots and cribs Safety requirements and test methods
- EN 16780:2018 Textile child care articles Safety requirements and test methods for children's cot bumpers

In parallel with the appraisal of the best safe sleeping practice, these standards were subjected to an analysis using a hazard-based approach and then to a further expert check.

As a starting point, a comprehensive template listing relevant hazards was developed (using CEN TR 13387 *Child care articles - General safety guidelines* as the basis). For each hazard the requirements and associated test methods in each standard were identified. The list of the hazards considered, together with other content of the standards, is presented in Table 3.1.

A short summary of the appraisal of how well each standard fulfilled the safe sleeping criteria is presented in Table 3.2.

The products examined were analysed in three groups:

- infant sleep furniture (cots and folding cots for domestic use, carry cots, and cribs for domestic use)
- bunk beds and high beds
- soft products used in the sleep environment (mattresses for cots and cribs, and children's cot bumpers).

The segregation was used as some hazards are more relevant to one group of products than others. The groupings do not represent the division of the products between the CEN technical committees:

- products in the first group (children's furniture) are handled by CEN/TC 207/WG 2 (Children's and Nursery Furniture) and CEN/TC 252/WG 2 (Sleeping, Relaxation and Lying Down),
- the bunk beds and high beds standard is the responsibility of CEN/TC 207/WG
 and
- the third group (soft products) is shared between CEN/TC 207/WG 2 and CEN/TC 248/WG 34 (Risks in the Sleeping Environment - a joint working group between CEN/TC 248 and CEN/TC 252).

Bunk beds and high beds were separated from other items of children's furniture as the prevention of sudden unexpected deaths in infancy (widely referred to as SUDI), primarily sudden infant death syndrome (SIDS), is not relevant to these products as they are intended for use by children aged outside the SIDS age risk group and who exhibit far more complex gross motor skills than children under

one year. However, they present their own injury risks, mainly falls and entrapments. The appraisal of the standard for these products related more strongly to the injuries identified in Task 1 (Results of the collection and analysis of deaths and injuries associated with sleep products - see section 1).

A series of questions drawn from Task 2 (Appraisal of product-related safe sleep evidence - see section 2) was "asked" of each standard to evaluate how and to what extent it facilitates the best safe sleeping practices identified, bearing in mind that this primarily looked at SUDI deaths. Using the final report from Task 1, a similar evaluation was undertaken to determine how and to what extent each standard addresses the deaths and injuries that the Task identified.

As Table 3.2 Summary of how well standards fulfil safe sleep criteria shows, the standards appear to have little regard for minimising the causes of SUDI deaths, whether injury-related or SIDS, that might be amenable to reduction through product modification.

Analysis of each spreadsheet across different standards allowed comparisons of how similar hazards are addressed in terms of the requirements and test methods between these standards, thus analysing gaps and inconsistencies that might exist.

The appraisal of the standards went beyond what was required to establish how well they fulfilled product-related safe sleeping criteria as several of the hazards considered had little relevance to such criteria. It was informative as it illustrated inconsistencies and gaps between standards that might be helpful in identifying issues and presenting solutions that ANEC might consider putting forward to standards committees.

0.5 Task 4 - Detailed analysis of products without standards and recommendations for actions

To carry out this Task in a consistent and structured way across the products, a framework was developed comprising three sections:

- a brief analysis of the functions of the product, the characteristics of its "users" (children and adults), and its popularity;
- drawing on the hazards listed in CEN TR 13387 *Child care articles General safety guidelines*, an extensive table that allowed the hazards associated with

each product to be identified, their significance assessed, and a judgement on whether or not the hazard should be addressed in a standard;

• a summary of the issues relating to the development of a new standard.

This framework was used to develop recommendations on whether or not new standardisation work should be promoted for some or all of the following products as required in the project contract:

- Baby nests
- Sleep positioners
- Baby boxes
- Bedside sleepers
- Cot beds
- Pop up travel cots¹ and UV tents
- Cots and travel cots supplied in combination with bassinets/changing tops/etc.

This is not a comprehensive list of sleep products that are on the market. Other products, such as suspended sleep products, including hammocks, and pods, should be considered for standardisation in the future. It should be noted that suspended baby beds are included in the European Commission Decision but it is not clear whether hammocks would be covered by the definition of such products used in the Decision.

The structured analysis of potential hazards associated with these products and the recommendations of whether or not ANEC should promote the development of standards for them drew on the safe sleeping guidance, knowledge of how hazards are addressed in existing standards and the analysis of deaths and injuries carried out by a separate contractor under Task 1. The detailed findings of this Task are presented in section 1 below.

In summary, the analysis concluded that standards should be developed for

- bed nests, as they present soft, padded areas close to the baby's face;
- cot beds, especially covering the transition from cot to bed and their bed function;

¹ The term "travel cot" is used in this report; in EN 716-1 and EN 716-2:2017 Furniture - Cots and folding cots for domestic use they are referred to as "folding cots"

 cots and travel cots supplied with accessories such as changing tables and bassinets.

The reasons why ANEC should not promote the development of standards for the other products are as follows:

- baby boxes the design and function of these is largely similar to carry cots and should be covered by EN 1466:2014 Child use and care articles. Carry cots and stands. Safety requirements and test methods;
- bedside sleepers and clip-on bassinets the current published standard EN 1130-1 and EN 1130-2:1996 Furniture - Cribs and cradles for domestic use is currently under revision as prEN 1130. The revision aims to address issues associated with bedside sleepers;
- pop up travel cots and UV tents these would be very difficult products to standardise as they contain multiple hazards that, if addressed, would effectively ban the products;
- sleep positioners none of the organisations surveyed as part of Task 2
 recommends using these products because babies have slipped out of them
 and suffocated and there is no evidence that they enhance safety.

0.6 Conclusions and recommendations

Taking forward the recommendations of this project needs further consideration. While it has identified issues that, in theory, need to be addressed by the relevant CEN technical committees' working groups (WGs), because of the heavy work programmes of the WGs, it might not be possible for them to progress matters. An alternative approach in the development of new standards in such circumstances might be commissioning organisations such as ANEC, which has the expertise among its members capable of developing the first draft of standards, to prepare first drafts. This would require the provision of resources by the European Commission and/or CEN.

The project illustrated the problems of how decisions on what products should be standardised should be taken. Ideally, representative, up to date and detailed epidemiological data should form the basis of such decision but in Europe this data is not available. Expert opinion, market penetration, experience of similar products, etc have to be used instead.

The project provided a valuable resource for ANEC members and others who sit on CEN working groups. It provides an illustration of what could be undertaken to ensure that the requirements and test methods in standards in other product areas are consistent and comprehensive. It can also act as the basis for comments on the relevant standards when they are due for revision.

Other sleep-related products – notably suspended sleep products, including hammocks, and pods – that were outside the scope of this project should be considered for standardisation. It should be noted that suspended baby beds are included in the European Commission Decision, but it is not clear whether hammocks would be covered by the definition of such products used in the Decision.

The product analysis methodology (section 4) could be used when new standardisation requests (mandates) are being considered as it used a systematic assessment of hazards, risks and summarises the issues relating to the development of a new standard.

1.0 SUMMARY OF CONTRACT TASK 1 REPORT: RESEARCH INTO REPORTED ACCIDENTS SINCE 2007

This section presents a summary of Task 1, undertaken by Consumer Risk Ltd (CRL). This summary has been drafted by the S2E4 team and might not reflect the views of Consumer Risk Ltd. Further, the priorities for action identified by CRL might not coincide with those of the S2E4 team.

The appendices to the Task 1 report need to be consulted for details of deaths and injuries identified in the CRL study (these are available from ANEC).

The information gathered during this Task was potentially of relevance to other aspects of the overall project by

- contributing to decisions on whether existing sleep product standards address all key injury issues and whether they are addressed appropriately (Task 3);
- for products without standards, helping to identify what hazards they present and the significance of the associated risks (Task 4);
- supporting decisions on which products for which standards do not currently exist should be prioritised.

1.1 Sources of information

The CRL study looked at information from the following six sources:

1.1.1 Fatalities and other cases described in public media

News media databases plus officially published reports and ad-hoc sources were searched for fatal accidents since 2000 involving any of the child sleeping products of interest.

1.1.2 Hospital-reported injuries in Europe

Case listings of individual accidents recorded in the hospitals participating in the European Injury Database (IDB) for cases since 2008 that involved any of the product codes of interest for which a narrative description of the incident was requested. In addition, a separate request to the Netherlands injury surveillance system (LIS) for both hospital-recorded cases since 2008 and fatalities recorded at any time involving the products of interest was submitted.

1.1.3 USA fatality and injury databases

Because of the uncertain availability of details of official sources in Europe, case descriptions from the hospital injury database of the US CPSC NEISS (United States Consumer Product Safety Commission National Electronic Injury Surveillance System) and the CPSC's separate database of fatal accidents involving consumer products reported to it by coroners and medical examiners across the USA were obtained and analysed. The numbers of years of data of injury cases varied between one and ten years for different products. For fatalities, ten years of data was analysed. However, this yielded an unnecessarily large sample of deaths of children under 12 months old in cribs/cots and ordinary beds where the death is unlikely to have been anything to do with the design of a product.

1.1.4 Consumer safety complaints in the UK

Consumer safety complaints relating to cots and other child care equipment were sought from the body that manages the central UK database covering a six year period. While many of the cases described products failing to conform to current standards, they did include serious incidents and consumer concerns not represented elsewhere.

1.1.5 Products recalled or withdrawn in Europe

Notifications from the European Commission's rapid alert system (RAPEX) for childcare products from 2009 to date were searched for sleep products. These were checked for reports of injuries or incidents and any risks that might not be covered by the current standards.

1.1.6 Academic review articles and reports

A product-categorised bibliography of reviews and cases since 2000 was created.

1.2 Summary observations relevant to standards in the scope of the CRL study

This section is an edited version of section 3 of the Consumer Risk Ltd report. It is important to refer to the original report for cross-references to the extensive appendices that include detailed tables, case listings, etc. (available from ANEC).

1.2.1 Cribs (including cradles and bedside sleepers) carry cots, bassinets, Moses baskets, baby boxes

One problem reported among the UK consumer complaints with stand-alone small sleeping products for babies (i.e. smaller than a standard cot) concerned the strength and stability of their legs or separate stands.

The number of unexplained falls out of cribs² for children under six months was unexpected: the barrier heights should have been more than adequate for a child who could do no more than roll. One possible explanation is suggested by the reconstruction of a fatality where the baby's sleeping surface appeared to have been raised almost to the level of the top of the barrier.

Moses baskets appear to be more prone to infestations than other types of construction.

Hammock or swinging designs had additional (or different) risks not covered by the requirements in the current standard.

Bedside sleepers presented different problems. Principally these were a) how they attach to a bed to prevent them moving apart or there being a gap between the two mattresses and b) the potential for circumstances to arise when the barrier between the bed and crib is lower than the full barrier height – or forms a 'step'.

The CRL study found hardly any incidents specifically involving carry cots (other than Moses baskets which are currently covered by the same European standard). This may have been because the authors did not include product categories for child transport – or simply that carry cots are rarely sold now other than as pram bodies (removable baby car seats have largely taken over this function).

No incidents involving baby boxes were found. Their use outside Finland may have been too recent a development to appear in the available data.

11

² Throughout this report, European nomenclature is used. (A crib in Europe is a bassinet in the USA; a cot in Europe is a crib in the USA, etc)

1.2.2 Cots

The bulk of accidents were likely to have been found to cots not complying with current European standards, parents putting unnecessary items in the cot or sudden unexplained infant deaths.

Drop sides are an inherently weaker and more complicated structure (and resulted in recalls of cots with an inadequate design of drop side). However, there was also a long experience in their manufacture and use. Whether the evidence of some defective products justified a complete ban (as adopted in the US) remains an open question until there is a scientific review of the experience of a ban in the US. Simple but fatal defects in designs led to trapping in drop sides.

The greater use of wood composites in cots nowadays may justify additional types of tests unnecessary for solid wood components. For example, there were consumer complaints of children being able to bite off pieces of wood while teething and being able to break struts. A bending test based on a child's arm/shoulder being pressed into the gap and trying to lever two struts apart may be a more challenging scenario than impacts or pulling on a single slat.

In the US, children putting their arms or legs between struts also seemed to lead to limb trappings and/or fractures which are absent or rare in mesh-sided travel cots. (These injuries may also sometimes be suspected as non-accidental by hospital staff as they seem to be comparatively rare outside the US.)

Travel cots (typically with mesh sides) seemed generally to be involved in fewer injuries, even allowing for they are not owned as widely (or used as often) as nonfolding designs (i.e. traditional wood with bars or slats). The design of a "travel cot" can be very radical introducing risks outside the concepts in the standard – a death in a portable sleep tent was noted.

Netting or other textile covering over the top of a cot has the potential to leave a gap a child can push its head through and then trap its neck. There have been few such incidents, but the standard should warn against this unless a cot and accessory have been tested together to ensure no gaps are created.

Some manufacturers offer teething strips that cover the top rails either included or as an optional extra. Unless well designed, these can pose a risk of a child getting their tooth or lip pinched underneath the plastic strip.

1.2.3 Cot-beds and child beds

Cot-beds have been growing as a proportion of the market as they are sold as offering a use for a longer time period. They appear to have (only) the same issues as cots while in the cot mode, but hardly any accidents when re-configured as beds (except those common to adult beds: toddlers and older children jumping off them, or children who are too young being placed on them and rolling off or getting wedged). However, designing a cot to be re-configurable can introduce unexpected structural defects in particular aspects of use. It also introduces more risk of users losing fasteners after disassembly or in storage and greater risk of the assembly instructions not being available every time it is re-assembled.

Similarly, few accidents mention child beds, but it is clear (from US bed injury and death data) that children moving to any first bed (typically at 18-24 months) are still at risk of some of the neck entrapment hazards against which cots provide protection. A child bed should not have dangerous gaps (relevant to that age) in its own construction (as required for a bunk bed) or when against a wall and should carry warnings restricting the gap between the bed and the wall. Headboards should not have features that can catch clothing or loops thus presenting a strangulation risk.

Bedguards are likely to be used temporarily with any 'first' bed (child or full-size) introducing additional gaps and need for attachment.

1.2.4 Bunk and high beds, including cabin beds

There will always be minor accidents from falls and jumps but the serious injuries are associated with children who are too young (either for top bunk or bottom) or with suspension by the neck either in a gap (in the bed or between bed and wall) or hanging by a belt or clothing caught on a post or hook.

Injuries in the US from ceiling fans or light fittings that get hot were identified that could possibly be addressed through appropriate warnings.

Cabin beds, a specific type of high bed, should not fall outside the scope of standards. This is an area where there have been products designed more like toys that a child can enter (e.g. designed to look like a bus) neglecting the bunk beds and high beds standard. Also, injuries associated with one-off bespoke designs incorporating sleeping space for children under 12 months that ignored all standards were identified. (Some types of cabin beds are also referred to as "fantasy beds".)

The bunk beds and high beds standard needs to clarify that sleeping space under top bunk (whether or not there is a lower bunk) is not suitable as a sleeping space for children of an age suited to a cot.

Gaps in and around ladders should be addressed.

1.2.5 Mattresses, bedding, bumpers, baby nests, sleep positioners

Cot bumpers were involved in 16 deaths in the US over ten years and one in the UK.

The main problems with cot mattresses were sizing to match the cot. Inflatable and additional mattresses were identified as a hazard.

The CRL study found very few reports of incidents involving sleep positioners.

The CRL study found no incidents involving products described as "baby nests" although there were two complaints about seeing them advertised on web sites.

Bedding was usually mentioned only when 'heavy' or the child was lying face down on it. There were a few mentions of deep-pile surfaces.

1.2.6 Adult beds and other sleeping environments

In the USA, the rate of accidental deaths of children under 12 months in full or child size beds was over 160 per year, the vast majority of which were described as having been co-sleeping. This compared to 43 per year for all accidental deaths in baby sleeping products of any type. While it is likely that many of both could equally have been categorised as SIDS (a medical cause) rather than asphyxia (an accidental cause) co-sleeping does seem to be an extra risk factor.

Note that there have been deaths of babies co-sleeping with older siblings (in a bed or cot and not always the parents' intention) and of twins sleeping together in one cot.

1.3 Comments on the contribution of Task 1 to Tasks 3 and 4

While the CRL study made contributions to the overall project, it had a number of weaknesses as a result of the nature of the information in the various data sources. This is not a criticism of the CRL study but is a consequence of the inadequacy and/or practicality of collecting data relevant to consumer product safety and the standardisation process. Its most significant failing was unsurprisingly that there was little, if any, information about issues that could inform the need for and detail needed to develop requirements and test methods in standards, such as

- the way that a product was assembled correct assembly/disassembly/reassembly (e.g. following the manufacturer's instructions, using all of the components supplied and not taking shortcuts)
- the use of the product was it used in accordance with the manufacturer's instructions, were additional components used (e.g. a second mattress in a crib that raises the baby to a height that could allow in it climb out), the placement of the product (e.g. next to a wall)?
- maintenance of the product was this undertaken and, if so, was it in accordance with the manufacturer's instructions?
- was the product new or second-hand if second-hand, was it damaged, did it have all the components, did it have instructions, had it been recalled?
- the age of the product had it been changed by the manufacturer in the light of experience?
- conformity with the current European standard did the product conform to the current standard, which might have addressed an identified shortcoming, or an older edition? Standards in the USA differ from those in Europe to issues that might relate to US products might not be seen in Europe.
- did the product reflect those available on the European market?
- the numbers of deaths and injuries relative to the market penetration of the product. This is always a challenging issue in the standardisation process but as deaths in particular often attract public interest it is one that needs to be considered.

2.0 TASK 2 - APPRAISAL OF PRODUCT-RELATED SAFE SLEEP EVIDENCE

2.1 Introduction

This section draws together information from reputable sources on safe and unsafe sleeping practices, mainly for babies under one year. This allowed the adequacy or otherwise of current sleep products to be assessed and improvements to be recommended as part of Task 3. It also gave guidance on the key issues to be considered if new work items (NWIs) for sleep products not currently covered by standards are to be developed under Task 4, and indeed whether such standards should be developed for products the use of which are not recommended as they do not contribute to or actually compromise safe sleeping.

2.2 Deaths in infancy

Every year, many babies die during sleep although the numbers have been declining worldwide over the past 25 years. Under the WHO International Classification of Diseases, infant deaths are categorised according to whether they were expected or unexpected, and if unexpected, whether or not they can be explained. The categorisation SUDI (Sudden Unexpected Death in Infancy – in the US known as SUID) covers all unexpected infant deaths, including both explained and unexplained. Explained SUDI may include congenital issues, sudden onset illnesses, accidents and infanticides. If a sudden infant death is unexplained it is often classified as SIDS (Sudden Infant Death Syndrome). [1]

SUDI deaths, whether injury-related or SIDS, can be related to a number of factors, a few of which might be amenable to reduction through the modification of sleep products. Deaths relating to the behaviours of the parents such as baby and parent sharing a sleep surface, maternal smoking in pregnancy, or putting the baby to sleep on its front or side rather than on its back, or environmental issues such as room temperature cannot be addressed through standards, except possibly through the provision of appropriate advice as part of the requirements for consumer information in the standards.

2.3 Definitions

For the purposes of this report, the following definitions taken from those adopted by Red Nose were used: [2] Sharing a sleep surface includes bed-sharing and co-sleeping practices.

<u>Bed-sharing</u> - bringing the baby on to a sleep surface where co-sleeping is possible, whether intended or not.

<u>Co-sleeping</u> - a mother and/or her partner (or any other person) being asleep on the same sleep surface as the baby.

2.4 Sources of information

Review of the guidance on safe sleeping produced by many organisations revealed consistent advice relating to sleep products, although there was some variation in the emphasis placed on the importance of some behavioural factors, most notably sharing the adult sleep surface. Almost all of the guidance related to preventing deaths as opposed to injuries.

The organisations whose advice was examined in relation to sleep products included the following:

- American Academy of Pediatrics
 (https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Preventing-SIDS.aspx) (USA)
- Centers for Disease Control and Prevention
 (https://www.cdc.gov/sids/Parents-Caregivers.htm) (USA)
- Change for our Children
 (http://www.changeforourchildren.nz/pepi pod programme/home) –
 information on Pepi-Pod® sleep space programme (New Zealand)
- Consumer Policy Safety Commission
 (https://onsafety.cpsc.gov/blog/2012/09/18/safe-sleep-bedding-pillows-safety-and-more/) (USA)
- Government of Canada through the joint statement of Canadian Paediatric Society, the Canadian Foundation for the Study of Infant Deaths, the Canadian Institute of Child Health, Health Canada, and the Public Health Agency of Canada (https://www.canada.ca/en/public-health/services/health-promotion/childhood-adolescence/stages-childhood/infancy-birth-two-years/safe-sleep/joint-statement-on-safe-sleep.html) (Canada)
- ISIS Infant Sleep Information Service (https://www.isisonline.org.uk/) (UK)

- Kidshealth (https://www.kidshealth.org.nz/. A joint initiative of Paediatric Society of New Zealand and Starship Foundation) (New Zealand)
- Kind en Gezin ((Child and Family) https://www.kindengezin.be/) (Belgium)
- National Childbirth Trust (https://www.nct.org.uk/parenting/sleeping-safely-cot) (UK)
- National Institute of Child Health and Human Development Safe to Sleep® campaign (https://www1.nichd.nih.gov/sts/Pages/default.aspx) (USA)
- NHS Choices (https://www.nhs.uk/conditions/sudden-infant-death-syndrome-sids/) (UK)
- Plunket (https://www.plunket.org.nz/) (New Zealand)
- Red Nose (<u>https://rednose.com.au/</u>. (Australia)
- The Lullaby Trust (https://www.lullabytrust.org.uk/) (UK)
- UNICEF UK (https://www.unicef.org.uk/babyfriendly-baby-friendly-resources/leaflets-and-posters/co-sleeping-and-sids/) (UK)
- US Food and Drug Administration
 (https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm227575.htm) –
 comments on sleep positioners (USA)
- VeiligheidNL ((SafetyNL) https://www.veiligheid.nl/) (Netherlands)

Other websites were examined but did not contain any specific information relating to sleep products:

- European Paediatric Association
- European Academy of Paediatrics
- European Society for Paediatric Research
- Paediatrics and Child Health Division of the Royal Australian College of Physicians
- Royal College of Paediatrics and Child Health
- World Health Organization

As the focus of this review was the aspects of sleep products that are, could or should be covered by standards, the many non-product issues relating to factors aimed at reducing the risk of SIDS and unintentional injury-related death – not smoking during and after pregnancy, breastfeeding, immunisation, pacifier use, room sharing, etc. – were not covered here.

Children's car seats, reclined cradles and infant swings were excluded as they are not primarily intended for a child to sleep in. The scope was restricted to those products identified above, that are all intended for use in the domestic environment. Nor did it include items of children's bedding (sleeping bags, duvets, blankets, etc) or products intended for use in non-domestic settings such as nurseries, hospitals and hotels. Supplementary devices such as bed guards were also excluded.

It should be stressed that even for products that facilitate safe sleeping, their correct use is essential and appropriate consumer information from product selection through assembly, use, checking and maintenance is very important.

2.5 Guidance on the prevention of SIDS and other sleep-related infant deaths

A comprehensive list of sources of national guidance on SIDS prevention can be found at https://www.ispid.org/infantdeath/id-prevention/id-leaflets/. Guidance from different sources includes similar advice including the following extracted from a UNICEF UK booklet [3]:

- Put your baby down on his or her back to sleep, never on his or her front or side.
- The cot is beside the parents' bed for at least the first six months.
- The mattress is firm and flat soft beds, bean bags and sagging mattresses are not suitable.
- Your baby is not overdressed or covered with too much bedding (no more than you would use yourself).
- The bedding must not be able to cover the baby's head.
- The room is not too hot (16-20°C is ideal).
- The room where your baby sleeps is a smoke-free zone.

Some parents choose to sleep with their baby in bed and some fall asleep with their baby during the night while feeding and comforting whether they intend to or not. The UNICEF UK booklet stresses that it is very important to consider the following points:

- Keep your baby away from the pillows.
- Make sure your baby cannot fall out of bed or become trapped between the mattress and wall.
- Make sure the bedclothes cannot cover your baby's face or head.
- Don't leave your baby alone in the bed, as even very young babies can wriggle into a dangerous position
- It is not safe to bed-share in the early months if your baby was born very small or preterm.
- Do not sleep with your baby when you have been drinking any alcohol or taking drugs that may cause drowsiness (legal or illegal).
- Do not sleep with your baby if you or anyone else is a smoker.
- Do not put yourself in a position where you could doze off with your baby on a sofa or armchair.

Most sleep product standards and hence the products themselves require warnings to be provided in their instructions for use on issues such as avoiding the risks of strangulation due to blind and other cords, keeping objects that could cause suffocation out of the product, and the importance of not placing the product close to heat sources. They might also require warnings on when the product should stop being used relative to the child's developmental capabilities (e.g. stop using the product as soon as the child can sit or kneel or pull itself up).

2.6 Sleep product guidance

The following information was extracted from the sources mentioned above.

2.6.1 Mattresses

Mattress should be firm, flat, have a waterproof cover and closely fit the cot or crib as discussed below. They should not have raised or cushioned areas.

Firm

The Lullaby Trust recommends that the surface of the mattress should be firm enough that when the baby is placed on it, its head does not sink in more than a few millimetres and have no soft or cushioned areas, particularly around baby's head. [4] It adds that soft mattresses are known to increase the risk of SIDS.

They make it harder for babies to lose body heat, which can cause them to become too hot.

The American Academy of Pediatrics (AAP) describes a firm surface as one that maintains its shape and will not indent or conform to the shape of the infant's head when the infant is placed on the surface. [5] It notes that soft mattresses, including those made from memory foam, could create a pocket (or indentation) and increase the chance of rebreathing or suffocation if the infant is placed in or rolls over to the prone position.

Flat

The term "flat" is regularly used in publications presenting this advice. However, the meaning of "flat" can be ambiguous as it can mean "smooth" or "horizontal". Advice from the American Academy of Pediatrics [5] gives an indication that "flat" should be interpreted as meaning "horizontal" in its statement

"If an infant falls asleep in a sitting device, he or she should be removed from the product and moved to a crib or other appropriate flat surface as soon as is safe and practical."

The Lullaby Trust gives similar advice, noting in its product guide that the mattress should be "entirely flat". [4]

Addressing the belief that elevating the baby's head can reduce gastrooesophageal reflux, the AAP notes

"Elevating the head of the infant's crib is ineffective in reducing gastrooesophageal reflux and is not recommended"

suggesting that a horizontal surface is advised. It also notes that elevating the head of the crib may result in the infant sliding to the foot of the crib into a position that may compromise respiration.

A detailed and heavily referenced information statement on sleeping position for babies with gastro-oesophageal reflux from Red Nose also advises against elevating the cot or placing a pillow or wedge (Fig 1)³ under the mattress to raise the baby's head during sleep as it does not reduce reflux and can introduce hazards if the baby slips down the cot. [6]



Fig 1 Example of a wedge

Red Nose also remarks that a safe mattress is one that is placed flat (not tilted or elevated). [7]

Waterproof covers

Red Nose notes that having a waterproof cover helps to keep the mattress clean and dry, as the cover can be wiped down. Red Nose and the AAP note that the cover should be thin, strong and a tight fit. [5, 6]

Gaps

There should be no or minimal gaps between the mattress and the side of product. This guidance relates to the dimensions of the mattress and the cot in which it is used. It is intended to reduce the risk of suffocation if the baby rolls and gets its face stuck between the side of the mattress and the side of the cot. The advice on the maximum permitted size of any gaps around a mattress varies slightly, usually 30 mm in Europe when the mattress is in any position. The AAP suggests [5] that only mattresses designed for the specific product should be used and that there should be no gap; this may reflect the types of cots on the US market and the ASTM standards for cots.

2.6.2 Nests (baby nests)



Fig 2 Typical baby nest

Nests are usually a softer type of sleep surface sometimes used instead of or in addition to a mattress, with areas around the baby that are raised and/or cushioned (Figs 2 and 3 – the term baby nest used within this study relates to those types of items pictured, and not the sleeping pad type products that were historically of the same name and covered by BS 6595:1985, withdrawn in 2001).

³ The figures in this report are for illustrative purpose only and do not imply that the products are safe or unsafe.

The Lullaby Trust advises that, when sleeping, babies should not lie on nor have anything soft around them (Fig 3), particularly their heads, as this can cause them to overheat and increases the risk of SIDS. Soft, squishy materials can also cover baby's mouth and nose if they are pressed against it. [4]



The AAP offer similar advice on soft objects although does not specifically mention nests:

Fig 3 Nest showing incorrect use

"Keep soft objects and loose bedding away from the infant's sleep area to reduce the risk of SIDS, suffocation, entrapment, and strangulation." [5]

2.6.3 Cot bumpers (bumper pads)

Most sources surveyed advise against the use of (and need for) cot bumpers (Fig 7). The AAP notes [5]

"... bumper pads or similar products that attach to cot slats or sides were originally intended to prevent injury or death attributable to head entrapment. Cots manufactured to newer standards have a narrower distance between slats to prevent head entrapment. Because bumper pads have been implicated as a



Fig 4 Example of padded cot bumper

factor contributing to deaths from suffocation, entrapment, and strangulation and because they are not necessary to prevent head entrapment with new safety standards for crib slats, they are not recommended for infants."

The Lullaby Trust states that bumpers pose a serious risk to babies as the baby can become entangled in the ties or material. [4]

The Canadian federal government department Health Canada does not recommend the use of cot bumpers, highlighting issues similar to those put forward by AAP. [11]

2.6.4 Sleep positioners

Some products claim that they can maintain the baby in a side or supine sleeping position (Fig 9). They are often made of two pieces of foam that are attached together by a piece of fabric that the baby sleeps on.

None of the organisations surveyed for this report recommends using these products



Fig 5 Example of a sleep positioner

because babies have slipped out of them and suffocated and there is no evidence that they enhance safety. [4, 6, 11, 12]

2.6.5 Pods

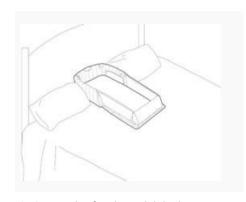


Fig 6 Example of pod on adult bed

Pods are usually similar to nests in that they are products intended to be used in the adult bed (Fig 4). They differ from nests by having rigid or semi-rigid sides. By virtue of their sides, they might reduce the risk of overlaying the baby and hence suffocating it. (They can also be used outside the adult bed.)

Many cultures around the world have used

devices to keep their infants close at all times, including during sleep. In New

Zealand, the Wahakura is a flax woven portable infant sleeping basket, traditionally used in Maori culture (Fig 5).[8]. Recently, the use of the Wahakura together with safe sleep messages has been promoted. A randomised study has shown that there were no significant differences in risk behaviours (head covering, side/prone



Fig 7 Example of a Wahakura

sleeping position, or bed sharing) when infants slept in the Wahakura compared to when infants slept in a crib. [8,9]. There was also no difference in maternal sleep or fatigue, but there was an increase in sustained breastfeeding. The authors of

the New Zealand study conclude that their findings suggest that the Wahakura is safe and can be promoted as an alternative to infant-adult bed-sharing.

A modern version of the Wahakura, developed in New Zealand, is the Pēpi-Pod® (Fig 6).[10] Red Nose describes the Pēpi-Pod® as follows: [8]



Fig 8 Two sizes of the Pepi-pod

"A Pēpi-Pod® sleep space is a protected place for babies to sleep when they are in, or on, an adult bed, on a couch, in a makeshift setting, or away from home. These situations have a higher risk of accidental suffocation for babies. The Pēpi-Pod® may be a safer and more convenient alternative to the "baby box" as it overcomes a number of the concerns raised about the "baby box". The Pēpi-Pod® is made of transparent plastic so is rigid, easily cleaned and lightweight. The baby can be easily observed and the pod has ventilation slits to allow air flow. The mattress is made from polyurethane enviro-foam and contains no chlorofluorocarbons. It is custom-made to fit the pod which should only be used with the supplied mattress and a fitted sheet is provided."

It should be stressed that the Pēpi-Pod® should be regarded as part of a safe sleep programme rather than a product in isolation.

AAP does not make any recommendations on the use of devices promoted to make bed-sharing "safe" because there have been no studies examining the association between these products and SIDS or unintentional injury and death, including suffocation. [5]

2.6.6 Hammocks



Fig 9 Example of a baby hammock

Hammocks are suspended or hanging sleep products (Fig 8), with a soft base.

They are not recommended for infants by a number of agencies. The Lullaby Trust notes that they do not have a firm flat surface for babies to sleep on, thus not meeting general advice on safe sleep surfaces. [4]

The Canadian federal government department Health Canada [11] does not recommend using baby hammocks because

- hammocks can become unstable causing the product to tip forward, causing a baby to become wedged into one corner or side and suffocate.
- hammocks intended to be used by infants and young children can suddenly twist around a child's neck, causing them to strangle.
- babies placed on soft bedding (including hammocks) can become wedged in positions where they cannot breathe.
- babies and young children using hammocks can fall from the high surface,
 causing injuries.

2.6.7 Bunk/high and cabin beds



Fig 10 Example of a bunk bed

Deaths and injuries associated with the upper bunk of bunk beds include falls, strangulation and entrapment. While bunk and cabin beds (Figs 10 and 11) are capable of being used by people of all ages, not just children, their safety features are intended to protect children.

The upper bunk can be an exciting place for children to play as well as sleep. The standards from Australia and New Zealand, Canada, USA and Europe include guidance on the age at which children should not use the upper bunk, varying from under six to under nine years. It is not clear whether the age guidance relates to using the bunk for play or sleep.



Fig 11 Example of a cabin bed

2.6.8 Baby boxes

These are cardboard boxes, sometimes with lids and sometimes laminated, that have been provided traditionally in Finland and recently in other jurisdictions (Fig 12). There is currently controversy on whether or not they contribute to a minimisation in the risk of SIDS. The International Society for the Study and Prevention of Perinatal and Infant Death (ISPID), a not-for-profit organization that is leading the world in discovering evidence-based preventive measures for stillbirth and sudden infant death, published a statement in May 2018

(https://www.ispid.org/infantdeath/id-statements/) commenting that there was no published evidence that the Finnish scheme reduced the SIDS rate. The Society stresses that the baby box should not be confused with the Wahakura or Pēpi-Pod®, both of which are designed to be brought into the parental bed to give infants their own unique sleeping space.



Fig 12 Example of a baby box

In Scotland where a baby box scheme is operating, the government claimed that the product complied with EN 1130:1996 Furniture - Cribs and cradles for domestic use although BSI (British Standards Institution) has pointed out that no standard covered cardboard baby boxes.

2.7 References

- 1. Infant Sleep Information Service. https://www.isisonline.org.uk/hcp/sleep health/understanding sids and sudi/. Accessed 25 May 2018.
- 2. Red Nose. National Scientific Advisory Group (NSAG). Information Statement: Sharing a sleep surface with a baby. Melbourne: Red Nose, 2015.

- 3. UNICEF UK. Caring for your baby at night. A guide for parents. London: UNICEF UK, 2017.
- 4. The Lullaby Trust. Product guide a guide to buying safer sleep essentials. London: The Lullaby Trust
- 5. AAP Task Force On Sudden Infant Death Syndrome. SIDS and Other Sleep-Related Infant Deaths: Updated 2016 Recommendations for a Safe Infant Sleeping Environment. *Pediatrics*. 2016;138(5):e20162938. http://pediatrics.aappublications.org/content/138/5/e20162938..info
- 6. Red Nose National Scientific Advisory Group (NSAG). Information Statement: Reflux: sleeping position for babies with gastro-oesophageal reflux (GOR). Melbourne: Red Nose, 2017.
- 7. https://rednose.com.au/article/what-is-a-safe-mattress. Accessed 28 May 2018.
- 8. Red Nose National Scientific Advisory Group (NSAG). Information Statement: Baby Safe Sleeping Products. Melbourne: Red Nose, 2017.
- 9. Baddock SA, Tipene-Leach D, Williams SM, et al. Wahakura Versus Bassinet for Safe Infant Sleep: A Randomized Trial. *Pediatrics* 2017;139.
- 10. http://www.changeforourchildren.nz/pepi pod programme/home. Accessed 29 May 2019.
- 11. Health Canada. Is Your Child Safe? Sleep Time. Ottawa: Health Canada, 2012. Also at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/consumer-education/your-child-safe/sleep-time.html.
- 12. Moon RY and AAP Task Force On Sudden Infant Death Syndrome. SIDS and Other Sleep-Related Infant Deaths: Evidence Base for 2016 Updated Recommendations for a Safe Infant Sleeping Environment. *Pediatrics*. 2016;138(5): e20162940.

3.0 TASK 3 - APPRAISAL OF THE PRODUCT STANDARDS

As required in the contract, the sleep products and standards studied under this Task were:

- EN 716-1 and EN 716-2:2017 Furniture Cots and folding cots for domestic use
- prEN 1466 *Child use and care articles. Carry cots and stands. Safety requirements and test methods* (currently under revision)
- prEN 1130 Furniture. Cribs and cradles for domestic use (currently under revision)
- EN 747:2012+A1:2015 Furniture Bunk beds and high beds
- EN 16890:2017 Children's furniture Mattresses for cots and cribs Safety requirements and test methods
- EN 16780:2018 Textile child care articles Safety requirements and test methods for children's cot bumpers

In parallel with the appraisal of the best safe sleeping practice, these standards were subjected to an analysis using a hazard-based approach and then to a secondary, independent check.

It contributes to the requirements of Commission Mandate M/497 and associated Commission Decision (see Section 0.1) that relate to the inclusion in standards of requirements for safe sleeping

As a starting point, a comprehensive template listing relevant hazards was developed (using CEN TR 13387 *Child care articles - General safety guidelines* as the basis). For each hazard the requirements and associated test methods in each standard were identified.

The list of the hazards considered, together with other content of the standards, is presented in Table 3.1. The table shows the hazards used during the analysis of the standards and the relevant subheadings for each main hazard, together with other content relating to safety. Some hazards were not considered as they were not relevant to sleep products. These included hazards from noise, drowning, electric shock, radiation, high intensity or concentrated light, and explosion.

(The analysis of the standards is presented in three large spreadsheets describing the requirements for each hazard and the associated test methods. The size of the complete spreadsheets is such that they are not attached to this report but comprise three separate electronic files that are available from ANEC. In the spreadsheets, black text has been used to populate the spreadsheets with data taken from the relevant standards (test requirements and test methods). Red text has been used to identify gaps and those clauses where improvements could be considered by the relevant standards committees.)

A short summary of the appraisal of how well each standard fulfilled the safe sleeping criteria is presented in Table 3.2.

The products examined were analysed in three groups:

- children's furniture (cots and folding cots for domestic use, carry cots, and cribs for domestic use)
- bunk beds and high beds
- soft products used in the sleep environment (mattresses for cots and cribs, and children's cot bumpers).

The segregation was used as some hazards are more relevant to one group of products than others. The groupings do not represent the division of the products between the CEN technical committees:

- products in the first group (children's furniture) are handled by CEN/TC 207/WG 2 (Children's and Nursery Furniture) and CEN/TC 252/WG 2 (Sleeping, Relaxation and Lying Down),
- the bunk beds and high beds standard is the responsibility of CEN/TC 207/WG
 2, and
- the third group (soft products) is shared between CEN/TC 207/WG 2 and CEN/TC 248/WG 34 (Risks in the Sleeping Environment - a joint working group between CEN/TC 248 and CEN/TC 252).

Bunk beds and high beds were separated from other items of children's furniture as the prevention of sudden unexpected deaths in infancy (SUDI), primarily SIDS, is not relevant to these products as they are intended for use by children aged outside the SIDS age risk group and who exhibit far more complex gross motor skills than children under one year. However, they present their own injury risks,

mainly falls and entrapments. The appraisal of the standard for these products related more strongly to the injuries identified in Task 1.

A series of questions drawn from Task 2 was "asked" of each standard to evaluate how and to what extent it facilitates the best safe sleeping practices identified, bearing in mind that this primarily looked at SUDI deaths. Using the final report from Task 1, a similar evaluation was undertaken to determine how and to what extent each standard addresses the deaths and injuries that the Task identified.

As Table 3.2 shows, the standards appear to have little regard for minimising the causes of SUDI deaths, whether injury-related or SIDS, that might be amenable to reduction through product modification. European Commission mandate M/497 and the associated Commission Decision require that "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". This table illustrates that none of the products analysed fully meet this requirement.

Analysis of the spreadsheet across different standards allowed comparisons of how similar hazards, not just those relating to safe sleeping criteria, are addressed in terms of the requirements and test methods between these standards, thus analysing gaps and inconsistencies that might exist.

Recommendations drawing on these analyses are presented in Annex 1. The appraisal is informative as it illustrates inconsistencies and gaps between standards that might be helpful in identifying issues and presenting solutions that ANEC might consider putting forward to standards committees.

Table 3.1 Hazards used during the analysis of the standards and the relevant subheadings for each main hazard

Head entrapment

General

Feet first opening

Head first opening

Bound/ v-shape openings

Finger entrapment

Bound/ v-shape/mesh

Entrapment of limbs/hands/feet

Hazards from moving parts

Shearing hazards

Crushing hazards

Hazards with folding products

Unintentional release of locking

mechanisms

Hazards related to attachment systems

and opening/closing systems

Unintentional operation

Entanglement hazards

Snagging

Cords, ribbons and ties

Loops

Choking hazards

Due to small parts - torque test

Due to small parts - tensile test

Accessibility of fillings

Airway obstruction

Suffocation hazards

From the product itself

Plastic decals and sheeting

Non air-permeable packaging

Ingestion hazards

Small parts

Hazardous edges and projections

Edaes

Rigid protruding parts

Points and wires

Structural integrity

Material suitability

Strength and durability of the

product

Product integrity

Dismantling for storage/transport

Ability to move the product when

required

Protective function

Barrier function/heights

Restraint systems

Footholds

Hazards associated with stability

Tip hazards

Flammability

Hazards due to rate of spread of

flame

Hazards due to flash effect

Hazards due to melting of materials

Hazards due to flame propagation

Hazards from contact with flames

Chemical

Hazards from contact with chemicals

Thermal hazards

Purchase information

At the point of sale

Instructions for use

Markings

Table 3.2 Summary of how well standards fulfil safe sleep criteria

	Does the standard support the following safe sleeping advice:						
Product types/ standards	position of baby in product (baby's feet at the foot of the sleep product)?	baby on its back on a flat, not raised or tilted surface?	baby in a separate cot/bed/crib?	firm flat mattress with waterproof cover, no gaps between mattress and side, and use of single mattress only?	sleep area clear of bumpers, toys and loose bedding?	correct ambient room temperature?	
Cots EN 716:2017	No advice regarding sleep positioning	No requirement that the mattress can be (or even can only be) used horizontally (or at least within 2 degrees to the horizontal)?	Yes - as a cot is a separate child bed	No requirement that any mattress supplied with a cot shall have a defined firmness nor shall it be waterproof or have a waterproof cover. There does not seem to be a requirement that a mattress supplied with the cot, whether an integral part of the product or not, shall comply with the mattress standard. Furthermore, there is no instruction that when purchasing a cot mattress, that it should comply with the cot mattress standard. Gaps are covered within the instructions	Instructions state that nothing should be left within the cot. Nor should the cot be placed next to an item that can be used as a foothold, nor items that present a danger of strangulation e.g. blind cords	Warning regarding the risks of open fires and other sources of strong heat (electric bar heaters, gas fires, etc.) in the nearby vicinity of the cot. This appears to be a flammability warning, so does not relate to the child possibly overheating?	
Cribs prEN 1130	No advice regarding sleep positioning	Yes - the standard states that products must be capable of use horizontally and not be tilted more than 10 degrees.	Only partially - as bed side sleepers are included in this standard.	There is no requirement that a supplied mattress fits snugly/safely. However crib mattresses are subject to EN16890.	No such requirement	No such requirement	

		Does the	standard support the	following safe sleepi	ng advice:	
Product types/ standards	position of baby in product (baby's feet at the foot of the sleep product)?	baby on its back on a flat, not raised or tilted surface?	baby in a separate cot/bed/crib?	firm flat mattress with waterproof cover, no gaps between mattress and side, and use of single mattress only?	sleep area clear of bumpers, toys and loose bedding?	correct ambient room temperature?
Carry Cots prEN 1466	No advice regarding sleep positioning	No as an inclined base of 30 degrees is allowed and no statement that there is a requirement for the mattress to be used horizontally.	Yes - as a carry cot is a separate child bed	Carry cot mattresses are not subject to any standard which is a concern, particularly regarding the indentation test. There is no warning regarding gaps, but the dimensions of the correct mattress must be stated.	No such requirement. However, a warning regarding not leaving handles inside the carry cot is included	No such requirement
Bunk beds and high Beds EN 747- 1&2:2012+A1 :2015	n/a	n/a	n/a	n/a	n/a	n/a
Mattresses for cots and cribs EN 16890: 2017	n/a	n/a	n/a	No instruction regarding the required use of waterproof covers. General concern regarding use of mattress toppers. Use of two mattresses is covered. Warning regarding gaps is included.	n/a	n/a
Cot bumpers EN 16780:2018	n/a	n/a	n/a	No – such products clearly go against safe sleeping advice.	n/a	n/a

4.0 TASK 4 - DETAILED ANALYSIS OF PRODUCTS WITHOUT STANDARDS AND RECOMMENDATIONS FOR ACTIONS

4.1 Framework for analysis

To carry out this Task in a consistent and structured way across the products, a framework was developed comprising three sections:

- a brief analysis of the functions of the product, the characteristics of its "users" (children and adults), and its popularity;
- drawing on the hazards listed in CEN TR 13387 Child care articles General safety guidelines, an extensive table that allowed the hazards associated with each product to be identified, their significance assessed, and a judgement on whether or not the hazard should be addressed in a standard;
- a summary of the issues relating to the development of a new standard.

4.2 Analysis of products without standards

The framework was used to develop recommendations on whether or not new standardisation work should be promoted for some or all of the following products:

- Baby nests
- Sleep positioners
- Baby boxes
- Bedside sleepers
- Cot beds
- Pop up travel cots and UV tents
- Cots and travel cots supplied in combination with bassinets/changing tops/etc.

This is not a comprehensive list of sleep products that are on the market. Other products such as suspended sleep products (which includes hammocks with a soft base, cribs with a firm base and pods) should be subject to safe sleep criteria and therefore considered for standardisation in the future.

The structured analysis of potential hazards associated with these products and the recommendations of whether or not ANEC should promote the development of standards for them drew on the safe sleeping guidance, knowledge of how hazards are addressed in existing standards and the analysis of deaths and injuries carried out by a separate contractor under Task 1.

The question on the hazard analysis proforma on whether the hazard should be included in safety requirements was answered with simply a Yes/No response. It was felt that a more detailed response was not needed as the outcome of Task 4 was only a recommendation of whether or not a standard should be developed, rather than a detailed outline of what a standard should contain.

The full results of the analysis of each product are presented in Annex 2.

4.3 Conclusions and recommendations from the product analyses 4.3.1 Baby nests

Baby nests are popular products usually intended for babies from birth for use in a supervised environment. The upper age range depends on the size of the product and whether the product can be adjusted with some being advertised to eight months and even well beyond this. Because of the need for supervision they are not suitable for night-time sleeping.

There is variation on the advice given about where baby nests should be used: the general rule is use them in a safe situation such as on the floor, not on a raised surface, and some retailers say that they should not be used in a cot or other sleep product.

Babies over about four months are generally able to roll and wriggle and could therefore turn their face into the side of the baby nest, risking suffocation. As the height of the sides of the baby nest are not controlled, a baby could also roll or climb out of the nest as it becomes more mobile. Some baby nests have carrying handles and tapes to allow adjustment – these could present a strangulation hazard.

Although there are no reports of such events, the risk of suffocation would appear to be similar to that associated with cot bumpers, which are regarded by reputable sources of safe sleeping as products to be avoided. (Cot bumpers are covered by EN 16780:2018 *Textile child care articles. Safety requirements and test methods for children's cot bumpers*). There could also be a risk of the baby overheating as a result of the padded sides being close to the baby.

Given the risks, we recommend that a standard should be developed for baby nests, ideally led by the CEN/TC 252/WG2, the technical committee responsible for products for sleeping, relaxation and lying down.

4.3.2 Cot beds

Cot beds are products for sleeping that can be converted from a cot to a small bed, usually covering babies and children from birth to about four years. Ideally, conversion should take place before the baby is able to climb as this reduces the risk of injuries from a fall over the top of the cot's side rails.

These products often require initial assembly and conversion from the cot mode to the bed mode by the purchaser. They are also capable of being dissembled for storage. Cots are designed to minimise entrapment hazards for babies. If the transition to bed mode takes place too early, these hazards could manifest themselves. There is also a risk of injury if the product is incorrectly disassembled when converted to the bed mode as a result of the loss of components or instructions.

The recommendation is that, when in cot mode, cot beds should comply with EN 716-1 and EN 716-2:2017 Furniture - Cots and folding cots for domestic use, although we note that this standard does not currently support best practice in terms of safe sleeping, and that a new standard should be drafted to cover the product when being converted to and when in bed mode. Alternatively, a junior bed standard could be developed to cover cot beds also.

4.3.3 Cots and travel cots supplied with accessories such as changing tables and bassinets

For practical reasons often associated with limited space, cots and travel cots (what might be termed the base products) are often used with various child care

accessories fitted to them. The accessories might be left in place or removed when not needed.

The base product can provide a sleeping function as a cot or travel cot, covered by EN 716; accessories can include changing tables, for which EN 12221 *Child use and care articles. Changing units for domestic use. Safety requirements* is relevant, a crib function covered by EN 1466, and even a bouncing chair/reclined cradle function for which EN 12790 *Child use and care articles. Reclined cradles* is relevant.

The problem is that if the accessories are supplied by a manufacturer other than the base product manufacturer, possibly sold as "generic" products intended to fit a range of base products, hazards can be introduced due to poor attachment, incorrect sizing, etc. The base product manufacturer has no control over what accessories are used. To ensure that no problems arise, all accessories would need to be tested in conjunction with all base products but this is clearly not practical. The hazards that can arise include falling if the accessory does not fit properly, and entanglement or entrapment due to ill-fitting accessories.

It is recommended that the only practical solution is that a single standard is developed for products supplied by a single manufacturer. However, this could be challenging given the standards for accessories that are already published and the fact that these are the responsibility of different technical committees.

4.3.4 Baby boxes

These products have been popular for many years in Finland. Their use has been extended recently to other jurisdictions, usually with the product being provided by official bodies as part of a programme to enhance the wellbeing of babies, improve parenting knowledge and skills, and provide some childcare items. The baby box is intended for the baby to sleep in, thus reducing the significant risk of suffocation associated with co-sleeping.

The product appears to be very similar in design to a carry cot except that it might not have straps that act as carrying handles. Some baby boxes have holes in their side structures to act as handholds to facilitate lifting and carrying.

Our analysis of the potential hazards associated with baby boxes suggests that there are several that would need to be addressed to reduce the risks of harm, the most serious being the risk of suffocation if the sides of the box are coated with a plastic material and the possibility that an active baby could roll or climb out if there is no control over the height of the sides. In addition, the strength of the handholds needs to be defined and tested to minimise the risk of the baby being dropped if the handholds fail. This structural integrity could be negatively affected if the product became wet, for example from urine, given the fact that the boxes are made from cardboard.

Given the product's similarity in terms of function and design to a carry cot in which these hazards are addressed through EN 1466 Child use and care articles. Carry cots and stands. Safety requirements and test methods, our view is that baby boxes should conform to this standard and that a separate standard for them is not needed.

4.3.5 Bedside sleepers

Bedside sleepers are addressed in the ongoing revision of EN 1130:1996 *Furniture. Cribs and cradles for domestic use* so the development of a separate standard is not recommended at this stage.

4.3.6 Pop up travel cots and UV tents

These products are intended for use by children from birth to about 24 months, a period over which they change from having virtually no gross and fine motor skills to being fully mobile and being capable of undertaking fine motor tasks such as

undoing closures, etc. They are popular products as they are portable and easy to assemble and dissemble.

Some of their functions are similar to those provided by travel cots (folding cots), which are covered by EN 716-1 and EN 716-2:2017 *Furniture - Cots and folding cots for domestic use*, and carry cots, covered by EN 1466 *Child use and care articles. Carry cots and stands. Safety requirements and test methods*, although there are few similarities in terms of design.

Looking at the products on the market, there appear to be multiple hazards largely as a result of the age range of their use. For mobile children, they offer little or no barrier function, and can present entanglement and entrapment hazards. For all ages, given that the tent might produce an enclosed space, there could be a risk of overheating.

While a standard might be expected to address the potential hazards, the effect could be to outlaw such products. It is therefore our recommendation that no standard is developed for pop up travel cots and UV tents.

4.3.7 Sleep positioners

The availability of these products has been reduced recently in parts of Europe as a result of reports of deaths associated with them. None of the organisations surveyed under Task 2 recommends the use of these products because babies have slipped out of them and suffocated. There is no evidence that they enhance safety.

It is our recommendation that no standard is developed for sleep positioners as it could suggest to the public that they are "safe" products.

5.0 CONCLUSIONS AND RECOMMENDATIONS

5.1 Deciding on what products to standardise

This project raises the question of how to decide on what products should be standardised. In section 4, recommendations have been made that the standardisation of three products should be promoted and that three should not be pursued. Developing such recommendations should be based on reliable and structured evidence but this is not always the way that such decisions are taken. Given that the technical committees and working groups have limited capacity to work on new standards while continuing to maintain existing standards, one challenge is deciding whether product A or product B should be prioritised.

Section 1 illustrates that within Europe there is currently a lack of information on deaths and injuries that is representative of product-related events. Reliable and up-to-date accident and injury data is of huge importance to a wide range of stakeholders as it informs decisions regarding priority setting, policy development, understanding of risk and the design of safety into new products. Required information must be up to date, easily accessible and include all the details required to inform what precise issues should be covered by standardisation. While the USA has better epidemiological data, it still does not provide the detail needed. To explore the product involvement in the generation of deaths and injuries one probably has to investigate events to the extent that coroners might undertake.

As a consequence, other sources of information might have to be used, but they also suffer from a lack the factors noted above. Sources such as consumer complaints can provide some in-depth information. In theory, the rates rather than the numbers of injuries and the severity of those injuries should contribute to the basis of prioritisation decisions. Calculating rates requires denominators, such as the market penetration of a product or the amount of time that it is used. This type of information is rarely available except on an ad hoc basis based on perceived product popularity as suppliers are not always willing to reveal product sales.

If statistically valid information is not available, one might have to use measures such as the expert assessments of hazards associated with products, drawing on

historical information of similar products and an understanding of the ways that children and adults use products. This is the method that was used in developing the recommendations set out in section 4, combined to a small extent with death and injury and complaints information from Task 1.

A further problem faced in taking prioritisation decisions is what the effect of a standard will be on the public's perception of a product. If a standard is developed for a product that has significant residual risks even after compliance with the standard, the fact that a standard number is placed on the product could make the public think that the product is "safe". Should a standard be developed for such a product?

5.2 The practicality of moving the recommendations forward

This project has recommended that standards should be developed for three sleep-related products – baby nests, cot beds and cots/travel cots with additional function/s. While these recommendations might be valid, based on expert opinion and some epidemiological information, one has to consider the practicality of moving the standardisation process forward.

The three products appear to fall within the domains of the working groups of two CEN technical committees – TC 207 WG 2 Children's and Nursery Furniture and TC 252 WG 2 Sleeping, Relaxation and Lying Down. Both working groups have extensive programmes so it is questionable whether, without additional resources being made available, they could take on major new work items. The first drafts of new standards could be commissioned by the European Commission and/or CEN through organisations such as ANEC if appropriate resources were provided. ANEC has experts familiar with the details of similar standards as Task 3 illustrates, who sit on the relevant working groups, and who were heavily involved in the development and maintenance of guides including CEN TR 13387 *Child care articles - General safety guidelines* and ISO/IEC Guide 50 *Safety aspects — Guidelines for child safety in standards and other specifications*.

ANNEX 1 RECOMMENDATIONS FROM APPRAISAL OF STANDARDS

As mentioned in Section 3, Task 3 required the team to thoroughly appraise all the standards listed in order to perform a full consistency check and gap analysis upon them. The idea was to establish whether the hazards associated with children's sleep products were being dealt with consistently, appropriately and thoroughly. Below is a list of the key issues that ANEC may consider raising with the appropriate standards committees. A full list of recommendations can be generated from the three large spreadsheets (as mentioned in section 3 and available separately to this report).

EN 716-1 and EN 716-2:2017 Furniture - Cots and folding cots for domestic use:

- The standard has no rationale
- The standard should be written as a single hazard-based standard
- Clause 4.4.2.3 Distance between cot base and sides and ends tests should be carried out in all positions of use
- Clause 4.4.4.3 Shear and squeeze points during use no test method is given
- Clause 4.4.5 Snag points clarification required, should the product fail once or all 3 times?
- Clause 4.4.6.2 All locking systems force should be applied gradually then maintained
- Clause 4.4.8.2 Distance between footholds and top of cot sides and ends
 is not consistent with safety barriers EN 1930 Child use and care
 articles. Safety barriers. Safety requirements and test methods requires
 600mm
- Clause 5 Packaging lacks detail; other child care articles standards have additional hazards listed
- Clauses 6 Instructions for use and Clause 7 Marking do not state whether the specific wording of some/all warnings are normative
- The standard does not list any purchase requirements
- Travel cots are quite different products from traditional cots and should be dealt with under a separate standard

EN 747:2012+A1:2015 Furniture - Bunk beds and high beds:

- The standard has no rationale
- The standard should be written as a single hazard-based standard
- Clauses 4.1.2 Accessible holes gaps and openings, 4.1.3 Bed base(s),
 4.1.4 Safety barriers, 4.1.5 Ladder or other means of access no force requirement for the 12 mm and 60mm probes and the shape assessment probe is not used
- Clause 4.1.3 Bed base(s) requires a test method or clarification to the requirement
- Clause 4.1.5 Ladder or other means of access difficult to interpret
- The standard does not list any chemical requirements (formaldehyde is of particular concern)
- The standard does not list any purchase requirements
- If these products are used in a non-domestic environment the criteria may have to change
- Whilst bunk beds are not intended for use by under 6s, it is widely accepted that they are. Should the standard be amended to include younger children and the associated hazards?

EN 16890:2017 Children's furniture - Mattresses for cots and cribs - Safety requirements and test methods:

- It is not clear why mattresses for carry cots and pram bodies, inflatable mattresses and water mattresses are excluded from this standard
- Clause 8.3.2.2.3 Removeable mattress covers requires a test method
- Clause 9.2 Purchase information warnings are too lengthy. Normative warnings and pictogram with supporting text regarding correctly fitting single mattress is strongly advised
- Clause 9.3 Instructions for use use of a waterproof cover should be advised

prEN 1466 Child use and care articles. Carry cots and stands. Safety requirements and test methods (currently under revision):

- Scope includes Moses baskets, but such products are not mentioned
 again definition required (or deletion of them from the Scope)
- Clause 7.1.2.2.1 Requirements for internal height of rigid carry cots requires a table to aid explanation
- Clauses 7.1.2.2.2.2 and 7.1.2.2.2.3 Tests for measurement of length and internal height of rigid carry cots require clarification. If a carry cot has a rigid handle, could the datum board interfere with the handle? EN 1130 Furniture. Cribs and cradles for domestic use. Safety requirements requires a minimum height of the sides of 200mm as carry cots and cribs have a sleeping function, should the heights be the same?
- Clause 7.1.3.1 Overall height of a carry cot with flexible handles requires an equivalent test for rigid handles
- Clause 7.1.6.1 Reclinable back rest allows a sloped/angled base which goes against safe sleep advice
- Clause 7.2.2 Entrapment hazards clarification required as to why different forces are used. Addition of the shape assessment probe is recommended
- Clause 7.3 Hazard from moving parts requires a test method for the finger probes. The 18 mm probe is not listed
- Clause 7.6.4.2 Hazards due to the softness of the base requires a thorough explanation to support the diagram. Also, could a carry cot have a stiff base but a soft mattress? If yes, such a product would pass this test but present a suffocation risk as it would allow the baby's head to create an indentation
- Clause 9.2 Purchase information is too detailed regarding practical sharing of information at point of sale
- Clause 9.3 Marking this is a sleep product, so children should be able to be left in it safely when unattended

prEN 1130 Furniture. Cribs and cradles for domestic use. Safety requirements (currently under revision):

- Clause 7 Flammability hazards requires a test method for flash effect
- Clause 8.3.3.2 Hazards due to unintentional folding of the crib requires a test method
- Clause 8.4.1.2 Test method for efficiency of the stops requires clarification
- Clause 8.4.1.3 Hazards due to the movement of cradles and suspended cribs, Test method to measure the angle requires a test method for obtaining the angle
- Clause 8.4.3.2 Locking system for foldable or adjustable legs and feet requires a test method
- Clause 8.5.1.2 Falling hazards, Height of sides and ends requires clarification
- Clause 8.5.2.2 Hazards due to inadvertent release of adjustable sides requires a test method
- Clause 8.5.3.2 Locking system for adjustment in height or angle of the base - requires a test method
- Clause 8.11.3.2 and 8.11.3.3 Strength of sides, structural members of the sides, ends and corners - not strict enough as entrapment could result. Use of a probe recommended
- Clause 10.3.1 Warnings concern that the standard requires too many warnings on the product, and one is far too long. Pictograms with supporting text strongly recommended
- There is no requirement for a tight-fitting mattress

<u>EN 16780:2018 Textile child care articles – Safety requirements and test methods</u> for children's cot bumpers:

- Standard should be written in a hazard based format
- Clause 4.1.1.2 Design characteristics incorrectly listed within Annex as suffocation hazard, should be entanglement

- Clause 4.1.1.3 Design characteristics requires clarification (for example see Clause 7.6.1 of EN 1466 Child use and care articles. Carry cots and stands. Safety requirements and test methods)
- Clause 4.1.3.2 Functional cords requires clarification to focus upon the length of the cord and it not being possible to make a loop
- Clause 4.1.3.3 Non-functional cords requires test method using a force to create maximum length. (Incorrectly listed within Annex as suffocation hazard - should be entanglement)
- Clause 4.1.4.2 Slide fasteners is a quality requirement
- Clause 4.4 Fire hazards uses the test method from EN 1103 but all other child care articles (CCA) standards use EN 71 part 3
- Clause 5.4 Instructions for use no requirement for instructions in the official languages of the country where the product is sold
- Clause 5.4 Instructions for use suggest addition of the following warning from EN 1466: WARNING: Ensure your child's face is not pressed against the fabric as its breathing may be restricted
- Clause 5.4 Instructions for use suggest warning b) is amended to include children who can roll as this can result in their face being pressed against the fabric
- Many clauses are without test methods (see the separate spreadsheets for details)

Finally, a general suggestion from the research team that applies to all the above standards - that a CEN Technical Report (TR) is developed to cover normative warnings and pictograms across all CCA products although we recognise that this could be difficult and time-consuming to produce. In addition, instructions regarding the assembly of child sleep products could generally be improved by use of a normative reference to EN 82079-1:2012 *Preparation of instructions for use.* Structuring, content and presentation. General principles and detailed requirements. An initial study for a limited number of pictograms has already been undertaken by AIJU (Insituto Technologico de prodcuto infantil y ocio).

ANNEX 2 RESULTS OF PRODUCT ANALYSES FROM TASK 4



Function(s) – sleep, play, transport, sitting, multiple, etc	Lying flat – when asleep or awake. Often placed on an elevated flat surface or in a cot, crib or adult bed.
Related products that are already covered by standards	Some similarities with cribs, carry cots and cot bumpers.
Principal "users" and their characteristics	
Children	
Age/developmental characteristics	Birth to about 4 months (although advertised as suitable for older babies and some products for children up to 3 years). Able to roll and wriggle/play towards top end of age range. Waves arms around.
Adults	
Manual dexterity if adjustment/assembly needed	Some products might require adjustment of ribbons/clips to modify the bolster. Correct use of product important to prevent suffocation and falls if placed on elevated surface.
Familiarity with product (informed, uninformed (e.g. rare user such as babysitter, grandparent))	Unfamiliar product for many.

Secondary "users"	
Children older than the principal "users" and adults usually external to product	Foreseen use by pets.
Legislative/political/popular framework	
Mandate/other legislation	GPSD
Product provided by official bodies or other major scheme (e.g. baby box by government	No
Media/public attitude to product	Popular product as newborns "fit" the product; generally colourful/fashionable. Highly portable item and seemingly offers a safe environment for baby.
Likely to be used in commercial settings?	No

BABY NESTS					
Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments	
MECHANICAL HAZARDS					
Hazards from gaps and openings:					
Entrapment of head and neck	no	-	-		
Entrapment of fingers	no	-	-		
Entrapment of limbs	yes	L	yes	Hazard would be present if clip is used to secure bolster	
Hazards due to moving parts, i.e. shearing and compression	no	-	-		
Hazards due to crushing	no	-	-		
Hazards due to protrusions	no	-	-		
Entanglement in cords, ribbons and parts used as ties	yes	Н	yes	Need to consider head/limb/finger entanglement from cords/loops/threads	

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Ingestion hazards	yes	Н	yes	Hazard possible from add-on decorations and ingestion from accessible fibres
Choking hazards	yes	Н	yes	Hazard possible from add-on decorations and ingestion from accessible fibres
Suffocation from product	yes	н	yes	Face could be pressed against fabric side of nest
Hazards from plastic decals or sheeting	yes	Н	yes	Consider add on plastic decorations
Hazards from packaging materials	yes	Н	yes	Issue for secondary users. Address in same way as in other standards
Hazardous edges	no	-	-	
Hazardous points and wires	no	-	-	
Hazards from inadequate stability	no	-	-	
Hazards from inadequate structural integrity	no	-	-	

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments	
Hazards from inadequate protective barrier function	yes	Н	yes	Hazard depends upon product placement. Should be covered in product design and instructions.	
Hazards from restraint systems	no	-	-	Fitted restraint system can cause strangulation hazard so should not be fitted	
Falling hazards due to footholds	no	-	-		
Hazardous heights (falls)	yes	М	yes	Hazard depends upon product placement. Should be covered in product design and instructions.	
Hazards from moving or rotating objects	no	-	-		
THERMAL HAZARDS					
Hazards due to flash effect	yes	L	yes	Some fabrics at risk	
Hazards due to flame propagation	yes	L	yes	Some fabrics at risk	

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazards due to melting behaviour of materials	no	-	-	
Hazards from contact with flames	no	-	-	
Hazards from hot or cold surfaces	no	-	-	
Hazards from hot or cold liquids or food	no	-	-	
Hypothermia or hyperthermia hazards	yes	М	yes	Overheating possible. Should be covered in instructions
OTHER HAZARDS				
Suffocation due to an enclosed space	no	-	-	
Biological hazards	yes	L	yes	Infestation hazard – must be washable
Likely to be used unsupervised	yes	Н	yes	Can lead to multiple hazards
Inadequate information	yes	н	yes	Product information must be supplied
Chemical	yes	L	yes	Use standard wording from other standards

SUMMARY OF ISSUES RELATING TO	THE DEVELOPMENT OF STANDARD FOR BABY NESTS
Similarity to or difference from related products with existing standards	Some aspects of the product are similar to those found in cribs, carry cots and cot bumpers, particularly with regard to suffocation risks.
Significance of risks (low/medium/high)	Medium risk of suffocation although little known of such events.
Rare product so no need for standard?	No; this is a popular product.
Standard could give inherently unsafe product impression of safety	Probably not
Need for standard unlikely to be accepted by stakeholders (e.g. relevant TC, industry, etc)	No
Suggested home for standards work	TC 252 WG 2 seems the obvious home, rather than a textile TC
Supports safe sleeping advice (feet to foot, not overheated, on back, flat horizontal surface, mattress fits, area free from suffocation hazards, etc.)	No – some risk of overheating, clearly a suffocation risk
Any other comments	
Priority for standard none/low/medium/high	Medium



Function(s) – sleep, play, transport, sitting, multiple, etc	Lying flat – when asleep or awake		
Related products that are already covered by standards	Cot (EN 716) covers part of use function. BS 8509:2008+A1:2011 Children's beds for domestic use. Safety requirements and test methods is also used in the UK		
Principal "users" and their characteristics			
Children			
Age/developmental characteristics	Birth to about 4 years. Used as a cot until child is likely to climb out, typically before about 18 months. Used as a bed (i.e. without the side rails and re-assembled in a lower mode) until the child outgrows it.		
Adults			
Manual dexterity if adjustment/assembly needed	Often sold requiring self-assembly. The transition from a cot to a bed usually requires disassembly and re-assembly in changed format. Some products may have bases that can be lowered when used as a cot.		
Familiarity with product (informed, uninformed (e.g. rare user such as babysitter, grandparent))	Common product so general familiarity with the product when assembled. Might be less familiar with the transition between cot and bed. Product often dissembled for storage and/or handing on and/or sold on second hand.		

Secondary "users"	
Children older than the principal "users" and adults usually external to product	Older children and adults will use the product, especially when in cot format, to insert and remove baby. Older children might play on bed.
Legislative/political/popular framework	
Mandate/other legislation	GPSD
Product provided by official bodies or other major scheme (e.g. baby box by government)	No
Media/public attitude to product	Popular product
Likely to be used in commercial settings?	No

COT BEDS					
Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments	
MECHANICAL HAZARDS				•	
Hazards from gaps and openings:					
Entrapment of head and neck	yes	Н	yes	Covered by EN 716 but should be retested as structure (bed ends) changes	
Entrapment of fingers	yes	L	yes	Covered by EN 716 but should be retested as structure (bed ends) changes. Holes that are needed for transition to bed need to be protected	
Entrapment of limbs	yes	L	yes	Covered by EN 716 but should be retested as structure (bed ends) changes	
Hazards due to moving parts, i.e. shearing and compression	no	-	-	Covered by EN 716	
Hazards due to crushing	yes	М	yes	Covered by EN 716 but should be retested as structure (bed ends) changes	

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazards due to protrusions	yes	Н	yes	Covered by EN 716 but should be retested as structure (bed ends) changes
Entanglement in cords, ribbons and parts used as ties	yes	М	yes	Covered by EN 716 but should be retested as structure (bed ends) changes
Ingestion hazards	yes	М	yes	Covered by EN 716 but should be retested as structure (bed ends) changes. Non-captive fitments may have to be used
Choking hazards	yes	М	yes	Covered by EN 716 but should be retested as structure (bed ends) changes. Non-captive fitments may have to be used
Suffocation from product	no	-	-	Covered by EN 716
Hazards from plastic decals or sheeting	no	-	-	Covered by EN 716
Hazards from packaging materials	no	-	-	Covered by EN 716

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazardous edges	yes	М	yes	Covered by EN 716 but should be retested as structure (bed ends) changes
Hazardous points and wires	yes	М	yes	Covered by EN 716 but should be retested as structure (bed ends) changes
Hazards from inadequate stability	yes	L	yes	Covered by EN 716 but should be retested as structure (bed ends) changes
Hazards from inadequate structural integrity	yes	Н	yes	Product collapse due to incorrect re- assembly/transition. Risk might be to child playing under bed as well as child in bed.
Hazards from inadequate protective barrier function	yes	Н	yes	Should be tested if sold with a barrier (possible entrapment risk also present).
Hazards from restraint systems	no	-	-	Restraint system should not be used due to risk of strangulation
Falling hazards due to footholds	no	-	-	Covered by EN 716

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazardous heights (falls)	yes	L	no	Low fall height so not needed in safety requirements
Hazards from moving or rotating objects	no	-	-	
THERMAL HAZARDS				
Hazards due to flash effect	no	-	-	Covered by EN 716
Hazards due to flame propagation	no	-	-	Covered by EN 716
Hazards due to melting behaviour of materials	no	-	-	Covered by EN 716
Hazards from contact with flames	no	-	-	Covered by EN 716
Hazards from hot or cold surfaces	no	-	-	Covered by EN 716
Hazards from hot or cold liquids or food	no	-	-	Covered by EN 716
Hypothermia or hyperthermia hazards	no	-	-	Covered by EN 716
OTHER HAZARDS				
Suffocation due to an enclosed space	no	-	-	
Biological hazards	no	-	-	

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Likely to be used unsupervised	yes	L	no	Possible minor injuries due to falls. Low fall height so not needed in safety requirements
Inadequate information	yes	Ħ	yes	Could lead to incorrect re-assembly and/or transition. Need to minimise risk of losing components or design product to make process inherently safe
Chemical	no	-	-	Covered by EN 716

SUMMARY OF ISSUES RELATING TO	THE DEVELOPMENT OF STANDARD FOR COTS BEDS
Similarity to or difference from related products with existing standards	In cot mode, product should comply with EN 716. Additional requirements are needed to cover transition and use as a bed.
Overall risk level (low/medium/high)	Low
Rare product so no need for standard?	Not a rare product
Standard could give inherently unsafe product impression of safety	No
Need for standard unlikely to be accepted by stakeholders (e.g. relevant TC, industry, etc)	Should not be a problem although TC 207 WG 2 has a full work programme
Suggested home for standards work	TC 207 WG 2
Supports safe sleeping advice (feet to foot, not overheated, on back, flat horizontal surface, mattress fits, area free from suffocation hazards, etc.)	EN 716 needs amendment to support safe sleeping
Any other comments	Fantasy beds (e.g. designed to resemble a bus) should be excluded
Priority for standard none/low/medium/high	Medium

COTS AND TRAVEL COTS WITH ADDITIONAL FUNCTION(S) e.g. changing table, bassinet, reclined cradle



Function(s) – sleep, play, transport, sitting, multiple, etc	Lay flat sleeping and playing
Related products that are already covered by standards	Cribs and changing tables
Principal "users" and their characteristics	
Children	
Age/developmental characteristics	Birth to about 24 months. Dexterous and able to move freely.
Adults	
Manual dexterity if adjustment/assembly needed	Quick assembly required when used as a travel cot and then affixing changing table/bassinet
Familiarity with product (informed, uninformed (e.g. rare user such as babysitter, grandparent))	Amalgamation of familiar products for many

Secondary "users"	
Children older than the principal "users" and adults usually external to product	n/a
Legislative/political/popular framework	
Mandate/other legislation	GPSD
Product provided by official bodies or other major scheme (e.g. baby box by government	No
Media/public attitude to product	Travel cot is popular as it's portable with numerous uses
Likely to be used in commercial settings?	Yes

COT AND TRAVEL COT WITH ADDITIONAL FUNCTION(S) Risk level **Include in safety Hazard present** Hazards **Comments** (Low/Medium/High) requirements **MECHANICAL HAZARDS** Hazards from gaps and openings: Entrapment of head In gaps, zippered Н yes yes and neck openings, pockets In gaps and zippered Entrapment of fingers L yes yes openings In gaps and zippered Entrapment of limbs L yes yes openings Hazards due to moving In gaps between parts, i.e. shearing and cot/travel cot and L yes yes changing table/bassinet compression In gaps between travel Hazards due to crushing L yes yes cot and changing table Snagging hazards could Hazards due to Η yes yes be present protrusions Ribbons and ties Entanglement in cords, frequently part of ribbons and parts used Η yes yes product as ties Zips and other small Ingestion hazards Н yes yes parts Zips and other small Choking hazards Н yes yes parts Face pressed against Suffocation from product Н yes yes fabric (plastic-like) side

COT AND TRAVEL COT WITH ADDITIONAL FUNCTION(S)

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazards from plastic decals or sheeting	yes	Н	yes	Potential suffocation risk
Hazards from packaging materials	yes	Н	yes	Issue for secondary users. Address in same way as in other standards
Hazardous edges	no	-	-	
Hazardous points and wires	no	-	-	
Hazards from inadequate stability	yes	Н	yes	Tipping hazard
Hazards from inadequate structural integrity	yes	Н	yes	Changing table/bassinet can detach. (Death reported when bassinet collapsed).
Hazards from inadequate protective barrier function	yes	М	yes	Child can roll off changing table
Hazards from restraint systems	yes	н	yes	Changing tables with restraint systems result in strangulation hazard
Falling hazards due to footholds	yes	Н	yes	Escape risk
Hazardous heights (falls)	yes	Н	yes	Risk of falls from changing table/bassinet

COT AND TRAVEL COT WITH ADDITIONAL FUNCTION(S)

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazards from moving or rotating objects	yes	Н	yes	Movement of changing table can lead to entrapment and crushing risk
THERMAL HAZARDS				
Hazards due to flash effect	yes	L	yes	Some fabrics at risk
Hazards due to flame propagation	yes	L	yes	Some fabrics at risk
Hazards due to melting behaviour of materials	yes	L	yes	Some fabrics at risk
Hazards from contact with flames	yes	L	yes	Some fabrics at risk
Hazards from hot or cold surfaces	no	-	ı	
Hazards from hot or cold liquids or food	no	-	-	
Hypothermia or hyperthermia hazards	yes	Н	yes	Possibility of overheating (from bassinet)
OTHER HAZARDS				
Suffocation due to an enclosed space	no	-	-	
Biological hazards	no	-	-	

COT AND TRAVEL COT WITH ADDITIONAL FUNCTION(S)

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Likely to be used unsupervised	yes	Н	yes	Can lead to multiple hazards
Inadequate information	yes	Н	yes	Product information must be supplied
Chemical	yes	L	yes	See other standards for examples of requirements

SUMMARY OF ISSUES RELATING TO THE DEVELOPMENT OF STANDARD FOR COTS AND TRAVEL COTS WITH ADDITIONAL FUNCTION/S Provides a sleeping function as a travel cot - EN 716 Similarity to or difference from related Provides a changing table function - EN 12221 products with existing standards Provides a crib function - EN 1466 Some new products also provide a bouncing chair/reclined cradle function - EN 12790 Overall risk level (low/medium/high) Known risks of falling, entanglement and entrapment Rare product so no need for standard? Widely available Standard could give inherently unsafe No product impression of safety Unknown Need for standard unlikely to be accepted by stakeholders (e.g. relevant TC, industry, etc) Suggested home for standards work Unclear as many standards to be considered Supports safe sleeping advice (feet to foot, Yes - in the main not overheated, on back, flat horizontal surface, mattress fits, area free from suffocation hazards, etc.) Possible standard only relevant to those products being supplied by the same Any other comments manufacturer. Will be challenging to deliver a standard that considers all standards already in place. Medium Priority for standard

none/low/medium/high



Function(s) – sleep, play, transport, sitting, multiple, etc	Lying flat – when asleep or awake. Often placed on an elevated flat surface or in a cot or adult bed.	
Related products that are already covered by standards	Many similarities with cribs and carry cots.	
Principal "users" and their characteristics		
Children		
Age/developmental characteristics	Birth to about 6 months. Able to roll and wriggle/play towards top end of age range. Waves arms around. Very similar to the requirements within EN 1466 (carry cots) so suggest the requirements for baby boxes are similar.	
Adults		
Manual dexterity if adjustment/assembly needed	None required.	
Familiarity with product (informed, uninformed (e.g. rare user such as babysitter, grandparent))	Unfamiliar product for many as new to market	

Secondary "users"	
Children older than the principal "users" and adults usually external to product	Foreseeable use by pets.
Legislative/political/popular framework	
Mandate/other legislation	GPSD
Product provided by official bodies or other major scheme (e.g. baby box by government	Yes – given free to all babies in Scotland and Finland, plus some health authorities in the UK are distributing them. Becoming more widespread.
Media/public attitude to product	Mixed. Public and professional variation in attitude.
Likely to be used in commercial settings?	No

BABY BOXES				
Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
MECHANICAL HAZARDS	1			-
Hazards from gaps and openings:				
Entrapment of head and neck	no	-	-	
Entrapment of fingers	no	-	-	
Entrapment of limbs	yes	L	yes	Potential minor injuries from entrapment within carry handles/holes
Hazards due to moving parts, i.e. shearing and compression	no	-	-	
Hazards due to crushing	no	-	-	
Hazards due to protrusions	no	-	-	
Entanglement in cords, ribbons and parts used as ties	no	-	-	
Ingestion hazards	no	-	-	
Choking hazards	no	-	-	
Suffocation from product	yes	н	yes	Face pressed against side of box if covered with plastic-like fabric

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazards from plastic decals or sheeting	no	-	-	
Hazards from packaging materials	yes	Н	yes	Issue for secondary users. Address in same way as in other standards
Hazardous edges	no	-	-	
Hazardous points and wires	no	-	-	
Hazards from inadequate stability	yes	М	yes	Placement of carry handle holes to prevent tipping when being carried important
Hazards from inadequate structural integrity	yes	Н	yes	Strength of handholds, structural integrity particularly when soiled
Hazards from inadequate protective barrier function	yes	L	yes	Low risk of rolling out risk – minimum height of sides required plus guidance in instructions
Hazards from restraint systems	yes	Н	yes	Must not have a restraint system as it can present a strangulation hazard
Falling hazards due to footholds	no	-	-	

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Hazardous heights (falls)	yes	Н	yes	Hazard depends upon product placement. Should be covered in instructions
Hazards from moving or rotating objects	no	-	-	
THERMAL HAZARDS				
Hazards due to flash effect	no	-	-	
Hazards due to flame propagation	no	-	-	
Hazards due to melting behaviour of materials	no	-	-	
Hazards from contact with flames	yes	L	yes	Cardboard can be flammable
Hazards from hot or cold surfaces	no	-	-	
Hazards from hot or cold liquids or food	no	-	-	
Hypothermia or hyperthermia hazards	yes	L	yes	Possibility of overheating. Should be covered in instructions
OTHER HAZARDS				
Suffocation due to an enclosed space	yes	М	yes	Must be used without the lid in place

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Biological hazards	yes	L	yes	Infestation risk from cardboard
Likely to be used unsupervised	yes	Н	yes	Can lead to multiple hazards. Intended for use unsupervised
Inadequate information	yes	М	yes	Product information must be supplied
Chemical	yes	М	yes	Formaldehyde in particular

SUMMARY OF ISSUES RELATING TO	THE DEVELOPMENT OF STANDARD FOR BABY BOXES
Similarity to or difference from related products with existing standards	Should/could be covered by the carry cot standard. Many aspects of the product are also similar to cribs.
Overall risk level (low/medium/high)	Medium risk of suffocation although little known of such events.
Rare product so no need for standard?	No; this is a popular product. Strongly suggest compliance with EN 1466.
Standard could give inherently unsafe product impression of safety	Debateable – again suggest compliance with EN 1466
Need for standard unlikely to be accepted by stakeholders (e.g. relevant TC, industry, etc)	Probably not
Suggested home for standards work	TC 252 WG 2 seems the obvious home
Supports safe sleeping advice (feet to foot, not overheated, on back, flat horizontal surface, mattress fits, area free from suffocation hazards, etc.)	No – possible suffocation risk (NB EN 1466 allows for a sloping base currently)
Any other comments	
Priority for standard none/low/medium/high	n/a – advise compliance with EN 1466



POP UP TRAVEL COTS/UV TENTS

Function(s) – sleep, play, transport, sitting, multiple, etc	Lay flat sleeping, playing, UV protection	
Related products that are already covered by standards	Travel cots	
Principal "users" and their characteristics		
Children		
Age/developmental characteristics	Birth to about 24 months. Dexterous and able to move freely.	
Adults		
Manual dexterity if adjustment/assembly needed	None required – they 'pop up'.	
Familiarity with product (informed, uninformed (e.g. rare user such as babysitter, grandparent))	Unfamiliar product for many	

Secondary "users"	
Children older than the principal "users" and adults usually external to product	Foreseeable play use by older children and siblings
Legislative/political/popular framework	
Mandate/other legislation	GPSD
Product provided by official bodies or other major scheme (e.g. baby box by government	No
Media/public attitude to product	Popular as lightweight and portable, with numerous uses
Likely to be used in commercial settings?	No

POP UP TRAVEL COTS/UV TENTS Risk level **Include in safety Hazard present** Hazards Comments (Low/Medium/High) requirements **MECHANICAL HAZARDS** Hazards from gaps and openings: Entrapment of head In zippered openings, Н yes yes and neck external pockets Entrapment of fingers L In zippered openings yes yes Entrapment of limbs In zippered openings yes L yes Hazards due to moving parts, i.e. shearing and no compression Hazards due to crushing no Hazards due to no protrusions Entanglement in cords, Ribbons and ties ribbons and parts used Н yes yes frequently used as ties Zips and other small Н Ingestion hazards yes yes parts Zips and other small Choking hazards Н yes yes parts

POP UP TRAVEL COTS/UV TENTS

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
Suffocation from product	yes	Н	yes	Face pressed against (plastic-like) fabric side. Possible hazard with access to mattress filling.
Hazards from plastic decals or sheeting	yes	Н	yes	Potential suffocation risk
Hazards from packaging materials	yes	Н	yes	Secondary user issue. Use approach from other standards
Hazardous edges	no	-	-	
Hazardous points and wires	yes	М	yes	Plastic wire type construction
Hazards from inadequate stability	no	-	-	
Hazards from inadequate structural integrity	yes	М	yes	Child who can sit, pull themselves up or stand will be able to tip the product so there is a potential fall hazard
Hazards from inadequate protective barrier function	yes	Н	yes	Very easy for child to escape as there is virtually no barrier function
Hazards from restraint systems	yes	Н	yes	Must not have such a system – suffocation hazard

POP UP TRAVEL COTS/UV TENTS Risk level **Include in safety** Hazards **Hazard present** Comments (Low/Medium/High) requirements Falling hazards due to no footholds Hazardous heights (falls) no Hazards from moving or no rotating objects THERMAL HAZARDS Hazards due to flash L Some fabrics at risk yes yes effect Hazards due to flame Some fabrics at risk yes L yes propagation Hazards due to melting Some fabrics at risk L yes yes behaviour of materials Hazards from contact Some fabrics at risk yes L yes with flames Hazards from hot or cold no surfaces Hazards from hot or cold no liquids or food Possibility of overheating (especially when used as Hypothermia or UV tent outdoors). Н yes yes hyperthermia hazards Should be covered in the instructions

POP UP TRAVEL COTS/UV TENTS

Hazards	Hazard present	Risk level (Low/Medium/High)	Include in safety requirements	Comments
OTHER HAZARDS	OTHER HAZARDS			
Suffocation due to an enclosed space	no	-	-	
Biological hazards	no	-	-	
Likely to be used unsupervised	yes	Н	yes	Can lead to multiple hazards. Not intended for use unsupervised
Inadequate information	yes	Н	yes	Product information must be supplied
Chemical	yes	L	yes	See other standards

SUMMARY OF ISSUES RELATING TO COTS/UV TENTS	THE DEVELOPMENT OF STANDARD FOR POP UP TRAVEL
Similarity to or difference from related products with existing standards	Provide a similar function to travel cots (which comply with EN 716) or carry cots (for infant use), but few similarities between the products themselves
Overall risk level	Totally inadequate barrier function – high risk of child escaping. Medium risk of suffocation. Medium risk of entanglement and entrapment. Risk of overheating when used outside
Rare product so no need for standard?	Becoming widely available
Standard could give inherently unsafe product impression of safety	Yes
Need for standard unlikely to be accepted by stakeholders (e.g. relevant TC, industry, etc)	Debatable
Suggested home for standards work	Difficult to suggest a home as carry cots fall under TC 252 WG 2 and travel cots fall under TC 207 WG 2. It will be very difficult to develop a standard for these products
Supports safe sleeping advice (feet to foot, not overheated, on back, flat horizontal surface, mattress fits, area free from suffocation hazards, etc.)	No – possible suffocation risk, escape risk, numerous entanglement/entrapment risks, risk of overheating when used outside
Any other comments	
Priority for standard none/low/medium/high	none