

Infant Inclined Products Issues Paper

19 July 2021

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Glossary

Term	Definition
ACCC	Australian Competition and Consumer Commission
ACL	Australian Consumer Law, Schedule 2 of the Competition and Consumer Act 2010 (Cth)
CCA	Competition and Consumer Act 2010 (Cth)
Health Canada	Government department, Health Canada
Infant	A child of less than 12 months of age
Infant Inclined Product	Broad category of products that positions an infant in an inclined angle (including Inclined Sleep Products and Inclined Non-Sleep Products)
Inclined Sleep Product	Any product that is designed, intended, marketed or contains any representation that it is suitable for an infant to sleep in, and has a sleep surface that has an inclined angle
Inclined Non-Sleep Product	Any infant product that is not designed, intended or marketed for sleep, and does not contain any representation that it is suitable for sleep, but does have a surface that has an inclined angle which an infant may fall asleep on in practice
Recall return rate	The rate at which a product that has been recalled is returned to the supplier or otherwise removed from the market
Red Nose	Red Nose Australia
SIDS	Sudden Infant Death Syndrome is a subset of Sudden Unexpected Deaths in Infancy (SUDI). Deaths are classified as SIDS where there is no cause that can be found for the death ¹
SUDI	Sudden Unexpected Deaths in Infancy is an umbrella term used to describe sudden and unexpected death of a baby where the cause is not immediately obvious unless an autopsy is

Red Nose, What Does Sudden Unexpected Death in Infancy (SUDI) Mean? Red Nose website, 2016. Accessed 9 July 2021.

	conducted. Following investigation, some deaths may be explained by existing health conditions, genetic disorders or accidental deaths. Some deaths may remain unexplained and are then attributed to Sudden Infant Death Syndrome (SIDS) ²
Standards Australia	An independent, not-for-profit organisation, recognised by the Australian Government as the peak non-government standards body in Australia
TGA	Therapeutic Goods Administration
US-CPSC	United States Consumer Product Safety Commission

Red Nose, <u>What Does Sudden Unexpected Death in Infancy (SUDI) Mean?</u> Red Nose website, 2016. Accessed 9 July 2021.

Questions for response

The ACCC is seeking your feedback in response to the questions below and repeated throughout the paper. The ACCC encourages you to respond to any questions that are relevant to you and to raise any additional issues that you consider relevant.

- 1. Do you consider the definitions and categorisation of Infant Inclined Products in Table 1 is accurate? Are there additional categories that should be added, removed or excluded? Please provide the reasons for your response.
- 2. What data or information can you provide about the number and type of product lines sold in Australia that might be considered an Inclined Sleep Product and/or Inclined Non-Sleep Product? Of those products how many:
 - (a) would be categorised as such due to marketing claims?
 - (b) comply with a relevant international mandatory or voluntary standard or international regulations?
- 3. What data or information can you provide on the size and value of the Australian market for Inclined Sleep Products and/or Inclined Non-Sleep Products?
- 4. Please provide any research or evidence that supports or contradicts an incline limit, including what incline angle the limit should be.
- 5. Do you consider that parents and carers of infants are sufficiently educated on safe sleeping practices generally, and also specifically in relation to Infant Inclined Products? If so, who are the leading providers of this education? Do you consider that increased consumer education is required? Please provide the reasons for your response.
- 6. What data or information can you provide about injuries, fatalities or near-misses caused by Inclined Sleep Products and/or Inclined Non-Sleep Products?
- 7. What research are you aware of that is directed to the prevention, or prevalence of injuries or fatalities caused by Inclined Sleep Products and/or Inclined Non-Sleep Products?
- 8. What measures could be taken to improve recall return rates of Infant Inclined Products and other products more generally? What barriers are there for consumers returning recalled Infant Inclined Products and do you consider these apply to all children's products? Please provide the reasons for your response.
- 9. If you are a supplier or manufacturer of Infant Inclined Products, do you adhere to the requirements of any international standards or regulations? How have you implemented these?
- 10. To what extent do international standards or regulations address the safety risks associated with Infant Inclined Products? Please provide the reasons for your response.
- 11. Do you consider that any of the following regulatory responses would prevent injuries or fatalities from Inclined Infant Products in Australia, either on their own or as part of a combined approach? Please provide the reasons for your response:
 - (a) a prohibition on the sale of Inclined Sleep Products (either temporary or permanent)
 - (b) a mandatory safety standard for Inclined Sleep Products and/or Inclined Non-Sleep Products
 - (c) a mandatory information standard for Inclined Sleep Products and/or Inclined Non-Sleep Products
- 12. What do you consider to be the costs involved in the implementation of the regulatory responses set out at question 11? Please provide the reasons for your response.

- 13. What other options do you consider may be effective in reducing the risks posed by Infant Inclined Products?
- 14. If you are a relevant organisation or agency, would you consider undertaking a consumer education campaign or assist the ACCC in increasing consumer awareness? If yes, please explain how you would assist the ACCC.
- 15. Please provide any other information you consider may be relevant to the ACCC's policy considerations in relation to a response to the risks associated with Infant Inclined Products.

1. Executive summary

Implementing strategies for unsafe infant sleeping products is a 2021 Product Safety priority for the Australian Competition and Consumer Commission (ACCC).³ Infant Inclined Products are a broad category of products used by parents and caregivers that position infants at an inclined angle. There are many different styles of Infant Inclined Products such as rockers, bouncers, swings, co-sleepers, wedges, recliners, bassinet-type products and inclined sleep accessories. These products pose a risk if an infant sleeps while positioned at an incline. The United States Product Safety Commission (US-CPSC) reported 73 infant fatalities associated with the use of such products between January 2005 and June 2019.⁴

Infant sleep at an inclined angle is contrary to safe sleeping advice. Since the first safe sleeping campaigns in the late 1980s, there has been an 85% decrease in Sudden Unexpected Deaths in Infancy (SUDI) fatalities in Australia.⁵

Research conducted in the United States has shown that fatalities in Infant Inclined Products are likely caused by:

- suffocation where the infant rolls for the first time and has their airway blocked by the mattress, or
- positional asphyxiation where the infant's head falls forward blocking the airway.⁶

The ACCC is not aware of any Australian fatalities directly attributed to Infant Inclined Products. Between 2004 and March 2020, there has been 2 infant fatalities in infant swings or rockers, but the cause of death for these is unexplained. Since January 2019, there has been 7 injuries reported which relate to Infant Inclined Products. These reports related to bouncers, rockers, swings and co-sleeper products with an incline function. It is not clear if these injuries are connected to the incline of the product or infant sleeping.

The ACCC considers there are broadly 2 categories of products that are of concern:

- Inclined Sleep Products, are those that are designed, intended, marketed or contain any
 representation that the product is suitable for an infant to sleep in and has an inclined
 angle. The ACCC considers these are the most concerning products because research
 has found that infant sleeping at an inclined angle is unsafe.
- Inclined Non-Sleep Products, which have a surface that has an inclined angle that an infant may fall asleep on, but are not designed, intended or marketed as suitable for sleep.

In Australia, there is currently no mandatory or voluntary safety standard dealing specifically with the risks of infants sleeping in Infant Inclined Products. However, products sold in Australia may comply with relevant international standards or regulations. These standards involve varying levels of protection with most standards including requirements for a safety warning stating that the products are not safe for unsupervised sleep by infants.

The ACCC is aware that Canada and New Zealand have implemented regulations seeking to address the risks of certain types of Infant Inclined Products.⁷ Those regulations prevent

More information about the ACCC's Product Safety Priorities 2021 can be found on the ACCC website: here

⁴ US-CPSC, <u>CPSC Cautions Consumers Not to Use Inclined Infant Sleep Products</u> [media release], US-CPSC, 31 October 2019, accessed 10 June 2021.

⁵ Red Nose, 'Why Back to Sleep is the Safest Position for Your Baby', Red Nose website, 2018, accessed 10 June 2021.

E. Mannen, 'Biomechanical analysis of inclined sleep products', Little Rock: University of Arkansas, 2019, p 5, accessed 10 June 2021.

Cribs, Cradles and Bassinets Regulations, SOR/2016-152 (Canada); Unsafe Goods (Inclined Infant Sleep Products) Amendment Notice 2020 (New Zealand).

the sale of infant sleeping products with an incline angle greater than 7 degrees. The US-CPSC has also recently announced that it will develop a mandatory safety standard applicable to infant sleep products generally which limits the maximum incline to 10 degrees and requires that these products meet additional requirements for bassinets and cradles.⁸ The ACCC understands that the stricter incline limit in Canada and New Zealand is based on research and internal risk assessments undertaken by these jurisdictions.

The ACCC has prepared this Issues Paper to seek views on Infant Inclined Product safety and the options available to address this issue.

US-CPSC, <u>CPSC Approves Major New Federal Safety Standard for Infant Sleep Products</u> [media release], US-CPSC, 2 June 20121, accessed 18 June 2021.

2. Introduction

The ACCC has prepared this Issues Paper to seek views from a range of stakeholders on Infant Inclined Products and the options available to address the risks associated with these products. The Issues Paper provides a broad overview of:

- the types of products that are categorised as Infant Inclined Products
- the current regulatory regime in Australia and internationally
- · the potential risks associated with these products, and
- · options available to reduce those risks.

The ACCC will consider submissions on this Issues Paper and whether a regulatory response is appropriate. If so, the ACCC will proceed to undertake a regulatory impact assessment, including further consultation with stakeholders before making any recommendation to the Australian Government about the development of new regulation.

3. Have your say

The ACCC invites interested parties to provide information and comment on this Issues Paper.

Submissions must be provided on or before 16 August 2021.

Where possible it is preferable that submissions be made using the Consultation Hub file upload function. If you would like to upload files that are larger than 25MB, or otherwise do not consider online submission is suitable please contact the team at IIPMarketReview@accc.gov.au and alternative arrangements can be discussed, for example using the ACCC's file sharing system.

Submissions can be lodged

Online (preferred) ACCC Consultation Hub at: https://consultation.accc.gov.au/

Email IIPMarketReview@accc.gov.au

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All submissions will be treated as public documents and published on the ACCC website: productsafety.gov.au, unless otherwise requested. Parties wishing to submit confidential information are requested to:

- clearly identify the information that is the subject of the confidentiality claim—the
 identified information must be genuinely of a confidential nature and not otherwise
 publicly available
- provide a non-confidential version of the submission in a form suitable for publication this public version should identify where confidential information has been redacted.

The ACCC will not disclose the confidential information to third parties, other than advisers or consultants engaged directly by the ACCC, except where permitted or required by law. For more information, see the ACCC/AER Information Policy.⁹

Any personal information you provide will be handled in accordance with the ACCC/AER Privacy Policy. 10

⁹ The ACCC/AER Information Policy is available <u>here</u>.

¹⁰ The ACCC/AER Privacy Policy is available <u>here</u>.

4. Background

4.1. What are Infant Inclined Products

The term '**Infant Inclined Products**' broadly describes products for infants that position the infant at an inclined angle. The products may be for sleep, or for other purposes, such as play, resting or soothing an infant.

The risks associated with an inclined position arise when sleep occurs. As a result, the ACCC considers that there should be a distinction made between products that are for sleep, and products that are for another purpose. Different regulatory responses may be appropriate depending on the category of the product. The ACCC proposes the following two categories:

- 'Inclined Sleep Product' means any product that is designed, intended, marketed or
 contains any representation that it is suitable for an infant to sleep in, and has a sleep
 surface that has an inclined angle.
- 'Inclined Non-Sleep Product' means any infant product that is not designed, intended or marketed for sleep, and does not contain any representation that it is suitable for sleep, but does have a surface that has an inclined angle which an infant may fall asleep on in practice.

Inclined Sleep Products are of most concern to the ACCC because research has found that infant sleeping at an inclined angle is unsafe (see Part 4.2). Given the greater risks associated with these products, it is likely that stronger risk controls are required (see Part 9). However, we remain concerned about Inclined Non-Sleep Products because it is foreseeable they will be used for sleep (either intentionally or otherwise). These risks may not be as high and different controls may be appropriate.

Table 1 shows proposed classifications of product types in the categories of Inclined Sleep Products and Inclined Non-Sleep Products. See Section 9 for more information about the options under consideration for each product category.

Table 1: Proposed classification of Infant Inclined Product categories

Product category	Example product types	Notes
Inclined Sleep Product	Inclined sleepers, Baby hammocks, Baby nests, Bassinets, Bed-side sleepers, Co-sleeping products, Moses baskets, Sleep positioners (such as wedges, pillows)	These products will only be considered Inclined Sleep Products if they are designed, intended, marketed or contain any representation that they are for sleep and they have an inclined sleep angle.
	Marketing claims such as 'napping', 'sleeper', 'dreamer'	
Inclined Non- Sleep Product	High chairs, Jolly jumpers, Infant swings, Bouncer seats, Rockers, Baby capsules, Baby carriers, Child restraints for use in motor vehicles, Prams and strollers	These products should not be designed, intended, marketed or contain any representation that they are for sleep.

The classifications in Table 1 are indicative only and submissions are welcome on the classification of such products. Each specific product should be considered using an objective assessment in accordance with the proposed definition of 'Inclined Sleep Product' i.e. whether a particular product is designed, intended, marketed or contain any representation that it is for sleep.

The ACCC notes that some products that may fall within these definitions are already subject to a mandatory standard, such as baby walkers, prams, strollers, car seats, household and portable cots.¹¹ If a regulatory response is taken, consideration will be given to whether exemptions should apply. These products could be subject to the additional requirement that they not be marketed for sleep and that they include suitable warnings in relation to infant sleep.

The ACCC considers that medical devices are not Infant Inclined Products, and notes that medical devices are subject to regulation by the Therapeutic Goods Administration (TGA). The ACCC notes that should regulatory action be taken there may be other product categories that should be excluded from scope.

Questions

- 1. Do you consider the definitions and categorisation of Infant Inclined Products in Table 1 is accurate? Are there additional categories that should be added, removed or excluded? Please provide the reasons for your response.
- 2. What data or information can you provide about the number and type of product lines sold in Australia that might be considered an Inclined Sleep Product and/or Inclined Non-Sleep Product? Of those products how many:
 - (a) would be categorised as such due to marketing claims?
 - (b) comply with a relevant international mandatory or voluntary standard?
- 3. What data or information can you provide on the size and value of the Australian market for Inclined Sleep Products and/or Inclined Non-Sleep Products?

4.2. The hazard

The design of Infant Inclined Products, in particular the incline, curvature of the backrest and soft sleeping surface can be hazardous for infants when sleeping. Suffocation, asphyxiation or carbon dioxide re-breathing can occur when an infant sleeps in an inclined position. Additional factors can further compound these vulnerabilities, such as respiratory tract infections, mild illnesses, exposure of cigarette smoke, drugs or alcohol and prematurity of birth.

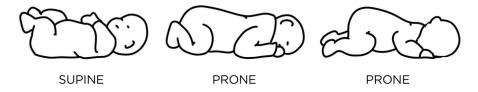
¹¹ More information about mandatory standards can be found on the Product Safety Australia website: here.

The Mannen Report

The US-CPSC reported 1,108 incidents and 73 fatalities in the United States associated with the use of Infant Inclined Products that occurred from January 2005 to June 2019. As a result of this, on 31 October 2019, the US-CPSC cautioned consumers to cease using products that fall within our definition of Inclined Sleep Products. The US-CPSC also commissioned and published a study by biometrics expert Erin Mannen PhD to conduct infant testing and evaluate the design of such products (the Mannen Report). To determine this, the study:12

- analysed incident reports relating to the products
- analysed various Inclined Sleep Products within the product category to determine design differences
- undertook a biomechanics study to understand how infants between 2-6 months of age
 move and use their muscles on inclined surfaces compared to a flat sleep product,
 including the strength required to change positions (supine prone, shown in Figure 1) or
 to lift their heads.

Figure 1: supine and prone positions



The Mannen Report found that infant fatalities in Inclined Sleep Products are likely due to asphyxiation caused by:¹³

- a) Suffocation, where the mouth and nose are covered by an external factor blocking the infant's airway. This is a particular issue where an infant rolls onto their side or stomach, causing their airway to be blocked by the fabric or padding of the side or base of the product.
- b) **Positional asphyxiation**, where the infant remains in a face-up position and:
 - i. the incline of the product causes the infant's head to fall forward during sleep, pressing the chin down towards the chest (chin to chest position), blocking the airway and reducing oxygen flow over time; or
 - ii. the infant's face has partial or near contact with the side of the product, restricting airflow and reduced oxygen, leading to carbon dioxide rebreathing.

In addition, the Mannen Report found:14

- The prone position in the Inclined Sleep Product puts infants at higher risk of suffocation.
- Inclined Sleep Products provide an opportunity for infants to roll for the first time and do so more easily from the supine to prone position.

E Mannen, 'Biomechanical analysis of inclined sleep products', Little Rock: University of Arkansas, 2019, p 3, accessed 10 June 2021.

E Mannen, 'Biomechanical analysis of inclined sleep products', p 5.

¹⁴ E Mannen, 'Biomechanical analysis of inclined sleep products', p 60.

- Inclined surfaces and Inclined Sleep Products resulted in significantly higher muscle activity, which may lead to quicker fatigue and suffocation if an infant finds themselves in a prone position in an Inclined Sleep Product.
- Some Inclined Sleep Products required greater neck adjustments during prone
 positioning, indicating that infants may struggle to adjust their posture to enable
 breathing.

The Mannen Report concluded that:

- Products with an incline angle of 10 degrees or less are likely safe for infant sleep and products with an incline of 20 degrees or greater are not safe for sleep. Further biomechanical testing is required to determine if products with angles between 10 and 20 degrees are safe for sleep.
- The surface of products should have a minimum rigidity, no curvature, and materials used should minimise rebreathing of the same air.
- Caregivers of infants who are sick, chronically ill, or born prematurely should exercise additional caution when using Inclined Sleep Products. Additional research should go into crafting warnings and guidance.

Overall, the Mannen Report stated that none of the Inclined Sleep Products tested or evaluated were safe for infant sleep based on the results of the incident report analysis, product analysis and the biomechanics study.¹⁵

The ACCC is seeking feedback on whether stakeholders consider an incline limit is appropriate, and if so, what the limit should be. As a preliminary view, the ACCC considers an incline limit of 10 degrees may be an appropriate threshold to manage the safety risk for Infant Inclined Products on the basis that:

- an incline angle of 10 degrees is gradual (and almost flat) and therefore allows some variance in manufacturing, and
- initial consultation with medical stakeholders and the Mannen Report suggest that products with an incline up to 10 degrees are likely to be safe.

The ACCC is aware that proposed regulation in the United States also uses an angle of 10 degrees, however Canada and New Zealand impose a stricter 7 degree limit (see discussion in Part 8 below).

Questions

4. Please provide any research or evidence that supports or contradicts an incline limit, including at what incline angle the limit should be.

¹⁵ E Mannen, 'Biomechanical analysis of inclined sleep products', p 61.

Safe sleep advice

In Australia, safe sleeping advice and education is made available to parents and caregivers via:

- The health departments in each state and territory provide online information and resources. Many have safe sleeping standards or guidelines for healthcare providers to promote consistent safe sleeping practices.¹⁶
- Safe sleep guidelines published by Red Nose Australia (Red Nose) recommend infants sleep on a flat, firm surface to reduce the risk of Sudden Infant Death Syndrome (SIDS).¹⁷ This advice aligns with international best practice and has been consistent for decades.¹⁸
- 'SIDS and Kids' are not-for-profit organisations based in South Australia, Tasmania and the Northern Territory.¹⁹ These organisations provide state-based education programs and undertake public awareness campaigns in relation to safe sleep practices.

Questions

5. Do you consider that parents and carers of infants are sufficiently educated on safe sleeping practices generally, and also specifically in relation to Infant Inclined Products? If so, who are the leading providers of this education? Do you consider that increased consumer education is required? Please provide the reasons for your response.

4.3. Consultation

Since the ACCC announced it would be conducting a safety review of Infant Incline Products, ²⁰ we have consulted with select stakeholders and international regulators regarding the findings of the Mannen Report and the safety of Infant Inclined Products supplied in Australia. These stakeholders included medical professionals, technical experts, industry members and advocacy groups. Consultation with these stakeholders has contributed to the ACCC's consideration of this issue.

5. Fatalities and injuries

5.1. Fatalities in Australia

The ACCC is not aware of any Australian fatalities directly attributed to Inclined Sleep Products. However, between 2004 to March 2020, 2 infant fatalities occurred in Australia in infant swings or rockers (both classified as 'Inclined Non-Sleep Products).²¹ The cause of death for both these fatalities is unexplained.

SA Health, <u>Safe Infant Sleeping Standards</u>. See also Health VIC, <u>Safe sleeping of infants</u>, 2018. WA Department of Health, <u>Safe Infant Sleeping Policy 2019</u>. Queensland Department of Health, <u>Safe Infant Sleeping Rouse Sharing</u>, 2013. ACT Health, <u>Safe Sleeping Guidelines – Neonates and Infants</u>, 2017.

¹⁷ Red Nose, 'Why should you sleep your baby on their back?,' Red Nose website, 2021, accessed 10 June 2021.

In the UK, the Lullaby Trust provides similar advice on the best sleeping position for infants. Lullaby Trust '<u>The best sleeping position for your baby</u>.'

¹⁹ For example SIDS and Kids South Australia website, accessed 1 July 2021.

²⁰ ACCC, <u>Safety review of baby bouncers, rockers and inclined sleep products</u>, 12 July 2019.

Data extracted from the Queensland Child Death Register and provided to the ACCC by the Queensland Family and Child Commission

5.2. Mandatory injury reports

Section 131 of the Australian Consumer Law (ACL) requires suppliers of consumer goods to report deaths, serious injuries or illnesses caused by consumer goods to the ACCC within 2 days of becoming aware of the incident. These reports are called mandatory injury reports.

Since January 2019, the ACCC has received 7 mandatory injury reports relating to Infant Inclined Products. However, these reports do not all relate to the incline of the product or infant sleeping.

The mandatory injury reports recorded by the ACCC may not constitute all incidents that have occurred in Infant Inclined Products due to under-reporting. Additionally, near misses are not required to be reported.

5.3. Consumer reports

Since January 2019, the ACCC has received 13 contacts from consumers relating to Infant Inclined Products. Of the 13 contacts:

- 5 related to bouncers
- 3 related to rockers
- 5 related to co-sleeper bassinets with an incline function.

The majority did not relate to infant sleep and injury occurring from it.

One state consumer affairs agency, the Western Australia Department of Mines, Industry Regulation and Safety, received 10 consumer reports relating to Infant Inclined Products. Again, the reports did not relate to infant sleeping.

5.4. International fatalities and injuries

Figure 2 depicts the number of fatalities and injuries that occurred each year in the United States between June 2010 and June 2019.

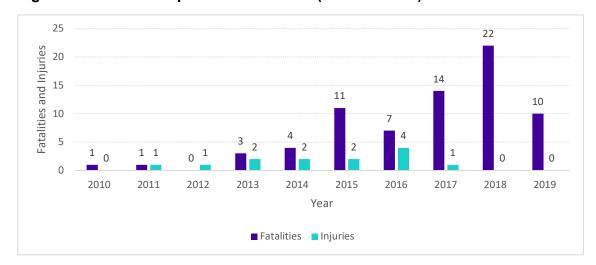


Figure 2: Inclined Sleep Product fatalities (United States)

Source: Mannen, E. M., et al. "Biomechanical analysis of inclined sleep products." Little Rock: University of Arkansas (2019), p 74

More recently, materials published by the US-CPSC record that between 1 January 2019 and 31 December 2020, there were 10 fatalities associated with the use of an Inclined Sleep Product.²² In 3 of these incidents, infants that were placed on their back and rolled over, resulting in suffocation or positional asphyxiation. All infants were 3 to 4 months old.

The United Kingdom has reported one infant fatality. The incident involved the Bednest co-sleeper that can be tilted and has sides that fold down to a half open position.²³ The infant was found on her chest, with her head over the side of the product and had died of positional asphyxia.²⁴ This product was recalled in the European Union in May 2016. The product was also subject to a recall in Australia in February 2016.²⁵

The ACCC has contacted product safety authorities in Canada, New Zealand and the European Union, none of which reported fatalities.

Questions

- 6. What data or information can you provide about injuries, fatalities or near-misses caused by Inclined Sleep Products and/or Inclined Non-Sleep Products?
- 7. What research are you aware of that is directed to the prevention, or prevalence of injuries or fatalities caused by Inclined Sleep Products and/or Inclined Non-Sleep Products?

²² US-CPSC, Briefing Package for a draft final rule for infant sleep products, 2021 accessed 10 June 2021, at p 25.

H Williams, 'Bednest: Everything you need to know about the safety of the Baby Crib.' Made for Mums, updated December 2016, accessed 10 June 2021. See also K Gilmour, 'Bassinet recall issued,' CHOICE, 22 February 2016. Accessed 10 June 2021.

²⁴ BBC News, 'Bednest cot death family agree settlement.' 5 April 2017. Accessed 10 June 2021.

²⁵ For more information about this recall, please see the Product Safety Australia website <u>here</u>.

6. Voluntary recalls

Section 128 of the ACL states that a voluntary safety recall of consumer goods may be initiated by suppliers in the following circumstances:

- the goods will or may cause injury
- a reasonably foreseeable use (including a misuse) of the goods will or may cause injury
- · the goods do not comply with a relevant safety standard
- the goods are subject to an interim or permanent ban.

Since 2019, there have been 2 voluntary recalls of Infant Inclined Products in Australia (see table 2). These products are collectively linked to 40 fatalities in the United States.

The recall return rates for these recalls is low, compared to other voluntary recalls carried out in Australia.

Table 2: Recalls of Infant Inclined Products in Australia since 1 January 2019

Date	Product name	Product Safety Australia recall number
2 May 2019	Mattel Pty Ltd - Fisher-Price Rock 'N Play Sleeper	PRA No. 2019/17520 ²⁶
6 June 2019	Kids II Australia Pty Limited — Various Rocking Sleepers	PRA No. 2019/17587 ²⁷

Questions

8. What measures could be taken to improve recall return rates of Infant Inclined Products and other products more generally? What barriers are there for consumers returning recalled Infant Inclined Products and do you consider these apply to all children's products? Please provide the reasons for your response.

7. Australian Regulation

7.1. Australian Consumer Law

The Australian product safety regime, which is set out in the ACL, does not currently impose any mandatory safety standards that specifically capture Infant Inclined Products. There are mandatory safety standards that specify design and construction, performance and safety labelling for 'folding cots' and 'household cots'. However, the proposed definition of Infant Inclined Products falls outside the scope of these standards.²⁸

Currently, Australia does not have a general safety provision which prohibits unsafe goods from being supplied (see discussion below in Part 8) and is therefore reliant on other avenues, including consumer guarantees (ACL Part 3-2) to give consumers the right to a

More information about this recall can be found on the Product Safety Australia website: here.

²⁷ More information about this recall can be found on the Product Safety Australia website: here.

²⁸ More information on mandatory safety standards is available on the Product Safety Australia website: here.

refund, or compensation for damage and loss caused by an unsafe product.²⁹ Among other things, the consumer guarantees in the ACL specify that goods should be of acceptable quality, which is defined in the ACL as being safe, fit for purpose and free from defects.

7.2. Voluntary standards

Currently there are no voluntary Australian standards for Infant Inclined Products. However, some Infant Inclined Products sold in Australia adhere to relevant international voluntary standards (see Table 3 and 4).

²⁹ More information about Consumer Guarantees can be found on the ACCC website: <u>here</u>.

Table 3: United States voluntary standards

	ASTM F3118- 17a: Standard Consumer Safety Specification for Infant Inclined Sleep Products	ASTM F2167-19: Standard Consumer Safety Specification for Infant Bouncer Seats	ASTM F2088-20: Standard Consumer Safety Specification for Infant Swings	ASTM F2906-13: Standard Consumer Safety Specification for Bedside Sleepers
Scope	Products, including accessories, with an inclined sleep surface that are intended and marketed as sleeping accommodation for infants up to 5 months old.	Freestanding products that support an infant bouncing.	Products with a powered mechanism providing a swinging or gliding seat/cradle. Does not cover products intended for sleep.	Products that provide a sleeping environment for infants and that are secured to an adult bed.
Does it mandate a maximum angle of incline?	Yes, maximum incline of 30 degrees.	No	No	No
Labelling requirements	Yes To address fall and suffocation hazards.	Yes To address fall and suffocation hazards.	Yes Warnings should state that products are not safe for unsupervised sleep.	Yes To address fall, suffocation and entrapment hazards.

Table 4: European voluntary standards

	EN 12790:2002 Child Care Articles: Reclined Cradles	EN 16232:2013 Child use and Care Articles – Infant Swings
Scope	Fixed or folding reclined cradles for children up to 9kg or those unable to sit up unaided.	Infant swings intended for children up to a weight of 9kg or unable to sit up unaided.
Does it mandate a maximum angle of incline?	No	No
Labelling requirements	Yes Warnings to never leave the child unattended and the product is not intended for prolonged sleep.	Yes Warnings to never leave the child unattended and the product is not intended for prolonged sleep.

Questions

- 9. If you are a supplier or manufacturer of Infant Inclined Products, do you adhere to the requirements of any international standards or regulations? How have you implemented these?
- 10. To what extent do international standards or regulations address the safety risks associated with Infant Inclined Products? Please provide the reasons for your response.

8. International approaches

8.1. Canada

The Canadian *Cribs, Cradles and Bassinets Regulations* relate to products that have the 'primary function' of providing sleeping accommodation for a child.³⁰ These regulations relate to specific product types, and are not limited by the age of the child (for example, it is expected that bassinets will be used for infants 3-4 months of age, however cribs may be used until a child reaches the age of 2).³¹

The regulations permit a maximum incline angle of 7 degrees and also regulate several other aspects of product design, such as mattress design, on-product warnings, stability and height of sides. The Canadian government reports that the use of a 7 degree incline was based on a risk assessment conducted by Health Canada, including consideration of relevant research.³²

Health Canada provides guidelines to industry about the factors it will consider when interpreting whether the 'primary function' of a product is to provide sleeping accommodation for a child.³³ These factors include the name of the product, marketing, listed use or function, recommended use and appearance. For example, a product with the name 'sleeper' in the title or a photograph of an unsupervised infant sleeping in the product would fall within the Canadian regulations. Products marketed solely for play, resting or soothing an infant are excluded, however, Health Canada advises consumers that products that do not fall within the regulations are not suitable as sleeping environments and infants should be supervised.³⁴

8.2. New Zealand

The New Zealand *Inclined Infant Sleep Products Unsafe Goods Notice* specifies that products that are designed, intended or marketed for infant sleep must not have an incline angle of more than 7 degrees.³⁵ This requirement is currently an interim ban only, and does not regulate other aspects of product design. The ban applies to any product that:

- is intended to contain a child under one year of age
- is designed, intended, marketed, or contains any representation that it is suitable for an infant to sleep in

³⁰ Cribs, Cradles and Bassinets Regulations, SOR/2016-152.

³¹ Health Canada, Industry Guide for the Classification of Cribs, Cradles, Bassinets and Related Products, 2015.

³² Government of Canada, <u>Regulatory Impact Analysis Statement</u>, 2015; S Beal 'The danger of freely rocking cradles', Journal of Paediatric Child Health, 1995, p 38-40.

³³ Health Canada, 'Industry Guide for the Classification of Cribs, Cradles, Bassinets and Related Products'.

³⁴ Health Canada, 'Industry Guide for the Classification of Cribs, Cradles, Bassinets and Related Products'.

³⁵ Unsafe Goods (Inclined Infant Sleep Products) Amendment Notice 2020 (NZ).

- is freestanding, or designed to be attached to another structure, and
- has a sleep surface angled more than 7 degrees from the horizontal.³⁶

Products marketed for play only, such as bouncers, are excluded.³⁷ There are several other exclusions for products such as medical devices, infant hammocks, car seats or capsules and prams or strollers.³⁸

Products that provide the warnings specified within European Standard EN 12790:2009 (see Table 4) are also excluded from the ban, because the product is not considered to be designed, intended or marketed as suitable for sleep. The relevant warning states:

WARNING

- Never leave the child unattended.
- It is dangerous to use the reclined cradle on an elevated surface, e.g. a table.
- This reclined cradle is not intended for prolonged periods of sleeping.
- Always use the restraint system.³⁹

8.3. United States

The Safe Sleep for Babies Act 2021 passed in the United States House of Representatives on 23 June 2021.⁴⁰ The Safe Sleep for Babies Act will now need to be considered by the Senate. If made into law, this legislation would ban inclined sleepers for infants regardless of the date of manufacture. Inclined sleepers for infants are defined as products with an inclined sleep surface greater than 10 degrees that are intended, marketed or designed to provide sleeping accommodations for an infant up to one year of age.⁴¹

Separately, on 2 June 2021 the US-CPSC approved the development of a new mandatory standard in relation to products marketed or intended for sleep for infants under 5 months of age.⁴² The US-CPSC has stated that a product will be considered to be marketed for sleep if its product packaging, marketing materials, inserts or instructions indicate that the product is for sleep, or includes pictures of sleeping infants.

From mid-2022, any products intended or marketed for sleep that do not already meet the requirements of an existing US-CPSC mandatory standard for infant sleep products must be tested to confirm that the angle of the sleep surface is 10 degrees or lower. Currently, there are 5 mandatory safety standards for full sized cribs, non-full-sized or baby cribs, bassinets or cradles, play yards and bedside sleepers in the United States.⁴³

Once this mandatory safety standard is in force, it will be unlawful to sell, offer for sale, manufacture for sale, distribute in commerce or import into the United States, any products marketed or intended for infant sleep that have an incline greater than 10 degrees, or otherwise do not meet the standard.

³⁶ Unsafe Goods (Inclined Infant Sleep Products) Amendment Notice 2020 (NZ), cl 5. See also Product Safety Trading Standards, 'Inclined infant sleep products Unsafe Goods Notice.'

³⁷ Unsafe Goods (Inclined Infant Sleep Products) Amendment Notice 2020 (NZ), cl. 4.2.e.

 $^{^{38}}$ Unsafe Goods (Inclined Infant Sleep Products) Amendment Notice 2020 (NZ), cl 4.a, 4.b, 5.

The European Committee for Standardization, EN 12790:2009 Child Use and Care Articles – Reclined cradles, cl 7.2.

⁴⁰ Schakowsky, Cárdenas Applaud House Passage of Safe Sleep for Babies Act, 23 June 2021.

H.R. 3172 – Safe Sleep for Babies Act of 2021.

⁴² US-CPSC, <u>CPSC Approves Major New Federal Safety Standard for Infant Sleep Products</u> [media release], US-CPSC, 2 June 20121, accessed 18 June 2021.

⁴³ US-CPSC, Final Rule: Safety Standard for Infant Sleep Products, at p 38.

8.4. European Union and the United Kingdom

General safety provisions operate in the European Union and the United Kingdom. Article 3(1) of the *European General Product Safety Directive*⁴⁴ states that producers shall be obliged to place only safe products on the market. A product is safe if it meets all statutory safety requirements under European or national law.

The United Kingdom also has similar legislation as a result of its previous membership of the European Union. The *General Product Safety Regulations 2005* (UK) require all products to be safe in their normal or reasonably foreseeable usage.⁴⁵ Where this obligation is not met, enforcement authorities have powers to take appropriate action.

9. Possible risk controls

Unlike other infant products such as cots or transportation capsules, Infant Inclined Products as a class of products fall outside the scope of existing Australian mandatory safety standards. The ACCC is considering a number of approaches to reduce the risks associated with Infant Inclined Products. Possible options may include:

- introduction of safety and/or information standards
- a prohibition (temporary or permanent) on the sale of certain categories of Infant Inclined Products
- voluntary standards, and/or
- consumer education and awareness.

The ACCC is seeking feedback on the likely effectiveness and cost of implementation of these options. Consideration will be given to the additional costs that regulatory intervention would impose on Australian suppliers, and whether such regulation might create barriers to trade. As Inclined Sleep Products and Inclined Non-Sleep Products are generally manufactured overseas, any regulatory response would allow a transitional period to enable manufacturers and suppliers time to implement any changes or testing required. If a regulatory intervention is pursued, further consultation will occur.

The risk control pursued in response to Infant Inclined Products may include more than one of the options outlined. Table 5 below includes possible regulatory responses, taking into account the different risk profiles of each product category.

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General Product Safety Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [2002] OJ L 11, p. 4-17.

⁴⁵ General Product Safety Regulations 2005 (UK).

Table 5: Possible regulatory options

Product category	Possible regulatory response	Example product types
Inclined Sleep Product	Interim or permanent ban, or both	Inclined sleepers, Baby hammocks, Baby nests, Bassinets, Bed-side sleepers, Co-sleeping products, Moses baskets, Sleep positioners (such as wedges, pillows)
		Marketing claims such as 'napping', 'sleeper', 'dreamer'
Inclined Non-Sleep Product	Safety and/or information standard requiring the product and/or packaging to contain warnings	High chairs, Jolly jumpers , Infant swings, Bouncer seats, Rockers, Baby capsules, Baby carriers, Child restraints for use in motor vehicles, Prams and strollers

Safety standards

Section 104 of the ACL enables the Commonwealth Minister to make a mandatory safety standard imposing certain requirements that 'are reasonably necessary to prevent or reduce risk of injury to any person'. If the Minister makes a safety standard, it may include requirements for the composition, contents, method of manufacture, design, construction, contents, finish, performance or packaging of consumer goods.

Section 105 of the ACL allows the Minister to declare a standard (or part thereof), prepared or approved by Standards Australia or by an association prescribed by the regulations, to be a safety standard under the ACL.

It is an offence to supply goods that do not comply with mandatory standards and pecuniary penalties may be applied.

Information standards

Section 134 of the ACL gives the Commonwealth Minister the power to make mandatory information standards to ensure that consumers are provided with important information about a product to assist them in making a purchasing decision.

In some instances, an information standard may be used in addition to a safety standard.

Interim ban

Section 109 of the ACL grants the Commonwealth Minister and the relevant state and territory Ministers the power to impose an interim ban on consumer goods or product-related services. A Minister may impose an interim ban if they consider:

- consumer goods of a particular kind will or may injure someone.
- as a result of the service being supplied, the product will or may injure someone,
- using or misusing the product, or the product to which the service relates, in a 'reasonably foreseeable' way will or may injure someone, or
- another Minister has imposed an interim ban on the product or service, which is still in force.

All interim bans last for 60 days unless extended by the relevant Minister for up to another 60 days.

Permanent bans

Section 114 of the ACL grants the Commonwealth Minister the power to declare a permanent national ban on a product or product-related service.

Section 132 of the *Competition and Consumer Act 2010* (CCA) requires that suppliers must be notified and given an opportunity to call a conference with the ACCC before the ban is imposed. However, if the Commonwealth Minister determines that there is imminent danger to the public, suppliers will be notified and have an opportunity to call a conference with the ACCC at the time, or shortly after the ban is imposed.

Voluntary Australian standards

As outlined above, there are no Australian voluntary standards for Infant Inclined Products. Any person or organisation can submit a project proposal to Standards Australia⁴⁶ to seek the development or amendment of a standard. If new Australian voluntary standards were implemented for the Infant Inclined Product category or for particular products within this category, consideration would need to be given to the content and potential efficacy of these standards.

Increased consumer education

A recent study surveyed Queensland primary caregivers of infants approximately 3 months of age to explore the prevalence of infant care practices and awareness of safe sleep recommendations. The study found that only 12.8% of families who participated in the survey reported sleeping routines and practices that were consistent with all 6 Red Nose Safe Sleeping Guidelines. Nearly half of the infants were reported to routinely sleep on surfaces for night or day sleeps that are not recommended for safe sleep.

Increased consumer education (either in conjunction with regulatory intervention or in isolation) may increase consumer awareness of safe sleeping practices and allow consumers to make more informed decisions in relation to the purchase and use of Infant Inclined Products.

Improved marketing and on-product warnings

As the risk associated with an inclined position in infants arises when sleep occurs, a key consideration is preventing sleep from occurring in the inclined position, and informing consumers of the risk. The ACCC considers that most Inclined Sleep Products are likely to fall within the proposed definition due to marketing claims, as opposed to their design or intended purpose. Given this, changes to ensure that marketing does not suggest Infant Inclined Products are safe for sleep may be an effective and efficient method of minimising the risk. Manufacturers and suppliers could agree to implement changes to their marketing and packaging to ensure Infant Inclined Products are not marketed as suitable for sleep, and that consumers are adequately informed of the risks of infant sleep in an inclined position.

A focus on appropriate marketing and on-product warnings, as distinct from changes to product design, could ensure that products to soothe or rest infants whilst supervised remain available to consumers, and limit regulatory burden on industry.

⁴⁶ Standards Australia is a not-for-profit organisation that develops voluntary standards. More information is available on their website: here.

⁴⁷ R Cole, J Young, L Kearney, JMD Thompson, 'Infant care practices and parent uptake of safe sleep messages: a cross-sectional survey in Queensland, Australia', BMC Pediatr. 2020 Jan 21;20(1):27.

Questions

- 11. Do you consider that any of the following regulatory responses would prevent injuries or fatalities from Inclined Infant Products in Australia, either on their own or as part of a combined approach? Please provide the reasons for your response:
 - a. a prohibition on the sale of Inclined Sleep Products (either temporary or permanent)
 - b. a mandatory safety standard for Inclined Sleep Products and/or Inclined Non-Sleep Products
 - c. a mandatory information standard for Inclined Sleep Products and/or Inclined Non-Sleep Products
- 12. What do you consider to be the costs involved in the implementation of the regulatory responses set out at question 11? Please provide the reasons for your response.
- 13. What other options do you consider may be effective in reducing the risks posed by Infant Inclined Products?
- 14. If you are a relevant organisation or agency, would you consider undertaking a consumer education campaign or assist the ACCC in increasing consumer awareness? If yes, please explain how you would assist the ACCC.
- 15. Please provide any other information you consider may be relevant to the ACCC's policy considerations in relation to a response to the risks associated with Infant Inclined Products.

10. Next steps

Submissions to the questions set out in this Issues Paper will assist the ACCC in developing a further understanding of Infant Inclined Product risks and the possible responses to that risk. The ACCC encourages you to respond to the questions that are relevant to you, and to raise any additional issues that you consider relevant. Submissions are due by 16 August 2021.

Submissions in response to this Issues Paper will inform the ACCC's development of a policy position on this issue, including whether it should recommend regulation. After reviewing submissions to the Issues Paper, the ACCC will make a further public announcement about its position in relation to Infant Inclined Products. Should a regulatory response remain a viable option, the ACCC will seek to engage more closely with relevant stakeholders and release a consultation paper for public comment.