



# Review of the mandatory safety standard for babies' dummies

Consultation paper

September 2016



### Disclaimer

The Australian Competition & Consumer Commission (ACCC) has developed this consultation paper to seek the views of stakeholders about the mandatory safety standard for babies' dummies.

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## 1. Introduction

The ACCC is reviewing the mandatory safety standard that sets out requirements for construction, design and labelling of babies' dummies because:

- The mandatory safety standard references AS2432:1991 Babies' Dummies, a 1991 voluntary Australian standard, which the 2015 version replaces.
- There is an interpretation problem with the 'shield test' in the mandatory safety standard meaning safe dummies can fail the safety standard. The 2015 voluntary Australian standard resolves this problem.
- The ACCC is considering whether to consolidate the safety provisions of the two bans on babies' dummies with unsafe decorations and unsafe dummy chains into the mandatory safety standard. The 2015 voluntary Australian standard includes provisions about unsafe decorations on dummies. This would maintain the safety requirements and the two bans would become redundant and could be revoked.
- The ACCC is considering trusted international standards as ways to demonstrate compliance.

**The consultation process outlined in this paper may be the only opportunity for you to provide input into this review.**

**You are encouraged to make a submission.**

## 2. Policy options

This consultation paper discusses four policy options:

- |          |   |
|----------|---|
| Option 1 | Keep the current mandatory safety standard (status quo).  |
| Option 2 | Allow the 1991 and 2015 voluntary Australian standards and incorporate the bans on dummy chains and dummies with unsafe decorations.              |
| Option 3 | Allow the 1991 and 2015 voluntary Australian and European standards and incorporate the bans on dummy chains and dummies with unsafe decorations. |
| Option 4 | Revoke the mandatory safety standard.   |

## 3. Background

A babies' dummy is comprised of a rubber or soft plastic teat, a hard plastic shield with holes, and a ring or handle to hold the device. Parents typically offer them to an infant from newborn. Infants will commonly use the dummy until two to three years of age, and the number of users and frequency of use diminishes with age.

The use of babies' dummies is common in Australia. A 2012 study of 670 first-time mothers found 69 per cent of infants used a dummy.<sup>1</sup>

The Australian market for babies' dummies is small when compared to the markets in Europe and the United States. The manufacture and importation of babies' dummies for the Australian market is limited to a small number of businesses. There is one local Australian manufacturer and all other products are imported. This is likely to be attributed to difficulties in entering this market given the specialised equipment required for manufacturing.

Babies' dummies are available from a variety of retailers including pharmacies, supermarkets, department stores, specialist infant product stores, discount variety chains and online stores.

The international industry reference point for babies' dummies appears to be the European standard. The 2015 voluntary Australian standard for babies' dummies aligns more closely with the European standard than previous version of the voluntary Australian standard.

In 2011, in response to new 'baby bling' products coming into the Australian market that posed a choking and inhalation hazard to babies, the Australian Government declared permanent bans on dummies with unsafe decorations and dummy chains with unsafe decorations.

## 4. Death and injuries

Prior to 2006, there were an increasing number of incidents of dummies coming apart during use or being stuck in infant's mouths posing a serious choking hazard.<sup>2</sup> At that time, there were no reported deaths in Australia associated with dummies. The ACCC also made international inquiries and we identified no reports of injuries or deaths.<sup>3</sup>

A recent search of coronial data has not identified any reports linking deaths to babies' dummies in Australia.<sup>4</sup> In addition, ACCC injury data has not identified any reports of injuries associated with babies' dummies. There have been some more recent reports of 'near miss' incidents associated with dummies in the United Kingdom and in the United States (US).<sup>5</sup>

## 5. The current safety standard

In 2006, the Australian Government introduced a mandatory safety standard for babies' dummies.<sup>6</sup> The mandatory safety standard exists to reduce the risk of infants choking from unsafe dummies.

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<sup>1</sup> Mauch CE, Scott JA, Magarey AM, Daniels LA. *Predictors of and reasons for pacifier use in first-time mothers: an observational study*. BMC Pediatrics. 2012;12:7. doi:10.1186/1471-2431-12-7, viewed 17 May 2016, [www.ncbi.nlm.nih.gov/pmc/articles/PMC3323436/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3323436/)

<sup>2</sup> Australian Competition and Consumer Commission, *Regulation Impact Statement – Babies' Dummies, p.1.*, Australian Competition and Consumer Commission, Canberra, 2006, viewed 25 July 2016, [www.productsafety.gov.au/content/index.phtml/itemId/980712](http://www.productsafety.gov.au/content/index.phtml/itemId/980712)

<sup>3</sup> Ibid. p 3

<sup>4</sup> The ACCC reviewed confidential data from the National Coronial Information System (NCIS) ([www.ncis.org.au](http://www.ncis.org.au)). There may be deaths that we did not identify due to either missing data or because cases were still open.

<sup>5</sup> Katie Moore, 16/09/2015, The Mirror UK, *Mum's horror after 13-month-old baby girl almost chokes to death on dummy*, viewed 24 June 2016, [www.mirror.co.uk/news/uk-news/mums-horror-after-13-month-6452463](http://www.mirror.co.uk/news/uk-news/mums-horror-after-13-month-6452463)

Safer Products.gov, Mam dummies search, viewed 24 June 2016, [www.saferproducts.gov/Search/Result.aspx?b=Mam&dm=0&p=3&pcid=786&srt=0](http://www.saferproducts.gov/Search/Result.aspx?b=Mam&dm=0&p=3&pcid=786&srt=0)

<sup>6</sup> Ibid.

The mandatory safety standard defines a babies' dummy as an article used to pacify a baby. The teat is only for the baby to suck on, not for obtaining fluid. The mandatory safety standard sets out minimum requirements for:

- the size and integrity of the dummy shield
- the strength of the teat
- the size and integrity of a ring, handle and plug
- packaging type
- product identification
- warning labelling
- instructions for the use and hygienic care of a dummy.

### **Permanent bans on dummies with unsafe decorations and on dummy chains with unsafe decorations**

The permanent bans on dummies with unsafe decorations<sup>7</sup> and dummy chains with unsafe decorations<sup>8</sup> both came into effect in September 2011.

Dummies with unsafe decorations include those bearing crystals, beads or other similar ornaments. The ornaments can detach from the dummy and become a small parts choking, inhalation or ingestion hazard, creating a risk of death, illness or injury to the baby.

The ban on dummy chains with unsafe decorations applies to pins, ribbons, strings, cords, chains, twines, leathers, yarns or any other similar article to which there are crystals, beads or other similar ornaments attached, which are designed to be attached to babies' dummies. These ornaments can detach and become a small parts choking, inhalation or ingestion hazard.

The 2015 voluntary Australian standard and the European standard specify requirements to address the hazard of dummies with unsafe decorations.

The ban on dummy chains with unsafe decorations includes requirements referenced in the European Dummy Chain Standard.

### **Voluntary Australian standard**

The mandatory safety standard references sections of the 1991 voluntary Australian standard. In 2015, Standards Australia published an updated voluntary Australian standard for dummies. The 2015 voluntary Australian standard includes new requirements that deal with decorations on dummies, consistent latex thickness and changes to warning labels and closely aligns with the European standard for babies' dummies.

In 2010, the ACCC commissioned testing of babies' dummies and found that inconsistent latex thickness contributed to structural weakness. The 2015 voluntary Australian standard has a requirement for latex thickness, although it does not reference a specific test method.

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<sup>7</sup> Federal Register of Legislation, Australian Government, Canberra ACT, viewed 24 June 2016, <https://www.legislation.gov.au/Details/F2011L01874>

<sup>8</sup> Federal Register of Legislation, Australian Government, Canberra ACT, viewed 24 June 2016, <https://www.legislation.gov.au/Details/F2011L01877>

The mandatory safety standard only prescribes those sections of the 1991 voluntary Australian standard considered reasonably necessary to prevent injury. The voluntary Australian standard includes quality requirements that are not safety related.

## 6. Compliance

The ACCC has regularly surveyed the market for babies' dummies, most recently in February 2016. This survey focused on safety labelling and packaging requirements. Where we identified non-compliance, this related to incorrect font size of the safety warning and absent Australian importer/distributor information.

Since 2010, the ACCC has received 20 reports about dummies. The main reasons for the reports were that the dummy fell apart or the teat had detached. Most of these reports related to dummies that the supplier had recalled or did recall later.

Since 2006, there have been 30 recalls of babies' dummies. Most recalls were for structural problems or a potential choking hazard with decorations or chains. In 2009, there were 17 recalls of babies' dummies. These recalls occurred following NSW Department of Fair Trading surveillance and testing. There were 11 recalls due to incorrect shield size, four due to teat detachment and two due to packaging issues.

The regular surveillance by the ACCC and other ACL regulators has found a sustained improvement in compliance since 2009. Since 2009, there have been two recalls of babies' dummies per year on average.

## 7. Standards assessment and comparison

The international standards for babies' dummies included in this review are the European standard and the US standard.

We use the following criteria when assessing international standards for use in Australia:<sup>9</sup>

- 1) Addressing safety concerns: Is there evidence that the international standard provides an acceptable level of consumer safety?
- 2) Comparable jurisdiction to Australia: Is the international standard published or developed by a legitimate standards body or government agency from an economy or nation with comparable economic and regulatory processes to Australia?
- 3) Applicability to the Australian context: Is the international standard applicable and sufficient in the Australian context?

Our consideration of the international standards referred to above when compared with the Australian mandatory safety standard is set out below.

### **European standard**

The European Committee for Standardization (CEN) developed the European standard. CEN is a not for profit standards organisation which develops standards for use in Europe. The European Commission has not yet recognised the European standard as a harmonised standard under the European Union General Product Safety Directive.

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<sup>9</sup> ACCC, International standards for the safety of consumer products - criteria for acceptance, ACCC policy principles, viewed 22 July 2015, [www.productsafety.gov.au/content/index.phtml/itemId/1014180](http://www.productsafety.gov.au/content/index.phtml/itemId/1014180).

The European standard specifies requirements for the safety of design, strength, durability and latex thickness of babies' dummies. The cleanliness and safety labelling (which includes the warning never to attach other ribbons or cords to the dummy) of the product are also specified.

The ACCC considers that the European standard provides an acceptable level of safety for consumers and is adequate for the Australian market. It is therefore suitable to be included in a policy option allowing compliance with trusted international standards.

## **US regulation**

The US Consumer Product Safety Committee (CPSC) developed the US standard, which is mandatory. Its role is similar to that of the ACCC Consumer Product Safety function.

The US standard is published in the Code of Federation Regulations at [16 CFR Part 1511](#) (2001).

There are some parallels between the US regulation, the mandatory safety standard and the 2015 voluntary Australian standard. These include the requirement that the dummy package does not contain any pin, ribbon, string, cord, chain, twine, leather, yarn or any other means of attachment and a warning not to tie the dummy around a baby's neck.

The US regulation differs from the 2015 voluntary Australian standard and the European standard in that:

- it does not specify the requirement for no decorations to be attached to any part of the dummy
- it does not specify requirements for the thickness of the rubber teat
- the required warning statement only addresses the strangulation hazard if the dummy is tied around the baby's neck and not the choking hazard posed by a worn, torn or broken teat.

The US regulation does not address the hazards of unsafe dummy decorations and inconsistent latex thickness. Consequently, it is not suitable to be included in a policy option allowing compliance with trusted international standards.

## **8. Reducing regulatory burden**

The ACCC has identified four potential areas to reduce the regulatory burden on suppliers of babies' dummies without compromising consumer safety.

### **Interpretation problems with the shield test**

The mandatory safety standard prescribes a test method for the dummy shield that relates to the alignment of the shield to the test template. The test method was from the 1991 voluntary Australian standard and suppliers found the test was ambiguous. The 2015 voluntary Australian standard adopts the European standard test method for the dummy shield that removes this ambiguity and any need for retesting which could occur under the current mandatory safety standard.



## **Streamlining regulations – ban on dummies with unsafe decorations**

Both the 2015 voluntary Australian standard and the European standard include clauses that prohibit applying unsafe decorations on dummies. Adopting these clauses from either of these standards would allow the ban on dummies with unsafe decorations to be revoked.

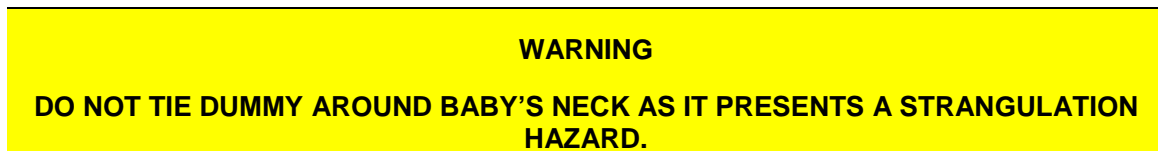
The US standard does not prohibit these decorations on babies' dummies.

## **Streamlining regulations – ban on dummy chains with unsafe decorations**

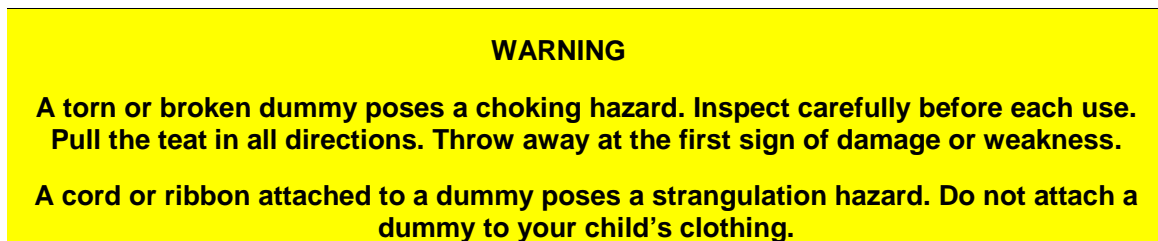
The ban on dummy chains with unsafe decorations includes requirements referenced in the European standard. Those requirements could be transferred to a new mandatory safety standard. This would allow the ban on dummy chains with unsafe decorations to be revoked.

## **Warning label**

The mandatory safety standard prescribes the following warning label for babies' dummies on the packaging:



The 2015 voluntary Australian standard prescribes the following warning label for babies' dummies either on the packaging or in a leaflet supplied with the product:



The new warning label is consistent with ISO 3864-2 *Graphic symbols – safety colours and safety signs- Part 2 Design principles for product safety labels*. A research report commissioned by the ACCC on the efficacy of warning labels showed that effective warnings:

- start with an alert word to draw attention and signal the degree of risk. The words DANGER, WARNING, CAUTION are the options that have come into common use. The alert is usually in capitals, with the remaining text in lower case. Key words can be in bold font.
- identify the risk
- specify a positive action to reduce the risk.

The warning in the 2015 voluntary Australian standard aligns with these criteria.

The current mandatory safety standard requires dummy packaging to display the warning, which means that dummy suppliers have to modify the packaging or produce special packaging for the Australian market.

The warning label requirements in the 2015 voluntary Australian standard allow suppliers to locate the warning on a pamphlet inside the packaging, which would allow them to add an Australian warning to the other international warnings that appear on the pamphlet inside the packaging. This new requirement would reduce the regulatory burden by allowing suppliers to use the same packaging across a range of jurisdictions.

The new warning text closely aligns with the warning text in the European standard so it would be reasonable to accept both the European warning as well as the 2015 voluntary Australian standard warning.

## 9. Detailed description of policy options

### Option 1 - Keep the current mandatory standard (status quo)

#### **Description**

Maintaining the current mandatory safety standard is the first policy option considered. The mandatory safety standard was imposed due to the risks of the teat separating from the dummy shield posing a serious choking hazard. Infants are particularly vulnerable to choking on small objects that may lodge in the throat or block the airway.

#### **Benefits**

Consumers would have the same level of protection they have now. Since the mandatory safety standard in 2006, design failures in babies' dummies have caused fewer injuries and no deaths.

There would be no increase in costs to business.

#### **Limitations**

It is likely that it will be difficult in the future to find testing organisations that will test to the 1991 voluntary Australian standard referenced in the mandatory safety standard. This may increase testing costs.

Maintaining the current mandatory safety standard will not provide the benefits of streamlining the regulation of babies' dummies by resolving the interpretation problems with the shield test, incorporating the requirements of the permanent bans on dummies with unsafe decorations and on dummy chains with unsafe decorations into a single regulation, and providing more flexible warning requirements.

Businesses would need to retest to the 1991 voluntary Australian standard when their dummies may already meet the European Standard.

Option 2 - Allow the 1991 and 2015 voluntary Australian standards and incorporate the bans on dummy chains and dummies with unsafe decorations.

### **Description**

An updated mandatory safety standard would include certain sections of the 2015 voluntary Australian standard. The regulation would also allow suppliers to sell babies' dummies that comply with the 1991 voluntary Australian standard.

Both the ban on dummies with unsafe decorations and the ban on dummy chains with unsafe decorations would be revoked. The safety requirements would be included in the new mandatory safety standard.

### **Benefits**

The new mandatory safety standard would ensure consumers are offered the same high level of protection they have now.

The 2015 voluntary Australian standard aligns closely with the European standard so importers would not have significant additional obligations when importing products for the Australian market. The regulation would be streamlined as the ban on dummies with unsafe decorations and the ban on dummy chains with unsafe decorations could be revoked.

### **Limitations**

Adopting the 2015 voluntary Australian standard, although it closely aligns with the European standard, means that for importers to ensure their products comply with a new mandatory safety standard, they would likely need to do additional testing to verify compliance.

The ACCC sought quotes on the cost of testing to the 2015 voluntary Australian standard that show it is marginally more expensive than the mandatory safety standard. However, this includes all sections of the voluntary standard, and if only selected sections of the voluntary standard were adopted, the costs would likely decrease.<sup>10</sup> Additionally if there was an increased demand for testing, that would likely put a downward pressure on testing costs.

Option 3 - Allow the 1991 and 2015 voluntary Australian and European standards and incorporate the bans on dummy chains and dummies with unsafe decorations.

### **Description**

An updated mandatory safety standard would allow suppliers to comply with either the superseded or the 2015 voluntary Australian standard or the European standard.

Both the ban on dummies with unsafe decorations and the ban on dummy chains with unsafe decorations would be revoked and the safety provisions incorporated into a new mandatory safety standard.

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<sup>10</sup> Quotes obtained from test laboratories.

## **Benefits**

Safety would not be compromised as the 2015 voluntary Australian standard aligns closely with the European standard. The mandatory safety standard would ensure consumers receive the same high level of protection they have now.

Businesses that manufacture for the European market would not be required to package a product specifically for the Australian market. Removing this barrier may result in a cost saving for consumers and greater consumer choice.

As with Option 3, the regulation would be streamlined as the ban on dummies with unsafe decorations and the ban on dummy chains with unsafe decorations could be revoked as the new mandatory safety standard would incorporate the European standard for dummy chains.

## **Limitations**

Businesses importing European dummies would experience reduced costs. However, businesses would continue to be unable to import dummies that comply with the US standard without retesting to the European or Australian standards.

## **Option 4 - Revoke the mandatory safety standard**

### **Description**

Most consumer goods in Australia are not regulated by mandatory safety standards. Revoking the mandatory safety standard would mean suppliers would still need to have regard to the consumer protection provisions of the Australian Consumer Law (ACL). The ACL provides consumers with specific protections for consumer transactions called statutory consumer guarantees every time they purchase goods or services. One of those guarantees is that goods will be of acceptable quality, meaning they are safe and fit for purpose.

Consumer protections also exist to safeguard against suppliers engaging in conduct that is likely to be misleading or deceptive. Additionally, there are provisions for injury reporting, recalls and product liability. These provisions give suppliers an incentive to ensure that the goods they supply are safe. The ACCC would still be able to take safety action if needed – for example, through recalls.

The bans on dummies with unsafe decorations and dummy chains with unsafe decorations would be retained under this option.

### **Benefits**

There would be no direct compliance costs for industry under this option. Any international trade restrictions resulting from the mandatory safety standard would be removed, making it easier for businesses to import products to Australia. This may result in lower prices and a wider range of products becoming available to Australian consumers.

### **Limitations**

Without the mandatory safety standard, the general ACL provisions may be insufficient and some manufacturers could stop safety activities to reduce costs. Suppliers adhering to voluntary standards could potentially lose market share. This could also lead to an increase in death and injury. Consumers may also need to assess the safety of these products in more detail. This could reduce consumer and retailer confidence in the industry and in the safety of these products.

## 10. Preliminary position

The ACCC is currently of the view that Option 3 is likely to provide the greatest benefit for consumers, suppliers and regulators.

Stakeholder submissions to this consultation will help us refine the benefits and safety outcomes for each option, and to recommend the most appropriate option to the Minister.

## 11. Key questions

1. Do you agree with the ACCC's assessment of international standards for babies' dummies?
2. Do you think that these proposals would reduce regulatory burden on suppliers? If so, by how much?
3. Are there any other safety hazards that we have not considered?
4. Which policy option do you support?
5. Are there any other policy options that the ACCC should consider?
6. How much time should the ACCC allow for suppliers to transition to the new mandatory safety standard?
7. Do you have any other comments?

## 12. Have your say

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

Consultation is open from 28 September to 4 November 2016.

The ACCC prefers submissions via the ACCC consultation hub at [consultation.accc.gov.au](http://consultation.accc.gov.au).

Alternatively, email submissions to [productsafety.regulation@acc.gov.au](mailto:productsafety.regulation@acc.gov.au)

Submissions can also be posted to:

Director  
Standards and Policy  
Consumer Product Safety Branch  
Australian Competition and Consumer Commission  
GPO Box 3131  
CANBERRA ACT 2601

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## Glossary

Term	Definition
<b>Babies' dummy</b>	The current mandatory safety standard defines a babies' dummy as an item comprised of a rubber or soft plastic teat, a hard plastic shield with holes and either a ring or a handle. Babies' dummies are also known as pacifiers or soothers.
<b>European Standard</b>	EN 1400:2013 Child use and care articles – Soothers for babies and young children – Safety requirements and test methods
<b>European Dummy Chain Standard</b>	EN 12586:2007 + A1:2011 Child use and care articles – Soother holder – Safety requirements and test methods
<b>Mandatory safety standard</b>	Consumer Protection Notice No. 4 of 2006 - Consumer Product Safety Standard: Babies' Dummies
<b>2015 voluntary Australian standard</b>	AS 2432:2015 Babies' Dummies
<b>1991 voluntary Australian standard</b>	AS 2432:1991 Babies' Dummies
<b>United States standard (US standard)</b>	16 CFR 1511 Requirements for pacifiers
<b>The mandatory safety standard'</b>	<a href="#"><u>Trade Practices Act 1974 - Consumer Protection Notice No. 4 of 2006 - Consumer Product Safety Standard: Babies' Dummies</u></a>
<b>Ban on dummies with unsafe decorations'</b>	<a href="#"><u>Competition and Consumer Act 2010 - Consumer Protection Notice No. 33 of 2011 - Revocation of interim ban and imposition of permanent ban on certain babies' dummies to which there are crystals, beads or other similar ornaments attached</u></a>
<b>Ban on dummy chains with unsafe decorations</b>	<a href="#"><u>Competition and Consumer Act 2010 - Consumer Protection Notice No. 34 of 2011 - Revocation of interim ban and imposition of permanent ban on certain pins, ribbons, strings, cords, chains, twines, leathers, yarns, or any other similar article to which there are crystals, beads or other similar ornaments attached, which are designed to be attached to babies' dummies</u></a>