

EXPLANATORY STATEMENT

Consumer Protection Notice No. 4 of 2006

Issued by the Authority of the Parliamentary Secretary to the Treasurer

Trade Practices Act 1974

Consumer Product Safety Standard – Babies’ Dummies

Subsection 65E(1) of the Trade Practices Act 1974 (the Act) provides that the Minister may, by notice in writing, declare that, in respect of goods of a kind specified in the notice, a particular standard, or a particular part of a standard, prepared or approved by Standards Australia, with additions or variations specified in the notice, is a consumer product safety standard for the purposes of section 65C.

Paragraph 65C(1)(a) of the Act provides that a corporation shall not, in trade or commerce, supply goods that are intended to be used, or are of a kind likely to be used, by a consumer, if the goods are of a kind in respect of which there is a consumer product safety standard and they do not comply with that standard.

This instrument declares certain parts of the Australian Standard for babies’ dummies AS 2432:1991, as varied, to be a Consumer Product Safety Standard for the purposes of section 65C. The purpose of the safety standard is to ensure that babies’ dummies have key safety features that address the product’s known safety hazards and so reduce the associated risk of injury.

The Australian Standard specifies safety requirements relating to the materials, design, construction and performance of babies’ dummies, together with recommendations for their use and hygienic care, all of which are considered desirable for the health and well-being of a baby.

The Consumer Product Safety Standard adopts only those parts of the Australian Standard considered necessary to address the critical choking and strangulation hazards, and comprise requirements for the minimum size and shape of the dummy shield, the provision of ventilation holes in the shield, the integrity of construction to help ensure that the dummy does not come apart in use, and the provision of a notice warning not to tie the dummy around the babies neck.

Where considered necessary, these requirements adopted from the Australian Standard have been varied to make them substantially compatible with the corresponding requirements of the European Standard for Soothers, EN 1400:2002, and the US Regulation for Pacifiers, 16 CFR Part 1511. The Australian market includes products made to comply with the Australian and European Standards and US Regulation, and compliance with any of these standards is considered to provide satisfactory levels of product safety.

A Regulation Impact Statement (RIS) for this Consumer Product Safety Standard, including a copy of the new standard, is at Attachment A. The RIS identifies the product safety issues and considers the options for addressing the issues. The case is presented for introducing a mandatory safety standard for dummies and the rationale for the content of the new standard is explained.

A draft of the Regulation Impact Statement was circulated for consideration by interested parties including manufacturers and suppliers of babies' dummies, State and Territory Fair Trading/Consumer Affairs agencies, consumer groups and child safety specialists. The consultation proceedings are reported on page 11 of the Regulation Impact Statement.

The Consumer Product Safety Standard is a legislative instrument for the purposes of the Legislative Instruments Act 2003.

The Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

REGULATION IMPACT STATEMENT



THE REGULATION OF BABIES' DUMMIES UNDER THE TRADE PRACTICES ACT 1974

October 2006

**Product Safety Policy Section
Australian Competition & Consumer
Commission**

INTRODUCTION

This Australian Competition and Consumer Commission (ACCC) regulation impact statement examines the need for government regulation of the supply of babies' dummies. The decision maker is the Parliamentary Secretary to the Treasurer.

Over the past 10 years, consumers have periodically raised concerns about the safety of babies' dummies in the Australian market. There have been a number of reports of dummies coming apart in use, typically resulting in a choking hazard when the teat separates from the dummy. From late 2005 the safety of some types of dummies have been brought into question following reports in Choice consumer magazine that infants have got dummies completely into their mouths and gagged on them. These reports were subsequently quoted in the general press, radio and television, and generated wide community concern.

Standards Australia established a safety standard for babies' dummies in 1991 which relates to similar standards developed overseas.

Market data indicates that pharmacies sell over 1 million babies' dummies annually in Australia at a cost to consumers of about \$4.3 m. The top 9 brands account for 90% of the products sold, and are supplied by 4 manufacturers. The remainder of the pharmacy market comprises some 200 brands from smaller manufacturers. The sole Australian manufacturer of dummies supplies 26% of the pharmacy market.

There is no readily available data for the non-pharmacy market, but it is expected that other retailers, which includes supermarkets, would sell at least as many dummies as pharmacies, but possibly with a smaller range of types. Based on the number of children in Australia under the age of 3, likely usage rates and estimated dummy life/replacement rates, it is estimated that a total of around 4 million dummies are sold annually in Australia.

Dummies on the Australian market range in price from about \$2 to \$8 each. They are often sold in packets of 2 or 3. Dummies having teats made of silicone rubber are generally more expensive than those made of natural rubber, and they are reputed to last longer. It was found that some of the cheaper dummies are fully compliant with the Australian Standard.

PROBLEM

What is the problem being addressed?

The problem to be addressed is the protection of infants against the risk of injury and death associated with the supply of unsafe babies' dummies. Currently, dummies supplied on the Australian market are not required to comply with any safety standards, and examples have been found that fail to provide basic critical safety features.

The majority (estimated 95%) of these products on the market in Australia meet voluntary safety standards such as the Australian Standard, the European Standard or the US Regulation for Pacifiers, and are considered to provide adequate levels of product safety. The remainder may not comply with any standard and may be a risk to infants.

Babies' dummies are widely used in the community to help comfort and settle infants by providing them with non-nutritive sucking. The nature of the product, being designed to be sucked by infants, has acute implications for infant safety.

Data showing safety related incidents and injuries associated with babies dummies provides clear evidence of failures occurring in the absence of a prescribed standard. In a sample of 13 randomly selected dummies which have been recently assessed, one did not survive pre-conditioning and exhibited major failures against key safety specifications. There have also been a concerning number of reports of teats separating from the dummy shield and introducing an immediate choking hazard. Although the underlying data is not available, the US Regulation on infant pacifiers was introduced some 10 years ago to address the level of choking deaths and related injuries associated with pacifiers which were occurring in that country.

Children up to the age of 3 years are particularly vulnerable to choking hazards because they have not developed the reflex to cough up objects that may lodge in the throat. The potential choking hazard of objects that young children may put in their mouths is recognised in various safety standards for children's toys, and is the specific focus of the Trade Practices Act mandatory consumer product safety standard for toys for children up to 3 years of age. The fact that babies' dummies in Australia are not subject to similar safety requirements is seen as an anomaly in consumer product safety regulation.

Deaths

A search of the (Australian) National Coroners Information System did not reveal any infant deaths associated with babies dummies.

Injury data

While there is currently no nationally coordinated collection of injury data that would allow a direct measure of total injuries in Australia associated with babies' dummies, data available to organisations such as Monash University Accident Research Centre (MUARC) give an indication of the injuries being sustained. MUARC analyses data from the Victorian Injury Surveillance System (VISS), which is collected by major Victorian hospital emergency departments and provides a significant data sample.

MUARC reports that VISS data for the period October 1995 to March 2006 lists 31 injuries associated with dummies. Most injuries involve infants falling over with a dummy in the mouth, typically resulting in lacerations to the lip. There were 2 cases where injuries may be attributed to defects in dummies, where parts of the dummy separated and caused a choking hazard. In

another case, an infant had bleeding gums when a dummy was removed from the mouth, but the cause was not recorded. The data does not identify details of the products involved.

Inquiries with other countries about recent injuries associated with the use of dummies generated responses from Denmark, Belgium, Czech Republic and Poland, and no reports of injury or death have been identified.

Consumer Reports

Thirty seven Australian consumer complaints about dummies have been identified for the period 2000 to 2006. Complaints have been received by the Australian Consumers' Association, State offices of Consumer Affairs/Fair Trading and the ACCC. The complaints comprised 22 reported incidents where dummies were stuck in the mouth, 10 incidents where dummies came apart, and 5 miscellaneous complaints. The reports of dummies stuck in the mouth comprised 3 different brands.

In late 2005, Choice published initial reports of infants getting dummies completely into their mouths and identified the dummies as being of European manufacture. These incidents were widely reported in the media, and it is possible that this focus may have encouraged subsequent complaints about the problem, resulting in skewing of the number of complaints made about certain dummy types. Complaints about this problem were rare before publication of the Choice reports.

Advice from paediatricians is that infants can manipulate typical types of dummies to get them completely into the mouth. It is reported to be common for infants to do this, but the presence of ventilation holes in the dummy shield as specified by major safety standards prevents serious injury. There have been some incidents where infants have sustained minor injuries to the mouth when the carer removes a stuck dummy, and it is noted that the carer may be subject to a degree of panic when seeing an infant gag on a dummy.

Denmark reported that a number of consumer complaints were received in the late 1990s where infants got dummies completely into their mouths, but there were no serious injuries associated with these reports.

Because dummy safety standards provide for the possibility of the dummy being taken completely into the mouth, such incidents are assessed as potentially far less serious than reports of teats separating from shields and presenting a choking hazard, or missing or inadequate ventilation holes in the dummy shield.

Product Surveys

The ACCC purchased samples of 13 types of dummies from retailers in Brisbane, Melbourne and Canberra and commissioned testing by a certified test laboratory. A number of dummies failed to meet the requirements of the Australian Standard for babies' dummies in relation to the shape of the dummy shield, but it is understood that those dummies were made to the

requirements of the European Standard. The two standards are based on similar requirements for shield shape, shield ventilation holes and structural integrity, but differ in their detailed specification such that a dummy may pass one standard but not the other. The level of safety afforded by either standard is considered adequate.

One of the tested dummies did not pass key requirements of the Australian Standard due to inadequate ventilation holes in the shield and a major structural failure when it was subjected to conditioning in boiling water. This is considered an example of a poor quality dummy that has the potential to cause injury or death, and should not be on the market. When notified of the problem by the ACCC, the supplier immediately undertook a voluntary recall of the product.

Potential for Injury

Child health and safety specialists recognise that infants are particularly vulnerable to choking on small objects that may lodge in the throat or block the airway. As dummies are a product designed for infants to suck, it is essential that they are safe for use in the mouth. Potential major hazards for this product include the possible release of small component parts that may lodge in the throat and cause choking and the possible lodgement of the dummy in the throat so as to block the infant's airway.

The reports of choking incidents with dummies confirms the existence of the hazard and illustrates the need for some action to ensure that these products provide at least basic levels of safety.

OBJECTIVES

What are the objectives of government action?

The Government's consumer protection policy includes the objective of ensuring that consumer products are safe. Particular attention is paid to products intended to be used by children. The Trade Practices Act includes provisions to support this objective through the establishment of mandatory consumer product safety and information standards, product bans, recalls of unsafe products and the issuing of product safety warning notices.

The Government's aim is to reduce the risk of serious injury and death to children as a result of accidents involving unsafe babies' dummies.

Is there a regulation currently in place? Who administers it?

There is no national regulation on the manufacture or supply of babies dummies in Australia.

The Victorian Government initiated a regulation for babies' dummies on 2 August 2006 through a temporary ban on the supply of babies' dummies that do not comply with certain clauses of the Australian Standard for babies' dummies. The ban effectively eliminated from the market many products that

are made to comply with the European Standard, and to overcome this unintended effect, the ban was amended on 25 August 2006 to apply only to products that do not comply with the European or US Standards for soothers/pacifiers.

The US has a long-standing government regulation for babies' pacifiers specifying safety requirements including shield shape, shield ventilation holes, attachment of the teat and structural integrity.

The European Product Safety Directive requires consumer products to comply with relevant national standards, which effectively means that dummies supplied in Europe must comply with the European Standard for soothers, EN1400. This Standard includes requirements for shield shape, shield ventilation holes, security of teat attachment and structural integrity.

OPTIONS

The viable options available to achieve the objective are:

1. Maintain the status quo, i.e. industry self-regulation;
2. Quasi-government regulation, being government endorsement of a voluntary industry program, such as a code of practice, that requires suppliers to adhere to safety standards;
3. Government regulation of babies' dummies. The appropriate mechanism would be to regulate the supply of dummies through a Trade Practices Act consumer product safety standard that specifies compulsory safety requirements drawn from existing safety standards.

Consumer education is not regarded as a viable stand-alone option because the technical nature of dummy safety mechanisms is such that it is unlikely that an average consumer would be able to reliably assess the safety of a dummy.

IMPACT ANALYSIS

Impact Groups (See *table of costs and benefits at Attachment B*)

The proposed viable options would affect consumers who purchase babies' dummies and their children, businesses involved in the supply of babies' dummies (manufacturers, importers, distributors and retailers), government (including consumer product regulators) and providers of emergency hospital services.

Option 1: Status Quo – Industry Self-Regulation (voluntary compliance with standards)

Continuing the present arrangements whereby industry determines which products it will supply would permit the supply of any dummies, regardless of compliance with product safety features. To date, this has resulted in the sale of some products that do not provide basic safety features, and the exposure of infants to serious risks.

Costs and benefits to consumers

The potential costs to consumers include:

- Continuing uncertainty that the dummies on sale provide an adequate level of safety;
- A continuation of the risk to infants where dummies do not provide basic levels of safety; and
- Medical and other costs of injury/death where this occurs.

The potential benefits to consumers include:

- Unrestricted supply of babies' dummies, providing consumers with a wide choice of products and competitive prices. The effect on prices of not requiring standards compliance is thought to be minimal since a number of cheaper products currently on the market do comply with the Australian Standard.

Costs and benefits to industry

The costs to industry include:

- Continuing uncertainty about the need for safety requirements for babies dummies;
- Continuing uncertainty about what safety standards are appropriate for the Australian market. Some suppliers adhere to the unique Australian Standard for babies' dummies, while some 50% of product on the market is made to comply with the widely used European Standard; and
- Continuing need for recalls of products that are identified as unsafe.

The benefits to industry would be some cost savings from not having to comply with a specific standard, allowing unrestricted product selection and pricing.

Costs and benefits to government

The costs to Government are:

- The need for consumer safety agencies to react to incidents involving unsafe products;
- Costs incurred as a result of reliance on the judicial system for redress in the case of the supply of dangerous goods; and
- Medical costs associated with the treatment of injuries associated with the use of dummies that are unsafe.

Option 2: Quasi-Regulation

This option would comprise the development of a voluntary industry program for the supply of babies' dummies. The program would typically involve a Government endorsed industry code of practice whereby suppliers of dummies voluntarily adhere to agreed product safety standards.

Costs and benefits to consumers

The costs to consumers could be

- A reduced choice in the market, as some existing products would be withdrawn because either they do not meet voluntary standards or the supplier would not be prepared to undertake testing of the product to confirm compliance;
- Not all suppliers would follow an industry code, leaving untested products on the market and requiring consumers to assess the safety of the product;
- The cost of injuries associated with dummies that do not provide adequate product safety.

The benefits to consumers would be an overall increase in the level of product safety, and an expected corresponding reduction in dummy related injuries.

Costs and benefits to industry

- The cost of putting in place and maintaining the infrastructure to support quasi-regulation. Previous experience with industry codes of practice suggests that these costs would amount to approximately \$20,000 per year;
- This would require an on-going cooperative commitment by all industry participants, involving some form of supplier registration, monitoring of the market and a system of review and redress for cases of non-compliance; and

- The costs to individual suppliers of ensuring that products meet agreed safety standards.

The benefit to industry would be improved consumer confidence that products on the market are safe.

It is considered that a large part of the market comprising pharmacies and major retailers already complies with voluntary safety standards for dummies, and the introduction of an industry code of practice would be unnecessary for these groups. However, the remaining sections of the market, such as independent retailers, may not be members of industry associations and would need to be convinced of the benefits to their businesses of following a code of practice.

Costs and benefits to government

- The cost of negotiating a suitable industry program, monitoring the program and monitoring the market to ensure that the initiative is effective. The estimated cost to government is \$20,000 per year.

The benefit to government would be an expected reduction in dummy-related injuries due to improved levels of product safety, which would result in less demand on public hospital emergency departments.

Option 3: Introduce a Mandatory Minimum Standard

It would be appropriate that a mandatory safety standard for babies' dummies be based on the relevant Australian Standard as it is derived from the US Standard and includes key safety requirements that are widely accepted.

However, the Australian Standard also includes some unique requirements, and is not fully compatible with the European and US Standards that are used internationally. In view of the ACCC's research showing that products complying with those Standards are not causing serious injuries, the mandatory minimum standard needs to make provision for products complying with those Standards.

Accordingly, an appropriate mandatory minimum standard might reference the key requirements of the Australian Standard, with variations where necessary to make those requirements compatible with the European and US Standards.

The key safety features of these standards considered justified for inclusion in a mandatory minimum standard are:

- Specification of shield size and shape to prevent the dummy lodging in the throat;
- Ventilation holes in the shield to prevent choking if the dummy is taken completely into the mouth;
- Secure attachment of the teat;

- Structural integrity of the dummy to prevent the release of small parts;
- A label warning against attaching the dummy with a ribbon around the child's neck to avoid a potential strangulation hazard.

A mandatory minimum standard incorporating these specifications would:

- Eliminate from the market those dummies that do not meet the key safety requirements, thereby reducing the level of risk to infants;
- Reduce the incidence of serious injury associated with poor quality products;
- Give consumers confidence that products on the market provide a reasonable level of safety; and
- Provide a framework for industry to determine appropriate levels of safety for these products.

A draft of the proposed TPA mandatory safety standard is at ***Attachment A***.

Possible trade implications

The Commonwealth Government is concerned that its regulations do not impose unnecessary barriers to trade by setting standards that make compliance by overseas manufacturers difficult, especially if it cannot be shown to be maintaining a higher level of consumer protection. However, under the terms of the Agreement on Technical Barriers to Trade, a Government is able to regulate to protect human life and health.

The US has a Regulation in place and the European Product Safety Directive is considered to provide its 25 member countries with similar effective consumer protection from unsafe dummies. There is a high degree of conformity among standards and therefore Australia is not setting a precedent by establishing a mandatory minimum standard for babies' dummies.

It is Standards Australia policy to mirror international (ISO) standards, but as there is no ISO Standard for babies' dummies, when the current Australian Standard for babies' dummies was established in 1991 it was based on a US regulation, but with some modifications. As a result, some aspects of the Australian Standard are unique, and if the Standard as a whole is made mandatory it would impose an unreasonable barrier to trade and may be seen to impact significantly on Australia's WTO commitments. Standards Australia has commenced a review of the Australian Standard, which will likely lead to a change in some of the technical specifications of the Standard, and better alignment with overseas standards. The review process might be expected to take 6-12 months to complete.

Accordingly, it is proposed that a suitable mandatory minimum standard would include safety requirements that are common to the Australian Standard, the European Standard and the US Regulation.

The proposed mandatory minimum standard would facilitate compliance by overseas manufacturers by being compatible with major overseas standards.

Costs and benefits to consumers

The costs to consumers would be some reduction in the choice of dummies and a possible loss of access to some cheaper models.

The benefits to consumers would be a reduced cost of injury associated with unsafe dummies due to the exclusion of unsafe products from the market, and an assurance that dummies on the Australian market are as safe as anywhere in the world.

Costs and benefits to industry

The possible costs to industry will be the loss of opportunity to retail an unrestricted choice of dummies and the cost of ensuring that products comply with prescribed safety requirements.

It is estimated that about 5% of dummies on the Australian market do not comply with suitable safety standards, mainly involving the suppliers of cheaper dummies such as discount variety stores. For these suppliers, the additional unit cost of sourcing products that comply with the proposed mandatory safety standard is estimated to be about 5%, and they might choose to supply complying products within their price structure. Because the suppliers do not specialise in baby products, dummies would represent a very minor component of their business and they may decide to discontinue selling the product with minimal effect on their business.

A mandatory minimum standard provides benefits to industry because it provides clarity as to what is required in providing a safe product, and should make it easier for suppliers to identify complying dummies.

This can reduce management and administrative effort to ensure compliance, a higher level of confidence in compliance, to avoid the cost and inconvenience of product recalls and to avoid litigation.

Costs and benefits to government

Enforcement costs are estimated at \$20,000 per annum, which would include the costs of market surveys to monitor the compliance of products with safety requirements and any associated enforcement action deemed necessary. To enforce the safety standard the ACCC would establish rigorous monitoring of the market to identify any non-complying products and allow their prompt removal. It is expected that the State and Territory Fair Trading agencies would mirror the Commonwealth regulation, thereby multiplying the capacity for monitoring of the safety of the market.

The benefits to government would be improved consumer safety due to the elimination from the market of unsafe products, an associated reduction in personal and community trauma, reduced medical and hospitalisation costs and a stronger and more responsible market. The wellbeing of the community

in general, and especially those most vulnerable, such as children, is a keystone of government policy, and establishing product regulation will assure the community that product safety is being addressed.

CONSULTATION

This Regulation Impact Statement setting out the case for the regulation of babies' dummies was submitted for consideration by industry, the Consumer Products Advisory Committee (CPAC) to the Ministerial Council on Consumer Affairs (MCCA) (comprising Commonwealth, State, Territory and New Zealand Consumer Affairs/Fair Trading officers). Other stakeholders include consumer groups, industry organizations including manufacturers, distributors and retailers, child safety experts such as Kidsafe, the Australian Breast Feeding Association and the medical and health sector. A period of up to 5 weeks was allowed for responses.

A total of twelve responses have been received from industry, product testing organisations, child safety agencies, Commonwealth and State Health Departments and Fair Trading agencies. All respondents supported the proposal to regulate the supply of dummies. Some suggested minor technical amendments to the requirements of the mandatory minimum standard and these have been accommodated where possible subject to trade and safety factor considerations.

Five respondents recommended the mandatory safety standard be expanded to include additional tests specified in the Australian Standard, particularly the test for protrusions on the front of the dummy. The requirement to limit protrusions on the front of the dummy is included in the Australian and European Standards and the US Regulation, and is intended to reduce the risk of injury when children fall face-down with a dummy in the mouth. However, it was found that there is already reasonable compliance with this requirement, and mandating in the proposed safety standard is considered not justified.

Two respondents recommended that a note in AS 2432 clause 6.4.2 which clarifies the specification for ventilation holes should be retained in the mandatory minimum standard, and this has been accepted.

CONCLUSION AND RECOMMENDED OPTION

Option 1 to continue the present industry self-regulation is not considered viable, given the level of risk to children and the lack of industry self-governance. An education campaign is not considered feasible on its own for the same reasons, in addition to the difficulties for consumers in assessing the safety of babies' dummies.

Option 2 to ensure the provision of safe babies' dummies through quasi-regulation is not considered feasible because of the uncoordinated nature of the market. Product sold through pharmacies might be effectively controlled through industry associations, but the product is also sold through a myriad of

supply chains and retail outlets for which there is no effective means of coordination.

Option 3 establishing explicit government regulation by declaring a mandatory minimum standard for babies dummies that includes the common safety requirements of Australian Standard AS 2432-1991, European Standard EN 1400 and US Regulation 16 CFR Part 1511, is considered the only effective means of achieving an improved level of protection for consumers. The proposed regulation would make compliance simple for industry and impose a minimum burden on consumers and industry. For these reasons, Option 3 is the preferred option.

If implemented, option 3 (a mandatory safety standard under the Trade Practices Act) would be supplemented by consumer and supplier product safety awareness materials and programs. The planned product safety awareness campaign will cost an initial \$20,000 for the program and materials.

The program would aim to ensure consumers purchased only those dummies which meet the mandatory minimum standard and that parents and carers took reasonable precautions when providing a dummy to infants. A supplier's guide would raise awareness of a supplier's responsibility to ensure that only dummies meeting the prescribed standard are manufactured or imported for sale in Australia.

The campaign would be ongoing with specific opportunities to target consumers being identified over the next 3-5 years and materials reprinted on a needs basis.

IMPLEMENTATION AND REVIEW

It is proposed that the new mandatory minimum standard for babies' dummies be introduced without delay. Any products currently on the market that do not meet the basic safety requirements of the major safety standards are considered unsafe for infants to use and should be immediately removed from sale. This is considered warranted in the case of babies' dummies even though there will be some costs on business from a proportionally small amount of unsaleable stock.

The new mandatory minimum standard would be expected to commence in October 2006 and be subject to review five years later, or when the Australian Standard is revised.

Compliance with the new mandatory minimum standard would be facilitated via comprehensive supplier information and guidance, and the mandatory minimum standard would be enforced by regular market surveillance and selected product testing by the ACCC.

The effectiveness of the regulation will be assessed through analysis of market survey findings, recall action, and the incidence of dummy related injuries that might be identified from injury data.

**ATTACHMENT A
DRAFT STANDARD****COMMONWEALTH OF AUSTRALIA**

Trade Practices Act 1974

Consumer Protection Notice No 4 of 2006

CONSUMER PRODUCT SAFETY STANDARD FOR BABIES' DUMMIES

I, Chris Pearce, pursuant to subsection 65E (1) of the *Trade Practices Act 1974* and for the purposes of section 65C of that Act, hereby DECLARE that the consumer product safety standard for babies' dummies is the standard approved by Standards Australia specified in Division 1 of the Schedule, as varied by Division 2 of the Schedule.

THE SCHEDULE**Division 1: The Standard**

Australian Standard AS 2432-1991, Babies' Dummies, published by Standards Australia on 15 November 1991.

Division 2: Variations

AS 2432-1991 is varied by

- (i) Deleting clauses 3 and 5;
- (ii) Amend clause 6.1 by deleting the words "and 6.3";
- (iii) Deleting clause 6.3;
- (iv) Amending clause 6.4.2 by deleting paragraph 6.4.2(a), in paragraph 6.4.2(c)(iii) deleting "25 mm" and substituting "15 mm", and in the note following 6.4.2(d)(ii) delete all the measurements "25 mm" and replace with "15 mm";
- (v) Amending clause 6.4.3 by deleting the notes following 6.4.3(c);
- (vi) Deleting clauses 7.2, 7.3 and 7.4;
- (vii) Deleting clause 9.1 and substituting a new clause 9.1 as follows:
 - "9.1 General** The pack shall be legibly labelled with the name and address of the Australian manufacturer or Australian distributor."
- (viii) Deleting clause 9.3 and all its subclauses and substituting a new clause 9.3 as follows:
 - "9.3 Warning notice** The pack shall bear a clear and legible warning notice which shall include the following words or words that have the same meaning:

WARNING

**DO NOT TIE DUMMY AROUND BABY'S NECK AS IT PRESENTS
A STRANGULATION HAZARD.**

In the warning notice the word 'PACIFIER' or 'SOOTHER' may be substituted for the word 'DUMMY'.’;

- (ix) Deleting Appendix A;
- (x) Amending Appendix C by deleting clause C2 and substituting a new clause C2 as follows:

“**C2 PRINCIPLE** A dummy is placed centrally on the test template with its major and minor axes aligned with the major and minor axes of the template and the teat protruding down through the opening. A specified tensile force is applied to the teat in an attempt to force the dummy through the opening in the template. If the dummy is not forced through the opening in the template, the dummy is inverted and the procedure repeated.”;
- (xi) Amending Appendix C clause C3 by deleting from the title the words “AND REAGENT”, and deleting from the text the words “and reagent are” and substituting the word “is”;
deleting paragraph C3(b); and
deleting the second paragraph of clause C3(c) and substituting the words,
“The test template shall have inscribed on it the major axis (I) and the minor axis (II).”;
- (xii) Amending Appendix C clause C4 by deleting the words, “shall be representative of the batch and”;
- (xiii) Amending Appendix C clause C6 by:
deleting paragraph C6(c);
deleting paragraph C6(d) and substituting a new paragraph as follows:

“(d) Place the dummy, teat down, in the opening of the template as shown in Figure C2, so that the major axis of the shield aligns with the major axis I-I of the template and the minor axis of the shield aligns with the minor axis II-II of the template.”;

deleting paragraphs C6(h) and C6(i);
deleting paragraph C6(j) and substituting a new paragraph as follows:

“(j) Place the dummy, teat up, in the opening of the template as shown in Figure C3, so that the major axis of the shield aligns with the major axis I-I of the template and the minor axis of the shield aligns with the minor axis II-II of the template.”; and

deleting paragraph C6(m);
- (xiv) Deleting Appendix D;
- (xv) Amending Appendix E clause E2 by deleting the words, “immersed in a wetting solution and then”;
- (xvi) Amending Appendix E clause E3 by deleting from the title the words “AND REAGENT”, deleting from the text the words “and reagent are” and substituting the word “is”; and
deleting clause E3(c);
- (xvii) Amending Appendix E clause E4 by deleting the words, “shall be representative of the batch and”;

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Regulation Impact Statement: Babies' Dummies

ATTACHMENT B

TABLE OF COSTS AND BENEFITS

		Option 1: Maintain Status Quo (Industry Self-Regulation)	Option 2: Quasi-Regulation (Industry Code)	Option 3: Government Regulation (preferred option)
COSTS	Consumers	Continuing uncertainty about the safety of dummies on the market. Continuing incidence of injuries associated with dummies that do not have key safety features.	Reduced choice in the market with the withdrawal of some non-complying products.	Reduced choice in the market with the withdrawal of non-complying products.
	Industry and Small Business	Continuing uncertainty about appropriate safety standards for dummies supplied in Australia. Continuing potential for product liability claims and product recalls where dummies prove to be hazardous.	Need to put in place and maintain the infrastructure to support quasi-regulation. Previous experience with industry codes of practice suggests that these costs would amount to approximately \$20,000 per year. The cost of ensuring that products meet safety standards.	Loss of opportunity to retail an unlimited choice of dummies. The cost of ensuring that products meet safety standards.
	Government	The need for consumer safety agencies to react to incidents involving unsafe products.	The need to invest considerable time and effort consulting with industry to educate and encourage the development of	Enforcement costs of approximately \$20,000 per annum, to be supported by an ongoing safety awareness

		Option 1: Maintain Status Quo (Industry Self-Regulation)	Option 2: Quasi-Regulation (Industry Code)	Option 3: Government Regulation (preferred option)
		<p>Potential costs incurred as a result of reliance on the judicial system for redress in the case of the supply of dangerous goods.</p> <p>Public health system costs related to the treatment of injuries associated with unsafe dummies.</p>	<p>arrangements for industry codes.</p> <p>Estimated costs of \$20,000 per annum.</p>	<p>campaign costing an initial \$20,000</p>
BENEFITS	Consumers	<p>Continuation of the present wide choice of dummies on the market.</p>	<p>Some reduction in infant injuries associated with dummies due to expected overall improvement in product safety.</p> <p>Increased confidence that the goods they buy are safe.</p>	<p>Minimised incidence of injuries associated with unsafe dummies.</p> <p>An assurance that dummies on the Australian market are as safe as anywhere else in the world.</p>
	Industry and Small Business	<p>Freedom to supply an unrestricted range of dummies and to decide appropriate levels of safety for the products supplied.</p>	<p>Industry guidance on appropriate levels of product safety.</p>	<p>Access to clear specific requirements which offer the opportunity to reduce management and administrative effort to ensure compliance.</p> <p>Avoidance of the cost and inconvenience of product recalls</p>

		Option 1: Maintain Status Quo (Industry Self-Regulation)	Option 2: Quasi-Regulation (Industry Code)	Option 3: Government Regulation (preferred option)
				and litigation.
	Government	The absence of any requirement to formally monitor the safety of products on the market.	A stronger and more responsible market. Some improvement in product safety.	Improved consumer safety. Minimised personal and community trauma. Reduced medical and hospitalisation costs.