

Dummies/Pacifiers
Investigation into the Need for a
Product Safety Standard

A Discussion Document

October 2005

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Submissions

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Purpose

1 The Ministry of Consumer Affairs has a role under the Fair Trading Act 1986 to protect consumers from goods that will or may cause injury to any person. Product safety standards are regulations made under section 29 of the Fair Trading Act 1986. They can declare a national standard or parts and variations thereof to be a product safety standard.

2 The discussion document considers the need for the declaration of a product safety standard as a means of ensuring the safety of dummies/pacifiers.

3 Under section 29(3) of the Fair Trading Act 1986, the Minister of Consumer Affairs is required to consult with parties considered to be substantially affected by a proposed product safety standard, to provide an opportunity for those parties to make any comment and to consider such comment.

4 This paper forms the first step in that consultation process. It is intended to assist anyone who may wish to make a submission on the merits or otherwise of developing a product safety standard.

5 The discussion paper has been issued to encourage consumers, traders and other interested parties to consider the issues relating to the safety of dummies/pacifiers and to put forward their views. This will enable the Minister to receive sound advice on all the issues relating to dummies/pacifiers and to take into account the views of those substantially affected.

Background

6 The Product Safety Standards (Children's Toys) Regulations 1992 declare NZS 5822:1992 *The Prevention of Ingestion and Inhalation Hazards in Toys Intended for Use by Children Under Three Years of Age* to be a product safety standard and dummies/pacifiers are currently included in the scope of the regulation. This relates to their small parts dimensions only. The 1992 regulations are revoked by the Product Safety Standards (Children's Toys) Regulations 2005 but will remain in effect until 8 September 2006.

7 The Product Safety Standards (Children's Toys) Regulations 2005 declare AS/NZS ISO 8124.1:2002 *Part 1: Safety aspects related to mechanical and physical properties* with variation to be a product safety standard. Dummies/pacifiers are considered nursery products and are therefore not covered in the scope of the international toy standard, on which the 2005 regulations are based.

8 A dummy/pacifier is a nursery product with a nipple intended for a young child to suck on, although is not designed to help a baby obtain fluid. The dummy usually has a guard or shield at the base of the nipple that keeps it from being sucked completely into a child's mouth. It also has a handle or ring, usually on the other side of the guard or shield from the nipple that is used to hold or grasp the dummy for the caregiver.

9 The 1992 regulation for children's toys, included dummies/pacifiers in the scope, and was originally established to address the hazard of small parts to children under the age of three years. NZS 5822:1992 outlines the small parts requirements for children under the age of 3 years, and sets out tests, such as a bite test and drop test, to ensure that such toys can be used by their intended user, without small parts breaking off. NZS 5822:1992 is derived from the larger national standard NZS 5820:1982 Specification for the safety of toys which sets out the general safety requirements for toys for children up to the age of fourteen years. The existing national standard NZS 5820:1982 *Specification for the safety of toys* has now been superseded by AS/NZS ISO 8124 *Safety of toys* series.

10 Comment was sought from the public on the revision of the Product Safety Standards (Children's Toys) Regulations 1992 and the need to consider the proposal for a mandatory standard for dummies and pacifiers. Stakeholders were asked how this product should be dealt with in the future and supported the proposal that a separate Product Safety Standard be developed for dummies and pacifiers. Continued regulation of pacifiers and dummies appeared to be warranted.

The Problem

11 Children under three years of age are still at the stage of exploring their world by putting things in their mouth. However they do not yet have a fully developed cough reflex and are therefore especially vulnerable to inhalation and ingestion hazards from products that produce small parts when they break.

12 Dummies/pacifiers are products that children put into their mouth. The objective of the regulations would be to reduce the risk to children less than three years of age choking on dummies/pacifiers, by ensuring that the dummies/pacifiers meet small parts size and performance criteria.

13 The Ministry of Consumer Affairs has received 15 complaints since 1988 for pacifiers and dummies. Maintaining the status quo is not considered a desirable option as the potential injury risk remains.

International

14 In assessing the options available for addressing the safety issues, the Ministry is expected to take into account the wider perspective of government and the global environment in which trade takes place.

15 Interventions that act as trade barriers have to be avoided. Nevertheless, a commitment to free trade has to be balanced by the need to ensure that consumer safety is not compromised.

Australia

16 Dummies/pacifiers considered children's nursery products would accord with the Australian approach, although at present Australia does not mandate the small part requirement for dummies/pacifiers.

United States

17 The US Consumer Product Safety Commission (CPSC) has regulation for pacifiers Requirements for Pacifiers, 16 C.F.R. Part 1511 (January, 2001).

18 "The rule requires that:

(1) the shield not be so small or flexible that it can be sucked into a child's mouth;

(2) the a pacifier have no handles or other protrusions, that are long enough to force the pacifier into the child's mouth if the child falls or lies on its face;

(3) pacifiers are labeled to warn caregivers not to tie the pacifier around the child's neck.

(4) a pacifier not produce small parts when tested." (Requirements for Pacifiers, 16 C.F.R. Part 1511 (January, 2001)

19 The American mandatory standard does not cover the chemical hazards associated with dummies/pacifiers. The CPSC recommends ASTM F963-03 *Standard Consumer Safety Specification for Toy Safety* and ASTM F1313-90(1999) *Standard Specification for Volatile N-Nitrosamine Levels in Rubber Nipples on Pacifiers* for this purpose.

20 The CPSC website highlights the frequency of product recalls for pacifiers and has logged 5 recalls for pacifiers in 2005.

Canada

21 Health Canada has regulation for pacifiers under the Hazardous Products Act, Hazardous Products (Pacifiers) Regulations 1991 which covers toxicity, design and construction tests, and includes the small part requirement.

Europe

22 Europe Union has a General Product Safety Directive (2001/95/EC) which imposes a general requirement on manufacturers and suppliers etc not to place a product on the market unless it is safe. Manufacturers must take all reasonable efforts to ensure their product is safe. Compliance with voluntary national standards is deemed to meet the general safety requirement.

Options

23 There are regulatory and non-regulatory options for addressing the safety concerns regarding dummies/pacifiers. A non-regulatory option includes:

- industry self-regulation.

24 Regulatory options in the form of product-specific intervention under the Fair Trading Act include:

- product safety standard
- unsafe goods notice (product ban)
- product recall.

Maintaining the Existing Requirements and industry self-regulation

25 The Product Safety Standards (Children's Toys) Regulations 1992 are revoked by the new regulations on 8 September 2006 and coverage will revert to the general safety obligations under the Consumer Guarantees Act 1993. Consumers and retailers would have to rely on suppliers to provide adequate information.

26 The removal of the 1992 regulation is not a “do nothing” option. The measures available under the Fair Trading Act, such as recalling products which are found to be unsafe or are likely to cause injury would continue to be available on a case-by-case basis. These measures are designed to deal with one-off situations.

27 Major suppliers have a long term commitment to the market and reputations to maintain. Small and often transient market participants however are a feature of this market sector. These suppliers appear largely unaware of some of the regulatory requirements and the prospect of gaining their voluntary compliance is not good.

Mandatory Product Safety Standard

28 This is the preferred option.

29 Stakeholders have already shown their support that continued regulation for dummies/pacifiers is warranted.

30 Product safety standards are designed to address generic safety issues that apply to an entire class of goods. Adopting national standards that have been drawn up by industry and consumer representatives, will provide achievable safety outcomes. This option is intended as a preventive measure against identified safety concerns and provides a benchmark of safety in terms of design,

construction, performance, and information as to use. Product safety standards are mandatory and are enforced by the Commerce Commission in the market, and the NZ Customs Services at the border.

31 The mandatory product safety standard will provide the necessary benchmark to ensure that dummies/pacifiers within the market meet minimum safety requirements. The mandatory standard would ideally specify the small part requirement of AS 2432-1991 *Babies' dummies* for dummies/pacifiers to ensure a safe product.

Contents of a mandatory standard

32 Should a product safety standard be declared, it is most likely to conform to the national voluntary standard AS 2432-1991 *Babies' dummies*.

33 AS 2432 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 important for the health and well-being of a baby. The standard applies to all babies' dummies except those intended for use by premature babies, or for therapeutic application or the like, in which the usage is under medical supervision or direction.

34 The small part test is considered the shield test in Appendix C of AS 2432:1991, the shield dimensions are stipulated with the template test or small part requirement (i.e. the shield must not pass through the template opening).

35 Comment is sought on the consideration of other tests incorporated in AS 2432:1991. For example, the ventilation holes requirement specifies providing air passages through which a baby could breathe if the dummy was accidentally 'swallowed', but the ventilation holes would also prevent the risk of the dummy being sucked into the oral pharynx since negative pressure would be generated. Also the requirement for the material to be used which stipulates that the material shall not contain any leachable constituent.

36 There are, however, other options that need to be considered, including the American and Canadian mandatory standards. Copies of the American and Canadian standards are available for viewing here:

- <http://www.cpsc.gov/BUSINFO/regsumpacifier.pdf>
- http://www.hc-sc.gc.ca/cps-spc/child-enfant/access/pacifiers-sucettes_e.html.

Costs

37 Although dummies/pacifiers are currently mandated by the Product Safety Standards (Children's Toys) Regulations 1992, a new regulation would impose an additional burden on the Commerce Commission's resources that may need to be met either with additional funding or with a reduction in enforcement activity in

some other area. These costs would be borne by taxpayers generally, rather than the purchaser of the product.

38 Additional burden would also be imposed on the New Zealand Customs Service's resources that may need to be met either with additional funding or with a reduction in enforcement activity in some other area. These costs would also be borne by taxpayers generally, rather than the purchaser of the product.

Unsafe Goods Notice (product ban)

39 Section 31 of the Fair Trading Act 1986 gives the Minister the power to declare goods to be unsafe goods by notice in the Gazette. Such a notice stays in force for a period of 18 months and has the effect of prohibiting the supply of the goods to which it applies. The Minister may use these powers "where it appears to the Minister that goods of any description or any class or classes of goods will or may cause injury to any person".

40 Unsafe goods notices are enforced by the Commerce Commission and at the border by the New Zealand Customs Service.

41 Unsafe goods notices are predominantly aimed at either a specific brand or model of good or a specified unsafe feature, (for example specific models of crossbow or any pistol crossbow without a safety catch). If the unsafe feature is generic to the entire class of that good, an unsafe goods notice may be used as an interim measure while a product safety standard is being prepared, (for example rubber hot water bottles).

42 A ban on the supply of a product is a severe regulatory option and would target the product unfairly. It is seen as a measure of last resort and must satisfy the elements of natural justice. Where this measure is adopted it must be clearly established that the product itself is the primary cause of injury and that any other mitigating circumstances have only a minor impact.

43 A ban is not considered a viable option. It would also not take account industry practices due to the current 1992 regulation for dummies/pacifiers.

Product Recalls

44 Section 32 of the Fair Trading Act 1986 gives the Minister powers to require the recall of goods which, which are of a kind which will or may cause injury. A product recall is not considered a viable option. Mandatory recalls are warranted on a case by case basis and are only used in extreme cases.

Discussion Points

45 The Ministry regards mandatory product safety standards as being appropriate when other options have been considered and it has been concluded that these options would be inappropriate or are likely to be ineffectual.

46 Thus the Ministry will recommend a mandatory standard if the following criteria are met:

- there is a proven problem with the safety of a product
- voluntary action by suppliers of the product is not possible or would not be effective
- an unsafe goods notice or a compulsory product recall would not be sufficient to eliminate a safety problem or would be inappropriate
- a cost/benefit analysis demonstrates that the benefit in making a mandatory standard outweighs the cost
- consideration of the Australian Standard AS 2432:1991, including both the small part requirement and other tests
- consideration of the American and Canadian mandatory standards
- a mandatory standard would solve the problem.

47 Comment on the criteria listed above has been made throughout this paper. However, this paper does not presume to have covered every issue relevant to dummies/pacifiers safety. The Ministry seeks the input of all interested parties to assist it in expanding the debate. To aid the Ministry's evaluation where possible, submissions should address the issues outlined above and raise any others that are considered relevant. Any information relating to costings or other commercial matters will be treated in the utmost confidence.

Submissions Requested

48 Your comments are sought on any matters raised in this paper or on any other matter that you may consider relevant to assist the Minister in her decision to develop a mandatory product safety standard for dummies/pacifiers.

49 Comments should be with the Ministry of Consumer Affairs by 9 December 2005, and directed to:

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