

REGULATION IMPACT STATEMENT



TRADE PRACTICES ACT 1974

**PROPOSED CONSUMER PRODUCT SAFETY STANDARD
LIMITS ON MIGRATION OF LEAD AND CERTAIN ELEMENTS IN
CHILDREN'S TOYS**

NOVEMBER 2008

Product Safety Policy Section

Australian Competition & Consumer Commission

Regulation Impact Statement: Proposed mandatory standard for limits on lead and certain elements in children's toys

INTRODUCTION

This regulation impact statement was developed by the Australian Competition and Consumer Commission (ACCC) to examine the need for government regulation of the migration levels of lead and other toxic elements in children's toys. The decision maker is the Minister for Competition Policy and Consumer Affairs.

The Australian/New Zealand (and International) Standard for the Safety of toys, Part 1, AS/NZS ISO 8124-1:2000 defines toys as any product or material designed or clearly intended for use in play by children under 14 years of age.

Over the last twelve months serious concerns have been raised about the levels of lead contained in children's toys. Large-scale recalls of children's toys because of potentially unsafe levels of accessible lead have occurred in the United States, Canada, the European Union and Australia. Australian product safety recalls are listed on the Product Recalls Australia website www.recalls.gov.au and US recalls are listed on the CPSC website www.cpsc.gov.

PROBLEM

What is the problem being addressed?

A problem with lead in children's toys became evident in 2007 when suppliers detected potentially unsafe levels of accessible lead and voluntarily recalled large numbers of toys. The toys were recalled due to unsafe levels of lead in painted coatings. Relevant toy recalls in Australia were:

- 91,200 Thomas & Friends wooden railway products 13/6/07.
- 43,000 Fisher Price character toys 2/8/07.
- 14,100 Barbie branded and Fisher Price Geotrax toys 5/9/07.
- 17,600 Thomas & Friends wooden toys 26/9/07.
- 2,088 Pirates of the Caribbean squeeze lights 11/10/07.
- 299 boats in toy sets 29/10/07
- Unknown number Little Rider, Cowboy and Knight Lovely Horse 10/12/07.
- 11,000 Makit & Bakit jewellery sets 10/6/08.
- 8,000 Knights sets 2/9/08.

The recalls illustrated a problem whereby large quantities of toys with unsafe accessible lead levels entered the Australian market and the homes of consumers.

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Lead is a toxin that can harm young children. Children are particularly at risk because their bodies are in the early stages of development and a young child's exposure to lead can cause learning and behavioral problems and possibly damage their brains, kidneys, and other organs. The severe toxic effect of lead was illustrated in 2006 in the US when a child died after ingesting a lead trinket.

Young children are vulnerable because their hand-to-mouth activities make them more likely to ingest lead in the form of paint chips or dust. Young children frequently put toys and their fingers in their mouths and occasionally ingest toys or parts of toys, creating ways for lead to enter the body. The main way most young children are exposed to harmful levels of lead is through contact with lead contaminated paint and dust. In nearly all cases lead dust is either breathed in or licked off surfaces or swallowed in paint chips that contain lead¹.

The World Health Organisation has identified serious health issues associated with excessive levels of lead, antimony, arsenic, barium, cadmium, chromium, mercury and selenium. These hazards presented by these elements are recognised in major safety standards for children's toys, which specify safe levels for contact by children.

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, because children cannot be expected to recognise risks to their safety and are therefore reliant on products they use being inherently safe. Children are also in the development phase of their lives and are particularly vulnerable to the adverse health effects of chemicals in the environment.

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 in relation to toxic elements in children's toys is to reduce the risk to children of serious injury and death associated with the use of toys.

¹ New York State Department of Health Home Page > Health and Safety in the Home, Workplace and Outdoors > Lead <http://www.health.state.ny.us/environmental/lead/>

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

Customs (Prohibited Import) Regulations restrict levels of migrateable lead and certain other elements in imported toys or playthings, money boxes, pencils and paint brushes, erasers resembling food in scent and appearance. The regulations were first introduced in 1956 at the request of State Health agencies and were based on voluntary standards in use at the time. With the revision and refinement of those voluntary standards over time, the Customs regulations came to be out of step with accepted Australian and international practice. The Customs regulations were updated on 25 August 2007 (Select Legislative Instrument 2007 No.245) to reflect the element levels specified in the current Australian/New Zealand/International Standards Organisation Standard: AS/NZS ISO 8124.3:2003 Safety of Toys, Part 3: Migration of Certain Elements.

The effectiveness of the Customs import regulations in controlling lead levels in children's toys is largely dependent on voluntary compliance by importers. Hazardous toys can only be detected by testing and analysing toy components, and the volume and range of toys imported into Australia prohibits Customs routinely testing all imported toys. Recent recalls of large numbers of imported toys because of concerns about lead content illustrated that compliance even by reputable toy companies is not reliable.

Architectural and decorative paint supplied in Australia, including paint used to decorate toys, is subject to the Uniform Paint Standard (UPS) declared under Appendix I of the Standard for Uniform Scheduling of Drugs and Poisons. The Standard is adopted by State governments and administered by State departments of health. Since the 1960s the UPS has limited lead in these paints to 0.1%. The National Industrial chemicals Notification and Assessment Scheme (NICNAS) published similar requirements for industrial paints in 2007. While the UPS prescribed lead levels are considered appropriate for general use, they are not as strict as the levels prescribed by standards developed specifically for toys (current toy standards specify maximum accessible lead levels of 90 ppm). The effectiveness of the UPS in controlling lead in toys is restricted to decorative paints used in Australia, and does not provide controls for imported toys or for other toy materials.

A temporary Trade Practices Act ban on the supply of children's toys having lead migration levels greater than 90 mg/kg, in line with the Customs regulation, was introduced on 19 September 2007. The ban was a response to the discovery and recall of toys in the Australian market containing lead, and operates for 18 months. The ban supports the customs regulation by facilitating monitoring of the domestic market by the ACCC. Some State authorities have introduced complementary bans, allowing them to also monitor the market.

Other Trade Practices Act provisions provide for the issuing of product safety warning notices or the compulsory recall of products where it can be shown that they will or may cause injury and suppliers do not take appropriate voluntary action. Recent recalls of toys because of excessive lead content

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were undertaken voluntarily by suppliers. These provisions are not considered sufficient to address the problem of potentially unsafe levels of lead in children's toys as they do not prevent children from coming into contact with such goods.

The European Product Safety Directive requires consumer products to comply with the relevant European standard. In effect, this means toys supplied in Europe must comply with the entire European Standard on the safety of toys, including limits on the migration of lead and other toxic elements as specified in the standard.

The United States Consumer Product Safety Commission (CPSC) administers a ban on toys and other consumer products bearing paint or a surface coating with a total lead content of more than 0.06% by weight (see US regulation 16 CFR part 1303). New US regulations were introduced in August 2008 to progressively add new limits for lead in toys, substantially in line with European requirements.

OPTIONS FOR ADDRESSING THE PROBLEM

The main options available for consideration in achieving the objective in the longer term are:

1. Maintain the status quo/industry self-regulation (with consumer education);
2. Introduce government regulation limiting migration levels of certain elements in children's toys through a new mandatory standard referencing the provisions of relevant safety standards.

Maintain the status quo/industry self regulation

Reliance on the Customs import regulations for lead in toys has been found insufficient to control the supply of toys with unacceptable levels of lead. The detection of hazardous products at the point of importation is difficult and to be fully effective would require comprehensive product testing.

The present TPA ban on lead in children's toys is a temporary arrangement implemented to address immediate concerns about the recent discovery of excessive levels of lead in a range of toys. The ban facilitates testing of products in the Australian market, covering both imported and Australian produced toys. Because the toxicity of children's toys is a complex matter, it is considered that provisions that might be specified in a relatively simple banning mechanism are not appropriate for application as a long term solution to the problem.

The longer term situation to be addressed is whether the toy industry is likely to effectively self-regulate in relation to the control of toxic elements in toys. Unfortunately, recent recalls of well-known brands because of concerns about lead content have shown that in a self-regulating environment the toy industry

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may make undetected mistakes in production, resulting in the supply of toys that contain hazardous elements.

It is understood that there are about 2295 toy shops or shops with toy departments in Australia, and an unknown number of pharmacies, newsagents, supermarkets and variety stores that also sell toys. While the major international suppliers of toys and Australian suppliers who are members of the Australian Toy Association are expected to upgrade their manufacturing and product testing procedures in response to recent toy safety problems, the toy industry as a whole is not a cohesive group and is unlikely to address the problem through a universal, ongoing co-operative program. Toys are supplied by a wide range of businesses, many of which are not members of specialist industry associations, so there is little prospect of the entire toy industry committing to a voluntary product safety plan covering all toys on the market.

Consumer education has a limited role in addressing the problem of hazardous elements in children's toys. Raising awareness of the possible hazard of toxic elements is not very helpful to consumers because the elements cannot be detected by consumer inspection, and product labelling may not provide consumers with a reliable indicator of product safety or standards compliance.

Responses from public consultation did not support the status quo option as a viable means for addressing the hazard of toxic elements in toys.

Mandatory standard specifying levels for accessible elements in children's toys

Submissions on the draft RIS unanimously supported regulatory intervention to mandate maximum levels of certain accessible elements in children's toys. One submission recommended extending the current temporary ban on lead in toys that is based on the Australian/New Zealand Standard for toys, and other submissions supported the proposed establishment of a mandatory standard.

The establishment of the proposed TPA mandatory safety standard for certain toxic elements in toys will provide a mechanism for the ACCC to monitor this aspect of toy safety in the Australian market. This will supplement Customs monitoring of imports and also allow monitoring of Australian produced toys, thereby multiplying the means of detecting hazardous products. Cooperation between the monitoring agencies would not only improve the detection of hazardous products, but the sharing of information can help in the identification of overseas sources of these products, allowing Customs to better target potentially hazardous imports.

The ACCC first proposed introducing a government regulation limiting migration levels of lead and certain other toxic elements in children's toys through a new mandatory standard referencing the element migration levels, testing procedures and interpretation of results specified in the Australian/New

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Zealand Standard AS/NZS ISO 8124.3:2003 Safety of toys Part 3: Migration of certain elements, the equivalent International Standard ISO 8124-3 and European Standard EN 71.3.

The Australian/New Zealand Standard AS/NZS ISO 8124.3:2003 is identical to the International (ISO) Standard and only minor differences have been identified between these standards and the European Standard EN 71.3 used by most international suppliers.

The majority of comments received in response to the circulation of the draft RIS supported the view that including the above range of similar standards in the mandatory standard would reduce the compliance burden for suppliers. Responses confirmed that most overseas suppliers produce toys for the world market and prefer to use the European Standard for toys, EN71. Products supplied in the US are also tested to the ASTM F963-07 standard for toys.

Consideration was given to including the ASTM standard as an option in the mandatory standard. It was reported that a small proportion of overseas suppliers produce toys for the US market only, and adhere to only the ASTM standard. It was confirmed that the inclusion of the ASTM standard in the proposed mandatory standard would be problematic because of differences between the standard and the Australian, International and European standards. While the ASTM standard includes test procedures similar to those in the AS/NZS, ISO and EN standards and specifies identical limits for tested elements, it does not detail the sample preparation techniques for various toy materials that are specified in clause 8 of those other standards. As a result, ASTM tests results may not be compatible with the other standards, and may differ in unpredictable ways, depending on the nature of the toy material being tested.

Accordingly, it is proposed to not reference the ASTM standard for toys in the mandatory standard because of the limited use of the standard for toys supplied in Australia, and the technical differences between that standard and the other nominated standards.

Considering the above issues, it is concluded that an effective TPA mandatory standard for controlling lead in toys which avoids unnecessary regulatory burden on suppliers and consumers would allow the application of three alternate standards that are commonly used by the toy industry:

- Australian/New Zealand Standard, Safety of toys – Part 3: Migration of certain elements, AS/NZS ISO 8124.3:2003;
- European Standard for the Safety of Toys – Part 3 Migration of Certain Elements, EN71-3:1994/A1:2000/AC:2002.
- International Standard, Safety of toys – Part 3: Migration of certain elements, ISO 8124-3:1997.

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Referencing multiple standards

A number of submissions opposed the proposal to reference multiple alternate standards due to the complexity of the proposed standard and potential compliance enforcement difficulties. Theoretically, where multiple alternate standards apply, proving non-compliance may require enforcement authorities to test a product to all of the declared standards. To overcome this problem it is proposed to reference only the Australian Standard, which is considered to be equivalent to the corresponding International and European standards. Industry representatives confirmed that such a standard, supported by a statement declaring that the three standards are equivalent would allow suppliers to rely on existing arrangements whereby toys are often certified to the European or International standards.

A suitable declaration on the equivalence of the standards might be included in the usual guidelines to the standard published by the ACCC. Compliance guidelines are published for all mandatory standards to clarify how the requirements are to be applied.

Mandatory regulation for other elements in children's toys

The ACCC considered whether there was sufficient information available to justify mandating acceptable levels for elements other than lead in children's toys as included in the referenced standards - antimony, arsenic, barium, cadmium, chromium, mercury or selenium. The public consultation sought comment on the need to include coverage of these elements in the proposed standard.

A number of responses strongly supported the case for including the other elements, reporting the discovery of other elements in product testing and pointing out that the presence of these toxic elements in children's toys is patently unacceptable. It was also reported that modern laboratory processes for detecting the presence of lead simultaneously detects the other elements, eliminating the need for additional testing.

Accordingly, it is agreed that the proposed mandatory standard should include coverage of the other elements listed in referenced standards. This aspect of the mandatory standard will then be consistent with the referenced standards.

Proposed specification of 0 to 6 years age range for general applicability of the mandatory standard

As young children are particularly vulnerable to lead ingestion through mouthing behaviours, the ACCC sought views on a proposal that the application of a mandatory standard for lead should be limited to toys intended for children 0 to 6 years of age.

The majority of respondents supported the case for a standard being applicable to all toys for children (0-14 years) rather than being limited to toys for children 0-6 yrs. It was noted that the toxic element hazards are relevant to

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all children and the established standards for children's toys include general requirements for all toys, with particular provisions for toys that are likely to be mouthed by young children (0-6 years).

It is accepted that the mandatory standard should apply to all toys for children, in accordance with the provisions of the referenced toy standards. This aspect of the mandatory standard will then be consistent with the referenced standards.

Children's face paints and toy cosmetics

It is the view of the ACCC that children's face paints and cosmetics sold as children's toys should be included in the proposed mandatory standard for lead in children's toys, and the requirements should apply to all such products for children (0-14 years).

Regulatory measures for children's face paints and cosmetics are considered necessary because children's skin can come into prolonged contact with these goods and they may be ingested. This view was supported by respondents in the public consultation process.

It is considered that the coverage of face paints and toy cosmetics as included in the proposed referenced standards will meet this requirement.

Finger paint

Finger paints are popular with young children and it is thought that most of the 1684 independent and specialist toy shops in Australia sell the product.

Young children apply finger paints with their hands, and therefore may ingest substantial amounts of the paint. Accordingly, finger paints are recognised to present a particular hazard in relation to children's exposure to various chemicals, including lead and other heavy metals. The European toy standards committee examined the hazards associated with finger paints and found that in order to ensure that children do not ingest hazardous levels of known toxins, finger paints need to be subject to limits on a range of chemicals, including limits on lead and other elements which are lower than those specified for other toys.

As a result, European Standard EN 71-7 for finger paints was introduced in 2002. The International toy standards committee is looking to adopt this standard and the corresponding Standards Australia committee reviewed the matter and adopted identical Australian Standard AS 8124.7 in 2003. Of particular relevance to the proposed mandatory standard for lead and certain elements in toys, clause 4.4 of the finger paint standard specifies appropriate maximum levels for these element levels.

There was support in public consultations for the specific coverage of finger paints in the proposed mandatory standard with seven respondents directly addressing the issue. The Australian Toy Association supports the proposed

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requirements for finger paints and advised that compliance by Australian suppliers should not be a problem. It is understood that most products already comply with the European standard.

Accordingly, it is recommended that the requirements for lead and certain elements be adopted from Australian Standard AS 8124-7:2003, clause 4.4, which is identical to European Standard EN 71-7:2002.

Toy jewellery

It is proposed that the mandatory safety standard for lead in toys should apply to jewellery sold as children's toys.

Respondents to public consultation on the draft RIS supported the proposal to include coverage of toy jewellery, as per provisions in the respective referenced standards. Some concerns were raised that toy jewellery should be defined so as to avoid possible confusion for suppliers. It is considered that references to definitions in the Australian/New Zealand/International standard for children's toys will help overcome these concerns, particularly:

- toys are items used by children in play; and
- fashion jewellery for children is excluded.

Some respondents suggested the standard might be broadened to cover other jewellery likely to be used by children. However, the need for such a broadening of the scope of the standard was not established and it would potentially cause difficulties for the jewellery industry because it would likely result in a need to test all jewellery to the requirements of the toy standard.

Requirements for toy jewellery are included in the referenced standards and are part of the proposed mandatory standard.

IMPACT ANALYSIS

Who is affected by the problem and who is likely to be affected by its proposed solution?

The presence of lead in children's toys affects consumers, being children who play with toys and their families or carers who purchase toys; industry being the manufacturers and suppliers of toys, and government including suppliers of health services that provide treatment for associated health problems and agencies having responsibility for monitoring the safety of consumer products in the market.

OPTION 1: Maintain the Status Quo

Costs and benefits to consumers

The potential costs to consumers of maintaining the status quo are the continuing uncertainty that toys on sale in Australia may contain unsafe levels

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of lead, and the possibility that children playing with contaminated toys will sustain health problems. Recent large-scale recalls of toys by major suppliers due to excessive lead levels demonstrates that the present system is not effective in ensuring the safety of toys.

The potential benefit to consumers of maintaining the present non-regulatory approach would be the continuing unrestricted availability of toys and maintenance of current product pricing. It is expected that there will be some improvement in toy safety and increased product costs as a result of overseas initiatives to address recent problems of lead in toys.

Costs and benefits to industry

A cost to industry of maintaining the status quo is continuing uncertainty that the products they supply may contain excessive levels of lead and other elements, and the possible costs of any resultant product recall or product liability action.

A benefit of maintaining the present system is that product testing would continue to be voluntary, and industry would determine the need for testing on commercial considerations.

There may be some increased costs and improved product safety with some manufacturing countries introducing regulations for lead levels in exported goods.

Costs and benefits to government

The benefit to government would be that continued self regulation as an alternative to government regulation avoids the need for legislation and an administration and enforcement regime, saving the cost of market surveys, enforcement action and reviews of a mandatory standard.

The cost to government would include health services to provide support for those suffering the effects of contact with lead and other toxic elements.

OPTION 2: A new mandatory standard referencing Australian New Zealand Standard AS/NZS ISO 8124:3: 2003 Safety of toys Part 3 - Migration of certain elements, and Australian Standard AS 8124.7-2003 Finger paints - requirements and test methods, clause 4.4.

Costs and benefits to consumers

There are likely to be additional costs to consumers in terms of marginally higher prices for toys resulting from the expected introduction of routine testing by manufacturers and suppliers. There may also be some reduction in the range of products available where the suppliers withdraw products from the market rather than complying with product safety regulation, and some toys may no longer be available in their current form. However, since the proposed standard will effectively bring Australia into line with toy safety

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requirements in the major world markets, the impact of an Australian standard on consumers would be minimal.

The benefit to consumers would be a greater level of confidence that children's toys on the Australian market do not contain excessive migration levels of lead and other toxic elements, and there will be a reduced risk of children suffering health problems as a result of handling hazardous toys.

Costs and benefits to industry

The introduction of a mandatory standard is expected to result in suppliers incurring additional costs for the routine testing of toys to verify compliance. The cost of testing a toy sample for lead and certain other element migration in Australia is approximately \$80-140 per colour per toy.

However, the additional costs resulting from the expected routine testing of toys may not be significant to many suppliers as most toys are produced overseas for international markets using the relevant ISO or EN standards, and the proposed mandatory standard would not create unique requirements for products supplied to the Australian market. Some manufacturing countries are introducing regulations for lead levels in exported goods, which may increase availability and reduce costs of testing as well as discouraging the practice of using unsafe levels of lead in the manufacture of children's toys. Industry is increasingly likely to be able to access documented evidence from overseas manufacturers that their products comply with the mandatory standard.

Costs and benefits to government

Costs to government in administering the regulation covering millions of toys are estimated to be about \$60,000 to cover market surveys, product testing, standards review, enforcement actions and other legal and educational expenses. Should the regulation be adopted by State administrations, they would incur costs associated with the administration of the State regulation.

The benefit to government would be the removal from the market of products containing lead and other hazardous elements at dangerous levels that have the potential to cause long-term injuries to children. As well as a social dividend in increased wellbeing, this would result in a reduced burden on the health and welfare systems as less injured or behaviourally affected children would present for treatment. A secondary benefit would be the increased public confidence that the product safety provisions of the TPA are being applied to safeguard the community.

There are few potential trade implications as the United States and the European Union already regulate for lead content in toys and the proposed regulation would not be a significant barrier to trade.

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CONSULTATION

A draft of this RIS setting out the case for action to address the hazards to children associated with toxic elements in toys was submitted for consideration by:

- consumer groups;
- 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);
- industry representatives;
- industry organizations including manufacturers, distributors and retailers;
- child safety experts such as Kidsafe; and
- the medical and health sector.

The draft RIS was circulated to a total of 80 relevant people or organisations in November 2007 with a period of five weeks allowed for responses.

In addition to the major options for addressing the identified product safety hazards, the draft RIS also sought comment on particular issues in relation to the content of the proposed mandatory standard.

Following that consultation process, the RIS was redrafted and circulated for final comment.

Comments received

Sixteen written responses were received during the primary public consultation and following amendments to the proposal, a further nine responses were received. The responses supported option 2 proposing to limit the migration of certain elements in toys through regulation. Comments received are summarised in the Attachment A as they relate to particular issues, together with ACCC responses.

The recommendations were accommodated to the extent possible on the basis of relevance to the objective, practicality, the perceived majority view, and the government policy of imposing the minimum level of regulation considered necessary to achieve the desired product safety outcomes.

Recommendations are acknowledged in discussions on relevant topics throughout this RIS.

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CONCLUSION AND RECOMMENDED OPTION

Option 1, to maintain the status quo is not seen to be an effective means of addressing the problem of toxic elements in children's toys. While it is expected that many toy suppliers will voluntarily improve levels of product safety following recent large-scale product recalls, the toy industry is considered not sufficiently cohesive to voluntarily adopt a universal approach to toy safety. The status quo option received no support during public consultation.

Option 2, the introduction of a mandatory safety standard for lead and certain elements in toys is recommended as the most cost effective mechanism for addressing the identified safety hazard.

Establishing explicit government regulation through a new mandatory standard for element migration levels in children's toys is considered the most effective means of achieving an improved level of protection for consumers.

Recommendations from public consultation on the proposed regulation supported adopting the toxic element migration levels for children's toys in general as specified in Australian/New Zealand Standard AS/NZS ISO 8124-3, and to address the safety of finger paints adopting clause 4.4 of Australian Standard AS 8124.7. These standards are equivalent to European Standards EN 71-3 and EN 71-7 (clause 4.4).

Proposed form of Mandatory Standard

Initial consideration of the form of a suitable mandatory standard suggested that AS/NZS ISO 8124.3, ISO 8124.3 and EN 71-3 standards should be referenced as alternates, so that suppliers dealing in products certified to one of the appropriate standards would not need to incur additional costs for further testing. However, it is understood that because these standards are considered to be equivalent, the various standards can be effectively included in the proposed mandatory standard by referencing only Australian/New Zealand Standards AS/NZS ISO 8124.3 and AS 8124.7 (finger paints), and issuing official guidelines stating that the corresponding International and European toy standards are considered to be equivalent and acceptable under the mandatory standard.

Accordingly, it is now proposed to adopt a simplified form of mandatory standard that references only the Australian/New Zealand standards, and to publish ACCC guidelines referencing the other standards. A draft copy of the proposed mandatory standard is at Attachment C.

The proposed standard imposes some additional costs on industry due to the need for suppliers to ensure that products they source comply with one of the nominated standards, but the costs are expected to be minimal. Where products are currently subject to testing to the Australian, International or European standards, suppliers would not incur additional cost. Where products are not tested to one of the relevant standards, suppliers may incur

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additional costs for testing. For these suppliers it is estimated that product costs might increase by 1-2%, which would likely be passed on to consumers in the form of slightly increased prices. Government would be subject to additional costs to maintain and enforce the proposed mandatory standard.

A variation to the adopted standard is proposed to omit the automatic application of the "use and abuse" tests that are specified in the respective Australian, International or European standards. The original wording of the standards lack clarity in when the tests should be applied, resulting in the possibility that in some circumstances some test laboratories may determine that the tests are required while others may determine they are not required. Omitting the requirement for the "use and abuse" tests in the mandatory standard effectively makes them optional, and avoids disputes about when they should be applied. The level of product safety achieved with or without the tests is considered adequate.

IMPLEMENTATION AND REVIEW

It is proposed that the new mandatory standard for lead and other elements in children's toys be declared as soon as the proposed standard can be finalised. As the new standard will include requirements that are not included in the current temporary ban on lead in toys or the relevant Customs Regulations it will be necessary to allow suppliers a period to confirm product compliance, and accordingly it is proposed that the regulation should take effect 12 months after declaration. Arrangements will be made to maintain the current TPA ban on toys containing excessive lead until the new standard takes effect.

The introduction of the mandatory standard would be supported by the publication of information on the new requirements and guidelines targeted to industry and product safety awareness material for consumers.

The effectiveness of the proposed standard will be assessed by monitoring market compliance through ACCC and State/Territory market surveys, related toy recall action and feedback from suppliers and the community.

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ATTACHMENT A

Analysis of comment received in response to public circulation of a draft RIS proposing Government action on Lead in Toys:

November 2007 – January 2008

16 responses received

ISSUE	COMMENT RECEIVED	ACCC RESPONSE
Option 1: maintain status quo	No support for this option.	Noted absence of support for status quo.
Option 2: introduce a TPA mandatory safety standard for lead in toys	All respondents supported some form of government regulation.	Noted general agreement with regulation proposal.
Ban on lead in toys	The current temporary ban on lead in toys appears to be effective and consideration might be given to making the ban permanent.	Proposal to extend ban considered not tenable as a long term solution.
Reference EU, ISO and AS/NZS as alternate standards	The mandatory standard should reference the EU and ISO standards for lead and other elements because these standards are widely applied in the industry.	Noted agreement with proposal for alternate stds.
	Inclusion of alternate standards allows most cost effective testing.	Noted agreement with proposal for alternate stds.
	Referencing multiple standards will reduce industry costs of compliance.	Noted agreement with proposal for alternate stds.
	Most toys are produced for multiple markets, so reference to common standards such as EN 71 is important. Note that EN 71 includes use and abuse tests that should be retained.	Noted agreement with proposal for alternate stds.
	The standards are appropriate as they assess the bioavailability of lead and other elements.	Noted agreement with proposal for alternate stds.

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
	<p>Multiple standards will make the legislation complex and confusing for compliance and enforcement, and possibly complex for industry. Recommend adoption of EN std only. Might research which standard is used by Chinese manufacturers.</p>	<p>Suite of similar alternate standards adds some complexity for enforcement, but reduces compliance burden for industry. Alternate form of std could be considered.</p>
	<p>The specification of multiple alternate standards would be confusing to industry and enforcement authorities.</p> <p>May be worthwhile to examine how lead migration limit of 90 mg/kg was developed.</p>	<p>There is general industry support for the proposal, but alternate form of std might be considered to address compliance issues.</p> <p>The lead limit of the standards is based on known health effects and is accepted internationally.</p>
<p>Reference US ASTM F963-07 Standard</p>	<p>Inclusion of ASTM is not warranted. Products for the US market may be tested to ASTM, but they would also be tested to EU or ISO for other markets.</p>	<p>Noted recommendation to not reference ASTM std.</p>
	<p>Inclusion of ASTM considered unnecessary as most suppliers would apply EU or ISO standards. ASTM is significantly different and cannot be easily aligned.</p>	<p>Noted recommendation to not reference ASTM std.</p>
	<p>ASTM should be included as an alternate standard to reduce the costs and inefficiencies of testing. Recent recalls resulted from a failure to comply with US regulation 16 CFR part 1303, and retailers may be at risk of recalls if products are not tested to an equivalent standard.</p> <p>If a product is sourced primarily for the US market, the present proposal would require additional testing for the Australian market.</p>	<p>Arguments of benefits to industry not seen to outweigh perceived problems of standards compatibility. ASTM as an <u>alternate</u> will not achieve outcome suggested: would not ensure that all products comply with 16 CFR part 1303.</p> <p>Noted that some products may require additional testing for supply in Australia. Other advice is this would not be a problem for most of the</p>

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
		market.
	Should not reference ASTM due to lack of consistency with other nominated standards resulting in enforceability problems. Inclusion of the ASTM would allow a different standard for domestic products compared to imported products, which may contravene WTO obligations.	Noted recommendation to not reference ASTM std and view on possible lack of ASTM consistency with Australian import regulations.
	ASTM may be considered less rigorous, hence its inclusion may make the regulation hard to enforce. Impact of not including ASTM standard is believed to be small because most international suppliers ensure compliance with both ASTM and EN standards.	Noted recommendation to not reference ASTM std and views on differences between ASTM and EN standards.
	At least 95% of toys are tested to both the ASTM and EN standards. Under the proposed regulation, toys that are tested to only the ASTM standard would need to be tested to an alternate standard at significant cost to the Australian distributor. ASTM F963-07 clause 4.3.5.2 would be an acceptable inclusion in the standard and would avoid the need for further testing.	Noted that current proposed standard not referencing the ASTM standard will result in costs to some importers.
	<p>The ASTM standard should not be considered as an alternate because it is not consistent with the other standards in that it excludes art materials and differs for toy samples containing grease, oil and wax. The standards are similar in respect of testing surface coatings.</p> <p>If the ASTM standard is not included, suppliers using the ASTM standard to test modelling clay and finger paint would be disadvantaged as they would need to meet the more stringent tests of the AS/NZS std.</p>	<p>Authoritative advice on technical differences between the ASTM and other referenced standards is noted.</p> <p>Noted that modelling clay and finger paint tested only to ASTM requirements may require testing to an alternate nominated standard.</p>
Verification of	Regulation should require ongoing verification of compliance with std to	Certification proposal not supported. Mandatory

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
compliance	ensure toy safety.	certification of products is not permitted in TPA regulations.
Inclusion of other elements as specified in toy standards	The inclusion in the standard of elements other than lead is not considered justified. The cost of additional testing is not known.	Other elements are recognised to be toxic and are found from time to time. Cost of testing for additional elements found to be minimal.
	Imported toys are subject to Customs Prohibited Import requirements in relation to elements other than lead, and these should also be considered for the TPA regulation.	Noted that import regulations limit lead and other elements.
	While there is no data on risks for other elements, it is understood that there is little or no extra cost to test for other heavy metals.	View on minimal cost noted.
	Other elements specified in the toy standard should be included in the mandatory standard. There is ample evidence of the toxicity of the other elements and children should not be exposed to them.	Agreed that toxic elements are not acceptable in toys.
	Should consider including all heavy metals specified in the toy standard to be consistent with the Customs regulation. The cost and time would be little different to testing for lead, and suppliers of imported toys need to ensure compliance with the Customs regulation.	Noted that import regulations limit lead and other elements. Noted view that additional cost of testing other elements would be minimal.
	Suppliers are obliged to ensure imported toys comply with the Customs requirements for other elements listed in the toy standard. It has been found that other elements may exceed the limits of the standard, but in the main are corrected and not related to toys for children up to 6 years.	Noted information that other elements have been detected in toys. Agree case for consistency between import and domestic regulations.

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
	<p>Include other elements because World Health Organisation assesses the hazards of other heavy metals to be comparable to lead hazards.</p> <p>Retain relevant tests of AS/NZS ISO 8124.3 for selection of test portions.</p>	<p>Noted international recognition of hazards of other elements.</p>
	<p>The listed elements are identified in the AS/NZS, ISO, EN and ASTM standards.</p> <p>Testing for the listed elements in addition to lead can be included at <u>no</u> additional cost.</p>	<p>Noted authoritative advice that testing additional elements would be at zero cost.</p>
	<p>Hazards of the other elements are widely accepted, having been banned in the EU since 1984 and are addressed in ISO, EN and AS/NZS standards. The substances are patently inappropriate for children's toys and should be covered by the standard.</p>	<p>Noted case for addressing the toxic hazards of other elements in toys.</p>
	<p>Would be difficult to test for additional elements and no evidence that they are present at unsafe levels.</p>	<p>Test for additional elements not difficult, zero cost.</p> <p>Evidence submitted of presence of other elements in toys.</p>
	<p>Testing additional elements would provide opportunity to monitor levels and be proactive in addressing potential hazards.</p>	<p>Noted arguments for including other elements to protect children.</p>
<p>Applicable age range 0-6 yrs or 0-14 yrs</p>	<p>Standard should apply 0-14yrs. It is noted that recent recalls due to lead are for toys for children >6yrs.</p>	<p>Noted incidents of lead in toys for children >6yrs.</p>
	<p>Applicable age range should be determined by studying mouthing behaviour. US requirement applies to children up to 14yrs.</p>	<p>Noted that existing toy standards are based on research addressing element contact for children 0-14 yrs, with particular requirements for 0-6 yrs.</p>

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
	Should be applicable for ages 0-14yrs	Noted
	Age range should be 0-6yrs, provided any regulation defines which toys are suitable for the age group.	Noted view on age range 0-6 yrs and possible guidelines. Not consistent with current standards.
	Age range should be 0-6yrs in conformity with standards being referenced.	0-6 yrs range would not be consistent with referenced stds.
	The standard should apply to the age range 0-14yrs as lead exposure is a health hazard to children over 6 yrs and they still put toys in their mouths and can have prolonged skin contact.	Health hazard for 0-14yrs noted. Referenced standards assess toy hazards for 0-14yrs, with particular mouthing hazard for toys for 0-6yrs.
	Should be consistent with EN and ISO, applicable to toys for 0-6yrs.	0-6 yrs range would not be consistent with referenced stds.
	The proposed age range 0-6yrs will create administrative difficulties; use uniform 0-14yrs range across whole standard.	Noted value of standard being inclusive, consistent with referenced stds.
	The regulation needs to be consistent with the wording of ISO and EN, ie toys for 0-6 yrs plus food, oral contact toys.	Agreed. Age range would need to be 0-14 yrs to be consistent with ISO, EN standards.
	Standard for lead should be limited to toys for children 0-6 yrs.	0-6 yrs range would not be consistent with referenced stds.
Include children's cosmetics and face paints	These toys are within the scope of the standard and should be included.	Agreed
	Agrees cosmetics and face paints should be included for ages 0-14yrs.	Noted that referenced standards acknowledge these products are applicable to children 0-14 yrs.
	Should be included as for finger paint.	Noted

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
	Items sold as toys should be included.	Noted
	Should cover age range 0-14yrs. Cosmetics and face paints not marketed for children may be applied to children and should carry a warning about their lead content.	It would not be appropriate for a toy standard to seek to regulate cosmetics in general.
	Toy cosmetics are covered in EN, ISO and AS/NZS, and should be included. Face paints not specifically mentioned in standards but are similar hazard and should be included.	Inclusion noted
	Excess levels have not been identified in these items, but they should be included in the regulation because they are applied directly to the skin.	Potential risk of direct contact noted.
Include finger paint	Finger paint should be regulated.	Noted particular hazard of finger paints.
	Finger paints should be included because they are just as great a risk as toys.	Noted
	EN 17-7 and AS 8124-7 are significantly more strict than EN71-3 and ISO 8124-3 and will create conflict and inconsistency.	Noted conflict in standards.
	Should be covered by EN pt 7 and AS being appropriate for the risk.	Noted
	Should have <u>no</u> lead content and also regulate other heavy metals such as cadmium.	Zero lead content is not supported by current standards.
	Add requirements from AS 8124-7 and EN 71-7. Conflicting requirements in AS/NZS 8124.3 should be varied in the regulation.	Noted differences between AS/NZS 8124.3 and AS 8124-7.
	AS/NZS ISO 8124.3 and AS 8124-7/EN 71-7 apply different limits for lead in finger paint. The standards require analysis to determine which limit is appropriate.	Standards committees have determined appropriate limits for new part 7.

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
Include toy jewellery	Regulating toy jewellery may prove problematic due to the difficulty in defining this jewellery.	Noted
	Toy jewellery should be included as it poses just as great a risk as other toys.	Noted
	Regulation would need to differentiate between toy jewellery and cosmetic jewellery, otherwise compliance would be difficult to manage.	Will seek to clarify that toys are used in play.
	Toy jewellery should be included, notwithstanding that there may be some potential confusion in identifying these products.	Noted
	In addition to toy jewellery, many children purchase cheap costume jewellery which may also be a major hazard.	The case for regulating costume jewellery would need to be considered under a broader review.
	Toy jewellery is included in the standards and should be included in the regulation. Toy jewellery is that which is part of a toy intended to be used in play, eg a necklace on a doll or a jewellery making kit.	Suggested definition of toy jewellery is drawn from AS/NZS ISO 8124-1.
	Requirement for toy jewellery needs to be supported with a definition of toy jewellery to avoid compliance problems. Suggest refer to AS/NZS ISO 8124.1 Scope and Annex E1.	Will seek to clarify that toys are used in play.
	It is understood that the majority of jewellery recalled in the US could be described as fashion jewellery. A clear definition of children's jewellery is needed.	Will seek to clarify that toys are used in play.
	The onus should be on suppliers to show that jewellery is not targeted to children.	Noted
UPS conflict	Toys painted in Australia would be subject to the Uniform Paint Standard, and the proposed new standard should	Considered reasonable to require paint on locally produced toys to comply with Australian and

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ISSUE	COMMENT RECEIVED	ACCC RESPONSE
	not conflict with the UPS.	international toy standards.
Include playground equipment	The definition of toys should include playground equipment.	Case for including playground equipment not made. Playground equipment is subject to a separate standard.
Timing of new regulation	Should be introduced immediately to ensure unsafe toys are removed from the market.	Date of effect will need to take account of market practicalities.
Precautionary principle	When an activity raises threats of harm to human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.	Product safety actions need to be shown to be reasonable and justified.
Conformity with standards	The regulation should be as close as possible to the referenced standards so that compliance with the standard will ensure compliance with the regulation. This reduces the complexity and compliance cost of regulation.	Agreed that variations to referenced stds should be minimal.
Referenced standards require update	Analytical correction included in nominated standards does not reflect current laboratory practice.	Issue will need to be considered by standards development organisations.
Phthalate hazard	The proposed mandatory standard should also address the hazard of phthalates in toys.	Phthalate hazard not addressed in referenced toy standards and would need separate consideration.

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ATTACHMENT B

TABLE OF COSTS AND BENEFITS

		Option 1: Maintain Status Quo (Industry Self-Regulation)	Option 2: Government Regulation (preferred option)
COSTS	Consumers	<p>Continuing uncertainty about the safety of toys on the market.</p> <p>Continuing risk of child health problems associated with toys that do not comply with voluntary safety standards.</p>	<p>Reduced choice in the market with the withdrawal of non-complying products. Marginally increased costs for toys due to the flow-on of industry compliance costs.</p>
	Industry and Small Business	<p>Continuing uncertainty about appropriate safety standards for toys supplied in Australia.</p> <p>Continuing potential for product liability claims and product recalls where toys prove to be hazardous.</p>	<p>Loss of opportunity to retail an unlimited choice of toys.</p> <p>The cost of ensuring that products meet safety standards.</p>
	Government	<p>The need for consumer safety agencies to react to incidents involving unsafe products.</p> <p>Public health system costs related to the treatment of child health problems resulting from contact with toxic elements in toys.</p>	<p>Enforcement costs of approximately \$60,000 per annum covering market surveys and testing product samples, supported by an ongoing industry and consumer awareness campaign costing an initial \$20,000</p>

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		Option 1: Maintain Status Quo (Industry Self-Regulation)	Option 2: Government Regulation (preferred option)
BENEFITS	Consumers	Continuation of the present unrestricted choice of toys on the market and product pricing.	<p>Minimised incidence of health problems associated with toxic elements in children’s toys.</p> <p>An assurance that toys on the Australian market are as safe as anywhere else in the world.</p>
	Industry and Small Business	Freedom to supply an unrestricted range of toys and to decide appropriate levels of safety for the products supplied.	<p>The application of universal safety requirements which offer the opportunity to reduce management and administrative effort to ensure compliance.</p> <p>Reduced potential for product recalls and litigation.</p>
	Government	The absence of any requirement to formally monitor the safety of products on the market.	<p>Provides mechanism to ensure that product complies with world safety standards.</p> <p>Minimised child health problems associated with certain toxic elements in toys and associated reduced health service costs.</p>

