



National strategy for improving the safety of button battery consumer products

2016-18

Version 1

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Foreword

There is need for a coordinated national approach to improving the safety of consumer products powered by coin or button cell lithium batteries.

Button battery safety is of pressing concern and requires the cooperative effort of diverse stakeholders including government, industry, community, standards and health bodies. A working group including the ACCC and State and Territory Fair Trading agencies has been formed to ensure that nationally we are working together to reduce the risks posed by button batteries.

On behalf of the ACCC, I look forward to working with our co-regulators and stakeholders to promote awareness and deliver practical, long-term solutions to this difficult problem.

ACCC Spokesperson

Introduction

This national strategy (2016–18) will focus on developing evidence to inform regulatory and other approaches to improve button battery safety. It is supported by a series of voluntary industry actions, which will be implemented and monitored for their effectiveness and will include continued education and awareness raising about button battery hazards as well as actions to encourage voluntary removal or other mitigation of unsafe button battery products already in retail supply.

The ACCC is leading the strategy with the assistance of state and territory government and invites industry, health agencies and the community to also contribute by sharing information, developing product specific responses and developing an evidence base in a format that will inform and enable future action.

A national approach

Preventing injuries to vulnerable consumers is a priority and the 'one law - multiple regulator model' of the Australian Consumer Law provides an effective basis for and is strengthened by coordinated national actions that will benefit Australian consumers.

Coronial investigations into child deaths have recommended regulatory intervention, including development of horizontal product safety standards. However, the issues around button battery safety awareness and management are complex and require all jurisdictions to work together to determine and implement the best approach. Implementation of the strategy encourages voluntary safety improvements, at the same time developing evidence to provide an authoritative base for any future regulatory proposals.

This strategy addresses consumer goods that are, or use, button batteries, and which may be accessible or attractive to young children. The strategy does not address goods that are subject to regulatory control by specialist regulators, medical devices or products for industrial or scientific use.

It includes consideration of toys for children up to and including 36 months of age which are already regulated. (While there is an existing mandatory safety standard for children's toys under the ACL there are aspects relating to button batteries that may be improved – either voluntarily or via amendment of current regulation.)

This strategy brings together and supports joint efforts across jurisdictions, but does not direct the content of any state, territory or local government activity.

Background

What are button batteries?

Button batteries are single cell batteries with diameters (generally less than 32 mm) that are greater than their height. Button battery is a loose term for two types of battery form and chemistry which present differing patterns of injury:

- Coin cells typically use lithium chemistry with 3 volt electrical output. They are coinshaped and are considered to represent the highest risk of injury because of their higher voltage and size (18-32mm in diameter). These batteries are more likely to get stuck in the oesophagus if ingested and lead to the most serious outcomes.
- Button cells typically use alkaline chemistry with 1.5 volt electrical output. They are button-shaped and less than about 16 mm diameter. Button cells can be inserted in nose, ear, eye, genitals and result in long-term impairment. Ingested button cells usually pass through gastrointestinal tract without problems.

Both of these battery types are associated with consumer injuries. Actions included in this strategy do not currently distinguish between the chemistries. However, one objective of the strategy is to develop a concluded view about whether approaches to button battery safety should be further distinguished according to chemistry.

What are button batteries used for?

Button batteries are used in a very wide range of consumer products such as television and garage remotes, kitchen scales, watches, calculators, cameras, jewellery, digital thermometers, promotional novelty products and many items attractive to small children.

What are the safety risks of exposure to button batteries?

When ingested, saliva triggers the batteries to generate a chemical reaction called 'hydrolysis', leading to chemical burns, including major internal injuries and in some cases death.

If diagnosis and removal of a battery is delayed, serious complications can develop in as little as two hours, and death is possible within 24 hours.

Any battery over 1.23 volts can still cause hydrolysis. This includes 'flat' (energy depleted) 3 volt lithium batteries as they will generally still have greater than 1.23 volts when 'flat' for normal use.

Small cylindrical batteries that are more than 1.23 volts (AA/AAA/others) can also present a similar hazard; however, injuries are much less frequent because the batteries do not lodge in the throat.

Injury data

The ACCC was first alerted to an incidents involving coin cell battery in 2010 when a five-year-old swallowed a battery accessed from a toy purchased from a confectionary outlet, and a one year old suffered serious injury from ingestion of a battery from 3D television glasses. In 2015 a Queensland coronial investigation concluded that ingestion of a button battery led to the death of a four year old child. Another investigation into the death of a fourteen month old toddler is still underway in Victoria. Other children been seriously injured and remain with ongoing disability.

Best currently available figures indicate that an estimated 20 children per week present to an emergency department because they have swallowed or inserted a button battery. Of these, five will be injured as a result; children under five years old are considered to be most at risk.

The ACCC currently relies on data from Australian injury surveillance units as well as international injury data to inform our understanding of the issue. In Australia there is comprehensive data to demonstrate the hazard and consequence of battery insertions and ingestions, but the source of the button batteries implicated in incidents is not well understood. The 2010 incident was attributed to a battery from a television remote control, but in other incidents the battery source has not been conclusively identified.

Based on US data, 62 per cent of ingested button batteries come from a consumer product and we expect the percentage would be similar in Australia.

Research conducted in the US suggests that batteries that were ingested by children who were younger than 6 years were obtained from battery packaging in 8% of cases and were loose in 30% of cases.¹

Toby Litovitz (MD) has conducted the most comprehensive analysis of US data, examining 8648 cases. According to her research, the most significant change in US data over the past 15 years is the steady increase in moderate, major and fatal outcomes. This is shown in the following graph, Figure 1, which is illustrated by the jointed line. ²

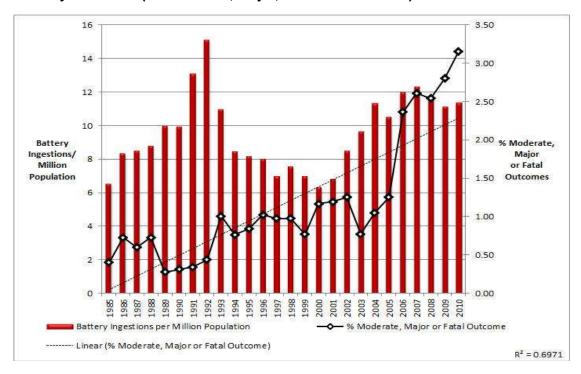
In the US, 13 fatalities were identified between 1997 and 2009. All fatalities occurred in 11-month-old to 3-year-old children. Only one battery ingestion was witnessed. The diagnosis was missed by health care providers in 7 of the 13 deaths because of nonspecific presenting symptoms of vomiting, fever, lethargy, poor appetite, irritability, cough, wheezing, and/or dehydration.³

³ Ibid.

¹Litovitz T, Whitaker N, Clark L, White NC, Marsolek M. <u>Emerging battery ingestion hazard: Clinical implications.</u> Pediatrics 2010; 125(6):1168-1177. Epub 2010 May 24.

²lbid.

US National Poison Data System (NPDS) Button Battery Ingestion Frequency and Severity 1985-2010 (for moderate, major, and fatal outcomes)



When do button batteries pose a risk?

Button batteries are hazardous at all stages in their consumer use life cycle—from purchase as a product in their own right, when installed in a consumer product and when removed for disposal. The risk of the exposure to the hazard, however, can be effectively reduced by safe packaging, use instructions and warnings, secured battery compartments in consumer products and provision for secure household battery disposal. The risk of an adverse outcome resulting from an exposure can also be effectively reduced by consumer awareness of the hazard, knowledge of appropriate steps to take if exposure is suspected, and awareness of the hazard by first responders and medical treatment staff.

Do any regulations already apply?

Regulatory controls already apply to consumer goods that are:

- i. Toys for children up to and including 36 months of age. These are covered by the mandatory safety standard requirements for children's toys under the ACL.
- ii. Goods that are subject to regulatory control by specialist regulators, medical devices or products for industrial or scientific use.

The above controls do not specifically address the hazard of button batteries and the majority of potentially hazardous consumer products containing button batteries are not subject to relevant mandatory safety standards.

Overview of the National Strategy

Key strategies and outcomes

Overarching aim

To prevent child exposure to uncontained button batteries through voluntary safety improvements in order to eliminate button battery related injuries in Australia.

Actions

Six key actions have been identified as a means of achieving this goal:

- Awareness
- Best Practice
- Monitoring
- Marketplace removal and voluntary recalls
- Research
- National cooperation and international leadership.

Principles

The principles outlined below will guide how the work to deliver the outcomes of the strategy will be achieved. The principles are:

- Proportionality measures to achieve the strategy outcomes will be proportionate to assessed risks and where possible control measures will be based on existing industry and government arrangements.
- Evidence-based policy and decisions decisions to take regulatory action or develop regulatory policy will be based on sound evidence and analysis from robust sources. Proposed measures will be cost effective and subject to a cost benefit analysis.
- **Transparency** activities will be conducted in an open and transparent manner and all stakeholders will have access to the information permitted by law to be made available.
- Stakeholder participation the risks of exposure to button batteries is a consumer household, community and business issue and consideration will be given to the interests of all stakeholders.
- Partnership responses and strategies will be developed in partnership with government and industry so that appropriate knowledge and needs can be effectively and efficiently integrated and outcomes are nationally consistent. Outcomes will take account of international arrangements that do not restrict competition and trade.

The Strategy: 2016-18

The strategy will continue to support the existing risk management approaches to button battery consumer products available for supply to Australian consumers. This will be complemented by collecting evidence, evaluating existing measures, and disseminating information to reduce risks. Year one includes work on areas where there is a widespread consensus. It will incorporate research, projects and testing of approaches to gather evidence, develop supporting tools and systems to identify options that reduce the risks posed by button batteries to consumers.

The knowledge and information developed during year one of the strategy will inform the direction of future actions; including setting any course for regulatory intervention. It is expected the work undertaken in year one will identify product categories and/or suppliers where voluntary actions to improve safety are or are likely to become effective. Products and/or suppliers that do not demonstrate safety improvement will be the focus of further work in year two to inform any case/s made for regulatory intervention. The number of products ultimately requiring regulatory intervention – in the form of ongoing regulatory control - would be an inverse measure of the overall success of the strategy.

Working with government

It is important that all jurisdictions work together and take an active role in raising awareness of button battery safety issues to reduce the incidence of unsafe products in retail supply and prevent injuries to consumers.

To achieve this, the Strategy promotes working in partnership with relevant Australian, state and territory government agencies and local government. Government stakeholders will also provide ongoing input into the implementation of the plan.

Working with stakeholders

In addition to government, the management of these products involves a diverse group which includes: researchers, industry, non-government organisations, consumer advocates and public health bodies. To ensure that stakeholder concerns are heard and addressed, the ACCC will inform all stakeholders of the strategy and provide opportunity to contribute.

Summary of roles

Achieving the primary objective of the strategy- to prevent child exposure to uncontained button batteries through voluntary safety improvements - requires all stakeholders to contribute from their relative positions of strength.

For Industry this may include:

- rapid adoption of the voluntary supplier code for button battery consumer products
- · encouraging peers to also adopt the code
- adopting safer battery technologies when available
- responding positively to regulatory advice or action
- asking for assistance from regulators where needed

For Regulators this may include:

- facilitating and amplifying a shared understanding of the issue
- nationally consistent, fair and predictable treatment of products already in supply chains

- · recognition of the Industry Code
- developing additional stakeholder guidance where needed
- simplified recall reporting processes
- holding, analysing and sharing relevant data as permitted by law
- drawing together evidence to assess the effectiveness of the strategy and need for regulatory intervention

For consumers and advocates this may include:

- knowing and communicating about the risks and relevant precautions
- bringing unsafe or risky products to the attention of suppliers and regulators

For public health bodies this may include:

- agreement on consistent treatment and emergency advice
- willingness to be advocates for improved safety
- bringing unsafe or risky products to the attention of regulators
- bringing newly observed hazards, incidents or injuries to the attention of regulators
- progressing and sharing the outcomes of safety initiatives already underway

Actions

Action one: Awareness

Many different government and non-government bodies have a role in increasing the public awareness of the hazards presented by button batteries. The effectiveness of these efforts can be improved through national coordination and targeting to areas of need.

Goal: Increase public awareness of the health risks posed by exposure of children to button batteries

Deliverables

- Review of awareness raising information, programmes and campaigns in Australia to identify gaps and improve awareness in the Australian community of the hazards presented by button batteries
- Reinforce the Product Safety Australia website as a "one-stop-shop" of information on button battery consumer product issues.

Outcomes

- 1.1 Increased community awareness of the risks posed by button batteries, especially where gaps are identified
- 1.2 Improved supplier awareness of risks and hazards associated with button battery products and community expectations that products supplied are safe
- 1.3 Improved access to information for suppliers and consumers including where and when to source information and advice.

Action two: Best practice

Best practice approaches need to be based on evidence. The strategy encourages discussion, information sharing, and promotion of best practice to improve the safety of button battery consumer products. The ACCC will facilitate further discussion with state, territory and local government, and relevant stakeholders to prioritise and seek partners to achieve these outcomes.

Goal: Identify and share best practice in design and supply, use, storage and disposal of button battery consumer products.

	- according to the acco		
De	eliverables	Outcomes	
•	Industry needs in awareness of hazards, available safety controls and training for suppliers and quality assurance staff	2.1 Evidence-based best practice guidance is available to minimise risks in identified targer areas.	
		2.2 Model training is available for suppliers.	
		2.3 Information about safety improvements available via new technology, including chemical and mechanical controls is communicated to Industry	
•	Review of health practitioner and first responder advice	2.4 2There is consistent/agreed health practitioner advice for first responders and treatment providers across all jurisdictions.	
•	Develop practical evidence-based safety information about button battery use and disposal for households.	2.5 Information and means for safe storage and disposal of button battery products is available to households.	
•	Promote best practice and support initiatives to encourage battery recycling at licensed facilities	2.6 More availability of supplier based facilities for return of used batteries	

Action three: Identification

There is currently an absence of consistent risk assessment tools for regulators to respond to button battery consumer products. Improving identification and sharing of existing information will enable the development of tools and evidence-based approaches to identify and prioritise products for action.

Goal: Improve the identification and risk assessment of hazardous button battery products

Deliverables			Outcomes		
•	Documentary review to identify relevant suppliers and products and linkages between products and consumer injuries		3.1 Relevant suppliers and industry association are identified and contacted to raise awareness of the strategy and expectation		
			3.2 Relationships between products and injury are understood and enable products/suppliers to be prioritised for attention		
			3.3 Better understanding of risks posed by different battery chemistries		
•	Ef	ficient responses to hazardous products	3.4 Information is available on govdex to reduce duplication of effort by regulators		
•		eview current practices with the aim of eveloping:	3.5 Development of a 'tool kit' for rapid identification of hazardous button battery		
	0	Consistent risk assessment approach for regulators	consumer products 3.6 Use of the toolkit by all jurisdictions		
	0	Consistent response to products based on risk	3.7 Effective coordinated response across jurisdictions when unsafe products are identified		

Action four: Removal (monitoring and recall)

Under the strategy, the activities undertaken in the removal strategy will inform the impact of future regulatory proposals.

Goal: Identify priority areas where button battery consumer products present a risk, identify the barriers to their safety, including barriers to effective recall, and assess the impacts of safety improvement.

Deliverables		Outcomes		
Co aw endTaMo	Conduct coordinated surveillance to raise awareness, identify hazardous products and	4.1 Coordinated retail surveys are undertaken in all jurisdictions.		
	encourage their removal from supply	4.2 Retailers take voluntary actions to improve the safety of products they supply		
•	Tailored risk-based approach to recalls	4.3 Options to remove products are practical, evidence-based and targeted towards products representing the highest risk to consumers		
•	Monitor recall effectiveness of button battery products	4.4 Barriers to improving safety are identified and understood		
•	Review of the potential risks and benefits of regulatory interventions	4.5 Industry is not unfairly affected by regulatory intervention.		
		4.6 The barriers to improving safety are reviewed and lead to proposals for policy advice consistent with regulatory best practice		

Action five: Research

Any work undertaken to improve consumer product safety requires a strong research base. There has been a significant amount of research and information regarding button batteries conducted in Australia and internationally. A nationally coordinated research approach will consider emerging technologies and regulatory approaches elsewhere.

Goal: Monitor and promote research into better design, use and disposal of button battery consumer products and treatment of incidents

Deliverables

- Identification of key national and international research and reports to enable better sharing of information to inform policy and best practice.
- Promotion of research into and trials of practical and innovative approaches to prevent or minimise risks from exposure to button

Outcomes

- 5.1 Monitoring and dissemination of new research supports and informs evidence based policy and practice.
- 5.2 Research that identifies practical and innovative approaches to prevent or minimise risks from exposure to button batteries is collated and shared: eg. Chemical and mechanical safety controls (bitterants, sealants and dyes); new battery technologies.

Action six: International leadership

The Australian economy does not lead the design of consumer products manufactured overseas. However, there is opportunity for Australia to play a leadership role in securing a consistent international approach to button battery safety.

Goal: Australia develops a leadership role in securing a consistent international approach to button battery consumer products

Deliverables

- Australian participation in international fora maintains focus on button battery safety as a priority for international action
- Proactively share knowledge, tools and information on best practice with other countries and relevant international organisations.

Outcomes

- 6.1 Australia informs and influences relevant International fora.
- 6.2 Australia is recognised as a strong international voice in improvement of button battery safety.
- 6.3 Information about best practice for awareness and safety of these products is shared internationally.

Monitoring and evaluation

The role of the ACCC and Working Group

The strategy will be coordinated by the ACCC and a working group of state and territory Australian consumer law regulators. The CDRAC and ultimately CAANZ will have oversight of the strategy.

Final report

An interim and final report on progress against the strategy will be published by the ACCC.

Access to further information

The Australian Government aims to provide services that are fair, easy to access and simple to use.

For assistance with accessing a copy of the National Strategy for Button Batteries or to make an enquiry or comment, please contact ACCC at:

Details tbc - consultation hub and website

Actions and outcomes summary

AIM: To prevent child exposure to uncontained button batteries in order to eliminate button battery related injuries in Australia.

PRINCIPLES: proportionality - evidence-based policy and decisions- transparency - stakeholder participation - partnership

ACTIONS	1: Awareness	2: Best practice	3: Monitoring	4: Removal (monitoring and voluntary recalls)	5: Research	6: International leadership
GOALS	Increase public awareness of the health risks posed by exposure of children to button batteries	Identify and share best practice in design and supply, use, storage and disposal of button battery consumer products.	Improve regulator responses to hazardous button battery products	Identify priority areas where button battery consumer products present a risk, identify the barriers to their safety, including barriers to effective recall, and assess the impacts of safety improvement	Monitor and promote research into better design, use and disposal of button battery consumer products and treatment of incidents	Australia develops a leadership role in securing a consistent international approach to button battery consumer products
OUTCOMES	 1.1 Increased community awareness of the risks posed by button batteries, especially where gaps are identified 1.2 Improved supplier awareness of risks and hazards associated with button battery products and community expectations that products supplied are safe 1.3 Improved access to information for suppliers and consumers including where and when to source information and advice. 	 2.1 Evidence-based best practice guidance is available to minimise risks in identified target areas. 2.2 Model training is available for suppliers. 2.3 Information about safety improvements available via new technology, including chemical and mechanical controls is communicated to Industry 2.4 There is consistent/agreed health practitioner advice for first responders and treatment providers across all jurisdictions. 2.5 Information about safe storage and disposal of button battery products is available to households. 2.6 More availability of supplier based facilities for return of used batteries 	 3.1 Relevant suppliers and industry associations are identified and contacted to raise awareness of the strategy and expectation 3.2 Relationships between products and injury are understood and enable products/suppliers to be prioritised for attention 3.3 Information is available on govdex to reduce duplication of effort by regulators 3.4 Development of a 'tool kit' for rapid identification of hazardous button battery consumer products 3.5 Use of the toolkit by all jurisdictions 3.6 Effective coordinated response across jurisdictions when unsafe products are identified 	 4.1 Coordinated retail surveys are undertaken in all jurisdictions 4.2 Retailers take voluntary actions to improve the safety of products they supply 4.3 Options to remove products are practical, evidence-based and targeted towards products representing the highest risk to consumers 4.4 Barriers to improving safety are identified and understood 4.5 Industry is not unfairly affected by regulatory intervention. 4.6 The barriers to improving safety are reviewed and lead to proposals for policy advice consistent with regulatory best practice. 	 5.1 Monitoring and dissemination of new research supports and informs evidence based policy and practice. 5.2 Research that identifies practical and innovative approaches to prevent or minimise risks from exposure to button batteries is collated and shared: eg. Chemical and mechanical safety controls (bitterants, sealants and dyes); new battery technologies. 	 6.1 Australia informs and influences relevant International fora. 6.2 Australia is recognised as a strong international voice in improvement of button battery safety. 6.3 Information about best practice for awareness and safety of these products is shared internationally.