

Attachment A: Button Battery Safety – Final Recommendation to the Minister



AUSTRALIAN COMPETITION
& CONSUMER COMMISSION

Button Battery Safety

Final Recommendation to the Minister

November 2020

Office of Best Practice Regulation Reference 25774

Acknowledgment

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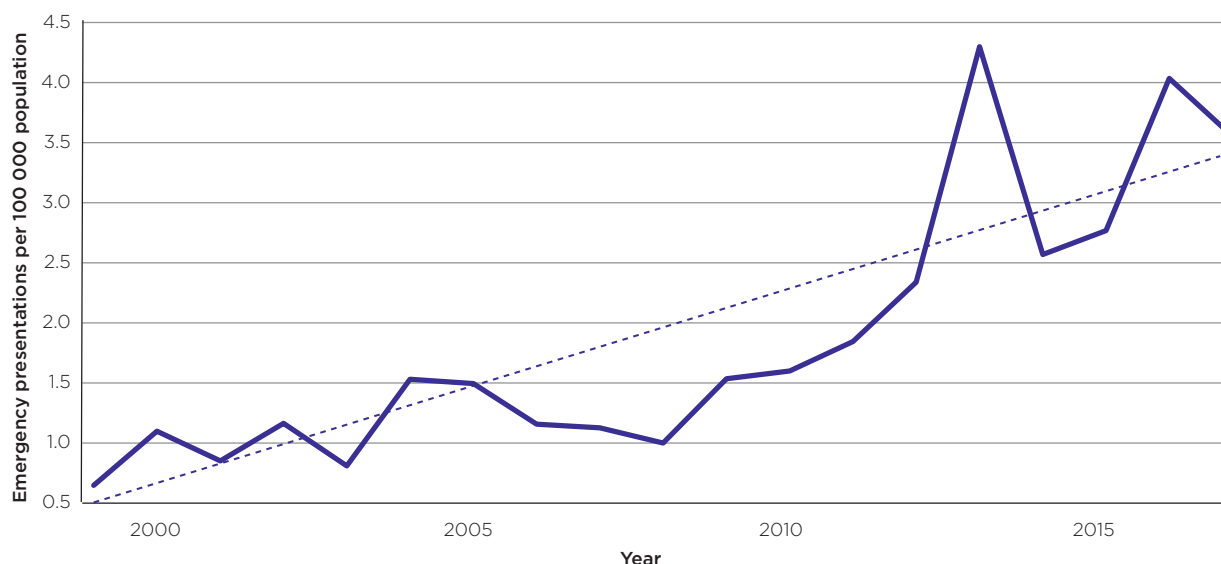
Executive summary

Button batteries are flat, round, single cell, coin-sized batteries with diameters up to 32 mm and heights ranging from 1–11 mm in thickness. Button batteries are available separately and as components of a huge range of consumer goods and household products.

Button batteries can cause severe injury and even death if swallowed, with children under five years of age proving to be at greatest risk. When a child swallows or inserts a button battery, it can get stuck in their throat or body. When lodged in the body and in contact with bodily fluid, button batteries can burn through tissue and cause catastrophic bleeding. Serious injury can occur in as little as two hours. In Australia and globally, there is a growing record of serious injuries and deaths from button batteries.

In Australia, three children have tragically died as a result of swallowing a button battery and more than one child a month is seriously injured after swallowing or inserting a button battery, with some of them sustaining lifelong injuries. Globally, at least 66 children have died and thousands have been injured from button batteries with some children sustaining lifelong injuries requiring ongoing treatments.¹ The number of severe injuries resulting from the ingestion of button batteries has increased significantly over the last 10 years.² Australian emergency department records also indicate a significant increase in button battery incidents.³

Button battery emergency department presentations in Australia



Source: Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health, ABS Population Estimates, ABS Population Projections

- 1 National Capital Poison Centre, *Fatal Cases*, retrieved from <https://www.poison.org/battery/fatalcases>, viewed 15 October 2020 (NCPC Fatal Cases); National Capital Poison Centre (NCPC), *Severe Cases*, retrieved from <https://www.poison.org/battery/severecases>, viewed 15 October 2020 (NCPC Severe Cases); Labadie M, O'Mahony E, Capaldo L, Courtois A, Lamireau T, Nisse P, Blanc-Brisset I, Puskarczyk E. *Severity of button batteries ingestions: data from French Poison Control Centres between 1999 and 2015*. *European journal of emergency medicine*. 2018 Aug 1; 25(4):e1-8. NCPC Fatal Cases lists 64 fatalities as at 15 October 2020. The French Poison control study includes reference to two fatalities that are not listed on the NCPC fatal case list.
- 2 NCPC Fatal Cases; NCPC Severe Cases.
- 3 Presentation rates and forecast presentation rates calculated using data provided to the ACCC by the Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health and Australian Bureau of Statistics Population estimates and projections.

The safety risk to children from button batteries arises when they can gain access to them. This may occur in different ways:

- Children gain access directly from consumer goods that contain button batteries that either do not have secure battery compartments or which easily release the batteries.
- Children gain access directly from packaging that is not child-resistant—this may be from packaging of button batteries themselves, or where button batteries are supplied loose in the packaging of a consumer good (and not pre-installed in the product).
- Children gain access when batteries are removed from consumer goods or packaging and are not stored safely out of reach, or otherwise not properly disposed of—old or spent button batteries can still hold a charge capable of causing injury.

Product safety best practice involves manufacturers adopting a precautionary approach when assessing the safety of consumer goods. Where possible, manufacturers should make design modifications to eliminate hazards caused by products associated with injuries at the design stage.⁴

The Hierarchy of Risk Control Framework (HORC Framework) assists in considerations for the management of identified hazards and risks and outlines the most and least effective control measures for eliminating or reducing risks. The HORC Framework identifies that the most effective measure to reduce risk is elimination of the hazard. Where elimination of a hazard is not feasible, other control measures include substitution, isolation, engineering controls, administrative controls and the use of personal protective equipment.

The serious hazard of button batteries has been realised by battery manufacturers for at least four decades. To date, despite some efforts, significant safety improvements to button batteries to reduce the risk to children if batteries are ingested have not occurred. The ACCC calls on battery manufacturers to urgently invest in and prioritise the funding of research and adoption of measures to improve the safety of their products. The ACCC is aware of emerging research and technologies focused on making button batteries safer, such as pressure sensitive coatings and alternative casings to prevent chemical reactions and tissue damage from occurring when batteries are ingested by children.

Manufacturers, distributors, importers, retailers and online suppliers need to make responsible decisions about button battery safety when procuring, designing, developing or retailing button battery powered devices. A primary consideration should be whether consumer goods containing button batteries are supplied at all, or may be powered by other types of batteries or use rechargeable batteries that are fully enclosed in the product and inaccessible to children.

The use of button batteries in a wide variety of products means that elimination of button batteries and products that contain button batteries is not a feasible risk control measure. Therefore, the next most effective measures, including substitution and engineering controls, should be considered.

For a third consecutive year, the ACCC has identified button battery hazards as a product safety priority.

This follows the implementation of the two-year [National strategy for improving the safety of button battery consumer products](#) (the national strategy). The national strategy began alongside the release of the voluntary [Industry Code for Consumer Goods that Contain Button Batteries](#) (the industry code), developed by industry and published in 2016. The industry code includes requirements only for consumer goods that contain button batteries, and does not include any child-resistant packaging or warning requirements for button batteries themselves.

A primary goal of the national strategy was to assess whether voluntary approaches like the industry code would sufficiently mitigate button battery hazards. The strategy also collected evidence to inform any possible regulatory or other approaches to improve button battery safety. The ACCC and other ACL regulators conducted market surveillance throughout the course of the strategy to gauge the uptake of the industry code by suppliers. The ACCC examined trends in injury reporting to see if there were any indications that exposures and injuries associated with button batteries were decreasing.

⁴ Standards Australia, Consumer Product Safety—Guidelines for Suppliers (AS ISO 10377:2017)—section 3.6.

In early 2019, the ACCC evaluated the impact of the national strategy and found voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries.

The ACCC considers that there is a market failure with regard to the safety of button batteries and consumer goods that contain these batteries. Mandatory regulation is necessary to prevent deaths and severe injuries to children resulting from button batteries, as voluntary supplier self-regulation has not sufficiently reduced the risk. An appropriate regulatory solution needs to capture the wide variety of consumer products that contain button batteries.

The ACCC is aware of significant efforts made by some suppliers but overall there continues to be a high number of unsafe consumer goods containing button batteries available in the Australian market, and there is not yet any meaningful decrease apparent in the rate of button battery exposures or injuries.

In March 2019, after issuing a [Safety Warning Notice](#) to the Australian public about the dangers of button batteries, the Hon. Stuart Robert, then Assistant Treasurer, asked the ACCC to expedite the regulatory impact assessment process for developing regulation to address button battery safety.⁵

The ACCC established a taskforce to conduct an investigation into button battery safety and consider regulatory options available under the ACL.

In August 2019 the ACCC released the [Button Battery Safety Issues Paper](#) (the issues paper) to seek stakeholder feedback on the issue of button battery safety and how the safety hazards posed by button batteries should be addressed. Submissions in response to the issues paper informed the ACCC's development of proposed regulatory options to reduce the likelihood of child exposure to button batteries.

In March 2020 the ACCC released the [Button Battery Safety—Assessment of regulatory options—Consultation paper](#) (the consultation paper) to seek stakeholder feedback on the proposed regulatory options. The policy options included mandatory requirements for secure battery compartments, child-resistant packaging and warnings and information.

The ACCC commissioned Exponent, Inc., a multi-disciplinary engineering and scientific consultancy based in the United States, to conduct a technical review of the proposed requirements outlined in the consultation paper. The technical review was led by a recognised expert in injury prevention, physical hazards and consumer goods risk assessment, with a focus on adolescent exposure.

In addition to expert advice, the ACCC also engaged with key stakeholders to discuss issues raised in submissions and to further explore the practicalities of proposed policy options. Based on the technical advice and stakeholder feedback, the ACCC has refined the policy options outlined in our consultation paper. Further data and information was also sought from industry stakeholders to help inform a thorough cost benefit analysis and regulatory burden estimate.

The ACCC considers the introduction of mandatory safety standards consisting of each of the requirements outlined in Option 4 is reasonably necessary to prevent or reduce the risk of injury to any person, as provided for in section 104 of the ACL. Similarly, the introduction of the mandatory information standards will address the significant harm arising from the lack of clear warnings and information available to consumers when purchasing button batteries and consumer goods containing button batteries.

Option 4 requires:

- secure battery compartments for consumer goods containing button batteries, where the batteries are intended to be replaced
- compliance testing of consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, to demonstrate the battery is secure and is not released during reasonably foreseeable use or misuse conditions

⁵ ACCC, Safety warning notice (button batteries), ACCC, Canberra, 2019, www.productsafety.gov.au/publication/safety-warning-notice-button-batteries, viewed 1 August 2019.

- child-resistant packaging for button batteries of lithium chemistry of all sizes, and for button batteries of a chemistry other than lithium with a diameter of 16 mm and above
- warnings and information provided on packaging and in instructions of consumer goods that contain button batteries, or otherwise attached or included with unpackaged products or products that are not supplied with instructions
- warnings and information to be provided on button batteries (“Keep Out of Reach of Children” symbol markings on button batteries of lithium chemistry with a diameter of 20mm and above) and packaging of all button batteries.

There is currently no mandatory regulation, in Australia or internationally, that horizontally addresses the hazards associated with button batteries across all consumer goods. There is also no general legislative provision on the supply of unsafe goods in Australia.⁶

Mandatory safety and information standards for consumer goods that contain button batteries would have broad application to a wide range of products, including some medical devices and electrical appliances that are subject to regulatory control by specialist regulators, such as state-based electrical safety regulators and the Therapeutic Goods Administration (TGA).

Although some state-based electrical equipment safety regulations require compliance with applicable industry standards, regulations vary significantly between states and territories in their scope and requirements for consumer goods that contain button batteries. This results in regulatory gaps for products that are commonly distributed throughout Australia.

Nationally consistent regulation will be achieved by the introduction of mandatory safety and information standards under the ACL. This will address the regulatory gaps that exist in state-based electrical equipment safety regulations and will ensure that regulatory requirements are consistent across all jurisdictions and apply to all consumer goods that contain button batteries to limit the risk of injury from these products.

In determining the proposed requirements of the mandatory safety and information standards, the ACCC has sought to harmonise the proposed mandatory requirements with the voluntary requirements of relevant national and international industry standards, where this will ensure an acceptable level of safety.

Importantly, mandatory safety and information standards will require compliance from suppliers that do not currently adhere to any button battery safety requirements of an industry standard or the industry code.

In recent years, the ACCC has led global product safety campaigns facilitated by the Organisation for Economic Co-operation and Development (OECD). The ACCC considers there is the potential for Australia to have a leading role in the development of button battery requirements globally. The ACCC is currently participating in the technical committee convened by Standards Australia to develop an Australian industry standard for button batteries, being a voluntary horizontal standard covering all products that contain button batteries, as well as button batteries themselves. Following the introduction of mandatory safety and information standards for button batteries in Australia, the ACCC proposes to collaborate with the OECD and international standards bodies to adopt button battery requirements in applicable international industry standards that require improvements, or otherwise develop an international horizontal industry standard for button batteries that can be adopted in other jurisdictions.

The ACCC has prepared this Final Recommendation for the Minister which includes an analysis of the costs and benefits of the outlined policy options. The ACCC has considered the status quo of taking no action, a non-regulatory option that would involve consumer awareness and education, and three regulatory options, including the ACCC’s preferred option that involves the introduction of mandatory safety and information standards under the ACL.

⁶ In October 2019, the Commonwealth Treasury began consultation on potential reform options for a General Safety Provision.

It is likely that if no government action is taken deaths and severe injuries associated with button batteries will continue to occur and possibly increase. Button batteries may become more prevalent in an increasing range of digital and portable electronic consumer products that can be accessible to young children in households, consistent with the expanding increased miniaturisation of electronic devices.

The ACCC estimates that four fatalities, 178 to 423 severe injuries and 8,900 emergency presentations will occur during the forecast period of 2022-2031.⁷ Based on these forecasts, the ACCC estimates the direct health costs and immediate costs associated with foregone economic output due to parents and other family members reducing work participation to be approximately \$47.5 million. The true total costs of fatalities and severe injuries to children that have resulted from button batteries are likely to be higher and are impossible to quantify. No economic analysis can appropriately account for the devastating impact on a child, their parents, family, carers and medical staff when a serious button battery incident occurs.

In considering the proposed regulatory options, the government may choose to consider societal benefits across a broader personal and social context. This may mean looking beyond direct and even indirect costs and benefits, to include the pain and suffering resulting from serious injury or deaths, particularly those involving children.

The ACCC considers that a combination of safety and warning requirements is likely to prevent more deaths and serious injuries by reducing incidents of child exposure to button batteries. Consumer goods that contain button batteries should have a secure battery compartment (where the batteries are intended to be replaced) and not release the batteries during reasonably foreseeable use or misuse (whether or not the batteries are intended to be replaced). Child-resistant packaging should be required for button batteries based on their risk profile. Warnings and information should be required when supplying consumer goods that contain button batteries, as well as button batteries themselves, to alert consumers and address information asymmetry issues by improving awareness of the hazard so that appropriate action can be taken when an incident occurs.

The ACCC considers that in implementing these mandatory safety and information standards, some exemptions and non-mandatory provisions are appropriate for products with a lower risk profile. These include exemptions from all requirements for:

- second-hand goods, that were first supplied to a consumer before the standards become mandatory
- professional equipment, subject to certain criteria
- audio visual and information communications technology equipment containing button batteries that are soldered in place.

Hearing aid devices and associated zinc-air batteries would be exempt from the secure battery compartment and child-resistant packaging requirements.

Hearing aids do not pose the same risk as other products because of their predominant use of zinc-air batteries which pose lower risks than other button battery types. A mandatory requirement for secure battery compartments and child-resistant packaging for hearing aid devices and associated zinc-air batteries would significantly reduce the usability and accessibility of the devices for these consumers, especially those with poor dexterity or vision impairment.

As part of a holistic approach to mitigate the safety risks associated with button batteries, the ACCC notes that additional risk mitigation measures should be considered by government to complement the introduction of the proposed mandatory safety and information standards, such as national awareness-raising campaigns and further development of secure containers for the safe disposal of button batteries.

⁷ The ACCC proposes an 18 month transition period, the forecast period commences after this period in 2022.

Glossary

Term	Definition
ACCC	Australian Competition and Consumer Commission
ACL	Australian Consumer Law, Schedule 2 of the <i>Competition and Consumer Act 2010</i>
APSU	Australian Paediatric Surveillance Unit
AS	Australian Standard
AS/NZS	Australian/New Zealand Standard
BSC	Battery Stewardship Council
CALD	culturally and linguistically diverse
CCA	<i>Competition and Consumer Act 2010</i> (Cth)
Consultation paper	Button Battery Safety—Assessment of regulatory options—Consultation paper released by the ACCC on 19 March 2020
CPSC	Consumer Product Safety Commission (US)
CRP	child-resistant packaging
ED	Emergency department
EN	European Standard
ERAC	Electrical Regulatory Authorities Council
HORC Framework	Hierarchy of Risk Control Framework
HSP	Hearing Services Program
IEC	International Electrotechnical Commission
Industry code	Industry Code for Products Containing Button Batteries
ISO	International Organization for Standardization
Issues paper	Button Battery Safety Issues Paper released by the ACCC on 16 August 2019
National strategy	National strategy for improving the safety of button battery consumer products
NBIH	National Battery Ingestion Hotline (US)
NCPC	National Capital Poison Center (US)
OBPR	Office of Best Practice Regulation
OECD	Organisation for Economic Co-operation and Development
PCBB	Products Containing Button Batteries
PIC	Poisons Information Centre
QISU	Queensland Injury Surveillance Unit
SIRDB	Severe Injury Related to Disc Battery
SKU	stock keeping unit
TGA	Therapeutic Goods Administration
VISU	Victorian Injury Surveillance Unit
VSL	value of a statistical life

Button battery types and related products

For the purpose of this Final Recommendation, button cell batteries and coin cell batteries are each referred to as 'button batteries'. In the battery industry, the term 'coin' is associated with lithium batteries and the term 'button' is associated with non-lithium batteries. The terms 'button batteries of lithium chemistry' or 'button batteries of a chemistry other than lithium' are used to distinguish between types of button batteries on the basis of their chemistry (or electrochemical system).

The range of different button batteries and related products is referenced below.⁸ There is a wide variety of button batteries available in different sizes, shapes and electrical charges.

Table 1: Button battery types

Battery type	Description
Alkaline	 <p>Alkaline button cell batteries have a nominal voltage of 1.5 volts and are generally less than 16 mm in diameter. Alkaline voltage drops gradually with use and alkaline button cell batteries average around half the life of lithium and silver oxide batteries.</p>
Lithium	 <p>Lithium coin cell batteries have a nominal voltage of 3 volts. They are available in a range of sizes, including the larger coin size, with diameters ranging from 9.5 mm to 32 mm and height from 1.2 mm to 10.8 mm.</p>
Silver oxide	 <p>Silver oxide button batteries have a nominal voltage of 1.5 volts and range in diameter from 4.8 mm to 11.6 mm and in height from 1.3 mm to 5.4 mm.</p>
Zinc-air	 <p>Zinc-air batteries have a nominal voltage of 1.4 volts and are typically smaller. They are available in a range of sizes (5.8 mm x 3.6 mm, 7.9 mm x 3.6 mm, 7.9 mm x 5.4 mm and 11.6 mm x 5.4 mm). These batteries are commonly found in hearing aid devices and require access to air (oxygen) to produce a current.</p>

⁸ Coin Cell/Button Cell Battery Guide, www.batteries.com/pages/coin-cell-button-cell-battery-guide, viewed 9 December 2019.

Button batteries are found in a broad range of consumer and household products including, but not limited to, remote controls (television remotes, car keys, garage door openers), watches, computers, cameras, calculators, torches, flameless candles, fitness devices, digital kitchen and bathroom scales, toys, games, novelty items, musical greeting cards and home medical devices (digital thermometers, pedometers, glucometers, heart rate monitors, hearing aids).

For the purposes of this Final Recommendation, the term ‘consumer goods that contain button batteries’ includes consumer goods that use, are powered by, or are intended to operate with button batteries, as well as consumer goods designed or intended to store button batteries, such as storage containers and organisers.

Figure 1: Common button battery-powered products



Recommended mandatory safety and information standards to address button battery safety

This Final Recommendation makes the following recommendations:

Consumer goods that contain button batteries

- Consumer goods containing button batteries that are intended to be replaced by the consumer be required to have a secure battery compartment that is resistant to being opened by young children.
- Consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, be required to be secure and not release the batteries during reasonably foreseeable use or misuse conditions.
- Compliance testing be required to demonstrate safety requirements have been met.
- Warnings be required with consumer goods that contain button batteries on the packaging or accompanying instructions, and at the retail point of sale for unpackaged products or products that are not supplied with instructions, to alert consumers that a button battery is included with the product and the hazard button batteries pose to children.
- Exemptions to apply to second-hand goods first supplied to a consumer before the standards become mandatory; professional equipment, subject to certain criteria; and audio visual and information communications technology equipment containing button batteries that are soldered in place. Hearing aids would be exempt from secure battery requirements, but subject to warning requirements.

Button batteries

- Packaging be required to be child-resistant for button batteries of lithium chemistry of all sizes, and button batteries of a chemistry other than lithium with a diameter of 16 mm or above.
- Compliance testing be required to demonstrate child-resistant packaging requirements have been met.
- Where multiple button batteries are supplied that include any of the applicable button batteries in scope of the child-resistant packaging requirements, blister packaging must be designed to release only one button battery at a time.
- Any spare button batteries that are supplied with a consumer good, where the battery is not pre-installed in a secure battery compartment, must be enclosed in child-resistant packaging.
- Button batteries of lithium chemistry with a diameter of 20mm and above be required to be marked with an internationally recognised “Keep Out of Reach of Children” symbol.
- Warnings and information be required on packaging of button batteries to alert consumers to the hazard button batteries pose to children and provide clear directions on what to do in the event a child is suspected to have swallowed or inserted a battery.
- Exemptions to apply to button batteries supplied in bulk for professional use (subject to certain criteria). Button batteries of zinc-air chemistry intended for hearing aids would be exempt from child-resistant packaging requirements, but subject to warning requirements.

Transition period

- The requirements be mandatory 18 months after the legislative instruments commence.

About this Final Recommendation

The Australian Competition and Consumer Commission (ACCC) is an independent Commonwealth statutory authority that promotes competition and fair trading in markets to benefit consumers, businesses and the Australian community. Our primary responsibility is to ensure that individuals and businesses comply with the *Competition and Consumer Act 2010* (the CCA), which includes the Australian Consumer Law (ACL).

Through the application of the ACL, the ACCC aims to prevent misleading behaviour and unconscionable conduct, minimise the risk posed by unsafe consumer products and ensure consumers are fully informed about safety risks.

Consumer product safety regulation in Australia is a shared responsibility between the ACCC and state and territory consumer protection regulators. The ACCC's product safety role involves identifying, prioritising and addressing risks to persons arising from unsafe consumer goods and product-related services.

We do this by administering the consumer product safety provisions of the ACL, which include powers for the Minister responsible for product safety to issue compulsory recalls, product bans, safety warning notices, and mandatory safety and information standards.

Mandatory safety and information standards made under the ACL make particular safety or information features compulsory for the legal supply of a specific product into the Australian market. They are introduced when considered reasonably necessary to prevent or reduce the risk of injury to a person, or, in the case of information standards, to provide important information about a product to assist consumers in making purchasing decisions.⁹

For the purposes of this Final Recommendation, all flat, disc-shaped cells or small round batteries that have a diameter greater than the battery's height are referred to as 'button batteries' regardless of their size or chemistry. 'Coin', 'disc' and 'button' cells or batteries are taken to be one and the same article. Where it is necessary to distinguish between types of button batteries, the relevant battery chemistries and diameter sizes are specified.

In response to continuing concerns about the hazards button batteries posed to children, the ACCC has conducted a safety investigation to identify regulatory options available under the ACL to improve the safety of button batteries and consumer goods that contain them. This Final Recommendation includes the findings from the safety investigation and an analysis of the costs and benefits of the outlined policy options. The process and analysis completed in developing the regulatory proposals in this Final Recommendation to address the hazard of button batteries is certified by the ACCC as equivalent to a Regulation Impact Statement.

In undertaking a cost-benefit analysis of each policy option to improve button battery safety, it is important to highlight that not all factors or impacts can be readily quantified or reducible to a monetary amount. To remedy this, the ACCC assessment for each policy option includes both quantitative and qualitative considerations.

⁹ Australian Government, *Federal Register of Legislation 2010*, Australian Government, Canberra, www.legislation.gov.au/Details/C2020C00006 ss. 104, 105, 134 and 135 of the Australian Consumer Law, viewed 5 February 2020.

1. Introduction

This Final Recommendation proposes regulatory options to reduce the number of severe injuries and deaths associated with children ingesting or inserting button batteries.

Button batteries are flat, round, single cell batteries with a diameter of up to 32 mm which range in height from 1–11 mm. These batteries are referred to as button or coin cell batteries. They are used in a broad range of consumer and household products including remote controls (television remotes, car keys, garage door openers), watches, computers, cameras, calculators, torches, flameless candles, fitness devices, digital kitchen and bathroom scales, toys, games, novelty items, musical greeting cards and home medical devices (digital thermometers, pedometers, glucometers, heart rate monitors and hearing aids).

Their small size, while suited to many uses, makes it easy for children to swallow and insert them into body orifices, such as their ears and nose.

In Australia, three children have tragically died as a result of swallowing a button battery and there are a growing number of young children suffering severe injuries following exposure to button batteries.¹⁰

Button battery safety and supporting strategies to prevent injuries and deaths in children is an ACCC product safety priority. The ACCC's button battery safety investigation has determined that the following safety measures are reasonably necessary to prevent or reduce the risk of injury to children from button batteries. The ACCC has also determined that important information, including warnings, are necessary to raise consumer awareness and provide informed choice when purchasing consumer goods containing button batteries, as well as button batteries themselves.

Consumer goods that contain button batteries

- Consumer goods that contain button batteries, where the batteries are intended to be replaced by the consumer, have a secure battery compartment that is resistant to being opened by young children and which does not release the batteries during reasonably foreseeable use or misuse conditions.
- Consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, be secure and not release the batteries during reasonably foreseeable use or misuse conditions.
- Suppliers of consumer goods that contain button batteries perform compliance tests to demonstrate the button battery safety requirements have been met.
- Warnings and information be provided with products that contain button batteries on the packaging and accompanying instructions, and at the retail point of sale for unpackaged products, to alert consumers that a button battery is included with the product and the hazard button batteries pose to children.
- Exemptions to apply to hearing aids, second-hand goods,¹¹ professional equipment (subject to certain criteria) and audio visual and information communications technology equipment containing button batteries that are soldered in place.

Button batteries

- Packaging to be child-resistant for button batteries of lithium chemistry, and button batteries of a chemistry other than lithium with a diameter of 16 mm or above.
- Button batteries of lithium chemistry with a diameter of 20mm and above to be marked with an internationally recognised "Keep Out of Reach of Children" symbol.

10 T Litovitz, N Whitaker, L Clark, NC White, M Marsolek, *Emerging battery-ingestion hazard: clinical implications*, *Pediatrics*, 125(6), 2010, 1168-1177.

11 The second-hand goods exemption would apply only to goods first supplied to a consumer before the standards become mandatory.

- Warnings and information on packaging of button batteries to alert consumers to the hazard button batteries pose to children and provide clear directions on what to do in the event that a child is suspected to have swallowed or inserted a battery.
- Exemptions to apply to zinc-air batteries intended for hearing aids and button batteries supplied in bulk for professional use, subject to certain criteria.

The ACCC recommends that these measures are implemented under the ACL to improve the safety of consumer goods that contain button batteries, as well as button batteries themselves. The ACL empowers the Minister responsible for product safety to make mandatory safety standards for consumer goods as well as information standards for goods of a particular kind, including consumer goods.

There is currently no mandatory regulation, in Australia or internationally, that horizontally addresses the hazards associated with button batteries across all consumer goods. There is also no general legislative provision that requires goods sold in Australia to be safe.¹²

The ACCC proposes a principles-based approach to the regulation of button batteries. This approach would involve mandatory safety and information standards that detail a minimum set of outcomes-based requirements, as well as best practice recommendations where applicable, that can be applied across relevant product types. Outcomes-based requirements are intended to avoid the need for prescriptive regulation, they focus on the outcome to be achieved rather than specifying how it is to be achieved. This approach provides for freedom in design and does not limit innovation.

The ACL defines ‘consumer goods’ as ‘goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption’.¹³ The use of button batteries in diverse consumer goods indicates that an appropriate regulatory solution, such as a mandatory standard, would need to be applied horizontally to capture the wide variety of consumer goods that contain button batteries.

Only a horizontal mandatory standard could efficiently address a common hazard across multiple product types. Currently, Australian mandatory standards generally focus ‘vertically’—addressing multiple hazards in a particular category of goods, such as children’s toys. A horizontal mandatory standard under the ACL would apply to a wide range of consumer goods, including household and consumer electronic devices.

Mandatory safety and information standards for consumer goods that contain button batteries would have broad application to a wide range of products, including some medical devices and electrical appliances that are subject to regulatory control by specialist regulators, such as state-based electrical safety regulators and the Therapeutic Goods Administration (TGA).

The ACCC has reviewed electrical safety regulations in each state and territory as they relate to products that contain button batteries and has engaged with electrical safety regulators and the Electrical Regulatory Authorities Council (ERAC) as to whether regulatory duplication would arise should mandatory safety and information standards under the ACL be introduced to apply to consumer goods that contain button batteries. ERAC considers that a horizontal standard under the ACL would not result in regulatory duplication.

The proposed principles-based approach would also avoid duplication with existing medical device warning and information requirements under the TGA’s regulatory framework.

Although some state-based electrical equipment safety regulations require compliance with applicable industry standards, regulations vary significantly between states and territories in their scope and requirements for consumer goods that contain button batteries. This results in regulatory gaps for products that are commonly distributed throughout Australia.

12 In October 2019, the Commonwealth Treasury began consultation on potential reform options for a General Safety Provision.

13 Australian Government, *Federal Register of Legislation 2010*, Australian Consumer Law, Schedule 2, Section 2(1), https://www.legislation.gov.au/Details/C2020C00006/Html/Volume_3#_Toc28948885.

Nationally consistent regulation will be achieved by the introduction of mandatory safety and information standards under the ACL. This will address the regulatory gaps that exist in state-based electrical equipment safety regulations and will ensure that regulatory requirements are consistent across all jurisdictions and apply to all consumer goods that contain button batteries to limit the risk of injury from these products.

In determining the proposed requirements of the mandatory safety and information standards, the ACCC has sought to harmonise the proposed mandatory requirements with the requirements of relevant national and international voluntary industry standards, where this will ensure an acceptable level of safety.

Harmonisation of mandatory requirements with relevant national and international industry standards will minimise the regulatory burden for suppliers that already adhere to industry standards that have acceptable button battery safety requirements. Harmonisation with international industry standards is also a necessary consideration from a trade barriers perspective having regard to the wide range of products that contain button batteries, most of which are manufactured overseas and imported into Australia and supplied to other regions.

There are a range of national and international voluntary industry standards for various products and equipment that have been developed to include button battery safety requirements. Many of these national and international industry standards apply vertically to specific product categories such as audio visual and information communications technology equipment, electric toys, lighting products. These do not effectively address safety for all products that contain button batteries for the following reasons:

- Compliance with industry standards is voluntary, subject to some state-based electrical equipment safety regulations that mandate the requirements of applicable industry standards, and a significant number of suppliers do not comply.
- While some industry standards have been updated to include button battery requirements, this is not the case for all industry standards that cover categories of products which may contain button batteries.
- There are many products that contain button batteries that do not appear to have an applicable industry standard, including a wide range of novelty and promotional products that do not adhere to any button battery safety requirements.

Importantly, mandatory safety and information standards will require compliance from suppliers that do not currently adhere to any button battery safety requirements of an industry standard or the industry code.

In developing a principles-based approach, the ACCC has recognised the challenges of harmonising the requirements across a range of relevant industry standards that do not contain uniform requirements, and in many cases, have slight differences.

To address this issue, for the purposes of conforming to the requirements of a mandatory safety standard for consumer goods that contain button batteries, the ACCC proposes that suppliers have alternative options to either:

- comply with the referenced clauses of an industry standard deemed to have acceptable button battery security and compliance testing requirements
- comply with principles-based button battery security and compliance testing requirements.

This 'dual-track' approach is considered necessary to achieve harmonisation of button battery security and compliance testing requirements with a range of industry standards that contain slight differences but which overall are deemed to have acceptable requirements.

ACCC recent consultation on the mandatory standard for toys for children up to and including 36 months of age

In November 2019, the ACCC published a separate consultation paper seeking views on proposed updates to the mandatory standard for toys for children up to and including 36 months of age (the mandatory toy standard).

This consultation paper sought views on proposed updates to the mandatory toy standard and considered the adoption of requirements in international standards to warn of the hazard of button batteries through labelling requirements. In addition, the further consultation on the mandatory toy standard considers the adoption of requirements in international standards relating to battery compartment security.

Stakeholders have submitted that the introduction of any additional requirements related to button batteries in the mandatory toy standard should be consistent with any mandatory requirements that may be introduced for consumer goods that contain button batteries more broadly.

The ACCC considers that toys for children up to and including 36 months of age that contain button batteries should be treated on a similar basis to other consumer goods that contain button batteries, unless there is a demonstrated reason why this should not be the case. This will provide consistency of regulation for manufacturers and suppliers.

The current mandatory toy standard includes specific requirements for secure battery compartments on toys that contain button batteries as these batteries fit within the standard small parts cylinder and are considered a choking hazard for children.

The ACCC intends to defer recommending any updates to the mandatory toy standard until a decision is made on the broader regulation of button batteries, which is intended to apply to all consumer goods that contain button batteries, including toys for children irrespective of their age.

2. Background

2.1 The button battery hazard

Button batteries are most hazardous to children because of their size, shape, design and electrical charge. Button batteries are defined in most international standards as small round batteries that have a diameter greater than their height.¹⁴

For the purposes of this Final Recommendation, all flat, disc-shaped cells or small round batteries that have a diameter greater than the battery's height are referred to as 'button batteries' regardless of their size or chemistry. 'Coin', 'disc' and 'button' cells or batteries are taken to be one and the same article. Where it is necessary to distinguish between types of button batteries, the relevant battery chemistries and diameter sizes are specified.

When a child swallows or inserts a button battery, it can get stuck in their throat or body. When lodged in the body and in contact with bodily fluid, button batteries can burn through tissue and cause catastrophic bleeding. Serious injury can occur in as little as two hours.

When a battery is lodged in the body and in contact with bodily fluid, the energy contained within the battery can generate a chemical reaction called electrolysis. An electrical potential of as little as 1.229 volts is sufficient to cause the reaction.¹⁵ At the negative terminal of the battery, hydroxide ions and hydrogen gas will be produced. The hydroxide ions act like caustic soda, chemically burning tissues and causing liquefactive necrosis.¹⁶ The terminals of a button battery collectively cover almost the entire battery surface area and are often separated by less than a millimetre. This greatly increases the chances of bodily fluids completing a circuit between the terminals and releasing the energy in the battery to create the corrosive hydroxide ions. Other types of batteries that can be ingested (such as AAA batteries) have comparatively smaller terminals separated by a greater distance, which decreases the chances of a circuit being completed between the terminals.

Tissue damage occurs when a battery is lodged in the oesophagus, gut, ear, nose or other orifice, rather than free-floating and in transit through the gastrointestinal tract. Following ingestion, a caustic burn can breach the oesophageal wall in as little as two hours, causing severe and life-threatening injuries, which may cause death. Death typically results from excessive blood loss and cardiac arrest.¹⁷ Recent studies indicate that ingestion can also result in gastric injury and perforation of the stomach.¹⁸ Insertion of a button battery into body orifices such as ears and noses can also lead to significant injuries including permanent hearing loss, facial nerve palsies and nasal deformities.¹⁹

Children are at the greatest risk of injury because of their narrower oesophagus and tendency to place small objects into their mouths, ears and noses. Diagnosis is challenging as many button battery ingestions go unwitnessed by parents and carers, and children are either non-verbal or generally do not say that they ingested a battery. The symptoms of a button battery ingestion are often non-specific and are similar to many other conditions, so it may not be suspected that the child has ingested a battery. Delays in presentation to a hospital, diagnosis and removal of a battery can have tragic consequences.

When it is suspected that a child has ingested a battery, an X-ray needs to be conducted as soon as possible to confirm the location of the battery and determine if it has lodged in the oesophagus. Many

14 In many international standards, single use and disposable button/coin cell batteries are referred to as primary cell batteries. Rechargeable batteries are referred to as secondary cell batteries.

15 M Chaplin 2019, London South Bank University, London, <http://www1.lsbu.ac.uk/water/electrolysis.html>, viewed 1 August 2019.

16 T Litovitz 2019, NCPCC, Washington DC, <https://www.poison.org/battery/mechanism-of-injury>, viewed 1 August 2019.

17 NCPCC Fatal Cases.

18 Alok S Patel, MD; Racha T Khalaf, MD, *With Button Battery Ingestion, Watch for Gastric Injury*, Medscape Gastroenterology www.medscape.com/viewarticle/915379 retrieved 9 October 2019.

19 R Barker and co-signatories submission to ACCC Button Battery Safety Issues Paper https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/consultation/published_select_respondent, viewed 19 October.

hospitals in regional and remote areas of Australia have limited or no X-ray facilities on site.²⁰ This can lead to delays in diagnosis and removal of the battery.

Battery removal is also technically challenging with children because of their small size and the potential complications of operating on the gastrointestinal tract.²¹ The damage caused by an ingested button battery continues to pose a significant risk even after the battery has been removed. Complications such as aorto-oesophageal fistula, exsanguination and cardiac arrest have been reported in children following the removal of a button battery from the oesophagus. There have been cases of severe uncontrollable internal bleeding leading to death occurring in patients up to 28 days after the battery has been removed.²²

In many cases children also require ongoing treatment and follow-up plans for injuries sustained from button battery ingestion for many years after battery removal. In particular, oesophageal tissue damage in young children is life changing because the scar tissue does not grow with the child. Caustic injury at a young age often requires many repeated oesophageal dilatations for the child to be able to swallow solids and carries a lifelong risk of oesophageal cancer.²³

There is no publicly available repository of information for button battery insertion incidents. There are, however, several studies that relate to insertion of foreign bodies more generally and some case studies that relate specifically to button batteries. A 2015 study of 260 foreign body insertions indicates that button battery insertions result in more significant complications than other foreign body insertions and have led to severe injuries including nasal septum perforation and saddle nose deformities.²⁴ All studies reviewed concluded that button battery insertions should be considered a medical emergency and should be removed without delay.

As detailed in table 2, the risk associated with battery exposure is determined by a number of interrelated factors. It is the combination of larger battery diameter, higher (and residual) voltage and exposure via swallowing that results in the most catastrophic injuries and death.

Table 2: Button battery risk factors

Factor	Risk
Charge/voltage of the battery	The greater the charge, the greater the propensity for the battery to cause tissue damage when ingested or inserted.
Time from exposure to recognition/ diagnosis and removal	Delays in diagnosis and removal of the battery often lead to more severe injuries.
Size of the battery	The size of the battery determines both the nature of the injury (insertion or ingestion) and likelihood of the battery becoming lodged in the oesophagus.
Age of the patient	Children from 0–5 years old are at the greatest risk of injury because of their narrower oesophagus and tendency to place small objects into their mouths, ears and noses.
Age of the battery	The age of the battery determines the charge; new batteries have the greatest potential to cause harm but even old or spent batteries can have enough residual charge (<1.229V) to cause damage.
Quantity of batteries supplied	The quantity of batteries supplied can increase the risk of injury, particularly when multiple batteries are ingested or inserted.

Button batteries generally operate using one of four chemistries: lithium, alkaline, silver oxide and zinc-air. A risk analysis by button battery chemistry is provided in table 3.

20 R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, *Button battery exposures in Australian children: a prospective observational study highlighting the role of poisons information centres*, *Clinical Toxicology*, vol. 57, no. 6, 2019, pp. 404–410.

21 Gastrointestinal tract includes the mouth, oesophagus, stomach, small intestine and large intestine.

22 NCPC Fatal Cases.

23 R Barker and co-signatories submission to ACCC Button Battery Safety Issues Paper https://consultation.accc.gov.au/product-safety/button-battery-safety-issues-paper/consultation/published_select_respondent, viewed 19 October.

24 M. Abou-Elfadl, A. Horra, R.-L. Abada, M. Mahtar, M. Roubal, F. Kadiri, *Nasal foreign bodies: Results of a study of 250 cases*, *European Annals of Otorhinolaryngology, Head and Neck diseases* 132 (2015) 343–346.

Table 3: Risk analysis by button battery chemistry

Battery chemistry	Risk analysis
Lithium²⁵	<p>Lithium batteries generally have an electrical output of 3 volts. These batteries pose the highest risk when new and can have sufficient charge at the end of their functional life to still cause tissue damage. The higher voltage coupled with the larger size of lithium batteries (16–32 mm diameter) pose the highest risk.</p> <p>Their larger size means that they are more likely to become stuck in a child’s oesophagus and their higher voltage means they can injure more quickly and for longer. Where the battery type is known, ingested lithium button batteries lead to the most severe injuries and most deaths.²⁶ The three deaths recorded in Australia have been associated with 3 volt lithium batteries.</p>
Alkaline	<p>Alkaline batteries have an electrical output of 1.5 volts or less and are generally less than 16 mm in diameter. Ingested alkaline batteries are more likely to pass through the gastrointestinal tract without causing significant problems. However, if an ingested alkaline battery remains undetected in the oesophagus for some time, it can produce damage comparable to a lithium battery, particularly if it is relatively new.</p> <p>The smaller alkaline batteries can also be inserted in body orifices such as ears and noses, causing severe injuries if undetected for some time. In addition there have been cases where a flat alkaline battery has been stuck in a child’s oesophagus for an extended time (weeks to months) and has corroded releasing the chemicals within.²⁷</p>
Silver oxide	<p>Silver oxide batteries have a nominal voltage of 1.5 volts and are available in sizes ranging from 4.8 mm x 1.6 mm to 11.6 mm x 5.4 mm. Silver oxide batteries have a greater leakage resistance than alkaline batteries and are also more lightweight and heat/cold resistant. This gives them a longer shelf life when compared with alkaline batteries which are more susceptible to corrosion.²⁸</p> <p>Their smaller size again means that they are more likely to pass through the gastrointestinal tract without causing significant problems. While they supply sufficient voltage to cause injury, available records have not indicated them becoming lodged in a child’s oesophagus. Smaller batteries are more usually implicated in insertions which can also lead to severe injuries.</p>
Zinc-air	<p>Zinc-air batteries are quite small, have a nominal voltage of 1.4 volts and come in a range of sizes. Zinc-air batteries are predominantly used in hearing aid devices and the size of battery needed depends on the hearing device. Zinc-air batteries require access to air (oxygen) to produce a current and so, when ingested, they are unlikely to produce an electrical current as other batteries may.</p>

25 Lithium batteries intended for single use have a different chemistry to rechargeable lithium-ion batteries. However, rechargeable lithium-ion button batteries present the same hazard to children if ingested or inserted. Lithium-ion chemistry is favoured for rechargeable tools, phones and similar devices and by some electric vehicle manufacturers. In most cases lithium-ion batteries are fully enclosed inside a product and are not intended to be replaced by the consumer.

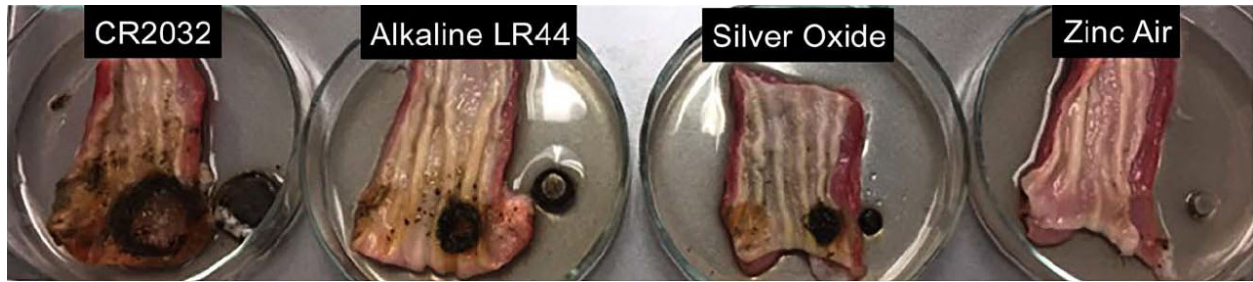
26 According to US data captured by the National Capital Poison Center. The NCPC publishes detailed information about severe and fatal button battery ingestion cases on its website. Fatal cases are recorded from 1977–2020 and severe from 1982–2020. Records were sourced from research, NBIH contact records and subsequent follow-up with health professionals. See: www.poison.org/battery/severecases; <https://www.poison.org/battery/fatalcases>.

27 T Litovitz, Mechanism of battery-induced injury, National Capital Poison Center, Washington US <https://www.poison.org/battery/mechanism-of-injury>, viewed 12 August 2019.

28 Coin Cell/Button Cell Battery Guide, www.batteries.com/pages/coin-cell-button-cell-battery-guide, viewed 9 December 2019.

Figure 2 also demonstrates the tissue damage that batteries of various chemistries can cause.

Figure 2: Tissue damage caused by batteries of various chemistries after 6 hours²⁹



Source: Kris R. Jatana, MD; Keith Rhoades, BS; Scott Milkovich, PhD; Ian N. Jacobs, MD, *Basic Mechanism of Button Battery Ingestion Injuries and Novel Mitigation Strategies After Diagnosis and Removal*, *Laryngoscope*, 127:1276-1282, 2017

2.2 Supply chain and applications of button batteries

According to *Global button cell batteries market report 2019*, approximately 69 million button batteries were sold to the Australian market in 2019.³⁰ Button batteries are not manufactured in Australia. Energizer and Duracell currently account for the largest share of button battery sales in Australia. Other major brands include Gold Peak, Varta, Renata, Panasonic, Sony, Maxell (Hitachi) and Toshiba.

Button batteries are sold as both wholesale and retail products. Button batteries are supplied wholesale and rebranded for sale by specific retailers and to manufacturers who make products powered by button batteries. Button batteries are also supplied as retail products for sale as replacements and as a component of a huge range of consumer goods. Replacement batteries are sold online and by many bricks-and-mortar retail stores including supermarkets, discount stores, hardware stores, service stations, department stores and by various specialist parts suppliers and repairers.

Their small size makes them suitable to power small electrical devices and they can be found in dozens of common household appliances, toys and novelty items. There has been a significant increase in the use of button batteries in digital and portable electronic consumer goods over recent years consistent with the expanding miniaturisation of electronic devices.³¹

Table 4 shows the breakdown of button batteries sold in Australia by product application category. Data is not available detailing the different consumer product categories that contain button batteries.

Table 4: Major product categories

Product application category	Market share
Digital products	53%
Toys	25%
Medical instruments	15%
Other	7%

Source: XYZ Research Energy Centre, *Global button cell batteries market report 2019 by manufacturer, region, type and application*, 2019.

The digital products category which has the highest market share (53%) is likely to include a wide range of everyday consumer and household electronic devices such as remote controls, watches, computers, calculators, fitness devices and digital scales. The medical instruments category is likely to include products such as digital thermometers, blood glucose monitors, heart rate monitors and hearing aids. The other category (7%) is likely to include products such as novelty and promotional items.

29 Kris R. Jatana, MD; Keith Rhoades, BS; Scott Milkovich, PhD; Ian N. Jacobs, MD, *Basic Mechanism of Button Battery Ingestion Injuries and Novel Mitigation Strategies After Diagnosis and Removal*, *Laryngoscope*, 127:1276-1282, 2017.

30 XYZ Research Energy Centre, *Global button cell batteries market report 2019 by manufacturer, region, type and application*, 2019.

31 *ibid.*

Products that contain button batteries are also available second-hand and given away as part of promotions at community, cultural and sporting events which means they can also be brought into the home without being purchased from a retail outlet.

2.3 Stakeholder engagement, consultation and expert review

Button Battery Safety—Issues paper

On 16 August 2019, as the first step in a regulatory impact assessment, the ACCC released the [Button Battery Safety Issues Paper](#) (the issues paper) for public consultation. The issues paper invited responses from interested stakeholders on how the safety hazards posed by button batteries should be addressed outlined and detailed the effectiveness of the voluntary [Industry Code for Products Containing Button Batteries](#) (the industry code), safety risks, consumer information and the button battery market in Australia.

The ACCC received 32 submissions in response to the issues paper from a broad range of stakeholders including manufacturers, representative bodies, individual consumers, businesses, health professionals and government agencies.³²

Generally, submissions received in response to the issues paper were supportive for the development of mandatory regulation to improve the safety of button batteries and products that contain them. There was also broad support for the development of an international horizontal standard to ensure consistent requirements globally.

A key point raised by many stakeholders was that supplier self-regulation was not sufficient and that safety requirements should be made mandatory and create an even playing field for all suppliers. Many stakeholders have advocated for the existing industry code which was developed by industry with ACCC assistance, to be made mandatory.

Most stakeholders were not in favour of banning any products from supply in Australia given the broad range of products in the market that contain button batteries.

While submissions in response to the issues paper provided broad support for the introduction of mandatory regulation, some industry stakeholders raised issues for consideration in determining the scope of mandatory requirements:

- Mandatory requirements for secure battery compartments to hearing aids and child-resistant packaging requirements to hearing aid button batteries could have a severe negative impact on elderly hearing aid users due to poor eyesight and dexterity issues.
- Mandatory requirements should apply only to button batteries of lithium chemistry that are most commonly associated with severe injuries and fatalities.
- Labelling requirements that are specific only to Australia may impose additional costs on suppliers and create barriers to trade.
- Mandatory regulation should align with existing national and international standards.

While there was little information provided in submissions in relation to the cost of mandating the requirements of the industry code, it was noted that any change to regulation is likely to have some financial cost on suppliers. Many industry submissions stated that they already comply with the requirements of the industry code and mandating the requirements of the code would not incur additional costs.

Submissions in response to the issues paper and targeted consultation with key stakeholders on issues raised informed the ACCC's assessment of proposed regulatory options for improving button battery safety that were subsequently released for consultation.

³² Public submissions in response to the ACCC's issues paper have been published on the [ACCC Consultation Hub](#).

Button Battery Safety—Assessment of regulatory options—Consultation paper

On 19 March 2020, the ACCC released the [Button Battery Safety—Assessment of regulatory options—Consultation paper](#) (the consultation paper) to seek stakeholder feedback on proposed regulatory options to reduce the likelihood of serious injuries resulting from child exposure to button batteries.

The consultation paper provided the ACCC's preliminary assessment and cost benefit analysis of the proposed regulatory options available under the ACL and sought feedback on the ACCC's preferred option that the following proposed requirements be mandated for button batteries and consumer goods that contain these batteries:

- Consumer goods that contain button batteries be required to have secure battery compartments and not release the batteries during reasonably foreseeable use or misuse conditions, to prevent children from gaining access to the batteries.
- Child-resistant packaging be required for all button batteries available for sale or supplied with consumer goods, to prevent children from gaining access to the batteries.
- Warnings and information be required with products that contain button batteries, as well as on packaging of button batteries to alert consumers that a button battery is included with the products and the hazard button batteries pose to children and provide clear directions on what to do in the event that a child is suspected to have swallowed or inserted a battery.

The consultation paper outlined that an exemption for hearing aids and associated zinc-air batteries was considered appropriate as follows:

- An exemption from the secure battery compartment requirement for hearing aid devices.
- An exemption from child-resistant packaging requirements for zinc-air batteries intended for hearing aid devices (i.e. zinc-air batteries packaged in a dial mechanism).

The consultation paper included detailed analysis of the quantified health benefits associated with the proposed requirements, but minimal information on the quantified costs of the regulations—this is because at that stage industry had provided only minimal costing information as the costs of the regulation are largely determined by the extent to which the requirements deviate from national and international industry standards. The consultation paper requested further information from industry of the costs of the proposed requirements.

The ACCC received 67 submissions in response to the consultation paper from a broad range of stakeholders, including national and international representative bodies, medical experts, relevant government agencies, international product safety regulators and advocacy organisations.³³

Given the timing of the release of the consultation paper occurred at the outset of COVID-19 in Australia, a short rapid response survey was distributed to health professionals. Over 300 responses were received from health professionals, with 99% in favour of the introduction of mandatory safety and information standards that would include button battery safety requirements, including secure battery compartments, child-resistant packaging and warnings and information; and 89% in favour of an exemption for hearing aids. While substantive submissions in response to the consultation paper provided broad support for action to improve button battery safety, many industry stakeholders raised concerns in relation to the proposed requirements. Key issues included:

- deviation from national and international standards and related costs
- scope of the proposed requirements to all types of button batteries
- warning requirements that are specific to Australia and in particular the proposed requirement that contact details for the Australian Poisons Information Centre (PIC) be provided on packaging
- the need for further exemptions.

³³ Public submissions in response to the ACCC's consultation paper have been published on the [ACCC Consultation Hub](#).

Industry stakeholders also claimed that mandatory standards under the ACL would result in a duplication of regulation and that any mandatory regulation should exclude suppliers that adhere to national and international industry standards mandated by state-based electrical equipment safety regulations.

The ACCC modified certain proposed requirements in response to stakeholder feedback and distributed two industry surveys to seek information from industry on the likely cost implications of these changes. Thirty-eight responses were received from manufacturers and suppliers in response to these two surveys.

Stakeholder engagement, including a list of stakeholders that provided submissions in response to the issues paper and consultation paper and stakeholder meetings is available at **Appendix A**.

Independent expert review by Exponent

The ACCC commissioned Exponent, Inc., a multi-disciplinary engineering and scientific consultancy based in the United States, to conduct a technical review of the proposed requirements outlined in the consultation paper. The technical review was led by Gene Rider, a recognised expert in injury prevention, physical hazards and consumer goods risk assessment, with a focus on adolescent exposure.

Based on stakeholder feedback, extensive consultation with key stakeholders and expert advice, the ACCC has refined the policy options outlined in the consultation paper and which are reflected in this Final Recommendation.

Section 4 details the key issues raised in relation to the proposed requirements outlined in the consultation paper, stakeholder feedback, expert advice and the ACCC's findings, including for proposed exemptions.

2.4 International approaches

There is currently no mandatory regulation, in Australia or internationally, that horizontally addresses the hazards associated with button batteries across all consumer goods. Many countries, however, have legislated general safety requirements which provide some protections to address button battery and similar hazards by requiring suppliers to ensure the safety of their products before placing them on the market.³⁴

There are a range of national and international voluntary industry standards for various products and equipment that have been developed to include button battery safety requirements. Many of these national and international industry standards apply vertically to specific product categories such as audio visual and information communications technology equipment, electric toys, lighting products. There are also voluntary international standards that apply to button batteries of lithium chemistry, button batteries of a chemistry other than lithium and an overseas standard that applies to products that contain button batteries of lithium chemistry. The requirements for products that contain button batteries in these standards vary, particularly with respect to warning requirements, and rely on manufacturers and suppliers adopting safety measures and requirements voluntarily.

In determining the proposed requirements of the mandatory safety and information standards, the ACCC has sought to harmonise the proposed mandatory requirements with the existing requirements of relevant national and international voluntary industry standards, where this will ensure an acceptable level of safety.

³⁴ The UK, EU, Canada, Malaysia, and 18 out of 21 countries who participate in the OECD's Working Party for Consumer Product Safety have a general safety duty.

Harmonisation of mandatory requirements relevant national and international industry standards will minimise the regulatory burden for suppliers that already adhere to industry standards that have acceptable button battery safety requirements. Harmonisation with international industry standards is also a necessary consideration from a technical barriers to trade perspective having regard to the wide range of products that contain button batteries, most of which are manufactured overseas and imported into Australia and supplied to other regions.

This is consistent with the ACCC's policy principles and criteria for considering and accepting international product safety standards when regulatory action is being considered to address safety problems with particular goods.³⁵

Safety standards for toys also typically include provisions to ensure children's toys do not include small parts that present a choking hazard to children.^{36 37 38} These standards cover toys and parts of toys for children up to 36 months and require that small parts that fit within a small parts cylinder (2.25 inches long by 1.25 inches wide) are not accessible to children under reasonably foreseeable use or misuse.³⁹ Button batteries and AAA batteries fit within the standard small parts cylinder and are considered a choking hazard for children. Many of these mandatory toy standards include specific requirements for secure battery compartments and specific warnings on toys that contain button batteries.

Further information about international approaches to managing button battery safety in the United States, New Zealand and United Kingdom is available at **Appendix B**.

35 ACCC, 2015, [International standards for the safety of consumer products: criteria for acceptance](#).

36 Government of Canada, 2019, Canada, www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/industry-professionals/industry-guide-safety-requirements-children-toys-related-products-summary/guidance-document.html#a3241, viewed 17 July 2019.

37 Hong Kong Standards and Testing Centre, *Choking/Suffocation/Hazardous Shape Requirements of Different Countries for Toys Testing*, Hong Kong, 2019, stc.dev1.ysdhk.com/getfile/index/action/images/name/566a2a7f73bdf.pdf, viewed 17 July 2019.

38 Public.Resource.Org, 2014, California US, law.resource.org/pub/eu/toys/en.71.1.2014.html#s8.2, viewed 17 July 2019.

39 A small parts cylinder is 2.25 inches long by 1.25 inches wide and approximates the size of the fully expanded throat of a child under three years old. It is roughly the size of an old film canister.

3. The problem and need for government intervention

3.1 What is the problem?

Button batteries can cause severe injury and even death if swallowed, particularly by young children aged 0–5 years. When a child swallows or inserts a button battery into an orifice, it can get stuck in their throat or body. When lodged in the body and in contact with bodily fluid, button batteries can burn through tissue and cause catastrophic bleeding. Serious injury can occur in as little as two hours. In Australia and globally, there is a growing record of serious injuries and deaths from button batteries.

In Australia three children have tragically died from injuries sustained as a result of swallowing a button battery. Coronial inquests have been conducted into the deaths of Summer Steer and Isabella Rees.

Summer Steer

Summer was four years old when she died on 30 June 2013 after ingesting a 20 mm button battery of lithium chemistry. Summer had presented to both her local general practitioner and her local hospital emergency department many times in the days prior to her death. The battery ingestion was not witnessed and the source of the battery remains unknown. The button battery lodged in Summer's throat burned a hole in her oesophagus and created an aorto-oesophageal fistula. This fistula led to profuse bleeding and eventually to her death.⁴⁰

Isabella Rees

Isabella was 14 months old when she died on 4 February 2015 after ingesting a 20 mm button battery of lithium chemistry. The ingestion of the battery was not witnessed and the source of the battery remains unknown. Isabella had a 19-day period of ill health prior to her death which included four presentations to an emergency department. The cause of Isabella's death was a gastrointestinal haemorrhage resulting from damage caused by the button battery lodged in her oesophagus.⁴¹

Brittney Conway

Brittney was three years old when she died on 28 July 2020 after ingesting a 20 mm button battery of lithium chemistry. Brittney had presented to both a local general practitioner and had been discharged from hospital following chest pain and vomiting. An X-ray was performed days later after she was rushed by ambulance to hospital and a battery was found lodged in her chest area. Brittney underwent a number of surgeries to remove the battery but she died eight days later, three weeks after first ingesting the battery.⁴²

There have also been, since December 2017, at least 44 individual cases where young children have suffered severe injuries following the ingestion or insertion of button batteries in Australia. This equates to more than one child sustaining a serious button battery injury every month, with some of them sustaining lifelong injuries.

There is no national database for consumer product-related injuries or attendances at hospital emergency departments in Australia. Consequently, there is no single point of reference for nationwide data on button battery exposures (ingestions or insertions) in Australia. Based on an extrapolation of the available data from NSW Health, Victorian Injury Surveillance Unit (VISU) and Queensland Injury

40 Office of the State Coroner 2015, Queensland Courts, Brisbane, https://www.courts.qld.gov.au/_data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf, viewed 20 February 2019.

41 Coroners Court of Victoria at Melbourne 2019, Coroners Court of Victoria at Melbourne, Melbourne, https://www.coronerscourt.vic.gov.au/sites/default/files/2019-04/IsabellaEstelleRees_059215.pdf, viewed 1 August 2019.

42 A Gaffney 2020, ABC, <https://www.abc.net.au/news/2020-10-23/gold-coast-family-calls-for-mandatory-button-battery-regulation/12797326>, viewed 26 October 2020.

Surveillance (QISU) for the year 2017, the ACCC estimates that thousands of Australian children have presented to emergency departments nationally due to either suspected or diagnosed ingestions or insertions of button batteries, with approximately 873 presentations in 2017 alone.⁴³

Children are at the greatest risk of injury because of their narrow oesophagus and tendency to place small objects into their mouths, ears and noses. While children more often ingest batteries, insertion of button/coin cell batteries into body orifices can also lead to significant injuries. The severity of injuries from ingestion and insertion of button batteries ranges from mild burns and ulcers to severe perforations, trachea-oesophageal fistulas, aorto-oesophageal fistulas, corrosion, twisting or inflammation of the spine, heavy metal poisoning, permanent hearing loss, facial nerve and vocal cord palsies and nasal deformities.

Examples of severe button battery injuries from across Australia

Victoria

This report is from the Monash Medical Centre in Clayton, Victoria. A 14-month-old boy with abnormal neck posture, poor feeding, drooling, cough and fever was taken to hospital where an X-ray found that he had ingested a button battery. The doctors removed the corroded battery and surrounding dead tissue. One week later the baby was taken to hospital again because of excessive bending of his neck and difficulty in breathing. The doctors found that the button battery had caused a condition called spondylodiscitis, which is infection and inflammation of a part of his spine.⁴⁴

Another case from Victoria is a five-year-old girl who complained that her throat hurt and that food wouldn't go down. She was tired and lethargic and lost a lot of weight. She was taken to a GP a number of times and eventually to a paediatrician. She suddenly started getting worse, developed a fever and started vomiting. She was taken to hospital where an X-ray eventually revealed the presence of a rusty eroded button battery in her oesophagus. Doctors estimated that the battery had been in her throat for about six months, blocking the flow of food to her stomach. She was rushed to Monash Children's Hospital, put in an induced coma and the battery was surgically removed. She recovered from the surgery and was tube-fed for a period of time. She will need to have ongoing treatment on her throat.⁴⁵

New South Wales

A seven-month-old girl presented to the ED at a district hospital after a choking episode and a reluctance to eat. She showed no signs of distress and was discharged. Her parents noticed a remote control in pieces with the button battery missing and took her to hospital the next day. A chest X-ray revealed a button battery stuck in her oesophagus. She was transferred to a larger hospital where a 3 volt lithium button battery was removed from her throat. There was severe corrosive damage to her oesophagus, a section of which was perforated and narrow. After one week of observation, she was discharged with a treatment and follow-up plan.⁴⁶

43 As outlined in appendix D, data from NSW Health, VISU and QISU was extrapolated to estimate the number of emergency department visits nationally.

44 V Kieu, S Palit, G Wilson, M Ditchfield, J Buttery, D Burgner, and PA Bryant, 'Cervical Spondylodiscitis Following Button Battery Ingestion', *The Journal of Pediatrics*, vol. 165, no. 6, 2014, pp. 1500-1500e.1.

45 K Caines 2019, Nine News, Australia, www.9news.com.au/national/button-battery-shaylah-carmichael-monash-hospital-melbourne-isabella-rees-inquest/164e95e5-a948-43a2-b8c8-f031353e6ea9, viewed 1 August 2019.

46 AY Liao and D McDonald, 'Oesophageal complication from button battery ingestion in an infant', *Journal of Paediatrics and Child Health*, vol. 49, no. 4, 2013, pp. 330-332.

Queensland

A one-year-old boy was brought to hospital 19 hours after choking on a foreign object. A chest X-ray revealed a coin-shaped object in his upper oesophagus. He was transferred to a larger hospital where the object was removed, by which time approximately 24 hours had elapsed. The object was a button battery. The battery had burned a part of his oesophagus. A week later, the boy had developed a trachea-oesophageal fistula which is a hole in his oesophagus that had created a passage into his windpipe. A feeding tube was inserted directly into his stomach because he could not swallow food through his oesophagus.⁴⁷

A four-month-old boy was referred to hospital for an X-ray by his GP after he developed a cough and breathing difficulties. An X-ray identified a small round object lodged in the child's oesophagus. The object was a small button battery which was removed approximately 14 hours later. The boy was taken home following the removal but returned to the hospital the next day when he began frothing at the mouth. Four weeks later the boy was taken back to hospital after becoming critically ill. He was placed in an induced coma and was transferred to a children's hospital. Scans revealed that the button battery had corroded the child's spine resulting in severe spinal damage. He was placed into a full body cast for eight months. At five years of age, the child is able to walk but will have severe restriction of movement for the rest of his life as he is unable to fully raise his head.⁴⁸

Western Australia

A 10-month-old boy from Bunbury ingested a button battery from his father's guitar. The doctors removed the battery from his oesophagus 12 hours after he had ingested it. Four weeks after the removal, he was taken to hospital because he couldn't breathe and blood was coming out of his mouth. He was urgently flown to Princess Margaret Hospital for Children in Perth, where doctors found that the button battery he had ingested had burned a hole in his oesophagus and caused an aorto-oesophageal fistula, the same injury that killed Summer Steer and Isabella Rees. The boy survived after 14 hours of surgery and a blood transfusion. He spent another two weeks in intensive care and almost three months in hospital, returning home two days before Christmas. One of the doctors on the medical team that treated the boy described the baby's injury as 'dreadful' and said that he was the only survivor in the world of this type of injury.⁴⁹

Tasmania

An 11-month old girl swallowed a lithium button battery. The battery was lodged in her oesophagus for 5 hours before being removed. She was placed on life support in Hobart and flown Melbourne's Royal Children's Hospital before being flown home. After initially showing improved health upon her return to Hobart, she was rushed back to the Melbourne hospital where she was again placed on life support. She suffered vocal cord paralysis and is now reliant on tubes for feeding.⁵⁰

The safety risk to children from button batteries arises when they can gain access to the batteries. This may occur in different ways:

- Children gain access directly from consumer goods that contain button batteries that either do not have secure battery compartments or which easily release the batteries—this may occur when poor quality products are dropped or broken.
- Children gain access directly from packaging that is not child-resistant—this may be from packaging of button batteries themselves, or where button batteries are supplied loose in the packaging of a consumer good (and not pre-installed in the product).

47 R Jarugula and T Dorofaeff, 'Oesophageal button battery injuries: Think again', *Emergency Medicine Australasia*, vol. 23, no 2, 2011, pp. 220–223.

48 Gail Groatorex, Product Safety Solutions, Button Battery Hazard—Size Does Matter!, <https://productsafetysolutions.com.au/button-battery-hazard-size-does-matter/>, October 16, 2019; Peter Hall 2015, *The Courier Mail*, 'Boy's spine corroded after he swallowed lithium battery', viewed 27 February 2020.

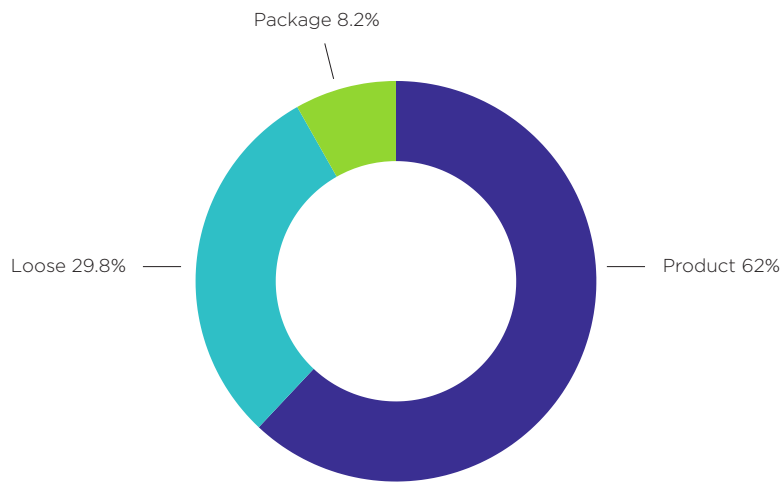
49 L Burke 2012, *The West Australian*, Perth, thewest.com.au/news/australia/a-battery-nearly-killed-our-son-ng-ya-334118, viewed 1 August 2019.

50 J Kitto 2020, *Gatton Lockyer & Brisbane Valley Star*, <https://www.gattonstar.com.au/news/mollie-target-fighting-for-her-life-after-swallow/4085234/?cspt=1602050867|3c3082aa707759e70faa905fe6475ecf>, viewed 7 October 2020.

- Children gain access when batteries are removed from consumer goods or packaging and are not stored safely out of reach of children, or otherwise not properly disposed of—old or spent button batteries can still hold a charge capable of causing injury.

As shown in figure 3, a study of button battery ingestion cases in the US between 1990 and 2008 found that in cases where the source of the battery was known (3,989 cases), children gained access to the battery directly from the product in 62% of cases; when batteries were left loose around the home in 30% of cases; and directly from packaging in 8% of cases.⁵¹

Figure 3: Source of button batteries involved in paediatric ingestions in the US between (1990 to 2008)



Source: T Litovitz, Preventing Battery Ingestions

Button battery ingestions can be very difficult to diagnose for a range of reasons. Many ingestions go unwitnessed by parents and carers, and in many cases children are either non-verbal or do not say that they ingested a battery. Symptoms of a battery ingestion are generally non-specific and may not appear for some time which can lead to delays in diagnosis and removal of the battery. Button batteries can also be mistaken for coins or other foreign objects when an X-ray is conducted. Since severe injury can occur in as little as two hours, a delayed presentation or misdiagnosis can result in severe injury or death.

Button battery exposures in Australia

Button battery exposures include all situations where an individual has been exposed to a button battery through ingestion or insertion, irrespective of whether the battery has actually caused an injury.

There is no national database for consumer product-related injuries or attendances at emergency departments in Australia. Consequently, there is no single point of reference for nationwide data on button battery exposures (ingestions or insertions) in Australia.

The ACCC has obtained available exposure data from hospital emergency departments and calls to Poisons Information Centres which reveals some common patterns and trends. See **Appendix D** for further information about data availability.

Poisons Information Centres' data shows that button battery exposures occur all over Australia and the number of exposures occurring in each jurisdiction is broadly consistent with relative population sizes in each state and territory.

⁵¹ T Litovitz, N Whitaker, L Clark, *Preventing Battery Ingestions: An analysis of 8,648 Cases*, American Academy of Pediatrics, 2010.

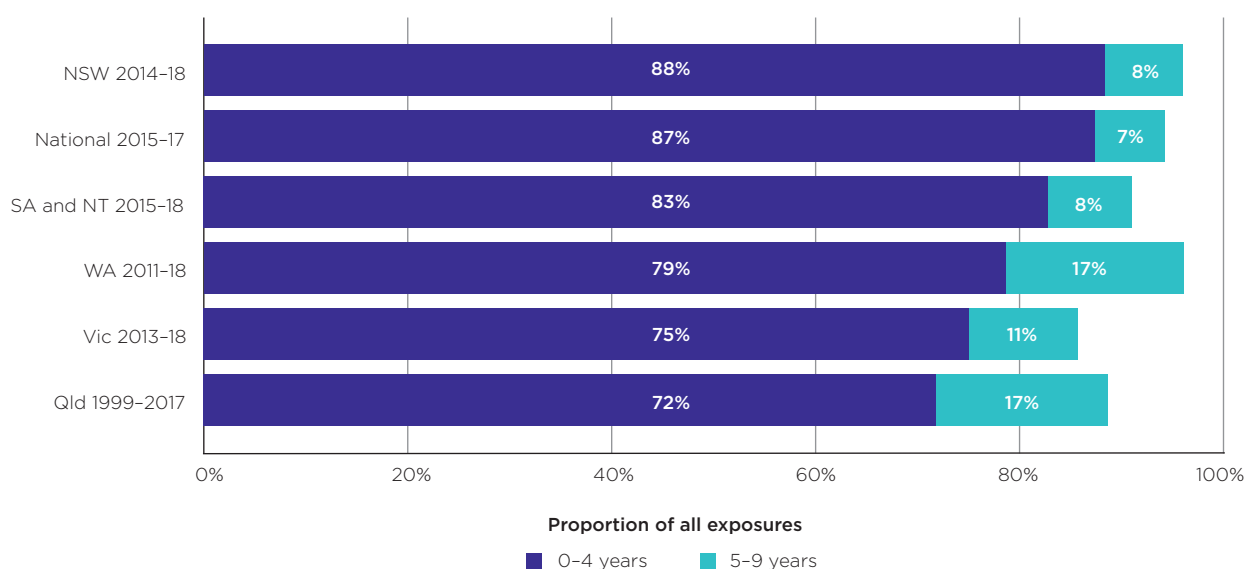
Table 5: Reported button battery exposures in Australia (2015 to 2018)

State/territory	Number of paediatric cases	Annual rate of exposures (per 100,000 people)
New South Wales	284	4.88
Victoria	229	4.96
Queensland	180	4.70
Western Australia	87	4.42
South Australia	85	6.92
Australian Capital Territory	18	5.83
Tasmania	16	4.26
Northern Territory	6	2.9
Total	905	

Source: NSW Poisons Information Centre.

Young children are most prone to button battery exposures. Emergency department and Poisons Information Centres data (figure 4) shows this pattern is consistent across all time periods and jurisdictions.

Figure 4: Reported button battery exposures—children aged under 10 years in Australia (1999 to 2018)



Source: NSW Poisons Information Centre, Kidsafe WA, QISU, VISU, NSW Health, WA Poisons Information Centre

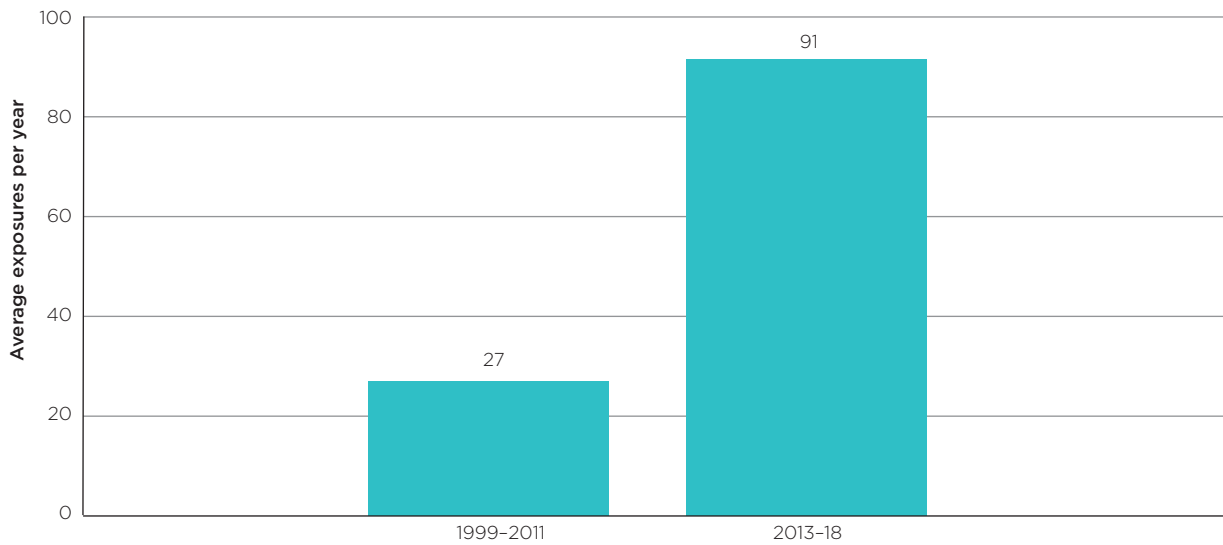
While most button battery exposures occur in children, adult exposures occur as well, although these represent a minor percentage of exposures.⁵²

Long-term data from Victoria (figure 5) and Queensland (figure 6) indicates that the numbers of reported button battery exposures in children under the age of five have been increasing.⁵³

52 Poisons Information Centres data indicates that from 2015 to 2017, there were 72 accidental adult exposures to button batteries. Where known (53 cases), hearing aids or cochlear implants were by far the most common products involved in adult exposures (89% of cases). During this period, Poisons Information Centres also recorded 12 cases of intentional adult ingestion of button batteries attributed to self-harm.

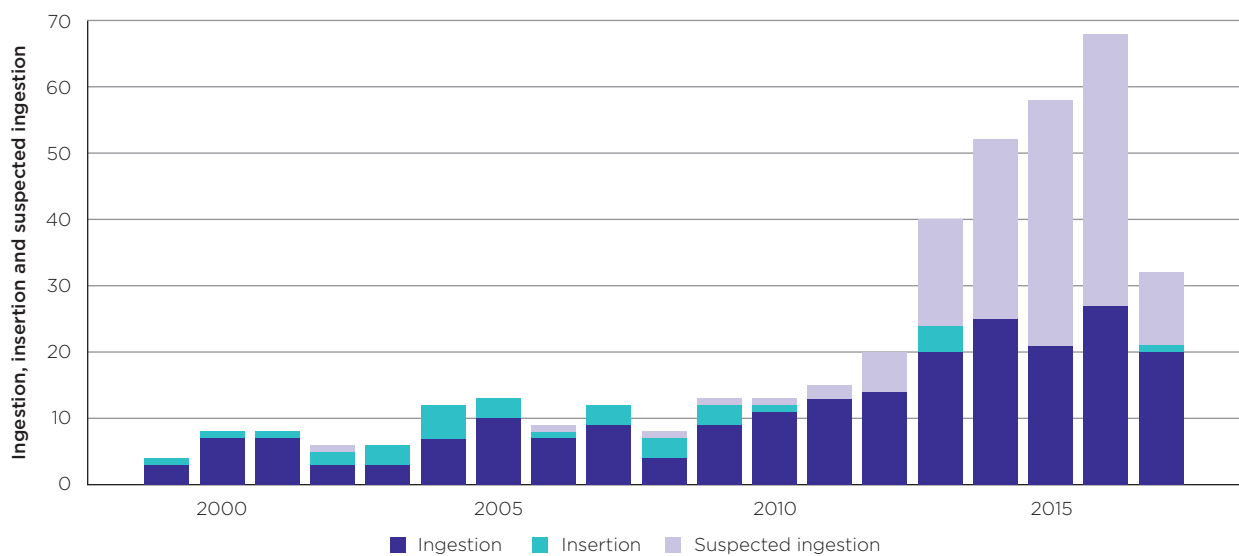
53 VISU data 1999-2011 and 2013-2018 were extracted from the Victorian Emergency Minimum Dataset which comprises de-identified demographic, administrative and clinical data detailing presentations at Victorian public hospitals with designated emergency departments. Both datasets are from similar numbers of hospitals.

Figure 5: Average reported button battery exposures per year in Victorian children under five years of age (VISU) (1999 to 2018)



Source: VISU.⁵⁴

Figure 6: Confirmed and suspected button battery exposures—Queensland children under five years of age by year (1999 to 2017)



Source: QISU, Report on button battery-related injury January 1999–December 2017.⁵⁵

Deaths and severe injuries

The ACCC has obtained data from a number of organisations tracking button battery ingestions and insertions. These organisations collect data from hospital emergency departments, injury surveillance units or calls to Poison Information Centres. As there is no standardised dataset for button battery injuries, these organisations have collected different types and ranges of data.

⁵⁴ Data was available to the ACCC for these two non-contiguous date ranges only. Data provided by VISU are extracted from the Victorian Emergency Minimum Dataset which includes records from all Victorian hospitals with a 24-hour emergency department.

⁵⁵ Data from participating Queensland emergency departments that together account for about one-fifth to one-quarter of all Queensland emergency department activity. Trends may be influenced by the number of participating hospitals each year. The introduction of a new electronic management system in 2016 resulted in a decrease in the number of reported incidents from that time.

In Australia and globally, there is a growing record of serious injuries and deaths of children from button batteries. In Australia, three children have tragically died from injuries sustained after ingesting a button battery. Globally, since 1977, there have been at least 66 confirmed child deaths from battery ingestions and thousands of exposures and injuries with some children sustaining lifelong injuries requiring ongoing treatments.⁵⁶

It is also likely that many cases have gone unreported. Dr Kris Jatana, Co-Chair of the United States National Button Battery Task Force, submitted details of a recent reporting survey of 417 otolaryngologists, gastroenterologists, and surgeons that manage children with foreign body ingestions.⁵⁷ This reporting practices survey was conducted in the United States in 2019 and revealed that overall injury reporting of button battery injuries is very low and may be ‘the tip of the iceberg’ with only 10% of button battery cases reported to any data source.

The Australian Paediatric Surveillance Unit (APSU) is conducting a study into severe injury related to button batteries.⁵⁸ The study began in December 2017. The purpose of the study is to collect information about injuries resulting from ingested or inserted button batteries as well as information about the battery-operated products associated with the injuries.

Between December 2017 and October 2020, the study identified 44 confirmed individual cases of severe injury following the ingestion or insertion of button batteries in Australia.⁵⁹ It is likely that this is an under-representation of the number of cases nationally as the study relies on doctors and individuals reporting severe incidents.

The peak age for severe injury due to a button battery is one year of age and almost two thirds of cases involved children younger than three years of age. In most cases (29), the button battery was located in the oesophagus. The button battery was found in the stomach in five cases, the ear in three cases and the nose in three cases. In all 44 cases, a medical procedure was required to remove the battery. The data also included an estimate of the size of the button battery involved—see table 6 below.

Table 6: Size of battery involved in severe injuries in APSU study between (December 2017 to October 2020)

Size	Diameter	Number of cases	Proportion of cases
Large	≥20 mm	25	57%
Medium	10–19 mm	9	20%
Small	≤10 mm	2	5%
Multiple*		1	2%
Unknown		7	16%
Total		44	100%

* In one case a child ingested 20 small and eight medium batteries.

The most comprehensive set of information on fatalities and severe injuries resulting from button batteries is available from the United States’ National Capital Poison Center (NCPC).⁶⁰ The NCPC has collated and published details of button battery severe injury and fatality cases from around the world from 1977 to 2020.

56 NCPC Fatal Cases; Labadie et al, 2018.

NCPC lists 64 fatalities as at 15 October 2020. The French Poison control study includes reference to two fatalities that are not listed on the NCPC fatal case list.

57 Dr Kris Jatana, Global Injury Research Collaborative, [submission](#) to ACCC Button Battery Safety—Assessment of regulatory options—Consultation paper, viewed 3 October 2020.

58 Australian Paediatric Surveillance Unit, 2017, Sydney, www.apsu.org.au/assets/new-studies/SIRDB-APSU-Protocol-FINAL-V5.1.pdf, viewed 1 August 2019.

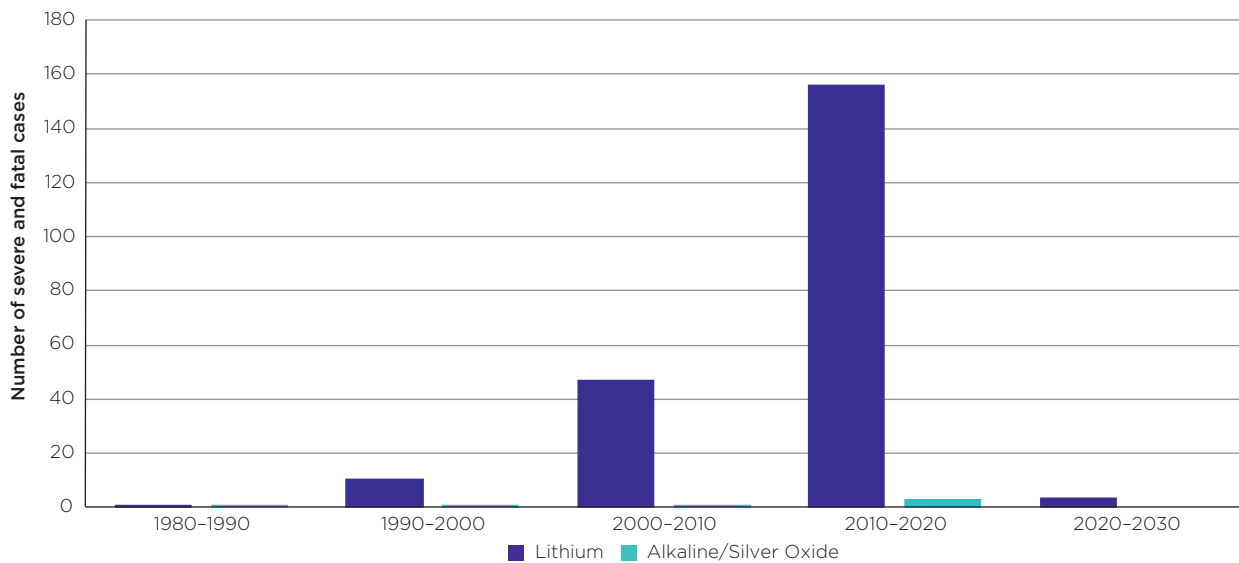
59 A severe injury as defined in the APSU study as a ‘newly diagnosed injury related to disc or button battery ingestion or insertion that required procedural intervention either to remove the battery or to assess or repair damage related to the battery.’

60 NCPC Fatal Cases; NCPC Severe Cases.

It is expected that the NCPC data understates the true number of global button battery fatalities and injuries as it is likely that many cases have gone unreported. Importantly, the NCPC data is limited to battery ingestions only and does not include data on button battery insertions, which can also result in severe injuries. The ACCC also understands that the completeness of the data presented on the NCPC website is affected from 2018 when it ceased operating the US National Battery Ingestion Hotline (NBIH).

Figure 7 demonstrates that the number of severe injuries and fatalities has been increasing rapidly decade on decade and that lithium batteries are responsible for this increase. In this dataset, severe injuries are those that involve debilitating and prolonged compromise of feeding or breathing and require multiple surgical procedures, tube feedings or tracheostomies.⁶¹

Figure 7: Global button battery deaths and severe injuries by chemistry (1977 to 2020)



Source: NCPC, *Severe Cases*; NCPC, *Fatal Cases* (Retrieved 15 October 2020).

Notes: Mercuric oxide batteries were withdrawn from sale in the 1990s due to mercury content. Incidents involving mercuric oxide batteries have been excluded from Figure 7.

Table 7 provides a summary of the button battery chemistries and diameters responsible for deaths and severe injuries as published by the NCPC.⁶² The size of the battery is unknown in 76 cases (25%) and the chemistry is unknown in 78 cases (26%).

Table 7: Global severe injuries and deaths by battery chemistry (1977 to 2020)

Chemistry	Diameter < 16 mm	Diameter ≥ 16 mm	Diameter unknown	Total cases
Alkaline/Silver Oxide	4		2	6
Lithium	1	205	13	219
Unknown	8	9	62	79
Total	13	214	77	304

Source: NCPC, *Severe Cases*; NCPC, *Fatal Cases*. (Retrieved 15 October 2020).

Notes: Mercuric oxide batteries were withdrawn from sale in the 1990s due to mercury content. Incidents involving mercuric oxide batteries have been excluded from Table 7.

Table 8 presents the number of severe injuries and fatalities by age group. Where the age of the child is known, children aged under 6 suffered severe injury or fatality in 271 of the 283 cases (96%).

⁶¹ The NCPC definition of 'severe injury' is different from the definition used by the APSU. The rate of severe injuries reported by the NCPC is not commensurate with the rates used for analysis in the cost-benefit analysis.

⁶² Injury and fatality records were sourced from literature review and through contacts to the United States National Battery Ingestion Hotline. Data for severe injuries is available from 1982-2019 and from 1977-2020 for fatal cases.

Table 8: Global severe injuries and deaths by age group (1977 to 2020)

Age <1	Age 1–6	Age 6 +	Total
58	215	12	285

Source: NCPC, *Severe Cases*; NCPC, *Fatal Cases*. (Retrieved 15 October 2020).

Notes: Battery chemistry and size is not relevant to the age of the child involved in an incident. Incidents involving mercuric oxide batteries are included in Table 8.

An analysis of the NCPC data reveals patterns relating to button battery ingestions similar to Australia:

- Most children involved in severe and fatal button battery incidents are aged 0–5 years.
- A growing number of children are suffering severe injuries and dying following exposure to button batteries.⁶³

Although lithium batteries with a diameter of 16 mm or greater are known to have caused the majority of the severe injuries and fatalities, all button batteries present a risk when ingested or inserted. The data presented above relates to button battery ingestions only. An equivalent dataset relating to button battery insertions into body orifices such as the ear and nose is not available, but the ACCC understands that smaller, non-lithium batteries are responsible for the majority of severe insertion incidents.

While the above data provides a general overview of button battery injury statistics in Australia, it does not demonstrate the extent of injuries button batteries have caused or can cause. Examples of severe button battery injuries from across Australia are provided in this section 3.1. These examples provide a clear picture of the life-threatening injuries and damage that button batteries can cause when ingested.

A 2015 study provides data on button battery insertion incidents.⁶⁴ This study analysed symptoms associated with 348 cases of button battery ingestion, inhalation and insertion. This study indicates that a significant proportion (45%) of button battery cases involve insertions. The study does not provide equivalent details to the dataset published by the NCPC as it does not detail the chemistry or provide detailed information on the size of the button batteries involved in insertion incidents, nor does it comment on the severity of complications.

Key findings from a review of published research reports and case studies that focus on ingestion and insertion of foreign bodies (including button batteries and other objects ingested/inserted) include the following:

- Insertion of foreign bodies is most common in children between 2 and 4 years old.
- Most foreign body insertions result in only minor lesions and are removed without complications.
- Button batteries make up a very small percentage of foreign body insertions.
- Button battery insertions result in the most significant complications and have led to severe injuries including nasal septum perforation and saddle nose deformities.
- There have been no recorded deaths or fatalities caused from insertion of a button battery.
- All studies reviewed indicated that button battery insertions should be considered a medical emergency and should be removed without delay.

63 61 NCPC, *Fatal Cases*; NCPC *Severe cases*.

64 E. Buttazzoni et al, Symptoms associated with button batteries injuries in children: An epidemiological review, *International Journal of Paediatric Otorhinolaryngology*, 2015.

3.2 Does the government have the capacity to intervene successfully?

There is currently no mandatory regulation, in Australia or internationally, that horizontally addresses the hazards associated with button batteries across all consumer goods. There is also no general legislative provision restricting the supply of unsafe goods in Australia.⁶⁵

Button batteries are manufactured overseas and imported into Australia. While there may be some local manufacturing of products that contain button batteries in Australia, the vast majority of the products that require button batteries are also imported from overseas.

The emergence of online shopping as well as significant technological advancements over the past two decades has meant that there is now a huge range of low-cost products manufactured overseas available in the domestic market. While consumers can benefit from increased access, innovation and choice, this also increases the risk of unsafe products being supplied to consumers.⁶⁶

Coronial inquests into the deaths of Summer Steer and Isabella Rees have identified a clear need to develop a consistent national approach to consumer product safety that captures the broad range of products that contain button batteries.

Mandatory safety and information standards may be made under the ACL that impose consistent requirements to apply 'horizontally' to all consumer goods that contain button batteries, as well as button batteries made available for sale.

Only a horizontal mandatory standard could efficiently address a common hazard across multiple product types. Currently, Australian mandatory standards generally focus 'vertically'—addressing multiple hazards in a particular category of goods, such as children's toys. For example, the Australian mandatory standard for toys for children up to and including 36 months of age prescribes requirements to ensure children's toys do not include small parts that present a choking hazard—these requirements incidentally cover button batteries as they fit the definition of a 'small part'. However, this requirement is limited to toys for this age group only. A horizontal mandatory standard under the ACL would apply to a wide range of consumer goods, including household and consumer electronic devices.

Importantly, mandatory safety and information standards will require compliance from suppliers that do not currently adhere to any button battery safety and information requirements of an industry standard or the industry code.

It should be noted that under the ACL, mandatory safety standards can only specify safety requirements that products must meet before they are supplied into the Australian market and cannot mandate requirements for the disposal of button batteries. However, this does not preclude other jurisdictions and agencies from pursuing battery disposal requirements as supplementary risk controls. In Australia, state and territory governments have the primary responsibility for regulating and administering waste, including waste management, licensing and regulation of waste transport, storage, treatment and resource recovery and disposal.

Mandatory information standards can, however, specify certain information to be provided to consumers when supplying particular kinds of goods, such as advice as to how to safely dispose of button batteries.

On 4 September 2020, the ACCC granted authorisation to the Battery Stewardship Council (BSC) to establish and operate a national scheme for managing expired batteries, including button batteries. The BSC has the primary goal of establishing a battery stewardship scheme in Australia that would see a significant increase in battery collections and recycling.

65 In October 2019, the Commonwealth Treasury began consultation on potential reform options to improve the effectiveness of the Consumer Product Safety System, including options for a General Safety Provision. The UK, EU, Canada, Malaysia, and 18 out of 21 countries who participate with Australia in the OECD's Working Party for Consumer Product Safety have a general safety provision.

66 OECD, *Online product safety: trends and challenges*, OECD Digital Economy Papers, No. 261, OECD Publishing, Paris, 2016.

The ACCC considered the risk that the scheme may inadvertently increase the safety hazard button batteries pose to young children by encouraging consumers to hold onto button batteries for subsequent collection and recycling. To address this issue of consumers potentially storing button batteries for later recycling, the ACCC has imposed a condition requiring BSC to develop a button battery safety strategy to be guided by an advisory group including the ACCC, relevant industry bodies and medical and child safety experts.⁶⁷

About mandatory standards

Consumer goods of a particular kind

Mandatory safety standards may be made under the ACL that impose consistent requirements to apply to consumer goods. Similarly, mandatory information standards may be made that apply to goods of a particular kind, including consumer goods.

To address the hazard of button batteries, mandatory safety and information standards are necessary to cover the following particular kinds of consumer goods: (1) consumer goods that contain button batteries; and (2) button batteries made available for sale.

The ACCC recommends that four mandatory standards be made under the ACL:

- a safety standard for consumer goods containing button batteries
- a safety standard for button batteries
- an information standard for consumer goods containing button batteries
- an information standard for button batteries.

Mandatory safety standards

Mandatory safety standards specify minimum requirements that products must meet before they are supplied. They are introduced when considered reasonably necessary to prevent or reduce the risk of injury to a person. If a product is subject to a mandatory safety standard, it must meet specific safety criteria before it can be supplied in Australia.

A mandatory safety standard can include requirements for:

- the performance, composition, contents, method of manufacture or processing, design, construction, finish or packaging of consumer goods
- the testing of consumer goods during or after the completion of manufacture or processing
- the form and content of labelling, including markings, warnings or instructions to accompany consumer goods.

Mandatory information standards

Mandatory information standards ensure that consumers are provided with information about a product to assist them in making a purchasing decision.

A mandatory information standard is required in order to specify the nature and form of information to be provided with consumer goods.

A mandatory information standard provides flexibility to include both mandatory requirements as well as best practice recommendations. There can be benefit in including all warning and information requirements in an information standard rather than in a safety standard as this will enable all relevant requirements and recommendations that apply to a class of consumer goods of a particular kind to be included within the one standard for clarity and ease of reference.

⁶⁷ ACCC, 4 September 2020, [Voluntary battery stewardship scheme granted authorisation](#).

3.3 Government and other measures so far to address the problem

Since 2012, the ACCC has been involved in a range of activities with both government and non-government bodies to increase the public awareness of the hazards presented by button batteries. The ACCC has sought opportunities to collaborate with key stakeholders to maximise the reach of safety messages through various channels including promotion of materials on the Product Safety Australia website, as well as media, social media and engagement activities.

The ACCC and other agencies have implemented a range of measures to reduce the risks posed by button batteries. Some examples are as follows:

- In 2012 The Battery Controlled campaign was launched to raise awareness about the risks associated with button batteries and provide key information on what to do if a child ingests a battery. The campaign was supported by ACCC in partnership with Energizer and Kidsafe Australia.
- In 2013 the ACCC met with industry stakeholders to discuss the issue of button battery safety. Following the meeting, many industry stakeholders agreed to voluntarily adopt a range of measures to improve safety of button batteries and products that contain them.
- In 2014 the Organisation for Economic Co-operation and Development (OECD) organised the International Awareness Week on Button Battery Safety. The event aimed to raise awareness worldwide of the risks and dangers posed by button batteries.⁶⁸ Twenty-six countries, including Australia, participated in the initiative to raise awareness of the issue and encourage authorities to take the necessary precautions to reduce the risk of injury and death from button batteries.
- In 2016 the voluntary [Industry Code for Consumer Goods that Contain Button Batteries](#) (industry code) was published. The industry code includes requirements for consumer goods that contain button batteries, but does not include any child-resistant packaging or warning requirements for button batteries themselves. The industry code was prepared by an industry working group assisted by the ACCC and was promoted by the ACCC and state and territory ACL regulators.
- From 2016–2018 the ACCC led the implementation of a two-year National strategy for improving the safety of button battery consumer products (the national strategy) with the assistance of other ACL regulators. The national strategy began alongside the release of the industry code. A primary goal of the national strategy was to assess whether voluntary approaches, like the industry code, would sufficiently mitigate button battery hazards. The strategy also collected evidence to inform any possible regulatory or other approaches to improve button battery safety. The ACCC and other ACL regulators conducted market surveillance throughout the course of the strategy to gauge the uptake of the industry code by suppliers. The ACCC examined trends in injury reporting to see if there were any indications that exposures and injuries associated with button batteries were decreasing.
- In 2016 the TGA began a review of home medical devices including hearing aids, digital thermometers and glucometers to determine if these products met the essential principles of the industry code. The TGA liaised with suppliers and encouraged them to adopt the industry code where possible.
- In early 2019 the ACCC evaluated the impact of the national strategy and found voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries. The ACCC recognised significant efforts made by some suppliers but found that overall there continues to be a high number of unsafe consumer goods that contain button batteries available in the Australian market, and there is not yet any meaningful decrease apparent in the rate of button battery exposures or injuries. The ACCC concluded that there was evidence of market failure in the safety of button battery consumer goods, where unsafe goods are supplied into the market place and consumers are injured, and that the voluntary industry code had not achieved a significant reduction in the risks posed by button batteries. The ACCC concluded regulatory intervention should be considered.
- In March 2019 after issuing a [Safety Warning Notice](#) to the Australian public about the dangers of button batteries, the Hon. Stuart Robert, then Assistant Treasurer, asked the ACCC to expedite the

68 OECD (2014), Paris, www.oecd.org/science/button-battery-safety-awareness-week.htm, viewed 3 December 2019.

regulatory impact assessment process for developing regulation to address button battery safety. The ACCC subsequently established a taskforce to conduct an investigation into button battery safety and consider regulatory options available under the ACL.

- In 2019 the ACCC published a summary of the industry code translated into 16 different languages in order to communicate the key safety requirements of the code with suppliers from culturally and linguistically diverse backgrounds.
- In 2020 for a third consecutive year, the ACCC identified button battery hazards as a product safety priority and finalised its investigation into button battery safety which has culminated in this Final Recommendation.
- In September 2020 the ACCC granted authorisation to the BSC to establish and operate a national scheme for managing expired batteries, including button batteries. The ACCC considered the risk the scheme may inadvertently increase the safety hazard that button batteries pose to young children by encouraging consumers to hold onto button batteries for subsequent collection and recycling. A condition of the authorisation requires BSC to develop a button battery safety strategy to be guided by an advisory group involving the ACCC, relevant industry bodies and medical and child safety experts.⁶⁹
- In October 2020 the ACCC launched a communications campaign targeting parents and carers to raise awareness of the health risks associated with button batteries amongst young children and to provide guidance on how to create a safer environment for families. The campaign included web content, social media messaging, a series of online videos, proactive media and social media advertising.

The ACCC has been engaged with the Queensland Consumer Product Injury Research Advisory Group and the Western Australian Consumer Product Advocacy Network throughout the course of the safety investigation and the national strategy. This engagement involved sharing information and providing updates on emerging issues and current activities relating to button battery safety across the broader community. These groups include representatives from various disciplines such as injury prevention, scientific research, behavioural economics and consumer protection.

A number of improvements have been made to clinical practice guidelines used by medical practitioners and hospitals to respond to the ingestion of foreign bodies including specific advice for managing suspected button battery ingestions.

In addition to the above measures, there are a range of national and international voluntary industry standards for various products and equipment that have been developed to include button battery safety requirements. Some state-based electrical equipment safety regulations require compliance with applicable industry standards, including those that include button battery safety requirements.

For the reasons discussed in section 3.4, applicable industry standards mandated in some state-based electrical equipment safety regulations do not effectively address safety for all products that contain button batteries.

3.4 Why have previous measures not worked?

The issue of button battery safety is complex, in part because of the use of button batteries in a wide range of consumer goods. Button batteries are sold individually and in multipacks as consumer-replaceable batteries or supplied either pre-installed in or packaged with consumer goods. The safety hazard is pervasive throughout the lifecycle of consumer goods that contain button batteries—primary supply, use, servicing, repair, secondary supply, disposal and recycling.

To reduce risk, product safety is best addressed when a product is at the design stage. The Australian Standard Consumer Product Safety—Guidelines for Suppliers (AS ISO 10377:2017) supports the application of the Hierarchy of Risk Control Framework (HORC) Framework. It encourages suppliers (designers, manufacturers, importers, distributors and retailers) to consider consumer product safety

⁶⁹ ACCC, 4 September 2020, [Voluntary battery stewardship scheme granted authorisation](#).

at the design stage and, where potential risks are identified with their products, manage these risks by eliminating them or reducing them to a tolerable level.⁷⁰

To date, despite some efforts, battery manufacturers have not made significant safety improvements to button batteries to reduce the risk to children if batteries are ingested.

Major battery manufacturer Duracell have recently developed a bitter coating to be applied on larger-sized button batteries of lithium chemistry. This is intended to make the battery unpalatable and act as a deterrent to ingestion. The ACCC understands that this is a proprietary composition that was in development for several years by Duracell that could possibly be licensed to other battery manufacturers. Duracell's larger-sized button batteries of lithium chemistry with a bitter coating are expected to be available to consumers in 2021. The ACCC estimates that Duracell accounts for approximately 20% of the supply of button batteries in Australia. Therefore, this partially effective measure will only apply to a minor share of overall supply of button batteries in Australia, although it would cover button batteries with the highest risk profile that are supplied by Duracell.

Studies into the use of bitterants on consumer products to deter ingestions provide mixed views on their effectiveness. A determination by the US Consumer Product Safety Commission (CPSC) regarding the regulation of small magnets considered stakeholder feedback that magnets could be coated in bitterants such as denatonium benzoate. The CPSC did not adopt this recommendation, responding that while in principle it is sensible and laboratory studies show it can be effective in deterring repeated ingestion, real-world investigations have not demonstrated its effectiveness, and that children in home settings frequently ingested unpalatable substances such as gasoline, toilet bowl cleaner and ammonia.⁷¹

While the ACCC see the introduction of bitterants on button batteries as a positive development, the safety measure will not prevent injuries from occurring if the battery is ingested. Solutions such as pressure-sensitive coatings and alternative metal casings are also being investigated but have not yet been adopted by battery manufacturers. Further information is available at **Appendix E**.

The design of button batteries themselves and their packaging should include consideration of safety under conditions of reasonably foreseeable use or misuse to ensure they are stored safely until they are enclosed within another product for use. Similarly, manufacturers of products that contain button batteries should consider safety and ensure that button batteries are not accessible under reasonably foreseeable use or misuse. While some responsible manufacturers, suppliers and retailers are adopting measures to improve the safety of their products, a wide variety of products that pose an unacceptable safety risk remain available.

Risk communication is also an important component of an overall risk management strategy. Markings, warnings or instructions are administrative controls that may help to further reduce the risk of exposure or facilitate injury aftercare. While they are more reliant on consumer behaviour than engineering changes to counteract inherent design limitations, they remain a valid tool especially when integrated with higher level controls such as design changes.

Market surveillance of button batteries and consumer goods that contain button batteries undertaken by ACCC and ACL regulators as part of the national strategy found that current warning labelling included on these products is highly variable and many products do not include any button battery warnings at all.

A number of awareness campaigns have been run by various agencies and organisations over recent years to educate parents and carers about the dangers of button batteries. While there is anecdotal evidence that these campaigns have been somewhat effective, education needs to be ongoing to ensure that new parents and caregivers continue to be informed of the dangers of button batteries and the risk they pose to children.

The development of the industry code was a significant step in attempting to improve the safety of consumer goods that contain button batteries. Some suppliers and retailers made significant efforts

70 ISO 10377:2013, Consumer Product Safety—Guidelines for Suppliers.

71 Consumer Product Safety Commission, Final Rule: Safety Standard for Magnet Sets, Federal Register 2014 Vol 79 No 192, 59971. See https://www.cpsc.gov/s3fs-public/pdfs/lawsuit_Attachment1.pdf.

to adopt the principles of the industry code and ensure that the products they supplied met the requirements of the code. While many major retailers adopted the industry code, market surveillance activities conducted as part of the national strategy found that many high-risk button battery-powered products continued to be sold and many suppliers and manufacturers were either unaware of the industry code and its requirements or did not adopt the requirements as they were not mandatory. The voluntary nature of the industry code also made surveillance activities and enforcement action difficult in cases when suppliers resisted taking voluntary action to address safety concerns.

Despite previous efforts by federal, state and territory governments, medical and healthcare providers, industry representative bodies, retailers and some manufacturers to raise awareness of the issue and encourage the adoption of voluntary safety measures, there has been no meaningful decrease in the number of severe injuries resulting from exposure to button batteries.

There are a range of national and international voluntary industry standards for various products and equipment that in recent years have incorporated button battery safety requirements. Many of these national and international industry standards apply vertically to specific product categories and do not effectively address safety for all products that contain button batteries for the following reasons:

- Compliance with industry standards is voluntary, subject to some state-based electrical equipment safety regulations that mandate the requirements of applicable industry standards, and a significant number of suppliers do not comply.
- While some industry standards have been updated to include button battery requirements, this is not the case for all industry standards that cover categories of products which may contain button batteries.
- There are many products that contain button batteries that do not appear to have an applicable industry standard, including a wide range of novelty and promotional products that do not adhere to any button battery safety requirements.

Although some state-based electrical equipment safety regulations require compliance with applicable industry standards, including those that include button battery safety requirements, regulations vary significantly between states and territories in their scope and requirements for consumer goods that contain button batteries. This results in regulatory gaps for products that are commonly distributed throughout Australia.

The ACCC has reviewed electrical safety regulations in each state and territory as they relate to products that contain button batteries. In considering electrical safety regulations for the purpose of button battery safety, there are two main categories of electrical equipment that are relevant:

- **Extra-low voltage:** Electrical equipment that operates with extra-low voltage (this means a voltage not exceeding 50 volts) and includes portable battery operated equipment, including products powered exclusively by button batteries.
- **Low voltage:** Electrical equipment that operates with low voltage (this means a voltage exceeding 50 volts but not exceeding 1,000 volts) and includes appliances that are connected to an electricity supply (mains power). Certain low voltage appliances that require mains power are supplied with accessories that are powered by button batteries, for example, remote controls as an accessory to the appliance connected to an electricity supply.

Victoria applies electrical safety regulations to both extra-low voltage and low voltage equipment. The scope of electrical safety regulations in other states and territories is more narrowly applied to low voltage equipment only, while the Northern Territory does not have a consumer product electrical safety framework. This means that in most states and territories button battery safety is not regulated as products that are powered exclusively by button batteries are not within scope.

There are two key reasons why nationally consistent regulation is required for all products containing button batteries.

- First, the varying scope and requirements of electrical safety regulations in different states and territories means that button battery powered products may be lawfully supplied irrespective of whether they comply with safety requirements specific to button batteries. This is because the *Mutual Recognition Act 1992* (Cth) has the consequence that button battery powered products and

accessories produced or imported into one state can be sold in a second state without having to comply with the electrical safety regulations in the second state.

- Secondly, in those instances where electrical safety regulations do apply to products powered by button batteries, compliance is demonstrated by meeting the requirements of relevant industry standards. While some national and international industry standards have been updated to include safety requirements for products powered by button batteries, this is not the case for all categories of products containing button batteries. There are many products powered by button batteries that are not covered by industry standards, or otherwise are not covered by an industry standards that includes button battery requirements.

The Productivity Commission's 2017 report into Consumer Law Enforcement and Administration noted state and territory governments should tackle the current impasse on standardising electrical goods safety laws.⁷² Greater national consistency would simplify regulation and enhance interactions between ACL regulators and specialist safety regulators.

3.5 Support for government action

Coronial inquests into the deaths of Summer Steer and Isabella Rees have recommended mandatory requirements for products that contain button batteries, including secure battery compartments and child-resistant packaging.

Advocacy groups have been vocal in their support of button battery regulation. Most recently on 23 October 2020 Kidsafe Australia issued a media release following the death of Brittney Conway calling for urgent action on button battery safety and the introduction of world-first legislation for all products containing button batteries.

Industry working group members responsible for developing the industry code, with input from the ACCC and other ACL regulators, have been strong advocates for improved button battery safety. Since the publication of the industry code in 2016, the industry working group consisting of retailers, representative associations and product safety consultants, met regularly to discuss how they are applying the principles of the industry code within their own businesses. The industry working group also considered opportunities for further promotion of the industry code and possible revisions or improvements that could be incorporated into future iterations such as expanding the scope of the code to include requirements for child-resistant packaging or warning requirements for button batteries themselves.

The National Retailers Association (NRA) was involved in establishing the Technical Standards Committee responsible for the development of the industry code. The NRA provides support and guidance for retail and service sector businesses. The NRA's Technical Standards Committee supports the implementation of a stronger regulatory tool to improve button battery safety.

In February 2019 CHOICE ran specific product testing and found that 10 out of 17 common household products that contain button batteries were not safe and did not meet the requirements of the industry code. The products presented a high risk to children as the batteries were easily accessible and warnings and labelling were inadequate.⁷³

In September 2019 CHOICE hosted a policy briefing at Parliament House with parent advocates, doctors and product safety experts titled 'Product Safety: Summer and Bella's stories'. CHOICE attended with two parent advocates, Allison Rees and Andrea Shoesmith, who lost their children due to button battery injuries.

In response to the ACCC's issues paper released in August 2019 and consultation paper released in March 2020, a wide range of stakeholders have provided views on the issue of button battery safety and how the safety hazards posed by button batteries should be addressed. Overall, there has been

72 Productivity Commission, [Consumer Law Enforcement and Administration—Study Report](#), 12 April 2017.

73 CHOICE website <https://www.choice.com.au/babies-and-kids/children-and-safety/avoiding-common-dangers/articles/choice-button-battery-test>, last updated 14 March 2019.

very strong support for the introduction of mandatory safety and information standards to improve the safety of button batteries and consumer goods that use them.

A key point raised by many stakeholders was that supplier self-regulation was not sufficient and that safety requirements should be made mandatory and create an even playing field for all suppliers. Many stakeholders have advocated for the industry code which had been developed by industry with ACCC assistance, to be made mandatory.

The timing of the release of the consultation paper occurred at the outset of COVID-19 in Australia, so a short rapid response survey was distributed to health professionals to assist in the provision of responses from these important stakeholders that may have limited time to prepare submissions. Over 300 responses were received from health professionals, with 99% in favour of the introduction of mandatory safety and information standards that would include button battery safety requirements, including secure battery compartments, child-resistant packaging and warnings and information.

The ACCC considers that nationally consistent regulation of button battery powered products will be achieved by introducing mandatory safety and information standards under the Australian Consumer Law. This will address the regulatory gap that exists in electrical safety regulations and will ensure that button battery safety requirements are consistent across all jurisdictions and would apply to all products containing button batteries to limit the risk of injury from these products.

The ACCC has engaged with electrical safety regulators and ERAC as to whether regulatory duplication would arise should mandatory safety and information standards under the ACL be introduced to apply to consumer goods that contain button batteries. ERAC considers that a horizontal standard under the ACL would not result in regulatory duplication and supports nationally consistent regulation through the introduction of mandatory standards under the ACL to address the safety risk to children from button batteries.

3.6 Alternatives to government action

Industry self-regulation and consumer and industry education awareness raising activities are the primary alternative to mandatory regulation by government.

Industry self-regulation

Industry safety initiatives to date have involved adoption of the voluntary industry code by some suppliers of consumer goods that contain button batteries and the adoption of requirements included in a range of national and international voluntary industry standards that have been developed to include button battery safety requirements. In addition, some major battery manufacturers have developed improved child-resistant packaging and include warning icons on larger button batteries of lithium chemistry.

Industry self-regulation is not considered an effective alternative to mandatory regulation as voluntary compliance has not effectively addressed the hazard presented by button batteries in the wide range of consumer goods for which they are used. The ACCC's recent evaluation of the impact of the national strategy found that although significant efforts have been made by some suppliers, a high level of unsafe products remained in the market and voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries.

Compliance with the industry code and industry standards is voluntary and a significant number of suppliers do not comply. Although some state-based electrical equipment safety regulations require compliance with applicable industry standards, regulations vary significantly between states and territories in their scope and requirements for consumer goods that contain button batteries. This results in regulatory gaps for products that are commonly distributed throughout Australia.

While some industry standards have been updated to include button battery requirements, this is not the case for all industry standards that cover categories of products which may contain button batteries. There are also many products that contain button batteries that do not appear to have an applicable industry standard, including novelty and promotional products that do not adhere to button battery safety requirements.

The ACCC considers that only a horizontal mandatory standard could efficiently address the hazard presented by button batteries across the wide range of consumer goods that contain them. Importantly, mandatory safety and information standards will require compliance from suppliers that do not currently adhere to any button battery safety requirements of an industry standard or the industry code.

The ACCC is not aware of any international standard relating to button batteries currently under development. In 2020 the national standard-setting body, Standards Australia, convened a technical committee for the development of an Australian industry standard for button batteries, being a voluntary horizontal standard covering all products that contain button batteries, as well as button batteries themselves. In September 2020 the British Standards Institute released for consultation a draft publicly available specification (PAS) on button and coin battery safety.⁷⁴ A PAS is not a British Standard, although can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or international standard. A PAS may be adopted as a British Standard following a two-year review.⁷⁵

The ACCC is currently participating in the technical committee convened by Standards Australia. In the event that mandatory safety and information standards under the ACL are introduced to address button battery safety, it is expected that the requirements of this voluntary horizontal Australian industry standard will necessarily be consistent with mandatory regulation. There is also the opportunity for this Australian industry standard to complement mandatory regulation, such as by detailing matters that are not currently detailed in national and international industry standards, such as increased clarity and testing requirements for certain battery compartment access mechanisms.

The ACCC intends to explore options to influence international industry standards to improve both the content and consistency of button battery safety requirements. Following the development of an Australian industry standard for button batteries, the ACCC will coordinate with Standards Australia to pursue the adoption of the standard from this process by the International Organization for Standardization (ISO) and will consider available options to influence international industry standards to adopt relevant requirements of this horizontal Australian industry standard, or otherwise adoption of an international horizontal standard for button batteries.

Raising awareness of button battery safety

Ongoing consumer awareness is necessary to educate consumers on the hazard of button batteries as not all risks associated with button batteries can be addressed by safety and warning requirements.

Ongoing awareness raising activities are not considered an effective alternative to mandatory regulation, but rather a complementary measure to support a multifaceted approach to addressing button battery safety. In addition to regulatory measures, awareness and education to consumers is necessary to communicate the risks button batteries pose to young children and provide guidance on safe storage and disposal of button batteries.

The ACCC and other ACL regulators have undertaken a range of consumer and industry education activities to raise awareness of the hazard of button batteries. Button battery safety messages are also part of cyclical product safety social media campaigns, such as the ‘Safe Summer’ campaign which promotes the safe use of products commonly used during summer and school holidays, and includes safety messages for buying Christmas gifts.

The Product Safety Australia website is the central point of information on button battery safety. It contains many resources and publications as well as information and advice on button battery safety, including a summarised version of the industry code translated into 16 languages.

The ACCC has produced a YouTube video, [Button battery safety in the home](#), and published a [warning poster](#) to educate parents and carers and give them practical advice to reduce children’s exposure to button batteries.

74 BSI Group, PAS 7055 Button Batteries, Button and coin battery safety—Specification, <https://standardsdevelopment.bsigroup.com/projects/2019-02625#/section>, viewed 9 October 2020.

75 Healthcare Safety Investigation Branch, *Undetected button battery ingestion in children*, <https://www.hsib.org.uk/investigations-cases/undetected-button-battery-ingestion-children/>, viewed 10 February 2020.

In October 2020 the ACCC launched a campaign to raise awareness of the serious risks button batteries pose to young children. The ‘Tiny batteries, Big danger’ campaign will include web content, social media messaging, a series of online videos, proactive media and social media advertising. This campaign will target first-time parents, parents of young children, carers and grandparents and will provide guidance on how to create a safe environment for families, including safe storage and disposal of button batteries in households as well as advice on what to do in the event that a child is suspected to have swallowed a button battery.

3.7 Cost of no government action

It is likely that if no government action is taken deaths and severe injuries associated with button batteries will persist and possibly increase. Consumer goods that contain button batteries are prevalent in a range of digital and portable electronic consumer products that can be accessible to young children in households, consistent with the expanding miniaturisation of electronic devices.

The ACCC estimates that four fatalities, 178 to 423 severe injuries and 8,900 emergency presentations will occur during the forecast period of 2022-2031.⁷⁶ Based on these forecasts, the ACCC estimates the direct health costs and immediate costs associated with foregone economic output due to parents and other family members reducing work participation to be approximately \$47.5 million. The true total costs of fatalities and severe injuries to children that have resulted from button batteries are likely to be higher and are impossible to quantify. No economic analysis can appropriately account for the devastating impact on a child, their parents, family, carers and medical staff when a serious button battery incident occurs.

Injuries sustained by children following exposure to button batteries can range in magnitude from minor (where the battery passes without incident) to life changing.

While no economic analysis can account for the devastating impact of losing a child, there are also wide-ranging and long-term costs faced by families as well as the government following the death of a child. The loss of a child significantly impacts the economic wellbeing of parents in subsequent years, including the likelihood of reduced family income, increased unemployment, increased likelihood of divorce and negative impacts on mental health.

⁷⁶ The ACCC proposes an 18 month transition period, the forecast period commences after this period in 2022.

4. Informing the options

Key points

Based on stakeholder feedback and expert advice, the ACCC has refined the policy options outlined in the consultation paper and which are reflected in this Final Recommendation.

Deviation from national and international industry standards was an area of strong objection raised by many industry stakeholders, advocating for the proposed requirements to harmonise with existing industry standards. It is claimed deviation from industry standards will result in a significant regulatory burden, including tooling/design changes for a wide range of products that already adhere to industry standards. For multinational suppliers, it is claimed deviation from international industry standards would create an international trade barrier and result in additional supply chain costs related to compliance management, smaller production runs, and higher inventory, or otherwise the withdrawal of many products from the Australian market.

Health professional stakeholders submitted that any additional costs to industry are insignificant when compared with the consequence of injuries and fatalities resulting from button batteries to young children, and the impact on their families. Medical professionals asserted that they have seen firsthand the devastating consequences of button battery ingestion by children and suggest that stringent regulatory measures are required. It is noted that the cost of these controls are insignificant when compared with the consequence of injuries to young, otherwise healthy infants.

In addition to an exemption for hearing aids and button batteries of zinc-air chemistry intended for hearing aids, a number of further exemption claims were raised. In considering claims for exemption, the ACCC has focused on the risk profile of the consumer good, in terms of accessibility of button batteries to children.

This section sets out stakeholder feedback, expert advice and the ACCC's findings on key issues raised in relation to the proposed requirements outlined in the consultation paper, including for proposed exemptions.

4.1 Access mechanisms for battery compartments

Overview

There are two variations for the accessibility of secure battery compartments in national and international industry standards:

- A requirement that button batteries are not accessible without the use of a tool.
- A requirement that button batteries are not accessible without the use of a tool or unless at least two independent movements have been applied simultaneously to the battery compartment.

The proposed requirements put forward in the consultation paper included a requirement that consumer goods containing button batteries that are intended to be replaced must have a secure battery compartment such that batteries are only accessible with the use of a tool.

Stakeholders were asked to comment on the proposed requirements for secure battery compartments, and what they viewed as appropriate access mechanisms for a battery compartment, including whether the use of a 'tool' should include the use of a coin.

Stakeholder feedback

There was broad support for a mandatory requirement that products that contain button batteries have a secure battery compartment. The majority of stakeholders were of the opinion that a secure battery compartment is the most critical requirement for preventing young children from accessing button batteries. Stakeholders were generally supportive that this critical requirement be enhanced by other

measures such as child-resistant packaging, improved warnings and consumer education. It was also raised that secure battery requirements should include a clear agreed set of compliance tests to ensure the performance and durability of the battery compartment and that the batteries are not released under reasonably foreseeable use or misuse conditions.⁷⁷

While there was broad support for a mandatory requirement that products that contain button batteries have a secure battery compartment, stakeholders provided mixed views on whether battery compartments should be accessible using two independent and simultaneous movements, and the inclusion of a coin as an acceptable tool to access the battery compartment.

Some stakeholders suggested that a battery compartment that can be opened using 'two independent and simultaneous movements', as permitted in some national and international industry standards, appeared less secure than other access mechanisms and can lead to misinterpretation and confusion for suppliers and regulators, and ultimately decreased safety. A more restrictive secure battery compartment requirement that would require a battery compartment be secured with a screw or bolt and only accessible with the use of a tool was put forward as the preferable requirement to improve safety.⁷⁸

Some stakeholders raised that a coin should not be permitted as an acceptable tool to open battery compartments. Stakeholders raised that a battery compartment closure that is capable of being opened with a coin presents a greater risk for children, as battery compartment closures that allow this access mechanism generally require a less complex movement, of less than one rotation, than closures requiring other tools. It is considered that children are more likely to be able to access a coin than other tools such as a screwdriver.⁷⁹

In contrast, many industry stakeholders, including major industry associations that represent manufacturers and suppliers of electronic products, submitted that both the use of a coin as a tool and the use of two independent and simultaneous movements as an access mechanism are permitted under national and international industry standards. Industry stakeholders raised strong concerns a mandatory standard that does not align to international industry standards will cause conflict between suppliers, lead to increased costs, including tooling/design changes, and create an international trade barrier.⁸⁰

Industry stakeholders suggested that the requirements for the accessibility of secure battery compartments should align with existing international standards. It is claimed deviation from national and international industry standards that require tooling/design changes to meet Australian specific product requirements may be uneconomical for many suppliers.⁸¹ Industry stakeholders submitted that the Australian market is relatively small for many electronic consumer products that are manufactured overseas and supplied to multiple jurisdictions, and product redesign may not be justified for a single market.⁸²

Australian industry representative bodies submitted that if a mandatory standard adopts button battery safety requirements set out in national and international industry standards, no cost is expected in relation to the secure batteries requirement for responsible suppliers. However, it is submitted that banning certain battery compartment access mechanisms (such as two independent and simultaneous movements and not allowing a coin as an acceptable tool to access a battery compartment closure) would result in many thousands of products requiring re-design or disappearing from the Australian market.⁸³

77 Choice submission to the ACCC consultation paper, pp.2-3.

78 Product Safety Solutions submission to the ACCC consultation paper, pp.2-3.

79 Kidsafe Australia submission to the ACCC consultation paper, p.2; Consumer Affairs Victoria, p.2.

80 CESA submission to the ACCC consultation paper, pp.2-4, 7; ATA submission, pp.2, 6-8; Lighting Council submission pp.6-10; NEMA submission, p.4; EPBA submission, p.4; Energizer submission, p.5; LG Electronics Australia submission, p.5.

81 CESA submission to the ACCC consultation paper, p.9.

82 LG Electronics Australia submission to the ACCC consultation paper, p.3.

83 CESA submission to the ACCC consultation paper, p.8.

Stakeholders noted that there is no data showing that access mechanisms for secure battery compartments that are permitted by international industry standards are failing, and there should not be a deviation from the international norm unless a failure can be shown.⁸⁴

It was noted by industry stakeholders that the requirement for a secure battery compartment would result in a small cost to suppliers. Many industry submissions stated that they already apply the requirements of the industry code so mandating a requirement for a secure battery compartment would have little to no financial impact.⁸⁵

Review by Exponent

Exponent supports an outcomes-based requirement of secureness that focuses on the overall security of the battery compartment, rather than prescribing specific access mechanisms. An outcomes-based test of secureness would allow for various access mechanisms, including two independent and simultaneous movements or the use of a coin as an acceptable tool, to be used providing that they satisfy battery compartment security requirements when tested.⁸⁶

Findings

The ACCC recommends an outcomes-based requirement for secure battery compartments that does not restrict the access mechanism that may be used for battery compartment closures. An outcomes-based requirement is considered necessary to provide flexibility given the wide range of products that contain button batteries that would be covered by a secure battery compartment requirement, including miniature products where it is not practice to secure the battery compartment with a screw or similar fastener. An outcomes-based test of secureness will not preclude design innovation and has the benefit of allowing new and innovative mechanisms to be developed in future.

4.2 Secure battery and compliance testing requirements

Overview

There are a range of national and international voluntary industry standards for various products and equipment that have been developed to include button battery safety requirements. Many of these national and international industry standards apply vertically to specific product categories such as audio/video and information communications technology equipment, electric toys, and lighting products.⁸⁷ There is also an overseas standard that applies horizontally to products that contain button batteries of lithium chemistry.⁸⁸

There are broad similarities between these national and international industry standards and each includes fundamental requirements for secure battery compartments for products that contain button batteries as well as compliance tests focussed on ensuring that batteries are not accessible to children from the battery compartment or otherwise liberated from the product when subjected to reasonably foreseeable use or misuse.

There are also slight differences in the specific secure battery requirements and compliance tests between these industry standards. For example, a captive fastener requirement is included in national and international industry standards for electric toys and lighting products as well as the overseas standard for products that contain lithium button batteries. However, a captive fastener requirement is

84 Ibid, pp.2-3; Lighting Council submission, p.7.

85 CESA submission to the ACCC consultation paper, p.7.

86 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.2.

87 IEC 62368-1: 2018 Audio/video, information and communication technology equipment—Part 1: Safety requirements; AS/NZS 62368.1:2018 Audio/video, information and communication technology equipment—Part 1: Safety requirements; AS/NZS 60065:2018 Audio, video and similar electronic apparatus--Safety requirements; ISO 8124-1:2018 Safety of toys—Part 1: Safety aspects related to mechanical and physical properties; AS/NZS 8124.1:2019 Safety of toys—Part 1: Safety aspects related to mechanical and physical properties AS/NZS 60598.1:2017 Luminaries Part 1: General requirements and tests.

88 UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies.

not included in national and international standards for audio/video and information communications technology equipment. A captive fastener ensures that where a battery compartment is secured by screws or similar fasteners, the fastener is captive and remains with the door, cover or equipment. This requirement is intended to avoid the potential loss of the fastener at the time of replacing batteries.

The international and Australian audio/video and information communication technology equipment standards do not include a captive fastener requirement as part of secure battery compartment requirements. These standards do include fundamental requirements to address button battery safety by requiring secure battery compartments as well as a range of compliance tests focused on ensuring that button batteries are not accessible to children from the battery compartment or otherwise liberated from the product when subjected to reasonably foreseeable use or misuse.

Stakeholder feedback

Many industry stakeholders, including major industry associations that represent manufacturers and suppliers of electronic products, raised strong concerns that requirements such as a captive fastener requirement which involve deviation from national and international industry standards may reduce the number of products that contain button batteries available in Australia as it may be uneconomical for suppliers to make product design changes specifically for the Australian market.⁸⁹

Australian industry representative bodies submitted that their members adhere to relevant voluntary industry standards that include button battery safety requirements and that there is no evidence that products that adhere to these voluntary industry standards have led to button battery exposures or incidents. Consequently, it is submitted that there is no case for introducing mandatory requirements more onerous than those that exist in these voluntary industry standards. While products that contain button batteries to which a voluntary standard may apply have been implicated in button battery incidents, the available button battery injury and fatality data does not enable an evaluation as to whether the relevant product associated with an injury or fatality adhered to a voluntary standard. These industry stakeholders suggest that the focus of mandatory regulation should be on recalcitrant suppliers or 'bad actors' that supply products that do not conform to any voluntary industry standards or industry code rather than imposing more stringent restrictions across the market to responsible suppliers that comply with voluntary standards.⁹⁰

Review by Exponent

Exponent supports that compliance with outcomes-based requirements for secure battery compartments, where batteries are intended to be replaced, and that batteries are not released during reasonably foreseeable use or misuse conditions, be demonstrated by testing reports that manufacturers and importers must have available.⁹¹

Compliance criteria in international standards can be specified to form a benchmark of the minimum tests that are considered necessary to comply. If alternative test methods are utilised, the testing method should provide a 'high degree or assurance' the products are secure and will not release button batteries.⁹²

Findings

The ACCC has recognised the challenges of harmonising secure battery requirements across a range of relevant national and international industry standards that do not contain uniform requirements, and in many cases, have slight differences.

To address this issue, for the purposes of conforming to the requirements of a mandatory safety standard for consumer goods that contain button batteries, the ACCC recommends that suppliers

89 LG Electronics Australia submission to the ACCC consultation paper, p.3; CESA submission, p.9.

90 CESA submission to the ACCC consultation paper, pp.2-3; Lighting Council submission, pp.7-8.

91 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.22.

92 Ibid, p.25.

have alternative options to conform to the secure battery requirements of a mandatory standard for consumer goods that contain button batteries.

Applicable industry standards (Option 1): Consumer goods that contain button batteries must comply with the referenced clauses of an industry standard deemed to have acceptable button battery security and compliance testing requirements.

Principles-based requirements (Option 2): Consumer goods that contain button batteries must comply with principles-based button battery security and compliance testing requirements.

Under option 1, suppliers of consumer goods that contain button batteries that currently adhere to an industry standard that is deemed to have acceptable button battery security and compliance testing, as referenced in the mandatory standard, may continue to comply with those requirements.

Under option 2, suppliers of consumer goods that contain button batteries that do not currently adhere to an industry standard that is deemed to have acceptable button battery security and compliance testing requirements may either comply with the principles-based requirements or the requirements of an industry standard deemed to have acceptable button battery security and compliance testing requirements, as referenced in the mandatory standard.

Option 2 requires compliance with the following principles-based requirements:

1. Consumer goods containing button batteries that are intended to be replaced by the consumer shall have a secure battery compartment that is resistant to being opened by young children.
2. Consumer goods that contain button batteries (whether or not the batteries are intended to be replaced) shall be secure and not release the batteries during reasonably foreseeable use or misuse conditions.
3. Consumer goods that contain button batteries that are secured by screws or similar fasteners shall be captive to ensure that they remain with the battery compartment door, cover or equipment.

This 'dual-track' approach is considered necessary to achieve harmonisation of button battery security and compliance testing requirements with a range of industry standards that contain slight differences but which overall are deemed to have acceptable requirements.

4.3 Scope of child-resistant packaging requirements

Overview

The risk associated with button battery exposure is determined by a number of interrelated factors. It is the combination of larger battery diameter, higher (and residual) voltage and exposure via swallowing that results in the most catastrophic injuries and death. The greater the battery charge, the greater the propensity for the battery to cause tissue damage when ingested or inserted. Smaller batteries are more likely to be implicated in insertion incidents while larger batteries are more likely to be implicated in ingestion incidents. The median diameter of batteries implicated in different incident types is as follows: insertion (ear) 6.5 mm, insertion (nose) 4 mm, ingestion 20 mm.⁹³

Button batteries operate using one of four chemistries: lithium, alkaline, silver oxide or zinc-air. Table 9 shows the size and voltage created by the four battery types:

⁹³ E. Buttazzoni et al, Symptoms associated with button batteries injuries in children: An epidemiological review, International Journal of Pediatric Otorhinolaryngology, 2015.

Table 9: Coin and button cell chemistry: voltage and size

Chemistry	Voltage	Diameter
Lithium	3 V +	9.5 mm–32 mm
Alkaline	1.5 V	≤ 16 mm
Silver Oxide	1.5 V	4.8 mm–11.6 mm
Zinc-air	1.4 V	≤ 11.6 mm

The proposed requirements put forward in the consultation paper included a child-resistant packaging requirement to extend uniformly to all button batteries regardless of their size or chemistry. Child-resistant packaging requirements were proposed for button batteries sold individually or in multipacks as consumer-replaceable batteries, and when supplied together with a consumer good (when not pre-installed in the product).

Stakeholder feedback

Stakeholder feedback indicated broad support for a mandatory requirement for child-resistant packaging for both button batteries made available for sale and when supplied with consumer goods. It was also submitted that child-resistant packaging should be mandatory for both button batteries sold separately and button batteries supplied with products, where the batteries are not pre-installed in the product.⁹⁴

Many stakeholders support child-resistant packaging for all button battery chemistries and sizes. This is on the basis that fully charged new batteries pose the greatest risk when inserted or ingested and all button batteries pose a risk to children.⁹⁵ Further, it is claimed that it would be complicated and confusing for suppliers and consumers if regulation varied for different chemistry types.

Director of QISU, Dr Ruth Barker, submitted that child-resistant packaging of high-risk pharmaceuticals and household chemicals has dramatically reduced rates of significant poisoning on a global scale. It is therefore considered likely that adopting existing child-resistant packaging standards for batteries will incrementally reduce unintended access by young children.⁹⁶

Industry stakeholders universally support measures to improve safety with respect to button batteries of lithium chemistry. Submissions from international industry associations that represent battery manufacturers, and battery manufacturers and distributors, indicated support for child-resistant packaging for button batteries of lithium chemistry only. These industry stakeholders opposed mandatory requirements for child-resistant packaging to all button battery types as this would involve a significant deviation from international industry standards. It is suggested the focus of regulation should be on button batteries of lithium chemistry that have the highest risk profile.⁹⁷

Many industry stakeholders submitted that button batteries of lithium chemistry and larger button batteries of a diameter 16 mm and above pose a significantly greater hazard than smaller button batteries of a chemistry other than lithium. Industry stakeholders submit that the different risk profile of button batteries of lithium chemistry and larger button batteries of a diameter 16 mm and above should be recognised in the development of any mandatory standard. Referencing the NCPC data, industry stakeholders raised that evidence does not exist to support regulation of smaller button batteries of a chemistry other than lithium. These stakeholders submit that for button batteries of a chemistry other than lithium, the time in which severe injuries can occur has not been fully investigated, although it is known the speed of the electrolysis reaction for button batteries of lithium chemistry is one thousand times greater at 3 volts than the reaction for button batteries of a chemistry other than lithium in the 1.5 volt range.⁹⁸

94 SA Public Health submission to the ACCC consultation paper, p.3.

95 Product Safety Solutions submission to the ACCC consultation paper, p.2.

96 R Barker and co-signatories submission to the issues paper, p.20.

97 NEMA submission to the ACCC consultation paper, p.4; EPBA submission, p.6; Energizer submission, p.5; Powercell submission, pp.5–6.

98 Energizer submission to the ACCC consultation paper, p.2; NEMA submission, p.1–2; and EPBA submission, p.2.

Industry stakeholders did not indicate concerns with the cost of complying with child-resistant packaging requirements as they relate to button batteries of lithium chemistry. Industry stakeholders raised concerns about significant cost increases if child-resistant packaging is required for all types of button batteries, including button batteries of a chemistry other than lithium. It was also raised that the introduction of child-resistant packaging requirements for button batteries of a chemistry other than lithium may result in a reduction of specialty button batteries being available to Australian consumers.

Health and industry stakeholders raised that child-resistant packaging requirements should not preclude innovation and need to allow for other innovative child-resistant packaging options other than blister packaging of button batteries which is the standard form of packaging at present.⁹⁹ For example, supplying button batteries in a container with a secure closure should be allowed. Industry stakeholders raised that battery storage containers and organisers should also be subject to a child-resistant packaging requirement.

Review by Exponent

Exponent supports requirements for child-resistant packaging, noting that new button batteries can cause the most damage in the shortest period because they have the highest electrical charge.¹⁰⁰

Exponent supports that replacement button batteries should be contained in packaging that is designed in an effort to eliminate child accessibility at all times, and that button battery blister packaging should be designed to only release one battery at a time.

Exponent recommended that mandated requirements should not preclude future innovations and technological developments for packaging of button batteries. To encourage innovation, the mandatory safety standard should not specify any particular form of packaging that must be used when supplying button batteries, only that the packaging must be child-resistant.¹⁰¹

Findings

The ACCC considers that all button batteries can pose a safety hazard. Button batteries that are swallowed and become lodged in the oesophagus present an acute emergency. Button batteries that are inserted into body orifices such as the ear and nose can cause severe injuries such as facial palsy and septum perforation. Button battery insertions, while also an emergency situation, do not present the same risk of life-threatening injury and fatality as ingested button batteries.

Button battery ingestion incidents have been the focus of most research and reporting. The available data indicates a significant difference in risk profiles between button batteries of lithium chemistry and button batteries of a chemistry other than lithium.

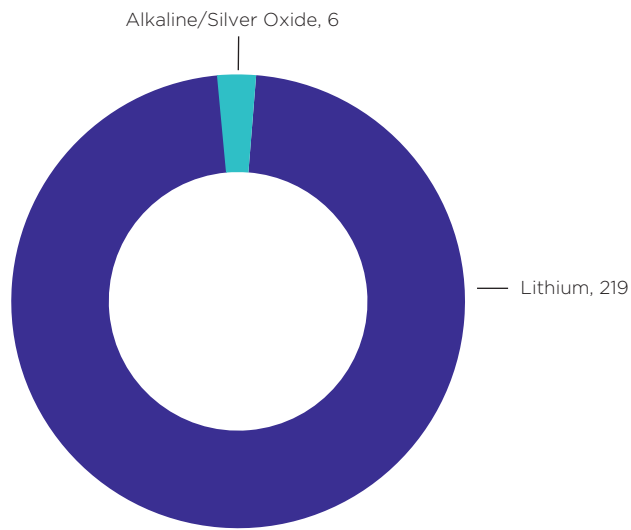
The data clearly identifies that button batteries of lithium chemistry are responsible for the vast majority severe injuries and deaths.

99 ANZSPO submission to the ACCC consultation paper p.2; ASOHNS submission p.3; ATA submission, p.5.

100 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.16.

101 Ibid, p.22.

Figure 8: Severe and fatal cases by chemistry (1977 to 2020)

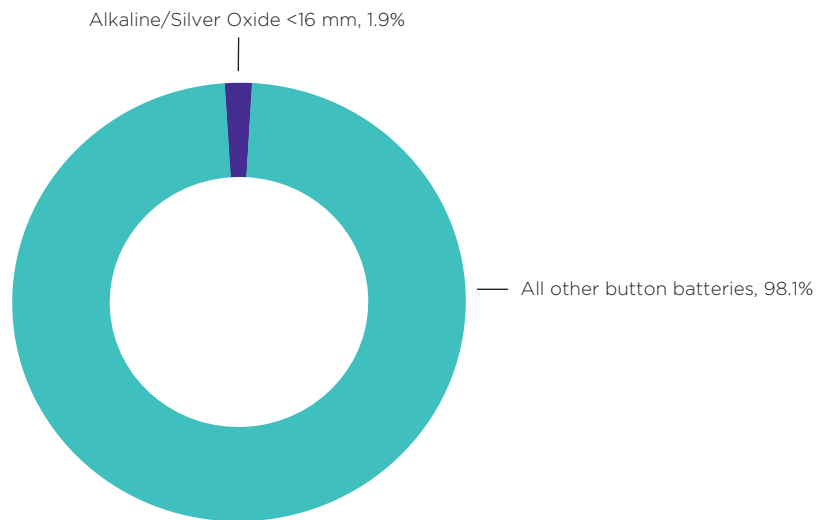


Source: NCPC, *Severe Cases*; NCPC, *Fatal Cases* (Retrieved 15 October 2020).

Notes: Mercuric oxide batteries were withdrawn from sale in the 1990s due to mercury content. Incidents involving mercuric oxide batteries have been excluded from Figure 8.

The most comprehensive set of information on fatalities and severe injuries resulting from button batteries is available from the United States' NCPC. Importantly, the NCPC data is limited to battery ingestions only—it does not include data on button battery insertions. According to NCPC data, 1.9% of severe and fatal cases have involved non-lithium button batteries with a diameter less than 16 mm.

Figure 9: Severe and fatal cases by battery profile (1977 to 2020)



Source: NCPC, *Severe Cases*; NCPC, *Fatal Cases* (Retrieved 15 October 2020).

Notes: Mercuric oxide batteries were withdrawn from sale in the 1990s due to mercury content. Incidents involving mercuric oxide batteries have been excluded from Figure 8.

Smaller button batteries are more likely to be inserted into body orifices such as the ear and nose. A 2015 study provides data on button battery insertion incidents and found that a significant proportion (45%) of button battery cases involved insertions.¹⁰² The study does not detail the chemistry or provide detailed information on the size of the button batteries involved in insertion incidents, nor does it comment on the severity of complications.

While all button batteries can pose a safety hazard, non-lithium button batteries have a lower risk profile.

Button batteries of lithium chemistry and other types of button batteries with a diameter of 16 mm and above have been associated with the majority of severe injuries and fatalities in both Australian datasets and available US data.

There are separate international standards that apply safety requirements to button batteries of lithium chemistry,¹⁰³ and button batteries of a chemistry other than lithium.¹⁰⁴ Child-resistant packaging is currently only a requirement in the international industry standard for button batteries of lithium chemistry. Child-resistant packaging is a requirement for button batteries of lithium chemistry that have a diameter of 16 mm and above.

The ACCC recommends that a mandatory safety standard for button batteries apply child-resistant packaging requirements to:

- button batteries of lithium chemistry of all sizes
- button batteries of a chemistry other than lithium with a diameter of 16 mm and above.

This recommended approach involves deviation from the international industry standard for batteries of lithium chemistry which only requires child-resistant packaging for button batteries of lithium chemistry with a diameter of 16 mm and above.

While there is value in aligning with international industry standards, the ACCC considers that this is an area where there is an opportunity to strengthen protections. The ACCC understands that Energizer already supplies button batteries of lithium chemistry of all sizes in child-resistant packaging.

At present, this recommended approach also involves deviation from the international industry standard for batteries of a chemistry other than lithium which does not apply any child-resistant packaging requirements. However, the ACCC understands that the international industry standard for button batteries of a chemistry other than lithium is being revised and is expected to include a child-resistant packaging requirement for button batteries of a chemistry other than lithium that have a diameter of 16 mm and above.

The ACCC recommends that child-resistant packaging requirements extend to button batteries supplied together with a consumer product, when not pre-installed in the product.

The ACCC recommends an outcomes-based requirement for child-resistant packaging that does not specify any particular form of packaging that must be used when supplying button batteries. An outcomes-based requirement allows button batteries to be supplied in blister packaging or in storage containers that are demonstrated to be child-resistant.

The ACCC recommends that where multiple button batteries are supplied that include any of the applicable button batteries in scope of the child-resistant packaging requirements, blister packaging be required to be designed to release only one button battery at a time—that is, each individual battery shall be separately contained, such that each battery is enclosed in child-resistant packaging even when another battery is removed from the packaging.

102 E. Buttazzoni et al, 2015.

103 IEC 60086-4:2019 Primary Batteries Part 4: Safety of lithium batteries.

104 IEC 60086-5:2016 Primary Batteries Part 4: Safety of batteries with aqueous electrolyte.

4.4 Warning requirements specific to the Australian market

Overview

Warning requirements put forward in the consultation paper proposed warnings be provided:

- on the product (where practicable), packaging and instructions of consumer goods that contain button batteries
- on the packaging and instructions for all button batteries available for sale (regardless of their size or chemistry).

There are a range of national and international voluntary industry standards for various products and equipment that include warning requirements, including international industry standards for audio visual and information communications technology equipment, electric toys, lighting products, button batteries of lithium chemistry, button batteries of a chemistry other than lithium as well as an overseas horizontal industry standard that applies to products that contain button batteries of lithium chemistry.

The warning requirements in these industry standards vary in terms of their application to products, packaging and instructions. Many industry standards that include button battery requirements typically include warning requirements that apply to the instructions only and in limited cases to include warnings on packaging. The warning requirements in many industry standards also apply specifically to button batteries of lithium chemistry or provide specific warnings depending on whether the button battery is of lithium chemistry, or a chemistry other than lithium.

While there is value in aligning with international industry standards, the variation in warning requirements across national and international industry standards presents a challenge in this regard. A principles-based approach has been taken to warnings.

The proposed requirements for warnings put forward in the consultation paper that involved deviation from national and international industry standards, and would be regulatory requirements, specific to the Australian market are as follows:

- Warnings required on the product such as alongside the battery compartment, where practicable, of consumer goods that contain button batteries.
- Warnings required on packaging of consumer goods that contain button batteries, as well as button batteries themselves, including specific text warnings.
- Warnings to include contact information for the Australian Poisons Information Centre (PIC).

General stakeholder feedback on warning requirements

There was general support for improved warnings and labelling on products that contain button batteries as well as button batteries themselves to ensure that consumers are provided with relevant safety information. It was noted that industry have a duty of care to provide safety advice to the consumer when they are buying a product. It was also raised that warning requirements will assist consumer awareness of the presence and hazards of button batteries and enable consumers to make an informed choice prior to the purchase of a product. Some stakeholders raised that warnings are the least effective form of risk mitigation and that instructions and labels are often not read or ignored by consumers.¹⁰⁵

Industry stakeholders did not raise significant concerns about warnings and information requirements in the event requirements are consistent with the industry code or national and international industry standards.

Industry stakeholders raised strong concerns with respect to warning requirements that are specific to Australia, claiming this would result in significant costs that are not commensurate with reduction in risk.

¹⁰⁵ Kidsafe Australia submission to the ACCC consultation paper, p.3; CFA submission, p.2; MBIE New Zealand submission, p. 3.

Industry stakeholders submitted that warning requirements that are specific to Australia would have significant cost implications and create international barriers to trade.¹⁰⁶

The cost implications raised with respect to warning requirements that are specific to Australia are not solely related to updating the product or packaging. The more substantial implications of warning requirements that deviate from international industry standards are those that relate to the need to create a separate production run and manage compliance for products to be supplied to the Australian market, including:

- management of production orders for an Australia-specific product version
- creation of a dedicated assembly line to produce Australia-specific products
- additional warehouse storage facility to segregate Australia-specific inventory
- scrapping of excess Australia-specific inventory which cannot be resupplied to other markets.¹⁰⁷

Given the relatively small volumes of supply to Australia, industry stakeholders assert that such costs may be uneconomical for many overseas suppliers and may result in the removal of products from the Australian market. It is suggested that labelling requirements should be in line with international industry standards.¹⁰⁸

On-product warnings

Stakeholder feedback

Industry stakeholders raised strong concerns with respect to on-product warnings that would involve a significant deviation from national and international industry standards and as a consequence would have a large financial impact on suppliers. It was raised that many products would require design/tooling changes to battery compartments and there would be legibility issues. For example, for certain miniature electronic devices, it may not be practical to include text warnings on the product's battery compartment given space limitations. It has also been raised that where an Australian supplier is unable to persuade an overseas manufacturer to make such a change for an on-product warning requirement that is specific to Australia, products manufactured overseas would need to be unpacked in Australia, and have a warning embossed, printed or adhesive label applied, and then repackaged.¹⁰⁹

Industry associations have raised that an adhesive label on battery compartments will not be durable for many products that contain button batteries. For example, an adhesive label on an item such as a car key fob would be unlikely to remain durable for the lifecycle of the car key. For other products that contain button batteries, adhesive labelling is either impractical due to the material to which it is to be applied, or is otherwise unlikely to be considered viable from an aesthetic or branding perspective for many international electronic equipment suppliers. For these reasons, industry associations have raised that for many products, an on-product warning would need to be printed or, in more extreme cases, the product will require design/tooling changes to emboss warnings on or near the battery compartment.¹¹⁰

Review by Exponent

Exponent advised that it was reasonable to require warning information on both the product and the packaging for consumer goods that contain button batteries, to inform consumers of the potential ingestion and insertion hazards.

106 Lighting Council submission to the ACCC consultation paper, p.10; CESA submission, p.7; responses to ACCC industry surveys.

107 Responses to ACCC industry surveys.

108 LG Electronics Australia submission to the ACCC consultation paper, p.2; NRA submission, p.11; ITIC submission, p.2.

109 CESA submission to the ACCC consultation paper, p.5; meeting with Australian Toy Association, 6 November 2019.

110 Responses to ACCC industry surveys.

Exponent supports a series of principles for warnings to be applied as a cascading system for location on products that contain button batteries, based on the available space. Principles for warnings in order of priority include:

1. an internationally recognised warning symbol
2. an alert word (eg. DANGER, WARNING or CAUTION)
3. a statement informing the consumer that the product uses button batteries, which can cause severe or fatal injuries in two hours or less if swallowed or placed in the body
4. a hotline number for expert advice and support if the consumer suspects a button battery might have been swallowed or placed inside any part of the body.¹¹¹

Findings

The ACCC recognises that given the wide variety of consumer goods that contain button batteries, flexibility for warning requirements on products is necessary.

A mandatory requirement for on-product warnings for all consumer goods that contain button batteries will involve significant deviation from national and international industry standards. Such an on-product warning requirement is included in an overseas industry standard that applies horizontally to products containing button batteries of lithium chemistry.¹¹² This overseas standard permits a safety alert symbol alone (exclamation point within a triangle) to be marked close to the battery compartment where it is not possible to include text warnings due to the size of the product.

The ACCC is also aware that some domestic suppliers that comply with the requirements of the industry code, which recommends affixing warning labels to products that contain button batteries, have adopted this recommendation and place stickers on the backside of remote controls alongside the battery compartment that include a warning icon and text to alert consumers that the device requires button batteries to operate and that these are hazardous to young children.

The ACCC recommends that the information standard for consumer goods that contain button batteries include a best practice recommendation that warnings be provided on products containing button batteries that are intended to be replaced. The on-product warning should be located, on or close to the battery compartment, in the form of an internationally recognised safety alert symbol.

A best practice recommendation for on-product warnings is consistent with the approach of the industry code which does not include on-product warnings as an essential requirement but rather recommends affixing warning labels to products that contain button batteries.

The ACCC recommends that the information standard for button batteries includes:

- a requirement for button batteries of lithium chemistry with a diameter of 20mm and above to be marked with an internationally recognised 'Keep Out of Reach of Children' symbol
- a best practice recommendation for button batteries to be marked with an internationally recognised 'Keep Out of Reach of Children' symbol.

This requirement for a warning symbol to be marked on the battery itself, for button batteries of lithium chemistry with a diameter of 20mm and above, is consistent with the international industry standard for button batteries of lithium chemistry.¹¹³ The ACCC notes that, based on NCPC data, button batteries of lithium chemistry 20mm and above are responsible for 97% of severe and fatal injuries.

These on-product warnings are intended to assist in reminding consumers of the hazard of button batteries when replacing batteries for the given product and to alert occasional caregivers, who may be less cognisant of the hazard.

111 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, pp.17-18.

112 UL4200A:2015 Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies.

113 IEC 60086-4.

Packaging warnings

Stakeholder feedback

Industry stakeholders raised strong concerns that a mandatory requirement for warnings to be included on the packaging for all products that contain button batteries will involve significant deviation from national and international standards that include button battery requirements. This is primarily because these industry standards include limited requirements to include warnings on packaging, with most warning requirements related to instructions for the product.¹¹⁴

Industry associations have raised that requirements for specific text warnings on the front panel of packaging presents an insurmountable problem for suppliers that have globally integrated supply chains and manufacturing and distribution is not separated by global region. This is because text warnings on the front panel of the packaging would need to be translated into over 30 languages for products supplied globally. It has been raised that a requirement for packaging warnings should align with industry standards, such as the Australian, US and international toy standards. These industry standards require packaging warnings for products that contain lithium button batteries and permit warnings on packaging to be conveyed through symbols in lieu of text.¹¹⁵ The use of symbols as a substitute for text is claimed to be a well understood solution for multi-lingual requirements in most markets.¹¹⁶

Review by Exponent

Exponent supports that, at a minimum, warnings should be included on the front panel of packaging of consumer goods that contain button batteries, as well as button batteries themselves, to identify the ingestion hazard of a button battery.¹¹⁷

Findings

The ACCC considers that requirements for warnings on the front panel of packaging of consumer goods that contain button batteries are necessary to alert consumers that a button battery is included with the product. Packaging warnings on the front panel of the packaging will assist to enable consumers to make an informed choice prior to the purchase of a product and are also considered beneficial in raising consumer awareness of the presence and hazards of button batteries.

The ACCC recognises that given the wide range of consumer goods that contain button batteries, flexibility for warning requirements on packaging is necessary to allow warnings on the front panel of the packaging to be conveyed through symbols in lieu of text. The ACCC considers that warning requirements on packaging of button batteries themselves should include both text and symbol warnings.

The ACCC recommends that:

- the information standard for consumer goods that contain button batteries includes:
 - a requirement that warnings are provided on the front panel of packaging in the form of an internationally recognised safety alert and warning symbol of a button battery
 - a best practice recommendation that text warnings are also provided on the front panel of packaging
- the information standard for button batteries include a requirement that text and symbol warnings are provided on the front panel of packaging, allowing flexibility for certain detailed warnings to be provided on a secondary panel of the packaging.

114 Lighting Council submission to the ACCC consultation paper, p.10.

115 AZ/NZS 62115:2018—Electric Toys—Safety; ASTM F963-17—Standard Consumer Safety Specification for Toy Safety; IEC 62115:2017—Electric Toys—Safety.

116 Response to ACCC industry surveys.

117 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.19.

Contact information for the Australian Poisons Information Centre

Stakeholder feedback

The proposed requirements detailed in the consultation paper included a warning requirement that contact information for the Australian PIC be provided on packaging of products that contain button batteries, as well as button battery packaging.

Stakeholder feedback on a warning requirement to provide contact information for the Australian PIC is mixed.

Medical professionals and health sector stakeholders, including Poison Information Centres throughout Australia, are in support of a warning requirement to provide contact information for the Australian PIC. These stakeholders have raised that the Australian PIC is the appropriate national organisation to provide the public with prompt and up-to-date and evidence-based clinical information in the timeliest manner. The survey of health professionals indicates that stakeholders from the health sector are generally supportive of a warning requirement to provide contact information for the Australian PIC. However, it was also raised that seeking immediate medical attention or going straight to a hospital emergency department may be more appropriate advice.

Industry stakeholders suggest that a warning requirement to provide contact information for the Australian PIC on packaging of products that contain button batteries would be ineffective as packaging is typically disposed of by consumers shortly after purchase and would not be available in the event of a button battery emergency. However, it has been raised that contact information for the Australian PIC may be more appropriate on button battery packaging that is more likely to be kept around the home.¹¹⁸

Many industry stakeholders opposed any warning requirements that would be specific only to Australia as this would impose additional costs on suppliers and create barriers to trade. Industry stakeholders raised that given the size of the Australian market, requiring a separate production run for the supply of such a wide range of consumer goods that contain button batteries products may be uneconomical for many suppliers. It is suggested warning requirements need to align with international industry standards that require a warning to seek immediate medical attention if a child is suspected to have swallowed a button battery.¹¹⁹

Review by Exponent

Exponent supports that warning requirements should include a principle that warnings include a hotline for carers to contact for fast, expert advice and support.¹²⁰

Findings

The ACCC recognises that the PICs provide valuable assistance to callers and that inclusion of contact information for the Australian PIC in warnings has benefit given the time-critical nature of button battery incidents. The Australian PIC can provide expert and timely advice in emergency situations, including directing callers on the best course of action. The Australian PIC can also direct callers, in particular those in regional and remote areas, to hospitals that have X-ray facilities and assist clinicians in the initial management of a suspected button battery exposure.

A study by Cairns et al examined button battery exposure data captured by NSW PIC over the 19-month period from November 2015 to May 2017. The study found that children in outer regional, remote and very remote areas were over-represented in the exposure data. It also identified at least 15 cases where patients were referred to a different hospital because X-ray facilities were not available

118 CESA submission to the ACCC consultation paper, p.5; ITIC submission, p. 5.

119 ITIC submission to the ACCC consultation paper, p.2; CESA submission to the ACCC issues paper, p.6; AIIA submission, p. 5.

120 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p. 19.

locally.¹²¹ The study concluded that a PIC-led protocol to direct initial management of button battery exposures could reduce delays and improve outcomes.

In 2015, following the coronial inquest into the death of Summer Steer, Coroner Hutton recommended that PICs serve as first point of contact for potential battery exposures.¹²² In 2019, following the coronial inquest into the death of Isabella Rees, this was further supported by Coroner English's recommendation that PICs should be promoted as the first point of contact in clinical guidelines.¹²³

Further, a study of paediatric exposure cases by NSW PIC (November 2015–May 2017) identified inconsistencies in the triage approaches of first responders and knowledge gaps about the dangers of button batteries and management of cases among some healthcare providers.¹²⁴

The ACCC also recognises the challenges that are presented for a wide range of consumer goods that contain button batteries that are supplied across many countries to include an Australian specific warning requirement, especially for suppliers that have globally integrated supply chains and manufacturing and distribution is not separated by global region.

The ACCC consulted with a range of health information services that can be contacted in the event of a button battery emergency. The ACCC understands that the policies of Poison Information Centres vary slightly between states when handling suspected button battery ingestions.

In New South Wales and Queensland, Poison Information Centres will provide advice to the caller on where the patient should be taken and contact medical facilities and hospitals in the vicinity of the caller ahead to ensure that appropriate equipment, such as X-ray, to reduce delays in diagnosis and that the hospital is prepared to take immediate action when the patient arrives.

In Western Australia and Victoria, Poison Information Centres will direct patients to seek immediate medical attention at the closest or most appropriate medical facility. In Western Australia, it is considered that in rural and remote regions where a caller is not located near a tertiary hospital or medical facility with X-ray equipment, it is preferable to present at the closest medical facility to receive immediate medical assistance from which transfers to another medical facility can be arranged. In Victoria, where all regional hospitals have X-ray facilities and can be reached within at least two hours, callers are directed to seek immediate medical attention from the closest hospital emergency department.

Other health and emergency information services provided divergent views as to whether warnings should include contact information for the Australian PIC or whether the key message should be to seek immediate medical attention.

The ACCC considers that given the wide range of consumer goods that contain button batteries, and the implications of mandating an Australian specific warning requirement, flexibility is necessary for the inclusion of contact information for the Australian PIC.

The ACCC recommends that the information standards for consumer goods that contain button batteries, as well as button batteries themselves, include (where applicable):

- a requirement for warnings to include advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body
- a best practice recommendation for warnings to include contact information for the Australian PIC, and which can be used as an alternative to advice to seek medical attention immediately.

121 R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, 'Button battery exposures in Australian children: a prospective observational study highlighting the role of poisons information centres', *Clinical Toxicology*, vol. 57, no. 6, 2019, pp. 404–410.

122 Office of the State Coroner 2015, Queensland Courts, Brisbane, www.courts.qld.gov.au/___data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf, viewed 28 January 2020.

123 Coroners Court of Victoria at Melbourne 2019, Coroners Court of Victoria at Melbourne, Melbourne, www.coronerscourt.vic.gov.au/sites/default/files/2019-04/IsabellaEstelleRees_059215.pdf, viewed 28 January 2020.

124 R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, Button Battery Exposures in Australia, November 2015–May 2017, NSW Poisons Information Centre.

A best practice recommendation for warnings to include contact information for the Australian PIC is consistent with the approach of the industry code which recommends that warning labels should include advice to immediately contact the Australian PIC if a child is suspected to have swallowed a button battery in addition to other warnings.

4.5 Point of sale warnings

Overview

Warning and information requirements put forward in the consultation paper suggested that warnings and information provided at the point of sale (and prior to purchase):

- be consistent with warnings and information provided on the packaging and instructions of a consumer good that contains button batteries
- be made available for unpackaged consumer goods that contain button batteries
- be made available for all button batteries and consumer goods that contain button batteries sold online.

Stakeholders were asked to comment on the proposed requirements for warnings to be made available at point of sale for consumer goods that contain button batteries sold online or unpackaged.

Point of sale requirements for the supply of consumer goods whether in bricks-and-mortar retail stores or online are not covered in relevant national and international industry standards that include button battery safety requirements. With respect to button battery related requirements, these industry standards are focused on requirements that relate to product design, compliance testing and warnings.

The industry code includes an essential requirement that information must be available at point of sale (including online) indicating that the product, or any included peripheral device, requires button batteries to operate and that these are hazardous to young children.

There was broad support for a requirement to have information available to consumers at the point of sale to enable consumers to make an informed choice prior to purchase. It was raised that point of sale requirements will also assist consumer awareness of the presence and hazards of button batteries.

Unpackaged consumer goods

Stakeholder feedback

Some industry stakeholders consider that point of sale warning requirements will create additional costs for suppliers and compliance will be difficult to monitor and enforce.¹²⁵ A major retailer suggested that it should be acceptable to bring warnings to consumers' attention by attaching swing tags or stickers to unpackaged products where reasonably possible taking into account size constraints.¹²⁶

Review by Exponent

Exponent supports warnings at the point of sale for unpackaged products that contain button batteries sold in bricks-and-mortar retail stores.¹²⁷

Findings

The ACCC considers that point of sale warnings for consumer goods that contain batteries made available for sale in bricks-and-mortar retail stores should apply only to unpackaged consumer goods. This is because consumer goods that contain button batteries that are supplied in packaging are required to provide warnings on the front panel of packaging which serves as a point of sale warning for these products.

125 ITIC submission to the ACCC consultation paper, p.2; Australian Toy Association submission, p.7.

126 Woolworths submission to the ACCC consultation paper, p.3.

127 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.20.

The ACCC recommends that the information standard for consumer goods that contain button batteries includes a requirement that warnings are attached or included with unpackaged consumer goods. This requirement extends to accessories that contain button batteries, such as remote controls or car keys, that are supplied unpackaged.

Online warnings

Stakeholder feedback

Some industry stakeholders, as well as advocacy groups and regulators, were supportive of online warnings. It was noted that online shopping is increasingly common and therefore online warnings are an important avenue to warning consumers.¹²⁸

Online marketplaces and retailers raised that warning requirements for consumer goods that contain button batteries would be costly and complex to implement and that a significant period of time would be required to develop systems to identify the wide range of products that contain button batteries. The complexity of identifying products that contain button batteries increases for online marketplaces that facilitate online supply of products that are listed by third party sellers, including third party sellers that may not realise that their product contains a button battery. Given the variety of business models that online marketplaces can operate within, they may not always have the ability to inspect goods to verify if they contain button batteries.¹²⁹

It was raised that the amount of control that an online marketplace or online retailer has over product listings will depend on the nature of the platform. Global online marketplaces, such as eBay, submitted they have limited control over a third party seller's listing beyond requiring that the seller comply with applicable terms and conditions, product safety policies and relevant Australian laws, including mandatory safety and information standards. On the other hand, online retailers may have full control over listings of products, or in some cases, a hybrid approach where the online retailer directly lists their own products as well as allowing third party sellers to list products.¹³⁰

Online marketplaces also raised that the scope of products that could potentially contain button batteries covers a multitude of product categories and as a result, rather than focusing on a particular category of consumer goods, site-wide system changes would be necessary. It was also raised that regardless of costs to implement system changes, online marketplaces will incur ongoing auditing costs if their compliance teams are required to ensure that listings comply with the requirements of a mandatory standard.¹³¹

Review by Exponent

Exponent advised that it was reasonable to expect online marketplaces and online retailers to provide warnings for products that contain button batteries as warnings on packaging will not be readily visible to consumers purchasing products online.¹³²

Findings

The ACCC recognises the need for flexible online warning requirements given the wide range of consumer goods that contain button batteries and array of operating models for the online supply of consumer goods that flexibility for online warning requirements is necessary.

The ACCC recommends that the information standards for consumer goods that contain button batteries, as well as button batteries themselves, include a best practice recommendation for warnings to be provided when supplying such products online.

128 LG Electronics Australia submission to the ACCC consultation paper, p.4; INPAA submission, p.3.

129 eBay submission to the ACCC consultation paper, p.3; Catch submission, p.3.

130 eBay submission to the ACCC consultation paper, p.3.

131 Ibid, p.3; Catch submission to the ACCC consultation paper, pp.3, 5.

132 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.20.

The ACCC will continue to engage with online marketplaces and online retailers with respect to improving product safety compliance and awareness of unsafe products among sellers through various educational initiatives. In this regard, the ACCC is particularly focused on establishing formal commitments with online platforms to strengthen product safety policies and processes within their marketplaces.

4.6 Battery disposal information

Overview

Children can gain access when batteries are not properly disposed of. Mandatory safety standards can only specify safety requirements that products must meet before they are supplied into the Australian market and cannot mandate requirements for the disposal of button batteries. Mandatory information standards can, however, specify certain information to be provided to consumers when supplying particular kinds of goods, such as advice as to how to safely dispose of button batteries.

For the purposes of this Final Recommendation, advice as to how to safely dispose of button batteries is aimed at preventing children gaining access to old or spent batteries, as opposed to disposal and recycling from an environmental perspective.

The proposed requirements put forward in the consultation paper did not detail button battery disposal advice to be included in mandatory information standards for consumer goods that contain button batteries, or button batteries themselves.

Stakeholder feedback

Some stakeholders suggested that warnings should include advice on safe storage and disposal of used batteries.¹³³

The ACCC has also considered feedback provided by stakeholders in the context of a recent authorisation application by the BSC.

In September 2020, the ACCC granted authorisation to the BSC to establish and operate a national scheme for managing expired batteries, including button batteries. The ACCC considered the risk the scheme may inadvertently increase the safety hazard that button batteries pose to young children by encouraging consumers to hold onto button batteries for subsequent collection and recycling.

A condition of the authorisation requires BSC to develop a button battery safety strategy to be guided by an advisory group involving the ACCC, relevant industry bodies and medical and child safety experts.¹³⁴

Findings

From a safety perspective, the ACCC's advice to consumers in relation to the disposal of button batteries is to dispose of used button batteries immediately to minimise the hazard that they pose to young children. This is because old or spent button batteries can still have enough residual charge to cause serious harm and children can gain access to button batteries when not properly disposed of.

The ACCC will participate in the advisory group that will consider BSC's button battery safety strategy. The ACCC is keen to ensure that safety considerations are given primacy and relevant industry bodies and the ACCC have the opportunity to provide input to the direction that will be taken to address the safety issues relating to button battery disposal and storage for subsequent collection and recycling.

¹³³ Issues paper responses from various health professionals, ABRI, Battery Stewardship Council and Diabetes Qld.

¹³⁴ ACCC, 4 September 2020, [Voluntary battery stewardship scheme granted authorisation](#).

The ACCC recommends that the information standards for consumer goods that contain button batteries, as well as button batteries themselves, include a best practice recommendation for information to be supplied with these consumer goods that includes advice as to how to safely dispose of the battery.

A best practice recommendation for battery disposal information is consistent with the approach of the industry code which recommends battery disposal warnings be provided with consumer goods that contain button batteries.

4.7 Claims for exemption and reduced requirements

Overview

The Minister responsible for product safety has discretion to exempt goods from a mandatory standard where the Minister considers it appropriate.

The consultation paper put forward exemptions for hearing aid devices—from a secure battery compartment requirement—and zinc-air batteries intended for hearing aid devices—from a child-resistant packaging requirement.

Stakeholders were asked to comment on the proposed exemptions and whether other categories of consumer goods should be exempt from any of the proposed requirements.

In response to the consultation paper, many stakeholders raised the need for further exemptions to apply for certain categories of products that contain button batteries.

Based on stakeholder feedback, extensive consultation with key stakeholders and expert advice, the ACCC considers that the following exemptions are appropriate. The ACCC has also recognised that for some categories of consumer goods that contain button batteries, more flexible warning requirements are appropriate having regard to their lower risk profile.

Exemption from requirements of mandatory safety standards

- Hearing aids and hearing instruments.
- Button batteries of zinc-air chemistry designed for, or intended to be used in, hearing aids or hearing instruments.

It is recommended that warning requirements would still apply to hearing aids and button batteries of zinc-air chemistry intended for hearing aids.

Exemption from requirements of mandatory safety and information standards

- Professional equipment to which all of the following applies:
 - The equipment is intended to be used in trades, professions or industries.
 - The equipment is not intended for sale to the general public.
 - The equipment is not intended to be used where children are present.
- Audio-visual and information and communications technology equipment containing button batteries that are soldered in place.
- Second-hand consumer goods—that is, consumer goods that were first supplied before the requirements of the instrument become mandatory.
- Button batteries supplied in bulk to which all of the following applies:
 - The button batteries supplied in bulk are intended to be used in trades, professions or industries.
 - The button batteries supplied in bulk are not intended for sale to the general public.

More flexible warning requirements for consumer goods that have a lower risk profile

Warning requirements are more flexible in relation to consumer goods that contain a button battery if one or more of the following apply:

- The consumer goods are hearing aids or hearing instruments.
- The button battery is fully enclosed in the consumer goods and is not intended to be accessible to the consumer.
- The button battery is not intended to be removed or replaced by a consumer.
- A specialist is required to replace or install the button battery.

For these consumer goods, at a minimum, warnings must be supplied in instructions.

Hearing aids and button batteries of zinc-air chemistry intended for hearing aids

Hearing aids and other hearing devices commonly used by consumers meet the broad definition of a consumer good under the ACL. These products are also subject to regulatory control by the specialist regulator the TGA, which is part of the Department of Health.

The Department of Health is responsible for managing and administering the Australian Government Hearing Services Program (HSP). This program aims to reduce the incidence and consequences of avoidable hearing loss in the Australian community by providing access to high-quality hearing services and devices. This program allows those eligible to purchase a hearing aid and have the cost refunded by the government. The HSP accounts for a majority share of the Australian hearing services market, estimated to be approximately 68% of the measurable market in the 2015–16 financial year.¹³⁵ The program includes two schedules for hearing aid devices, one being a partially subsidised schedule and the second a fully subsidised schedule of approved devices.

It is estimated that in Australia 3.6 million people are affected by some sort of hearing impairment with the majority (75%) of those affected being over 60 years of age. It is estimated that the average hearing aid user in Australia is 79 years of age and hearing aids are generally designed to be independently managed by this consumer demographic.

A report by Deloitte Access Economics estimated that the total cost of hearing loss in Australia in 2017 was \$33.3 billion. This includes financial costs as well as the value of lost wellbeing.¹³⁶ Hearing impairment can reduce an individual's ability to communicate and participate in social situations and can affect a person's education and employment opportunities. Communication problems can lead to mental health issues which can then lead to or exacerbate physical conditions. Studies have also shown that there is an association between hearing loss and increased mortality rates.¹³⁷

Stakeholder feedback

Hearing aid manufacturers and representative bodies raised concerns about the implications of mandatory requirements for secure battery compartments on hearing aids and child-resistant packaging for hearing aid batteries. The main points raised included that:

- hearing aids do not pose the same risk as other products because of their near exclusive use of button batteries of zinc-air chemistry which have a lower risk profile relative to other button battery types. Button batteries of zinc-air chemistry pose a low risk because they are typically smaller, have a lower voltage and are chemically different to button batteries implicated in severe injuries and death

135 PwC Report Executive Summary, Australian Government Department of Health, www.hearingservices.gov.au/wps/portal/hso/site/about/whoarewe/publications/pwc_report_executive_summary_html/, viewed 5 November 2019.

136 Deloitte Access Economics: *An Update of the Social and Economic Cost of Hearing Loss and Hearing Health Conditions in Australia*, July 2017.

137 Ibid.

- button batteries of zinc-air chemistry require access to air (oxygen) to produce a current and when ingested do not establish an electric current as other button batteries may. This lower risk profile needs to be weighed against the clinical and therapeutic benefits of hearing aids
- hearing aid batteries need to be changed approximately once per week and hearing aids need to be designed to ensure they can be independently managed by elderly users—the average age of a hearing aid user in Australia is 79 years¹³⁸
- a mandatory requirement for a secure battery compartment would make independent management of hearing aid battery changes virtually impossible for many users (particularly for elderly users with vision impairment and/or poor dexterity) and the likely result would be that many users would stop using their hearing aids because of difficulties with changing the batteries¹³⁹
- the economic and social costs of mandating this requirement for hearing aids and hearing devices would far outweigh the safety benefit achieved by including them in the mandatory standard
- technological developments will increase the availability of hearing aids with rechargeable batteries although this remains some years away.

Hearing aid manufacturers and representative bodies raised similar concerns about a mandatory requirement for child-resistant packaging of hearing aid batteries which would negatively affect hearing aid users because of the poor eyesight and limited dexterity of many elderly users.

Overall, there was broad support for an exemption for hearing aids from secure battery compartment requirements and associated zinc-air batteries from child-resistant packaging requirements, including from the Department of Health, which includes the TGA.

It was raised that a mandatory requirement for hearing aids to have a secure battery compartment would have a significant impact on the availability of hearing aid products that are fully, or partially, subsidised by the Government. One hundred per cent of hearing aids currently offered under the HSP would be non-compliant if the mandatory safety requirements were applied to them, as would an estimated 85% of devices on the wider market.¹⁴⁰ Therefore it would be costly and logistically challenging to transition Australians to hearing aids that have a secure battery compartment.¹⁴¹ The alternatives, rechargeable lithium-ion batteries that are fully enclosed in the device, are comparatively more expensive and will take time to fit for all consumers, while technological developments to increase their availability remain some years away.

Hearing aid manufacturers and representative bodies have advised that hearing aids designed and intended for use by children incorporate a tamper-resistant battery compartment that requires a tool to remove the battery, in accordance with international industry standards that apply to hearing aids intended for use by infants under 36 months.

Health professionals observed that smaller button batteries such as button batteries of zinc-air chemistry are more usually implicated in insertion incidents, rather than ingestion, as smaller button batteries tend not to get lodged in the oesophagus when ingested.¹⁴² It was raised that nasal cavity and ear canal injuries can still occur from insertions of button batteries of zinc-air chemistry, where oxygen may be available to allow the battery to generate an electrical charge.¹⁴³ Health professionals also suggest it is unclear whether button batteries of zinc-air chemistry pose a significant risk of tissue destruction when lodged for prolonged periods in the oesophagus, which is not an anoxic (no oxygen) environment.

Some stakeholders raised a degree of concern and caution with respect to button batteries of zinc-air chemistry, including that such batteries are prevalent in exposures. It was raised that elderly users of hearing aids may potentially drop hearing aid batteries and forget to retrieve them, or be unable to retrieve them due to movement restrictions. These dropped batteries could then subsequently be

138 HAMADAA issues paper response.

139 Issues paper responses from Sivantos, Widex, HAMADAA and catch.com.au.

140 Audiology Australia issues paper response.

141 Issues paper responses from Hearing Care Industry Association and HAMADAA.

142 NSW Poisons Information Centre issues paper response.

143 Global Injury Research Collaborative issues paper response.

found and picked up by a child who is visiting.¹⁴⁴ The NSW PIC identified that 45% of the button battery exposures they recorded in NSW in 2019, where the battery source was known, was due to hearing aid button batteries.¹⁴⁵

One stakeholder raised that if an exemption is granted to hearing aids and associated batteries, the exemption should be explicitly limited to button batteries of zinc-air chemistry. If a generalised exemption were created this could leave open the possibility of other more dangerous battery chemistry types being used in the future for hearing aids which would not be regulated by the standard.¹⁴⁶

Some stakeholders indicated that if an exemption was granted for hearing aids, it should be reviewed periodically or subject to a sunset clause, in order to encourage the hearing aid industry to develop safer hearing aid device technology.¹⁴⁷

Review by Exponent

Exponent supports exempting hearing aid devices intended for adult use, and associated zinc-air batteries, from child-resistant packaging and secure battery compartments.

Exponent recommended that a requirement should be considered for the front panel of hearing aid packaging, the replacement battery packaging, and the hearing aid instruction manual to contain warnings.¹⁴⁸

Findings

The ACCC considers that hearing aid devices should be exempt from a secure battery compartment requirement and button batteries of zinc-air chemistry intended for hearing aid devices should be exempt from child-resistant packaging requirements. The economic and social costs of mandating these requirements for hearing aids and button batteries of zinc-air chemistry intended for hearing aid devices would outweigh the safety benefit achieved by including them in the mandatory standard.

A mandatory requirement for hearing aids to include a secure battery compartment would significantly reduce the usability and accessibility of the devices for these consumers, especially those with poor dexterity or vision impairment. Many hearing aid users may struggle to independently change their hearing aid batteries there is a risk people may use their hearing devices less or stop using them entirely.

Button batteries of zinc-air chemistry have a lower risk profile relative to other button batteries due to their:

- smaller size (-10mm diameter or less): zinc-air batteries are available in a range of sizes which are generally less than or slightly over 10mm in diameter. This means that they are less likely to become caught in the oesophagus of a child if swallowed
- composition: zinc-air batteries have a nominal voltage of 1.4 volts, and require oxygen to generate an electrical charge, minimising the risk they will produce an electrical current and cause tissue damage for ingestion incidents.

The data available from the Australian PIC and the US National Battery Ingestion Hotline indicates that hearing aids are the most common source of batteries involved in paediatric ingestions. Despite this, zinc-air batteries are not represented in the available injury data. This may be because of their smaller size and lower voltage, and because they require access to oxygen to create a charge. While these batteries have a lower risk profile in comparison with other chemistry types, their smaller size predisposes them to be inserted into body orifices such as the ear and nose where oxygen may be available and they can cause tissue damage. The ACCC considers that it is appropriate to limit an

144 Jewellers Association of Australia issues paper response.

145 NSW Poisons Information Centre issues paper response.

146 *ibid.*

147 Issues paper responses from DMIRS, Kidsafe Australia, Jeremy Wong, Consumers Federation of Australia.

148 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.21.

exemption to hearing aid devices and button batteries of zinc-air chemistry intended for hearing aid devices, while still requiring other consumer goods that contain button batteries of zinc-air chemistry to be subject to the requirements of a mandatory safety standard.

The ACCC recommends that hearing aid devices and button batteries of zinc-air chemistry intended for hearing aid devices should be exempt from the mandatory safety standards, while subject to the mandatory information standards that include warning requirements.

Hearing aid manufacturers and representative bodies raised that hearing aids are typically supplied and fitted by a clinician and that providing warnings in instructions is appropriate.

The ACCC recommends that the information standards for consumer goods that contain button batteries, include:

- a requirement for hearing aids to be supplied with warnings, at a minimum, in accompanying instructions
- a best practice recommendation for consumer goods that contain button batteries to be supplied with warnings on the product and on the front panel of the packaging.

The ACCC does not support placing an expiry date on an exemption for hearing aids as the exemption can be considered as part of a review of mandatory standards introduced to address button battery safety.

Professional and other equipment excluded from international industry standards

Mandatory safety standards under the ACL apply to consumer goods, which are defined as goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption. If professional equipment or specialist trade tools are not a consumer good, they are not required to comply with a mandatory safety standard.

Stakeholder feedback

A number of industry stakeholders called for an exemption for professional equipment, such as specialist trade tools and other professional products not intended for supply to the general public, on the basis that such products are unlikely to be used in locations where they can be accessed by children.¹⁴⁹

Some industry stakeholders have expressed concern at the complexity of the ACL definition of a consumer good and the uncertainty this creates for suppliers. Some stakeholders expressed a preference for the scope of mandatory standards to be defined in the same manner as in national and international industry standards that include button battery safety requirements.

Industry associations raised that national and international industry standards for audio visual and information communications technology equipment exclude professional equipment from button battery safety requirements. Professional equipment, in this context, is 'equipment for use in trades, professions or industries and which is not intended for sale to the general public'.¹⁵⁰ Equipment sold through normal electronics stores is considered not to be professional equipment.¹⁵¹

In addition to excluding professional equipment, national and international industry standards for audio visual and information communications technology equipment do not apply button battery safety requirements to equipment for use in locations where it is unlikely that children will be present; or equipment containing button batteries that are soldered in place.¹⁵²

149 CESA submission to the ACCC consultation paper, p.7; Lighting Council submission, p.11; NRA submission, p.11.

150 IEC 62368-1 Audio/video, information and communication technology equipment—Part 1: Safety requirements

151 CESA submission to the ACCC consultation paper, p.7.

152 Ibid.

Findings

The ACCC recognises that there may be products that contain button batteries that are professional in nature yet still fall within the ACL definition of a consumer good. Certain products that contain button batteries may be used in a professional setting but are also sold directly to consumers and used in households and therefore there is an overlap between some professional equipment and 'consumer goods' under the ACL.

Professional equipment and specialist trade tools can pose a lower risk to children in terms of accessibility to button batteries in comparison to other products.

The ACCC recommends that certain professional equipment be exempt from the requirements of the mandatory standards subject to criteria that focuses on the risk profile of the product. For the purposes of this exemption, products would only be deemed to be professional equipment where all of the following apply:

1. The equipment is intended to be used in trades, professions or industries.
2. The equipment is not intended for sale to the general public.
3. The equipment is not intended to be used where children are present.

The ACCC recognises that equipment that contains button batteries that are soldered in place also pose a low risk in terms of the accessibility of the button battery to children. International industry standards for audio visual and information communication technology equipment exclude such equipment that contains button batteries soldered in place.

The ACCC recommends that audio visual and information communications technology equipment that contains a button battery that is soldered in place be exempt from the requirements of the mandatory standards.

Second-hand goods

Mandatory safety and information standards under the ACL apply to the supply of consumer goods by way of re-supply, such as second-hand goods. The ACL provides that a person must not, in trade or commerce, supply consumer goods of a particular kind if they do not comply with mandatory safety or information standards.

Second-hand goods that are supplied by a business are required to comply with relevant standards, but not private sales between individuals where the seller does not obtain an income from regular selling activities.

Mandatory safety and information standards may specifically exempt second-hand goods from requiring compliance.

Stakeholder feedback

Some stakeholders raised the need for an exemption for second-hand goods that contain button batteries, noting the impracticality of including second-hand goods in the regulatory proposal. It was raised that compliant products would flow through in due course.¹⁵³ In contrast, it was also raised that requirements need to apply at all levels of the supply chain.¹⁵⁴

Findings

The ACCC considers that the requirements of the mandatory standards should not apply to consumer goods that were first supplied before the requirements of the mandatory standards take effect. The ACCC recommends that an 18-month transition period apply after introduction of the mandatory standards to allow suppliers to adapt to the requirements.

153 NRA submission to the ACCC consultation paper, p.11; Product Safety Solutions submission, p.4.

154 SA Health submission to the ACCC consultation paper, p.3.

The ACCC recognises the practical considerations of applying physical/design requirements to consumer goods that were not subject to such requirements at the point of their first supply, when re-supplied as a second-hand good. This is because compliance with such construction requirements would ordinarily occur at the manufacturing phase of a product. The ACCC considers that consumer goods that are supplied after the requirements have become mandatory would continue to be subject to the requirements of the mandatory standards when re-supplied as second-hand goods.

Similarly, it would not be practical to apply product packaging requirements to consumer goods when re-supplied, as in many cases, the packaging of the consumer good will have been discarded. Subject to a consumer good having been supplied after the requirements have become mandatory, warnings should be attached or included when the consumer good is re-supplied second-hand, in circumstances where packaging is no longer available.

The ACCC recommends that the mandatory standards should apply to second-hand consumer goods that contain button batteries that are supplied by persons carrying on a business, where the relevant consumer good was first supplied after the requirements have become mandatory.

Button batteries supplied in bulk for professional use

Button batteries may be supplied in bulk to professionals, such as jewellers, watchmakers or services persons that install and replace button batteries on behalf of consumers. Button batteries supplied in bulk are packed in trays and not supplied in child-resistant packaging.

Stakeholder feedback

It has been raised that the requirements of the mandatory standards for button batteries that would include child-resistant packaging and warning requirements should not apply to button batteries supplied in bulk for professional use on the basis that the use of button batteries supplied in bulk occurs in a commercial or manufacturing setting and are unlikely to be accessed by children.¹⁵⁵

Findings

The ACCC considers that button batteries supplied in bulk to professionals pose a low risk as they are unlikely to be used in locations where they can be accessed by children.

The ACCC recognises that button batteries supplied in bulk would typically be unlikely to be considered a 'consumer good' under the ACL, which is defined as goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption. However, the ACCC notes the concerns expressed by some industry stakeholders at the complexity of the ACL definition of consumer goods and the uncertainty this creates for suppliers.

The ACCC recommends that the mandatory safety and information standards for button batteries should not apply to button batteries supplied in bulk to which all of the following applies:

- The button batteries supplied in bulk are intended to be used in trades, professions or industries.
- The button batteries supplied in bulk are not intended for sale to the general public.

Consumer goods with a lower risk profile

Many industry stakeholders have suggested that exemptions should apply for certain consumer goods that contain button batteries that pose a low risk to children in terms of accessibility of the button batteries in comparison to other products, including where:

- the button battery is fully enclosed in the consumer good and is not intended to be accessible to the consumer
- the button battery is not intended to be removed or replaced by a consumer
- a specialist is required to replace or install the button battery.

¹⁵⁵ EPBA submission to the ACCC consultation paper, p. 3; ACCC discussion with Powercell, 25 August 2020.

Stakeholder feedback

Many industry stakeholders suggested an additional exemption should be considered for products that contain button batteries which are not intended to be replaced by the consumer, or are only replaceable by a service person, such as for certain premium watches or personal computers.¹⁵⁶

The basis for this exemption is that these products present a very low risk of children accessing batteries as the batteries are either fully enclosed, such as where the product does not have a battery compartment, or are only accessed by a service person or a person with specialist tools and knowledge. It has been raised that the child accessibility risk associated with these products is extremely low, and as such an exemption would align with international industry standards. Some industry stakeholders raised that warning requirements should not be required for products that have a low risk profile, such as where batteries are not intended to be replaced or that require a service person to replace.

It has been raised that many toys, novelty and promotional products that contain button batteries are generally not intended to be replaced by the user, and these products are often supplied unpackaged and without instructions. For this reason, it is suggested that these products should be accompanied with a warning to allow the consumer to make an informed purchase, or where the product is complimentary, alert the user to the hazard button batteries pose to children.

Review by Exponent

Exponent advised that some consumer products (for example, watches, specialised trade tools, medical devices) contain button batteries that can only be accessed by a technician with specialised tools.

Exponent supports that if the button batteries contained with these categories of products are not accessible when tested under reasonably foreseeable use or misuse conditions, these products could be exempt from warning and labelling requirements.¹⁵⁷

Findings

The ACCC recognises that some consumer goods that contain button batteries can present a lower risk in terms of their accessibility to children, such as where the button battery is not intended to be replaced or fully enclosed (for example, personal computers), or where a service person is required to replace the battery (for example, premium watches). However, this is not the case for all such consumer goods that contain button batteries that have these features. For example, musical greeting cards can present a high risk of attraction and accessibility to children and the security of the button battery inside such products is critical and should be required to satisfy compliance tests to ensure that the battery does not become liberated during reasonably foreseeable use or misuse conditions. The accessibility of button batteries in such products is not typically associated with the security of the battery compartment, but rather the overall security of the battery in the product.

The ACCC considers that it is appropriate that consumer goods deemed to have a lower risk profile, and which satisfy compliance tests to ensure battery security, be subject to more flexible warning requirements, such that warnings may be supplied, at a minimum, in accompanying instructions. In the event that the consumer good is not supplied with accompanying instructions, warnings should be required to be either attached or included with the consumer good.

The ACCC recommends that the safety standard for consumer goods that contain button batteries requires compliance testing to demonstrate that consumer goods that contain button batteries, whether or not the batteries are intended to be replaced), shall be secure and not release the batteries during reasonably foreseeable use or misuse conditions.

This approach is consistent with the industry code which requires that button batteries not intended to be replaced by the consumer must not be accessible when the device is subjected to reasonably foreseeable use or misuse.

156 Australian Toy Association submission to the ACCC consultation paper, p. 5; Lighting Council submission, p. 11; EPBA submission, pp. 3,5; Federation of the Swiss Watch Industry submission, p. 4.

157 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p. 19.

The ACCC recommends that the information standards for consumer goods that contain button batteries include:

- a requirement for consumer goods deemed to have a lower risk to be supplied with warnings, at a minimum, in accompanying instructions
- a requirement for consumer goods that are not packaged to be supplied with a warning attached or included with the consumer good
- a requirement for consumer goods that are not supplied with accompanying instructions to be supplied with a warning attached or included with the consumer good
- a best practice recommendation for consumer goods that contain button batteries to be supplied with warnings on the product and on the front panel of the packaging.

The following categories of products are deemed to have a lower risk profile:

- The button battery is fully enclosed in the consumer goods and is not intended to be accessible to the consumer.
- The button battery is not intended to be removed or replaced by a consumer.
- A specialist is required to replace or install the button battery.

Category wide exemption claims

Some stakeholders suggested that there should be a general exemption for medical devices. In contrast, it was specifically raised that the mandatory standards should be applicable to medical devices such as digital thermometers and blood glucose monitors which are available in children's wards at hospitals and are often found in the home environment.¹⁵⁸ With respect to blood glucose monitors, it was raised that secure battery compartment requirements should not impede the use of diabetic care devices, noting that certain forms of arthritis can be more common in people with types of diabetes and this can limit the dexterity of users. There was broad support that warnings should be provided on packaging of all products including medical devices.

Some stakeholders suggested that there should be a general exemption for information communications technology equipment, personal computers or quartz watches. Industry stakeholders also raised that warning requirements should not be required for such equipment where the batteries are to be replaced infrequently and by specialist technicians.¹⁵⁹

Findings

The ACCC does not consider that there are sufficient grounds for considering a category wide exemption from the mandatory standards for medical devices, or more specifically for blood glucose monitors. The ACCC notes that a mandatory safety standard under the ACL would only be applicable to medical devices that meet the definition of a 'consumer good', that is goods that are intended to be used, or are of a kind likely to be used, for personal, domestic or household use or consumption.

The ACCC understands that blood glucose monitors are typically powered by button batteries of lithium chemistry with a 20mm diameter that have the highest risk profile and which have also been identified in severe injury data as a product source from which batteries have been accessed by children. The ACCC also understands that blood glucose monitors are used intermittently and are conservatively estimated to require battery replacement every 3 months. This compares with hearing aids which are used for long periods on a daily basis and typically require battery replacement each week.

The ACCC does not consider that there are sufficient grounds for considering a category wide exemption from the mandatory standards for information communications technology equipment, or for product classes such as personal computers or quartz watches.

158 SA Health (Biomedical Engineering) submission to the ACCC consultation paper, p. 6.

159 ATA submission to the ACCC consultation paper, p.5; INPAA submission, p. 3.

The ACCC considers that it is necessary in framing any exemption to a category of consumer goods, to focus on the risk profile of the product in terms of accessibility of button batteries. This approach avoids complications which may come from defining specific product exemptions and also ensures that products that are intended to be subject to the requirements of the mandatory standards, such as remote controls, would not be inadvertently exempted through an overly broad category wide exemption.

The ACCC recognises that certain consumer goods that contain button batteries pose a lower risk in terms of the accessibility of the battery. This is reflected in the ACCC's recommendation for an exemption for professional equipment, subject to criteria that focuses on the risk profile of the product, and reduced warning requirements for consumer goods deemed to have a lower risk profile.

4.8 Transition period

Overview

The consultation paper proposed that any new mandatory safety and information standards for button batteries and consumer goods that contain button batteries be subject to a 12-month transition period from the date of commencement.

A transition period is intended to provide sufficient time for industry to implement any manufacturing and design changes to products and packaging and undertake any testing necessary to ensure compliance with a new mandatory safety and information standard, as well as provide a period of time for industry to exit non-complying stock or source new stock that is compliant.

Stakeholder feedback

Stakeholders provided divergent views on the appropriate length of time to allow for transition to mandatory safety and information standards. Some stakeholders raised that manufacturers and suppliers have had adequate time to understand the risks of button batteries and that a 12-month transition period was sufficient.¹⁶⁰

Many industry stakeholders proposed a longer transition period, ranging from 18–36 months. These stakeholders emphasised that suppliers will require significant time to adapt to new regulation due to the resource burden of implementing changes in design and testing, as well as the impact of COVID-19. A number of stakeholders raised that while some of the proposed requirements are easier to implement than others, some merchandise remains in distribution channels for a significant amount of time. In the event that warning requirements have too short a transition period, a significant amount of stock may need to be scrapped adding to the regulatory burden of the proposal.¹⁶¹

Industry stakeholders have advised that it is preferable for transition periods to be aligned for all requirements, rather than the requirements being staggered such as applying a shorter period for warning requirements and a longer period for requirements relating to physical/design changes to products and packaging.

Review by Exponent

Exponent advised that a 24-month transition period would align with the implementation schedule which is typically provided in international industry standards that include button battery safety requirements.¹⁶²

160 ASOHNS submission to the ACCC consultation paper, p.3; CAV submission, p.4.

161 Catch submission to the ACCC consultation paper, p.5; CESA submission, pp.9-10; Energizer submission, p.7; LG Electronics Australia submission, p.5; NEMA submission, p.6; NRA submission, p.13; Powercell submission, pp.9-10; The Toy Association submission, p.9; Woolworths submission, p.4.

162 G. Rider, Technical Review of ACCC Proposed Regulatory Options for a Mandatory Safety and Information Standard that Would Apply to Button Batteries and Consumer Goods that Use Button Batteries, June 2020, p.26.

Findings

The ACCC recommends that all of the requirements of the proposed mandatory safety and information standards be mandatory 18 months after commencement.

The ACCC considers this is a reasonable period of time based on stakeholder feedback and expert advice. In considering the appropriate length of time for suppliers to adapt to the mandatory safety and information standards, the ACCC has had regard to the extent to which the refined requirements harmonise with national and international industry standards.

5. The regulatory options

Key points

There are four options identified to reduce the risks posed by button batteries to young children—the baseline option (status quo) and three regulatory options.

Option 1—Take no action to address button battery safety (status quo)

- This represents the baseline option and does not include any regulatory changes to address button battery safety.

Option 2—Make a mandatory safety standard to require secure battery compartments and compliance testing of consumer goods that contain button batteries

- Under this option, a mandatory safety standard would be introduced to require secure battery compartments, where batteries are intended to be replaced, and compliance testing, whether or not batteries are intended to be replaced, to demonstrate the battery is secure and not released during reasonably foreseeable use or misuse conditions.

Option 3—Make mandatory safety standards that adopt requirements in Option 2 and require child-resistant packaging for button batteries based on risk profile

- Under this option, in addition to all the requirements of Option 2, a mandatory safety standard would be introduced for button batteries to require child-resistant packaging when supplying button batteries of lithium chemistry, as well as button batteries of a chemistry other than lithium that have a diameter of 16 mm and above.

Option 4—Make mandatory safety and information standards that adopt requirements in Option 3 and require warnings when supplying button batteries and consumer goods that contain button batteries

- Under this option, in addition to all the requirements of Option 3, mandatory information standards would be introduced to require warnings and information when supplying consumer goods that contain button batteries as well as button batteries themselves.

Improving awareness about button battery safety is envisaged as an adjunct to each of these options, but is not considered as an effective stand-alone option as it is only one layer of a multifaceted approach needed to reduce the risk of children accessing button batteries.

Consumer and industry education and awareness raising activities are considered beneficial as a complementary measure. In addition to regulatory measures, awareness and education to consumers is necessary to communicate the risks button batteries pose to young children and provide guidance on safe storage and disposal of button batteries.

This section sets out key features of the options and evidence relating to the requirements.

5.1 Option 1: Take no action to address button battery safety (status quo)

Option 1 represents the baseline option and would result in no regulatory intervention to address button battery safety. This option is not recommended. The ACCC considers that regulatory action is necessary to address the hazard of button batteries and improve safety.

Under the status quo, industry safety initiatives may be adopted on a voluntary basis by suppliers, including the measures outlined in the industry code and compliance with a range of national and international industry standards.

Maintaining the status quo relies to a significant extent upon voluntary self-regulation to address the hazard of button batteries as state-based electrical safety regulations have narrow coverage across the wide range of products that contain button batteries which results in regulatory gaps for products that are commonly distributed throughout Australia.

Retailers, manufacturers and importers would still need to comply with relevant provisions of the ACL, including the consumer guarantees that require goods will be of acceptable quality, fit for purpose and free from defects. While acceptable quality has a number of factors, including that the goods will be as safe as a reasonable consumer would regard as acceptable, consumer guarantees are not considered a substitute for mandatory safety standards as they are not suited to industry-wide regulation, are generally enforced by the consumer asserting the failure to comply on a case by case basis, and remedies are limited.

The majority of products that contain button batteries, as well as button batteries themselves, supplied in Australia would not have to meet any additional safety requirements.

Some responsible suppliers would continue to supply compliant products that adhere to the voluntary requirements of the industry code or industry standards. Although some industry standards have been updated to include button battery requirements, this is not the case for all industry standards and a significant number of suppliers do not comply. There are also many products that contain button batteries that do not appear to have an applicable industry standard, including novelty and promotional products.

Some suppliers would continue to comply with electrical safety regulations in those Australian states and territories that mandate the requirements of applicable industry standards that include button battery requirements. However, state-based electrical safety regulations have narrow coverage and will not effectively address safety for all consumer goods that contain button batteries.

Suppliers would continue to be required to comply with the existing mandatory standard for toys for children up to and including 36 months of age. This mandatory safety standard applies only to toys for this age group and includes requirements that indirectly cover button batteries as they meet the definition of a 'small part' that presents a choking hazard.

There is currently no international industry standard relating to button batteries being developed by any international standards setting body. Standards Australia has convened a technical committee to develop an Australian industry standard for button batteries, being a voluntary horizontal standard covering all products with button batteries, as well as button batteries themselves. Once this standard has been developed, it may lead to improvements in button battery safety if voluntarily adopted by manufacturers and suppliers. However, the ACCC's evaluation of the national strategy found that supplier self-regulation, including through the adoption of voluntary measures have not meaningfully reduced the risk of injury or death to young children from exposure to button batteries. The ACCC has found through surveillance activities that although significant efforts have been made by some suppliers, a substantial number of unsafe products remain available for sale.

Options may be explored to encourage and influence relevant international industry standards to be improved in terms of content and consistency of button battery safety requirements, or otherwise seek for an international industry standard for button batteries to be introduced and adopted. The introduction of an international industry standard for button batteries is speculative, and in any event, would appear likely to take many years to be developed and adopted internationally, and ultimately would continue to rely on voluntary compliance by suppliers.

To date, despite some efforts, battery manufacturers have not made significant safety improvements to button batteries to reduce the risk to children if batteries are ingested. The recent introduction of a bitter coating on some larger-sized button batteries of lithium chemistry by one major battery manufacturer are a positive development, but are not proven to be effective and will not prevent injuries occurring if the battery is ingested. Solutions such as pressure-sensitive coatings and alternative metal casings are being investigated but have not yet been adopted by battery manufacturers.

Technological developments are likely to increase the availability of consumer goods with fully enclosed rechargeable batteries, although this future state remains some years away for the wide range of consumer goods that contain button batteries.

It is likely that if no action is taken deaths and severe injuries associated with button batteries will persist and possibly increase. Consumer goods that contain button batteries prevalent in a range of digital and portable electronic consumer products that can be accessible to young children in households, consistent with the expanding miniaturisation of electronic devices.

5.2 Option 2: Make a mandatory safety standard to require secure battery compartments and compliance testing of consumer goods that contain button batteries

Option 2 is to make a mandatory safety standard that requires consumer goods that contain button batteries to have secure battery compartments, where the batteries are intended to be replaced, and compliance testing, whether or not batteries are intended to be replaced, to demonstrate the battery is secure and not released during reasonably foreseeable use or misuse conditions.

The ACCC considers that secure battery requirements are the most crucial safeguard to improve safety and address the hazard of button batteries.

Under this option, subject to exemptions, secure battery requirements would apply for all consumer goods that contain button batteries, regardless of the size or chemistry of the button battery suitable for the product:

- Consumer goods containing button batteries that are intended to be replaced by the consumer would be required to have a secure battery compartment that is resistant to being opened by young children.
- Consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, would be required to be secure and not release the batteries during reasonably foreseeable use or misuse conditions.

Compliance testing would be required to demonstrate safety requirements have been met.

Secure battery requirements would also be applicable to consumer goods intended to store button batteries, such as storage containers and organisers.

Exemptions would apply to hearing aids, second-hand goods,¹⁶³ professional equipment (subject to certain criteria) and audio visual and information communications technology equipment containing button batteries that are soldered in place.

Evidence supporting the requirements

In 2015, following the coronial inquest into the death of Summer Steer, Coroner Hutton made a range of recommendations including that manufacturers, distributors and retailers of products containing button batteries implement the requirements of the existing toy standard to ensure that batteries are secured in a child-resistant battery compartment within the product.¹⁶⁴

In 2019, following the coronial inquest into the death of Isabella Rees, Coroner English accepted the view that primary prevention is the most important aspect of treatment and that the battery compartment on all devices requiring button batteries should be secured with a screw (or similar).¹⁶⁵

The industry code includes a requirement that all consumer goods that contain button batteries must be designed and manufactured such that the batteries are not accessible to young children when the device is subjected to reasonably foreseeable use or misuse. This requirement is considered

163 The second-hand goods exemption would apply only to goods first supplied to a consumer before the standards become mandatory.

164 Office of the State Coroner 2015, Queensland Courts, Brisbane, www.courts.qld.gov.au/___data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf, viewed 18 November 2019.

165 Coroners Court of Victoria at Melbourne 2019, Coroners Court of Victoria at Melbourne, Melbourne, www.coronerscourt.vic.gov.au/sites/default/files/2019-04/IsabellaEstelleRees_059215.pdf, viewed 18 November 2019.

best practice and is consistent across a wide range of voluntary industry standards for specific product types. National and international industry standards provide alternative options for battery compartments to be secured, either to be accessible by the use of a tool or unless at least two independent movements have been applied simultaneously to the battery compartment.

A study by Litovitz et al in 2010 analysed 8,648 cases of battery ingestion reported to the US National Battery Ingestion Hotline between July 1990 and September 2008. The study found that batteries ingested by children from 0–5 years were obtained directly from the product in 62% of the 3,989 cases where the source of the battery was known.¹⁶⁶ The ACCC estimates that a mandatory secure batteries requirement could prevent two to three fatalities and 85 to 262 severe injuries during the forecast period of 2022–2031.

Given that the majority of button batteries involved in reported incidents have been accessed directly from products, a requirement for consumer goods that contain button batteries to have secure battery compartments, where batteries are intended to be replaced, and compliance testing, whether or not batteries are intended to be replaced, to demonstrate the battery is secure, has been identified as a key requirement to improving safety.

Assessment of the requirements

The ACCC has undertaken a detailed analysis of the industry code and existing national and international standards that include requirements for secure battery compartments for products that contain button batteries (see **Appendix C** for a list of relevant standards considered).

Consistent with national and international industry standards that include button battery safety requirements, secure battery requirements would apply for all consumer goods that contain button batteries, regardless of the size or chemistry of the button battery suitable for the product.

Secure battery compartment and compliance testing requirements would also be applicable to consumer goods intended to store button batteries, such as storage containers and organisers.

Exemptions

The following products are exempt from the requirements:

1. Second-hand consumer goods—that is, consumer goods that were first supplied before the requirements of the instrument become mandatory.
2. Hearing aids and hearing instruments—that is, equipment that picks up sound and delivers processed sound to the ear canal through air-conduction.
3. Professional equipment—that is, equipment to which all of the following applies:
 - the equipment is intended to be used in trades, professions or industries
 - the equipment is not intended for sale to the general public
 - the equipment is not intended to be used where children are present.
4. Audio-visual and information and communications technology equipment containing button batteries that are soldered in place.

Conformance options

Suppliers of consumer goods that contain a button battery would have alternative options to conform to the secure battery requirements of a mandatory standard for consumer goods that contain button batteries.

- *Applicable industry standards (Option 1):* Consumer goods that contain button batteries must comply with the referenced clauses of an industry standard deemed to have acceptable button battery security and compliance testing requirements.

¹⁶⁶ T Litovitz, N Whitaker, L Clark, 'Preventing battery ingestions: an analysis of 8,648 cases', *Pediatrics*, 2010.

- *Principles-based requirements (Option 2):* Consumer goods that contain button batteries must comply with principles-based button battery security and compliance testing requirements.

Suppliers of consumer goods that contain button batteries that currently adhere to an industry standard that is deemed to have acceptable button battery security and compliance testing, as referenced in the mandatory standard, may continue to comply with those requirements.

Suppliers of consumer goods that contain button batteries that do not currently adhere to an industry standard that is deemed to have acceptable button battery security and compliance testing requirements may either comply with the principles-based requirements or the requirements of an industry standard deemed to have acceptable button battery security and compliance testing requirements, as referenced in the mandatory standard.

Secure battery requirements

Consumer goods containing button batteries that are intended to be replaced by the consumer must have a secure battery compartment that is designed to be resistant to being opened by young children.

Consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, must be secure and not release the batteries during reasonably foreseeable use or misuse conditions.

Suppliers of consumer goods that contain button batteries must perform compliance tests to demonstrate the safety requirements have been met.

Consumer goods that are intended to store button batteries (of all sizes and chemistries), including storage containers, organisers and similar products, would also be required to prevent removal of the battery by children under reasonably foreseeable use or misuse.

Applicable industry standards (Option 1)

Under Option 1, suppliers comply with one of the following industry standards (or set of industry standards) deemed to have acceptable button battery security and compliance testing requirements.

IEC 62368-1: 2018 Audio/video, information and communication technology equipment—Part 1: Safety requirements	Clauses 4.8.3, 4.8.4, 4.8.5 *	The tests outlined in each of these standards are near identical and are designed to test security and durability of products that contain button batteries, including certain tests which are focused on testing battery compartments.
AS/NZS 62368.1:2018 Audio/video, information and communication technology equipment—Part 1: Safety requirements	Clauses 4.8.3, 4.8.4, 4.8.5 *	
AS/NZS 60065:2018 Audio, video and similar electronic apparatus—Safety requirements	Clauses 12.7.2, 12.7.3, 12.7.4	
IEC 62115:2017 Electric toys—Safety and ISO 8124-1:2018 Safety of toys—Part 1: Safety aspects related to mechanical and physical properties	Clause 13.4.1, 13.4.2, 13.4.6 (IEC 62115:2017) Clause 5.24 (ISO 8124-1:2018)	Tests include pre-conditioning tests (stress relief test and battery replacement test); abuse tests (drop test, impact test, crush test) and compliance test (force test applying a rigid test finger).
AS/NZS 62115:2018 Electric toys—Safety and AS/NZS 8124.1:2019 Safety of toys—Part 1: Safety aspects related to mechanical and physical properties	Clause 13.4.1, 13.4.2, 13.4.6 (AS/NZS 62115:2018) Clause 5.24 (AS/NZS 8124.1:2019)	
AS/NZS 60598.1:2017 Luminaries Part 1: General requirements and tests	Clause 4.101.1 and 4.101.2	
UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies	Section 5 and 6	

* The tests in these clauses are to be applied to all consumer goods that contain button batteries, regardless of their size or chemistry.

Where a mandatory safety standard is in force and specifies alternative methods of complying, a supplier must nominate the applicable safety standard on request by a regulator.¹⁶⁷

Principles-based requirements (Option 2)

Under Option 2, suppliers must comply with the following principles-based requirements outlined in the instrument:

1. Consumer goods containing button batteries that are intended to be replaced by the consumer shall have a secure battery compartment that is resistant to being opened by young children.
2. Consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, shall be secure and not release the batteries during reasonably foreseeable use or misuse conditions.
3. Consumer goods that contain button batteries that are secured by screws or similar fasteners shall be captive to ensure that they remain with the battery compartment door, cover or equipment.

Requirements for compliance testing

To ensure an acceptable level of safety flows from secure battery requirements, the ACCC considers that it is necessary that consumer goods that contain button batteries be subjected to certain compliance tests contained in relevant industry standards.

Under both options, suppliers of consumer goods that contain button batteries must perform compliance tests to demonstrate to a minimum standard that the button battery safety requirements have been met.

The ACCC has selected tests that are specifically focused on:

- the security and durability of battery compartments and their doors/covers to ensure that the design and manufacture of secure battery compartments is adequate to prevent button batteries becoming accessible
- ensuring that batteries remain fully secured inside consumer goods when subjected to reasonably foreseeable use or misuse.

Test requirements (Option 1)

Under option 1, suppliers must perform the compliance tests of the nominated industry standard that is deemed to have acceptable button battery security and compliance testing requirements, as referenced in the instrument.

During or after the completion of the manufacture or processing of the consumer goods 10 or more representative samples of the consumer goods must be tested in accordance with, and meet the compliance test requirements of, the nominated industry standard.

Where a specific compliance test in an industry standard is inappropriate to apply to a given product, an alternative compliance test may be applied on the condition that the compliance tests applied to the given product ensure that button batteries are secure and shall not be accessible to children or become liberated from the product when subjected to reasonably foreseeable use or misuse conditions.

¹⁶⁷ Section 108 of the ACL.

Test requirements (Option 2)

Under Option 2, suppliers must perform the compliance tests outlined in the instrument that have been selected from a range of industry standards.

- *Requirement to test for use and misuse—consumer goods with non-replaceable button battery:* This test requirement is in relation to consumer goods that contain a button battery where the button battery is not intended to be replaced by the consumer. The following must occur in relation to the consumer goods during, or after the completion, of the manufacture or processing of the consumer goods:
 - a. 10 or more representative samples of the consumer goods must be tested in accordance with section 6.2 and 6.3.2 to 6.3.4 of *UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies*.
 - b. The button batteries contained in the samples must not be released.
- *Requirement to test for use and misuse—consumer goods with replaceable button battery:* This test requirement is in relation to consumer goods that contain a button battery where the button battery contained is intended to be replaced by the consumer. The following must occur in relation to the consumer goods during, or after the completion of, the manufacture or processing of the consumer goods:
 - a. 10 or more representative samples of the consumer good must be tested in accordance with section 6.2 and 6.3.2 to 6.3.4 of *UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies*.
 - b. Those samples, after that testing, must be compliant with section 6.3.5 of *UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies*.
- *Requirement to test consumer goods with non-replaceable button battery for secureness:* This test requirement is intended for musical greeting cards and other relevant consumer goods that use/contain a button battery and the following applies:
 - a. The button battery contained in the consumer goods is not intended to be replaced by a consumer.
 - b. The button battery is accessible to the consumer.

During or after the completion of the manufacture or processing of the consumer goods, 10 or more representative samples of the consumer good must meet the test set out in section 6.4 of the *UL 4200A UL Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies*.

- *Requirement to test consumer goods with button battery in compartment secured with screws or similar fasteners:* This test requirement applies in relation to consumer goods that contain a button battery and the following applies:
 - a. The button battery is contained in a compartment in the consumer goods.
 - b. The door or cover providing access to the compartment is secured by screws or similar fasteners.

During or after the completion of the manufacture or processing of the consumer goods, 10 or more representative samples of the consumer good must meet the test set out in clause 13.4.6 of *IEC 62115:2017 Electric toys-Safety*.

Transition period

The requirements will be mandatory 18 months after the instrument commences.

5.3 Option 3: Make mandatory safety standards that adopt requirements in Option 2 and require child-resistant packaging for button batteries based on risk profile

Option 3 is to adopt all requirements in Option 2, and make a mandatory safety standard that requires child-resistant packaging when supplying button batteries based on their risk profile. Child-resistant packaging requirements would apply to:

- button batteries of lithium chemistry of all sizes
- button batteries of a chemistry other than lithium with a diameter of 16 mm and above.

Button batteries can be sold individually or in multipacks. Where multiple button batteries are supplied, that include any of the applicable button batteries in scope of the child-resistant packaging requirements, blister packaging must be designed to release only one button battery at a time.

Button batteries can also be supplied as spare batteries inside the packaging of a consumer good that is powered by a button battery for installation by the consumer. In accordance with the scope of the child-resistant packaging requirements, spare button batteries that are supplied with a consumer good (where the battery is not pre-installed in a secure battery compartment) would need to be enclosed in child-resistant packaging.

Child-resistant packaging requirements would not specify any particular form of packaging or container that must be used when supplying button batteries, only that the packaging or container must be child-resistant. This will not preclude design innovation and has the benefit of allowing for child-resistant packaging options other than blister packaging which is the standard form of child-resistant packaging for button batteries at present.

Compliance testing would be required to demonstrate safety requirements have been met.

Evidence supporting the requirements

The safety risk to children from button batteries arises when they can gain access to the batteries. Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. It is designed in a way that limits the ability for a child to access the hazardous good. It is not necessarily child-proof, and a determined child may be able to break through this packaging given enough time or with certain tools (for example, scissors). Despite this, the adoption of child-resistant packaging for high risk pharmaceuticals and household chemicals has drastically reduced the rates of poisonings globally, and it is considered that adopting child-resistant packaging standards for button batteries will similarly reduce unintended access to batteries by young children.

The use of child-resistant packaging is proven as an effective measure for preventing children from accessing consumer goods that pose a hazard or high risk to children. A report by Sarika Malhotra et al (2013) on the effectiveness of child-resistant packaging on medical products in the Netherlands found that following the introduction of legislation requiring child-resistant packaging for household chemicals and human medications, the number of hospitalisation and treatments following ingestion of these products decreased by around 33%.¹⁶⁸

In 2015, following the coronial inquest into the death of Summer Steer, Coroner Hutton recommended that the ACCC should develop a regulation mandating the Australian standard for child-resistant packaging of non-pharmaceutical products to apply to all battery packaging, including button batteries.¹⁶⁹

168 S Malhotra, RK Arora, B Singh, U Gakhar, R Tonk, 'Child resistant packaging: a prime concern for packaging of medicinal products', *International Journal of Pharmaceutical Sciences Review and Research*, globalresearchonline.net/journalcontents/v22-2/16.pdf, viewed 5 February 2020.

169 Office of the State Coroner 2015, Queensland Courts, Brisbane, www.courts.qld.gov.au/_data/assets/pdf_file/0004/444289/cif-steer-sa-20151103.pdf, viewed 28 January 2020.

Exposure data from the NBH indicates that where the source of the battery is known, button batteries were removed from the original battery packaging by the child in around 8% of cases.

The most comprehensive set of information on fatalities and severe injuries resulting from button batteries is available from the United States' NCP. Importantly, the NCP data is limited to battery ingestions only and does not include data on button battery insertions

Button battery ingestion incidents have been the focus of most research and reporting. The available data indicates a significant difference in risk profiles between button batteries of lithium chemistry and button batteries of a chemistry other than lithium. The data clearly identifies that button batteries of lithium chemistry are responsible for almost all severe injuries and deaths.

The risk associated with battery exposure is determined by a number of interrelated factors. It is the combination of larger battery diameter, higher voltage and exposure via swallowing that results in larger diameter button batteries of lithium chemistry causing the most catastrophic injuries and death.

Button batteries of lithium chemistry have a higher voltage (3 volts) than other types of button batteries (1.5 volts or less). Button batteries of lithium chemistry are also commonly supplied in larger diameter sizes. Button batteries of lithium chemistry with a diameter of 20 mm or more are the most dangerous, however smaller button batteries of lithium chemistry are also high risk as their higher voltage can result in tissue damage more quickly than other button batteries of a chemistry other than lithium.

Larger diameter button batteries, irrespective of chemistry, also pose a high risk as they have a greater propensity to become lodged in the oesophagus if ingested.

Smaller button batteries are more commonly associated with injuries following insertion into body orifices such as the ear and nose. Button battery insertions, while also an emergency situation, do not present the same risk of life-threatening injury and fatality as ingested button batteries.

While all button batteries can pose a safety hazard, smaller button batteries of a chemistry other than lithium have a lower risk profile than that of other button battery types.

Button batteries of lithium chemistry and other types of button batteries with a diameter of 16 mm and above have been associated with the majority of severe injuries and fatalities in both Australian datasets and available US data.

The ACCC recommends child-resistant packaging requirements should apply to button batteries of lithium chemistry of all sizes and button batteries of non-lithium chemistry with a diameter 16 mm and above.

This approach deviates from the industry code, which recommends but does not require child-resistant packaging for all button batteries regardless of size and chemistry.

This approach also involves deviation with international industry standards that apply to button batteries, but are voluntary in nature. The international industry standard for batteries of lithium chemistry requires child-resistant packaging for button batteries of lithium chemistry with a diameter of 16 mm and above. The ACCC understands that the international industry standard for button batteries of a chemistry other than lithium is being revised and is expected to include a child-resistant packaging requirement for button batteries of a chemistry other than lithium that have a diameter of 16 mm and above.

Energizer, one of the world's largest manufacturers of batteries, has already adopted child-resistant packaging for all lithium button batteries and for non-lithium button batteries greater than 16 mm and above in diameter. However, recent market surveillance of packaging of button batteries by the ACCC and state and territory regulators found that child-resistant packaging has not been commonly adopted, with less than a third of product lines having packaging deemed to be child-resistant.

Child-resistant packaging is likely to be effective in preventing children from accessing button batteries directly from packaging or containers, and hence will substantially reduce the risk these products pose to the health of children.

Industry standards and the industry code are silent on the use of alternative packaging types. The proposed outcomes-based approach to child-resistant packaging allows compliance with existing child-resistant packaging standards. This is intended to allow manufacturers and suppliers freedom to innovate in making packaging inaccessible to children, whether using enclosures, containers or similar devices.

Assessment of the requirements

The ACCC has undertaken a detailed assessment of existing national and international standards that include requirements for child-resistant packaging (see Appendix C for a list of relevant standards considered).

Child-resistant packaging requirements would not specify any particular form of packaging or container that must be used when supplying button batteries, only that the packaging or container must be child-resistant in accordance with specified compliance tests.

Exemptions

The following products are exempt from the requirements:

1. Button batteries of zinc-air chemistry designed for, or intended to be used in, hearing aids or hearing instruments—that is, equipment that picks up sound and delivers processed sound to the ear canal through air-conduction.
2. Button batteries supplied in bulk to which all of the following applies:
 - The button batteries supplied in bulk are intended to be used in trades, professions or industries.
 - The button batteries supplied in bulk are not intended for sale to the general public.

Child-resistant packaging requirements

The packaging of an applicable button battery must be designed to be resistant to being opened by young children.

Child-resistant packaging requirements, based on risk profile, would apply to:

- button batteries of lithium chemistry of all sizes
- button batteries of a chemistry other than lithium with a diameter of 16 mm and above.

Compliance testing would be required to demonstrate child-resistant packaging requirements have been met.

Where multiple button batteries are supplied, blister packaging must be designed to release only one button battery at a time.

Any spare button batteries that are supplied with a consumer good, where the battery is not pre-installed in a secure battery compartment, would need to be enclosed in child-resistant packaging.

Requirements for compliance testing

To ensure an acceptable level of safety flows from child-resistant packaging requirements, the ACCC considers that it is necessary that button battery packaging be subjected to compliance tests contained in relevant industry standards.

Test requirements for blister packaging

1. *IEC 60086-4:2019 Primary Batteries Part 4: Safety of lithium batteries*—a button battery's packaging complies with the requirements if the packaging of 10 or more representative samples comply with Annex E of the Primary Batteries Standard, as that Annex is modified by (2).
2. The Annex E tests of the Primary Batteries Standard required for the packaging of a button battery are consistent with the scope of button batteries to which this instrument applies.

Test requirements for other types of reclosable and non-reclosable packaging

- *AS 5808-2009 Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*—a button battery’s packaging complies with the construction requirements if the packaging complies with clause 3.2.1.
- *EN 862:2016 Packaging—Child resistant packing—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*—a button battery’s packaging complies with the requirements if the packaging complies with clause 3.2.1.
- *ISO 28862:2018 Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*—a button battery’s packaging complies with the requirements if the packaging complies with clause 4.2.1.
- *AS 1928-2007 Child-resistant packaging—Requirements and testing procedures for reclosable packages*—a button battery’s packaging complies with the construction requirements if the packaging complies with clause 4.3.1.
- *ISO 8317-2015 Child-resistant packaging—Requirements and testing procedures for reclosable packages*—a button battery’s packaging complies with the requirements if the packaging complies with clause 3.3.1.
- *USA: 16 CFR §1700 Poison Prevention Packaging Standard*—a button battery’s packaging complies with the requirements if the packaging complies with paragraphs 1700.15(a) and (b) (1) and section 1700.20.

Transition period

The requirements will be mandatory 18 months after the instrument commences.

5.4 Option 4: Make mandatory safety and information standards that adopt requirements in Option 3 and require warnings

Option 4 is to adopt all requirements outlined in Options 2 and 3 and make two mandatory information standards for warnings and information to complement these options, as follows:

- An information standard for consumer goods that contain button batteries (complementing Option 2).
- An information standard for button batteries (complementing Option 3).

An information standard can only be made in relation to ‘consumer goods of a particular kind’. Button batteries and consumer goods that contain button batteries are separate ‘consumer goods of a particular kind’ and therefore two separate information standards are required to complement the two mandatory safety standards.

An information standard is required in order to specify the nature and form of information to be provided with consumer goods. An information standard is required in addition to a safety standard to mandate that warnings and information must be made available to consumers at the point of sale, which may be applicable for some consumer goods that contain button batteries, such as unpackaged consumer goods.

Consumer goods containing button batteries: The information standard for consumer goods that contain button batteries will require warnings on the packaging or accompanying instructions, and at the retail point of sale for unpackaged products, to alert consumers that a button battery is included with the product and the hazard button batteries pose to children.

Button batteries: The information standard for button batteries will require that high risk profile button batteries be marked with an internationally recognised “Keep Out of Reach of Children” symbol. It will also require warnings on packaging of button batteries to alert consumers to the hazard and provide clear directions on what to do in the event that a child is suspected to have swallowed or inserted a battery.

The information standards are proposed to include both mandatory requirements and recommendations. This reflects that the information standards cover a wide range of products that are imported into Australia, as well as supplied to other regions. As a result, the warning requirements in the information standards seek to harmonise with international industry standards, whilst also recommending best practice warnings to include on products.

The ACCC considers that there is benefit in including all warning and information requirements in the information standards rather than the safety standards, as this will enable each information standard to respectively include all relevant requirements and recommendations that apply to a class of consumer goods to be included together for clarity and ease of reference.

The ACCC recognises that for some categories of consumer goods that contain button batteries, more flexible warning requirements are appropriate having regard to their lower risk profile. Consumer goods that contain button batteries deemed to have a lower risk profile, as specified in the information standard, would be required to be supplied with warnings, at a minimum, in accompanying instructions. The following categories of products are deemed to have a lower risk profile:

- The button battery is fully enclosed in the consumer goods and is not intended to be accessible to the consumer.
- The button battery is not intended to be removed or replaced by a consumer.
- A specialist is required to replace or install the button battery.

Consumer goods that are not packaged would be required to be supplied with a warning attached or included with the consumer good. Similarly, consumer goods that are not supplied with accompanying instructions would be required to be supplied with a warning attached or included with the consumer good.

The ACCC recognises the challenges that are presented for a wide range of consumer goods that contain button batteries that are supplied across many countries and the implications of certain warning requirements. The ACCC considers that, in addition to mandatory requirements, the information standards should include best practice recommendations to provide flexibility in the application of warnings while at the same time providing clarity as to best practice.

Best practice recommendations include that:

- warnings be marked on products containing button batteries that are intended to be replaced (located on or close to the battery compartment)
- text warnings are provided on the front panel of packaging of consumer goods that contain batteries
- button batteries of all sizes and chemistries be marked with an internally recognised “Keep Out of Reach of Children” symbol
- online warnings are provided when supplying consumer goods that contain button batteries, as well as button batteries
- warnings provided on button battery packaging, as well with consumer goods that contain button batteries, include contact information for the Australian PIC
- warnings provided on button battery packaging, as well with consumer goods that contain button batteries, include advice as to how to safely dispose of the battery.

Evidence supporting the requirements

A foundation of consumer protection is that products are suitably labelled to warn consumers of any hazard the product may encompass.

In 2018 the ACCC commissioned a review of the research relating to the Efficacy of Warning Labels.¹⁷⁰ The review confirmed that warning labels can be effective in highlighting hazards to consumers. The review also noted that symbols and wording should be provided together to limit the confusion or misinterpretation the display of symbols alone may provide.

The warning label guidelines in the international standard ISO 3864-1:2011 *Graphical symbols—Safety colours and safety signs—Part 1: Design principles for safety signs and safety markings* indicate that a warning label should indicate the hazard, the consequence and the mitigation actions.

Market surveillance and consultation with industry indicate a wide difference in the safety symbols and warning messages included on packaging of button batteries. While major brands and Australian suppliers are already including some form of safety symbol and/or warning on battery packaging, there are large differences in the wording of the warnings and use of pictograms. A review of safety symbols used on the packaging of button battery products identified at least 12 different symbols currently being used.

The lack of consistency in the market in relation to the warnings provided on packaging supports the view that requirements and best practice recommendations for the use of warnings is warranted. Having regard to the wide range of consumer goods that contain button batteries that are supplied across many countries, and which range in size, some of which are miniature and others which are accessories to consumer goods that are unpackaged, it is necessary to afford some flexibility in the prescription of warnings.

Assessment of the requirements

The ACCC has undertaken a detailed assessment of the industry code and existing national and international standards that include warnings and information text related to button batteries (see Appendix C for a list of relevant standards considered).

Requirements: warnings for consumer goods that contain button batteries

Warning and information requirements would apply for all consumer goods that contain button batteries, regardless of the size or chemistry of the button battery.

Warnings should be required on both the packaging and instructions of consumer goods that contain button batteries:

- Warnings on packaging will enable consumers to make an informed purchase and should also assist in increasing consumer awareness of the hazard of button batteries.
- Warnings in instructions provide an opportunity for information to be available for future reference.

In accordance with the proposed requirements, warnings and information should be provided in the form of text and a safety symbol that is clearly visible, prominent and legible, to aid low-literacy and culturally and linguistically diverse (CALD) users.

Warning and information requirements should also be applicable to consumer goods intended to store button batteries, such as storage containers and organisers.

¹⁷⁰ Austin Adams from the School of Psychology at the University of New South Wales and James Cook University undertook the research review.

Exemptions

The following products are exempt from the requirements:

1. Second-hand consumer goods—that is, consumer goods that were first supplied before the requirements of the instrument become mandatory.
2. Professional equipment—that is, equipment to which all of the following applies:
 - The equipment is intended to be used in trades, professions or industries.
 - The equipment is not intended for sale to the general public.
 - The equipment is not intended to be used where children are present.
3. Audio-visual and information and communications technology equipment containing button batteries that are soldered in place.

Packaged consumer goods

If the consumer goods are packaged, the front panel of the packaging of the consumer goods must be marked with an internationally recognised safety alert symbol that is clearly visible, prominent and legible and which identifies that the consumer good uses or contains a button battery.

A suitable example of an internationally recognised safety alert symbol is the combination of ISO 7010 W001 (triangle with exclamation mark) and IEC 60417-6367 (coin cell battery symbol).



Consumer goods: with instructions / unpackaged / no instructions

Consumer goods that contain button batteries must include warnings in the accompanying instructions. If the consumer good is supplied unpackaged, or not supplied with instructions, warnings must be attached or included with the consumer good.

Warnings should include the substance of all of the following:

- a. An alert word with the letters in upper case (such as DANGER, WARNING or CAUTION).
- b. An internationally recognised safety alert symbol.
- c. A statement to keep batteries away from children.
- d. A statement that:
 - *For button batteries of lithium chemistry:* a button battery can cause severe or fatal injuries in 2 hours or less if the battery has been swallowed or placed inside any part of the body
 - *For button batteries of a chemistry other than lithium:* a button battery can cause serious injury if swallowed or placed inside any part of the body.
- e. Advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body.

Consumer goods that have a lower risk profile

Warning requirements are more flexible in relation to consumer goods that contain a button battery if one or more of the following apply:

- The consumer goods are hearing aids or hearing instruments.
- The button battery is fully enclosed in the consumer goods and is not intended to be accessible to the consumer.
- The button battery is not intended to be removed or replaced by a consumer.
- A specialist is required to replace or install the button battery.

For these consumer goods, at a minimum, any accompanying instructions with the consumer good must be marked with warnings consistent with those that apply in instructions more generally for consumer goods that contain button batteries.

Warnings to comply with size, legibility and durability standards

Warnings included with consumer goods that use/contain a button battery must comply with *ISO 38642: 2016 Graphical Symbols-Safety colours and safety signs-Part 2: Design principles for product safety labels*—clause D.5 (size and legibility of product safety labels) and D.7 (durability of product safety labels).

Best practice recommendations: warnings for consumer goods that contain button batteries

Consumer goods that contain button batteries that are intended to be replaced should have a warning on the product (on or close to the battery compartment)

Consumer goods containing button batteries intended to be replaced by the consumer should be marked with a warning about the button battery that is:

- a. clearly visible, durable and remains legible for the expected life of the good
- b. located on or close to the battery compartment or where the battery is accessible.

At a minimum, an internationally recognised safety alert symbol should be marked on the consumer good, and subject to available space, text warnings should be marked on the consumer goods that include the substance of all of the following:

- (i) An alert word with the letters in upper case (such as DANGER, WARNING, or CAUTION).
- (ii) A statement to keep batteries away from children and that button battery are hazardous and can cause internal chemical burns if swallowed.

Packaged consumer goods/consumer goods supplied online

If the consumer good is packaged, the packaging of the consumer good should be marked with a warning about the button battery that is clearly visible, prominent and legible and located on the front panel of the packaging.

If the supply of the consumer good is made through an electronic platform, the supplier should include a warning about the button battery that is clearly visible, prominent and legible in the description of the consumer goods on the platform.

Warnings should include the substance of all of the following:

- a. An alert word with the letters in upper case (such as DANGER, WARNING or CAUTION).
- b. A statement to keep batteries away from children.
- c. A statement that:
 - *For button batteries of lithium chemistry:* a button battery can cause severe or fatal injuries in 2 hours or less if the battery has been swallowed or placed inside any part of the body
 - *For button batteries of a chemistry other than lithium:* a button battery can cause serious injury if swallowed or placed inside any part of the body.
- d. Advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body.

Where limited space is available, (a), (b) and (c) should be located on the front panel of the packaging as a priority and other warnings located on a secondary panel of the packaging.

Contact information for Australian Poisons Information Centre should be included with consumer goods that contain button batteries

Consumer goods that contain a button battery should be supplied with a warning that includes the substance of the statement “Where it is suspected a button battery has been swallowed or placed inside any part of the body, call the 24hour Australian Poisons Information Centre on 13 11 26 for fast, expert advice”.

This warning should be provided on the packaging and in the accompanying instructions of the consumer good. This warning can be used as an alternative to advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body.

Advice as to how to safely dispose of button batteries

Consumer goods that contain a button battery should be supplied with information that is clearly visible, prominent and legible that includes advice as to how to safely dispose of the battery.

Requirements: warnings for button batteries

Warning and information requirements would apply for all button batteries, regardless of size or chemistry.

Warnings should be required on the packaging of button batteries to provide an opportunity for information to be available for future reference and also assist in increasing consumer awareness of the hazard of button batteries.

In accordance with the proposed requirements, warnings and information should be provided in the form of text and a safety symbol that is clearly visible, prominent and legible, to aid low-literacy and CALD users.

Exemptions

The following products are exempt from the requirements:

- Button batteries supplied in bulk to which all of the following applies:
 - The button batteries supplied in bulk are intended to be used in trades, professions or industries.
 - The button batteries supplied in bulk are not intended for sale to the general public.

Packaging of button batteries

The packaging must be marked with a warning that is clearly visible, prominent and legible and includes the substance of all of the following:

- a. An alert word with the letters in upper case (such as DANGER, WARNING or CAUTION).
- b. An internationally recognised safety alert symbol.

- c. An internationally recognised “keep out of reach of children” symbol.
- d. A statement to keep batteries away from children.
- e. A statement that:

For button batteries of lithium chemistry: a button battery can cause severe or fatal injuries in 2 hours or less if the battery has been swallowed or placed inside any part of the body

For button batteries of a chemistry other than lithium: a button battery can cause serious injury if swallowed or placed inside any part of the body.

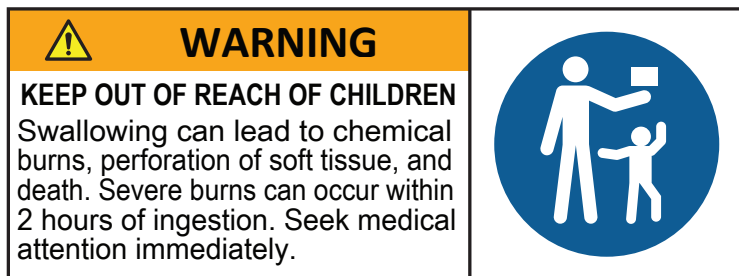
- f. Advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body.

Where limited space is available, (a), (b), (c) and (d) should be located on the front panel of the packaging as a priority and other warnings located on a secondary panel of the packaging.

A suitable example of an internationally recognised safety alert symbol is ISO 7010 W001 (triangle with exclamation mark) and a suitable example of an internationally recognised “Keep Out of Reach of Children” symbol is ISO7010-M055. These symbols are to be used in combination.



A warning in the form specified in figure 9 of clause 7.2 of the Primary Batteries Standard (*IEC 600864: 2019 Primary Batteries Part 4: Safety of lithium batteries*) is taken to be a warning that includes the warnings specified in (a) to (f).



IEC

Markings on button batteries of lithium chemistry with a diameter 20mm and above

Button batteries of lithium chemistry with a diameter of 20mm and above must be marked with an internationally recognised “keep out of reach of children” symbol that is clearly visible, prominent and indelible.

Warnings to comply with size, legibility and durability standards

Warnings included with consumers goods that use/contain a button battery must comply with *ISO 38642: 2016 Graphical Symbols-Safety colours and safety signs-Part 2: Design principles for product safety labels*—clause D.5 (size and legibility of product safety labels) and D.7 (durability of product safety labels).

Best practice recommendations: warnings for button batteries

Markings on button batteries

All button batteries should be marked with an internationally recognised “keep out of reach of children” symbol that is clearly visible, prominent and indelible.

Button batteries supplied online

If the supply of button batteries is made through an electronic platform, the supplier should include a warning about the button battery that is clearly visible, prominent and legible in the description of the consumer goods on the platform and that includes the substance of all of the following:

- a. An alert word with the letters in upper case (such as DANGER, WARNING or CAUTION).
- b. An internationally recognised safety alert symbol.
- c. A statement to keep batteries away from children.
- d. A statement that:
 - *For button batteries of lithium chemistry*: a button battery can cause severe or fatal injuries in 2 hours or less if the battery has been swallowed or placed inside any part of the body.
 - *For button batteries of a chemistry other than lithium*: a button battery can cause serious injury if swallowed or placed inside any part of the body.
- e. Advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body.

Contact information for Australian Poisons Information Centre should be included on packaging of button batteries

Button batteries should be supplied with a warning that includes the substance of the statement “Where it is suspected a button battery has been swallowed or placed inside any part of the body, call the 24hour Australian Poisons Information Centre on 13 11 26 for fast, expert advice”.

This warning should be provided on the packaging of button batteries and can be used as an alternative to advice to seek medical attention immediately if it is suspected a button battery has been swallowed or placed inside any part of the body.

Advice as to how to safely dispose of button batteries

Button batteries should be supplied with information that is clearly visible, prominent and legible that includes advice as to how to safely dispose of the battery.

Transition period for the information standards

The requirements will be mandatory 18 months after the instrument commences.

5.5 Summary of preferred option

The ACCC considers that regulation targeted at improving button battery safety is essential to ensure that manufacturing and design changes are implemented and that improved safety information is provided to consumers. These changes are likely to protect Australian children from avoidable severe injuries and death.

The ACCC considers that Option 4 is likely to prevent more deaths and severe injuries than all of the other options by reducing incidents of child exposure to button batteries. It also best addresses information asymmetry by improving consumer awareness of the hazard and directing appropriate action when an incident occurs.

Option 4 involves the following mandatory standards under the ACL:

- A safety standard for consumer goods that contain button batteries.
- A safety standard for button batteries.
- An information standard for consumer goods that contain button batteries.
- An information standard for button batteries.

A mandatory safety standard is required to specify the minimum requirements that consumer goods must meet before they are supplied.

A mandatory information standard is required in order to specify the nature and form of information to be provided with consumer goods. An information standard is required in addition to a safety standard to mandate that warnings and information must be made available to consumers at the point of sale.

Option 4 requires all of the following:

Consumer goods that contain button batteries

- Consumer goods containing button batteries that are intended to be replaced by the consumer be required to have a secure battery compartment that is resistant to being opened by young children.
- Consumer goods that contain button batteries, whether or not the batteries are intended to be replaced, be required to be secure and not release the batteries during reasonably foreseeable use or misuse conditions.
- Compliance testing be required to demonstrate safety requirements have been met.
- Warnings be required with consumer goods that contain button batteries on the packaging or accompanying instructions, and at the retail point of sale for unpackaged products or products that are not supplied with instructions, to alert consumers that a button battery is included with the product and the hazard button batteries pose to children.
- Exemptions to apply to second-hand goods¹⁷¹, professional equipment (subject to certain criteria) and audio visual and information communications technology equipment containing button batteries that are soldered in place. Hearing aids would be exempt from secure battery compartments, but subject to warning requirements.

Button batteries

- Packaging be required to be child-resistant for button batteries of lithium chemistry of all sizes, and button batteries of a chemistry other than lithium with a diameter of 16 mm or above.
- Compliance testing be required to demonstrate child-resistant packaging requirements have been met.
- Where multiple button batteries are supplied, blister packaging must be designed to release only one button battery at a time.
- Any spare button batteries that are supplied with a consumer good, where the battery is not pre-installed in a secure battery compartment, must be enclosed in child-resistant packaging.
- Button batteries of lithium chemistry with a diameter of 20mm and above be required to be marked with an internationally recognised “Keep Out of Reach of Children” symbol.
- Warnings and information be required on packaging of button batteries to alert consumers to the hazard button batteries pose to children and provide clear directions on what to do in the event that a child is suspected to have swallowed or inserted a battery.
- Exemptions to apply to button batteries supplied in bulk for professional use (subject to certain criteria). Button batteries of zinc-air chemistry intended for hearing aids would be exempt from child-resistant packaging requirements, but subject to warning requirements.

Transition period

- The requirements be mandatory 18 months after the legislative instruments commence.

¹⁷¹ The second-hand goods exemption would apply only to goods first supplied to a consumer before the standards become mandatory.

6. Impacts of the options (costs and benefits)

This section sets out the estimated regulatory costs and benefits of each of the policy options under consideration. A cost-benefit analysis is undertaken to assess the net economic impacts of the policy options. The cost-benefit analysis compares likely outcomes under alternative policy options to outcomes under the status quo baseline option (take no action) to yield estimates of the net benefit of each policy option.

Introducing safety regulations can provide a range of benefits that can be hard to measure. These include avoiding the loss of life and avoiding severe injuries. However, introducing effective safety regulations may also incur economic costs to industry (to comply with the safety regulation) and government (to enforce the safety regulation). In undertaking a cost-benefit analysis of each policy option to improve button battery safety, it is important to highlight that not all factors or impacts can be readily quantified or reduced to a monetary amount. A cost-benefit analysis emphasises, to the extent possible, valuing the gains and losses from introducing safety regulations in monetary terms.

As a result, the true total costs of fatalities and severe injuries to children that have resulted from button batteries are impossible to quantify. As recognised by the OECD¹⁷² and the National Research Centre for OHS Regulation,¹⁷³ strict cost-benefit analysis focused on quantitatively derived estimates can narrowly define economic impacts and ignore other significant effects. To address this, the ACCC's analysis of costs associated with button battery incidents includes both quantitative and qualitative considerations.

There are wide-ranging and long-term costs faced by families as well as the government following the death or serious injury of a child. These costs are important factors in considering the effect of introducing safety regulations to address the hazard of button batteries. Data is not available to project these costs into the future for the purposes of a quantitative analysis.

Uncertainty exists in respect of a number of future costs, and the impact each regulatory option will have. A range of costs and benefits were calculated to demonstrate the range of possible outcomes for each option. The median costs and benefits are presented here. See **Appendix D** for details of the methodology used to arrive at the figures presented below.

172 OECD Regulatory Policy Outlook 2018.

173 Hopkins, 'The Cost-Benefit Hurdle for Safety Case Regulation', January 2014

Social impact and economic costs to families following the death of a child

Losing a child has been classified as one of the most extreme stressors a human can face.¹⁷⁴

While no economic analysis can account for the devastating emotional and psychological impact of losing a child, it is important to highlight the wide-ranging and long-term costs that can be faced by families following a button battery-related fatality.

The Compassionate Friends (Victoria) commissioned a study to measure the economic cost and social impact to families following the death of a child.¹⁷⁵ The findings include the following:

- There are significant unbudgeted expenses that many families experience considerable difficulty in meeting following the death of a child, including funeral and burial costs.
- Ongoing medical expenses are also commonly borne by families following the death of a child for a number of years, including mental and psychological health-related expenses.
- Substantial and persistent financial costs include a loss of income from employment. This can arise from premature retirement, premature resignation, voluntary or involuntary demotion, leave without pay, absences and selling or leaving a business. The most common impact of the death of a child on employment involves parents taking leave without pay, often after exhausting other forms of leave. In many cases, parents choose or are forced to resign from their employment following the death of a child.

In Australia, coronial inquests have occurred following the deaths of Summer Steer and Isabella Rees. Coronial inquests result in substantial costs, including legal expenses and representation, which are borne both directly by families, as well as funded by government.

The loss of a child has strong effects on the economic and psychological wellbeing of parents in subsequent years, including the likelihood of reduced family income, increased unemployment, increased likelihood of divorce and reduced mental health.¹⁷⁶ Reduced health, income and employment as well as family breakdown typically result in a range of costs that are borne by families as well as the government.

It is estimated that the financial loss faced by one bereaved Australian family following the death of their child after ingesting a button battery amounts to approximately \$3.6 million, based on immediate and long-term costs including reduced employment and loss of future income, legal fees including coronial inquest-related expenses, funeral expenses and ongoing medical and mental health counselling expenses.

174 American Psychiatric Association (1987), 'Diagnostic and Statistical Manual of Mental Disorders', 3rd ed, revised, Washington DC, American Psychiatric Press.

175 Stebbins and Batrouney, The Compassionate Friends (Victoria), 'Beyond the death of a child', July 2007.

176 Berg, Lundborg and Vikstrom, IAZ Discussion Paper No. 7010, 'The Economics of Grief', November 2012.

6.1 Benefits and costs of Option 1: Take no action to address button battery safety (status quo)

Option one represents the baseline option and would result in no regulatory intervention to address button battery safety. No additional regulatory costs would be imposed on manufacturers, distributors or retailers and no restrictions would be placed on the supply of consumer goods that contain button batteries if the status quo is maintained.

Industry safety initiatives may be adopted on a voluntary basis by suppliers. Manufacturers and retailers who have not already voluntarily adopted safer practices are not likely to do so. Unsafe products will continue to flow into the market and many more children and their families are likely to suffer significant harm or death as a result of button battery incidents.

The ACCC assumes that maintaining the status quo (taking no action) will result in button battery incidents continuing to occur at the current rate.

Table 10 shows the upper and lower estimates of the number of incidents estimated to occur during the forecast period, and health costs associated with those incidents. The ACCC will assess the net benefits of the three alternative policy options against the base case of maintaining the status quo.

Throughout this section, forecast incidents account for population growth and assume that emergency presentations, injury and fatality rates will remain constant on a per person basis. Economic costs are discounted at a rate of 7% with a base year of 2020 to reflect the opportunity cost of funds and enable appropriate comparisons to be made between cash flows occurring at different times. All costs are presented in 2020 dollars. Benefits and costs are calculated with the assumption that the exemptions and flexible options for compliance previously outlined in this document are implemented.

Due to uncertainty with respect to the number of button battery incidents that may occur during the forecast period, and the effect that safety regulation will have on the number of incidents, a lower and upper bound of estimates was calculated. The benefits and costs outlined in this chapter are the median values unless otherwise specified. Appendix D provides detailed information about how the figures presented were calculated.

Table 10: Forecast button battery incidents and costs: (2022 to 2031¹⁷⁷)

Component	Forecast incidents	Median health sector and productivity costs (NPV, 7% discount rate)
Fatalities	4	\$14,588,998
Severe injuries	178-423	\$14,801,720
ED Presentations	8,906	\$4,082,441
Severe injuries (ongoing treatment)		\$11,006,111
Productivity (severe injuries)		\$334,625
Productivity (severe injuries) (ongoing treatment)		\$1,651,800
Productivity (ED Presentations)		\$992,610
Total		\$47,458,305

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, ABS Population projections, ABS Life Tables, Mumford et al, ACCC analysis.

Notes: Health sector costs presented here are the median in the ACCC's estimated range of potential costs if the status quo remains.

¹⁷⁷ See Appendix D for detailed information about how the figures presented in this section were calculated.

The ACCC estimates that four fatalities, 178 to 423 severe injuries and 8,900 emergency presentations will occur during the forecast period of 2022–2031.¹⁷⁸ Based on these forecasts, the ACCC estimates the direct health costs and immediate costs associated with foregone economic output due to parents and other family members reducing work participation to be approximately \$47.5 million. The true total costs of fatalities and severe injuries to children that have resulted from button batteries are likely to be higher and are impossible to quantify. No economic analysis can appropriately account for the devastating impact on a child, their parents, family, carers and medical staff when a serious button battery incident occurs.

The costs identified above do not account for factors such as emotional distress, long-term psychological impacts and disruptions to family life.

6.2 Benefits and costs of Option 2: Make a mandatory safety standard to require secure battery compartments and compliance testing of consumer goods that contain button batteries

Stakeholder feedback in response to the issues paper and consultation paper indicates that industry supports implementing a regulation that mandates a secure battery compartment for consumer goods that contain button batteries, provided the regulation aligns with industry standards.

Option 2 is to make a mandatory safety standard that includes secure battery compartment requirements for consumer goods that contain button batteries. Under the proposal, products that adhere to an applicable industry standard deemed to have acceptable secure battery and compliance testing requirements would comply with the mandatory standard.

Benefits

This option will help to reduce the number and cost of button battery related exposures, injuries and fatalities as unsafe products are replaced or discarded.

Mandating secure battery compartment and compliance testing requirements for consumer goods that contain button batteries will enable enforcement measures to be taken where products do not meet these safety requirements. Implementing a clear set of enforceable rules for all manufacturers and suppliers means that all suppliers will be required to meet the same requirements and the responsibility for reducing incidents is placed on all suppliers, not just those who voluntarily meet the requirements of the industry code or existing standards.

It is likely that secure battery requirements as well as mandated compliance tests will result in the removal of many disposable novelty items from the Australian market.

In 62% of button battery incidents, the button batteries are obtained from a consumer product.¹⁷⁹ Secure battery compartment and compliance testing requirements are therefore assumed to impact 62% of current button battery incidents. A summary of the expected benefits from Option 2 is presented in table 11.

¹⁷⁸ The ACCC proposes an 18 month transition period, the forecast period commences after this period in 2022.

¹⁷⁹ T Litovitz, N Whitaker, L Clark, 'Preventing Battery Ingestions: An analysis of 8,648 Cases', *Pediatrics*, 2010.

Table 11: Option 2: incidents prevented and economic benefits (2022 to 2031)

Component	Incidents prevented	Benefit (NPV, 7% discount rate)
Fatalities	2-3	\$7,895,706
Severe injuries	85-262	\$8,409,389
ED Presentations	4,231-5,521	\$2,196,729
Severe injuries (ongoing treatment)		\$6,252,803
Productivity (severe injuries)		\$190,113
Productivity (severe injuries) (ongoing treatment)		\$938,422
Productivity (ED Presentations)		\$528,531
Total		\$26,411,694

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

Industry costs

The proposed secure battery compartment and compliance testing requirements would apply to consumer goods containing button batteries. Voluntary industry standards with button secure battery requirements are in place for the vast majority of products in this category; medical devices are the notable exception.

Under the proposal, products that adhere to an applicable industry standard deemed to have acceptable secure battery and compliance testing requirements would comply with the mandatory standard.

Industry stakeholders have provided that a significant proportion of products in the market already comply with voluntary industry standards that include button battery safety requirements. For example, the ATA advises that all of its members (90% of the toy market) supply products that comply with existing, voluntary industry standards.¹⁸⁰

Products containing button batteries that do not adhere to any industry standard or the industry code pose the greatest risk and are responsible for most button battery exposure incidents.

Virtually all products that contain button batteries are imported into Australia. Australian businesses that currently supply consumer goods that do not comply with relevant industry standards will be forced to select products that do comply with these standards. Both large businesses and industry associations that represent small to medium sized businesses¹⁸¹ have advised the ACCC that there is likely no significant cost associated with switching to products that comply with secure battery requirements in existing industry standards.

The regulatory burden of the secure batteries policy is significant only for medical devices that are consumer goods—especially digital thermometers and glucometers¹⁸²—because industry standards for these devices do not contain button battery safety requirements. The proposed requirements would not apply to specialised medical devices that are not consumer goods.

Medical device manufacturers will be required to re-design products without button battery safety features to ensure that they meet button battery safety requirements. The ACCC has received a wide range of estimates for the cost of redesigning a product, and re-tooling manufacturing equipment to transition to secure battery compartments. The ACCC estimates an average cost of \$155,833¹⁸³ per stock keeping unit (SKU) to transition 53 medical devices that do not currently comply with secure

180 ATA submission to ACCC button battery consultation paper

181 Industry survey response from LG Electronics, ATA; Consultation paper responses ATA and LCA, Submission by Australian Promotional Products Association.

182 The ACCC is proposing that hearing aids be exempt from secure batteries requirements.

183 ACCC industry surveys, 2020.

battery requirements.¹⁸⁴ Over the forecast period, and discounted with a base year of 2020, the ACCC estimates costs to industry of \$7.2 million.

Government costs

In the event that button battery safety regulations are mandated increased compliance and enforcement activity will ensure that the maximum benefit from regulation is realised. Consumer awareness campaigns and education to the community is also necessary on an ongoing basis to address button battery safety. The ACCC expects that costs will be incurred over a five year period. Discounted at a rate of 7% with a base year of 2020, the ACCC estimates costs to government of \$5.75 million.

Cost related to hearing aid devices (if no exemption is applied)

The costs of Option 2 to industry, government and users of hearing aid devices are substantially higher should a secure battery compartment requirement apply to hearing aid devices.

The average age of hearing aid users in Australia is 78. Hearing aid batteries generally require changing about once per week. The ACCC has been advised that because of the degree of miniaturisation in hearing aids, it would be very difficult to design acceptably small hearing aids that secure batteries with a screw. Design challenges aside, it would still be impractical for hearing aids to have batteries secured with a screw given the dexterity required to open a secure battery compartment on such a small device, the age of many hearing aid users, and the frequency with which batteries need to be changed.

Were Option 2 to apply to hearing aids, the only practical course of action for hearing aid suppliers would be the sale of hearing aids with fully enclosed, rechargeable batteries. Currently, only about 15% of hearing aids on the market use this technology. None of the devices fully subsidised by the HSP use fully enclosed, rechargeable batteries. Hearing aids with this newer technology are much more expensive. The adoption of Option 2 with respect to hearing aids would result in significant costs to industry, consumers and government.

Net benefits of Option 2

The ACCC estimates that adopting Option 2 would result in a net economic benefit of \$13.45 million during the forecast period of 2022–2031.

Table 12: Benefit cost comparison, Option 2, (2022 to 2031) (NPV, 7% discount rate)

Benefits	Industry and government costs	Net benefit
\$26,411,694	\$12,965,292	\$13,446,402

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

¹⁸⁴ TGA briefing to the ACCC re medical device battery security, 2019.

6.3 Benefits and costs of Option 3: Make mandatory safety standards that adopt requirements in Option 2 and require child-resistant packaging for button batteries based on risk profile

Option 3 is to make a mandatory safety standard that adopts all requirements in Option 2, and includes a requirement for button batteries—except for button batteries of zinc-air chemistry, and other button batteries of a chemistry other than lithium (with a diameter less than 16 mm)—to be supplied in child-resistant packaging.

There is currently no requirement to supply button batteries in child-resistant packaging, though some major battery manufacturers already supply certain types of button batteries in child-resistant packaging on a voluntary basis in accordance with industry standards.

Benefits

Adopting child-resistant packaging will reduce the risk of exposure and injury rates by preventing children from accessing button batteries direct from packaging. Further, the lack of consistency in child-resistant packaging creates confusion among consumers who may not be aware of the hazard of these products for children.

Improvements to packaging will likely reduce risk and injury rates. Button batteries obtained from packaging account for 8.2% of button battery incidents.

The ACCC estimates that Option 3 would result in an economic benefit of \$29.76 million. Table 13 shows the button battery incidents that are estimated to be prevented and the median estimated economic benefit if Option 3 is adopted.

Table 13: Option 3: incidents prevented and economic benefits (2022 to 2031)

Component	Incidents prevented	Benefit (NPV, 7% discount rate)
Fatalities	2–3	\$8,923,114
Severe injuries	98–293	\$9,451,778
ED Presentations	4,894–6,184	\$2,488,237
Severe injuries (ongoing treatment)		\$7,027,791
Productivity (severe injuries)		\$213,678
Productivity (severe injuries) (ongoing treatment)		\$1,054,733
Productivity (ED Presentations)		\$598,434
Total		\$29,757,765

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

Cost to industry

In addition to the costs outlined in Option 2, introducing a requirement for child-resistant packaging may result in increased manufacturing costs for battery manufacturers.

For firms that do not already supply applicable button batteries in scope of the requirements in child-resistant packaging, transitioning to child-resistant packaging involves costs associated with setting up manufacturing equipment and additional per unit costs because of the higher grade plastic required for

child-resistant packaging. Notably, Duracell and Energizer (which have a combined 50% market share)¹⁸⁵ already supply applicable button batteries in scope of the requirements in child-resistant packaging.

A market share approach was taken to estimating industry costs associated with the child-resistant packaging requirement. In response to an ACCC survey, a firm with approximately 3.5% of market share indicated it would likely incur a fixed cost of \$27,000 in the first year and an ongoing variable cost of \$63,929. Excluding the portion of the market that is already compliant with this proposed policy, and scaling up this cost estimate to the remaining proportion of the market, the ACCC estimates the total cost to industry of implementing a child-resistant packaging requirement is \$5.76 million discounted at a rate of 7% over the forecast period.

Cost to government

The secure battery compartment and compliance testing policy would be the most complicated and resource intensive regulation for the ACCC to enforce. As the secure battery requirements are included in each of the policy options, this analysis assumes a flat government cost across the three proposed options. That estimate may understate costs for Options 3 and 4. The ACCC estimates costs to government of option 3 to be \$ 5.75 million in 2020 dollars, discounted at a rate of 7% over the forecast period.

Cost related to hearing aid devices (if no exemption is applied)

The adoption of Option 3 including applying child-resistant packaging to button batteries of zinc-air chemistry intended for hearing aid devices would result in costs to users of hearing aids. Elderly users of hearing aids with poor eyesight or limited dexterity may have difficulties accessing batteries in child-resistant packaging.

Button batteries of zinc-air chemistry intended for hearing aid devices are packaged in a dial mechanism that requires the dial to be turned to allow a new battery to be released. The packaging has an open top slot at the back of the packaging card that allows the batteries to be dialled and easily released individually. This type of packaging is not child-resistant. Advice from industry suggests that this form of packaging allows aged users with dexterity issues to more easily access replacement batteries.

Net benefit of Option 3

The ACCC estimates that adopting Option 3 would result in a net economic benefit of \$11 million during the forecast period of 2022–2031.

Table 14: Benefit cost comparison, Option 3, (2022 to 2031) (NPV, 7% discount rate)

Benefits	Industry and government costs	Net benefit
\$29,757,765	\$18,726,328	\$11,031,438

Source: NCP, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

¹⁸⁵ XYZ Research Energy Centre, 2019.

6.4 Benefits and costs of Option 4: Make mandatory safety and information standards that adopt requirements in Option 3 and require warnings

Option 4 is to make a mandatory safety standard and an information standard that includes all requirements in Options 2 and 3 and includes a requirement for warnings and information.

Under this option, warnings and information would be required as follows:

- Packaged goods: warning symbols on packaging and additional information in the instructions.
- Unpackaged goods and products not supplied with instructions: warning symbols and information attached or included with the good (for example swing tags or stickers).
- Button batteries sold separately: warning symbols and information on the button battery packaging.

The cumulative benefit of these requirements is outlined in the benefits section and the individual costs quantified in the industry costs section that follows.

Benefits

The inclusion of warnings and information for all button batteries and consumer goods that contain button batteries, irrespective of chemistry or size, will ensure that consumers are alerted to the hazards associated with these products. Consistent warnings and safety symbols will ensure that consumers can readily understand the messages and that they are effective in communicating actions to be taken.

Loose batteries account for 30% of button battery incidents.¹⁸⁶ This analysis assumes that warnings will impact incidents resulting from loose batteries. In combination with targeted education campaigns, warnings will increase consumer awareness of the risks associated with button batteries. Increased awareness is likely to reduce the number of incidents associated with loose batteries. A range of possible outcomes was calculated to demonstrate the possible benefits resulting from Option 3 being implemented. These calculations are presented in Appendix D. The range of incidents expected to be prevented, and the median estimated economic benefit of Option 4 is presented below in Table 15.

The ACCC estimates that Option 4 will result in an economic benefit of \$37.46 million during the forecast period of 2022–2031.

Table 15: Option 4: incidents prevented and economic benefits (2022 to 2031)

Component	Incidents prevented	Benefit (NPV, 7% discount rate)
Fatalities	3–4	\$11,169,252
Severe injuries	115–377	\$11,956,806
ED Presentations	5,779–7,953	\$3,096,521
Severe injuries (ongoing treatment)		\$8,890,455
Productivity (severe injuries)		\$270,310
Productivity (severe injuries) (ongoing treatment)		\$1,334,282
Productivity (ED Presentations)		\$746,333
Total		\$37,463,959

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

¹⁸⁶ Litovitz et al, 2010.

Industry costs

Warning and information costs are in addition to the costs outlined in Option 3. Only select industry standards require the warnings proposed under Option 4, and current compliance rates vary by product type.

To comply with Option 4, suppliers of products that contain button batteries that do not currently provide the proposed warnings would need to make changes to the artwork on packaging and update instructions or, for unpackaged goods, create or update a swing tag or sticker. Suppliers of batteries sold separately may be required to update artwork and other information on their battery packaging.

The ACCC sought information from industry stakeholders about the likely costs associated with each separate warning requirement. A summary of estimated costs associated with warning requirements is set out in table 16. The full methodology used to arrive at these estimates is set out in Appendix D.

Table 16: Option 4: industry costs by warning requirement (2022 to 2031) (NPV, 7% discount rate)

Product type	Estimate
Packaged goods	\$ 1,229,285
Unpackaged goods / products not supplied with instructions	\$ 3,506,917
Battery packaging	\$ 1,625,429
Total	\$ 6,361,630

Source: ACCC industry surveys, XYZ Research Energy Centre, ACCC Analysis.

Cost to government

As with Options 2 and 3, the ACCC estimates costs to government of Option 4 to be \$5.75 million in 2020 dollars, discounted at a rate of 7% over the forecast period.

Net benefit of Option 4

The ACCC estimates that adopting Option 4 would result in a net economic benefit of \$12.38 million during the forecast period of 2022–2031.

Table 17: Benefit cost comparison, Option 4, (2022 to 2031) (NPV, 7% discount rate)

Benefits	Industry and government costs	Net benefit
\$37,463,959	\$25,087,958	\$12,376,001

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

6.5 Benefits and sensitivities

The net benefit for each policy option is presented in table 18. Net benefit was calculated by subtracting the total industry and government cost from the overall benefit for each option. Due to uncertainty with the number of incidents that may occur if the status quo remains, and the effect safety regulations will have on reducing the number of incidents, an upper and lower bound benefit was calculated. The median benefit value is presented here. See Appendix D for discussion of the upper and lower bound estimates.

Option 2, implementing the secure battery compartment and compliance testing policy only, results in the greatest net benefit of \$13.45 million during the forecast period of 2022–2031.

Table 18: Net benefit by option, (2022 to 2031) (NPV, 7% discount rate)

Policy options	Benefits	Industry and government costs	Net benefit
Option 2: Secure batteries	\$26,411,694	\$12,965,292	\$13,446,402
Option 3: Secure batteries + Child-resistant packaging	\$29,757,765	\$18,726,328	\$11,031,438
Option 4: Secure batteries + Child-resistant packaging + Warnings	\$37,463,959	\$25,087,958	\$12,376,001

Source: NCPCC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

Benefit-cost ratios

Benefit-cost ratios are calculated by dividing the total benefit by the total cost associated with a policy. The higher the value, the more efficient the use of resources. Table 19 compares the median benefit-cost ratio for each policy option, and at the discount rates of 3, 7 and 10%.¹⁸⁷

Cost benefit ratios are above one for all policy options at the median value for benefits. Option 2 is the most efficient of the policy options under consideration based on elements of this analysis that could be monetised.

Table 19: Benefit-cost ratio (median benefit) (2022 to 2031)

Policy option	Benefit-cost ratio		
	3%	7%	10%
Discount rate			
Option 2: Secure batteries	2.35	2.04	1.85
Option 3: Secure batteries + Child-resistant packaging	1.77	1.59	1.47
Option 4: Secure batteries + Child-resistant packaging + Warnings	1.65	1.49	1.39

Source: ACCC Analysis. Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

Sensitivities

It is also evident from table 19 that the discount rate selected has a strong influence on the comparative benefit-cost ratios of the policy options. This influence is pronounced when conducting sensitivity analysis for the lower bound estimate of benefits.

Table 20 demonstrates that taking the most conservative approach to estimating benefits, the discount rate will have an effect on whether the regulatory option chosen is net beneficial: the benefit-cost ratio is greater than one in respect of Option 2 and in respect of Option 3 only at a discount rate of 3%.

¹⁸⁷ Sensitivity analysis at these rates is required by the Office of Best Practice Regulation's Cost-benefit analysis guidance note. See: <https://www.pmc.gov.au/resource-centre/regulation/cost-benefit-analysis-guidance-note>.

Given that real long-term government bond yields have fallen considerably over the last decade and are currently close to or below zero, a lower rate may present a more accurate picture as to the long-term benefits associated with implementing regulations for button battery safety.

There is some risk that the discount rate will affect whether Options 3 and 4 are net beneficial at the lower bound. However, this result should be interpreted in the context that it has not been possible to monetise and account for all benefits likely to be realised if the proposals were to be introduced.

Table 20: Benefit-cost ratio (lower and upper bounds) (2022 to 2031)

Policy option	Benefit-cost ratio					
	Lower bound benefit			Upper bound benefit		
Discount rate	3%	7%	10%	3%	7%	10%
Option 2: Secure batteries	1.42	1.19	1.06	3.29	2.88	2.63
Option 3: Secure batteries + Child-resistant packaging	1.09	0.96	0.87	2.44	2.22	2.08
Option 4: Secure batteries + Child-resistant packaging + Warnings	0.96	0.85	0.78	2.34	2.14	2.00

Source: ACCC Analysis. Notes: 'Lower bound' and 'Upper bound' refers to ACCC's estimated range of potential economic benefits.

6.6 Preferred option

This analysis objectively weighs, to the extent possible, monetary costs and benefits of the proposed policy options to inform consideration of the most appropriate regulatory response to address the safety hazard of button batteries. Each of the options under consideration presents a net benefit. Within the context of benefits that can be quantified, Option 2 is the most efficient.

While quantitative analysis points to Option 2 as the preferred option, it is impossible to quantify the true total costs and full impact of the trauma associated with severe and fatal button battery incidents and therefore the benefits associated with preventing those incidents. Option 4 is forecast to save more lives and prevent more children from suffering severe button battery injuries. For this reason, Option 4 is the preferred Option.

Table 21: Incidents prevented by policy (2022 to 2031)

Incident type	Incidents prevented		
	Option 2	Option 3	Option 4
Fatalities	2-3	2-3	3-4
Severe injuries	85-262	98-293	115-377
ED Presentations	4,231-5,521	4,894-6,184	5,779-7,953

Source: ACCC Analysis. Notes: 'Lower bound' and 'Upper bound' refers to ACCC's estimated range of potential economic benefits.

6.7 Regulatory burden estimate

The proposed regulations impose a regulatory burden on businesses, but they do not impose any regulatory burden on individuals or community organisations.

The proposed requirements would affect businesses differently depending on the category or categories of consumer goods they supply across a broad range of markets. The degree to which products supplied by businesses are already compliant with industry standards is also determinative in the regulatory burden imposed. It has not been possible to calculate the exact number of businesses affected by each of the proposed policies. However, compliance costs—both substantive and administrative—are built into the estimated industry costs outlined above. Given that the proposed regulations do not require applications or approvals, no delay costs are expected.

Secure batteries

Under this proposal, consumer goods that adhere to the secure battery requirements of an applicable industry standard would be deemed to comply with the mandatory standard. A significant proportion of products in the market already comply with voluntary industry standards.

Virtually all products that contain button batteries are imported into Australia. Australian businesses that currently supply consumer goods that do not comply with relevant industry standards will be forced to select products that do comply with these standards. Both large businesses and industry associations that represent small to medium sized businesses¹⁸⁸ have advised the ACCC that there is likely no cost associated with switching to products that comply with secure battery requirements in existing industry standards because such products are widely available.

Industry standards for medical devices do not include button battery safety requirements. Some businesses in this sector will be required to re-design the products they manufacture to comply with button battery safety regulations or switch to another power source (such as a rechargeable battery or AAA batteries). The proposed requirements would apply only to medical devices that are consumer goods (digital thermometers and blood glucose monitors, for example). Specialised medical devices that are not consumer goods would not be captured by the proposed requirements. These costs are incurred on a per-product line basis.

Child-resistant packaging

In respect of the child-resistant packaging requirement, manufacturers that do not already supply button batteries in child-resistant packaging would be required to make changes to battery packaging which involves setup costs in the first year, and ongoing costs associated with a higher grade of plastic.

Warnings

In order to comply with the warning requirements, manufacturers will be required to make changes to packaging artwork. These costs are incurred on a per-product line basis. Some manufacturers or retailers may incur a small ongoing cost associated with placing warnings on unpackaged goods offered for sale. These costs are incurred on a per-product line and per-unit basis.

Based on the data available including information provided by businesses through our consultation process, we estimate that the new regulations will impose a burden of \$13.35 million in the first year as businesses adjust their operations, and an ongoing burden of \$1.35 million per annum. As shown in table 22, estimated regulatory costs over the 10 year forecast period is therefore \$2.55 million per annum.

¹⁸⁸ Industry survey response from LG Electronics, ATA; Consultation paper responses ATA and LCA, Submission by Australian Promotional Products Association.

Table 22: Average annual regulatory costs (from business as usual)

Change in costs (\$ million)	Business	Community organisations	Individuals	Total change in costs
Total, by sector	\$2.55	\$0	\$0	\$2.55

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

Notes: 'Benefit' refers to the median in the ACCC's estimated range of potential economic benefits.

Regulatory offsets

Button batteries are available separately and as a component in a wide range of consumer goods and household products.

The proposed regulation has a small impact on a large number of businesses across a wide range of market sectors. The ACCC considered whether an appropriate measure to offset the regulatory burden of the proposed safety policy exists, but no appropriate measure is available within the ACCC's remit that could target the affected businesses due to the unique nature of this proposed safety regulation.

7. Recommended approach

7.1 Preferred option

The ACCC recommends Option 4 based on the available information as it is expected to prevent more deaths and severe injuries to children and reduce the burden on the health system to a greater extent than all of the other options.

The ACCC considers there is a market failure with regard to the safety of button batteries and consumer goods that contain them, and that mandatory regulation is necessary. The ACCC's recent evaluation of the impact of the national strategy found that voluntary supplier self-regulation had not sufficiently reduced the risk of injury or death to children from exposure to button batteries.

Over time, adoption of the preferred option is expected to reduce the number and rate of button battery injuries among children and reduce the overall burden of button battery injuries on Australians. Regulatory intervention is needed as there has been a significant increase in the use of button batteries in digital and portable electronic consumer goods over recent years consistent with the expanding miniaturisation of electronic devices.

In considering the preferred option, the government may choose to consider societal benefits across a broader personal and social context. This may mean looking beyond direct and indirect costs and benefits, to include the pain and suffering resulting from serious injury or deaths, particularly those involving children.

As part of a holistic approach to mitigate the safety risks associated with button batteries, the ACCC notes that additional risk mitigation measures should be considered such as national awareness-raising campaigns and further development of secure containers for the safe disposal of button batteries. The ACCC will continue its work in this regard.

7.2 Implementation and review

Under the ACL, the Commonwealth Minister has the power to make or declare a mandatory safety standard or information standard for a consumer product or product-related service. These standards apply nationally.

Section 104 of the ACL allows the Commonwealth Minister to make a mandatory safety standard which sets out requirements that consumer goods must meet before they are supplied. They are introduced when considered reasonably necessary to prevent or reduce the risk of injury to a person.

Section 134 of the ACL allows the Commonwealth Minister to make a mandatory information standard. Mandatory information standards ensure that consumers are provided with important information about a product to assist them in making a purchasing decision.

Product safety regulation in Australia is a shared responsibility and is enforced by the ACCC and state and territory fair trading agencies.

Transition period

The ACCC considers that new mandatory safety and information standards for button batteries, and consumer goods that contain them, should both be subject to an 18-month transition period from the date of commencement.

This transition period is expected to allow industry to implement any manufacturing and design changes to products and packaging and undertake any testing necessary to ensure compliance. This transition period will also provide time for industry to exit non-complying stock or source new stock that is compliant.

The ACCC considers the transition period to be a reasonable period of time given the wide range of consumer goods likely to be affected and noting that products that currently comply with the industry code would largely meet the requirements of the proposed mandatory safety and information standard. In considering the appropriate length of time for suppliers to adapt to the mandatory safety and information standards, the ACCC has had regard to the extent to which the refined requirements harmonise with national and international industry standards.

Review of standard

The ACCC considers that a formal review of the operation of any new mandatory safety and/or information standard should be conducted at the end of five years from the date of commencement.

Any review should consider compliance levels with mandatory standards, changes in battery/product design and changes in the prevalence of button battery injuries and deaths.

Administrative guidance

In the event that mandatory standards to address button battery safety are introduced, the ACCC expects to issue administrative guidance to provide further clarity to industry on the application of the requirements and best practice recommendations.

7.3 Further work to improve international industry standards

The ACCC considers there is the potential for Australia to have a leading role in the development of button battery requirements globally. The ACCC is not aware of any international standard relating to button batteries currently under development.

In 2020, the national standard-setting body, Standards Australia, convened a technical committee for the development of an Australian industry standard for button batteries. The ACCC is currently participating in the technical committee which is working to develop an Australian industry standard that would apply horizontally covering all products with button batteries, as well as button batteries themselves. The requirements of an Australian industry standard for button batteries would be expected to be consistent with any mandatory regulation introduced under the ACL. Such requirements could potentially form a basis for development of an international standard in future. In recent years, the ACCC has led global product safety campaigns facilitated by the OECD. Following the introduction of mandatory safety and information standards for button batteries in Australia, the ACCC would propose to collaborate with OECD and international standards bodies to adopt button battery requirements in applicable international industry standards that require improvements, or otherwise develop an international industry standard that would apply horizontally to button batteries.

Further information on international approaches and initiatives is available in **Appendix B**.

Appendix A: Stakeholder engagement

Submissions received in response to ACCC button battery consultation papers

- Aged & Community Services Australia
- Andrew McMeikan
- Audiology Australia
- Australian Battery Recycling Initiative (ABRI)
- Australian Information Industry Association (AIIA)
- Australia & NZ Society of Paediatric Otolaryngology (ANZSPO)
- Australian Society of Otolaryngology Head & Neck Surgery (ASOHNS)
- Australian Toy Association
- Baby Bunting Australia
- Battery Association of Japan
- Battery Stewardship Council (BSC)
- Catch of the Day
- CHOICE
- Commissioner for Children & Young People, Tasmania
- Consumer Affairs Victoria
- Consumer Electronics Supplier Association
- Consumers Federation of Australia
- Diabetes NSW & ACT
- Diabetes QLD
- Dr Kris Jatana, Global Injury Research Collective
- eBay Australia & New Zealand
- Electrical Regulator Authorities Council (ERAC)
- Energizer
- European Portable Battery Association (EPBA)
- Federation of the Swiss Watch Industry
- Gary Gerson
- Hearing Aid Manufacturers and Distributors Association Australia (HAMADAA)
- Hearing Australia
- Hearing Care Industry Association (HCIA)
- Infant & Nursery Products Alliance of Australia (INPAA)
- Information Technology Industry Council
- JB Hi-fi
- Kerri Crocker
- Kidsafe Australia

- Kmart
- Lighting Council of Australia
- MBIE Trading Standards, New Zealand
- National Electrical Manufacturers Association (US)
- National Retail Association (NRA)
- NSW Poisons Information Centre
- Office of Hearing Services, Department of Health / Therapeutic Goods Administration (TGA)
- Powercell
- Precision Acoustics Victoria
- Product Safety Solutions
- Queensland Family & Child Commission
- Queensland Injury Surveillance Unit / Dr Ruth Barker
- Richard Barnes, Monash Children's Hospital
- Royal Australasian College of Surgeons (RACS)
- SA Health (Biomedical Engineering)
- SA Health (Public Health)
- Standards Australila
- Super Retailer Group (SRG)
- Toy Association (US)
- Victorian Poisons Information Centre
- WA Poisons Information Centre
- Woolworths

Stakeholder meetings and engagement

- Aged & Community Services Australia (ACSA)
- Australian Information Industry Association (AIIA)
- Australian Promotional Products Association (APPA)
- Australian Toy Association
- Catch of the Day
- Consumer Electronics Suppliers Association (CESA)
- Council of Ambulance Authorities (CAA)
- Diabetes Australia
- eBay
- Energizer
- European Portable Battery Association (EPBA)
- Federation of the Swiss Watch Industry
- Healthdirect Australia
- Hearing Aid Manufacturers and Distributors Association of Australia (HAMADAA)
- Hearing Care Industry Association (HCIA)
- Information Technology Industry Council (ITIC)

- Lighting Council Australia (LCA)
- Mitsubishi Motors Australia
- New South Wales Poisons Information Centre
- Nurse-on-Call
- Powercell
- Victorian Poisons Information Centre
- Western Australia Poisons Information Centre

Engagement with government and experts

The ACCC engaged with a number of international and domestic government agencies and experts throughout the investigation, including:

- BSI Group, UK
- Consumer Affairs Victoria
- Consumer Product Safety Commission (US)
- Department of Health / Therapeutic Goods Administration (TGA)
- Department of Mines, Industry Regulation and Safety Western Australia (DMIRS)
- Dr Kris Jatana, Global Injury Research Collaborative Inc.
- Dr Ruth Barker, Queensland Injury Surveillance Unit
- Electrical Regulatory Authorities Council (ERAC)
- Energy Safe Victoria (ESV)
- Gene Rider, Exponent Inc.
- Health Canada
- Intertek
- Landsdowne Labs
- Ministry of Business, Innovation and Employment, New Zealand
- NSW Office of Fair Trading
- Product Safety Solution
- Queensland Office of Fair Trading
- SGS
- South Australia Public Health
- US Button Battery Taskforce

Appendix B: International approaches and initiatives

United States

The United States has a record of button battery ingestion injuries in children dating back to at least 1977. Some of the prominent organisations involved in addressing the dangers of button batteries include the NCPC, the CPSC and the US Button Battery Taskforce.

The NCPC, based in Washington DC, has been at the forefront of addressing battery injury incidents since 1980 and has extensive button battery-related research, management and safety information available on its website.¹⁸⁹ NCPC data includes data from the NBIH, which was created to gather case data, create triage algorithms and identify methods to reduce the hazard. The NBIH also provides the public and healthcare providers with guidance on suspected battery ingestion cases. Management of the NBIH moved from the NCPC to the Rocky Mountain Poison & Drug Safety organisation in 2018.

The CPSC is an independent government agency responsible for regulating product safety in the US. The CPSC is heavily involved in promoting awareness of the dangers of button batteries. The CPSC collaborates with the US Button Battery Taskforce on initiatives to address the issue including the development of voluntary industry standards, research, education and awareness activities.

In 2011 a Button Cell Battery Safety Bill was introduced to Congress. The Bill included requirements for secure battery compartments and warnings on the packaging of button batteries and on products powered by button batteries. The Bill did not pass Congress.

The US Button Battery Taskforce was then established in 2012 as a collaborative effort of representatives from relevant organisations in industry, medicine, public health and government to develop, coordinate and implement strategies to reduce the incidence of button battery injuries in children. The US Button Battery Taskforce includes members of at least five American medical associations, and representatives from industry, government, poison control and public health. The US Button Battery Taskforce is open to anyone around the world to participate.

The US Button Battery Taskforce has conducted a range of research activities and collected injury and incident data from hospitals to build an evidence base to inform government and influence change in both the battery industry and medical practice.

The US Button Battery Taskforce has successfully worked with industry representatives and manufacturers to develop voluntary industry standards that include requirements for button batteries of lithium technology.

In 2017 the CPSC voted to approve the ASTM F963-17: Standard Consumer Safety Specification for Toy Safety (table 6) as a mandatory toy safety standard. The standard requires toys designed for children under 14 years of age to have warnings on packaging and instructions to alert consumers on the hazard of button batteries. The standard also includes new testing requirements for button batteries of 1.5 volts or more.

¹⁸⁹ NCPC 2019, Washington DC, www.poison.org/.

United Kingdom

The European Union has a General Product Safety Directive 2001/95/EC, which obliges suppliers to place only safe consumer goods into the market.¹⁹⁰ The General Product Safety Directive complements sector-specific legislation such as specific rules that apply to toys, electrical and electronic goods, cosmetics, chemicals and other specific product groups.

In the United Kingdom a number of young children have swallowed or choked on small button batteries and at least two children have died from button battery injuries.¹⁹¹

In the UK, batteries in children's toys are covered by toy safety regulations and are required to be contained within secure battery compartments. Similar to Australia, a range of existing voluntary British Standards include requirements for button batteries for specific product types including electric toys, audio/video equipment and household and electrical appliances.

The Department for Business, Energy & Industrial Strategy and the UK Office for Product Safety and Standards are currently working with the British Standards Institute to develop a publicly available specification (PAS) that will include guidance to stakeholders on safe packaging, labelling, product design, use and disposal of button batteries.

In September 2020 the British Standards Institute released for consultation a draft PAS on button and coin battery safety—PAS 7055, Button and coin battery safety—Specification.¹⁹² A PAS is not a British Standard, although can be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or international standard. A PAS may be adopted as a British Standard following a two-year review.¹⁹³

New Zealand

In New Zealand, the government, industry and the medical profession are involved in dealing with the button battery hazard. The New Zealand Minister of Commerce and Consumer Affairs issued a product safety policy statement on button batteries in February 2018.¹⁹⁴

The policy statement was developed to highlight the risks associated with button batteries in household goods and provide guidance to suppliers on how these risks can be mitigated. Suppliers are encouraged to voluntarily adopt the recommendations in the policy statement. The recommendations include that products containing button batteries, or supplied with button batteries, should:

- have a secure battery compartment
- be subject to use and misuse testing and
- include warnings on packaging.

The statement also recommends that button batteries available for sale should be supplied in packaging that is child-resistant, and marked with warnings to alert consumers to the hazards of button batteries to children.

The safety criteria included in the policy statement are similar to those included in the industry code in Australia.

190 European Commission, ec.europa.eu/info/general-product-safety-directive_en, viewed 29 January 2020.

191 Child Accident Prevention Trust www.capt.org.uk/button-batteries, viewed 29 January 2020.

192 BSI Group, PAS 7055 Button Batteries, Button and coin battery safety—Specification, <https://standardsdevelopment.bsigroup.com/projects/2019-02625#/section>, viewed 9 October 2020.

193 Healthcare Safety Investigation Branch, Undetected button battery ingestion in children, <https://www.hsib.org.uk/investigations-cases/undetected-button-battery-ingestion-children/>, viewed 10 February 2020.

194 Ministry for Business Innovation and Employment 2018, NZ Government, Wellington, www.consumerprotection.govt.nz/assets/PDFs/Product-safety-policy-statement-Button-batteries-safer-products-and-packaging-FINAL-as-published-on-website-2018-02-02.pdf, viewed 29 January 2020.

Appendix C: Relevant standards considered

Secure battery requirements

UL4200A:2015—Standard for Safety Products Incorporating Button or Coin Cell Batteries of Lithium Technologies

ISO 8124.1:2018—Safety of toys—Part 1: Safety aspects related to mechanical and physical properties

ASTM F963-17—Standard Consumer Safety Specification for Toy Safety

IEC 62115:2018 / AS/NZS 62115:2018—Electric toys—Safety

AS/NZS 60335.1:2011—Household and similar electrical appliances

AS/NZS 60950-1:2015—Information technology equipment—Part 1: General requirements

AS/NZS 60065:2018—Audio, video and similar electronic apparatus

IEC 62368-1:2018 / AS/NZS 62368.1:2018—Audio/video, information and communication technology equipment—Part 1: Safety requirements

IEC 60598.1: 2017 / AS/NZS 60598.1:2017—Luminaires Part 1: General requirements and tests

ISO 1413:2016—Horology—Shock resistant wrist watches

AS/NZS 3820:2020—Essential safety requirements for electrical equipment

AS/NZS 3100:2017—Approval and test specification—general requirements for electrical equipment

ISO/IEC 17025—General requirements for the competence of testing and calibration laboratories

Child-Resistant Packaging

IEC 60086- 4:2019—Primary Batteries—Part 4: Safety of lithium batteries

AS 1928-2007—Child-resistant packaging—Requirements and testing procedures for reclosable packages

ISO 8317-2015—Child-resistant packaging—Requirements and testing procedures for reclosable packages

AS 5808:2009—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

EN 862:2016 Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

ISO 28862:2018—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products

USA:16 CFR §1700—Poison Prevention Packaging

ISO/IEC 17025—General requirements for the competence of testing and calibration laboratories

Warnings and Labelling

UL4200A:2015—Standard for Safety Products Incorporating Button or Coin Cell Batteries of Lithium Technologies

IEC 60086-4:2019 Primary Batteries—Part 4: Safety of lithium batteries

IEC 60086-5:2016 Primary Batteries—Part 5: Safety of batteries with aqueous electrolyte

ASTM F963-17—Standard Consumer Safety Specification for Toy Safety

IEC 62115:2018 / AS/NZS 62115:2018—Electric toys—Safety

AS/NZS 60065—Audio, video and similar electronic apparatus

IEC 62368-1:2018—Audio/video, information and communication technology equipment—Part 1: Safety requirements

AS/NZS 60598.1:2017—Luminaires Part 1: General requirements and tests

ISO 3864.2:2016—Graphical symbols—Safety colours and safety signs—Part 2: Design principles for product safety labels

Appendix D: Cost-benefit analysis methodology

This annexure sets out the methodology used to conduct the cost-benefit analysis referred to in Chapter 6 of this document: Impacts of the options.

General notes and assumptions

Affected stakeholders

The main affected stakeholder groups are:

- manufacturers, distributors and retailers of button batteries
- manufacturers, distributors and retailers of products that contain button batteries
- health professionals and the healthcare system
- families and children exposed to button/coin cell batteries.

General assumptions

- An 18 month transition period is proposed. The base year of the cost-benefit analysis is 2022 and the assessment is conducted over a 10-year period.
- Sensitivity analysis, using discount rates of 3, 7 and 10% has been conducted.
- All monetary values are presented in June 2020 Australian dollars which is the base year for discounting.
- All exemptions outlined above are in place.

Data availability

Where possible, data from Australian sources has been used to determine costs associated with button battery exposures. The ACCC obtained data from a number of organisations tracking button battery ingestions and insertions. These organisations collect data from hospital emergency departments, medical specialists or calls to Poisons Information Centres. As there is no standardised dataset for button battery injuries, these organisations have collected different types and ranges of data.

Australian sources provide a significant amount of information about button battery exposures. However, the two fatalities recorded in Australia do not provide data that allows for the calculation of expected future fatality rates. Fatality rates available in data from the United States are used in this analysis.

The United States NBIH statistics¹⁹⁵ provide the best insight into button battery injury and fatality rates of any available dataset. These statistics were compiled from calls to the hotline and through extensive follow-up with health professionals. The National Battery Ingestion Hotline dataset provides rates of ingestion, injury and fatality per capita from 1985 to 2017.¹⁹⁶ Given lifestyle and demographic similarities between Australia and the United States, the fatality rates published in this dataset are good proxies for those ratios in the Australian data.

The NBIH records information in relation to button battery ingestions but not insertions. Australian Poisons Information Centres record information in relation to ingestions and insertions. NBIH data has

195 National Capital Poison Centre, Statistics, retrieved from <https://www.poison.org/battery/stats>, viewed 15 October 2020. (NCPC Statistics)

196 The NCPC advised the ACCC that it ceased operating the NBIH in mid-2018 and that information relating to button battery injuries on its website is complete only to the end of 2017.

been applied in the Australian context despite this difference as it is likely to provide the most accurate fatality rates given the large sample size used to quantify the number of fatalities.

The ACCC has relied on information provided by industry stakeholders and market research to estimate industry costs associated with the proposed button battery safety regulations.

In August 2020, the ACCC circulated two surveys—one relating to products containing button batteries and the other to replacement button batteries sold separately to over 280 industry stakeholders including manufacturers, importers, retailers and industry associations to gather specific information about the likely costs of implementing the proposed policies. The ACCC received 28 responses to the products survey and 10 responses to the batteries survey. Not all respondents provided specific costing information. The ACCC relied on these surveys, in conjunction with market research to estimate industry costs associated with button battery safety regulation.

There will be a cost involved for the ACCC to adequately monitor compliance and enforce the proposed regulations should they come into force. In order to estimate government costs, the ACCC conducted an internal analysis, involving input from various divisions, to estimate the costs associated with expected compliance and enforcement activities.

Button battery incidents: upper and lower estimates

There is a degree of uncertainty with respect to the number of severe injuries and the costs associated with button battery fatalities that may occur during the forecast period. In order to account for that uncertainty, upper and lower bounds have been estimated for these metrics.

Estimating health sector costs related to button battery incidents

Cost categories

Button battery incidents can cause a wide range of complications and in extreme cases they can be fatal. Not all button battery ingestions and insertions result in complications, however diagnostic imaging is required for most incidents. The ACCC divided button battery incidents into three categories, as shown in table D1, to account for the degree of variability between cases. Costs are calculated separately for each category.

Table D1: Button battery incident categories

Costing category	Description	Sources
Fatalities	Button battery ingestion or insertion incidents that result in a fatality.	NCPC, NSW PIC, ABS, PM&C.
Severe injuries	Any child under 16 years of age with newly diagnosed injury related to disc or button battery ingestion or insertion that required procedural intervention either to remove the battery or to assess or repair damage related to the battery.	APSU, ABS
Emergency presentations	Where a person presents at a hospital emergency department because of a button battery ingestion or insertion incident but is not admitted to hospital.	NSW Health, VISU, QISU, ABS, IHPA.

Forecasting fatalities in Australia

Fatality rates from the United States NBIH were used to estimate fatality and injury rates in Australia.

During the period of 2015–2017, an average of 3,274 button battery ingestions were reported to the NBIH each year.¹⁹⁷ This equates to 0.001019 fatalities per reported incident.

During a similar three-year period (November 2015–October 2018), an average of 344 unintentional button battery incidents per year were reported to Australian Poisons Information Centres¹⁹⁸—a similar service to the NBIH.¹⁹⁹ This equates to 1.3985 reported incidents per 100,000 population annually.²⁰⁰ Assuming the rate of fatalities to reported incidents is the same in Australia as it is in the United States, 0.001424 fatalities per 100,000 population are expected to occur in Australia each year. Taking projected population²⁰¹ into account, four button battery fatalities are expected to occur in Australia during the forecast period.

Table D2: Forecast Australian fatalities based on calls to Australian PICs and US fatality rates

Year	Population (estimate or projection)	Fatalities per 100,000 population	Forecast fatalities
2022	26,873,947	0.001	0.382
2023	27,349,900	0.001	0.389
2024	27,829,520	0.001	0.396
2025	28,311,405	0.001	0.403
2026	28,796,151	0.001	0.409
2027	29,283,507	0.001	0.416
2028	29,773,492	0.001	0.423
2029	30,264,147	0.001	0.430
2030	30,755,046	0.001	0.437
2031	31,245,852	0.001	0.444
Total			4.135

Source: NSW PIC, NBIH, ABS Population Estimates, ABS Population projections

Cost of fatalities

The Office of Best Practice Regulation (OBPR) estimates the value of a statistical life (VSL) to be \$4.9 million in 2019 dollars.²⁰² This estimate is based on Abelson’s willingness-to-pay calculations and assume a healthy person living for another 40 years.²⁰³

197 NCPIC Statistics.

198 R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, 'Button battery exposures in Australian children: a prospective observational study highlighting the role of poisons information centres', *Clinical Toxicology*, vol. 57, no. 6, 2019, pp. 404–410.

199 The NBIH records ingestion incidents only, whereas Australian Poisons Information Centres record ingestion and insertion incidents. Despite this difference, it is reasonable to apply NBIH injury rates in the Australian context given both incident types cause injury.

200 Australian Bureau of Statistics, 2018, *Quarterly Population Estimates (ERP), by State/Territory, Sex and Age*, ABS.Stat Dataset, cat. no. 3101.0, stat.data.abs.gov.au/Index.aspx?DatasetCode=POP_PROJ_2011#, viewed 28 November 2019.

201 Australian Bureau of Statistics. (2020). Table B9. Population projections, by age and sex, Australia—medium series [Time series spreadsheet]. Population Projections, Australia 2017 (base)—2066 Retrieved October 8, 2020. <https://www.abs.gov.au/statistics/people/population/population-projections-australia/latest-release#data-download>

202 Department of Prime Minister and Cabinet, Office of Best Practice Regulation, Guidance note: Value of statistical life, 2016, Canberra, www.pmc.gov.au/sites/default/files/publications/value-of-statistical-life-guidance-note_0_0.pdf, viewed 26 February 2020.

203 Abelson P., *Establishing a monetary value for lives saved: issues and controversies*. Canberra: Office of Best Practice Regulation, Department of Finance and Deregulation. Abgerufen am. 2008;5:2012.a.

The age at death is known for 63 fatal button battery ingestions globally; the average age at death is 1.9 years.²⁰⁴ For the period 2016–2018, life expectancy at birth was 80.73 years for males and 84.87 for females in Australia.²⁰⁵ Using averages weighted by sex, 81.1 years of life are lost per button battery fatality.

Given that the average number of years lost is more than twice that accounted for in the standard VSL calculation, it is reasonable to assume that costs associated with button battery fatalities may be higher than \$4.9 million per statistical life. An adjusted VSL was calculated to account for the very young age of children that have lost their life following ingestion of button batteries. The adjusted VSL, along with the standard VSL calculation, are used to demonstrate the range of possible costs associated with button battery fatalities.

The adjusted VSL was calculated using Abelson’s VSL (\$3.5 million) and VLY (\$151,000) in 2007 dollars.²⁰⁶ A constant VLY was set and a discount rate of 3% per year applied.²⁰⁷ Given an average of 81 years lost, the adjusted VSL equates to \$4.6 million (2007) or \$6.0 million (2020).²⁰⁸

Costs were discounted using the upper and lower rates recommended by the OBPR (3% and 10%) to account for uncertainty in future costs.²⁰⁹ As shown in table D3, costs associated with button battery fatalities are expected to be between \$13.1 million and \$16 million during the forecast period. The figures presented here are in 2020 dollars, which is the base year for discounting.

Table D3: Forecast cost of fatalities in Australia

Incident type	Health costs, lower, 2022–2031 (NPV, 7% discount rate)	Health costs, median, 2022–2031 (NPV, 7% discount rate)	Health costs, upper, 2022–2031 (NPV, 7% discount rate)
Fatalities	\$13,131,745	\$14,588,998	\$16,046,252

Source: Source: NCPIC, ABS Population Estimates, ABS Consumer Price Index, Abelson 2008, ABS Population projections, ABS Life Tables, Litovitz et al, ACCC analysis.

Forecasting severe injuries in Australia

The Australian Paediatric Surveillance Unit began its study, Severe Injury Related to Disc Battery (SIRDB), in December 2017. The study aims to develop a body of knowledge that will assist in formulating recommendations for the prevention of severe injuries related to button batteries. Among its objectives is to estimate the incidence of severe injuries related to button batteries in Australian children aged under 16 years. Severe injury cases are those involving a:

‘disc or button battery ingestion or insertion that required procedural intervention either to remove the battery or to assess or repair damage related to the battery’.²¹⁰

The study’s Principal Investigator and Director of the QISU, Dr Ruth Barker, provided updates to the ACCC on the study’s findings thus far (34 months of data). The rates of severe injury recorded in this study are used as the basis for estimating the rates of severe injury during the forecast period.

The reported rate of severe injury is significantly higher in Queensland than in other jurisdictions. This is likely because Dr Barker ensures that all Queensland cases are reported to the study, whereas cases

204 Labadie et al, 2018.

205 Australian Bureau of Statistics, 2019, *Life Tables, States, Territories and Australia, 2016–2018*, Data Cube, Table 1: Life tables, States, Territories and Australia—2016–2018, cat. no. 3101.0, www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3302.0.55.0012016-2018?OpenDocument, viewed 28 November 2019.

206 Abelson, 2008.

207 *ibid.*

208 Abelson, 2008; ABS Consumer Price Index; Australian Bureau of Statistics, 2018, Consumer Price Index, Australia, June 2020, ‘TABLES 1 and 2. CPI: All Groups, Index Numbers and Percentage Changes’ time series spreadsheet, cat. no. 6401.0, www.abs.gov.au/ausstats/meisubs.nsf/log?openagent&640101.xls&6401.0&Time%20Series%20Spreadsheet&199CA54C56CEED5BCA2585B3001F2D25&0&June%202020&29.07.2020&Latest, viewed 8 October 2020.

209 Department of Prime Minister and Cabinet, Guidance note.

210 Australian Paediatric Surveillance Unit, Provided to the ACCC.

from other jurisdictions may not be reported. Dr Barker advised the ACCC that, in her view, the rate of severe injury recorded in Queensland is likely to be close to the actual rate of severe injury nationally.

Given the uncertainty with respect to the rate at which severe injuries occur in Australia, this analysis will test two possible severe injury rates: the national average rate as reported to the SIRDB study and the Queensland rate reported to the SIRDB study, extrapolated to the national population.

During the 34-month period the study covered, a total of 44 severe injuries have been reported from seven jurisdictions. The number of severe injuries per 100,000 population was calculated using July 2019 population estimates.²¹¹

Table D4: Severe injuries per 100,000 population (December 2017 to October 2020)

State	Severe injuries	Severe injuries per year	Population	Severe injuries per 100,000 population
Queensland	21	7.41	5,095,100	0.15
New South Wales	10	3.53	8,089,526	0.04
Victoria	4	1.41	6,594,804	0.02
South Australia	3	1.06	1,751,693	0.06
Tasmania	3	1.06	534,281	0.2
Western Australia	2	0.71	2,621,680	0.03
Australian Capital Territory	1	0.35	426,709	0.08
Northern Territory	0	0	245,869	0
National average				0.07

Source: APSU, ABS Population Estimates.

Upper and lower estimates of the incidence of severe injuries during the forecast period were calculated by applying the rate of severe injury per 100,000 population to the projected national population²¹² for each year of the forecast period. Between 178 and 423 severe injuries are expected to occur during the forecast period.

211 July 2019 population estimate. See: Australian Bureau of Statistics, *Quarterly Population Estimates (ERP), by State/Territory, Sex and Age*.

212 ABS Population Projections, 2020

Table D5: Forecast severe injuries in Australia (2022 to 2031)

Year	Severe injuries (National Rate)	Severe injuries (Qld Rate)
2022	16.46	39.09
2023	16.75	39.79
2024	17.04	40.48
2025	17.34	41.18
2026	17.63	41.89
2027	17.93	42.60
2028	18.23	43.31
2029	18.53	44.02
2030	18.83	44.74
2031	19.13	45.45
Total	177.88	422.56

Source: APSU, ABS Population Projections.

Cost of severe injuries

De-identified health cost information was made available to the ACCC in relation to 11 Queensland severe injury cases for the 2017–18 and 2018–19 financial years. The data provided represents direct costs related to severe button battery injuries and include surgical costs, admission costs, social work and child and youth mental health service support. Not all severe button battery injury cases are the same. Depending on a number of factors, one case may be more complex than another or require more frequent or intensive interventions. The costings provided to the ACCC represent a range of case types within the severe injury category of incident, allowing for average cost per incident to be calculated.

Table D6: Average cost per severe injury

APSU Case number	Battery location	Treatment cost
1	Oesophagus	\$85,364
2	Oesophagus	\$134,598
6	Oesophagus	\$267,723
8	Ear	\$15,108
9	Oesophagus	\$54,342
13	Oesophagus	\$38,432
17	Oesophagus	\$55,366
21	Oesophagus	\$123,522
23	Stomach	\$3,566
24	Oesophagus	\$20,135
31	Oesophagus	\$76,294
Average		\$79,495

Source: APSU

In cases of severe button battery injury, significant health costs are incurred soon after the incident. However, health costs continue to accrue years after an incident. Dr Barker advised the ACCC that because of the nature of the injuries sustained in cases of severe button battery injury, ongoing observation and treatment is often required until adulthood. Of the 11 cases for which health cost data has been provided to the ACCC, five incidents occurred during the 2017–2018 financial year; two years of health cost data is available for those cases.

To identify the proportion of costs which are likely to continue to accrue, treatment costs were grouped by date for each case as follows:

- Group 1: costs incurred with one year of an incident occurring.
- Group 2: costs incurred more than one year, and within two years of an incident occurring.

On average, 94.2% of health costs are incurred during the first year after an incident occurs and 5.79% are incurred in the second year.²¹³

Given the proportion of costs incurred in the first and second years after an incident occurs and the overall average cost per severe injury, first-year health costs are estimated to be \$75,812 per severe injury. Allowing for uncertainty as to future costs and rates of injury, costs associated with severe injuries are estimated to total between \$8.8 million and \$20.8 million during the forecast period.

Table D7: Forecast first year cost of severe injuries (2022 to 2031)

Component	Health costs, lower, 2022–2031 (NPV, 7% discount rate)	Health costs, median, 2022–2031 (NPV, 7% discount rate)	Health costs, upper, 2022–2031 (NPV, 7% discount rate)
Severe injuries	\$8,770,057	\$14,801,720	\$20,833,382

Source: APSU, ABS Population Estimates, ABS Population Projections.

Severe injuries—ongoing costs

In addition to the expected \$75,812 first-year cost, a cost of \$4,568 (in 2020 dollars) is expected to be incurred for each severe injury in the second year after the incident occurs and each subsequent year of the forecast period.

The average age at the time of injury in the SIRDB study is 2.95 years. Given Dr Barker’s advice that severe injury patients require ongoing treatment until adulthood, this analysis assumes that first year costs are incurred in the fourth year of life. In each case, a cost of \$4,568 is incurred in each of the fifth to eighteenth years of life (14 years). The rate of severe injury per 100,000 population is assumed to be constant in the 14 years preceding 2022 and during the 10 year forecast period. The number of severe injuries occurring in each year is calculated using annual estimated historical population or projected future population as appropriate. The number of cases incurring ongoing costs in a year is calculated from the cumulative number of severe injuries in the preceding 14 years.

²¹³ The five cases for which data is available from the 2017–18 and 2018–19 financial years occurred partway through the 2017–18 financial year. The proportion of costs incurred in the second year after an incident is likely to be understated because cost information is not available for a full second year for any case.

Table D8: Severe injury cases requiring ongoing treatment by year

Year	Population (estimate or projection)	Severe injuries per 100,000 (National Rate)	Severe injuries per 100,000 (Qld Rate)	Severe injuries (National Rate)	Severe injuries (Qld Rate)	Severe injuries being treated (National Rate)	Severe injuries being treated (Qld Rate)
2007	20,827,622	0.061	0.145	12.8	30.3		
2008	21,249,199	0.061	0.145	13.0	30.9		
2009	21,691,653	0.061	0.145	13.3	31.6		
2010	22,031,750	0.061	0.145	13.5	32.0		
2011	22,340,024	0.061	0.145	13.7	32.5		
2012	22,733,465	0.061	0.145	13.9	33.1		
2013	23,128,129	0.061	0.145	14.2	33.6		
2014	23,475,686	0.061	0.145	14.4	34.1		
2015	23,815,995	0.061	0.145	14.6	34.6		
2016	24,190,907	0.061	0.145	14.8	35.2		
2017	24,601,860	0.061	0.145	15.1	35.8		
2018	24,982,688	0.061	0.145	15.3	36.3		
2019	25,364,307	0.061	0.145	15.5	36.9		
2020	25,936,500	0.061	0.145	15.9	37.7		
2021	26,402,046	0.061	0.145	16.2	38.4		
2022	26,873,947	0.061	0.145	16.5	39.1	203.3	482.9
2023	27,349,900	0.061	0.145	16.7	39.8	206.7	491.1
2024	27,829,520	0.061	0.145	17.0	40.5	210.2	499.3
2025	28,311,405	0.061	0.145	17.3	41.2	213.7	507.7
2026	28,796,151	0.061	0.145	17.6	41.9	217.4	516.4
2027	29,283,507	0.061	0.145	17.9	42.6	221.1	525.2
2028	29,773,492	0.061	0.145	18.2	43.3	224.9	534.2
2029	30,264,147	0.061	0.145	18.5	44.0	228.7	543.3
2030	30,755,046	0.061	0.145	18.8	44.7	232.7	552.7
2031	31,245,852	0.061	0.145	19.1	45.5	236.7	562.3

Source: APSU, ABS Population Estimates, ABS Population Projections.

Allowing for uncertainty as to future costs and rates of injury, ongoing costs associated with severe injuries are estimated to be between \$6.5 million and \$15.5 million during the forecast period.

Table D9: Forecast ongoing costs associated with severe injuries (2022 to 2031)

Incident type	Health costs, lower, 2022–2031 (NPV, 7% discount rate)	Health costs, median, 2022–2031 (NPV, 7% discount rate)	Health costs, upper, 2022–2031 (NPV, 7% discount rate)
Severe injuries (ongoing treatment)	\$6,521,149	\$11,006,111	\$15,491,073

Source: APSU, ABS Population Estimates, ABS Population Projections.

While every effort has been made to forecast the cost of severe injuries, we expect the figures outlined above to underestimate the actual cost associated with severe injuries. An example of costs not accounted for in this analysis is the cost of emergency transport for a patient to a hospital that has appropriate facilities to treat a serious button battery incident. While the ACCC had insufficient data to forecast emergency transport costs, we are aware of one case where transporting a child from a remote location cost in excess of \$38,000 and two cases where transport costs were about \$10,000.

Forecasting emergency presentations in Australia

New South Wales Health, VISU and QISU provided the ACCC with data relating to button battery emergency department presentations. The most recent data available from all of these jurisdictions is for 2017.

Records are stored and queried differently in each jurisdiction. The relevant agency in each jurisdiction queried a database of emergency department records drawn from participating public hospitals as follows:

- New South Wales: 66 public hospitals accounting for about 85% of state-wide emergency department activity
- Victoria: all 38 public hospitals with 24-hour emergency departments
- Queensland: nine Hospital and Health Service areas (including metropolitan and regional areas) representing 20-25% of state-wide emergency department activity.

On this basis, the ACCC assumed that the following proportions of incidents are accounted for in the data provided and extrapolated accordingly to estimate the number of presentations in each jurisdiction:

- New South Wales: 85%
- Victoria: 100%
- Queensland: 25%.

Cases where an emergency presentation is admitted to hospital are excluded from this category of the analysis because those costs are considered to be accounted for in the severe injuries category. The proportion of non-admitted emergency presentations by jurisdiction is as follows:

- New South Wales: 91%
- Victoria: 86%
- Queensland: 80%.

Table D10: Non-admitted emergency presentations per 100,000 population (2017)

State	Population	Presentations	Proportion of ED activity represented	Proportion not admitted	Estimated Non-admitted presentations	Estimated non-admitted presentations per 100,000 population
New South Wales	7,867,936	263	0.85	0.91	281.56	3.58
Queensland	4,927,629	51	0.25	0.80	162.63	3.30
Victoria	6,321,606	165	1	0.86	141.90	2.24
Total	19,117,171				586.09	3.07

Source: Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health, ABS Population estimates.

Assuming that the rate of emergency presentations to population remains constant, 8,906 non-admitted emergency presentations are expected to occur during the forecast period.

Table D11: Forecast emergency presentations in Australia (2022 to 2031)

Year	Population (estimate or projection)	ED Presentations per 100,000	ED Presentations
2022	26,873,947	3.07	824
2023	27,349,900	3.07	838
2024	27,829,520	3.07	853
2025	28,311,405	3.07	868
2026	28,796,151	3.07	883
2027	29,283,507	3.07	898
2028	29,773,492	3.07	913
2029	30,264,147	3.07	928
2030	30,755,046	3.07	943
2031	31,245,852	3.07	958
Total			8,906

Source: Queensland Injury Surveillance Unit, Victorian Injury Surveillance Unit, NSW Health, ABS Population Projections.

Cost of emergency presentations

In 2017, non-admitted emergency presentations cost \$553 on average.²¹⁴ Independent Hospital Pricing Authority reports indicate that the cost per non-admitted emergency presentation rose consistently between 2009 and 2017.²¹⁵ While the cost per presentation is unlikely to continue to grow indefinitely, this analysis assumes that cost per presentation will continue to grow at the rate of 3% per year during the forecast period.

Upper and lower bounds have not been calculated for costs associated with emergency presentations. Discounting to account for the uncertainty of future costs, non-admitted button battery-related emergency presentations are estimated to cost \$4 million during the forecast period.

Table D12: Forecast cost of non-admitted emergency presentations (2022 to 2031)

Component	Health costs, 2022–2031 (NPV, 7% discount rate)
ED Presentations	\$4,082,441

Source: NCPIC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, ABS Population projections, Litovitz et al, ACCC analysis.

Poisons Information Centre costs

Poisons Information Centres provide specialist information and advice in the event of a button battery incident. The New South Wales PIC advised the ACCC that a cost of \$100–\$120 is incurred for each button battery-related contact.

Poisons Information Centres handle about 200,000 contacts per year from healthcare professionals and the public.²¹⁶ An average of 344 unintentional button battery incidents per year were reported

214 IHPA, National Hospital Cost Data Collection Report, Public Sector, Round 21 (Financial year 2016–17) Appendix Tables, www.ihpa.gov.au/sites/default/files/publications/national_hospital_cost_data_collection_australian_public_hospitals_cost_report_round_21_2016-17_-_appendix_tables.xlsx.

215 IHPA, National Hospital Cost Data Collection Report, Public Sector, Round 16 (Financial year 2011–12) Appendix Table, www.ihpa.gov.au/sites/default/files/publications/chapter-4-tables.xlsx.
IHPA, National Hospital Cost Data Collection Report, Public Sector, Round 18 (Financial year 2013–14) Appendix Tables, www.ihpa.gov.au/sites/default/files/publications/2_round_18_cost_report_appendix.xlsx.
IHPA, Round 21.

216 R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, *Button battery exposures in Australia, November 2017–May 2017*, prepared for NSW Fair Trading by NSW Poisons Information Centre.

to Australian PICs between November 2017 and October 2018.²¹⁷ Thus the cost from button battery incidents to PICs is relatively low in comparison to the total costs of such incidents. Moreover, there is some uncertainty about the incremental cost of button battery-related contacts, as opposed to the average cost.

Due to the comparatively low costs associated with PIC contacts and uncertainty with respect to calculating the effect of regulation on those costs, PIC costs are not quantified in the cost-benefit analysis.

Estimating non-medical costs related to button battery incidents

During consultation, the ACCC received submissions highlighting the non-medical costs resulting from button battery injuries and deaths. While it is not possible to quantify many non-medical costs such as emotional distress and long-term psychological impacts, the ACCC considers it reasonable to include an estimate of foregone economic output due to parents and other family members reducing work participation. This is particularly because there is generally a higher level of family involvement when a child is injured compared to when an adult is injured.²¹⁸

For example, the Productivity Commission's recent draft report on mental health found that the quantifiable costs to the Australian economy of mental ill-health and suicide ranged from \$43–\$51 billion in 2018–19. Of this, direct expenditure on mental healthcare and support services amounted to \$18 billion. Another \$10–18 billion were attributable to lower economic participation and lost productivity. The ACCC estimates the value of lost productivity from button battery injuries using a similar methodology.

Severe Injuries

A recent Australian study (Mumford et al, 2018) based on a survey of parents attending Westmead hospital in Sydney in 2016 found that parents had on average foregone 1.12 days of paid and volunteer work per day their child was in hospital, as a result of caring for their child and other dependants. The children of parents completing the survey had experienced an average length of stays in the hospital up to and including the date of the surveys of 5.6 days, while the median length of stays to that point was approximately 2 days.²¹⁹ Mumford et al (2018) noted that data from the Australian Institute of Health and Welfare showed that the average length of stay for 0–19 year olds across Australian hospitals was 2.6 days.²²⁰

Informed by Mumford et al (2018), the ACCC assumes that for a severe button battery injury, a child spends on average 5 days in hospital in the year of the incident and a further 2 days in each subsequent year until the child turns 18. Assuming that severe injuries are sustained at a relatively young age, this assumption should result in an average length of hospital stay for severe injuries below the 2.6 day average duration adopted in Mumford et al (2018). The ACCC also conservatively assumes that for each day a child spends in hospital, parents forego 1 day of paid and volunteer work.

The full-time Australian adult average weekly ordinary time earnings for May 2020 was \$1,713.90.²²¹ Combining this earnings measure²²² with the number of forecasted severe and ongoing severe injuries gives a total value of lost productivity resulting from severe injuries of \$1.18 million to \$2.8 million for the 2022–2031 forecasted period.

217 R Cairns, JA Brown, K Lachireddy, C Wylie, J Robinson, AH Dawson and NA Buckley, *Button battery exposures in Australia, November 2017–October 2018*, prepared for the ACCC by NSW Poisons Information Centre.

218 Mumford et al, 'Measuring the financial and productivity burden of paediatric hospitalisation on the wider family network' *Journal of Paediatrics and Child Health* 54 (2018) pp.987-996 (Mumford et al (2018)), p.994.

219 Mumford et al (2018), pp.988 and 995.

220 Mumford et al (2018), p.993.

221 ABS, <https://www.abs.gov.au/statistics/labour/earnings-and-work-hours/average-weekly-earnings-australia/may-2020>.

222 For the sake of simplicity, the ACCC values paid and unpaid work equivalently, consistent with Mumford et al (2018), p.988 and Table 1, p.992.

ED Presentations

There is little information available on the average time taken off work by parents when presenting at an emergency department. Nevertheless, based on the estimates from Mumford et al (2018), the ACCC assumes that for each emergency department presentation, parents take on average 0.5 days off paid and volunteer work.

Combining weekly earnings for May 2020 with the number of forecasted ED presentations gives a total value of lost productivity resulting from ED presentations of \$993,000 for the 2022–2031 forecasted period.

Table D13: Forecast non-medical costs (2022 to 2031)

Component	Productivity costs, lower, 2022–2031 (NPV, 7% discount rate)	Productivity costs, median, 2022–2031 (NPV, 7% discount rate)	Productivity costs, upper, 2022–2031 (NPV, 7% discount rate)
Productivity (severe injuries) (ongoing treatment)	\$978,696	\$1,651,800	\$2,324,905
Productivity (ED Presentations)	\$992,610	\$992,610	\$992,610
Productivity (severe injuries)	\$198,266	\$334,625	\$470,984
Total	\$2,169,572	\$2,979,035	\$3,788,499

Source: Mumford et al, ABS Average Weekly Earnings, APSU, ABS Population Estimates, ABS Population projections.

Total cost of button battery incidents

The quantifiable total cost associated with button battery incidents is calculated by adding the costs of each cost category (fatalities, severe injuries, emergency presentations and productivity).

Overall, button battery incidents are estimated to cost between \$34.7 million and \$60.2 million. The median estimated estimate is \$47.5 million.

Table D14: Cost associated with button battery incidents if status quo remains, (2022 to 2031)

Component	Costs, lower, 2022–2031 (NPV, 7% discount rate)	Costs, median, 2022–2031 (NPV, 7% discount rate)	Costs, upper, 2022–2031 (NPV, 7% discount rate)
ED Presentations	\$4,082,441	\$4,082,441	\$4,082,441
Fatalities	\$13,131,745	\$14,588,998	\$16,046,252
Productivity (ED Presentations)	\$992,610	\$992,610	\$992,610
Productivity (severe injuries)	\$198,266	\$334,625	\$470,984
Productivity (severe injuries) (ongoing treatment)	\$978,696	\$1,651,800	\$2,324,905
Severe injuries	\$8,770,057	\$14,801,720	\$20,833,382
Severe injuries (ongoing treatment)	\$6,521,149	\$11,006,111	\$15,491,073
Total	\$34,674,964	\$47,458,305	\$60,241,646

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, ACCC analysis.

Estimating the impact of government action

The proposed regulations impact two categories of goods: button batteries, and products containing button batteries. Three types of requirement exist within the package of proposed regulations:

- Warnings.
- Child-resistant packaging.
- Secure batteries (design and durability requirements for products containing button batteries).

National Battery Ingestion Hotline data²²³ reveals the proportion of child battery incidents by battery source (see table D15). The analysis that follows assumes that children would, in the absence of regulation, access batteries from these sources in the same proportions during the forecast period.

Table D15: Battery access mode

Source	Proportion of button battery incidents
Product	62%
Battery packaging	8.2%
Loose	29.8%

Source: Litovitz et al, 2010.

There is uncertainty as to the impact that the proposed regulation may have in respect of reducing button battery incidents. Given this uncertainty, upper and lower and median estimates have been calculated to demonstrate the range of possible incidents prevented and economic benefits for each proposed requirement. Ongoing costs related to severe injuries that occurred before 2020 will not be affected by the introduction of safety requirements. The upper and lower estimates make the following assumptions (where relevant for each category).

Lower estimate	Upper estimate
Standard VSL	Adjusted VSL
National severe injury rate	Qld severe injury rate
Warnings prevent 1/3 of applicable incidents	Warnings prevent 2/3 of applicable incidents

Secure batteries

The economic benefits associated with introducing a secure battery requirement for products that contain button batteries will begin to accrue once products that do not have button batteries secured in a battery compartment are replaced with products in which batteries are secured. These benefits will accrue in relation to products manufactured in the forecast period and to products manufactured after the forecast period.

A broad range of products contain button batteries. Some are low value and have a very short lifetime, while others are high-value products (or accessories to high-value products, such as remote controls) and not replaced as often. Data is not available to accurately calculate the number of consumer goods that contain button batteries in homes or the rate at which they will be replaced.

Given the uncertainty with respect to how quickly benefits will begin to accrue after the introduction of a secure battery requirement, two different methods have been used to forecast the range of possible benefits: the 'product lifetime' method and the 'simple' method.

Simple method

This method makes the simple assumption that all products are compliant with the proposed secure battery requirement at the beginning of the forecast period.

²²³ Litovitz T, Preventing Battery Ingestions.

Product lifetime method

Research conducted for the European Parliament identifies the expected lifetime for various categories of consumer goods.²²⁴ Products identified as the source of a button battery exposure in NBIH data were grouped according to the categories presented in the European Parliament study.²²⁵ This allowed for the calculation of product replacement rates.

Table D16 shows the rate at which consumer goods that contain button batteries are likely to be replaced. More than 90% of button battery products are estimated to be replaced within four years of the introduction of a secure battery requirement coming into effect.

Table D16: Product replacement rates

Years	Proportion Replaced
1	0%
2	48%
3	48%
4	94%
5	94%
6	94%
7	94%
8	94%
9	94%
10	95%

Source: Montalvo et al, NCPC.

Incidents prevented: upper and lower bounds

Button batteries were accessed directly from a product in 62% of incidents reported to the NBIH.²²⁶ Assuming that the source of the battery is the same for incidents in Australia, a secure battery requirement will impact 62% of incidents. Table D17 shows the number of incidents likely to be prevented by the introduction of a secure battery requirement using the simple and product replacement methods.

Table D17: Secure battery requirement, incidents prevented, (2022 to 2031)

Incident type	Lower estimate	Upper estimate
ED Presentations	4,231	5,521
Fatalities	2	3
Severe injuries	85	262

Source: NCPC, ABS Population Estimates, NSW PIC, NSW Health, QISU, VISU, Litovitz et al, Montalvo et al.

Child-resistant packaging

Button batteries obtained from packaging account for 8.2% of incidents reported to the NBIH.²²⁷ The proposed child-resistant packaging policy would apply to all lithium button batteries and non-lithium button batteries with a diameter of 16 mm or greater. Table D18 sets out the proportion of severe and fatal incidents by battery size and chemistry. Battery size and chemistry data is not available in relation to ED presentations. This analysis assumes that the child-resistant packaging policy will prevent

224 Montalvo C, Peck D, Rietveld E. *A longer lifetime for products: benefits for consumers and companies*, European Parliament, Directorate General for Internal Policies, 2016.

225 NCPC, *Button Battery Ingestion Statistics*. 127 Litovitz T, *Preventing Battery Ingestions*.

226 Litovitz T, *Preventing Battery Ingestions*.

227 Litovitz T, *Preventing Battery Ingestions*.

incidents relating to all but the Alkaline/silver oxide < 16 mm category outlined below across all incident types (fatalities, severe injuries and ED presentations).

Table D18: Batteries by size and chemistry responsible for severe and fatal incidents

Battery size and chemistry	% severe and fatal incidents
Lithium 16 mm+	97.58%
Lithium < 16 mm	0.48%
Alkaline/Silver Oxide 16 mm+	0.00%
Alkaline/Silver Oxide < 16 mm	1.93%

Source: NCPC Severe cases, NCPC Fatal cases

Data is not available to determine how long batteries are stored in packaging in homes. This analysis assumes that all packaging of button batteries in homes would be child-resistant within one year of a child-resistant packaging requirement taking effect.

Incidents prevented and forecast benefits

No reduction in incidents is applied to the first year of the forecast period. An 8.2% reduction in incidents is expected in each of the subsequent years. Table D19 shows the number of incidents estimated to be prevented by the introduction of a requirement for button batteries to be supplied in child-resistant packaging on that basis.

Table D19: Child-resistant packaging, incidents prevented, (2022 to 2031)

Incident type	Lower estimate	Upper estimate
ED Presentations	663	663
Fatalities	0.31	0.31
Severe injuries	13	31

Source: NCPC, ABS Population Estimates, NSW PIC, NSW Health, QISU, VISU, Litovitz et al, Montalvo et al.

Warnings and information

Warnings and information on button batteries sold separately and products that contain button batteries will increase consumer awareness of the risks associated with these batteries and direct them to seek immediate medical attention the event of a suspected button battery incident. Increased awareness is likely to reduce the number of incidents associated with loose batteries.

Loose batteries accounted for 29.8% of incidents reported to the NBIH. Data is not available to calculate the number of incidents that would be prevented following the introduction of a requirement for warnings and information. A range of possible outcomes (between one-third and two-thirds of incidents prevented) have been calculated to demonstrate the possible range of benefits resulting from the introduction of a requirement for warnings and information.

Incidents prevented and forecast benefits

The upper estimate shown in table D20 is based on the assumption that warnings and information will prevent two-thirds of loose button battery incidents. The lower estimate assumes the prevention of one-third of incidents involving loose batteries.

Table D20: Warnings and information, incidents prevented, (2022 to 2031)

Incident type	Lower estimate	Upper estimate
ED Presentations	885	1,769
Fatalities	0.41	0.82
Severe injuries	18	84

Source: NCPC, ABS Population Estimates, NSW PIC, NSW Health, QISU, VISU, Litovitz et al, Montalvo et al.

Estimating the economic benefit of government action

The reduction in button battery incidents caused by the introduction of safety regulations creates an economic benefit due to the reduced burden on the health care system, and reduced productivity costs. The benefit assigned to each of the policies is shown by cost component in table D21.

Table D21: Economic benefit by policy and cost component

Policy	Incident type	Lower	Median	Upper
Child-resistant packaging	ED Presentations	\$291,507	\$291,507	\$291,507
	Fatalities	\$924,783	\$1,027,408	\$1,130,033
	Productivity (ED Presentations)	\$69,903	\$69,903	\$69,903
	Productivity (severe injuries)	\$13,963	\$23,565	\$33,168
	Productivity (severe injuries) (ongoing treatment)	\$68,914	\$116,311	\$163,707
	Severe injuries	\$617,618	\$1,042,389	\$1,467,159
	Severe injuries (ongoing treatment)	\$459,183	\$774,989	\$1,090,794
Secure batteries	ED Presentations	\$1,862,346	\$2,196,729	\$2,531,113
	Fatalities	\$5,842,737	\$7,895,706	\$9,948,676
	Productivity (ED Presentations)	\$441,644	\$528,531	\$615,418
	Productivity (severe injuries)	\$88,215	\$190,113	\$292,010
	Productivity (severe injuries) (ongoing treatment)	\$435,404	\$938,422	\$1,441,441
	Severe injuries	\$3,902,081	\$8,409,389	\$12,916,697
	Severe injuries (ongoing treatment)	\$2,901,140	\$6,252,803	\$9,604,465
Warnings	ED Presentations	\$405,522	\$608,284	\$811,045
	Fatalities	\$1,304,420	\$2,246,138	\$3,187,855
	Productivity (ED Presentations)	\$98,599	\$147,899	\$197,199
	Productivity (severe injuries)	\$19,694	\$56,632	\$93,569
	Productivity (severe injuries) (ongoing treatment)	\$97,217	\$279,549	\$461,881
	Severe injuries	\$871,159	\$2,505,029	\$4,138,899
	Severe injuries (ongoing treatment)	\$647,767	\$1,862,664	\$3,077,560

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, ACCC analysis.

Estimating industry costs associated with the proposed requirements

In March 2020, the ACCC released its Button battery safety assessment of regulatory options consultation paper. The ACCC received a total of 67 responses to the consultation paper from industry, health, advocacy and government stakeholders and a further 307 responses to a short form survey from health sector stakeholders.

After each of the issues paper and consultation paper, the ACCC conducted targeted consultation with key stakeholders including:

- industry stakeholders
- medical experts
- relevant government agencies
- international product safety regulators
- International testing houses.

In August 2020, the ACCC circulated two surveys—one relating to products containing button batteries and the other to replacement button batteries sold separately to over 280 industry stakeholders including manufacturers, importers, retailers and industry associations to gather specific information about the likely costs of implementing the proposed policies. The ACCC received 28 responses to the products survey and 10 responses to the batteries survey. Not all respondents provided specific costing information.

Impact of regulations on industry

The proposed regulations relate to two separate categories of products:

- Products containing button batteries (PCBB).
- Button batteries supplied separately (i.e. replacement batteries).

It is proposed that both performance and information requirements be mandated for each category of product, necessitating four separate instruments: two safety standards and two information standards.

The effect of the proposed regulations would be to mandate the following:

- PCBB
 - Secure battery requirement
 - Product packaging and instruction warnings
 - Unpackaged goods warnings
- Button batteries sold separately
 - Child-resistant packaging
 - Warning symbols and information on battery packaging.

An 18 month transition period is proposed for all requirements. This analysis assumes the transition period commences at the beginning of 2021. Costs and benefits are estimated over a 10 year period from the end of the transition period. It is assumed that fixed costs are borne at the end of the transition period in June 2022.

The ACCC has consulted extensively with industry on the likely impact of mandatory regulation for button battery safety. In response to feedback from industry stakeholders, the proposals set out in the consultation paper have been modified to align as closely as possible to existing industry standards and reduce the burden on industry where it is practicable to do so without significantly decreasing the effectiveness of the proposed policy.

Available data and approaches to estimating costs

Given data limitations, the ACCC took different approaches to estimating costs for each category of products—PCBB and button batteries sold separately—to achieve the most accurate overall estimate possible.

Market data is available for button batteries, including market share and sales volumes for manufacturers with a material market share. The ACCC used a market share approach to estimate industry costs associated with the regulation of button batteries sold separately.

The proposed regulations for PCBB are horizontal standards—they would apply to a broad range of products from a variety of product categories. Neither market share nor sales volume data is available for PCBB. In this instance, the ACCC used an estimated sales approach. Button battery sales volume data was used to estimate sales volumes of PCBB.

The ACCC also received 38 responses to surveys from industry stakeholders that contain information about the number of units sold per SKU and information about costs associated with each of the proposed requirements.

There is an increasing trend towards the use of rechargeable battery types in miniature products. The effect of this across the forecast period is unknown. This analysis assumes that there is no significant growth in button battery sales during the forecast period, which will tend to understate the net benefits.

Products containing button batteries

Secure batteries

The proposed secure batteries policy relates to PCBB. Voluntary industry standards with button secure battery requirements are in place for the vast majority of products in this category; medical devices are the notable exception.

Under the proposal, products that adhere to the secure battery requirements of an applicable industry standard would be deemed to comply with the mandatory standard.

A significant proportion of products in the market already comply with voluntary industry standards. For example the Australian Toy Association (ATA) advises that all of its members (90% of the toy market) supply products that comply with existing, voluntary industry standards.

PCBB that do not adhere to industry standards pose the greatest risk and are responsible for most button battery exposure incidents.

Virtually all products that contain button batteries are imported into Australia. Australian businesses that currently supply products that do not comply with relevant industry standards will be forced to select products that do comply with these standards. Both large businesses²²⁸ and industry associations that represent small to medium sized businesses²²⁹ have advised the ACCC that there is likely no cost associated with mandating secure battery requirements in existing industry standards because compliant products are widely available.

The regulatory burden of the secure batteries policy is significant only for medical devices because industry standards for medical devices do not contain button battery safety requirements.

Fixed costs—Secure batteries

Medical equipment supplied in Australia must be registered with the TGA. In 2019, the TGA conducted an assessment of medical devices for compliance with button secure battery principles. The TGA advised the ACCC via a briefing that it found 53 product lines that did not adequately secure button batteries.

228 For example, Woolworths.

229 For example, the Australian Promotional Products Association, Lighting Council Australia.

Three large, global manufacturers provided information to the ACCC about the likely costs associated with design, tooling and manufacturing changes associated with transitioning to secure battery compartments. Given the size of the firms involved, we expect that cost estimates provided are likely to be higher than average.

Table D22: Compliance with secure batteries policy: average fixed cost

Organisation	Fixed cost
Manufacturer C	\$32,500
Manufacturer J	\$85,000
Manufacturer S ²³⁰	\$350,000
Average	\$155,833

Source: ACCC industry surveys

Variable costs—Secure batteries

Industry stakeholders advised the ACCC that once factories are setup to manufacture redesigned products, the ongoing costs associated with manufacturing the products remains about the same. Thus, the ongoing incremental cost associated with the policy is likely minimal. A variable cost component is not included in relation to the secure battery policy.

Table D23: Total cost of secure batteries policy (2022 to 2031)

Product lines affected	53
Average fixed cost per product line	\$155,833
Total cost	\$8,259,167

Source: ACCC industry surveys, TGA

Discounting with a base year of 2020 and a rate of 7%, the net present value of industry costs in relation to the secure batteries requirement is:

Secure batteries—total cost (NPV, 7% discount rate) = \$7,213,876

Warnings for packaged goods

For goods sold in packaging, warning symbols would be required to be displayed on the packaging and further warning information provided in instructions or otherwise with the item (for example on a leaflet).

Internationally recognised industry toy standards already require relevant warning symbols to be displayed on packaging, and warning information in instructions. However, these symbols are not required for PCBB in other categories. The regulatory burden of warning requirements for PCBB is significant for products other than toys that contain button batteries.

²³⁰ Manufacturer S provided an estimate of \$300,000 to \$400,000. The middle of this range (\$350,000) was used to calculate average fixed costs.

Fixed costs—packaging

Cost estimates for updating packaging warning provided by industry stakeholders are as follows:

Table D24: Packaging warning: average cost per SKU

Organisation	Cost per SKU
Manufacturer D	\$500
Manufacturer F	\$700
Manufacturer K	\$3,832
Industry association P	\$200
Average cost per SKU	\$1,308

Source: ACCC industry surveys

Industry responses to the product survey indicate that, on average, 8621 units of PCBB are sold per PCBB SKU in Australia each year.

Including button batteries installed in products, 69.44 million button batteries were sold in Australia in 2019.²³¹ Data is not available for the number of PCBB sold in Australia each year. Research commissioned by the National Environment Protection Council Service Corporation (the NEPCS report) indicates that of handheld batteries²³² supplied each year, approximately 75% are batteries sold separately and approximately 25% are sold as part of equipment (see Table D25)²³³. While these figures apply to all handheld batteries, similar data is not available in relation to button batteries only. This analysis makes the assumption that the proportion of batteries sold separately and batteries sold within equipment (PCBB) are the same as these proportions.

Table D25: Battery sales by level of integration in products

Battery integration	Number	Proportion
Sold separately	298,800,000	74.63%
Part of equipment	101,600,000	25.37%
Total	400,400,000	100.00%

Source: NEPCS report

If 25% of button batteries sold each year are:

$$\begin{aligned}
 PCBB \text{ sales (units)} &= \frac{\text{Battery sales}}{4} \\
 &= \frac{69\,440\,000}{4} \\
 &= 17\,360\,000
 \end{aligned}$$

231 XYZ Research Energy Centre.

232 The NEPCS report defines handheld batteries as 'battery or cell of any chemistry that weighs 5 kg or less.'

233 K O'Farrell, R Veit & D A'Vard, *Study into market share and stocks and flows of handheld batteries in Australia*, 2014, p.26. Retrieved 4 October 2020, batteryrecycling.org.au/stocks-and-flows-of-handheld-batteries-report-final/.

The number of SKUs where a PCBB is sold per year is calculated using the average number of units per SKU provided to the ACCC in response to industry surveys:

$$\begin{aligned}
 \text{PCBB sales (SKUs)} &= \frac{\text{PCCB sales (units)}}{\text{Average units per PCBB SKU}} \\
 &= \frac{17\,360\,000}{8621} \\
 &= 2014
 \end{aligned}$$

The sales share of batteries by product application is as follows²³⁴:

Table D26: sales share by product application

Product category	Sales share (2019)
Digital products	52.55%
Toy	25.22%
Medical Instruments	14.93%
Others	7.30%

Source: XYZ Research Energy Centre

Given that the proposed requirement aligns with requirements set out in toy standards, only non-toy product categories are affected. So, the number of affected SKUs is calculated as follows:

$$\begin{aligned}
 \text{Non – toy sales (SKUs)} &= \text{PCCB SKUs sales} \times (1 - \% \text{ of toy products}) \\
 &= 2685 \times (1 - 0.2522) \\
 &= 1506
 \end{aligned}$$

Market data is not available for the proportion of PCBB this is sold packaged and un-packaged. Industry association P provided estimates of units supplied by its members for packaged and unpackaged goods. This is the only information the ACCC has received about the ratio of packaged and unpackaged PCBB.

Table D27: Industry association P—packaged vs unpackaged goods

Packaging type	Unit per year	Proportion
Packaged	1,000,000	71.43%
Un-packaged	400,000	28.57%

Source: XYZ Research Energy Centre.

²³⁴ XYZ Research Energy Centre, 2019.

To calculate the number of non-toy products that are supplied in packaging, the proportion of packaged products identified by industry association P is applied across the market to calculate the total number of affected SKUs supplied:

$$\begin{aligned}
 \text{Affected SKUs (packaging)} &= \text{Non – toy sales (SKUs)} \times \% \text{ of packaged products} \\
 &= 1506 \times 0.7143 \\
 &= 1076
 \end{aligned}$$

Applying the average cost per SKU to the number of SKUs affected by the packaging warning proposal, a fixed cost of \$2,813,508 is expected.

$$\begin{aligned}
 \text{Total fixed cost (packaging)} &= \text{Affected SKUs (packaging)} \times \text{Average cost per SKU} \\
 &= 1076 \times \$1308 \\
 &= \$ 1\,407\,408
 \end{aligned}$$

Variable costs—Packaging

Industry stakeholders have advised the ACCC that if symbols alone are required on packaging, there are not likely to be significant ongoing costs associated with this requirement. A variable cost component is not included in relation to packaged goods warning requirements.

Total cost—Packaging

Given there is no variable cost component to this element of the proposal, the fixed cost of \$1,407,408 is the total cost of the packaged goods warning proposal. Discounting with a base year of 2020, the total industry cost for PCBB packaging warnings is:

Packaged goods total cost 2022–2031 (NPV, 7% discount rate) = \$1,229,285

Warnings for unpackaged goods

For goods sold unpackaged, warning symbols and information would be required to be provided with the item (for example, on a swing tag). Warnings for unpackaged goods are not currently required by any industry standards, so all unpackaged PCCB will be affected.

Fixed costs—unpackaged goods

Only one response to ACCC surveys provided information about costs in relation to unpackaged goods. Industry association P estimates a \$500 fixed cost per SKU for unpackaged goods warnings. This analysis assumes that a similar cost will be incurred for each SKU where the PCBB is sold unpackaged. The total fixed cost for unpackaged goods is calculated as follows:

$$\begin{aligned}
 &\text{Total fixed cost (unpackaged)} \\
 &= \text{PCCB Sales (SKUs)} \times \% \text{ unpackaged goods} \times \text{Cost per SKU} \\
 &= 2014 \times 0.2857 \times \$500 \\
 &= \$ 287\,700
 \end{aligned}$$

Variable costs—unpackaged goods

The unpackaged goods warning requirement would be unique to Australia. Industry association P estimated a per unit variable cost of \$0.10 for labour associated with adding a warning to unpackaged goods. Using this information, variable costs associated with unpackaged goods warnings are calculated as follows:

$$\begin{aligned} & \text{Variable cost (unpackaged)} \\ &= \text{cost per unit} \times (\text{PCCB sales (units)} \times \% \text{ unpackaged}) \\ &= \$0.10 \times (17\,360\,000 \times 0.2857) \\ &= \$495\,975 \end{aligned}$$

Total cost—unpackaged goods

Discounting at a rate of 7% over the forecast period with a base year of 2020, the total cost of the proposed unpackaged goods warning requirement is as follows:

Table D28: Unpacked goods warnings—total industry costs (2022 to 2031)

Year	Fixed cost	Variable cost	Total cost
2022	\$287,700	\$495,975	\$783,675
2023	\$0	\$495,975	\$495,975
2024	\$0	\$495,975	\$495,975
2025	\$0	\$495,975	\$495,975
2026	\$0	\$495,975	\$495,975
2027	\$0	\$495,975	\$495,975
2028	\$0	\$495,975	\$495,975
2029	\$0	\$495,975	\$495,975
2030	\$0	\$495,975	\$495,975
2031	\$0	\$495,975	\$495,975

Source: ACCC industry surveys, XYZ Research Energy Centre, ACCC Analysis.

Unpackaged goods total cost (NPV, 7% discount rate) = \$3,506,917

Button batteries sold separately

Child-resistant packaging

Under this proposal, button batteries other than alkaline and silver oxide batteries with a diameter less than 16 mm will be required to be supplied in child-resistant packaging. Some manufacturers already supply all relevant button batteries in child-resistant packaging (CRP). Costs associated with the CRP policy will be significant only where manufacturers do not already supply relevant button batteries in CRP.

Fixed costs—CRP

There are 10 manufacturers with a material share of the button battery market (> 2%) in Australia.²³⁵ Of the 10 manufacturers with a material share of the Australian market, three are either already compliant with the proposal, or the proposal does not affect the manufacturer as follows:

- Manufacturers C and Q already supply relevant batteries in child-resistant packaging.
- Manufacturer R does not supply batteries for retail sale (batteries it supplies are exempt from the proposed policy).

Supplier L, who is the exclusive Australian distributor for a brand of button battery, provided detailed cost estimates—both fixed and variable—for transitioning to CRP. Child-resistant packaging requires a heavier plastic to be used on an ongoing basis, which increases the cost of materials for manufacturers. Supplier L estimated costs as follows:

- Fixed costs—\$27,000
- Variable costs \$63,929 per annum.

Fixed costs associated with setting up manufacturing equipment and testing are likely to be similar for each manufacturer that transitions to child-resistant packaging, regardless of market share. Given this assumption, total fixed costs are calculated by multiplying the number of manufacturers with a material market share by the fixed costs estimated by Supplier L:

$$\begin{aligned} \text{Total fixed cost (CRP)} &= \text{No. of manufacturers} \times \text{Fixed cost of transition} \\ &= 7 \times \$27\,000 \\ &= \$189\,000 \end{aligned}$$

Variable costs—CRP

Supplier L estimates that it would incur annual variable costs of \$63,929 in relation to the CRP policy. Supplier L's share of the button battery market in Australia is 3.46%.²³⁶ As outlined above, the ACCC is aware of three manufacturers that already comply with the CRP policy. The combined market share of these three manufacturers is 53.86%.²³⁷

To estimate the industry wide variable cost component of the CRP policy, Supplier L's estimated costs are scaled up to the proportion of the market that is not already compliant as follows:

$$\begin{aligned} \text{Annual variable cost (CRP)} &= \frac{\text{Supplier L variable cost}}{\text{Supplier L market share}} \times \% \text{ non-compliant market share} \\ &= \frac{\$63\,929}{0.0346} \times 0.4614 \\ &= \$852\,509 \end{aligned}$$

²³⁵ XYZ Research Energy Centre, 2019.

²³⁶ XYZ Research Energy Centre, 2019.

²³⁷ Ibid.

Total cost—CRP

Discounting at a rate of 7%, the total cost of the proposed packaged goods warning policy is as follows:

Table D29: CRP—total industry cost—(2022 to 2031)

Year	Fixed costs	Variable costs	Total cost
2022	\$189,000	\$852,510	\$1,041,510
2023	\$0	\$852,510	\$852,510
2024	\$0	\$852,510	\$852,510
2025	\$0	\$852,510	\$852,510
2026	\$0	\$852,510	\$852,510
2027	\$0	\$852,510	\$852,510
2028	\$0	\$852,510	\$852,510
2029	\$0	\$852,510	\$852,510
2030	\$0	\$852,510	\$852,510
2031	\$0	\$852,510	\$852,510

Source: ACCC industry surveys, XYZ Research Energy Centre, ACCC Analysis.

Child-resistant packaging total cost (NPV, 7% discount rate) = \$5,761,035

Battery packaging warnings

Under this proposal the packaging for all button batteries supplied via retail channels in Australia would be required to include certain warning symbols and text. The proposed requirements are drawn from industry standards. Regulatory costs are significant where manufacturers are not currently providing warnings that would be required under this proposal.

Fixed costs—Battery packaging warnings

According to ACCC surveillance only one supplier with material market share supplies batteries that are compliant with all aspects of the proposed policy, and only in relation to lithium batteries. The proportion of the market that is non-compliant can be calculated as follows:

$$\begin{aligned} \text{Non – compliant market share} &= 1 - (\% \text{ compliant manufacturer market share} \times \% \text{ lithium batteries}) \\ &= 1 - (0.2882 \times 0.2936) \\ &= 91.54 \% \end{aligned}$$

Three suppliers with material market share provided an estimate to the ACCC for costs associated with transitioning packaging to become compliant with the proposed policy. Using the market share of each manufacturer, estimated fixed costs were scaled up to 100% market share as follows:

$$\text{Scaled up fixed cost (battery packaging)} = \frac{\text{Fixed cost}}{\text{Market share}}$$

Table D30: Battery packaging warnings—average, scaled-up fixed cost

Organisation	Total cost	Market share	Scaled-up fixed cost (battery packaging)
Manufacturer C	\$1,080,000	28.82%	\$3,747,398
Manufacturer K	\$78,960	4.18%	\$1,888,995
Manufacturer L	\$16,000	3.46%	\$462,428
Average cost			\$2,032,940

Source: ACCC industry surveys, XYZ Research Energy Centre, ACCC Analysis.

The average of the scaled-up estimates is taken as the total fixed cost associated with the battery packaging warning requirement if 100% of product were non-compliant. This figure is reduced by the proportion of product that is already compliant as follows:

Total fixed cost (battery packaging)

$$= \text{Scaled – up fixed cost (battery packaging)} \times \% \text{ non – compliant product}$$

$$= \$2\,032\,940 \times 0.9154$$

$$= \$1\,860\,953$$

Variable costs—Battery packaging

Industry stakeholders have advised the ACCC that once design changes are made to battery packaging, the cost of production remains the same, so there are no or minimal ongoing costs associated with the battery packaging warning proposal.

Total cost—Battery packaging warnings

Given that there are no ongoing costs in relation to the battery packaging warning proposal, the fixed cost component of this proposal makes up the total cost for the forecast period of 2022–2031.

Battery packaging warnings—total cost (NPV, 7% discount rate) = \$1,625,429

Total Industry costs

Total industry costs are calculated by combining the elements of each of the proposed policies. Total costs are summarised in Table D31.

Table D31: Total industry costs by requirement (NPV, 7% discount rate)

Requirement	Total cost, 2022–2031 (NPV, 7% discount rate)
Battery packaging warnings	\$1,625,429
Child-resistant packaging	\$5,761,035
Packaged goods warning	\$1,229,285
Secure batteries	\$7,213,876
Un-packaged goods warning	\$3,506,917
Total	\$19,336,542

Source: ACCC industry surveys, XYZ Research Energy Centre, ACCC Analysis.

Estimating government costs associated with the proposed requirements

In the event that button battery safety regulations are mandated increased compliance and enforcement activity will ensure that the maximum benefit from regulation is realised. The government will incur costs to ensure that the new mandatory standard is understood by industry, to monitor compliance and, where necessary, to enforce new regulations. The ACCC expects that costs will be incurred over a five year period.

Functions the ACCC would need to perform include:

- consumer and business education, awareness raising and compliance engagement on the new button battery standards
- market surveillance
- enforcement
- other functions (liaise with domestic and international standard setting bodies and industry/consumer associations, complaint/enquiries/injury monitoring).

In order to perform the functions associated with a compliance and enforcement campaign such as this, the ACCC will need to dedicate resources to:

- staffing
- education
- market surveillance
- enforcement activities.

Discounting at a rate of 7% with a base year of 2020, the net present value of government costs for compliance and enforcement activities is estimated at \$ 5,751,416.

Total costs and benefits

Upper and lower bounds for the benefits that are forecast to result from the introduction of button battery safety regulations are presented in Table D32. Upper and lower bounds were not estimated for industry or government costs.

Table D32: Benefits (upper, median and lower), industry costs and government costs (2022 to 2031) (NPV, 7% discount rate)

Policy options	Benefits (lower)	Benefits (median)	Benefits (upper)	Industry costs	Government costs
Option 2: Secure batteries	\$15,473,567	\$26,411,694	\$37,349,821	\$7,213,876	\$5,751,416
Option 3: Secure batteries + Child-resistant packaging	\$17,919,438	\$29,757,765	\$41,596,093	\$12,974,911	\$5,751,416
Option 4: Secure batteries + Child-resistant packaging + Warnings	\$21,363,818	\$37,463,959	\$53,564,100	\$19,336,541	\$5,751,416

Source: NCPC, ABS Population Estimates, QISU, VISU, NSW Health, IHPA Round 16, IHPA Round 18, IHPA Round 21, ABS Consumer Price Index, Abelson 2008, Montalvo et al, ABS Population projections, ABS Life Tables, Litovitz et al, Mumford et al, XYZ Research Energy Centre, ACCC industry surveys, ACCC analysis.

The median value for benefits is used for comparison between the three regulatory options. The net benefit is greatest where all three regulatory proposals—secure batteries, child-resistant packaging and warnings—are adopted.

Benefit cost ratios and sensitivity analysis

Benefit-cost ratios were calculated at a discount rate of 7% for median estimated benefits for each of the regulatory options outlined in Chapter 6. Two sensitivity analyses were conducted given the uncertainty around the predicted impacts of the regulatory options and their appropriate monetary valuation:

1. Benefit-cost ratios were calculated using discount rates of 3 and 10% to determine if the rate selected has a material impact on expected benefits.
2. Benefit-cost ratios were calculated using lower and upper bounds of estimated benefits for each of the regulatory options.

At each of the assumed discount rates, the benefit cost-ratio is greatest for Option 2: secure batteries only. Nevertheless, due to the bulk of industry and government costs occurring relatively early in the forecast period, and the ongoing, sustained benefit expected from implementing button battery safety regulation, the discount rate selected exerts quite a strong influence on the benefit-cost ratio.

Table D33: Benefit-cost ratio (Median benefit) (2022 to 2031)

Policy option			
Discount rate	3%	7%	10%
Option 2: Secure batteries	2.35	2.04	1.85
Option 3: Secure batteries + Child-resistant packaging	1.77	1.59	1.47
Option 4: Secure batteries + Child-resistant packaging + Warnings	1.65	1.49	1.39

Source: ACCC analysis.

Conducting sensitivity analysis for the range of estimated benefits highlights the uncertainty around the predicted impacts of the regulatory options and their appropriate monetary valuation. Table D34 demonstrates that taking the most conservative approach to estimating benefits, the discount rate impacts whether the regulatory option is efficient. The benefit-cost ratio is greater than one in respect of Option 2 and in respect of Option 3 only at a discount rate of 3%.

Given that real long-term government bond yields have fallen considerably over the last decade and are currently close to or below zero, a lower rate may present a more accurate picture as to the long-term benefits associated with implementing regulations for button battery safety.

Table D34: Benefit-cost ratio (Lower benefit) (2022 to 2031)

Policy option			
Discount rate	3%	7%	10%
Option 2: Secure batteries	1.42	1.19	1.06
Option 3: Secure batteries + Child-resistant packaging	1.09	0.96	0.87
Option 4: Secure batteries + Child-resistant packaging + Warnings	0.96	0.85	0.78

Source: ACCC analysis.

Upper bound benefit estimates also show that the discount rate selected exerts a strong influence on the expected benefits of the policies (see table D35). However, upper bound benefit estimates result in benefit-cost ratios of two or higher for all regulatory options at discount rates of 3, 7 and 10%.

Table D35: Benefit-cost ratio (Upper benefit) (2022 to 2031)

Policy option			
Discount rate	3%	7%	10%
Option 2: Secure batteries	3.29	2.88	2.63
Option 3: Secure batteries + Child-resistant packaging	2.44	2.22	2.08
Option 4: Secure batteries + Child-resistant packaging + Warnings	2.34	2.14	2.00

Source: ACCC analysis.

Appendix E: Emerging research and technologies

Researchers have been working on measures to improve the safety of button batteries. These measures are aimed at:

- making button batteries less harmful if ingested or inserted
- detecting and deterring button battery ingestions
- controlling access to button batteries.

Pressure sensitive coating

Substances can be added to the exterior of button batteries during the manufacturing process that render the battery inert when contact with saliva is made. Researchers with Landsdowne Labs in the US are working on developing this technology to prevent button batteries from conducting electricity should they be ingested.²³⁸

The material used to coat the batteries is called a quantum tunnelling composite, which is a rubber-like material usually made of silicone embedded with metal particles. The material allows the battery to conduct when under pressure but acts as an insulator when the batteries are not compressed. Once the coating has been applied, the batteries remain the same in look, size and capacity, and their functionality is not impacted. It has been estimated that the manufacturing cost of applying the coating would be less than five cents per battery. The technology is currently undergoing a range of testing and is still under development.

Water sensitive coating

Duracell have developed and patented a coating that can be applied to button batteries which causes them to deactivate when ingested.²³⁹ This process works by adding a short circuit path between the cathode and the anode in an immersion event.

The safety layer is a polymer material that is conductive in non-aqueous areas, but becomes non-conductive in an aqueous solution. A short circuit is created when the battery becomes wet that drops the voltage of the battery below the level capable of causing electrolysis and tissue damage (e.g. under 1.5v but ideally under 1.2v). The patent notes that while the moisture in the atmosphere generally will not trigger the protective layer, the layer can short if exposed to high humidity environments for extended periods.

Acid neutralisation

Energizer have a patent pending on another method of mitigating coin cell ingestions that involves coating the button battery with an acid or other additive that will release when the battery comes into contact with saliva. This additional acid acts to neutralise the hydroxide that is typically formed by the chemical reaction between a button battery and saliva, meaning that in effect this hydroxide is 'countered' before it causes tissue damage.²⁴⁰

238 B Laulich, G Traverso, V Deshpande, R Langer, and JM Karp, 'Simple battery armor to protect against gastrointestinal injury from accidental ingestion', *Proceedings of the National Academy of Science*, vol. 111, no. 46, 2014, pp. 16 490–16 495.

239 Patent US10637011B2 <https://patents.google.com/patent/US10637011B2/en>.

240 Patent US 20180076467A1 <https://patents.google.com/patent/US20180076467A1/en>.

Safer batteries

When lodged in the body and in contact with bodily fluids, the electric current generated from button batteries creates corrosive substances that burn through and severely damage internal tissues and organs. Researchers in Italy have developed a new type of non-toxic battery for small toys that does not generate these corrosive substances when in contact with organic tissues and fluids. The battery is 10 mm in diameter and made of aluminium and carbon. It is a 2 volt battery but with a much lower current capacity (2.5 mAh) than the commercial lithium button batteries (220 mAh) that have been involved in deaths and severe injuries.²⁴¹

Protective oesophageal irrigations

Researchers in the US have conducted a study to test various household liquids for their ability to act as protective oesophageal irrigations to minimise injury when a button battery has been ingested and until the battery has been removed. Liquids including apple juice, orange juice, Gatorade, Powerade, honey, and maple syrup were tested on a 3 volt lithium button battery using a cadaveric and live animal model. The liquids were administered at 10 minute intervals following the placement of the button battery in the oesophagus. The study found that using both honey and sucralfate (Carafate) decreased the severity of injury caused by the button battery. The researchers concluded that in the crucial period between button battery ingestion and removal the frequent ingestion of honey or sucralfate (Carafate) has the potential to reduce injury severity and improve patient outcomes.²⁴²

The administration of honey at regular intervals where button battery ingestion is suspected is now included in triage protocols in the US.²⁴³ The protocols include advice that honey should be administered if:

- there is a risk that the child has ingested a lithium cell battery
- the child is over 12 months old
- the battery was ingested within the last 12 hours
- the child is able to swallow
- honey is immediately available.

Administration of honey to children under 12 months of age is not recommended as raw honey can contain bacteria that can germinate in an immature digestive system and cause infant botulism which can be fatal.

The protocols also include a warning that honey is not a substitute for seeking immediate removal of a battery lodged in the oesophagus. Administering honey can slow the development of a battery injury but it will not stop it from occurring.

Australian triage protocols are similar to those in the US. However, the current advice provided by Australian PICs and other health organisations is to not allow children to eat or drink anything following a suspected ingestion until a full assessment has been made.²⁴⁴ An article published by Dr Neil Long and peer reviewed by Dr Ruth Barker (Director, QISU) suggests that the studies completed on honey are controversial and that more research is needed before these treatments are included in current protocols. It also notes that these treatments may be worth considering in rural settings with transport delays.²⁴⁵

241 A Rossi, S Vignola, F Nason, F Boschetti, M Bramero, A Bailini, G Pinarello, 'Safe energy source in battery operated toys for children', *Journal of Pediatric Gastroenterology and Nutrition*, vol. 65, no. 5, 2017, pp. 496-499.

242 RR Anfang, KR Jatana, RL Linn, K Rhoades, J Fry, IN Jacobs, 'pH-Neutralising Esophageal Irrigations as a Novel Mitigation Strategy for Button Battery Injury', *Laryngoscope*, vol.129, no.1, 2019, pp. 49-57.

243 NCPIC 2018, Washington DC, <https://www.poison.org/battery/guideline>, viewed 1 August 2019.

244 NSW Poisons Information Centre 2019, Sydney, <https://www.poisonsinfo.nsw.gov.au/Factsheets/Button-Battery-Factsheet.aspx>, viewed 1 August 2019.

245 Dr Neil Long, 2019, Life in the Fast Lane, <https://litfl.com/button-battery-update>, viewed 1 August 2019.

Bitterants

Coating an object with a bittering or pungent agent is intended to make the object unpalatable and act as a deterrent to ingestion. The CPSC has previously conducted a report into the use of aversive agents, which found that bitterants may not be effective in stopping single ingestions that occur before the bitter taste registers to the child. However, bitterants could have a high degree of utility in preventing multiple battery ingestion incidents, provided that the child's body recognises the taste as unpleasant.²⁴⁶

Some product manufacturers have voluntarily added bittering agents to their products, including Nintendo who are using denatonium benzoate on their Switch game cartridges.

Duracell have recently developed a bitter coating to be applied on larger-sized button batteries of lithium chemistry. The ACCC understands that this is a proprietary composition that was in development for several years by Duracell that could possibly be licensed to other battery manufacturers. Duracell's larger-sized button batteries of lithium chemistry with a bitter coating are expected to be available to consumers in 2021. The ACCC estimates that Duracell accounts for approximately 20% of the supply of button batteries in Australia. Therefore, this partially effective measure will only apply to a minor share of overall supply of button batteries in Australia, although it would cover button batteries with the highest risk profile that are supplied by Duracell.

Dr Ruth Barker and co-signatories noted that "bitterants are less likely [than dyes] to be effective. Not everyone is able to taste bitter substances".²⁴⁷

Dyes

Coating an object with a dye is intended to create a coloured trace on a person's tongue, saliva or stomach contents that signals a product has been ingested. This could be particularly useful in the case of button batteries, as it may often be difficult for a parent to identify that the symptoms their child is expressing are the result of a button battery ingestion. The coloured trace left by a dye could be used by medical professionals to help distinguish between swallowed batteries and swallowed coins (as swallowed coins can look like button batteries in X-ray imaging).

Dr Ruth Barker and co-signatories support the use of dyes, noting that "dyes ... have the potential to identify a child with an occult ingestion if that child is vomiting / regurgitating / drooling..[a]s a single strategy, bitterants and dyes will not work in all cases. As part of a combined comprehensive strategy of risk reduction they may have some utility, though there are currently no studies demonstrating their effectiveness for prevention or identification of ingested foreign bodies".²⁴⁸

A researcher at the Victoria University of Wellington has developed a method to improve the safety of button batteries that includes deterring ingestion and early detection of ingestion. His invention involves a saliva soluble coating containing a dye and embittering compound being added to the battery during manufacture. The embittering compound is intended to deter children from ingesting the battery by triggering a pungent taste, encouraging them to spit the battery out. The dye is activated by saliva, indicating that a child has placed the battery in their mouth and potentially ingested it, alerting caregivers and enabling them to seek immediate medical treatment.²⁴⁹

Identifying ingestions with metal detectors

Several studies have been conducted to determine the effectiveness of using hand-held metal detectors to identify the presence or absence of ingested coins in children. One of the main objectives of these studies was to determine if the use of hand-held metal detectors could be used to safely reduce the number of X-rays requested in cases of coins ingested by children.

246 Consumer Product Safety Commission (US), Final Report Study of Aversive Agents (1992) <https://web.archive.org/web/20110616104140/http://www.cpsc.gov/LIBRARY/FOIA/foia99/os/aversive.pdf>.

247 Ruth Barker QISU and Cosignatories, submission to ACCC button batteries issues paper, 15.

248 *ibid.*

249 Victoria University Wellington 2016, Wellington, <http://www.viclink.co.nz/technologies/child-safe-batter/>, viewed 1 August 2019.

Results from these studies have found that use of a hand-held metal detector is an accurate and effective method of identifying and localising coins ingested by children.²⁵⁰ The device is very accurate in detecting the presence of ingested coins (99.4%), but it does not appear to be as effective when expanded to other metallic foreign bodies ingested by children. In one study, the device identified only 47% of non-coin objects.²⁵¹

No known specific study has yet been completed investigating the use of these devices specifically in relation to button batteries. These devices may be beneficial to confirm ingestion in circumstances where there X-ray facilities are not available such as some remote and regional hospitals in Australia. This may speed up the relocation of patients where it is confirmed that a metallic foreign body is present. However, any clinical presentation should be corroborated with imaging to ensure that ingestion of a button battery requiring urgent removal is not misdiagnosed.²⁵² The reduced effectiveness of these devices in identifying metallic objects other than coins also indicates that they are not a reliable substitute for medical imaging.

Secure storage of replacement and used batteries

A Brisbane-based initiative called Battguard²⁵³ is developing an innovative solution for secure packaging, secure storage and responsible disposal of button batteries. Battguard is a small packaging unit for replacement batteries wherein a flat battery being replaced is needed to push the fresh battery out of the packaging. The old battery is then retained securely within the pack. When all new batteries are similarly replaced within the pack, the pack and used batteries within can be disposed of as a unit to recycling or waste as available.

250 JB Lee, S Ahmad, CP Gale, 'Detection of coins ingested by children using a handheld metal detector', *Emergency Medicine Journal*, vol. 22, 2005, pp. 839-844.

251 PL Chaffin, JM Grischkan, PS Malhotra, KR Jatana, *Endoscopic Management of Paediatric Airway and Esophageal Foreign Bodies*, Intech Open, London UK, 2015, <https://www.intechopen.com/books/endoscopy-innovative-uses-and-emerging-technologies/endoscopic-management-of-pediatric-airway-and-esophageal-foreign-bodies>, viewed 1 August 2019.

252 *ibid.*

253 See <https://battguard.com.au>.



AUSTRALIAN COMPETITION
& CONSUMER COMMISSION

