EXPLANATORY STATEMENT

Consumer Goods (Button/Coin Batteries) Safety Standard 2020

Overview

In March 2019, the Commonwealth Assistant Treasurer issued a Safety Warning Notice about the dangers of button/coin batteries and in April 2019, requested that the Australian Competition and Consumer Commission (ACCC) expedite a regulatory impact assessment process for developing regulation to address button/coin battery safety.

The Commonwealth Assistant Treasurer (the Minister), has made a safety standard for button/coin batteries pursuant to section 104 of the Australian Consumer Law (ACL), which is Schedule 2 of the *Competition and Consumer Act 2010* (Cth) (CCA).

This safety standard has been introduced to reduce the risk of fatality and injury associated with the use of button/coin batteries. Button/coin batteries can cause severe injury and even death if swallowed, particularly for young children aged 0-5 years.

In Australia and globally, there is a growing record of serious injuries and deaths of children from button/coin batteries. In Australia, three children have tragically died as a result of swallowing a coin battery and there are an increasing number of young children suffering severe injuries following the ingestion or insertion of button/coin batteries. Globally, since 1977, there has been at least 66 deaths and thousands of exposures and injuries with some children sustaining lifelong injuries requiring ongoing treatments.

This instrument forms part of a package of safety and information standards to improve the product safety of consumer goods containing button/coin batteries, as well as button/coin batteries themselves. This safety standard for button/coin batteries has been developed in conjunction with the following instruments:

- Consumer Goods (Products Containing Button/Coin Batteries) Safety Standard 2020
- Consumer Goods (Products Containing Button/Coin Batteries) Information Standard 2020
- Consumer Goods (Button/Coin Batteries) Information Standard 2020.

The estimated cost to the Australian economy of button/coin battery related fatalities, injuries and exposures is at least $47.5 million during a 10-year forecast period of 2022-2031.

Button/coin 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. In this safety standard, they are collectively referred to as ‘button/coin batteries’. Button/coin batteries generally operate using one of four chemistries: lithium, alkaline, silver oxide and zinc-air. Lithium button/coin batteries pose the highest risk. Their typically larger diameter means they are more likely to become stuck in a child’s oesophagus if ingested and their higher voltage means they can cause tissue damage more quickly.

Available data indicates that lithium button/coin batteries and other types of button/coin batteries with a diameter of 16 mm and above pose the greatest risk and have been responsible for most severe injuries and fatalities.

Purpose

The purpose of this safety standard is to require child-resistant packaging when supplying button/coin batteries, based on their risk profile, to reduce the risk of death or serious injury to children as a result of accessing these batteries directly from packaging.

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).

Requirements

This safety standard includes child-resistant packaging requirements for lithium button/coin batteries (of all sizes) and other types of button/coin batteries with a diameter of 16mm and above. Button/coin battery packaging refers to all types of packaging or containers used when supplying applicable button/coin batteries. The packaging of an applicable button/coin battery must be designed to be resistant to being opened by young children.

Blister packaging is the standard form of packaging for button/coin batteries at present. This safety standard does not specify any particular form of packaging or container that must be used when supplying button/coin batteries, only that the packaging or container must be child-resistant in accordance with specified compliance tests.

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

Button/coin batteries can also be supplied as spare batteries inside the packaging of a consumer good that is powered by a button/coin battery for installation by the consumer. In accordance with the scope of the child-resistant packaging requirements, any spare button/coin 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.

This safety standard includes reference to compliance tests in industry standards and overseas regulations that must be performed on packaging or containers to demonstrate the child-resistant packaging requirement has been met.

Tests may be performed using suitable in-house expertise/facilities or by external testing bodies/laboratories.

Exemptions

This safety standard does not apply to zinc-air button batteries intended for hearing aids, such as zinc-air button batteries packaged in a dial mechanism. Zinc-air button batteries are predominantly used in hearing aids and elderly users of hearing aids with poor eyesight or limited dexterity may have difficulties accessing zinc-air button batteries from child-resistant packaging.

This safety standard does not apply to button/coin batteries supplied in bulk intended to be used in trades, professions or industries and which are not intended for sale to the general public. Button/coin batteries supplied in bulk are typically packed in trays and are used by professionals such as jewellers, watchmakers or services persons that install and replace batteries on behalf of consumers.

Definitions

The definitions used in this safety standard are set out in section 4 and include the following definitions:

- ***applicable button/coin battery*** means:
  (a) a small, single cell battery of lithium chemistry with a diameter greater than the battery's height; or
  (b) a small, single cell battery of a chemistry other than lithium with a diameter of 16 mm or greater.

- ***Australian (Non-reclosable Packaging) Standard*** means the Australian Standard *AS 5808-2009 Child-resistant packaging Requirement and testing procedures for non-reclosable packages for non-pharmaceutical products*, published by Standards Australia, as in force or existing at the time when this instrument commences.

- ***Australian (Reclosable Packaging) Standard*** means the Australian Standard *AS 1928-2007 Child-resistant packaging-Requirements and testing procedures for reclosable packages,* published by Standards Australia, as in force or existing at the time when this instrument commences.

- ***European (Non-reclosable Packaging) Standard*** means the European Standard *EN 862: 2016 Packaging-Child resistant packing-Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*, published by the European Committee for Standardization, as in force or existing at the time when this instrument commences.

- ***International (Non-reclosable Packaging) Standard*** means the International Standard *ISO 28862: 2018 Packaging-Child-resistant packaging-Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*, published by the International Organization for Standardization, as in force or existing at the time when this instrument commences.

- ***International (Reclosable Packaging) Standard*** means the International Standard *ISO 8317: 2015 Child-resistant packaging-Requirements and testing procedures for reclosable packages*, published by the International Organization for Standardization, as in force or existing at the time when this instrument commences.

- ***Primary Batteries Standard*** means the International Standard *IEC 60086-4: 2019 Primary Batteries Part 4: Safety of lithium batteries*, published by the International Electrotechnical Commission, as in force or existing at the time when this instrument commences.

- ***US Poison Prevention Packaging Standard*** means Subchapter E (Poison Prevention Packaging Act of 1970 Regulations) of Chapter 2 (Consumer Product Safety Commission) of Title 16 of the Code of Federal Regulations, published by the Office of the Federal Register National Archives and Records Administration of the United States of America, as in force or existing at the time when this instrument commences.

Access to Australian and international standards

Where practical, product safety legislative instruments only reference extrinsic material that is readily accessible for free by the public. However, as in the current case, many product safety legislative instruments need to incorporate extrinsic technical standards over which certain bodies have copyright, which means the standards must be purchased.

The Australian (Non-reclosable Packaging) Standard, the Australian (Reclosable Packaging) Standard, the European (Non-reclosable Packaging) Standard and the Primary Batteries Standard could in 2020 be purchased from SAI Global's website (https://www.saiglobal.com).

The International (Non-reclosable Packaging) Standard and the International (Reclosable Packaging) Standard could in 2020 be purchased from the International Organization for Standardization's website (https://www.iso.org).

The ACCC can also make a copy of these standards available for viewing at one of its offices, subject to licensing conditions.

Consultation

Section 131E of the CCA provides that a safety standard made under section 104 of the ACL is a legislative instrument for the purposes of the *Legislation Act 2003.* Section 17 of the *Legislation Act* requires that the rule maker should consult prior to making a legislative instrument.

The ACCC released an issues paper in August 2019 and received 32 submissions from stakeholders in response to questions in relation to the issue of button/coin battery safety and how the safety hazards posed by button/coin batteries should be addressed. The issues paper was a necessary first step in the regulatory assessment process due to the wide range of products likely to be affected by any mandatory standard.

The ACCC released a *Button Battery Safety - Assessment of regulatory options - consultation paper* in March 2020. The consultation paper sought stakeholder feedback on proposed regulatory options to reduce the likelihood of serious injuries resulting from child exposure to button/coin batteries. 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.

In addition to the two formal consultation periods, the ACCC met individually with 43 key stakeholders and also distributed surveys to industry and health professionals.

The ACCC also notified the World Trade Organization (WTO) of proposed requirements for the button/coin battery related safety and information standards on 29 September 2020 under the WTO Agreement on Technical Barriers to Trade.

Disallowance

This legislative instrument is not subject to disallowance due to section 44 of the *Legislation Act 2003.*

Commencement

This legislative instrument commences on the day after it is registered on the Federal Register of Legislation.

Transitional arrangements

This instrument provides a transitional period of 18 months, beginning on the day this instrument commences.

Sunsetting

This legislative instrument is not subject to sunsetting due to section 54 of the Legislation Act 2003.

Regulation impact assessment

The ACCC has self-certified that a process equivalent to that of a Regulation Impact Assessment has been undertaken. Office of Best Practice Regulation Ref. 25774

Details of the *Consumer Goods (Button/Coin Batteries) Safety Standard 2020*

Part 1 - Preliminary

Section 1 – Name

This section provides the title of the legislative instrument is the *Consumer Goods (Button/Coin Batteries) Safety Standard 2020*.

Section 2 – Commencement

This section provides that the instrument commences on the day after it is registered.

Section 3 – Authority

This section provides that the safety standard is made under section 104 of the ACL.

Section 4 – Definitions

This section provides the definitions of terms used in the safety standard.

The Australian and European Reclosable and Non-reclosable Packaging Standards are based on the respective ISO standards. All three versions are provided because the Australian and European versions contain region-specific modifications.

Section 5 – Application

This section provides that the safety standard applies to button/coin batteries as well as button/coin batteries supplied together with other consumer goods.

The section also provides that the safety standard does not apply to:

- button batteries of zinc-air chemistry intended for use in hearing aids
- button/coin batteries supplied in bulk intended to be used in trades, professions or industries and which are not intended for sale to the general public
- button/coin batteries that are pre-installed in consumer goods before the consumer goods are supplied.

Suppliers must provide applicable button/coin batteries in child-resistant packaging if supplying to consumers, regardless of whether the batteries are deemed to be supplied in bulk.

Part 2 – Requirements

Section 6 – Requirements

This section provides that an applicable button/coin battery's packaging must comply with the requirements from the application day.

Section 7 – Child accessibility requirements—general

This section provides the general requirement that packaging of an applicable button/coin battery must be designed to be resistant to being opened by young children.

This section applies to both reclosable and non-reclosable packaging. An outcomes-based requirement for child-resistant packaging allows button/coin batteries to be supplied in packaging or in storage containers that are demonstrated to be child-resistant.

This section identifies the requirements that packaging of button/coin batteries must comply with, including specific compliance tests in relevant industry standards and overseas regulations to be performed on packaging or containers to demonstrate compliance.

Suppliers of button/coin batteries must select one of the compliance test options identified in this section and nominate the applicable requirements on request by a regulator.

Section 8 – Child accessibility requirements—blister packaging

The section provides the specific requirement that where one or more applicable button/coin batteries are packaged in blister packaging, the packaging must be designed to be child resistant and only release one battery at a time to prevent children from accessing multiple batteries.

This section identifies the requirements that packaging of button/coin batteries must comply with when blister packaging is used including specific compliance tests in a relevant industry standard to be performed to demonstrate compliance.