

This document has been electronically approved and signed.

Ballot Vote Sheet

DATE: August 31, 2023

THROUGH: Austin C. Schlick, General Counsel Jason K. Levine, Executive Director

Alberta E. Mills, Secretary

The Commission

TO:

- **FROM:** Daniel R. Vice, Assistant General Counsel, Regulatory Affairs Mary A. House, Attorney, Regulatory Affairs
- **SUBJECT:** Reese's Law Implementation: (1) Commission Determination Regarding UL-4200A-2023 and Draft Direct Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries in 16 C.F.R. part 1263 and (2) Draft Final Rule to Amend Part 1263 to Establish Labeling Requirements for Button Cell or Coin Battery Packaging

BALLOT VOTE DUE: _____Friday, September 8, 2023

To eliminate or adequately reduce the risk of serious injury or death from ingestion of button cell or coin batteries by children six years old and younger during reasonably foreseeable use or misuse conditions, the Office of the General Counsel is forwarding for the Commission's consideration a staff briefing package recommending that the Commission implement Reese's Law (Pub. L. No. 117-171; 15 U.S.C. § 2056e) by publishing in the *Federal Register* the following two attached draft documents:

- Commission Determination under section 2(d) of Reese's Law (15 U.S.C. 2056e(d)(1)) that ANSI/UL 4200A, Standard for Safety for Products Incorporating Button Batteries or Coin Cell Batteries (UL 4200A-2023), approved on August 30, 2023, meets the performance and labeling requirements in section 2(a) of Reese's Law, and a Direct Final Rule incorporating by reference UL 4200A-2023 as the Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, to be codified at 16 C.F.R. part 1263; and
- Final Rule to Amend Part 1263 to Establish Labeling Requirements for Button Cell or Coin Battery Packaging.

Please indicate your vote on the following options:

U.S. Consumer Product Safety Commission 4330 East-West Highway Bethesda, MD 20814 National Product Testing and Evaluation Center 5 Research Place Rockville, MD 20850

Page 1 of 3

Vote 1: Publication of the Commission's Determination Regarding UL 4200A-2023 and a Direct Final Rule incorporating by reference UL 4200A-2023 as the Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

I. Determine that UL 4200A-2023 meets the performance and labeling requirements in section 2(a) of Reese's Law (15 U.S.C. 2056e(a)) by approving publication of the attached draft *Federal Register* notice containing the Commission's determination regarding UL 4200A-2023 and a direct final rule incorporating by reference UL 4200A-2023 as the Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, to be codified at 16 C.F.R. part 1263, as drafted.

(Signature)

(Date)

II. Determine that UL 4200A-2023 meets the performance and labeling requirements in section 2(a) of Reese's Law (15 U.S.C. 2056e(a)) by approving publication of the attached draft *Federal Register* notice containing the Commission's determination regarding UL 4200A-2023 and a direct final rule incorporating by reference UL 4200A-2023 as the Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, to be codified at 16 C.F.R. part 1263, with the following changes:

(Signature)

(Date)

III. Do not determine that UL 4200A-2023 meets the performance and/or labeling requirements in section 2(a) of Reese's Law (15 U.S.C. 2056e(a)) and direct the staff to submit for the Commission's consideration a draft final rule to establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries that meets the requirements of section 2 of Reese's Law.

(Signature)

(Date)

IV. Take other action specified below.

(Signature)

(Date)

Vote 2: Publication of a Final Rule to Amend Part 1263 to Establish Labeling Requirements for Button Cell or Coin Battery Packaging

I. Approve publication of the attached draft final rule to amend part 1263 to establish labeling requirements for button cell or coin battery packaging in the *Federal Register*, as drafted.

(Signature)

(Date)

(Date)

(Date)

II. Approve publication in the *Federal Register* of the attached draft final rule to amend part 1263 to establish labeling requirements for button cell or coin battery packaging, with the following changes:

(Signature)

III. Do not approve publication of the attached draft final rule to amend part 1263 to establish labeling requirements for button cell or coin battery packaging in the *Federal Register*.

(Signature)

IV. Take other action specified below:

(Signature)

(Date)

Attachments: (1) Draft *Federal Register* Notice containing Commission Determination Regarding UL 4200A-2023 and a Direct Final Rule incorporating by reference UL 4200A-2023 as the Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, codified at 16 C.F.R. part 1263 and (2) Draft Final Rule to Amend Part 1263 to Establish Labeling Requirements for Button Cell or Coin Battery Packaging

OS 4 DRAFT

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1263

[CPSC Docket No. 2023-0004]

Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In February 2023, as required by Reese's Law, the U.S. Consumer Product Safety Commission (CPSC or Commission) issued a notice of proposed rulemaking (NPR) to eliminate or adequately reduce the risk of injury from ingestion of button cell or coin batteries by children six years old and younger. In the NPR the Commission preliminarily determined that no existing voluntary standard met the requirements in Reese's Law at that time. In this notice, however, the Commission determines that one voluntary standard, substantially revised since publication of the NPR, now meets the requirements in Reese's Law with respect to performance and labeling requirements for consumer products containing button cell or coin batteries. Reese's Law states that after a determination of sufficiency by the Commission, such a qualifying voluntary standard is treated as a consumer product safety rule. The Commission is publishing this determination, as required by Reese's Law, as well as a direct final rule to incorporate the voluntary standard by reference into our regulations. Consumer products subject to performance and labeling requirements in this direct final rule must be tested and certified as compliant with the direct final rule.

DATES: Consumer products containing button cell or coin batteries that are manufactured or imported after [INSERT 30 DAYS AFTER PUBLICATION IN THE

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

OS 5 DRAFT

FEDERAL REGISTER] must comply with this direct final rule unless the Commission receives a significant adverse comment by [INSERT DATE 14 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. If the Commission receives such a comment, we will publish a notice in the *Federal Register*, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. The revision to part 1112, adding a Notice of Requirements (NOR) for the new part 1263 and requiring third-party testing of children's products, is effective [INSERT 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]. In recognition of limited testing availability, however, the Commission's Office of Compliance and Field Operations has issued guidance granting a transitional period of enforcement discretion for the new requirements of UL 4200A-2023. That guidance is available at [INSERT LINK].

ADDRESSES: Submit comments, identified by Docket No. CPSC–2023–0004, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: https://www.regulations.gov. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (e-mail), except as described below. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504-7479. If you wish to submit confidential business information, trade secret information, or other sensitive

OS 6 DRAFT

or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may e-mail them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: https://www.regulations.gov. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: https://www.regulations.gov, and insert the docket number, CPSC–2023–0004, into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: William Cusey, Small Business

Ombudsman, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone 301-504-7945; email: SBO@CPSC.gov.

SUPPLEMENTARY INFORMATION:¹

On February 9, 2023, pursuant to section 2 of Reese's Law (Pub. L. No. 117-171, 15 U.S.C. 2056e), the Commission published an NPR to establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries. 88 FR 8692. As required by section 2(a) of Reese's Law, the NPR contained performance and labeling requirements for consumer products containing button cell or coin

¹ To implement Reese's Law, on September X, 2023, the Commission voted (x-x) to publish this determination and a direct final rule to incorporate by reference, UL 4200A-2023, approved August 30, 2023, as the mandatory standard for consumer products containing button cell or coin batteries.

OS 7 DRAFT

batteries² and labeling requirements for button cell and coin battery packaging. *See* 15 U.S.C. 2056e(a). The NPR also proposed to require notification of additional point-of-sale performance and technical data related to the safety of button cell or coin batteries using the Commission's authority under section 27(e) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2076(e). 88 FR 8709. Based on staff's assessment of existing voluntary standards, the Commission preliminarily determined in the NPR that no voluntary standard in existence at that time met the performance or labeling requirements of section 2 of Reese's Law, and requested comment on that preliminary finding. 88 FR 8702, 8705. The Commission received 38 comments during a 30-day comment period ending in March 2023; four of the comments were duplicates. CPSC received two late-filed comments; one is out-of-scope for this rulemaking. We also received nine comments in response to an April 11, 2023 Paperwork Reduction Act (PRA) notice. 88 FR 21652. Tab A of Staff's Final Rule Briefing Package³ and section III of this preamble summarize and respond to the comments CPSC received.

After consideration of the comments and the relevant existing voluntary standards, the Commission determines that a recent revision of ANSI/UL 4200A, *Standard for Safety for Products Incorporating Button Batteries or Coin Cell Batteries*, published on August 30, 2023 (UL 4200A-2023), does meet the performance and labeling requirements in section 2(a) of Reese's Law with respect to consumer products containing button cell or coin batteries. 15

² Reese's Law defines the phrase "consumer product containing button cell or coin batteries" as "a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately." Notes to 15 U.S.C. 2056e,

³ The information in this Commission determination and direct final rule is based on information and analysis provided in the August 31, 2023, Staff Briefing Package: Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's Final Rule Briefing Package), available at: insert link, and on the January 11, 2023, Staff Briefing Package: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's NPR Briefing Package), available at: https://www.cpsc.gov/s3fs-public/NoticeofProposedRulemakingSafetyStandardandNotificationRequirementsforButtonCellorCoinBatteriesand ConsumerProductsContainingSuchBatteries.pdf?VersionId=kDinNeydktkt3T8RRtzN4u1GTXPRjpEl.

OS 8 DRAFT

U.S.C. 2056e(a) and (d). Accordingly, under section 2(e) of Reese's Law, UL 4200A-2023 is treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058) as of the date of the Commission's determination.⁴ 15 U.S.C. 2056e(e). The Commission is publishing this determination in the *Federal Register*, as required by Reese's Law. 15 U.S.C. 2056e(d)(2).

This notice of the Commission's determination includes a direct final rule (DFR) to incorporate by reference UL 4200A-2023 into the Code of Federal Regulations as the mandatory consumer product safety rule for consumer products containing button cell or coin batteries. Consistent with the Administrative Procedure Act (APA), 5 U.S.C. 553, the DFR has an effective date of 30 days after publication. Further, in recognition of limited testing availability the Office of Compliance and Field Operations has issued guidance granting a transitional period of enforcement discretion for the new requirements of UL 4200A-2023. That guidance is available at [INSERT LINK]. [DATES AND LINK TO BE ADDED BEFORE FEDERAL REGISTER PUBLICATION.]

The Commission is issuing a separate final rule to establish labeling requirements for button cell or coin battery packaging as required by Reese's Law, because such products are not within the scope of UL 4200A-2023. 15 U.S.C. 2056e(d)(1). Currently the Commission is not finalizing the proposed requirements in the NPR for consumer notification of performance and technical data under section 27(e) of the CPSA; although, the UL 4200A-2023 revision includes some of the notification requirements proposed in the NPR. The name of the rule to be codified

⁴ Reese's Law states that if the Commission makes a determination with respect to a voluntary standard, the requirements of such voluntary standard shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058) beginning on the later of either (A) the date of the Commission's determination with respect to the voluntary standard described; or (B) the effective date contained in the voluntary standard. UL 4200A-2023 does not contain an "effective date," and the Commission is making this determination after publication of the UL 4200A-2023 standard. Accordingly, the later of the two dates in section (e)(2) of Reese's Law (15 U.S.C. 2056e(e)(2)) is the date of the Commission's determination.

OS 9 DRAFT

in 16 CFR part 1263 reflects this change by removing the phrase "and Notification Requirements"; the rule is now entitled "Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries."

I. Statutory and Regulatory Background

A. Reese's Law

President Biden signed Reese's Law on August 16, 2022. 15 U.S.C. 2056e. The purpose of Reese's Law is to protect children six years old and younger against hazards associated with the ingestion of button cell or coin batteries. Section 5 of Reese's Law broadly defines a "button cell or coin battery" as "(A) a single cell battery with a diameter greater than the height of the battery; or (B) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard."⁵ Thus, the definition of a consumer product with an in-scope battery depends on the shape of the battery (which contributes to the ingestion-related risk) and, as stated in part (B), whether the battery otherwise is associated with an ingestion hazard, which is consistent with the stated purpose in section 2(a)(1) of Reese's Law.⁶ 15 U.S.C. 2056e(a)(1).

Section 2(a)(1) of Reese's Law mandates that a rule must include performance requirements for button cell or coin battery compartments on consumer products to secure them in a manner that eliminates or adequately reduces the risk of injury from the ingestion of button cell or coin batteries by children who are six years old or younger, during reasonably foreseeable use or misuse of the product. 15 U.S.C. 2056e(a)(1).

⁵ The definitions in section 5 of Reese's Law are codified in the Notes to 15 U.S.C. 2056e.

⁶ This direct final rule focuses on addressing button cell and coin batteries under part (A) of the definition because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type or degree of ingestion hazard as button cell or coin batteries. If CPSC becomes aware of a serious ingestion hazard associated with another battery type that is not adequately addressed by voluntary standards, section 2(g) of Reese's Law allows the Commission to undertake additional rulemaking to address the hazard. 15 U.S.C. 2056e(g).

OS 10 DRAFT

Section 2(a)(2) of Reese's Law mandates warning label requirements in a rule. Warnings are required:

• On the packaging of button cell or coin batteries (15 U.S.C. 2056e(a)(2)(A));

• On the packaging of consumer products containing button cell or coin batteries

(15 U.S.C. 2056e(a)(2)(A));

• In any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries (15 U.S.C. 2056e(a)(2)(B));

• As practicable, directly on a consumer product that contains button cell or coin batteries in a manner visible to the consumer upon installation or replacement of the button cell or coin battery (15 U.S.C. 2056e(a)(2)(C)(i));

• As practicable, in the case of a product for which the battery is not intended to be replaced or installed by the consumer, directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information shall be placed on the packaging or instructions (15 U.S.C. 2056e(a)(2)(C)(ii)).

Warning labels required by section 2(b) of Reese's Law must (1) clearly identify the hazard of ingestion and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice. 15 U.S.C. 2056e(b).

To address ingestion of button cell or coin batteries, section 2(a) of Reese's Law requires the Commission to publish a final consumer product safety standard for button cell or coin batteries, and consumer products containing button cell or coin batteries, not later than 1 year after the date of enactment. 15 U.S.C. 2056e(a). However, if the Commission determines before promulgating a rule that an existing voluntary standard meets the performance and labeling

OS 11 DRAFT

requirements in section 2(a) of Reese's Law, then under section 2(d)(1) of Reese's Law the requirement for the Commission to promulgate a rule does not apply. 15 U.S.C. 2056e(d)(1). Instead, the Commission must publish such determination of a voluntary standard's sufficiency in the *Federal Register*. 15 U.S.C. 2056e(d)(2). As set forth in section IV of this preamble, the Commission determines that UL 4200A-2023 meets the performance and labeling requirements in section 2(a) of Reese's Law with respect to consumer products containing button cell or coin batteries.

Section 2(e) of Reese's Law states that the requirements of a voluntary standard the Commission determines to meet section 2(a) of Reese's Law shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058) beginning on the date that is the later of either the date the Commission makes the determination under section 2(d), or the effective date in the voluntary standard. 15 U.S.C. 2056e(e)(2). The UL standard does not include an "effective date." Rather, UL standards are published when approved through a consensus process by a majority vote that meets UL's procedural requirements.⁷ Publication of UL 4200A-2023 occurred before publication of the Commission's determination, and therefore the date of this publication is the relevant effective date for purposes of section 2(e)(2) of Reese's Law.

The Commission makes the determination that UL 4200A-2023 meets the requirements of section 2(a) of Reese's Law with respect to performance and labeling requirements for consumer products that contain button cell or coin batteries; therefore, by operation of law, UL 4200A-2023 is a consumer product safety rule as of the date of this determination. 15 U.S.C.

⁷ See ULSE ANSI Accredited Procedures, Approved December 2, 2022, available at: https://ulstandards.ul.com/wp-content/uploads/2023/03/ULSEANSIAccreditedProcedures 20221202.pdf.

OS 12 DRAFT

2056e(e)(2).⁸ The Commission additionally is codifying UL 4200A-2023 into a regulation, and the effective date of the DFR is 30 days from publication, as described in section VII of this preamble. As noted, the Commission's Office of Compliance and Field Operations has issued guidance to industry and the public regarding a transitional period of enforcement discretion. *See* [web link].

Section 2(f)(1) of Reese's Law establishes a process for subsequent revision of a voluntary standard the Commission has adopted as a mandatory standard under section 2(d). In addition, section 2(g) of Reese's Law provides that any time after a voluntary standard is treated as a consumer product safety rule under section 2(e), or a revised voluntary standard becomes enforceable as a consumer product safety rule under section 2(f), the Commission may initiate a rulemaking in accordance with 5 U.S.C 553 to modify the requirements of the standard or revised standard. 15 U.S.C. 2056e(g).

Section 4 of Reese's Law specifically exempts from the performance and labeling requirements in section 2 of the law, any toy product⁹ that is in compliance with the battery accessibility and labeling requirements in 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys. Notes to 15 U.S.C. 2056e. However, children's products that contain button cell or coin batteries and that are not a "toy product," are required to meet the performance and labeling requirements in this final rule. An example of such products would be children's apparel, such as shoes, that light up and use a button cell or coin battery as a power source.¹⁰

⁸ UL 4200A-2023 does not, however, address labeling of battery packaging. Accordingly, in a separate *Federal Register* notice, the Commission is finalizing a rule to require labeling on button cell or coin battery packaging. Notes to 15 U.S.C. 2056e.

⁹ Consistent with 16 CFR part 1250, a "toy product" is defined as "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." Notes to 15 U.S.C. 2056e.

¹⁰ Section 3 of Reese's Law requires special packaging for button cell or coin batteries. These requirements, codified in the Notes to 15 U.S.C. 2056e, are self-implementing, and do not require CPSC to issue a rule. Section 3 of Reese's Law was effective by operation of the statute on February 12, 2023.

B. Description of the NPR

The NPR proposed a rule to address the battery ingestion hazard for children six years of age or younger. The NPR explained that children access button batteries from consumer products that are powered by the batteries, either directly from the battery compartment or because the batteries have escaped from the compartment. 88 FR 8698-99. CPSC has not identified any additional hazard patterns since the NPR. Figure 1 provides examples of button cell and coin batteries, and Figure 2 shows a few examples of consumer products that contain button cell or coin batteries.

LR44 84, + 57					
LR44 button cell, 11.6mm	LR754 button cell, 7.9 mm	LR626 button cell, 6.8 mm			
(0.45 inch) diameter x 5.4mm	(0.31 inch) diameter, 5.4mm	(0.26 inch) diameter, 2.6mm			
(0.21 inch) thick	(0.21 inch) thick	(0.10 inch) thick			
Lithium Cell CR2032 3V sc	Lithium Cell CR2025 3V sc	Lithium Cell CR2450 3U Sc			
CR2032, 20mm	CR2025, 20mm	CR2450, 24mm			
(0.787 inch) diameter	(0.787 inch) diameter	(0.945 inch) diameter			

Figure 1. Example button cell and coin batteries.



Figure 2. Example products that use button cell or coin batteries.

OS 14 DRAFT

In accordance with Section 2 of Reese's Law, the NPR contained performance and labeling requirements for consumer products that contain button cell or coin batteries.

Performance requirements: As required by Reese's Law, the NPR proposed that consumer products containing button cell or coin batteries require the battery to be secured in a manner that would eliminate or adequately reduce the risk of injury from the ingestion hazard to children during reasonably foreseeable use or misuse conditions. In developing the NPR, the Commission drew upon requirements stated in:

- UL 4200A-2020, Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies (UL 4200A-2020);
- ASTM F963-17 Standard Consumer Safety Specification for Toy Safety (ASTM F963);
- Voluntary standards referenced by Australian F2020L01656, including:
 - IEC 62368-1:2018 Audio/video, information and communication technology equipment-Part 1: Safety requirements (IEC 62368-1);
 - IEC 62115:2017 International Standard for Electric Toys Safety (IEC 62115);
 - AS/NZS 60065:2018 Audio, video and similar electronic apparatus-Safety requirements (AS/NZS 60065:2018); and
 - AS/NZS 60598.1:2017 Luminaires Part 1: General requirements and tests (AS/NZS 60598.1:2017).

Table 7 of the NPR summarized the Commission's analysis of the performance requirements in these voluntary standards. 88 FR 8701. Based on the analysis in Tab D of Staff's NPR Briefing Package, the Commission preliminarily concluded that none of these voluntary standards alone contained performance requirements that are adequate to address the

OS 15 DRAFT

requirements in Reese's Law. 88 FR 8701-02. Therefore, to address the performance requirements mandated in Reese's Law, the proposed performance requirements in CPSC's NPR differed from the requirements in the voluntary standards in several ways, including:

- Broader scope to match the scope of products covered by Reese's Law;
- Clarification that a locking mechanism requiring two simultaneous and independent actions does not include actions that can be combined into one single action by a single finger or digit, to address poor locking mechanism designs observed in testing;
- Addition of the compression test from the ASTM F963-17 toy standard, codified in16 CFR part 1250, to address children pressing on areas of the battery compartment not directly impacted by the drop test;
- Requirement that all products, including products weighing more than 18 kg, be subjected to 10 drops;
- Addition of the torque and tensile tests from the toy standard to address a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth.

88 FR 8702-04. Tables 8 and 9 in the NPR, 88 FR 8702, summarized CPSC's proposed performance requirements for consumer products with replaceable and non-replaceable button cell or coin batteries.

Warning label requirements: For consumer products containing button cell or coin batteries, Reese's Law requires warnings on:

- The packaging of consumer products;
- Accompanying literature; and
- Consumer products, as practicable.

OS 16 DRAFT

15 U.S.C. 2056e(a)(2). Reese's Law also requires warnings on packaging of button cell or coin batteries. *Id.* Warning statements must clearly identify the hazard of ingestion and instruct consumers, as practicable, to keep new and used batteries out of the reach of children, seek immediate medical attention if a battery is ingested, and follow any other consensus medical advice. 15 U.S.C. 2056e(b).

The NPR assessed warning requirements in several voluntary standards, and preliminarily concluded that none of the voluntary standards were adequate to meet the requirements in Reese's Law. Tab C of Staff's NPR Briefing Package; 88 FR 8704-05. Tables 10 and 11 in the NPR summarized the Commission's assessment of the warning label requirements in voluntary standards, in relation to the requirements of Reese's Law. 88 FR 8705.

Because none of the voluntary standards met the requirements in Reese's Law at the time of the NPR, the Commission proposed warning requirements for the packaging of consumer products containing button cell or coin batteries, accompanying literature, and, as practicable, consumer products. 88 FR 8706-09. The NPR also proposed warnings requirements for the packaging of button cell or coin batteries, which are being established by the Commission in a separate final rule. 88 FR 8706-07.¹¹

II. Assessment of Performance and Labeling Requirements in UL 4200A-2023

Several pertinent voluntary standards have been revised since the NPR published on February 9, 2023. IEC 62368-1 published a new edition (Edition 4, or IEC 62368-1:2023) in May 2023. In January 2023, ASTM balloted a revision to the battery compartment construction

¹¹ The NPR additionally proposed to require point-of-sale warnings of the ingestion hazard and other battery safety information under section 27(e) of the CPSA to improve safety communication to consumers to address the unreasonable risk of injury and death to children from ingesting or inserting button cell or coin batteries into the body, and other hazards. 88 FR 8709-11. The Commission is not finalizing proposed requirements under section 27(e) of the CPSA at this time.

OS 17 DRAFT

requirements in ASTM F963. In April 2023, UL balloted a revised version of UL 4200A, which was further revised and reballoted in July 2023, and comment responses were recirculated in August 2023. UL published its most recent revisions on August 30, 2023, as UL 4200A-2023. Tab E of Staff's Final Rule Briefing Package contains staff's detailed assessment of ASTM F963, UL 62368-1, and the revised IEC 62368-1:2023. Based on staff's updated assessment of ASTM F963, UL 62368-1, and IEC 62368-1:2023, the Commission cannot determine that any of these standards is adequate to meet the requirements in section 2(a) of Reese's Law.

However, for the reasons stated below and further elaborated in Tab E of Staff's Final Rule Briefing Package, the Commission determines that UL 4200A-2023 meets the performance and labeling requirements in section 2(a) of Reese's Law as applied to consumer products containing button cell or coin batteries. Table 1a summarizes CPSC's evaluation of the performance requirements in the updated voluntary standards.

	Performance Requirements for Button Cell or Coin Batteries						
		UL 4200A- 2023	ASTM F963 (Ballot)	UL 62368-1	IEC 62368- 1:2023	IEC 62115	
	Battery Chemistry Type	Any*	Any	Any	Any	Any	
Scope	Product Type	Any	Toys	Audio/ Visual Equipm ent	Audio/ Visual Equipm ent	Electro nic Toys	
	Opens with Tool	А	А	А	А	А	
	Captive screws	А	А	Ι	А	А	
Construction	Threaded attachment requirements	А		Ι	А		
Performance	Opens with two independent and simultaneous movements	А	0	Ι	Ι	О	
	Accessibility	А	А	А	А	А	
	Pre-conditioning in oven	А		А	А		
	Open/close and remove/install battery/screw(s) 10 times	А		А	А	Ι	
	Drop test - based on product weight/type	А	Ι	Ι	Ι	Ι	
Use and Abuse	Drop test - based on age grading	0	Ι	0	0	0	
	Impact Test	А		А	А	Ι	
	Crush Test (big surface area)	А		А	А		
	Torque Test	А	А				
	Tension Test	А	А			А	

Table 1a. Assessment of Existing Voluntary Standards' Performance Requirements for Button Cell or Coin Batteries

Tension Test - Seams	А	А			А
Compression Test (little surface area)	А	А	Ι	Ι	
Accessibility Probe Compliance Test	А	Ι	Ι	Ι	А
Securement (non-removable batteries)	А	0	0	0	0

*Excludes zinc-air batteries, which are not known to be used in consumer products.

 $Blank-Does \ not \ address \ requirements, \ I-In adequately \ address s \ requirements, \ A-Adequately \ address s \ requirements, \ O-Otherwise \ adequately \ address s \ requirements$

Table 1b, below, summarizes CPSC's assessment of warning label requirements for consumer

products containing button cell or coin batteries in existing voluntary standards.

Consumer Products Containing Button Cell or Coin Batteries									
		ASTM F963 (Ballot)	UL 4200A- 2023	ASTM F2999-19	ASTM F2923-20	IEC 62115	UL 62368-1		
	Battery Chemistry Type	All	All*	All	All	All	All		
Scope	Product Type	Toys	All	Jewelry	Children's Jewelry	Toys	Audio/Visual Equipment		
	On Consumer Product Packaging	Ι	А			Ι			
Labeling	In instructions or accompanying literature	Ι	А			Ι	Ι		
	On consumer product		А				Ι		

 Table 1b. Assessment of Existing Voluntary Standards' Labeling Requirements for Consumer Products Containing Button Cell or Coin Batteries

*Excludes zinc-air batteries, which are not known to be used in consumer products. Blank – Does not address requirements, I – Inadequately addresses requirements, A – Adequately addresses requirements

Although, as reflected in these tables, UL 4200A-23 satisfies all performance requirements of

Reese's law section 2(a), and the law's requirements for labeling of consumer products that

contain button cell or coin batteries, this UL standard does not address labeling of battery

packaging, for which Reese's Law also has requirements.

Below, we address in detail two significant aspects in which the former UL 4200A-2020

fell short of Reese's Law's requirements, but that the recent revisions to the standard-as we

interpret them-do address adequately.

A. Captive Screw Exceptions

Section 5.6 of UL 4200A-2020 included an exception from the requirement for fasteners to remain captive to the battery enclosure for large panel doors on large devices, which are not likely to be discarded or left off the equipment. The Commission did not include such captive

OS 19 DRAFT

screw exception in the NPR and stated that the range of products to which that exception would apply is unclear. 88 FR 8703.

Section 5.6 of UL 4200A-2023 contains a revised requirement for captive screws. Two related exceptions exist for the requirement, both of which apply only to products containing button cell or coin batteries that are not intended to be replaced by the consumer, and where there are instructions and warnings that clearly state the battery is not to be replaced by the consumer. The first exception applies to products containing button cell or coin batteries "that can only be accessed through the removal of multiple enclosures or panels using a tool." The second captive screw exception applies to "products only to be opened by a professional service center (where children are not present)."

Regarding the first exception, products designed and labeled to not have the battery replaced by the consumer provide the consumer with less incentive or need to access a button cell or coin battery compartment. The requirement to remove multiple enclosures or panels to reach a button cell or coin battery provides an extra layer of protection that prevents immediate access to batteries, even if screws to those panels are lost or discarded. CPSC is unaware of ingestion incidents involving access to button cell or coin batteries through multiple enclosures on consumer products. Products that might fit into the first exception include desktop and laptop computers, with batteries that frequently last longer than the product itself.

The second exception applies to products "only to be opened by a professional service center (where children are not present)." The text of the UL 4200A-2023 does not further explain this exception. We think it plain, however, that to avoid undermining the safety purpose of the captive screw requirement, the design of the consumer product, as well as its warning language and literature, must be consistent with professional-only access to the battery compartment. Accordingly, we interpret the professional service center exception for captive

OS 20 DRAFT

screws to only apply to consumer products with design and construction characteristics that are inconsistent with consumers accessing the batteries at home, for example by having a battery compartment that cannot be opened with a common household tool such as a straight-blade screwdriver, Phillips screwdriver, pliers, or a coin. For example, watch battery compartments that require a special professional tool to open would not require captive screws. However, watch battery compartments secured only with a straight blade or Phillips screw would not qualify for this captive screw exception, because such a product could be opened by consumers in their homes with readily available household tools.

B. Drop Test Requirements

To address the accidental liberation of button cell or coin batteries from consumer products, UL 4200A-2020 called for "portable" products to be dropped a total of three cycles in testing, and "hand-held" products a total of 10 cycles. In the NPR, the Commission proposed to require all products within the scope of the rule to be subject to 10 drop cycles. 88 FR 8713.

After reviewing the comments received on the NPR (which are discussed in section III below), the Commission agrees that it is appropriate to distinguish between products that are "portable" and those that are "handheld," provided those definitions are clear and able to be applied consistently. *See* Tab E of Staff's Final Rule Briefing Package.

Section 4.3A of UL 4200A-2023 now defines "hand-held product" to mean a product that is "reasonably foreseeable to be used or misused when being held in one or both hands." This category includes only "[p]roducts specifically designed to be carried easily, with a mass not exceeding 4.5 kg (10 lbs)." Section 4.4 of UL 4200A-2023 revises the definition for "portable device" to mean a "device that is reasonably foreseeable to be routinely carried or lifted as part of its use or misuse but not operated during transit with a mass not exceeding 18 kg (39.7 lb)." The Commission concludes that these definitions reasonably distinguish between handheld

OS 21 DRAFT

consumer products that are likely to be handled often and dropped frequently (such as a television remote control, for example), and other products that are moveable but not routinely handheld. The 10-drop requirement applies to the former, while a 3-drop requirement applies to the latter. The Commission determines that this framework in UL 4200A-2023 meets the requirements for Reese's Law section 2(a).

III. Comments on the NPR

CPSC received 38 comments during the comment period (four were duplicates), from February 9 through March 13, 2023, and two late-filed comments (one is out-of-scope for this rulemaking). Also, CPSC received nine comments on a separate PRA notice estimating the burden of the proposed rule. Commenters included medical professionals, standards development associations, consumers, consumer advocates, retail and manufacturing associations, and battery and consumer product manufacturers.

Thirty-three commenters generally supported the safety purpose and scope of Reese's Law. Commenters noted the potential deadly risk of injury associated with ingestion and insertion of button cell and coin batteries and their ubiquitous use in many different types of consumer products that are accessible to young children. Medical professionals informed the Commission regarding the difficulty in diagnosing an unwitnessed button cell or coin battery ingestion that requires prompt removal of the battery to prevent life-threatening esophageal burns and soft tissue damage, because the symptoms can mimic other health issues such as colds or upset stomach. Commenters generally supported the development of strong performance and labeling requirements for consumer products to prevent the ingestion hazard, as most button cell or coin battery ingestion incidents involve batteries obtained from consumer products.

Many commenters suggested that the CPSC find one of the reviewed voluntary standards adequate to meet Reese's Law requirements and to adopt a voluntary standard for the rule.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

OS 22 DRAFT

Because many of the comments received are relevant to the Commission's favorable determination on the UL 4200A-23 voluntary standard, we summarize and respond to them here.

Comments in Response to Questions on Performance Requirements

A. Whether any consumer products (as opposed to medical devices, such as hearing aids) contain zinc-air button cell or coin batteries, and whether such products should be required to meet the performance requirements for battery compartments on consumer products.

Comment 1: Other than use in hearing aids, a medical device, no commenters identify any consumer products using zinc-air button cell or coin batteries. An international battery trade association and a coalition of medical and consumer organizations (American Academy of Pediatrics, Consumer Reports, Public Citizen, Consumer Federation of America, Kids In Danger, and U.S. Public Interest Research Group) state that they are unaware of any consumer products (as defined in section 3 of the CPSA, 15 U.S.C. 2052(a)(5)) using zinc-air batteries. The coalition of medical and consumer organizations state that the Commission should reserve the ability to take further action regarding zinc-air button cell and coin batteries.

Response 1: Because the Commission is not aware of any consumer products that contain zinc-air button cell or coin batteries and commenters did not submit information regarding such products, and because such batteries present a low risk of causing an ingestion hazard as described in Tab C of Staff's Final Rule Briefing Package, the NPR proposed that zinc-air button cell or coin batteries, and products that use such batteries, should not be subject to the performance requirements in the final rule. Section 1.2 of UL 4200A-2023 contains a similar zinc-air battery exception.

B. Whether any voluntary standard meets the performance and labeling requirements of Reese's Law.

OS 23 DRAFT

Comment 2: Multiple commenters argue for Commission determinations that various voluntary standards satisfy the requirements of section 2(a) of Reese's Law. Five commenters (The Toy Association, Retail Industry Leaders Association (RILA), Permanent European Horological Committee (CPHE), Federation of the Swiss Watch Industry (FH), and American Watch Association (AWA)) recommend that CPSC accept the voluntary standard ASTM F963 as adequate to address the risk of ingestion by children. The commenters generally state that ASTM F963 adequately fulfills the objectives of Reese's Law, and that no data exists to suggest that the standard creates an accessibility hazard for products containing button cell or coin batteries that comply with the standard. However, a coalition of medical and consumer organizations recommend that the ASTM toy standard subcommittee incorporate some of CPSC's proposed requirements, such as improving testing for fastener retention and threading to avoid stripped screw holes and other possible scenarios that might lend access to the batteries.

Five commenters (Garmin International Inc. (Garmin)), CPHE, FH, AWA, and TechNet) recommend that CPSC accept the voluntary standard UL 4200A as adequate to address the risk of child ingestion. Four commenters (Japan Electronics and Information Technology Industries Association (JEITA), Consumer Technology Association (CTA), TechNet, and Information Technology Industry Council (ITI)) further state that CPSC should accept IEC 62368-1 or UL 62368-1 as adequate to address the risk of injury for products within the scope of that standard. The Battery Association of Japan (BAJ), Duracell, Energizer, and the National Electrical Manufacturers Association (NEMA) state that CPSC should accept IEC 60086 or ANSI C18 standards as adequate for battery package labeling requirements. Finally, the Power Tool Institute states that the Commission should work with voluntary standards organizations to improve and codify a voluntary standard.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

OS 24 DRAFT

Response 2: Reese's Law states that the Commission can rely on a voluntary standard, rather than drafting and implementing a rule for covered products, if the Commission determines that: (A) the voluntary standard meets the requirements for a standard promulgated under subsection (a) with respect to the products; and (B) the voluntary standard is in effect at the time of the determination, or will be in effect not later than 180 days after August 16, 2022 (February 12, 2023). 15 U.S.C. 2056e(d)(1). The Commission finds that UL 4200A-2023 meets the requirements of Reese's Law. As set forth in Staff's Final Rule Briefing Package and summarized in Tables 1a and 1b, however, the Commission does not find that any other voluntary standard, as described by the commenters, is adequate to meet the requirements of Reese's Law or to address the risk of injury from child ingestion.

Tabs D and E of Staff's Final Rule Briefing Package discuss staff's updated assessments of the voluntary standards based on feedback received from public comments. None of the commenters provide sufficient analysis, critique, or justification for the Commission to make a determination that any voluntary standard, other than UL 4200A-2023, meets the performance or labeling requirements in Reese's Law.

C. Whether the requirements for accessibility of battery compartments should incorporate test methods commonly used on toy products, such as the torque and tensile tests for parts of the product that can be gripped by a child's fingers or teeth, or a tensile test for pliable materials.

Comment 3: Two commenters (Landsdowne Labs and a coalition of medical and consumer organizations) support the incorporation of test methods commonly used on toy products.

Response 3: Incorporating test methods such as torque and tensile tests for parts of a consumer product that can be gripped by a child's fingers or teeth, or a tensile test for pliable

OS 25 DRAFT

materials, decreases the likelihood of children gaining access to button cell or coin batteries. Based on staff's assessment of these test methods in the ASTM F963 toy standard, the Commission determines that their inclusion in UL 4200A-2023 adequately tests the durability and integrity of battery compartments in products with pliable materials, such as shirts and greeting cards that light up or make sound using batteries. The Commission agrees with the commenters that these requirements will eliminate or adequately reduce the risk of ingestion in pliable products, as required by Reese's Law.

D. For consumer products that use button cell or coin batteries and have large panel doors, what consumer products have such doors, and should the Commission exclude large panel doors from the requirement for captive screws; why or why not (i.e., why does a large panel door represent a different risk of injury from battery access without using captive screws than a smaller battery compartment door does)?

Comment 4: Three commenters (UL Solutions, CTA, and ITI) state that the large panel door exemption from the captive screw requirement exists for products—like desktop computers which commonly use coin batteries on the motherboards to provide backup power—where the panel forms part of system enclosure which is not intended to be opened regularly by the consumer. The commenters state that consumers are unlikely to leave off or discard screws for these large panel doors. ITI notes that UL 62368-1 states that captive screws are for batteries that need to be replaced regularly.

Response 4: Section 5.6 of UL 4200A-2023 states that products containing button cell or coin batteries with large panel doors are excepted from the captive screw requirement as long as the batteries are not intended to be replaced by the consumer. The intent of the captive screw requirement is to prevent consumers from discarding screws securing battery enclosures after battery replacement during the product's lifetime. For products requiring battery replacement,

OS 26 DRAFT

consumers foreseeably may discard the screws to make replacing the batteries easier, without appreciating the battery ingestion hazard; or consumers may lose the screw and think the product is safe to use without properly securing the battery compartment. However, as explained in section II.A of this preamble, if a product's battery is not meant to be replaced, consumers are unlikely to open large panel doors to access the battery; therefore, requiring captive screws is not reasonably necessary to address the ingestion hazard in Reese's Law.

Exception 1 in section 5.6 of UL 4200A-2023 provides that captive screws are not required for products containing button cell or coin batteries that are not intended to be replaced by the consumer, and that products containing such batteries that can only be accessed through the removal of multiple enclosures or panels using a tool do not need captive screws. UL 4200A-2023 also requires that to meet the exception, such products must have instructions and warnings that clearly state the battery is not to be replaced by the consumer. Such products must also meet use and abuse testing requirements. The Commission determines that the requirements for multiple enclosures in UL 4200A-2023, which can include large panel doors, are adequate to meet the requirements in section 2(a) of Reese's Law.

E. Whether a double-action locking mechanism used to secure battery compartment enclosures, meaning those mechanisms that rely on two independent and simultaneous hand movements to open (versus a screw, for example), should be allowed to secure button cell or coin battery compartments.

Comment 5: Two commenters (RILA and The Toy Association) provide comments on whether double-action locking mechanisms, which are more accurately described as "multi-action" locking mechanisms to reflect that there can be more than two motions, should be allowed to secure button cell or coin battery compartments. RILA supports including the option for multi-action locking mechanisms, especially for products where it may not be feasible to

OS 27 DRAFT

secure battery compartments with an enclosure that requires a tool. The Toy Association opines that multi-action locking mechanisms are susceptible to be opened by applying forces in a single action or for one or both mechanisms to be disengaged, reducing the safety or efficacy of the mechanism. The Toy Association also comments that multi-action locking mechanisms may present a "false positive" to the consumer, appearing to be closed but susceptible to opening upon product operation.

Response 5: We agree with RILA that multi-action locking mechanisms can be a safe and effective alternative method to securing battery enclosures. Many products that use button cell or coin batteries are small and sometimes may not have enough space in the design to incorporate a screw to secure the battery enclosure. Therefore, providing multi-action locks as an alternative provides industry with some flexibility for designing their products in a safe manner. Staff's review of consumer products demonstrates a variety of different multi-action locking mechanisms that can be effective.

Moreover, both the NPR and UL 4200A-2023 address the Toy Association's concerns. To address incidents involving multi-action locks that could be opened with a single action, and to ensure consistent and reliable testing, the NPR specified that "[t]he movements to open cannot be combinable to a single movement with a single finger or digit." 88 FR 8721. Section 5.5(b) of UL 4200A-2023 also contains this language to clarify requirements for multi-action locking mechanisms. Because the actions must be simultaneous, the first action must be maintained while the second and successive actions are completed for the lock to open. If the design of the mechanism allows the battery compartment to open when the first action disengages, the battery compartment does not comply with the requirements of UL 4200A-2023. Therefore, the requirements of the UL standard and this DFR are intended to prevent the scenario envisioned by the Toy Association.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

OS 28 DRAFT

Additionally, regarding the Toy Association's comment on multi-action locking mechanisms presenting a "false positive" in which they appear to be closed, this scenario may occur in both multi-action locking enclosures and enclosures secured via screws or other fasteners. After replacing the battery, consumers may inadvertently neglect to screw or retighten a fastener, leaving the enclosure ineffective. To decrease this risk for all products, regardless of their battery compartment securement design, UL 4200A-2023 requires that all products containing a button cell or coin battery include warnings in product instructions to ensure proper securement of the battery enclosure.

Comment 6: Four commenters (coalition of medical and consumer organizations, CTA, the Consumer Safety Consultancy (CSC), and Mark Strauch) recommend adding tests to prove the effectiveness of multi-action locking mechanisms because, for example, locking mechanisms requiring a push and turn could be opened accidentally. CTA opines that specifying independent hand movements cannot be combinable to a single movement is redundant, because if the end point of the first movement is the starting point of the second movement, then the movements would not be independent. CSC recommends that the requirement for multi-action locking mechanisms be revised to require independent and sequential motions rather than independent and simultaneous motions as proposed in the NPR. Strauch comments that the NPR's clarification that "[t]he movements to open cannot be combinable to a single movement than an issue with the standard.

Response 6: Multi-action locking mechanisms that secure button cell or coin battery compartments are adequate to prevent access to children, so long as the actions cannot be combinable into one single action. Through testing, CPSC staff identified multiple products that were designed with the intent of requiring two independent actions to open the battery

OS 29 DRAFT

compartment that could be defeated by applying a single force to disengage the lock and expose the battery. Accordingly, the NPR included an additional clarification specifying, "[t]he movements to open cannot be combinable to a single movement with a single finger or digit." This requirement addresses the concerns from the coalition of medical and consumer organizations' comment that locking mechanisms that require a push and turn could be accidentally opened.

The Commission disagrees with commenters that a final rule should require independent sequential actions, rather than simultaneous actions, because sequential actions can be achieved more easily than simultaneous actions. The requirement for at least two independent and simultaneous actions allows for sequential actions, so long as the first action is held by the consumer while the second action occurs. Independent sequential actions, by contrast, would not require that the first action be held by the consumer while the second action occurs for the battery compartment to open, making the scenario of a child accidentally opening the battery compartment more likely.

UL 4200A-2023, as incorporated into this DFR, requires two independent *and simultaneous* movements that cannot be combined into a single movement. This requirement adequately addresses the risk of opening by young children or inadvertent action by older consumers, and provides testing laboratories with clearer criterion for assessing the adequacy of multi-action locking mechanisms.

F. Whether the proposed secureness test based on UL 4200A-2020 is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries.

OS 30 DRAFT

Comment 7: ITI asked for clarification on how the secureness test is applied to products, questioning whether the force application per the secureness test is to the exterior battery enclosure or to the battery itself.

Response 7: Under §1263.3(f) of the NPR's proposed rule, the secureness test was applicable only to button cell or coin batteries that are accessible based on proposed § 1263.3(d), which specifies removing "any part of the battery compartment enclosure that can be opened or removed without a tool or that can be opened or removed with anything less than two independent and simultaneous movements."

Section 6.4 in UL 4200A-2023 contains a similar requirement. After removing any components, testers should apply an accessibility probe to any opening of the battery compartment. If the probe makes contact with any battery, the battery is considered accessible, and the secureness test applies a force, directed outwards, using the test hook on the battery itself at all points where an application of a force is possible. This step is intended to demonstrate that the battery cannot be liberated from the product.

Comment 8: The CTA and ITI comment that the NPR incorrectly states that UL 4200A-2020 and IEC 62368-1 do not require abuse testing for products with button cell or coin batteries "that are held fully captive by soldering, fasteners, or any equivalent means." The commenters explain that UL 62368-1 requires robustness tests for solid safeguards which address accessibility of other hazards such as shock, fire, mechanical, and burn. The commenters state that these requirements are independent of the button cell or coin batteries because they are general requirements for all solid enclosures or barriers.

Response 8: The commenters are correct. UL 62368-1 requires all products containing solid safeguards to comply with the standard's relevant robustness tests, which include a steady force test (*i.e.*, small surface compression test), drop test, impact test, and other abuse tests based

OS 31 DRAFT

on the specific construction materials (such as glass or thermoplastic). These tests are required regardless of whether the product contains a button cell or coin battery. CPSC staff considered these comments in its revised appraisal of UL 62368-1 and concluded that the securement test was otherwise adequately addressed with other requirements in the standard. *See* Briefing Memorandum of Staff's Final Rule Briefing Package.

CPSC's proposed rule required products with non-removable button cell or coin batteries that are secured to the product via soldering, fasteners, or equivalent means to comply with the secureness test in §1263.3(f), and not to the abuse testing in § 1263.3(e). UL 4200A-2023 requires that button cell or coin batteries held fully captive by the use of soldering, fasteners such as rivets, or equivalent means must pass the secureness test in section 6.4 of UL 4200A-2023. This requirement is similar to the NPR's approach and is adequate to meet the requirements in Reese's Law.

G. Whether Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032, is adequate to verify accessibility of a button cell or coin battery in a battery compartment.

Comment 9: Three commenters (CTA, ITI, and UL Solutions) recommend applying a 45 N force application with Test Probe 11 per UL 62368-1 and UL 4200A-2020 to determine whether a battery can be liberated from a consumer product by children up to age six. CTA and ITI opine that the 50 N force in the NPR's proposed rule, which was based on IEC 62115, is intended for a scope of children up to 14 years old, and is too great because Reese's law is intended to protect children up to age six. Furthermore, they state the lack of incidents involving products certified to the 45 N requirement is evidence of adequacy. UL Solutions opines that the toy standard containing the 50 N force, IEC 62115, was developed based on the expectation that toys are continually used by children over its lifetime; whereas UL 4200A-2020 was developed

OS 32 DRAFT

assuming that children would likely come into contact with in-scope products, but not continually over the product's lifetime.

Response 9: Section 6.3.5.1 of UL 4200A-2023 requires the higher force of 50 N based on requirements in IEC 62115 and IEC 61032. We disagree that the 45 N test in UL 4200A-2020 is adequate because the standard was developed for products that are not continuously used by children over a product's lifetime. The 50 N compliance test accounts for reasonable, foreseeable use and abuse over the course of a product's lifetime, presuming that most consumer products are likely to be accessible to children. Indeed, most of the incident data for button cell and coin battery ingestions involve batteries liberated from consumer products by children, including products that are not intended to be used by children. UL 4200A-2023 now relies upon the test probe in IEC 61032, which specifies a force of 50 N. This higher force will adequately protect against children accessing button cell or coin batteries from consumer products during reasonably foreseeable use and misuse conditions, as required by Reese's Law.

H. Whether there are any additional performance requirements that should be considered, either for specific types of products, or in general.

Comment 10: A coalition of medical and consumer organizations recommends adding a test to prove the effectiveness of multi-action locks. They add that small, disc-shaped products that require a push and turn double-action can be mimicked by a child putting their hand on the product, putting the product on the floor, and then turning.

Response 10: As explained in response to comments five and six, we agree that some multi-action locking mechanisms can be defeated by applying a single force, effectively combining the two motions of a double-action lock. For this reason, the proposed rule and UL 4200A-2023 clarify that "[t]he movements to open cannot be combinable to a single movement with a single finger or digit." Based on staff's testing and review of consumer products, the

Commission finds this clarification adequate for test laboratories to determine the effectiveness of multi-action lock designs without additional testing.

Comment 11: Two commenters (a consumer and CTA) discuss the requirement for twiston enclosures requiring a minimum of 90° rotation to remove. The consumer commenter recommended that a 90° rotation is insufficient whereas CTA considers this requirement adequate.

Response 11: The requirement for minimum rotation angle for twist-on enclosures is based on a requirement in section 5.5(a) of UL 4200A-2020. This requirement is maintained in section 5.5(a) of UL 4300A-2023. Based on staff's testing and the lack of more stringent requirements in any other standards, CPSC does not have any data to support a greater rotation angle to prevent children ages six years and younger from accessing the button cell or coin battery. Accordingly, the Commission finds the 90° rotation angle requirement as set forth in UL 4200A-2023 compliant with Reese's Law section 2(a).

I. Whether one or more performance requirements should be based on IEC 62368-1, in addition to, or instead of, performance requirements based on UL 4200A-2020.

Comment 12: Two commenters (ITI and Garmin) discuss the fastener torque requirements based on Table 20 of UL 60065. ITI comments that the torque requirements in §1263.3(e)(1)(ii) for fasteners based on Table 20 of the *Standard for Audio, Video and Similar Electronic Apparatus – Safety Requirements*, UL 60065, are outdated and superseded by Table 37 of the *Standard for Safety: Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements*, UL 62368-1. Garmin comments that the fastener torque requirements from Table 20 of UL 60065 do not consider small fasteners that cannot withstand the specified torque values.

OS 34 DRAFT

Response 12: Commission staff advises that Table 20 of UL 60065 is superseded by Table 37 of UL 62368-1 as noted by ITI and Garmin, and recommends updating this reference table. While UL 4200A-2023 does not include this update, the comments do not suggest that this constitutes a failure to satisfy the requirements of Reese's Law. Further, we disagree with Garmin's position that Table 20 of UL 60065 (and similarly Table 37 of UL 62368-1) do not account for small fasteners. The torque values in these tables are dependent on the size of the fasteners, with the lowest torque requirement of 0.4 Nm for fasteners up to 2.8 mm in diameter. As discussed in Tab D of Staff's NPR Briefing Package, fasteners that do not meet the minimum required torque often fail the preconditioning and abuse tests and therefore are inadequate to secure battery compartments and reduce the battery ingestion risk to children.

J. Whether the proposed performance requirements are needed and are likely to eliminate or adequately reduce the ingestion hazard associated with access to button cell or coin batteries from consumer products.

Comment 13: Three commenters (CPHE, FH, and AWA) opine that watches present a significantly lower risk than other products containing button cell or coin batteries. These commenters recommend imposing different requirements for accessing the battery for products designed to be opened by consumers versus those intended to be opened only by professionals. The commenters state that most watches are intended to be opened by professionals because watches cannot be opened without the use of special tool that is not commercially available; therefore, the risk that screws or the battery cover could be lost or discarded by consumers does not exist.

Moreover, the commenters opine that the NPR's proposed securement requirements are not feasible for watches because of the limited space within the product to implement more complex designs. The Switzerland Federal Department of Economic Affairs, Education and

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OS 35 DRAFT

Research (Switzerland) similarly asks why the NPR does not differentiate the requirements for the removal or replacement of the button cell or coin batteries by the consumer themselves from removal by professionals.

Response 14: The NPR proposed that watches would be required to comply with the requirements of § 1263.3(b) for removable batteries, which requires (1) twist-on covers with minimum torque of 0.5 Nm to open and a minimum angle of rotation of 90°, or (2) fasteners must engage a minimum of two full threads and be held captive to the closure. We agree, however, with the commenters that products containing button cell or coin batteries that require a special tool to access, and can only be replaced by professionals, should have different requirements for battery accessibility than products with consumer-replaceable batteries. In particular, because the risk of discarding or losing an enclosure screw is low for products intended to only be opened by professionals, it is not reasonably necessary to impose a captive screw/fastener requirement for such products to reduce the risk of injury to young children.

Unlike the NPR, UL 4200A-2023 contains different requirements for products with battery compartments only intended to be opened by a professional service center where children are not present. As explained in section II.A of this preamble, CPSC interprets UL 4200A-2023 consistent with its purpose, so that battery compartments intended to only be opened by a professional service center must have both appropriate labeling and inability for the battery compartment to be opened using a common household tool, such as a straight-blade screwdriver, a Phillips screwdriver, pliers, or a coin. Battery compartments that cannot be opened with a common household tool and have warnings stating that the battery is not to be replaced by the consumer are less likely to be opened by a consumer, and therefore do not need to have captive screws to address the ingestion hazard. At the same time, products intended to be opened only by professionals can be opened through reasonable, foreseeable use and abuse, exposing the

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OS 36 DRAFT

button cell or coin battery. Accordingly, UL 4200A-2023 reasonably requires use and abuse testing for these products, to reduce the risk of children under six years old accessing a battery from a battery compartment.

Comment 15: JEITA requests an exemption from the scope of the rule implementing Reese's Law for products that use button cell or coin batteries that are not intended to be replaced by the user or cannot be removed (*i.e.* user-inaccessible). JEITA notes that IEC 62368-1 does not apply tests and warning label requirements if button cell or coin batteries cannot be removed because such products do not present a battery ingestion risk.

Response 15: Reese's Law defines "consumer products containing button cell or coin batteries" as "a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately." Notes to 15 U.S.C. 2056e. Therefore, the Commission's implementing rule must address batteries that are not intended for consumer replacement. Moreover, we disagree with JEITA that all products containing button cell or coin batteries that are not intended to be replaced are adequately safe under Reese's Law. Consumer products may experience use and abuse during the product's life that may result in batteries becoming dislodged or otherwise accessible to children, even if the batteries are not intended to be user replaceable. For example, incident narratives collected by CPSC describe products without replaceable batteries that fall apart when dropped. *See* Footnote 1 in Tab A of Staff's Final Rule Briefing Package.

Comment 16: Two commenters (CTA and ITI) recommend that a drop test with three repetitions is adequate for some products. While the commenters state that they agree that ten total drops, as proposed in the NPR, are appropriate for hand-held products such as remote

OS 37 DRAFT

controls, they recommend that three drops are adequate for other portable products such as equipment that is transportable but not intended to be held in hand while in use.

Response 16: As explained in section II.B. above, we agree that requiring ten drops for all consumer products is not reasonably necessary to reduce the risk of button battery access to children. UL 4200A-2023 requires a different number of repetitions for the drop test, based on whether a product is considered "hand-held" or "portable." Per UL 4200A-2023's drop test requirements, portable products are dropped three times and hand-held products are dropped ten times. The Commission finds that the approach taken in UL 4200A-2023 is reasonable and adequately protective under Reese's Law.

Comments in Response to Questions on Marking and Labeling Requirements

K. Whether staff's assessment [in section V.F of the NPR preamble] that virtually all consumer products can accommodate either the full warning or one of the scaled icons is accurate.

Comment 17: Four commenters (The Toy Association, CTA, ITI, and RILA) do not support on-product warning labels, citing limitations due to small product size. Other concerns presented by commenters pertain to textured surfaces, product material, or unspecified "other" limitations. The Toy Association asserts that labeling requirements will add significant costs in terms of timing, tooling, and molding. Four commenters (JEITA, CTA, HCPA, and ITI) request exemptions from on-product labeling where button cell or coin batteries are not accessible and not intended to be replaced by the consumer.

Response 17: Reese's Law requires that, where practicable, warning labels be placed directly on a consumer product in a manner that is visible to the consumer upon installation or replacement of the battery. Even for products with non-replaceable batteries, Reese's Law requires warning labels to be placed in a manner that is visible upon access to the battery

OS 38 DRAFT

compartment, where practicable. As summarized in Table 1b above, UL 4200A-2023 satisfies Reese's Law's requirements for warning labels on consumer products and consumer product packaging.

L. Whether the internationally recognized safety alert symbol, as shown in yellow color, indicating the presence of a button cell or coin battery, should be required on all consumer products containing such batteries.

Comment 18: A coalition of medical and consumer organizations, RILA, and Landsdowne Labs support on-products alert symbols as some consumers are not aware that the product uses a button cell or coin battery. JEITA and ITI propose products that do not have user accessible batteries be exempt from requiring an alert. Garmin does not support the use of a color for alert symbol on the product.

Response 18: Reese's Law requires products containing button cell or coin batteries not intended for consumer replacement to have a warning label on the consumer product in a manner that is visible to the consumer upon access to the battery "as practicable." 15 U.S.C. 2056e(a)(2)(C)(ii). If it is impracticable to label the product, this information must be placed on the packaging or instructions. *Id.* Section 7 of UL 4200A-2023 meets these requirements. The Commission's NPR proposed an alternative to the on-product warning label to increase the visibility that a product contains a button cell or coin battery and likelihood for all products to feature an alert where it otherwise may not be practicable. However, based on the comments, the proposed yellow color may not be clear or appropriate in all cases. Section 7B of UL 4200A-2023 does not require use of the yellow color unless the label already uses more than one color.

OS 39 DRAFT

Comments in Response to Questions on Other Topics Posed in the NPR

M. Whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and to provide specific information to support such a later or an earlier effective date.

Comment 19: Commenters differed in their recommendations for an effective date for a final rule of the Commission, from the proposed 180 days (consumer advocates) to up to 3 years (manufacturer associations). A few commenters provided detailed timelines of the necessary activities (product redesign, testing, certification sourcing, supply chain management, etc.) which ranged from 12 months to 36 months in total. A commenter also contended that additional time is required to accredit third party laboratories for a large variety of product types. Energizer and NEMA request that battery manufacturers be allowed to sell through their existing stocks of child-resistant packaging and labels that were purchased to comply with section 3 of Reese's Law.

Response 19: Because the Commission determines that UL 4200A-2023, which is currently effective as a voluntary standard, meets the performance and labeling requirements in section 2(a) of Reese's Law with regard to consumer products containing button cell and coin batteries, section 2(e) of Reese's Law states that UL 4200A-2023 is treated as a consumer product safety rule as of the date of the Commission's determination. 15 U.S.C. 2056e(d) and (e). However, because the Commission is codifying its incorporation of UL 4200A-2023 in the Code of Federal Regulations, the DFR provides a 30-day effective date for that new rule. As noted, moreover, the Commission's Office of Compliance and Field Operations has issued guidance to industry and the public regarding a transitional period of enforcement discretion. *See* [web link].

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OS 40 DRAFT

N. In the IRFA, the number of small firms impacted and expected cost impact on small firms (as a percentage of annual revenue) of the proposed rule.

Comment 20: One firm commented that staff's estimate of a testing cost of \$150 to \$350 is too low and that a quote received by the firm to perform similar tests exceeded staff's estimate by more than \$1,650 per sample tested. The firm stated this would pose a substantial burden to the firm as they do not possess the necessary skill set or expertise to mitigate these costs by developing a reasonable testing program in lieu of performing third party testing.

Response 20: The Commission's determination regarding UL 4200A-2023 is not required to be done through notice and comment rulemaking, and thus we have no requirement to provide a Final Regulatory Flexibility (FRFA) analysis for this DFR. Nevertheless, staff collected an additional price quotation from an accredited test laboratory and revised the estimated testing cost from \$150 to \$350 per sample to \$150 to \$460 per sample, as presented in Tab F of Staff's Final Rule Briefing Package. Staff's revised estimate is lower than the estimate provided by the commenter, which we do not find credible as a representative cost.

Comment 21: One firm (Nite Ize) commented that CPSC failed to account for potential costs related to patent filing and enforcement. The firm expressed concern that current product patents for novel product lines would need new filings to provide robust intellectual property protection.

Response 21: CPSC has not been provided with sufficient information to assess whether current consumer product patents would lose any or all value due to the implementation of Reese's Law, or whether a new patent filing would be required to legally enforce intellectual property rights. We note, however, that a new patent filing could provide a longer period of protection, which could mitigate any loss in the value of prior patents.

Comment 22: Nite Ize and the Toy Association state that the IRFA's cost per product line estimates for research, development, and retooling are too low as CPSC failed to account for product lines that require unique solutions.

Response 22: While a FRFA is not required, commenters do not provide specific alternative cost estimates or justification of their view.

Comments Addressing Other Issues

O. International regulations.

Comment 23: Garmin and RILA support harmonization with Australia's regulations addressing performance and labeling requirements for products containing button cell or coin batteries.

Response 23: Reese's Law requires the Commission to promulgate a rule that contains a performance standard that will eliminate or adequately reduce the risk of injury from button cell or coin battery ingestion and warning labels. Reese's Law allows the Commission to rely on a voluntary standard if it determines that a voluntary standard would meet the performance and labeling requirements for a standard issued under section 2(a) of Reese's Law. 15 U.S.C. 2056e(d)(1). The Australia regulation is not a voluntary standard. However, for the NPR, CPSC staff reviewed the voluntary standards referenced by the Australian regulation, and the Commission preliminarily determined that none of those standards met the requirements of Reese's Law. Tabs D and E of Staff's Final Rule Briefing Package, and section II of this preamble, contain updated assessments of the voluntary standards, including UL 4200A-2023, which is adequate to meet the performance and labeling requirements in section 2(a) of Reese's Law.

P. Silver-oxide battery chemistries.

Comment 24: CPHE, FH, AWA and Renata SA state that silver-oxide button cell and coin batteries should be excluded from a Commission rule implementing Reese's Law because of a lack of fatal incident data with these batteries and children's inability to access these batteries in watches. Duracell states that silver-oxide batteries should contain different warnings than lithium batteries because they are lower voltage. Switzerland asks whether silver oxide batteries could be excluded from the rule.

Response 24: As reviewed in Tab C of Staff's Final Rule Briefing Package, Jatana *et.al.* (2017) found in testing using an animal model that silver-oxide button or coin cell batteries caused severe esophageal injuries. Based on the medical literature, staff does not recommend excepting silver-oxide batteries from the scope of the final rule, and UL 4200A-2023 does not contain such an exception.

Q. Firearm accessories and other household products containing button cell or coin batteries.

Comment 25: Bushnell states that firearm accessories appear to be subject to the proposed requirements, and that the firearm itself is intended to act as the battery door or cover for these products.

Response 25: Modular consumer products or component parts of consumer products containing button cell or coin batteries, like the firearm accessories described by the commenter, must meet the same requirements as other consumer products, independent of their intended use. Modular consumer products can be attached to or installed by a consumer on other products to change the host product's design or capabilities. A modular consumer product, however, could foreseeably remain unattached from the product(s) it is designed to complement. To eliminate or adequately reduce the risk of injury from battery ingestion, these products must independently

OS 43 DRAFT

meet the performance requirements in the final rule, to prevent unintended access to button cell or coin batteries by children.

Comment 26: A consumer safety consultant (Mary Toro) and RILA state that some products containing button cell or coin batteries are made of fragile materials (such as glass or ceramic materials) that are likely to break during the proposed testing protocol. RILA states that the testing proposed in the NPR is not appropriate for these products, and that alternative test methods should be allowed for such products.

Response 26: The performance requirements in UL 4200A-2023 are likely to cause products made of materials like glass or ceramic to break. Because it is also reasonably foreseeable that a glass or ceramic product may break if knocked to the ground or dropped, which could make accessible to a child a button cell or coin battery contained inside, the button cell or coin battery could be further contained in a battery compartment that meets the requirements of the final rule. The manufacturer can test its product to ensure the product meets the requirements of the final rule, or use in its product a battery compartment that has already been tested or certified to the requirements, as allowed by 16 CFR part 1109.

R. "Try Me" buttons.

Comment 27: A consumer asks for clarification whether "Try Me" buttons containing button cell or coin batteries, that are used only in stores and not intended for sale, are within the scope of the final rule. UL Solutions states that products can incorporate "Try Me" buttons in retail displays or as part of product packaging, and their disposal should be addressed.

Response 27: "Try Me" buttons are within the scope of the final rule because they are consumer products that are used by consumers. Purchase of a product is unnecessary to be considered a "consumer product" under CPSC's jurisdiction. 15 U.S.C. 2052(a)(5) (stating, *inter alia*, that a consumer product is for "the personal use, consumption or enjoyment of a consumer

OS 44 DRAFT

in or around a permanent or temporary household or residence, a school, in recreation, or otherwise."). Consumers, including children, are subject to hazards associated with "Try Me" buttons. "Try Me" buttons may experience drops, impacts, and other patterns of use and abuse similar to any other product within the scope of the final rule and are therefore subject to the rule. In fact, CPSC is aware of at least one incident involving a coin battery from a "Try Me" button.¹²

S. Use of color in the requirements for marking and labeling.

Comment 28: Several commenters (JEITA, Duracell, Garmin, HCPS and CTA) state that the use of color on packing, instructions, or manuals, and on some consumer products, would be challenging and add costs to the manufacturing and printing process, particularly for those materials that do not already incorporate color. Duracell and Technet also stress that various product safety standards (*e.g.*, ASTM F963, ANSI C18.3, or ANSI Z535 series) do not mandate the use of colors and accept black and white printing or contrasting colors to the background. Commenters state, however, that if color is used for the signal panel, then colors should conform to ANSI Z535.1 safety colors that correspond to the safety message. The Toy Association and RILA state that the use of color may not be reasonable to print on certain product materials, for example, colored or textured plastics.

Response 28: Applying color to some materials (*e.g.*, consumer product packaging, manuals, or other collateral material) that do not already contain color may present a burden to some manufacturers. UL 4200A-2023 requires the use of color when the subject materials already use printed color processing; otherwise, the use of black and white or contrasting colors is acceptable. The use of color is not specified in Reese's Law; thus this variation from the NPR does not conflict with the statute and is safety neutral because the label or icon will visually align

¹² See Footnote 6 in Tab A of the Staff's Final Rule Briefing Package.

OS 45 DRAFT

with other information on the display while ensuring that it is noticeable due to its contrast or color.

T. Text size, icons, and alternative symbols for marking and labeling.

Comment 29: Renata Batteries, ITI, The Toy Association, RILA, BAJ, and Duracell express cost concerns with increased packaging sizes required to accommodate larger warning labels and font sizes, especially for small products. Another commenter states that the minimum letter size requirements for packaging warnings may make other warnings on product packaging less prominent.

Response 29: The NPR proposed that font size requirements for both on-product and onpackaging warning labels be determined based on the size of the principal display panel (generally the front face) of the package or the product display panel (such as the surface area on, near, or in the battery compartment). Reese's Law requires that warning labels clearly identify the hazard of ingestion, and this requirement is met when warning labels are displayed prominently on the principal display panel. For very large products or packages with principal display panels exceeding 400 inch², the required letter size could be larger than standard font sizes usually referenced in other standards.

UL 4200A-2023 contains the same size requirements set forth in the NPR. The minimum letter size is comparable to font sizes in other standards, and therefore of similar prominence when displayed on the same panel. The largest packaging will have ample room for additional warnings that are of comparable size to the requirements in the NPR. This level of prominence is appropriate to inform consumers which products contain button cell or coin batteries and to adequately reduce the risk of injury from ingestion.

Comment 30: A consumer (Fo Xu) asks how to determine the size of the text for consumer products and its packaging and whether it is acceptable to use smaller size labels on

OS 46 DRAFT

the consumer products. Energizer requests clarification whether CPSC will identify the surface size for which the alternative on-product label can be used, or whether manufacturers can use reasonable judgement.

Response 30: The NPR proposed that consumer products be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or coin battery. "Product display panel" was defined in proposed §1263.2(f). The NPR proposed that text size be determined based on Table 1 in the regulation text, or if on a sticker label, using the minimum size requirements in §1263.4(a)(7). UL 4200A-23 incorporates these requirements from the NPR. The minimum text size is dependent on the size of the principal display panel or the product display panel. Manufacturers can use alternative on-product labels in situations where the full label does not fit in the measured product display panel area, as described in UL 4200A-2023.

Comment 31: The Toy Association recommends that for consumer product packaging and instructions, the "Keep Out of Reach" icon be changed to the safety alert symbol for coin batteries because the intent of the icon is not to keep the consumer product away from children.

Response 31: We agree with the commenter. Some products that contain button cell or coin batteries are intended for use by children, so using the "Keep Out of Reach" icon on those products may confuse consumers by appearing to instruct caregivers to keep the product, rather than the battery, away from children. To prevent consumer confusion, UL 4200A-2023 provides the option of replacing the "Keep Out of Reach" icon on consumer product packaging, as well as instructions, with the safety alert symbol to indicate "Warning: Contains Coin Battery." Accordingly, manufacturers will have a choice based on the product's intended user. See Tab D of Staff's Final Rule Briefing Package for a more detailed discussion of this issue.

OS 47 DRAFT

Comment 32: CTA states that in the NPR the proposed symbol for "Warning: Contains Coin Battery" has a different aspect ratio and is rotated farther than the internationally accepted symbols for coin and button cell batteries and that the symbol should match internationally recognized symbols.

Response 32: While UL 4200A-2023 includes the icon from the NPR, the button cell or coin battery portion of the symbol can be replaced with other internationally recognized symbols in ISO 7000-W0001 and IEC 60417-6367, to have consistency.

U. Tolerances for values specified in the proposed rule.

Comment 33: ITI comments that the proposed rule did not include tolerances for its specified values and opines that the purpose of tolerances is to give reasonable allowances (*e.g.*, manufacturability and testability) that will not have a significant impact on test results. The commenter contends that eliminating tolerances could force unnecessary retesting or could make it impractical to apply the test without custom test equipment. ITI recommends including tolerances in the rule that align with voluntary standards.

Response 33: Because the Commission is incorporating by reference UL 4200A-2023 as the mandatory standard, tolerances as stated in the UL standard are included in the final rule.

V. Warning label permanency.

Comment 34: RILA states that the permanency requirement for warning labels in the NPR is unclear. One commenter recommends on-product permanency be tested in accordance with the test requirements in UL 62368-1 section F.3.9.

Response 34: We agree with the commenter that on-product warning label permanence should comply with the test requirements in UL 62368-1: F.3.9. This test evaluates the legibility of printed or screened markings and ensures adhesive labels cannot be easily removeable by hand. Section 7D of UL 4200A-2023 includes requirements for label permanence. All warning

OS 48 DRAFT

statements or icons shall be prominent, legible, easily discernable under normal lighting conditions, and permanently marked; and printed and screened markings are tested in accordance with the label permanency test method adapted from UL 62368-1 section F.3.10 (consistent with the requirements in UL 62368-1: F.3.9).

W. CPSC's statutory authority.

Comment 35: The AWA filed a late comment stating that certain parts of the NPR's proposed rule relating to securement of battery compartments constitute design or construction standards, which are not allowed by the CPSA or Reese's Law.

Response 35: To meet the performance requirements in UL 4200A-2023 for securement of battery compartments, manufacturers may choose to use either any type of fastener that requires a tool of the manufacturers' choice, or a multi-action locking mechanism. The market already employs many different battery compartment enclosure designs that depend on the size, shape, and materials of the consumer product. For example, remote controls include battery compartments that are either secured with screws or that slide out of the base (and typically require two independent and simultaneous actions to do so); many garage door openers require a tool to open but do not use screws or twist-on access covers; and battery compartments in lightup clothing are frequently stitched into the clothing.

Additionally, the UL 4200A-2023 performance requirements specify that battery compartments for replaceable batteries using screws or fasteners are to remain captive to the battery compartment door, cover, or closure when loosened. These performance requirements do not specify how the manufacturer must design the battery compartment to ensure the screw or fastener remains captive. Many possible solutions exist, including a retaining washer, a press fit cap, a tether, or other means.

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OS 49 DRAFT

X. Product categories.

Comment 36: In response to the April 11, 2023 *Federal Register* notice requesting comment on the Paperwork Reduction Act (PRA) burden associated with non-children's products subject to the proposed rule (88 FR 21652), the China National Center of Standards Evaluation and P.R. China suggest that products be categorized by risk level depending on how frequently a child comes into contact with the products, and that CPSC should develop a list of products to which the regulation applies.

Response 36: Although this comment was filed in response to the PRA notice, the comment is about the substance of the rule. The commenters' suggestion to broadly qualify implementation of Reese's Law is contrary to the requirements of the statute, which requires CPSC to promulgate a rule or identify a voluntary standard, with performance and labeling requirements, for all consumer products that contain or are designed to use button cell or coin batteries. The rule or voluntary standard must eliminate or adequately reduces the risk of ingestion to children six years old or younger during foreseeable use and misuse conditions. Accordingly, the Commission will not adopt the commenters' suggestion to exclude from the Commission's implementation of Reese's Law a potentially large number of consumer products that are covered by the law and present at least some degree of ingestion hazard.

Y. Toy products.

Comment 37: In response to the April 11, 2023, *Federal Register* notice requesting comment on the PRA burden associated with non-children's products subject to the proposed rule (88 FR 21652), Switzerland asks why products containing button cell or coin batteries that are subject to Reese's Law must fulfill more stringent requirements than those imposed for toys

OS 50 DRAFT

that are compliant with the toy standard of ASTM F963, as incorporated by reference in 16 CFR part 1250.

Response 37: Although this comment was filed in response to the PRA notice, the comment is about the substance of the rule and not about the paperwork burden. Section 4 of Reese's Law, Notes to 15 U.S.C. 2056e, specifically exempts "any toy product that is in compliance with the battery accessibility and labeling requirements" of 16 CFR part 1250. Accordingly, toy products are not within the scope of the rule and are already covered by the existing toy standard. However, we agree with the commenter that the requirements for children's and non-children's products that contain button cell or coin batteries that are subject to this final rule are more stringent than those imposed for toys. On March 20, 2023, CPSC staff sent a letter to the ASTM F15.22 toy subcommittee requesting that the subcommittee consider changes to ASTM F963 which would adequately address incidents and hazards involving toys.¹³

Comments Addressing the PRA

Z. The accuracy of CPSC's estimate of the burden of the proposed collection of information.

Comment 38: ITI, CTA, JEITA, AWA, and RILA believe that the CPSC underestimated the burden of the collection of information proposed in the NPR. ITI believes that the labor rates used may under-represent the burden cost. ITI and RILA request that CPSC provide additional detail on how the PRA burden estimates were derived. While CTA indicates that it is standard practice within the technology sector to include warnings on product labels, the labeling is different enough to warrant additional hourly PRA burden associated with labeling. Relatedly,

¹³ Staff's letter to the ASTM F15.22 subcommittee can be found here: <u>https://www.cpsc.gov/s3fs-public/Letter-to-ASTM-F15-22-Reeses-Law-NPR-230320.pdf</u>?VersionId=6ZGPs5nSLhBGIFdoz1IWHF1wo.oOgarH.

OS 51 DRAFT

ITI suggests that product labeling should not be considered "usual and customary" and is within the definition of "PRA burden."

ITI indicates that manufacturers may have more than two product families and therefore the estimate of 15,363 firms with 2 products each understates the number of unique nonchildren's products containing coin/button cells on the U.S. market.

Response 38: Based upon the comments received, CPSC is adjusting its burden estimates upward, as shown in Table 6 in this preamble. Additionally, CPSC adopts a higher wage rate to represent total compensation costs for private industry workers in goods producing industries. We provide the substance of this revised PRA burden estimate in section X of this preamble.

AA. Ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques when appropriate, and other forms of information technology.

Comment 39: JEITA notes that the final rule would impose requirements different from those of international standards, and that this will burden manufacturers as labeling and testing for products intended for use in the United States would need to be completed separately from labeling and testing for other markets.

Response 39: Burdens and potential efficiencies associated with testing to international standards, in addition to CPSC standards, are outside the scope of PRA burden estimates for the proposed rule.

BB. The estimated burden hours associated with labels and hang tags, including any alternative estimates.

Comment 40: ITI, CTA, JEITA, and AWA provide estimates of hourly burden for various industry sectors. *See* Tab A, Issue 36, in Staff's Final Rule Briefing Package. CPSC did not receive any detailed estimates on the total number of respondents to which this collection

OS 52 DRAFT

would apply, but data provided by various commenters on the number of firms to which the collection would apply imply that CPSC has likely overestimated the number of respondents. Commenters provided alternative estimates for the frequency of response based upon the number of product families to which the rule might apply. However, these estimates were not provided at the establishment level and are therefore difficult to compare to CPSC estimates, which are based on U.S. Census Bureau establishment data.

Response 40: Although burdens will vary for different industry sectors and by product as pointed out by commenters, the estimates provided by commenters generally support the Commission's average burden calculations. CPSC assumes, moreover, that industry sectors responding to the public notice likely will experience comparatively large impacts from implementation of Reese's Law.

CC. The estimated respondent cost other than burden hour cost.

Comment 41: JEITA believe that the cost of test samples should be included in the estimated respondent cost.

Response 41: According to guidance provided by the Office of Management and Budget (OMB) and General Services Administration (GSA), the burdens calculated under the PRA typically do not include estimating the cost of test samples. *See* https://pra.digital.gov/about/.

Comments Addressing Out-of-Scope Issues

Tab A of Staff's Final Rule Briefing Package discusses comments received on topics that are out of scope for this rulemaking.

IV. Commission Determination Regarding UL4200A-2023 and Description of the Final Rule's Requirements

After consideration of the public comments summarized in section III of this preamble and Staff's Final Rule Briefing Package, and for the reasons given in this *Federal Register* notice, the Commission determines that UL 4200A-2023 meets the performance and labeling

OS 53 DRAFT

requirements in section 2(a) of Reese's Law for consumer products that contain button cell or coin batteries. 15 U.S.C. 2056e(d)(1). The Commission does not make this determination with respect to the labeling of battery packaging, because UL 4200A-2023 does not address the labeling of battery packaging. Pursuant to section 2(e) of Reese's Law, UL 4200A-2023 is a consumer product safety rule on the date the Commission makes this determination, [insert vote date]. However, because the Commission is codifying the requirements in the Code of Federal Regulations, for purposes of the direct final rule, the rule is effective 30 days after publication in the *Federal Register*. Furthermore, the Commission's Office of Compliance and Field Operations has announced a transitional period of enforcement discretion. *See* [WEB LINK].

Table 3 summarizes the performance requirements in UL 4200A-2023 applicable to consumer products with battery compartments for replaceable button cell or coin batteries, and Table 4 summarizes the standard's performance requirements applicable to consumer products with battery compartments for non-replaceable button cell or coin batteries.

	with Battery Compartments for Replaceable Button Cell or Coin Batteries				
Button cell or coin batteries must not become accessible or liberated					
when tested to these requirements:					
Performance Requirements for Battery Compartment Securement (UL Section 5.2-5.6)					
	Option 1: Coin, screwdriver, or other tool.				
	Captive screws				
Battery Compartment Securement Options (UL Section 5.5-5.6)	 Capitive servers Exceptions for products containing batteries not intended to be replaced by the consumer. Such products shall have instructions and warnings that clearly state the battery is not to be replaced by the consumer. Exception 1: Products that can only be accessed through the removal of multiple enclosures or panels using a tool. Exception 2: Products that are only to be opened by a professional service center (where children are not present). Two threads engaged or minimum torque + spin angle Option 2: At least two independent & simultaneous hand movements. 				
	• Shall not be combinable to a single movement with a finger or digit.				
Accessibility Test (UL Section 5.3-5.4)	Open or remove any part of the compartment not meeting <i>Option 1</i> or <i>Option 2</i> . Apply Tension Test for Seams from ASTM F963 on pliable materials, using a force of 70.0 N (15.7 lbf). Determine whether Test Probe 11 from IEC 61032 can touch the battery.				
Preconditioning Requirements (UL Section 6.2)					
Preconditioning in Oven					
(UL Section 6.2.1)	temperature.				

Table 3. Summary of Performance Requirements in UL 4200A-2023 for	
onsumer Products with Battery Compartments for Replaceable Button Cell or Coin Batterie	s

OS 54 DRAFT

Simulated Battery Replacement (UL Section 6.2.2)	Open/Close and remove/install battery 10 times.			
	Use and Abuse Tests (UL Section 6.3)			
Drop Test (UL Section 6.3.2)	Handheld products are 10 drops while portable products are 3 drops. Each drop is from 1 m (39.4 in) on hardwood, in positions likely to produce maximum force.			
Impact Test (UL Section 6.3.3)	3 impacts on battery compartment with steel sphere, 2 J (1.5 ft-lbf) of energy.			
Crush Test (UL Section 6.3.4)	$330 \text{ N} \pm 5 \text{ N}$ (74.2 lbf ± 1.1 lbf) for 10 s, using 100 by 250 mm (3.9 by 9.8 in) flat surface.			
Compression Test (UL Section 6.3.4A)	Test from 16 CFR Part 1250, using a force of at least 136 N (30.6 lbf).			
Torque Test (UL Section 6.3.4B)	Test from 16 CFR part 1250, using a torque of at least 0.50 Nm (4.4 inlbf).			
Tension Test (UL Section 6.3.4C)	Test from 16 CFR part 1250, using a force of at least 72.0 N (16.2 lbf).			
Probe for Accessibility (UL Section 6.3.5)	Apply 50 N to 60 N (11.2 lbf to 13.4 lbf) with Test Probe 11 from IEC 61032 to confirm compliance.			

Table 4. Summary of Performance Requirements in UL 4200A-2023 for Consumer Products with Battery Compartments for Non-Replaceable Button Cell or Coin Batteries

Consumer Froducts with Battery Compartments for Non-Replaceable Button Cen of Com Batteries					
Products that incorporate button cell or coin batteries that are not intended for user removal or replacement shall					
	effectively prevent removal of the battery by the user or children.				
Option 1 – Not Accessible (UL Section 5.7(a)) • Made inaccessible by an enclosure that meets the same applicable precondit and use and abuse test requirements as battery compartments for replaceable batteries.					
Option 2 – May be Accessible (UL Section 5.7(b))	 Secured with soldering, fasteners such as rivets, or equivalent means. Confirmed with secureness test: test hook applies a force of 20 N ± 2 N (4.5 lbf ± 0.4 lbf) directed outwards for 10 s, at all possible points. Battery cannot liberate from the product. 				

The warning label requirements for consumer products and consumer product packaging

in UL 4200A-2023 are substantively similar to the warning label requirements in the NPR (88

FR 8706-09), with the following differences:

- Colored markings must comply with the ISO 3864 series of standards;
- Color is required only when the markings are printed on a label using more than one color;
- Manufacturers may choose to use either the "Keep Out of Reach of Children" icon or the "Warning: Contains Coin Battery" icon on the consumer product packaging label;
- Permanence of markings is tested consistent with the requirements in UL 62368-1 section

F.3.9;

OS 55 DRAFT

- Inclusion of an additional warning statement in instructions and manuals to "Always completely secure the battery compartment. If the battery compartment does not close securely, stop using the product, remove the batteries, and keep it away from children."
- Removal of requirements for battery package warnings because they are being finalized in a separate final rule, and removal of certain performance and technical data requirements proposed under section 27(e) of the CPSA, which are not being finalized at this time.

In the following discussion, we provide a section-by-section summary of the final rule.

A. Section 1263.1 Scope, purpose, effective date, and exemption.

Final rule § 1263.1(a) explains the scope and purpose of the safety standard required by Reese's Law, as proposed in the NPR, with two modifications: the removal of the provision for units, which is addressed instead in UL 4200A-2023, and removal of the provision for battery package labeling, which is addressed in a separate final rule. 15 U.S.C 2056e, Public Law No. 117-171. Based on section 2 of Reese's Law, the scope of the final rule includes consumer products containing button cell or coin batteries, including the packaging of such consumer products and accompanying literature.

Section 1.3 of UL 4200A-2023 provides the scope of the voluntary standard, stating that the requirements apply to consumer products containing button batteries or coin cell batteries.¹⁴ This scope is consistent with Reese's Law, which defines a "consumer product containing button cell or coin batteries" as "a consumer product containing or designed to use one or more button

¹⁴ Section 1.3 of UL 4200A-2023 also states that the standard does not include "products that by virtue of their dedicated purpose and instructions are not intended to be used in locations where they may be accessed by children, such as products for dedicated professional use or commercial use in locations where children are not normally or typically present." The Commission interprets this exclusion from the scope of the standard consistent with the Commission's jurisdictional authority in section 3 of the CPSA. For example, products used solely in professional settings are within the jurisdiction of the Occupational Safety and Health Administration. However, consumer products generally available for use or purchase by consumers are within the Commission's jurisdiction. 15 U.S.C. 2052(a)(5).

OS 56 DRAFT

cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately."¹⁵ This definition includes products that are not sold with a battery but are designed to use a button cell or coin battery.

Section 1263.1(b) of the final rule establishes the effective date of the direct final rule. Because the Commission determines that UL 4200A-2023 meets the requirements in section 2(a) of Reese's Law, section 2(e) of Reese's Law provides that the voluntary standard is treated as a consumer product safety rule as of the date of the Commission's determination. However, for the direct final rule, the effective date is 30 days after publication, as explained in section VII of this preamble. Consistent with section 6 of Reese's Law (Notes to 15 U.S.C. 2056e), the rule requires that all consumer products and packaging containing button cell or coin batteries that are subject to the final rule, and that are manufactured or imported 30 days after publication of the final rule in the *Federal Register*, must comply with the requirements of this part. The Commission's Office of Compliance and Field Operations has announced a transitional period of enforcement discretion. *See* [WEB LINK].

Final rule § 1263.1(c) describes the exemption in Reese's Law for toy products that meet ASTM F963, as incorporated into 16 CFR part 1250. UL 4200A-2023 excludes the same products from its scope.

Final rule § 1263.1(d) retains the exception for button cell and coin batteries that do not pose an ingestion hazard as proposed, meaning zinc-air batteries. This exception is also stated in UL 4200A-2023.

¹⁵ Notes to 15 U.S.C. 2056e. The term "consumer product" has the same meaning as that in section 3(a) of the Consumer Product Safety Act (CPSA). 15 U.S.C. 2052(a).

B. Section 1263.2 Definitions.

Final rule § 1263.2 provides applicable definitions as proposed in the NPR, explaining that the definitions in section 3 of the CPSA and section 5 of Reese's Law also apply to this rule. The final rule codifies several definitions from Reese's Law relevant to requirements for consumer products containing button cell or coin batteries, such as "button cell or coin battery" and "consumer product containing button cell or coin battery." Definitions related to battery package labeling are being finalized in a separate final rule.

C. Section 1263.3 Requirements for consumer products containing button cell or coin batteries

Final rule § 1263.3 incorporates by reference the requirements in UL 4200A-2023, approved on August 30, 2023, as the mandatory standard for performance and labeling of consumer products containing button cell or coin batteries. Sections 5 and 6 of UL 4200A-2023 contain performance requirements, and labeling requirements are in sections 7 and 8 of UL 4200A-2023. Tabs D and E of Staff's Final Rule Briefing Package, and Tables 3 and 4 in this preamble, describe the performance and labeling requirements in UL 4200A-2023 that are incorporated by reference.

V. Testing, Certification, and Notice of Requirements

Section 14(a) of the CPSA includes requirements for certifying that consumer products comply with applicable mandatory standards. 15 U.S.C. 2063(a). Section 14(a)(1) addresses required certifications for non-children's products, and sections 14(a)(2) and (a)(3) address certification requirements specific to children's products.

Non-Children's Products. Section 14(a)(1) of the CPSA requires every manufacturer (which includes importers per 15 U.S.C. 2052(a)(11)) of a non-children's product that is subject to a consumer product safety rule under the CPSA or a similar rule, ban, standard, or regulation under any other law enforced by the Commission to certify that the product complies with all

OS 58 DRAFT

applicable CSPSC-enforced requirements. 15 U.S.C. 2063(a)(1). Section 14(g) of the CPSA contains content and availability requirements for certificates. 15 U.S.C. 2063(g).

Children's Products. A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or younger." 15 U.S.C. 2052(a)(2). Section 4 of Reese's Law specifically exempts from the performance and labeling requirements in section 2 of the law, any toy product that is in compliance with the battery accessibility and labeling requirements in 16 CFR part 1250, the mandatory toy standard. However, all non-toy children's products that contain button cell or coin batteries are subject to the final rule and must be tested by a CPSC-accepted third party laboratory and certified as compliant.

The following factors are relevant when determining whether a product is a children's product:

- manufacturer statements about the intended use of the product, including a label on the product if such statement is reasonable;
- whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger;
- whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger; and
- the Age Determination Guidelines issued by CPSC staff in January 2020, and any successor to such guidelines.

Id. "For use" by children 12 years and younger generally means that children will interact physically with the product based on reasonably foreseeable use. 16 CFR 1200.2(a)(2). Children's products, for example, may be decorated or embellished with a childish theme, be sized for children, or be marketed to appeal primarily to children. *Id.* § 1200.2(d)(1).

OS 59 DRAFT

Section 14(a)(2) of the CPSA requires the manufacturer or private labeler of a children's product that is subject to a children's product safety rule to certify, based on a third party conformity assessment body's testing, that the product complies with the applicable children's product safety rule. 15 U.S.C. 2063(a)(2). The Commission's requirements for children's product testing and certification are codified in 16 CFR part 1107. Section 14(a) of the CPSA also requires the Commission to publish a notice of requirements (NOR) for a third party conformity assessment body (*i.e.*, testing laboratory) to obtain accreditation to assess conformity with a children's product safety rule. 15 U.S.C. 2063(a)(3)(A). Because some consumer products that contain button cell or coin batteries are children's products, the direct final rule incorporating by reference UL 4200A-2023 is a children's product safety rule, as applied to those products.

The Commission published a final rule, codified at 16 CFR part 1112, entitled *Requirements Pertaining to Third Party Conformity Assessment Bodies*, that established requirements and criteria concerning testing laboratories. 78 FR 15836 (Mar. 12, 2013). Part 1112 includes procedures for CPSC to accept a testing laboratory's accreditation and lists the children's product safety rules for which CPSC has published NORs. When CPSC issues a new NOR, it must amend part 1112 to include that NOR. CPSC did not receive any comments regarding the proposed NOR. Accordingly, this DFR amends part 1112, as proposed, to add the "Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries" to the list of children's product safety rules for which CPSC has issued an NOR.

Testing laboratories that apply for CPSC acceptance to test whether children's products containing button cell or coin batteries comply with the new rule will have to meet the requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted third party conformity assessment body, the laboratory can apply to CPSC to include 16 CFR part

OS 60 DRAFT

1263, *Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries*, in the laboratory's scope of accreditation of CPSC safety rules listed on the CPSC website at: www.cpsc.gov/labsearch.

VI. Incorporation by Reference

Section 1263.2 of the direct final rule incorporates by reference UL 4200A-2023. In accordance with regulations of the Office of the Federal Register (OFR), 1 CFR 51.5(b), section IV of this preamble, Commission Determination Regarding UL4200A-2023 and Description of the Final Rule's Requirements, summarizes the provisions of UL 4200A-2023 that the Commission incorporates by reference into 16 CFR part 1263. The standard is reasonably available to interested parties in several ways. You may purchase a copy from Underwriters Laboratories, Inc (UL), 333 Pfingsten Road, Northbrook, IL 60062, or through UL's Web site: <u>www.UL.com</u>. Before incorporation by reference, a read-only copy of UL 4200A-2023 is available for viewing on UL's website at: https://www.shopulstandards.com/. After CPSC incorporates the UL standard, a free, read-only copy is also available at: <u>https://www.ulstandards.com/IBR/logon.aspx</u>. Finally, interested parties can schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone: 301-

504-7479; email: cpsc-os@cpsc.gov.

VII. Direct Final Rule Process and Effective Dates

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551-559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency "for good cause finds" that notice and comment are "impracticable, unnecessary, or contrary to the public interest." *Id.* 553(b)(B).

OS 61 DRAFT

Reese's Law states that if the Commission determines that an already-effective voluntary standard meets the requirements in section 2(a) of Reese's Law before promulgating a final rule implementing those same requirements, then the voluntary standard shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058) effective on the date of the Commission's determination, which must be published in the *Federal Register*. 15 U.S.C. 2056e(d)-(e).

The purpose of this direct final rule is to codify in the Code of Federal Regulations the requirements in UL 4200A-2023 as the mandatory standard as for consumer products containing button cell or coin batteries, by incorporating by reference UL 4200A-2023. Although the Commission provided notice and collected comment on similar requirements in the NPR, Reese's Law does not require a rulemaking if the Commission makes a favorable determination on a voluntary standard; therefore, once the Commission makes the determination under section 2(d) with regard to UL 4200A-2023, the voluntary standard is treated as a consumer product safety rule. Accordingly, additional public comments would not lead to substantive changes to the direct final rule. Under these circumstances, notice and comment are unnecessary.

In Recommendation 95-4, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are noncontroversial and that are not expected to generate significant adverse comments. *See* 60 FR 43108 (Aug. 18, 1995). ACUS recommends that agencies use the direct final rule process when they act under the "unnecessary" prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 14 days of this notification, the direct final rule will become effective 30 days after publication, on [INSERT DATE 30

OS 62 DRAFT

DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] (subject to a transitional period of enforcement discretion as stated at [WEB LINK]). In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be "one where the commenter explains why the rule would be inappropriate," including an assertion that undermines "the rule's underlying premise or approach" or a showing that the rule "would be ineffective or unacceptable without change." 60 FR 43108, 43111. As noted, this rule codifies in the CFR a consumer product safety rule created by statute now that the Commission has made a determination under section 2(d) of Reese's Law. 15 U.S.C. 2056e(d).

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule.

Section 14(a)(3)(A) of the CPSA, however, requires that certification to an NOR is not effective until 90 days after publication of an NOR. 15 U.S.C. 2063(a)(3)(A). Accordingly, to provide the mandatory period for third party laboratories to become ISO accredited and CPSCaccepted to perform testing to part 1263, third party testing and certification of children's products subject to this rule is not required until on or after [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

VIII. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment" and therefore do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c)(1). Safety standards providing performance and labeling

OS 63 DRAFT

requirements for consumer products containing button cell or coin batteries fall within this categorical exclusion.

IX. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601-612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* Although the Commission prepared an Initial Regulatory Flexibility Act analysis for the NPR to implement Reese's Law and a Final Regulatory Flexibility Act analysis (*see* Tab F of Staff's Final Rule Briefing Package) that provides information for the public, the Commission's determination under section 2(d) of Reese's Law, 15 U.S.C. 2056e(d), that UL 4200A-2023 meets the performance and labeling requirements of section 2(a) of Reese's Law, 15 U.S.C. 2056e(a), does not require notice and comment rulemaking. Because the Commission has determined that notice and the opportunity to comment are unnecessary for this DFR to codify UL 4200A-2023 as the mandatory standard for consumer products containing button cell or coin batteries, the RFA does not apply with respect to the subject matter of this rule.

X. Paperwork Reduction Act

This DFR contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3521). Under the PRA, an agency must publish the following information:

- A title for the collection of information;
- A summary of the collection of information;

OS 64 DRAFT

- A brief description of the need for the information and the proposed use of the information;
- A description of the likely respondents and proposed frequency of response to the collection of information;
- An estimate of the burden that will result from the collection of information; and
- Notice that comments may be submitted to OMB.

44 U.S.C. 3507(a)(1)(D). In this DFR, the Commission is amending the collection of information for children's products to add the burden associated with performance and labeling requirements of the final rule, and is establishing an OMB control number for testing, certification, and paperwork retention requirements for general use, non-children's products subject to this final rule. The Commission proposed to amend the children's product collection in the NPR (88 FR 8717), and issued a separate *Federal Register* notice to collect comment on the estimated burden for testing and certification of non-children's products. 88 FR 21652 (April 11, 2023). In accordance with the PRA's requirements, the Commission provides the following information:

Title: (1) Amendment to Third Party Testing of Children's Products, approved previously under OMB Control No. 3041-0159 and (2) creation of new collection for Testing and Labeling of Non-Children's Products Containing or Designed to Use Button Cell or Coin Batteries and Labeling of Button Cell or Coin Battery Packaging.¹⁶

Type of Review: Amendment of existing collection for Third Party Testing of Children's Products, and creation of a new collection of information for testing and labeling of non-children's products containing or designed to use button cell or coin batteries and labeling of

¹⁶ The Commission is finalizing requirements for the labeling of button cell or coin battery packaging in a separate *Federal Register* notice, but for convenience, consistency with the IRFA, and clarity to stakeholders, we include the PRA requirements for all non-children's products subject to performance or labeling requirements for button cell or coin batteries in this single PRA analysis.

OS 65 DRAFT

button cell or coin battery packaging. Both children's and non-children's products subject to this rule require: (1) testing of products containing or designed to use button cell or coin batteries, including creating a certificate of conformity; however, unlike non-children's products, children's products require third party testing by a laboratory whose accreditation has been accepted by CPSC to conduct such testing; (2) labeling requirements for products and for button cell or coin battery packaging, including, as applicable, warnings on battery compartments, product packaging, accompanying written materials (*i.e.*, instructions, manuals, hangtags, or inserts)); and (3) recordkeeping requirements.

Summary, Need, and Use of Information: Based on the requirements in Reese's Law, 15 U.S.C. 2056e(a) and (b), the proposed consumer product safety standard prescribes performance requirements for child-resistant battery compartments on consumer products, including children's and non-children's products, that contain button cell or coin batteries, and warning requirements for button cell and coin-battery packaging, consumer product packaging, consumer products, and instructions and manuals. These performance and labeling requirements are intended to reduce or eliminate injuries and deaths associated with children six years old and younger ingesting button cell or coin batteries.

<u>Children's Products</u>: Section 4 of Reese's Law specifically exempts from the performance and labeling requirements in section 2 of the law, any toy product¹⁷ that is in compliance with the battery accessibility and labeling requirements in 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys. However, some consumer products that are not toys subject to the toy standard are considered children's products. A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or

¹⁷ For purposes of Reese's Law, a "toy product" is "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." Notes to 15 U.S.C. 2056e.

OS 66 DRAFT

younger." 15 U.S.C. 2052(a)(2). The Commission's regulation at 16 CFR part 1200 further interprets the term. Section 14 of the CPSA requires that children's products be tested by a third party conformity assessment body, and that the manufacturer of the product, including an importer, must issue a children's product certificate (CPC). Based on such third party testing, a manufacturer or importer must attest to compliance with the applicable consumer product safety rule by issuing the CPC. The requirement to test and certify children's products falls within the definition of "collection of information," as defined in 44 U.S.C. 3502(3).

The requirements for the CPCs are stated in section 14 of the CPSA, and in the Commission's regulation at 16 CFR parts 1107 and 1110. Among other requirements, each certificate must identify: the manufacturer or private labeler issuing the certificate; any third party conformity assessment body on whose testing the certificate depends; the date and place of manufacture; the date and place where the product was tested; each party's name, full mailing address, and telephone number; and contact information for the individual responsible for maintaining records of test results. The certificates must be in English. The certificates must be furnished to each distributor or retailer of the product and to the CPSC, if requested.

The Commission has an OMB control number, 3041-0159, for children's product testing and certification. This final rule would amend this collection of information to add testing and certification to the performance requirements for child-resistant battery compartments on children's products (that are not toys) that contain button cell or coin batteries, as well as warnings on the packaging of these children's products, the battery compartment of these children's products, and any accompanying instructions and manuals, as set forth in the rule. The Commission did not receive any comment on the NPR's estimated PRA burden for children's products subject to this rule. The requirements in UL 4200A-2023 are materially similar to the NPR requirements and do not change the Commission's PRA burden analysis.

OS 67 DRAFT

Accordingly, CPSC has submitted the information collection requirements of this final rule for children's products containing button cell or coin batteries to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d).

<u>Non-Children's Products</u>: This collection of information is solely for non-children's consumer products, meaning (1) performance and labeling requirements for products that contain or are designed to use button cell or coin batteries and *are not* designed or intended primarily for children 12 years old or younger, and (2) labeling of packages containing button cell or coin batteries. 15 U.S.C. 2052(a)(2); 16 CFR part 1200. Section 14(a) of the CPSA requires that manufacturers (including importers) of non-children's products subject to a rule issue a general certificate of conformity (GCC).

GCCs certify the products as being compliant with applicable regulations and must be based on a test of each product or a reasonable testing program. Unlike children's products, products that have GCCs are not required to undergo third party testing. Section 14(g) and 16 CFR part 1110 state the requirements for GCCs. Among other requirements, each certificate must identify: the manufacturer issuing the certificate; any laboratory conducting testing on which the certificate depends; the date and place of manufacture; the date and place where the product was tested; each party's name, full mailing address, and telephone number; and contact information for the individual responsible for maintaining records of test results. The certificates must be in English. The certificates must be furnished to each distributor or retailer of the product and to the CPSC, if requested.

CPSC received nine comments in response to the estimated PRA burden for nonchildren's products. Based on the comments, CPSC is increasing the estimated PRA burden as described in this section of the preamble, and will submit these revised estimates to OMB for review.

OS 68 DRAFT

Respondents and Frequency: Respondents include manufacturers and importers of nontoy children's products and non-children's products that contain, or are designed to use, button cell or coin batteries. Manufacturers and importers must comply with the information collection requirements when children's and non-children's products that contain button cell or coin batteries are manufactured or imported after the effective date of the rule.

Estimated Burden: CPSC has estimated the respondent burden in hours, and the estimated labor costs to the respondent.

Estimate of Respondent Burden for Non-Toy Children's Products: The hourly reporting burden imposed on firms that manufacture or import non-toy children's products that contain button cell or coin batteries include the time and cost to maintain records related to third party testing, the time to issue a CPC, and the time to include required warning labels on children's product battery compartments, children's product packaging, and to update instructions or manuals with required warnings.

Burden Type	Total Annual	Length of	Annual Burden
Burden Type	Responses	Response	(hours)
Third-party testing, recordkeeping and record	6,046	5.0 hours	30,230
maintenance			
Certification and labeling	1,209	1.0 hours	1,209
Total Burden			31,439

 Table 5: Children's Products Estimated Annual Reporting Burden.

Three types of third party testing of children's products are required: certification testing, material change testing, and periodic testing. Manufacturers must conduct sufficient testing to ensure that they have a high degree of assurance that their children's products comply with all applicable children's product safety rules before such products are introduced into commerce. 16 CFR § 1107.20(a). If a manufacturer conducts periodic testing, they are required to keep records that describe how the samples of periodic testing are selected. 16 CFR §§ 1107.21 and

.26.

OS 69 DRAFT

CPSC estimates that 0.4 percent of all children's products sold annually, or 6,046 children's products, are children's products that contain button cell or coin batteries and would be subject to third-party testing under this rule; for each of which 5.0 hours of recordkeeping and record maintenance will be required. Thus, the total hourly burden of the recordkeeping associated with certification is 30,230 hours ($5.0 \times 6,046$). Additionally, battery compartments, product packaging, and instructions and manuals must be updated to include the required warnings statements. We estimate that the time required to make these modifications is about 1 hour per product. Based on an evaluation of a sample of supplier product lines, there are a total of 1,209 affected products; therefore, the estimated burden associated with warnings and labeling is 1,209 hours.

We estimate the hourly compensation of workers in industries that will have PRArelevant burden imposed by this collection is \$36.80 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," Sept. 2022, total compensation for all sales and office workers in goods-producing private industries: https://www.bls.gov/news.release/archives/ecec_ 12152022.pdf). Therefore, the estimated annual cost to industry associated with the collection burden for non-toy children's products is \$1,156,955 (\$36.80 per hour x 31,439 hours = \$1,156,955.2). No operating, maintenance, or capital costs are associated with the collection.

This estimate is the largest burden reasonably possible, assuming that every manufacturer had to modify three product labels (battery compartment, packaging, and instructions/manual). However, many non-toy children's products that contain button cell or coin batteries already contain some type of warning on the product or product packaging. Accordingly, product modification for warnings and any associated burden could be much lower than the estimate.

Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons

OS 70 DRAFT

in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." To the extent that warning statements on one or more battery compartments, product packaging, and instructions/manuals are usual and customary for non-toy children's products that contain button cell or coin batteries, CPSC can estimate that no burden hours are associated with the labeling requirements in the proposed rule. We requested comment on this potential estimate of no burden for warning labels and received no comment with regard to children's products. The largest possible burden estimate for warning labels for children's products stated in the NPR was 1,209 hours at a cost of \$44,491 annually. However, because we received no contrary comment on the estimate of no burden for children's products, CPSC relies on the "usual and customary" exception and finalizes an estimate of no burden.

Estimate of Respondent Burden for Non-Children's Products: The PRA *Federal Register* notice (88 FR 21652) estimating the hourly reporting burden imposed on firms that manufacture or import non-children's products that contain button cell or coin batteries, and firms that manufacture or import button cell or coin batteries, included the time and cost to create and maintain records related to testing of consumer products (including issuing a GCC), as well as product labeling, including required warning labels on, as applicable, consumer product battery compartments, product packaging, and accompanying written materials (*i.e.*, instructions, manuals, inserts, or hangtags).

Though data provided by commenters are helpful, commenters have compared one-time burden estimates to annual respondent burden calculated by CPSC. CPSC assumes suppliers will continue to introduce products on a rolling basis, and that up-front costs will diminish over time.

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OS 71 DRAFT

Based on the comments, however, the Commission has revised the estimated burden. We have removed estimates for point-of-sale notices, including for websites offering the sale of button cell or coin batteries, because this requirement is not being adopted at this time. However, based upon the comments received (Comment 38 in section III of this preamble), CPSC is adjusting the burden estimates upward, as shown in Table 6. Additionally, CPSC adopts a higher wage rate to represent total compensation costs for private industry workers in goods producing industries.¹⁸

Burden type	Respondents	Frequency of	Hours per	Annual burden	Annual burden
		response	response	(hours)	(costs)
Labeling	abeling 15,363		1	30,726	\$1,332,586.62
		3	1.25	57,611.25	2,513,002.72
Testing	15,363	2	3	92,178	\$3,997,759.86
		3	3.5	161,311.5	7,036,407.63
Recordkeeping	15,363	2	1	30,726	\$1,332,586.62
		3	1.25	57,611.25	2,513,002.72
Total Burden				153,630	\$6,662,933.10
				276,534	\$12,062,413.10

Table 6. Estimated Annual Respondent Burden (Revisions in bold, italics)

CPSC staff used establishment data from the U.S. Census Bureau by NAICS code to estimate the number of entities with at least one product subject to the rule. Then, weights were assigned to each NAICS sector to estimate both the duration of the required response as well as the estimated average number of responses. *See* Table 7. Additionally, CPSC staff obtained estimates from testing laboratories on the costs of certification testing. For non-children's products, CPSC assumes that firms will test in-house or send the product to a lab for testing, but not both. Children's products (that are not toys) subject to the rule must be third party tested by a CPSC-accepted laboratory. According to information collected, the cost of third-party testing varies but is consistent with an estimate of \$261.72 per response ($$12,62,413.10 \div 3$ responses \div 15,363 respondents = \$261.72).

¹⁸ The March 2023 hourly total compensation costs for private industry workers in goods producing industries is \$43.62, according to the U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation (https://www.bls.gov/news.release/archives/ecec_06162023.pdf).

OS 72 DRAFT

	Table 7. Estimates by NAICS S	1		
NAICS		Industry	Estimated	Estimated
Code		Weight	PRA Hours	Number of
				Responses
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	0.035099	8	4
334290	Other Communications Equipment Manufacturing	0.020788	8	4
334310	Audio and Video Equipment Manufacturing	0.029919	8	4
335210	Small Electrical Appliance Manufacturing	0.003445	8	4
335912	Primary Battery manufacturing	0.005116	8	4
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	0.023391	8	4
339920	Sporting and Athletic Goods Manufacturing	0.061625	2	1
339940	Office Supplies (except Paper) Manufacturing	0.005479	2	1
339999	All Other Miscellaneous Manufacturing	0.037159	2	1
423420	Office Equipment Merchant Wholesalers	0.029336	2	1
423430	Computer and Computer Peripheral Equipment and Software Merchant Wholesalers	0.38266	8	4
423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers	0.131072	4	2
423690	Other Electronic Parts and Equipment Merchant Wholesalers	0.117874	8	4
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	0.060731	2	1
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	0.056308	2	1

Table 7. Estimates by NAICS Sector

Labor Cost of Respondent Burden for Non-Toy Children's Products. According to the

U.S. Bureau of Labor Statistics (BLS), Employer Costs for Employee Compensation, the total compensation cost per hour worked for all private industry workers in goods-producing industries was \$43.62 (March 2023, https://www.bls.gov/news.release/archives/ecec_ 06162023.pdf). Based on this analysis, CPSC estimates that labor cost of respondent burden would impose a cost to industry of approximately \$12,062,413 annually (276,534 hours as stated in Table $6 \times 43.62 per hour = \$12,062,413.08).

Cost to the Federal Government. The estimated annual cost of the information collection requirements to the Federal Government is approximately \$4,448, which includes 60 staff hours to examine and evaluate the information, as needed, for Compliance activities. This is based on a GS-12, step 5 level salaried employee; the average hourly wage rate for a mid-level salaried GS-12 employee in the Washington, DC metropolitan area (effective as of January 2023) is \$51.15 (GS-12, step 5). This represents 69.0 percent of total compensation (U.S. Bureau of

OS 73 DRAFT

Labor Statistics, "Employer Costs for Employee Compensation," September 2022, Table 2., percentage of wages and salaries for all civilian management, professional, and related employees: https://www.bls.gov/news.release/archives/ecec_12152022.pdf). Adding an additional 31.0 percent for benefits brings average annual compensation for a mid-level salaried GS-12 employee to \$74.13 per hour. Assuming that approximately 60 hours will be required annually, this results in an annual cost of \$4,448 (\$74.13 per hour × 60 hours = \$4,447.8).

CPSC has submitted the information collection requirements of this final rule for both children's and non-children's products to OMB for review in accordance with PRA requirements. 44 U.S.C. 3507(d).

XI. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the Federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances.

Section 2(a) of Reese's Law requires the Commission to issue a "consumer product safety standard for button cell or coin batteries and consumer products containing button cell or coin batteries." However, if the Commission makes a determination under section 2(d) of Reese's Law, determining that an existing voluntary standard meets the requirements in section 2(a) of Reese's Law, section 2(e)(1) of Reese's Law states that such voluntary standard shall be treated as a consumer product safety standard promulgated under section 9 of the CPSA (15

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

OS 74 DRAFT

U.S.C. 2058). Therefore, the preemption provision of section 26(a) of the CPSA applies to all consumer products that fall within the scope of this DFR.

XII. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a "major rule." Pursuant to the CRA, OIRA designated this rule as not a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third-party conformity assessment body.

16 CFR Part 1263

Administrative practice and procedure, Consumer protection, Batteries, Consumer protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons discussed in the preamble, the Commission amends chapter II, subchapter B, of title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

OS 75 DRAFT

2. Amend § 1112.15 by adding paragraph (b)(55) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * * * (b) * * *

(55) 16 CFR part 1263, Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries.

* * * * *

3. Add part 1263 to read as follows:

PART 1263—SAFETY STANDARD FOR BUTTON CELL OR COIN BATTERIES AND CONSUMER PRODUCTS CONTAINING SUCH BATTERIES

Sec.

1263.1 Scope, purpose, effective date, and exemption.

1263.2 Definitions.

1263.3 Requirements for consumer products containing button cell or coin batteries.

Authority: 15 U.S.C. 2052, 2056e.

§ 1263.1 Scope, purpose, effective date, and exemption.

(a) *Scope and purpose*. As required by Reese's Law (15 U.S.C 2056e, Public Law 117-171), this part establishes performance and labeling requirements for consumer products containing button cell or coin batteries to prevent child access to batteries during reasonably foreseeable use and misuse of the consumer product. The rule is intended to eliminate or adequately reduce the risk of injury and death to children 6 years old and younger from ingesting these batteries. This part also establishes warning label requirements for packaging of consumer products containing

OS 76 DRAFT

button cell or coin batteries, these consumer products, and instructions and manuals accompanying these consumer products.

(b) *Effective date*. Except as provided in paragraph (c) of this section, all consumer products containing button cell or coin batteries subject to the rule that are manufactured or imported after [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*] must comply with the requirements of this part.

(c) *Exemption for toy products*. Any object designed, manufactured, or marketed as a plaything for children under 14 years of age that is in compliance with the battery accessibility and labeling requirements of 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys, is exempt from the requirements of this part.

(d) *Batteries that do not present an ingestion hazard*. Button cell or coin batteries that the Commission has determined do not present an ingestion hazard are not subject to this rule. These are: zinc-air button cell or coin batteries.

§ 1263.2 Definitions.

In addition to the definitions given in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) and section 5 of Reese's Law (Notes to 15 U.S.C. 2056e), the following definitions apply for purposes of this part:

Button cell or coin battery means: (1) a single cell battery with a diameter greater than the height of the battery; or (2) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard.

Consumer product containing button cell or coin batteries means a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately.

OS 77 DRAFT

Ingestion hazard means a hazard caused by a person swallowing or inserting a button cell or coin battery into their body whereby: (1) the button cell or coin battery can become lodged in the digestive tract or airways; and (2) can potentially cause death or serious injury through choking, generation of hazardous chemicals, leaking of hazardous chemicals, electrical burns, pressure necrosis, or other means.

§ 1263.3 Requirements for consumer products containing button cell or coin batteries.

Each consumer product containing button cell or coin batteries shall comply with ANSI/UL 4200A, *Standard for Safety for Products Incorporating Button Batteries or Coin Cell Batteries,* approved on August 30, 2023. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the U.S. Consumer Product Safety Commission and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: cpsc-os@cpsc.gov. For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. A free, read-only copy of the standard is available for viewing on UL's website at https://www.ulstandards.com/IBR/logon.aspx. You may also obtain a copy from Underwriters Laboratories, Inc (UL), 333 Pfingsten Road, Northbrook, IL 60062, or through UL's Web site: www.UL.com.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

OS 78 DRAFT

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1263

[CPSC Docket No. 2023-0004]

Revision to Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: In February 2023, as required by Reese's Law, the U.S. Consumer Product Safety Commission (CPSC or Commission) issued a notice of proposed rulemaking (NPR) to establish performance and labeling requirements for consumer products containing button cell or coin batteries, and requirements for labeling of button cell or coin battery packages, to eliminate or adequately reduce the risk of injury from ingestion of button cell or coin batteries by children six years old and younger. In a separate *Federal Register* notice, the Commission is publishing a direct final rule to incorporate by reference a voluntary standard as the mandatory standard for consumer products containing button cell or coin batteries. The Commission issues this final rule to complete Reese's Law requirements for warning labels on the packaging of button cell or coin batteries. Button cell or coin battery packaging subject to this final rule must be certified as compliant with these warning label requirements.

DATES: Button cell or coin battery packaging manufactured or imported after [INSERT DATE 1 YEAR AFTER PUBLICATION IN THE *FEDERAL REGISTER*] must comply with this final rule.

OS 79 DRAFT

FOR FURTHER INFORMATION CONTACT: William Cusey, Small Business

Ombudsman, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone 301-504-7945; email: sbo@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority¹

On February 9, 2023, pursuant to Reese's Law (Pub. L. No. 117-171, 15 U.S.C. 2056e), the Commission published an NPR to establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries. 88 FR 8692. Consistent with section 2(a) of Reese's Law, the NPR proposed performance and labeling requirements for consumer products containing button cell or coin batteries² and labeling requirements for button cell and coin battery packaging. 15 U.S.C. 2056(a).

CPSC received 38 comments during a 30-day comment period ending in March 2023; four of the comments were duplicates. CPSC received two late-filed comments; one is out-ofscope for this rulemaking. We also received nine comments in response to an April 11, 2023 Paperwork Reduction Act (PRA) notice. 88 FR 21652. Most of the public comments concerned performance and labeling requirements for consumer products, which are addressed in a separate direct final rule establishing 16 CFR part 1263. That direct final rule incorporates by reference ANSI/UL 4200A, *Standard for Safety for Products Incorporating Button Batteries or Coin Cell Batteries*, approved on August 30, 2023 (UL 4200A-2023), as the mandatory standard for consumer products containing button cell or coin batteries.

¹ To implement requirements in Reese's Law for labeling of button cell or coin battery packaging, on September X, 2023, the Commission voted (x-x) to publish this final rule.

² The Notes of Reese's Law, 15 U.S.C. 2056e, define the phrase "consumer product containing button cell or coin batteries" as "a consumer product containing or designed to use one or more button cell or coin batteries, regardless of whether such batteries are intended to be replaced by the consumer or are included with the product or sold separately."

OS 80 DRAFT

UL 4200A-2023 does not contain warning label requirements for button cell or coin battery packaging. Accordingly, in this notice, pursuant to section 2(a)(2)(A) and 2(b) of Reese's Law, we review and respond to the public comments related to warning labels for packaging of button cell or coin batteries and finalize a rule for such warning labels. 15 U.S.C. 2056e(a)(2)(A) and (b). As explained in section I.D of this preamble, based on the comments, the final rule contains several modifications to requirements for battery package labeling from the NPR.³

A. Reese's Law

President Biden signed Reese's Law on August 16, 2022. 15 U.S.C. 2056e. The purpose of Reese's Law is to protect children six years old and younger against hazards associated with the ingestion of button cell or coin batteries during reasonably foreseeable use or misuse conditions. 15 U.S.C. 2056e(a)(1). Section 5 of Reese's Law broadly defines a "button cell or coin battery" as "(A) a single cell battery with a diameter greater than the height of the battery; or (B) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard."^{4, 5} Notes to 15 U.S.C. 2056e.

Section 2(a)(2) of Reese's Law mandates that the Commission establish, by rulemaking, warning label requirements for consumer products containing button cell or coin batteries, and for packaging of button cell or coin batteries. The warning labels required by section 2(a)(2) of

³ The information in this final rule is based on information and analysis provided in the August 31, 2023, Staff Briefing Package: Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's Final Rule Briefing Package), available at: insert link, and on the January 11, 2023, Staff Briefing Package: Draft Proposed Rule to Establish a Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries (Staff's NPR Briefing Package), available at: https://www.cpsc.gov/s3fs-

public/Notice of Proposed Rule making Safety Standard and Notification Requirements for Button Cellor Coin Batteries and Consumer Products Containing Such Batteries.pdf? Version Id=kDinNeydktkt3T8RRtzN4u1GTXPRjpEl.

⁴ The definitions in section 5 of Reese's Law are codified in the Notes to 15 U.S.C. 2056e.

⁵ This final rule focuses on addressing button cell and coin batteries under part (A) of the definition because other batteries where the diameter is less than the height, such as AAA cylindrical batteries, do not pose the same type or degree of ingestion hazard as button cell or coin batteries.

OS 81 DRAFT

Reese's Law must (1) clearly identify the hazard of ingestion, and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice. 15 U.S.C. 2056e(b).

In a companion rulemaking notice, the Commission determines that UL 4200A-2023 meets the performance and labeling requirements of section 2(a) of Reese's Law, and issues a direct final rule to incorporate by reference UL 4200A-2023 as the mandatory standard for consumer products containing button cell or coin batteries. As the scope of UL 4200A-2023 is on consumer products, it does not require the warnings mandated by Reese's Law for the packaging of button cell or coin batteries. 15 U.S.C. 2056e(a)(2)(A). Accordingly, we issue this final rule to establish warning label requirements for packaging of button cell or coin batteries to complete implementation of section 2 of Reese's Law.

Section 2(g) of Reese's Law provides that any time after the promulgation of a final consumer product safety standard under section 2(a), the Commission may initiate a rulemaking in accordance with 5 U.S.C. 553 to modify the requirements of the standard or revised standard. 15 U.S.C. 2056e(g). Any rule promulgated under section 2(g) of Reese's Law will also be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058). *Id*.

Section 3 of Reese's Law requires special packaging, meaning child-resistant packaging, for button cell or coin batteries. These requirements, codified in the Notes to 15 U.S.C. 2056e, are self-implementing, and do not require CPSC to issue a rule. Section 3 of Reese's Law was effective by operation of the statute on February 12, 2023.

Section 4 of Reese's Law, Notes to 15 U.S.C. 2056e, states that the special packaging requirements in section 3(a) do not apply with respect to button cell or coin batteries that are in

OS 82 DRAFT

compliance with the marking and packaging provisions of the ANSI Safety Standard for Portable Lithium Primary Cells and Batteries (ANSI C18.3M). This exemption does not apply to the requirements for battery package labeling in section 2 of Reese's Law, which this final rule implements.

B. Updated Incident Data

Based on information in the National Electronic Injury Surveillance System (NEISS), the NPR reflected staff's estimate that from 2011-2021, approximately 54,300 emergency room visits were associated with human ingestion, impaction, or insertion of button cell or coin batteries. The data show that these incidents occur most often with children aged 4 years or younger. Ingestion of a button battery has caused severe injuries and deaths: based on data in the Consumer Product Safety Risk Management System (CPSRMS), the NPR identified 25 fatalities from 2016 through 2021. 88 FR 8696-98.

Since the NPR, 2 additional deaths of children in the United States associated with ingestion of button or coin cell batteries have been added to the CPSRMS database, for the years 2020-2021. Moreover, reporting to CPSC through May 1, 2023, indicates another 5 more recent deaths of children–3 in 2022 and 2 in the first three months of 2023. Combining all reported deaths since 2011, CPSC staff has identified 32 reported deaths in the United States from button cell or coin battery ingestion for the period January 1, 2011 through March 31, 2023. *See* Tab B of Staff's Final Rule Briefing Package.

Additionally, Tab C of Staff's Final Rule Briefing Package updates incident data from the National Capital Poison Center (NCPC). Since the NPR, from June 2022 through May 2023, the NCPC reported 2 additional child deaths due to ingestion of button cell or coin batteries. Both cases were from lithium button cell or coin batteries impacted in the esophagus; one battery was impacted for 25 days, the other for 3 days. The children died of hematemesis and sepsis,

OS 83 DRAFT

respectively. This brings the total fatal cases tracked by NCPC to 71 since 1977. Also, since the NPR, from June 2022 through May 2023, NCPC reported 13 additional cases of severe injury from button cell or coin battery ingestion, bringing the total since 1977 to 280.

C. Description of Battery Packaging Labeling Requirements in the NPR

The NPR proposed a rule to address the battery ingestion hazard for children six years of age or younger. Children can potentially gain access to button cell or coin batteries from battery packaging and be exposed to the ingestion hazard. Six out of 119 fatal and nonfatal incident narratives in the CPSRMS refer to loose batteries or battery packaging hazards, and staff estimates that at least 7 percent of NEISS incidents involve loose batteries or batteries liberated from the packaging. Figure 1 shows examples of button cell or coin batteries that, when packaged, are subject to this final rule.

LR44 8++ 9-+ 5				
LR44 button cell, 11.6mm	LR754 button cell, 7.9 mm	LR626 button cell, 6.8 mm		
(0.45 inch) diameter x 5.4mm	(0.31 inch) diameter, 5.4mm	(0.26 inch) diameter, 2.6mm		
(0.21 inch) thick	(0.21 inch) thick	(0.10 inch) thick		
Lithium Cell CR2032 3V sc	Lithium Cell CR2D25 3V sc	Lithium Cell CR2450 3U Sc		
CR2032, 20mm	CR2025, 20mm	CR2450, 24mm		
(0.787 inch) diameter	(0.787 inch) diameter	(0.945 inch) diameter		

Figure 1. Example button cell and coin batteries.

The NPR assessed warnings requirements in several voluntary standards, and preliminarily concluded that none of the voluntary standards were adequate to meet the requirements in Reese's Law. Tab C of Staff's NPR Briefing Package. 88 FR 8704-05. Table 11 in the NPR summarizes the Commission's assessment of warnings requirements in voluntary standards for button cell and coin battery packaging, finding that none of the voluntary standards

OS 84 DRAFT

adequately address warnings on battery packaging in accordance with Reese's Law. 88 FR 8705.

Because none of the voluntary standards were deemed to meet the requirements in Reese's Law, the Commission proposed warnings requirements for button cell and coin battery packaging and packaging of batteries included separately with consumer products , explaining that labeling of button cell or coin battery packaging is intended to reduce the likelihood of loose batteries being liberated from these products and to warn caregivers of the battery ingestion hazards to children. 88 FR 8706-09. The proposed requirements followed the format requirements in ANSI Z535.4, *Product Safety Signs and Labels*, and were based on warnings found in ANSI C18.3M, ASTM F963, UL 4200A-2020, and other voluntary standards. *Id*.

The NPR also defined two terms relevant to placement of warning labels. The "principal display panel" is the display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package. The "secondary display panel" means a display panel for a retail package of a button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

The NPR proposed a warning for the principal display panel of the battery packaging, shown in Figure 2, to meet the requirements in section 2 of Reese's Law.

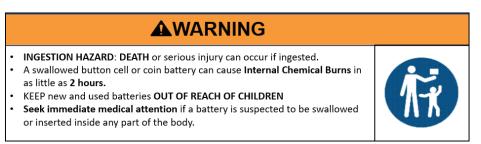


Figure 2. Warning of Ingestion Hazard for Battery Packaging.

OS 85 DRAFT

The NPR proposed that battery packaging include the following warning statements:

- **"INGESTION HAZARD: DEATH** or serious injury can occur if ingested." This sentence identifies the hazard of ingestion, as required by section 2(b)(1) of Reese's Law.
- "A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours." This sentence provides warning label requirements, as stated in Reese's Law; an effective warning should have an explanation of how and why ingestion of a button cell or coin battery is hazardous.
- "KEEP new and used batteries **OUT OF REACH OF CHILDREN**." This sentence implements language in section 2(b)(2) of Reese's Law. In addition, use of the icon recognized for keeping items out of children's reach is intended to quickly convey the required message and direct the reader's attention to the label.
- "Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body." This sentence implements language in section 2(b)(2) of Reese's Law and informs the consumer what actions should be taken if a button cell or coin battery is ingested or inserted into any part of the body. The warning includes the term "inserted" because insertions into the nose can be aspirated into the trachea and lead to ingestion, with the same risk of injury as oral ingestion.

The NPR proposed that the icon incorporated with the warning must be at least 8 mm (0.31 in.) in diameter for visibility, and that text size be calculated per Table 1 in the regulation text (Table 12 in the NPR preamble at 88 FR 8706). The NPR also stated that if space prohibits the full warning with the icon shown in Figure 2 in accordance with the formatting requirements of Table 1 of the regulation text, packaging is required to use the "Keep out of Reach" icon (Figure 3) on the principal display panel and the warning text must be placed on the secondary

OS 86 DRAFT

display panel, as shown in Figure 4. 88 FR 8707. The icon must be at least 20 mm (0.79 in.) in diameter for visibility.



WARNING INGESTION HAZARD • DEATH or serious injury can occur • A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours • KEEP new and used batteries OUT OF REACH OF CHILDREN • Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.

To address the hazard of button cell or coin batteries that become loose or separated from packaging, and to provide critical safety-related information should an ingestion incident occur, the NPR proposed that the following information implementing section 2(b)(2) of Reese's Law be placed on the secondary display panel of the packaging:

- "Keep in original package until ready to use." This statement instructs consumers to leave the batteries in child-resistant packaging as a means of keeping new batteries out of the reach of children.
- (2) "Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash." This statement instructs consumers on how to prevent ingestion hazards from used batteries by keeping used batteries out of the reach of children, including out of household trash.
- (3) "Call a local poison control center for treatment information." This statement makes more actionable the guidance to "immediately seek medical attention" as described in section 2(b)(2) of Reese's Law, and provides consumers with a resource for obtaining medical advice suitable to their situation.

88 FR 8707.

Figure 4. Warning Text Without Icon.

OS 87 DRAFT

D. Changes Adopted in the Final Rule

Based on the consideration of comments received and analysis in Staff's Final Rule Briefing Package, the labeling requirements for button cell or coin battery packaging are being finalized as proposed, with three modifications:

• *Warning label colors*: The final rule clarifies that specific colors on warning labels, in accordance with ANSI Z535, are required only if the label is present in more than one color, to allow flexibility in warning label designs and align with existing requirements in relevant voluntary standards.

• *Warning label letter size*: The final rule clarifies that the minimum text size for warning labels must be based on the product display panel size.

• *Treatment information*: To provide specific guidance to consumers on an available contact for treatment information, the final rule requires that button battery packaging display the National Battery Ingestion Hotline phone number. Additionally, the final rule replaces the warning statement "Call a local poison control center for treatment information" with the more actionable presentation of the National Battery Ingestion Hotline phone number.

E. Scope of Battery Packaging Subject to the Final Rule

This rule finalizes the warning label requirements for packaging of button cell or coin batteries, including batteries packaged separately with consumer products. Although section 4 of Reese's Law, Notes to 15 U.S.C. 2056e, states that the special packaging requirements in section 3(a) do not apply with respect to button cell or coin batteries that are in compliance with the marking and packaging provisions of the ANSI Safety Standard for Portable Lithium Primary Cells and Batteries (ANSI C18.3M), this exemption does not apply to the labeling requirements of this rule. Therefore, all packages of button cell or coin batteries that fall within the definition of a "button cell or coin battery," except batteries listed in §1263.1(d) (currently zinc-air

OS 88 DRAFT

batteries), must comply with the warning label requirements in this rule. Consistent with the NPR, the final rule does not require warning labels on zinc-air batteries. These requirements are consistent with ANSI C18.3M; battery packaging can comply with both the labeling requirements in ANSI C18.3M and this final rule.

F. Assessment of Labeling Requirements for Packaging of Button Cell or Coin Batteries in Existing Voluntary Standards

None of the voluntary standards addressing warning labels on button cell or coin battery packaging have been updated since publication of the NPR. Accordingly, and for the reasons further discussed in Part II below, the Commission adopts the NPR's assessment that no existing voluntary standard meets the warning label requirements that section 2 of Reese's Law establishes for battery packaging.

II. Comments on the NPR

Below we summarize and respond to the comments received in response to the NPR that relate to the proposed requirements for battery package labeling.

Comments in Response to Questions on Marking and Labeling Requirements

A. Whether all button cell or coin battery packaging should include the warning on the principal display panel.

Comment 1: Several commenters, including a coalition of medical and consumer organizations, the Battery Association of Japan (BAJ), Energizer, Duracell, Landsdowne Labs, National Electrical Manufacturers Association (NEMA), and the Consumer Technology Association (CTA), support warning labels on the packaging of button cell and coin battery packaging. The coalition of medical and consumer organizations and Duracell support the use of a conspicuous warning label on the principal display panel, whereas others (BAJ, Energizer, CTA, Information Technology Industry Council (ITI)) request flexibility in the warning label location and the placement of the "KEEP OUT OF REACH" icon, citing limitations of battery

OS 89 DRAFT

packaging size. Seven commenters support warning label placement as allowed by current voluntary standards, as such standards do not mandate the warning label location. BAJ suggests, however, that the icon be accompanied by the warning "KEEP OUT OF REACH" because the icon may not be well known.

Response 1: Reese's Law requires warning labels on the packaging of button cell or coin batteries and minimum content requirements. Existing voluntary standards (IEC 60086-4 &-5) do not set forth location requirements, or specify that warnings be on the back of the packaging (ANSI C18.3). Existing voluntary standards often do not specify the content of the warning label. While the use of an icon is permissible in voluntary standards, icon use is based on the diameter of the battery.

Consistent with Reese's Law and the ANSI standard, the final rule requires battery packaging to identify the hazard, explain how to avoid the hazard, and requires that warnings be conspicuous on the front of the packaging where it is more likely to be seen. The final rule requires a warning label on all button cell and coin battery packages within the scope of the rule, regardless of battery chemistry or battery size. The warning's content also outlines options for a condensed warning label in the form of an icon on the front with additional text to be placed on the back, to accommodate limited space on the battery packaging. The "KEEP OUT OF REACH" text is not required to accompany the icon; however, manufacturers may choose to include the text voluntarily to clarify the icon's meaning. The final rule does not include any changes to the warning on the front of the battery packaging as a result of these comments.

B. Whether the requirement for the "Keep Out of Reach" icon to be at least 20 mm in diameter for visibility purposes, when alone on the front of battery packaging, provides a sufficient warning of the ingestion hazard.

OS 90 DRAFT

Comment 2: Renata SA comments that the 6 mm minimum icon size requirements in the IEC 60086-4 voluntary standard are adequate. BAJ commented that the icon sizes of minimum 20 mm and minimum 8 mm are not necessary because "based on the market results so far" a minimum size of 6 mm icon is sufficient.

Response 2: We do not have the details of the "market results so far" that BAJ references to determine whether the 6 mm icon is sufficiently attention-getting for consumers, recognized by consumers, and adhered to by industry. Based on an evaluation of existing battery packaging, staff assesses in Tab D of Staff's Final Rule Briefing Package that the recommended sizes of icons in the proposed rule are feasible and likely to get the attention of the consumer. After reviewing a number of battery packages, staff advises that the 20 mm diameter icon is sufficiently large to be visible to most consumers, and sufficiently small to fit on existing battery packaging. The final rule contains no changes in response to these comments.

C. Whether the Commission should require ingestion warnings on zinc-air button cell or coin battery packaging.

Comment 3: Three commenters (Duracell, Energizer, and NEMA) agree that warning labels on zinc-air batteries are not needed regarding the ingestion hazard, citing low risk of injury. Landsdowne Labs Inc., a coalition of medical and consumer organizations, and Dr. Ian Jacobs (Director at the Center for Pediatrics Airway Disorders at the Children's Hospital of Philadelphia) support warning labels on packaging for zinc-air batteries, because they pose an insertion hazard. BAJ states that labeling on zinc-air batteries should be a recommendation, rather than a requirement, and that if zinc-air batteries are labeled, then they should use the word CAUTION instead of WARNING. Dr. Jacobs and Dr. Jatana (Director of Pediatric Otolaryngology in the Department of Otolaryngology Head and Neck Surgery at Nationwide Children's Hospital and Wexner Medical Center at Ohio State University) state that zinc-air

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OS 91 DRAFT

batteries pose a risk of injury when inserted into the ear canals and nasal cavities, and should be labeled accordingly.

Response 3: Tab C of Staff's Final Rule Briefing Package reviews the literature and the incident data regarding ingestion of zinc-air batteries. Staff advises that labeling of zinc-air batteries for an ingestion hazard is unnecessary, and may cause consumer confusion, because zinc-air batteries are not associated with an ingestion hazard.

D. Comments addressing silver-oxide battery chemistries.

Comment 4: CPHE, FH, AWA and Renata SA state that silver-oxide batteries should be excluded from a Commission rule implementing Reese's Law because of the lack of data on fatal incidents with these batteries and children's inability to access them from watches. Duracell states that silver-oxide batteries should contain different warnings than lithium batteries because they are lower voltage. Switzerland asks whether silver oxide batteries could be excluded from the rule.

Response 4: Based on the medical literature, staff does not recommend that silver-oxide batteries be removed from the scope of the final rule. As reviewed in Tab C of Staff's Final Rule Briefing Package, Jatana *et.al.* (2017) found in testing using an animal model that silver-oxide button or coin cell batteries caused severe esophageal injuries.

Comments in Response to Questions on Other Topics Posed in the NPR

E. Whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and to provide specific information to support such a later or an earlier effective date.

Comment 5: Commenters differed in their recommendations for an effective date, from the proposed 180 days (consumer advocates) to up to 3 years (manufacturer associations). Multiple manufacturers, trade associations, and Switzerland provided comments stating that a

OS 92 DRAFT

longer effective date is required to provide compliant products to the U.S. market. A few commenters provided detailed timelines of the necessary activities (product redesign, testing, certification sourcing, supply chain management, *etc.*), which ranged from 12 months to 36 months in total. A commenter also explained that additional time is required to accredit third party laboratories for a large variety of product types. Energizer and NEMA request that battery manufacturers be allowed to sell their existing stock of child-resistant packaging and labels that were purchased to comply with section 3 of Reese's Law.

Response 5: Arguments made by manufacturers for a longer effective date relate primarily to performance and labeling requirements for consumer products, and not to battery package labeling. For example, battery packaging is not a children's product that requires third party testing; manufacturers can self-certify compliance to labeling requirements. However, the Commission recognizes that warning label requirements may compel manufacturers to revise or reprint existing packaging, and manufacturers may want to consult outside laboratories regarding compliance. Nevertheless, changes to labeling of battery packaging does not require extensive product redesign. To provide time for battery manufacturers to comply with this final rule, the Commission is establishing an effective date of one year after publication in the *Federal Register*, the low end of the time frame sought by commenters for the NPR's proposals, generally.

F. Comments addressing the use of color in the requirements for marking and labeling.

Comment 6: Several commenters (JEITA, Duracell, Gramin, HCPS and CTA) state that the use of color on packing, instructions, or manuals, and on some consumer products would be challenging and, in most cases, add costs to the manufacturing and printing process, particularly to those materials that do not already incorporate color. Duracell and Technet also stress that

OS 93 DRAFT

other product safety standards (*e.g.*, ASTM F963, ANSI C18.3, or ANSI Z535 series) do not mandate the use of colors and accept black and white printing or contrasting colors to the background it is printed on. Commenters state, however, that if color is used for the signal panel, colors should conform to ANSI Z535.1 safety colors that correspond to the safety message. The Toy Association and RILA state that the use of color may not be reasonable for printing on certain product materials, for example, colored or textured plastics.

Response 6: Applying color to some materials (*e.g.*, consumer product packaging, manuals, or other collateral material) that do not already contain color may present a burden to some manufacturers. ANSI Z535.4 provides flexibility for special circumstances that limit the use of colors while preserving the visibility and noticeability of the label by requiring contrast. To address commenter concerns, the final rule requires the use of color when the subject materials already use printed color processing; otherwise, the use of either black and white or contrasting colors is acceptable. The use of color is not specified in Reese's Law, and with this modification the label or icon will visually align with other information on the display while still being noticeable due to its contrast or color.

G. Comments addressing text size, icons, and alternative symbols for marking and labeling.

Comment 7: Renata Batteries, ITI, The Toy Association, RILA, BAJ, and Duracell express cost concerns with increased packaging dimensions required to accommodate larger warning labels and font sizes, especially for small products. Another commenter states that the minimum letter size requirements for packaging warnings may reduce the prominence of other warnings on product packaging.

Response 7: The NPR proposed that font size requirements for both on-product and onpackaging warning labels be determined based on the size of the principal display panel (*e.g.*, the

OS 94 DRAFT

front face) of the package or the product display panel (*e.g.*, surface area on, near, or in the battery compartment). Reese's Law requires that warning labels clearly identify the hazard of ingestion, and this requirement is met when warning labels are displayed prominently on the principal display panel. For very large products or packages with principal display panels exceeding 400 inch², the required letter size could be larger than standard font sizes usually referenced in other standards. The required letter size in the final rule is proportional to the display panel size and allows easy visibility and noticeability of the label. The minimum letter size is otherwise comparable to font sizes in other standards, and therefore of similar prominence when displayed on the same panel. The largest packaging will have ample room for additional warnings that are of comparable size to the requirements in the final rule. This level of prominence is appropriate to inform consumers which products contain button cell or coin batteries and to adequately reduce the risk of injury from ingestion.

H. Whether the requirement to provide other information related to the safety of button cell or coin batteries is sufficient to address the risk of ingestion and other hazards associated with button cell or coin batteries.

Comment 8: One commenter (Billie Jo Burr) states that labeling should provide consumers with the nationwide poison control center phone number to ease the process of obtaining assistance quickly.

Response 8: We agree with the commenter that providing consumers with an appropriate contact phone number will provide an actionable step that will ease the process of obtaining assistance quickly if a caregiver suspects a button cell or coin battery ingestion. The National Battery Ingestion Hotline (NBIH) is dedicated solely to addressing battery ingestions, and is therefore an immediate and practical resource available to consumers who suspect a battery

OS 95 DRAFT

ingestion. The final rule adds the contact number for the NBIH, currently 1-(800) 498-8666, on the required warning labels for battery packaging.

Comments Addressing the Paperwork Reduction Act

Tab A of Staff's Final Rule Briefing Package and the companion direct final rule to establish in 16 CFR part 1263 a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, provide CPSC's final rule PRA burden estimate for battery package labeling, and summarize and respond to comments related to CPSC's PRA burden estimate in the NPR.

III. Description of the Final Rule

This final rule adds to 16 CFR part 1263 warning label requirements for packaging of button cell or coin batteries, including such batteries packaged separately with a consumer product. Primarily, the final rule adds § 1263.4, requirements for labeling of button cell or coin battery packaging. We also add several provisions in the scope and definitions to fully implement and explain the required warnings.

The final rule amends the last sentence in the NPR's proposed § 1263.1(a) to state that part 1263 establishes warning label requirements for "packaging of button cell or coin batteries, including button cell or coin batteries packaged separately with a consumer product," to ensure that the scope of the rule reflects requirements for battery package labeling. The final rule also amends § 1263.1(b) to add a one-year effective date for battery packaging labeling, as explained in section V of this preamble.

Final rule § 1263.2 adds two definitions for the "principal display panel" and the "secondary display panel." Section 1263.4 uses these definitions to explain requirements for the placement of battery package labeling.

OS 96 DRAFT

Final rule § 1263.4 adds requirements for warning labels for button cell or coin battery packaging, including for such batteries packaged separately with a consumer product. The NPR's warning label requirements are explained in section I.C of this preamble. They are being finalized with the three modifications explained in section I.D of this preamble.

IV. Testing, Certification, and Notice of Requirements

Section 14(a) of the CPSA includes requirements for certifying that consumer products comply with applicable mandatory standards. 15 U.S.C. 2063(a). Section 14(a)(1) addresses required certifications for non-children's products, and sections 14(a)(2) and (a)(3) address certification requirements specific to children's products. Packages of button cell and coin batteries are unlikely to ever be children's products and therefore do not require third party testing. Manufacturers can self-certify compliance with the labeling requirements in this final rule.

Section 14(a)(1) of the CPSA requires every manufacturer (which includes importers per 15 U.S.C. 2052(a)(11)) of a non-children's product that is subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other law enforced by the Commission, to certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a)(1). Section 14(g) of the CPSA contains content and availability requirements for certificates. 15 U.S.C. 2063(g).

V. Effective Date

The APA generally requires that the effective date of a rule must be at least 30 days after publication of a final rule. 5 U.S.C. 553(d). In the NPR, the Commission proposed that a final rule containing (1) performance and warning label requirements for consumer products containing button cell or coin batteries, and (2) warning label requirements for button cell or coin battery packaging, would become effective 180 days after publication of a final rule in the

OS 97 DRAFT

Federal Register. Section II.E of this preamble describes comments from multiple manufacturers and trade associations stating that a longer effective date is required to supply compliant products to the U.S. market. Commenters provided detailed timelines of the necessary activities to become compliant, including time for product redesign, testing, certification sourcing, supply chain management, and other issues, with the timeline ranging from 12 months to 36 months in total. A commenter also explained that additional time is required to accredit third party laboratories for a large variety of product types.

The Commission recognizes that the rule's warning label requirements may require manufacturers to revise or reprint existing packaging. However, battery packaging is not a children's product that requires third party testing. Manufacturers can self-certify compliance to labeling requirements. Also, changes to labeling of battery packaging do not require extensive product redesign; revising labeling on battery packaging will not require a lengthy timeframe. To provide time for battery manufacturers to comply with this final rule, the Commission establishes an effective date of one year after publication in the *Federal Register*, the low end of the time frame suggested by commenters with respect to the full set of requirements proposed in the NPR.

VI. Environmental Considerations

The Commission's regulations address whether the agency is required to prepare an environmental assessment or an environmental impact statement. Under these regulations, certain categories of CPSC actions normally have "little or no potential for affecting the human environment," and therefore, do not require an environmental assessment or an environmental impact statement. 16 CFR 1021.5(c)(1). Safety standards providing labeling requirements for packaging of button cell or coin batteries fall within this categorical exclusion.

OS 98 DRAFT

VII. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601-612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603, 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* However, a regulatory flexibility analysis is not required if an agency certifies that a rule will not have a significant impact on a substantial number of small businesses. Tab H of Staff's Final Rule Briefing Package contains an economic analysis for this final rule establishing labeling requirements for packaging of button cell or coin batteries. Based on the information in that analysis, the Commission certifies that this final rule will not have a significant impact on a substantial number of small businesses.

VIII. Paperwork Reduction Act

This final rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). For convenience and clarity to stakeholders, section XII of the preamble for the direct final rule, Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries, contains the PRA analysis for both rules implementing Reese's Law, including this rule addressing the labeling of packaging of button cell or coin batteries.

CPSC has submitted the information collection requirements of this final rule for button cell or coin battery package labeling to OMB for review in accordance with PRA requirements. *See* 44 U.S.C. 3507(d).

IX. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that when a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a standard or regulation that prescribes requirements for the performance, composition, contents, design, finish, construction, packaging, or labeling of such product dealing with the same risk of injury unless the state requirement is identical to the Federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances.

Section 2(a) of Reese's Law requires the Commission to issue a "consumer product safety standard for button cell or coin batteries and consumer products containing button cell or coin batteries," and section 2(c) of Reese's Law states that a consumer product safety standard promulgated under subsection (a) shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058). Therefore, the preemption provision of section 26(a) of the CPSA applies to all consumer products that fall within the scope of this final rule issued under section 2 of Reese's Law. 15 U.S.C. 2056e.

X. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a "major rule." Pursuant to the CRA, OIRA designated this rule as not a "major rule," as defined in 5 U.S.C. 804(2). To comply

OS 100 DRAFT

with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

List of Subjects

16 CFR Part 1263

Administrative practice and procedure, Consumer protection, Batteries, Consumer

protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

PART 1263—SAFETY STANDARD FOR BUTTON CELL OR COIN BATTERIES AND CONSUMER PRODUCTS CONTAINING SUCH BATTERIES

- The authority citation for part 1263 continues to read as follows:
 Authority: 15 U.S.C. 2052, 2056e.
- 2. Add the following section to the table of contents:

1263.4 Requirements for labeling of button cell or coin battery packaging.

3. Add the following sentence to the end of § 1263.1(a):

"Additionally, this part establishes warning label requirements for packaging of button cell or coin batteries, including button cell or coin batteries packaged separately with a consumer product."

4. Add the following sentence to the end of § 1263.1(b):

"Packages of button cell or coin batteries manufactured or imported after [INSERT DATE 1

YEAR AFTER PUBLICATION IN THE FEDERAL REGISTER] must meet the labeling

requirements for battery packaging in § 1263.4."

5. Add the following definitions to § 1263.2:

OS 101 DRAFT

Principal display panel means the display panel for a retail package of button cell or coin batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.

Secondary display panel means a display panel for a retail package of button cell or coin batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

6. Add the following section to part 1263:

§ 1263.4 Requirements for labeling of button cell or coin battery packaging.

(a) *General Requirements for labeling of button cell or coin battery packaging*. (1) All warning statements must be clearly visible, prominent, legible, and permanently marked.

(2) Warning statements must be in contrasting color to the background onto which the warning statement is printed.

(3) Warning statements must be in English.

(4) The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.

(5) The signal word "WARNING" and safety alert symbol must be in black letters on an orange background unless this would conflict with §1263.4(a)(1)-(2) or only one color is present, in which case, the signal word and safety alert symbol must contrast to the background on which they are printed. The signal word must appear in sans serif letters in upper case only.

OS 102 DRAFT

(6) Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels (Figure 1 to paragraph (b)(1) and Figure 3 to paragraph (b)(2)) to get the attention of the reader.

(7) For labels that are required to be on the packaging of button cell and coin batteries, text size must be dependent on the area of the principal display panel. Text size must be determined based on Table 1 to this paragraph (a)(7).

Letter size measurements in inches								
Letter size measurements in inches								
Display Area: Inches ²	0–2	+2-5	+5-10	+10-15	+15-30	+30–100	+100-400	+400
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32
Letter size measurements in cm (for reference only)								
Display Area: cm ²	0-13	+13-32	+32-65	+65-97	+97-194	+194-645	+645-2,581	+2,581
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397

Table 1 to Paragraph (a)(7)—Letter size for recommended warning labels.[Information based on 16 CFR part 1500.19(d)(7).]

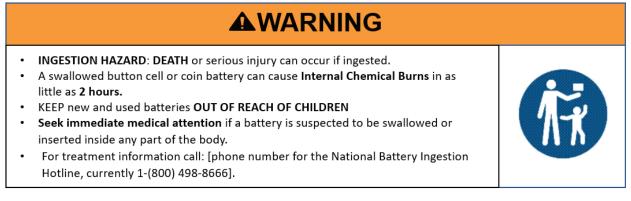
(b) Warning label requirements for button cell or coin battery packaging. (1) The principal

display panel of the packaging must include the warning label in Figure 1 to this paragraph

(b)(1). The icon must be at least 8 mm (0.3 inches) in diameter. The text must state the

following warnings as shown in Figure 1 to this paragraph (b)(1).

Figure 1 to Paragraph (b)(1)



(2) If space prohibits the full warning label shown in Figure 1 to paragraph (b)(1), place the

icon shown in Figure 2 to this paragraph (b)(2) on the principal display panel with the text shown

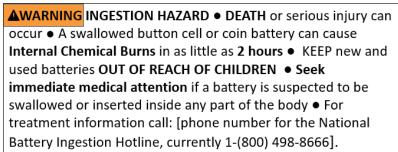
OS 103 DRAFT

in Figure 3 to this paragraph (b)(2) on the secondary display panel. The icon must be at least 20 mm in diameter. The text must state the following warnings as shown on Figure 3 to this paragraph (b)(2).

Figure 2 to Paragraph (b)(2)



Figure 3 to Paragraph (b)(2)



(3) The following safety-related statements must be addressed on the principal display panel

or secondary display panel:

(4) Keep in original package until ready to use.

(5) Immediately dispose of used batteries and keep away from children. Do NOT dispose of

batteries in household trash.

(6) For button cell or coin battery packaging included separately with a consumer product,

only paragraphs (b)(1) and (2) of this section apply.

Alberta E. Mills

Secretary, Consumer Product Safety Commission.

OS 104



Staff Briefing Package

Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

August 31, 2023

For additional information, contact:

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This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

Table of Contents

Briefing Memorandum	1
TAB A – Response to Comments	47
TAB B – Epidemiology	81
TAB C – Health Sciences	87
TAB D – Engineering Sciences, Human Factors	93
TAB E – Engineering Sciences, Mechanical Engineering	108
TAB F – Regulatory Flexibility Analysis	131
TAB G – Staff-Recommended Regulatory Text	144
TAB H – Small Business Economic Analysis	

Briefing Memorandum



Briefing Memorandum

TO:	The Commission Alberta E. Mills, Secretary	DATE: August 31, 2023
THROUGH:	Austin C. Schlick, General Counsel Jason Levine, Executive Director DeWane Ray, Deputy Executive Director for Operations	
FROM:	Duane E. Boniface, Assistant Executive Director, Office of Hazard Identification and Reduction	
	Daniel Taxier, Children's Program Manager, Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences	
SUBJECT:	Draft Final Rule: Safety Standard for Button Cell or Coin Batteries a Containing Such Batteries	and Consumer Products

I. Introduction

On February 9, 2023, the U.S. Consumer Product Safety Commission published a notice of proposed rulemaking (NPR) proposing to issue a safety standard and notification requirements for button cell or coin batteries and consumer products containing such batteries in accordance with Section 2 of Reese's Law, 15 U.S.C. § 2056e(a), as well as requirements for performance and technical data in accordance with section 27(e) of the Consumer Product Safety Act, 15 U.S.C. § 2076(e). 88 Fed. Reg. 8,692. Staff reviewed public comments responding to the NPR, and prepared recommendations for responses and a draft final rule with clarifications and modifications to the performance and labeling requirements that were proposed in the NPR, as summarized in section II.B of this memorandum. Simultaneously, in response to the NPR, UL Standards & Engagement (ULSE) hosted meetings of Technical Committee (TC) 4200 to revise ANSI/UL 4200A Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies (UL 4200A-2020). The resulting standard, ANSI/UL 4200A Standard for Safety for Products Incorporating Button on August 30, 2023 (UL 4200A-2023), incorporates many of the proposed requirements from the NPR, with modifications that are consistent with staff's draft final rule.

Staff recommends that the Commission determine UL 4200A-2023 meets the requirements of Reese's Law for consumer products using button cell or coin batteries and incorporate by reference the requirements of UL 4200-2023 into a final mandatory consumer product safety rule. UL 4200A-2023 does not address battery package labeling, so staff recommends the Commission additionally issue a final rule to address the warning label requirements for battery packaging in Reese's Law. Staff also recommends a future rulemaking to revise requirements that had been proposed in the NPR as performance and technical data in accordance with section 27(e), as discussed in section VII of this memorandum. This briefing package includes for the Commission's consideration both (1) staff's

Staff Briefing Package: Draft FR for Reese's Law | August 31, 2023 | cpsc.gov

recommendation that UL 4200A-2023 be determined adequate to meet Reese's Law requirements (UL 4200A Determination), and (2) staff's draft final rule, as set forth in Tab G (Draft Final Rule).

CPSC staff's briefing package provides:

- An updated assessment of incident data, including data received since the data extraction for the NPR;
- An updated assessment of the hazards posed by zinc-air button cell or coin batteries;
- An updated assessment of current voluntary standards;
- Summaries of the public comments received on the proposed rule and staff's responses to those comments;
- Recommendations for the UL 4200A Determination;
- Considerations for a Draft Final Rule; and
- Recommendations for a future rulemaking.

II. Discussion

A. Reese's Law Requirements

Section 2(a) of Reese's Law directs the adoption of:1

- (1) a performance standard requiring the button cell or coin battery compartments of a consumer product containing button cell or coin batteries to be secured in a manner that would eliminate or adequately reduce the risk of injury from button or coin cell battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions; and
- (2) warning label requirements—
 - (A) to be included on the packaging of button cell or coin batteries and the packaging of a consumer product containing button cell or coin batteries;
 - (B) to be included in any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries; and
 - (C) to be included, as practicable-
 - directly on a consumer product containing button cell or coin batteries in a manner that is visible to the consumer upon installation or replacement of the button cell or coin battery; or
 - (ii) in the case of a product for which the battery is not intended to be replaced or installed by the consumer, to be included directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information shall be placed on the packaging or instructions.

Section 2(d) of Reese's Law states, however, that the Commission shall not promulgate a final rule for consumer products that contain button cell or coin batteries if the Commission determines, with respect to any consumer product, that a voluntary standard that meets the requirements of section 2(a) of

¹ 15 U.S.C.§ 2056e(a)(1)-(2).

Reese's Law is either in effect at the time of the Commission's determination, or will be in effect not later than 180 days after the enactment of Reese's Law (*i.e.*, February 12, 2023). Pursuant to section 2(d)(2) of Reese's Law, if the Commission determines that such a voluntary standard exists, the Commission must publish such determination in the Federal Register.

Β. Overview of NPR

The NPR proposed a rule to address the battery ingestion hazard for children 6 years of age or younger. Based on information in the National Electronic Injury Surveillance System (NEISS), the NPR reflected staff's estimate that from 2011-2021, there were approximately 54,300 emergency room visits associated with ingestion, impaction, or insertion of button cell or coin batteries. Figure 1 shows examples of these batteries. The data show that these incidents occur most often with children aged 4 years or younger. Ingestion of a button battery has caused severe injuries and deaths: the NPR identifies in Consumer Product Safety Risk Management System (CPSRMS) data 25 fatalities from 2016 through 2021. Children access button batteries from consumer products that are powered by the batteries, either directly from the battery compartment, or because the batteries have escaped from the compartments. Figure 2 shows a few examples of consumer products that contain such batteries.

LR44 83,44, Pb 65		
LR44 button cell, 11.6mm (0.45 inch) diameter x 5.4mm (0.21 inch) thick	LR754 button cell, 7.9 mm (0.31 inch) diameter, 5.4mm (0.21 inch) thick	LR626 button cell, 6.8 mm (0.26 inch) diameter, 2.6mm (0.10 inch) thick
+ Lithium Cell CR2032 3V sc	+ Lithium Cell CR2025 3V sc	Lithium Cell CR2450 BV Sc
CR2032, 20mm (0.787 inch)	CR2025, 20mm (0.787 inch)	CR2450, 24mm (0.945 inch)
diameter	diameter Example button cell and coin batte	diameter

Figure 1. Example button cell and coin batteries.



Figure 2. Example products that use button cell or coin batteries: LED candles (left), watches (middle), keychain flashlights (right).

In accordance with Section 2 of Reese's Law, the NPR contained:

- Performance requirements for consumer products containing button cell or coin batteries that require the battery to be secured in a manner that would eliminate or adequately reduce the risk of injury from the ingestion hazard to children during reasonably foreseeable use or misuse conditions. The NPR was based on UL 4200A, ASTM F963-17, UL 62368-1, and IEC 62115. The Commission preliminarily concluded the draft NPR to be adequate to address the risk of injury, based on CPSC's engineering analysis and testing of consumer products, with the following modifications:
 - A wider scope to match the scope of products covered by Reese's Law;
 - Clarification that a locking mechanism requiring two simultaneous and independent actions does not include actions that can be combined into one single action by a single finger or digit, to address poor locking mechanism designs observed in testing;
 - The addition of the compression test from the toy standard, 16 C.F.R. part 1250 (ASTM F963-17), to address children pressing on areas of the battery compartment not directly impacted by the drop test;
 - The requirement that all products, including products weighing more than 18 kg, be subjected to 10 drops, rather than just hand-held products, to reduce subjectivity in the test method based on the term "hand-held" being undefined;
 - The addition of the torque and tensile tests from the toy standard, 16 C.F.R. part 1250 (ASTM F963-17), to address a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth.
- 2) Warning label requirements for:
 - The packaging of button cell or coin batteries and the packaging of consumer products containing button cell or coin batteries;
 - Accompanying literature; and
 - Consumer products, as practicable.

The NPR tentatively concluded that no one standard adequately addresses the warning label requirements in Reese's Law. The proposed requirements followed the format requirements in ANSI Z535.4 and are based on warnings found in ANSI C18.3M, ASTM F963, UL 4200A, and other standards.

The NPR additionally proposed to require point-of-sale warnings of the ingestion hazard and other battery safety information under section 27(e) of the Consumer Product Safety Act (CPSA) to improve safety communication to consumers to address the unreasonable risk of injury and death to children from ingesting or inserting button cell or coin batteries into the body, and other hazards.

C. Public Comments, Response, and Modifications from NPR

The Commission's NPR published on February 9, 2023, with comments due on March 14, 2023. NPR comments can be found on docket number CPSC-2023-0004 at: https://www.regulations.gov/. CPSC received 38 comments during the public comment period. Four of the comments were duplicates of other comments. CPSC received two late-filed comments; one was out of scope for this rulemaking. CPSC also received nine comments in response to the Paperwork Reduction Act notice. In Tab A, staff summarizes the comments and provides responses to the issues raised. Additional detailed responses are provided throughout the briefing package, where comments led to changes in staff's Draft Final Rule. Comment topics include epidemiological analysis; scope, including exemptions; the adequacy of various voluntary standards; the proposed performance and labeling requirements; costs; effective date; international regulations; and a variety of issues outside the scope of this rulemaking. UL 4200A-2023 also addresses several of the topics raised in the public comments, as discussed in Tab A.

After reviewing and considering the comments, staff prepared the following clarifications and modifications in the Draft Final Rule, as compared to the NPR's proposed rule:

Performance Tests

- Drop test procedure add definitions for "hand-held products," to be dropped 10 times, and "portable products," to be dropped 3 times, so that products containing button cell or coin batteries are tested appropriately based on their foreseeable use and misuse.
- Performance requirements for removable or replaceable button cell or coin batteries clarify the test methods used to ensure the battery compartment remains secure.
- Performance requirements for consumer products containing non-replaceable button cell or coin batteries clarify that battery compartments for batteries not intended for removal or replacement by the consumer can be constructed differently than battery compartments for replaceable batteries, so long as they require the use of a tool that is not a common household tool to open, meet the applicable requirements in the performance tests section, and are labeled appropriately on the product packaging and in the instructions.
- Testing for consumer products containing permanently secured non-replaceable batteries clarify that products containing permanently secured batteries must be tested to the appropriate performance tests.
- Battery replacement update the Torque to be Applied to Screws table to reference Table 37 in UL 62368-1, which updates and simplifies the requirements for tightening screws during the battery replacement test.

• Revised minimum values – adjust the minimum force values in the tension tests, crush test, compression test, and secureness test to reflect the minimum acceptable values in IEC 62115, UL 4200A, and ASTM F963.

Reese's Law Warnings

- Label permanency clarify warning label permanency requirements with an additional test of onproduct labels based on UL 62368-1 section F.3.9 to verify the label remains legible, and to verify sticker labels do not curl or peel.
- Warning label colors clarify that specific colors on warning labels, in accordance with ANSI Z535, are only required if the label is present in more than one color, to not prohibitively restrict warning label designs and to align with existing requirements in relevant voluntary standards.
- Warning label letter size clarify that the minimum text size for on-product warning labels must be based on the product display panel size by adding a reference to the product display panel in the minimum text size requirement.
- Treatment information require the National Battery Ingestion Hotline phone number be placed on the warning label on packaging and in instructions to provide specific guidance to consumers on an available contact for treatment information.
- Remove Redundant Warning Statement remove the warning statement to "Call a local poison control center for treatment information," because it has been made redundant by the addition of the National Battery Ingestion Hotline phone number to warning labels.
- Consumer product packaging clarify that manufacturers can choose to use either the "Keep Out
 of Reach of Children" icon or the "Warning: Contains Coin Battery" icon on consumer product
 packaging to address foreseeable misinterpretation of the "Keep Out of Reach of Children" icon
 on products used by children.
- Instructions and manuals clarify in instructions and manuals that battery compartments for removable or replaceable button cell or coin batteries should be completely secured, and that consumers should stop using and remove batteries from products if compartments do not close securely, to address foreseeable misuse of the battery compartment.

27(e) Performance and Technical Data

- Requirements for performance and technical data clarify the requirements for performance and technical data by placing them in a new section of the regulation text.
- Zinc-air batteries clarify with a warning label on battery packaging that zinc-air batteries pose a hazard when inserted into the ear or nose in the performance and technical data section.
- Icons on button cell or coin batteries clarify that button cell or coin batteries must be kept out of reach of children with a requirement for button cell or coin batteries visible within the packaging to be durably and indelibly marked with the "Keep Out of Reach of Children" icon, where size permits.
- Warning statement applicability clarify that only applicable warning statements must be addressed, to ensure performance and technical data are clearly and appropriately communicated.
- Future rulemaking staff recommends seeking comment on the recommended changes to the requirements for performance and technical data through a future rulemaking.

Effective Date

• Effective date – extend the effective date of the Draft Final Rule from 6 months after publication as proposed in the NPR to 18 months after publication, to ensure availability of safe, compliant products and accommodate an expected high volume of laboratory product testing for a variety of product types that use button cell or coin batteries.

D. Updated Incident Data and Hazard Pattern Analysis

1. Fatal incidents

The National Capital Poison Center (NCPC), or Poison.org, tracks button cell or coin battery ingestions occurring from 1977 to the present. References for these incidents come from the news, medical literature, or from the National Battery Ingestion Hotline.² Since the NPR, from June 2022 through May 2023, the NCPC reported 2 additional deaths due to ingestion of button cell or coin batteries.³ Both cases were from lithium button cell or coin batteries getting impacted in the esophagus; one battery was 20 mm, and the other was greater than or equal to 20 mm. One battery was impacted for 25 days, the other for 3 days. The children died of hematemesis and sepsis respectively. This brings the total fatal cases tracked by NCPC to 71 since 1977.

Staff identified 32 fatalities from button cell or coin battery ingestions reported nationally in the Consumer Product Safety Risk Management System (CPSRMS) from January 1, 2011, to May 1, 2023 (Tab B).⁴ Staff identified seven additional deaths since the NPR, occurring from 2020 to March 2023. The source of the battery was unknown in each case. The cases are consistent with the mechanism of death reported in the NPR.

2. Nonfatal incidents

Since the NPR, from June 2022 through May 2023, NCPC reported 13 additional cases of severe injury from button cell or coin battery ingestion, bringing the total since 1977 to 280.⁵ Sources of the batteries were car key fob, novelty tea light candle, remote control (2), and glucometer. Nine of the batteries were 20 mm in diameter or bigger. In four cases, the injury led to vocal cord paralysis. Five ingestions led to esophageal burns, and five ingestions led to esophageal stricture. Other ingestion injuries involved two tracheoesophageal fistulas, one aortoesophageal fistula, and one tracheo-bronchi-esophageal fistula. All injuries required endoscopic or surgical removal of the batteries. Three required surgical esophageal and repair of the fistula, and one required cardiopulmonary bypass and surgical reconstruction of the trachea. The cases are consistent with data reported in the NPR.

² <u>Poison Control Center (batteryingestionhotline.com)</u>. The National Battery Ingestion Hotline transferred from the National Capital Poison Center to the Rocky Mountain Poison Center in 2017, and has not been included in the National Capital Poison Center data since then.

³ Fatal Cases (poison.org) Fatal Button Battery Ingestions: 71 Reported Cases (accessed May 2023).

⁴ Incidents reported via CPSRMS as of May 2023. Staff expects additional reporting of CPSRMS incidents for the most recent years 2021-2023, due to a time lag in reporting to CPSC. The reported incidents may be included in the NCPC data, including two incidents reported by CPSC to NCPC.

⁵ Severe Cases (poison.org) Nonfatal Button Battery Ingestions with Severe Esophageal or Airway Injury: 280 Cases. (Accessed May 2023) (Note: the number of cases in the website title is likely to change as additional cases are publicized.)

E. Updated Analysis of Injuries Associated with Button Cell or Coin Battery Chemistries

Most of staff's analysis of the hazards posed by button cell or coin batteries remains unchanged. However, public comments on silver oxide batteries and zinc-air batteries prompted additional investigation for those battery chemistries (See Tab C Health Sciences).

1. Silver Oxide Batteries

Silver oxide batteries are frequently used in watches. Jatana et.al. (2017) found in testing using an animal model that silver oxide button cell or coin batteries caused severe esophageal injuries. These injuries were visible on the tissue within 15 minutes. While lithium batteries induced the most severe visible injury, the lower voltage silver oxide batteries reached the pH of 12 leading to corrosive tissue damage⁶ as with the 3V lithium batteries but it took 4 hours longer than the lithium batteries. Therefore, silver oxide batteries cause severe esophageal injury but it takes longer to occur than lithium batteries.

While most severe injuries are from 20 mm lithium batteries, researchers have found that smaller 1.5V non-lithium batteries less than 20 mm (11.6mm - 16mm) can cause severe or fatal outcomes in children aged 22 days to 10 months (Litovitz et.al. 2010). Silver oxide batteries are up to 11.6 mm, therefore they fall within the size range to cause esophageal injury if ingested. Staff therefore recommend that silver oxide batteries and the consumer products which use them not be excluded from the rule, because silver oxide batteries can cause the ingestion hazard.

2. Zinc-Air Batteries

The NPR preliminarily stated that zinc-air batteries do not pose the same type of ingestion hazard as other batteries and sought comment on whether any consumer products contain these batteries and whether the Commission should require ingestion warnings on these batteries or their packaging. Zincair batteries are used in hearing aids, which are medical devices and not consumer products under the CPSA. Although the batteries themselves may be considered consumer products, commenters were not aware of any consumer products that use zinc-air batteries. However, two commenters stated that zincair batteries pose a hazard when impacted in the ear or nose, and that they should be labeled appropriately. Staff reviewed additional literature to confirm the comments (see Tab C). Jatana et. al. (2017) found in testing using an animal model that zinc-air batteries did not cause any damage to esophageal tissue. Researchers found that the fluid from the moist environment of the esophagus blocked the entrance of oxygen to the battery, and the battery was unable to discharge. Therefore, based on the comments and additional research, staff's position remains consistent with the NPR, that zinc-air batteries do not pose an ingestion hazard. However, Sancaktar et.al. (2020) showed in animal nasal septal model that zinc-air batteries did cause necrosis to the tissue. Staff's analysis is that the irregular shape and drier environment of nasal passages (and similar shapes and environment in ears) allow the zinc-air battery to discharge, causing voltage and tissue damage in the nasal cavity or in ears. Therefore, staff recommends requirements for a warning label that provides performance and technical data under section 27(e) of the CPSA to address the hazard of insertion of zinc-air batteries into the ears or nose.

⁶ Hydroxide ions cause corrosive tissue damage above a pH of 11.

3. Summary

The medical literature, CPSC data, and data from the NCPC show that button cell and coin batteries cause serious injury and death when ingested, due to impaction in the esophagus. Injuries that occur include esophageal burns and perforations, vocal cord paralysis, and fistulas created by burning through the esophagus and surrounding tissues creating a connection between the esophagus and the trachea or blood vessels. One researcher found that a majority (61.8%) of button cell or coin batteries involved in ingestions over an 18-year period came directly from a consumer product, supporting the requirement that the battery compartment on consumer products must be strengthened to address the ingestion hazard (Litovitz et al., 2010b).

Although not within the scope of Reese's Law, staff also found from CPSC data and the medical literature that serious injury results from button cell or coin batteries that are inserted into the nose and ear. Batteries inserted into the nose can be aspirated and ingested and cause associated ingestion injuries. Insertion injuries also include septal perforation, decreased structural support of the nose, and hearing loss. Therefore, staff recommends requirements for a warning label that provides performance and technical data under section 27(e) of the CPSA to address the hazard of insertion of zinc-air batteries into the ears or nose.

F. Hazard Pattern

The hazard pattern identified in the NPR for button cell or coin battery ingestion scenarios involves children accessing batteries. The primary ways children gain access to button cell or coin batteries before ingesting them remain the same, but incident totals are updated based on 7 newly reported deaths in CPSRMS:

- 1. Access to the battery from a product's intact battery compartment.
 - a. Seventy-nine out of 119 fatal and nonfatal CPSRMS incident narratives identified in Tab A refer to products with button cell and coin battery compartments that are potentially easily accessed by children.⁷ Ten of the 79 incident narratives refer to batteries in compartments that appeared easy to open or defeat. These batteries did not accidentally come out of a battery compartment but appeared easily accessible to children while in a compartment.
- 2. The battery compartment broke or failed to contain the battery as intended.
 - a. Sixty-nine of the 79 fatal and nonfatal CPSRMS incidents involving products describe the batteries coming out of the battery compartment or the product or the battery compartment opening or breaking, often while a child was interacting with the product. In some cases, the battery was found to have come from a product only after a child was diagnosed with having ingested the battery. Eighteen of these incidents specifically describe products with screws that were ineffective, including comments about stripped threads, continuous spinning, screws that were "too short," and compartments that popped open even though there was a screw.
- 3. Victim removed battery from battery packaging, or battery was loose and not contained within the packaging or product and accessed by victim.

⁷ Out of the 79 products included in this hazard pattern analysis, 77 are consumer products and 2 are household medical devices (body temperature thermometer and toothbrush).

a. Six out of 119 fatal and nonfatal CPSRMS incident narratives refer to loose batteries or battery packaging hazards, and staff estimates that at least 7 percent of NEISS incidents involve loose batteries or batteries liberated from the packaging.

Staff notes that knowledge of where an ingested button cell or coin came from appears to play a role in outcome: for 25 out of 32 (78%) fatal CPSRMS incidents, the source of the battery was unknown, compared to 9 out of 87 (10%) nonfatal CPSRMS incidents. The source of a battery is more likely to be unknown if an ingestion goes undetected.

Section 3 of Reese's Law requires child-resistant packaging for button cell or coin battery packaging. Consistent with Section 2 of Reese's Law and the NPR, staff concludes the remaining hazards can be addressed with performance requirements for consumer products containing button cell and coin batteries and labeling requirements for such products and for the packaging of button cell or coin batteries by:

- 1. Reducing the risk of injury to children by preventing direct access the battery compartment of these products,
- 2. Reducing the likelihood of loose batteries liberated from these products, and
- 3. Warning caregivers of the battery ingestion hazards to children.

G. Recalls

No new recalls of products containing button cell or coin batteries occurred since the NPR that were intended to address the ingestion hazard. Details of each recall can be found in the NPR (88 Fed. Reg. 8,692) and in Staff's NPR Briefing Package, Tab F.

H. Voluntary Standards

In the NPR, the Commission reviewed existing voluntary standards intended to address ingestion by children with requirements for child-resistant battery compartments in consumer products to determine whether such standards meet the performance and labeling requirements in section 2(a) of Reese's Law. Preliminarily, the Commission concluded in the NPR that no existing voluntary standard contains performance and labeling requirements that would eliminate or adequately reduce the risk of button cell or coin battery ingestion. CPSC assessed the following voluntary standards in the NPR:

- UL 4200A-2020, Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies
- ASTM F963 Standard Consumer Safety Specification for Toy Safety
- Voluntary standards referenced by Australian F2020L01656, including:
 - IEC 62368-1 Audio/video, information and communication technology equipment-Part 1: Safety requirements
 - IEC 62115 International Standard for Electric Toys Safety
 - AS/NZS 60065:2018 Audio, video and similar electronic apparatus-Safety requirements
 - o AS/NZS 60598.1:2017 Luminaires Part 1: General requirements and tests

One standard, IEC 62368-1, had a new edition (Edition 4, or IEC 62368-1:2023) published in May 2023. Additionally, UL balloted and published a revised version of UL 4200A (UL 4200A-2023), and ASTM balloted a revision to the battery compartment construction requirements in ASTM F963. Public comments on the NPR pointed out that CPSC did not fully assess UL 62368-1 (the U.S. version of the international standard IEC 62368-1). Staff reviewed UL 4200A-2023 and the contents of the UL 4200A and ASTM F963 ballots, and reviewed UL 62368-1 based on the public comments. Staff also reviewed IEC 62368-1:2023. Staff's assessment of the remaining standards remains unchanged since the NPR.

1. UL 4200A Ballots

UL Standards and Engagement (ULSE) began hosting meetings of Technical Committee (TC) 4200, the TC responsible for UL 4200A, after publication of the NPR. The TC proposed to update UL 4200A-2020 such that the voluntary standard would align more closely with the Commission's NPR. The TC set up a task group to compare the NPR to UL 4200A-2020 and develop specific proposals to update the standard. CPSC staff participated in TC and task group meetings and provided feedback with information from the NPR to participants to support the proposed changes. Ultimately, the task group decided not to follow the NPR for some requirements, and the TC published a ballot on April 28, 2023 containing the task group's recommendations. The ballot included changes to scope, performance requirements, and labeling requirements for consumer products and product packaging. Staff reviewed the April 28 ballot and provided feedback on ballot items which were not consistent with Reese's Law or the NPR.⁸ Staff's assessment of the April 28 ballot was that a majority of the changes align with the NPR and/or staff's Draft Final Rule; however, two performance requirements and one warning label requirement did not align with the NPR or the Draft Final Rule, and staff assessed that they do not meet the requirements of Reese's Law:

- Captive screw exceptions;
- Drop test; and
- Warning label display panels.

Staff's assessment of these requirements can be found in Tabs D and E.

Recirculation Ballot

TC 4200 met on June 22, 2023 to discuss all of the comments on the April 28 ballot and revised the ballot language. This recirculation ballot was published on July 7, 2023. Revisions included the captive screw exceptions, the definitions for "hand-held product" and "portable device" used to determine the number of drops in the drop test, and the compression test.

Captive Screw Exceptions

Both exceptions to the requirement for captive screws apply only to products containing button cell or coin batteries not intended to be replaced by the consumer and require instructions and warnings that clearly state the battery is not to be replaced by the consumer. Additionally, the first exception applies to products containing button cell or coin batteries "that can only be accessed through the removal of

⁸ https://downloads.regulations.gov/CPSC-2023-0004-0076/content.pdf

multiple enclosures or panels using a tool." The second exception is for "products only to be opened by a professional service center (where children are not present)."

Products designed and labeled not to have the battery replaced by the consumer provide the consumer with less incentive or need to access the battery. Additionally, multiple enclosures or panels will provide an extra layer of protection that prevents immediate access to button cell or coin batteries, even if screws to those panels are lost or discarded. Some products that might fit into the first exception include desktop and laptop computers; these products have button cell or coin batteries in their motherboards that often require multiple panels and components to be removed before the battery can be accessed, and the battery frequently lasts longer than the product itself, so has no need to be replaced. There are no known incidents involving access to button cell or coin batteries through multiple enclosures. Products only to be opened by a professional service center will lack features that allow consumers to access the battery with a common household tool such as a straight-blade or Phillips screwdriver, pliers, or a coin. Some secure watches which require a special tool will fall into this category, and would not require captive screws; however, watches secured only with straight blade or Phillips screws would not fall into this category, and thus would be required to have captive screws. This interpretation of the exception is a logical and appropriate one, but it is not explicit in the UL standard, and a manufacturer or test lab could potentially interpret that a consumer product with a battery compartment that is easily openable by a consumer with a simple household tool only needs a label stating that the battery is to be replaced at a professional service center for the product not to have captive screws. Such screws could be easily discarded or lost and cause the battery compartment to be easily accessible by a child. However, staff assesses that with appropriate guidance in place, this interpretation of the exception would be unlikely to occur. Staff therefore conclude these exceptions could be determined to be adequate to meet Reese's Law.

Drop Test

The definition for "hand-held product" was revised to mean products that are "reasonably foreseeable to be used or misused when being held in one or both hands. Products specifically designed to be carried easily, with a mass not exceeding 4.5 kg (10 lbs)." This revision aligns closely with staff's own recommended definition for hand-held products (discussed in Section III.A of this memorandum, below).

The definition for "portable device" was revised to mean a "device that is reasonably foreseeable to be routinely carried or lifted as part of its use or misuse but not operated during transit with a mass not exceeding 18 kg (39.7 lb)." This is a narrower definition than that recommended by staff (discussed in Section III.A of this memorandum, below), as the phrase "routinely carried" could exclude some products, such as heavy desktop computers or some televisions, from a required drop test. The phrase "routinely carried" is subjective and could result in different manufacturers or test labs subjecting different tests to otherwise similar products. However, staff are not aware of any incidents involving access to batteries from these products resulting from a drop or similar use or misuse. Staff assesses that clear guidance from the Commission could address any potential instances of inconsistent testing. Staff therefore conclude these definitions could be determined to be adequate to meet Reese's Law.

Warning Label Display Panels

UL added definitions for the principal display panel, secondary display panel, and product display panel, consistent with the NPR. These definitions addressed staff's concerns that on-product warning labels could be placed in a manner not visible to the consumer when installing or replacing a battery. Therefore,

staff concludes the product packaging and on-product warning labels are adequate to meet the requirements in Reese's Law.

Assessment Summary and Publication

TC 4200 met on August 11, 2023 to discuss comments on the July 7 recirculation ballot. The TC decided not to ballot further changes. As a result, all but one of the proposed changes were published in ANSI/UL 4200-2023 on August 15, 2023. Due to ANSI/UL balloting protocol, the proposal to add the small surface area compression test, based on the test in ASTM F963, was recirculated for additional comments and was published on August 30, 2023. Staff assesses that the August 30, 2023 version of UL 4200A-2023 is adequate to meet Reese's Law.

2. ASTM F963 Ballot

ASTM released a ballot item on January 12, 2023, F15(23-02) item 3, which would strengthen requirements for toys containing batteries:

- 1. Toys containing batteries that fit within the small parts cylinder (including button cell and coin batteries) intended for children 8 years and older (up to 14 years of age) would be subject to drop testing. Previously, only toys for children less than 8 years old were subject to drop testing.
- 2. For toys that use a fastener to secure the battery compartment, the fastener must remain attached to the toy or battery compartment cover. This effectively adds a captive screw requirement.

Staff expect this ballot item to be published in the next version of ASTM F963. Staff commented on the ballot with concerns that the revision, which would allow specialty fasteners (such as hex or torx) to be used for consumer-replaceable battery compartments, could contribute to hazards which may not have been mitigated;⁹ for example, if a consumer loses the required special tool that is provided with the toy to open a battery compartment with a specialty fastener, the consumer could foreseeably try to use the wrong tool and inadvertently damage the battery compartment, which may result in the battery becoming easily accessible to a child.¹⁰ However, staff are working with ASTM to address staff's concerns, and believe that the ballot item is overall an improvement to safety.

Staff revised its assessment of the performance requirements in ASTM F963 assuming that this ballot item is published. Staff concludes the captive screw requirement is adequate. The drop test, however, relies on user age to determine the drop height, the maximum weight of products to be tested, and the maximum number of drops. These restrictions are not appropriate for non-toy products, which are likely to be interacted with by a variety of age groups and have a large age range of potential users. Therefore, staff conclude the drop test requirements in the F963 toy standard are inadequate for the purpose of Reese's Law, which applies to a broader range of products.

⁹ Staff's comments on the ballot item can be found here: <u>https://www.cpsc.gov/s3fs-public/ASTM-F963-Update-Ballot-Items-2-13-23.pdf?VersionId=IWOEOtm4pnAvrnxk2oVjWITWqqOmroxe</u>

¹⁰ The ballot includes instructions for parents on tool storage, but does not provide instructions for obtaining a replacement tool, if needed. Possible mitigations for this hazard are to provide consumers the information necessary to obtain replacement special tools and to instruct consumers not to open the battery compartment without the appropriate tool.

3. UL 62368-1

The NPR includes an assessment of IEC 62368-1, in which the Commission preliminarily found the standard to be inadequate to address Reese's Law. In its responsive comments, the Consumer Technology Association stated that CPSC should assess UL 62368-1, which has localized differences from IEC 62368-1 that are more protective, and that CPSC did not fully address the requirements in the voluntary standard. Upon review, staff confirmed that a compression test was present in both versions of the standard and was not assessed in the NPR; that an impact test in UL 62368-1 differs from the same test in IEC 62368-1; and that labeling requirements were present in the standard but were not addressed in the NPR. These points are discussed below.

Compression Test

For the NPR, staff reviewed a compression test for small surface areas from the voluntary standard ASTM F963-17, Standard Consumer Safety Specification for Toy Safety. 88 Fed. Reg. 8704 (February 9, 2023). The test in ASTM F963 applies compression to any area of the surface of a toy that is accessible to a child, and inaccessible to a flat surface contact during the impact test. For products within scope of the NPR, staff found this test effective for testing the robustness of battery compartment enclosures that are inaccessible to flat surface contact during the proposed drop or crush abuse testing. Staff advised that this small surface compression test was effective especially for products where the battery compartment is recessed due to the shape of the product. Staff concluded that this test is adequate to simulate foreseeable interactions such as a child pressing on a small area of the product that may house a button cell or coin battery (NPR staff briefing package, Tab D). Staff also concluded that UL 4200A-2020 and IEC 62368-1 do not contain performance requirements to address this risk. However, the Consumer Technology Association provided comment stating that section 4.4.3 of UL 62368-1, which is the equivalent voluntary standard to IEC 62368-1 for the United States, contains general robustness requirements that subject an enclosure or barrier to a steady force test. The intent of the robustness tests is primarily for enclosures that protect against users making contact with energy sources with much greater voltage than a button cell or coin battery. Although the associated hazard for these tests is more related to shock injuries, staff determined that these tests can also be effective for preventing access to button cell or coin batteries.

UL 62368-1's steady force test applies a compressive force on a surface of a product based on the type of safeguard an enclosure is intended to provide. For most products within the scope of this rulemaking, the test subjects a steady force of 100 N \pm 10 N (22.5lbf \pm 2.2 lbf) over a circular plane surface 30 mm (1.2 inches) in diameter for 5 seconds. The test repeats to the top, bottom, and sides of the product. UL 62368-1 specifies limited compliance criteria for the general robustness tests, only requiring that "safeguards shall remain effective." Staff assess that the compression test in UL 62368-1 would be applied more frequently than the test in ASTM F963, because the UL test is not restricted to surfaces not contacted during the drop test. However, the average pressure (defined as force over area) of 2.05 N/mm² applied during the ASTM F963 compression test is 47% greater than the average pressure of 1.40 N/mm² applied during the UL 62368-1 steady force test. Staff assess that while the ASTM F963 compression test is 47% greater than the UL 62368-1 were staff assess that while the ASTM F963 compression test is 5.5 the two staff assess that while the ASTM F963 compression test is 4.5 the staff assess that while the ASTM F963 compression test is 5.5 that while the ASTM F963 compression test is 4.5 the test applied during the UL 62368-1 steady force test. Staff assess that while the ASTM F963 compression test, based on 16 C.F.R. part 1500.50 and as proposed in the NPR, adequately prevents hazardous small parts from being created and ingested, the pressure applied during the UL 62368-1 steady force test is substantially less and may not reach the levels necessary to prevent hazardous small

parts. Therefore, staff assess the UL 62368-1 steady force test is inadequate to address the ingestion hazard.

Impact Test

In the NPR, the Commission stated that the required impact energy for the impact test in IEC 62368-1 was dependent on the type of product: 0.5 J impact for 3D glasses and 2 J for all other products. 88 Fed. Reg. 8704 (February 9, 2023). Public comments point out that the equivalent US voluntary standard, UL 62368-1, deviates from the international IEC version by deleting the 0.5 J requirement for 3D glasses, and therefore requires 2 J of impact energy for all products. This effectively makes the impact test performance requirement in UL 62368-1 the same as UL 4200A and CPSC's proposed rule. Staff therefore assess that the impact test in UL 62368-1 is adequate.

Warning Labels and Instructions

The NPR did not include an assessment of the labeling requirements in IEC 62368-1. Based on public comments, ESHF staff reviewed the requirements in UL 62368-1, the localized version of IEC 62368-1.

UL 62368-1 contains requirements for instructional safeguards. Safeguards on products may include symbols and text that identifies the nature and classification the hazardous energy source. An instructional safeguard is not required when these batteries are not intended to be replaced or are only accessible after damaging the equipment.

Requirements for products that contain coin or button cell batteries pertain to those items that are "likely to be accessible to children" and "contain a coin or button cell battery that is less than 32mm. These products must display the following warnings:

- "Do not ingest battery, Chemical Burn Hazard" or equivalent,
- "[The remote control supplied with] This product contains a coin/button cell battery. If the coin/button cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death."
- "Keep new and used batteries away from children."
- "If the battery compartment does not close securely, stop using the product and keep it away from children."
- "If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention."

Instructional safeguards found on-product may also be provided in the product instructions or installation manual.

Reese's Law requires warning labels addressing the ingestion hazard to be included, as practicable, on all consumer products containing button cell or coin batteries. UL 62368-1 contains requirements for products that are "likely to be accessible to children," which is subjective and may exclude some consumer products that contain button cell or coin batteries. Additionally, Reese's Law requires that warning labels on products for which the battery is not intended to be replaced or installed by the consumer be included directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information

shall be placed on the packaging or instructions. UL 62368-1 does not require instructional safeguards when batteries are not intended to be replaced. Therefore, the requirement in UL 62368-1 is inadequate to address the on-product label placement requirement in Reese's Law.

Additionally, Reese's Law requires consumer product packaging and any literature that accompanies a consumer product to contain warning labels addressing the ingestion hazard. UL 62368-1 does not address the required warning label for consumer product packaging. Additionally, UL 62368-1 allows, but does not require, instructional safeguards addressing the ingestion hazard in accompanying literature. Therefore, the requirements in UL 62368-1 are inadequate to address the required warning labels on product packaging and in accompanying literature.

4. IEC 62368-1:2023

Staff's review of IEC 62368-1:2023 identified differences in the general requirements and construction performance requirements for equipment containing button cell or coin batteries. All other aspects remain substantively similar to the previous version of the standard, and staff's assessment of those aspects remains the same.¹¹

General Requirements

The previous version of IEC 62368-1 included exceptions to some of the specific performance requirements for products using button cell or coin batteries.¹² The exceptions included professional equipment, equipment for use in locations where it is unlikely that children will be present, and equipment containing button cell or coin batteries that are soldered in place. In IEC 62368-1:2023, these exceptions remain the same, and an additional exception is added:

• Equipment for which it is unlikely that the coin or button cell battery will be removed by children due to location of the battery within the equipment; in such cases, the instructional safeguard still applies.

This exception may exclude certain products from the construction performance requirements and the specific test sequence for products containing button cell or coin batteries, like laptops or desktop computers which have the coin battery buried under internal components or panels. However, a manufacturer might argue that a series of panels that are openable by hand with a single action or a non-replaceable button battery in an easily broken plastic compartment meets the criterion for the exception. Other use and abuse tests in the standard are not likely to be as rigorous or address other hazards than those specifically for products containing button cell or coin batteries. The exception is subjective and difficult to enforce. Staff considers this exception inadequate to meet Reese's Law.

¹¹ Staff's original assessment of IEC 62368-1 can be found in the NPR staff briefing package; staff's assessment of the compression test, warning labels and instructions for UL 62368-1 in this briefing package also apply to IEC 62368-1.

¹² The exceptions do not mean that these products are not tested, as other performance and labeling requirements in the standard still apply, including similar tests. However, construction performance requirements and (in some cases) instructional safeguards would not apply.

Construction Performance Requirements

IEC 62368-1:2023 includes construction performance options that either require the use of a tool or a series of hand movements, like the previous version of the standard. The options are more specific than the previous version, and a total of five options are available:

- If a tool is required to open or remove the battery compartment, door or cover, any of the following options may be used:
 - If one or more screws or similar fasteners is used to secure the compartment, door or cover, a minimum of two full rotations of the screw or fastener are required to open or remove the coin or button cell battery compartment, door or cover. The screw or fastener shall be captive to the coin or button cell battery compartment, door, cover, or to the equipment; or
 - for a cover which is required to be rotated to be opened, a minimum torque of 0.5 Nm shall be required to unlock the cover and start its rotation. A minimum rotation of 90° shall be required to remove the cover; or
 - $_{\odot}$ for a cover which is secured by one or more latches, a minimum torque of 0.5 Nm is required to release the latches.
- If no tool is required to remove the button cell or coin battery compartment door or cover, either of the following options for opening by hand shall apply:
 - \circ The application of a minimum of two different and interdependent movements; or
 - The application of simultaneous movements to engage two mechanisms requiring the use of multiple fingers.

The options requiring the use of a tool are similar to those proposed in the NPR,¹³ with a specific performance requirement added that latches require a minimum torque of 0.5 Nm. The NPR proposes a performance requirement for battery compartments to open with a torque greater than 0.5 Nm, and the latch performance requirement is consistent with this requirement. Staff considers the construction performance requirements adequate to meet Reese's Law.

The first option not requiring a tool is the application of a minimum of two different and interdependent movements, or at least two different movements that are dependent on each other. Because the different and interdependent movements are not clearly required to be simultaneous (or, because the movements can apparently occur sequentially), a scenario can occur in which a user may perform the first movement, and then a child may later perform the second movement, and easily access the battery compartment. This requirement is not adequate to meet Reese's Law.

The second option not requiring a tool is the application of simultaneous movements to engage two mechanisms requiring the use of multiple fingers. This option requires two simultaneous and independent movements with multiple fingers, thus would meet the requirement proposed in the NPR. This option therefore is adequate to meet Reese's Law.

Staff assesses that four of the options for construction performance are adequate to meet Reese's law, while one is not adequate. Staff also assesses that the exception added to the general requirements for

¹³ "Secure the battery compartment enclosure so that it requires a minimum of two independent and simultaneous hand movements to open. The movements to open cannot be combinable to a single movement with a single finger or digit."

OS 124

products using button cell or coin batteries is overly subjective and does not meet Reese's Law. The rest of IEC 62368-1:2023 is substantively similar to the previous version, which staff assessed as not adequate to meet Reese's Law. Staff concludes IEC 62368-1:2023 is not adequate to meet Reese's Law. Law.

5. Comparison and Assessment of Standards in Addressing Battery Access in Consumer Products

The NPR includes a comparison of the scope, required action to open the battery compartment(s), and abuse testing to simulate foreseeable use and misuse conditions for the listed standards and found that none of the individual standards adequately address the ingestion hazard associated with child access to button cell or coin batteries in consumer products. 88 Fed. Reg. 8,702. Table 1 updates the summary of how currently published standards, including UL 4200A-2023 and UL 62368-1, address the battery ingestion hazard with performance requirements.

Standard	Scope	Action to Open Battery	Abuse Testing
		Compartment	
UL 4200A- 2023	Household type products that incorporate or may use button cell or coin batteries	 (1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand. The movements to open cannot be combinable to a single action. 	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test –74 lbf. over 38 square inches for 10s in positions likely to produce the most adverse results (4) Small surface compression test –30.6 lbf over 1 square inch for 10 seconds (5) Torque test – 4.4 in-lbs. of torque over 10 seconds (6) Tension test – 16.2 lbs. of tension over 10 seconds
ASTM F963	Toys intended for use by children under 14 years of age	Coin, screwdriver, or other common household tool required to open battery compartment	 (1) Drop test – maximum 10 times at 4.5 ft in random orientation; minimum of 4 times at 3 ft in random orientation (2) Torque test – 2-4 in-lbs. of torque over 10 seconds (3) Tension test – 10-15 lbs. of tension over 10 seconds (4) Tension test for pliable materials – 10-15 lbs. of tension over 10 seconds (5) Small surface compression test – 20-30 lbf over 1 square inch for 10 seconds
IEC 62368-1 ed. 3 (US equiv. UL 62368-1)	Electrical and electronic equipment within the field of audio,	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times

Table 1. Summary of Voluntary Standards Performance Requirements

Standard	Scope	Action to Open Battery Compartment	Abuse Testing
	video, information and communication technology, and business and office machines with a rated voltage not exceeding 600 V	fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand	Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test – apply 74 lbf. for 10s in positions likely to produce the most adverse results (4) Small surface compression test – 100 N ± 10 N (22.5lbf) over 30 mm diameter area for 5 seconds
IEC 62368- 1:2023	Electrical and electronic equipment within the field of audio, video, information and communication technology, and business and office machines with a rated voltage not exceeding 600 V	 (1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two different and interdependent movements to open by hand, or the application of simultaneous movements to engage two mechanisms requiring the use of multiple fingers 	 Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test – apply 74 lbf. for 10s in positions likely to produce the most adverse results (4) Small surface compression test – 100 N ± 10 N (22.5lbf) over 30 mm diameter area for 5 seconds
IEC 62115	Electric toys being any product designed or intended for use in play by children under 14 years of age	Batteries that fit wholly within the small parts cylinder shall not be removable without the aid of a tool, screw fasteners must be captive.	 (1) Screw test – Remove/replace screws 10 times with torque applied (2) Drop test – maximum 10 times at 93 cm ± 5 cm (36.6 in.) in random orientation; minimum 4 times at 93 cm ± 5 cm (36.6 in.) in random orientation (3) Impact test – 3 impacts by hammer imparting 0.5-J of energy (4) Tension test – 70 N ± 2 N (15.7 lbs.) of tension over 10 seconds (5) Tension test – 70 N ± 2 N (15.7 lbs.) tension force on a textile seam over 10 seconds

Table 7 in the NPR summarizes the Commission's preliminary assessment whether the standards reviewed by staff eliminate or adequately reduces the risk of injury from button cell or coin battery ingestion by children age six or under. Table 2 below summarizes staff's evaluation of UL 62368-1, UL 4200A-2023, and the balloted content for ASTM F963. Specifically, the table includes the scope of the voluntary standard, and whether the scope includes all relevant battery chemistry types that create an ingestion hazard and associated consumer products, as seen in the incident data; whether the standard's performance requirements for constructing and securing related to the construction of the battery compartment, and the methods to secure the battery compartment, would eliminate or adequately reduce the risk of injury from access to batteries from consumer products and their ingestion, as seen in the incident data; and whether the standard addresses use and abuse testing, and if so, the adequacy of the use and abuse testing to eliminate or adequately reduce ingestion incidents as seen in the data. Additionally, staff revises the assessment in cases where the requirement is not directly addressed by the standard, but the hazard addressed by the requirement is otherwise adequately addressed - these cases are now marked as O, rather than blank. For example, ASTM F963 and IEC 62115 require that toys containing button cell or coin batteries be secured in a manner that requires a tool to open; locks requiring two independent and simultaneous movements to open are not allowed on these products, and

staff considers this adequate. Similarly, UL 4200A, UL 62368-1, and IEC 62115 do not require age grading of products to determine the appropriate testing, which staff considers appropriate for general use products. And ASTM F963, UL 62368-1, and IEC 62115 do not allow products to contain accessible button cell or coin batteries even when these batteries are permanently secured, while UL 4200A allows products with accessible but permanently secured button cell or coin batteries so long as they meet the appropriate performance requirements; staff considers both approaches to be adequate.

	Performance Requirements for B	UL 4200A- 2023	ASTM F963 (Ballot)	UL 62368-1	IEC 62368- 1:2023	IEC 62115
	Battery Chemistry Type	Any*	Any	Any	Any	Any
Scope	Product Type	Any	Toys	Audio/ Visual Equipm ent	Audio/ Visual Equipm ent	Electron ic Toys
	Opens with Tool	A	Α	A	Α	A
	Captive screws	A	А	I	A	A
Construction	Threaded attachment requirements	A		I	A	
Performance	Opens with two independent and simultaneous movements	А	0	I	I	0
	Accessibility	A	Α	A	A	А
	Pre-conditioning in oven	A		A	A	
	Open/close and remove/install battery/screw(s) 10 times	А		А	А	I
	Drop test - based on product weight/type	А	Ι	I	Ι	I
	Drop test - based on age grading	0	I	0	0	0
	Impact Test	А		A	Α	I
Use and Abuse	Crush Test (big surface area)	Α		A	Α	
	Torque Test	Α	А			
	Tension Test	Α	Α			A
	Tension Test - Seams	А	А			A
	Compression Test (little surface area)	А	А	I	I	
	Accessibility Probe Compliance Test	A	I	I	I	A
	Securement (non-removable batteries)	А	0	0	0	0

Table 2. Assessment of Existing Voluntary Standards
Performance Requirements for Button Cell or Coin Batteries

*Excludes zinc-air batteries, which are not known to be used in consumer products.

Blank – Does not address requirements, I – Inadequately addresses requirements, A – Adequately addresses requirements, O – Otherwise adequately addresses requirements

For the final rule, staff's updated assessment is that UL 4200A-2023 is the only voluntary standard that the Commission could determine adequately addresses the performance requirements in Reese's Law.

Tables 10 and 11 in the NPR detail the Commission's review of warning label requirements in existing voluntary standards. Table 3 below provides an updated summary of staff's assessment of product

standards, including the addition of UL 62368-1 and the balloted content for ASTM F963 and UL 4200A. Staff's assessment of labeling in battery standards (Table 11 in the NPR) remains unchanged. Staff concludes that UL 4200A-2023 adequately addresses the requirements for consumer product and consumer product packaging warning labels in Reese's Law. The standard does not address battery package labeling.

		ASTM F963 (Ballot)	UL 4200A- 2023	ASTM F2999- 19	ASTM F2923-20	IEC 62115	UL 62368-1 and IEC 62368- 1:2023
	Battery Chemistry Type	All	All*	All	All	All	All
Scope	Product Type	Toys	All	Jewelry	Children's Jewelry	Toys	Audio/Visual Equipment
	On Consumer Product Packaging	I	А			I	
Labeling	In instructions or accompanying literature	I	А			I	I
	On consumer product		А				I

Table 3. Summary of Staff's Assessment of Labeling Requirements in Standards for Consumer Products Containing Button Cell or Coin Batteries

*Excludes zinc-air batteries, which are not known to be used in consumer products. Blank – Does not address requirements, I – Inadequately addresses requirements, A – Adequately addresses requirements

III. Recommended UL 4200A Determination

Staff recommends that the Commission determine that UL 4200A-2023 meets the requirements of Reese's Law and codify it by reference in a direct final rule.

A. UL 4200A-2023 Determination

A determination that UL 4200A-2023 meets the requirements of Reese's Law would establish a consumer product safety rule which contains a performance standard and warning label requirements for consumer products using button cell or coin batteries. The performance requirements are summarized in Table 4 and Table 5 below.

	ry of UL 4200A-2023 Performance Requirements for ucts with Compartments for Replaceable Batteries	
Button cell or coin batteries must not become accessible or liberated		
	when tested to these requirements:	
Performance Requirements for Battery Compartment Securement		
	Option 1: Coin, screwdriver, or other tool.	
Battery	Captive screws	
Compartment Securement	• Exceptions for products containing batteries not intended to	
Options (Ballot Items 3 and	be replaced by the consumer. Such products shall have	
4)	instructions and warnings that clearly state the battery is	
	not to be replaced by the consumer.	

	 Exception 1: Products that can only be accessed through the removal of multiple enclosures or panels using a tool. Exception 2: Products that are only to be opened by a professional service center (where children are not present). Two threads engaged or minimum torque + spin angle <i>Option 2</i>: At least two independent & simultaneous hand movements. 1) Shall not be combinable to a single movement with a finger or digit. 		
Accessibility Test	Open or remove any part of the compartment not meeting <i>Option 1</i> or <i>Option 2</i> . Apply Tension Test for Seams from ASTM F963 on pliable materials, using a force of 70.0 N (15.7 lbf). Determine whether Test Probe 11 from IEC 61032 can touch the battery.		
	Preconditioning Requirements		
Preconditioning in Oven	Thermoplastics - 7 hours at 158°F or greater, based on operational temperature.		
Simulated Battery Replacement	Open/Close and remove/install battery 10 times.		
Use and Abuse Tests			
Drop Test	Handheld products are 10 drops while portable products are 3 drops. Each drop is from 1 m (39.4 in) on hardwood, in positions likely to produce maximum force.		
Impact Test	3 impacts on battery compartment with steel sphere, 2 J (1.5 ft-lbf) of energy.		
Crush Test	330 N ± 5 N (74.2 lbf ± 1.1 lbf) for 10 s, using 100 by 250 mm (3.9 by 9.8 in) flat surface.		
Compression Test	Test from 16 C.F.R. Part 1250, using a force of at least 136 N (30.6 lbf).		
Torque Test	Test from 16 C.F.R. part 1250, using a torque of at least 0.50 Nm (4.4 inlbf).		
Tension Test	Test from 16 C.F.R. part 1250, using a force of at least 72.0 N (16.2 lbf).		
Probe for Accessibility	Apply 50 N to 60 N (11.2 lbf to 13.4 lbf) with Test Probe 11 from IEC 61032 to confirm compliance.		

Table 5. Summary of Proposed Performance Requirements for Consumer Products with Non-Replaceable Batteries

	corporate button cell or coin batteries that are not intended for user removal or nt shall effectively prevent removal of the battery by the user or children.
Option 1 – Not Accessible	Made inaccessible by an enclosure that meets the same applicable preconditioning and use and abuse test requirements as battery compartments for replaceable batteries.
Option 2 – May be Accessible	 Secured with soldering, fasteners such as rivets, or equivalent means. Confirmed with secureness test: test hook applies a force of 20 N ± 2 N (4.5 lbf ± 0.4 lbf) directed outwards for 10 s, at all possible points. Battery cannot liberate from the product.

The performance requirements are generally consistent with the NPR, with a few modifications consistent with staff's Draft Final Rule, as discussed in Tab A and in the assessment in section II.H.1 above.

The warning label requirements in the new version of UL 4200A are substantively similar to the warning label requirements in the NPR for consumer products and consumer product packaging, with the following differences:

- Colored markings are to comply with the ISO 3864 series of standards (similar to ANSI Z535, which was used as the basis for many of staff's recommendations for warning label formatting).
- Color is required only when the markings are printed on a label using more than one color (consistent with staff's recommendations for the Draft Final Rule).
- Manufacturers may choose to use either the "Keep Out of Reach of Children" icon or the "Warning: Contains Coin Battery" icon on the consumer product packaging label.
- Permanence of markings is tested consistent with the requirements in UL 62368-1 section F.3.9.
- An additional warning statement is included in instructions and manuals to "Always completely secure the battery compartment. If the battery compartment does not close securely, stop using the product, remove the batteries, and keep it away from children."

All of these differences from the NPR are consistent with staff's recommendations for the Draft Final Rule and the requirements of Reese's Law.

UL 4200A-2023 does not include warning label requirements for button cell or coin battery packaging, so a final rule for battery package labeling is still required to meet Reese's Law. Staff's recommended warning label requirements for battery package labeling are discussed in section IV.B below and Tab D. Staff's small business impact analysis for the battery package labeling is in Tab H.

B. Effective Date

Reese's Law states that if the Commission determines that an already-effective voluntary standard meets the requirements in section 2(a) of Reese's Law before promulgating a final rule implementing those same requirements, then the voluntary standard shall be treated as a consumer product safety rule promulgated under section 9 of the CPSA (15 U.S.C. 2058) effective on the date of the Commission's determination, which must be published in the Federal Register. 15 U.S.C. 2056e(d)-(e).

Staff recommends the Commission publish a direct final rule to codify the requirements in UL 4200A-2023 as the mandatory standard for consumer products containing button cell or coin batteries, by incorporating by reference UL 4200A-2023. As the draft direct final rule (DFR) states, unless CPSC receives a significant adverse comment within 14 days of publication in the *Federal Register*, the DFR will become effective 30 days after that publication.

Section 14(a)(3)(A) of the CPSA, however, requires that certification to a Notice of Requirements (NOR) is not effective until 90 days after publication of an NOR. 15 U.S.C. 2063(a)(3)(A). Accordingly, to provide the mandatory period for third party laboratories to become ISO accredited and CPSC-accepted to perform testing to part 1263, staff recommends that third party testing and certification of children's products subject to the new rule not be required until on or after 90 days after publication in the *Federal Register*.

In consideration of the public comments on the NPR, staff recommends a transitional period of enforcement discretion for the new requirements of UL 4200A-2023.

Staff recommends the final rule for labeling of battery packaging have an effective date of one year after publication in the Federal Register. This is the low end of the time frame sought by commenters on the NPR, and is consistent with the timeframe recommended by some battery manufacturers.

IV. Considerations for a Draft Final Rule

If the Commission does not determine that UL 4200A-2023 meets the requirements of Reese's Law, it could instead finalize a rule based on the NPR and in consideration of the comments as described in Tab A.

A. Recommended Performance Requirements

The NPR includes proposed performance requirements based on a review of the incident data, engineering analysis, and testing of consumer products. The proposed performance requirements incorporated general requirements and abuse testing based on elements of UL 4200A, ASTM F963-17, IEC 62368-1, and IEC 62115, with modifications to eliminate or adequately reduce the risk of injury from button cell or coin battery ingestion. Staff's updated review of voluntary standards remains consistent with the NPR: no one standard contains adequate performance requirements to address a child accessing the battery enclosures in consumer products. Staff recommends changes to the performance requirements based on public comments received in response to the NPR. Table 6 and Table 7provide a summary of staff's recommended performance requirements for the Draft Final Rule, based on staff analysis and public comments to the NPR.

Consumer Fi	oducts with Compartments for Replaceable Batteries
Button cell or	coin batteries must not become accessible or liberated
	when tested to these requirements:
Performance	Requirements for Battery Compartment Securement
	Option 1: Coin, screwdriver, or other household tool.
Patton	Captive screws
Battery Compartment Securement	 Two threads engaged or minimum torque + spin angle
Options	Option 2: At least two independent & simultaneous hand movements.
	Cannot be combinable to a single movement with a finger or digit.
Accessibility Test	Open or remove any part of the compartment not meeting <i>Option 1</i> or <i>Option 2</i> . Apply Tension Test for Seams from 16 C.F.R. part 1250 on pliable materials, using a force of at least 68.0 N (15.3 lbf). Determine whether Test Probe 11 from IEC 61032 can touch the battery.
	Preconditioning Requirements
Preconditioning in Oven	Thermoplastics - 7 hours at 158°F or greater, based on operational temperature.
Simulated Battery Replacement	Open/Close and remove/install battery 10 times.
	Use and Abuse Tests
Drop Test	Handheld products are 10 drops while portable products are 3 drops. Each drop is from 1 m (39.4 in) on hardwood, in positions likely to produce maximum force.

Table 6. Summary of Recommended Performance Requirements for Consumer Products with Compartments for Replaceable Batteries

Impact Test	3 impacts on battery compartment with steel sphere, at least 2 J (1.5 ft- lbf) of energy.
Crush Test	At least 325 N (73.1 lbf) for 10 s, using 100 by 250 mm (3.9 by 9.8 in) flat surface.
Compression Test	Test from 16 C.F.R. Part 1250, using a force of at least 131 N (29.5 lbf).
Torque Test	Test from 16 C.F.R. part 1250, using a torque of at least 0.50 Nm (4.4 inlbf).
Tension Test	Test from 16 C.F.R. part 1250, using a force of at least 68.0 N (16.2 lbf).
Probe for Accessibility	Apply 50 N (11.2 lbf) with Test Probe 11 from IEC 61032 to confirm compliance.

Table 7. Summary of Proposed Performance Requirements for Consumer Products with Compartments for Non-Replaceable Batteries

Option 1 – Not Accessible	 Requires a tool that is not a common household tool to open or the battery is secured with soldering, fasteners such as rivets, or equivalent means. Meets the same applicable preconditioning and use and abuse test requirements as battery compartment for replaceable batteries.
Option 2 – Accessible	 Battery is secured with soldering, fasteners such as rivets, or equivalent means. Applicable preconditioning and use and abuse test requirements apply. Confirmed with secureness test: test hook applies a force of 18 N (4.1 lbf) directed outwards for 10 s, at all possible points. Battery cannot liberate from the product.

Each of staff's recommended modifications to the performance requirements for the Draft Final Rule are described below, and are discussed in greater detail in Tab E.

1. Battery Compartment Securement – Non-Replaceable Batteries

The proposed rule requires products containing non-removable button cell or coin batteries to comply with requirements pertaining to accessibility of batteries. The rule states that batteries shall be made inaccessible by either: (1) using an enclosure that requires a tool to open via fasteners held captive to the enclosure or twist-on access cover or using an enclosure that requires two independent and simultaneous hand movements to open (§ 1263.3(b)); or (2) securing the button cell or coin battery, if accessible, using soldering, fasteners such as rivets, or equivalent means, that passes the Secureness Test. The proposed rule effectively requires products containing non-removable button cell or coin batteries that are inaccessible to comply with performance requirements that are at least as effective as those for products containing batteries that are intended to be replaced by the consumer.

Commenters, including UL Solutions, Consumer Technology Association (CTA), Information Technology Industry Council (ITI), Permanent European Horological Committee (CPHE), Federation of the Swiss Watch Industry (FH), and American Watch Association (AWA) describe the requirement for captive screws on battery compartments to be replaced by professionals or non-replaceable batteries as design restrictive and onerous. Staff agree that captive screws are intended to prevent screws from being discarded or lost on products which require battery replacement by the consumer, and are not necessary on battery compartments for which the battery is not intended to be replaced by the consumer. Staff concludes that battery compartments for which the battery is not intended to be replaced by the consumer should not be openable with a common household tool and should have packaging and instructions which state the battery is not to be replaced by the consumer.

For the final rule, staff recommends modifying § 1263.3(c) to have products with batteries that are not intended to be removed or replaced by consumers to be excluded from § 1263.3(b) requirements, and only comply with the performance requirements of § 1263.3(e), including use and abuse testing, to ensure the batteries do not liberate from the product. Furthermore, staff recommends adding to § 1263.3(c)(1) that the battery compartment enclosure cannot be opened with a common household tool, such as a flat blade or Phillips head screwdriver, pliers, or coin. Additionally, staff recommends that the warning statement for products with non-replaceable button cell or coin batteries, originally proposed as technical information under section 27(e) of the CPSA, should instead be required under Reese's Law, as the warning statement can be used to help determine the appropriate performance and labeling requirements under the statute. In particular, the warning statement would directly address 15 U.S.C.§ 2056e(a)(2)(C)(ii), which describes the warning label requirements for products "for which the battery is not intended to be replaced or installed by the consumer." These changes will ensure that battery compartments of products containing non-replaceable button cell or coin batteries are secured in a manner that would eliminate or adequately reduce the risk of injury without unnecessarily restricting the designs of these products.

2. Drop Test

The NPR requires products to be subject to drop tests based on requirements from UL 4200A; however, UL4200A requires a different number of drops depending on whether the product is classified as portable (three drops) or hand-held (ten drops). Staff observed that the term "hand-held" is undefined in UL 4200A and therefore can be subjective, which may lead to a product being subjected to a different number of drops by different testers. To avoid this confusion, in the NPR staff recommended subjecting all in-scope products to the greater number of ten drops, as ten drops was considered adequate to address the risk of injury for hand-held products, and fewer drops was not.

CTA and ITI recommended that a drop test with three repetitions is adequate for some products. While the commenters state that they agree that ten total drops as specified in the NPR is appropriate for handheld products such as remote controls, they recommend that three drops is adequate for other portable products such as equipment that is transportable but not intended to be held in hand while in use. Examples of portable products include a desktop computer which uses a coin battery, and can be carried and transported, but is intended to be used while sitting on a stable surface. Commenters opine that it is not reasonably foreseeable that such portable products will be dropped ten times over the course of their life.

Staff agrees that requiring ten drops is not reasonably necessary to reduce the risk of children accessing button batteries for some portable products. Staff observes that to align with Reese's Law, the number of drops must be based on foreseeable use and misuse, and therefore staff recommends clear criteria for distinguishing categories of products with different foreseeable drop risks (as described in Tab A). Existing definitions in published voluntary standards that differentiate the types of products subject to drop testing do not meet these requirements. For the Draft Final Rule, staff recommends adding definitions for "portable" and "hand-held" products and requiring three or ten drop repetitions,

respectively, based on the product type. Additionally, staff advises that the number of times a product must be dropped should use the product's weight and foreseeable use and misuse while being used or carried as a primary determining factor for drop frequency. Products that are lighter are more often carried by hand or often operated while in hand; therefore, more opportunities exist for consumers to inadvertently drop these products. This is especially true for lightweight products that young children may be able to lift and carry and possibly play with. Heavier objects tend to be carried less frequently and are often used while sitting on a surface such as a tabletop. Staff considered the requirements in Reese's Law, public comments, and existing requirements in voluntary standards to develop recommended definitions for "hand-held" and "portable" products.

The Draft Final Rule builds on voluntary standards. In particular, ASTM F963-17 specifies a drop test for toys based on weight and intended age range in section 8.7.1. The ASTM standard requires toys less than 10 lb. \pm 0.01 lb. (4.5 kg) intended for children younger than 96 months (8 years) old to be subject to the drop test. Based on this weight criteria, because children are more likely to carry, use, and potentially drop such objects, staff recommends similarly defining a "hand-held product" as:

• A consumer product that is reasonably foreseeable to be held by hand during use or misuse and that is 4.54 kg (10.0 lb.) or less in mass.

Hand-held products must be dropped ten times.

Based on the definition from UL 4200A, staff recommends defining a "portable product" as:

• A consumer product that requires lifting or handling as part of its reasonably foreseeable use or misuse and that is 18 kg (40 lb.) or less in mass.

Portable products must be dropped three times.

Per these definitions, hand-held products, such as remote controls, tracking devices, flashlights, flameless candles, and most laptops, among others, would be subjected to ten total drops. Such products are commonly carried by hand by both adults and children, and therefore are more likely to be dropped frequently over the course of their lifetime. Products such as desktop computers and other large or heavy audio/visual equipment, among others, would be considered portable products because they can be lifted and transported, but are most commonly sitting on a surface when in use, and therefore are likely to be dropped less frequently over the course of their lifetime. Staff advises, consistent with UL 4200A, that products weighing greater than 40 lb. are not considered to be routinely, easily, or foreseeably carried and are less likely to experience drops through the course of their lifetime; therefore, it is not reasonably necessary for these products to be subject to the drop test. These products would still be subject to the other performance requirements.

In summary, staff agrees with comments that the NPR's proposal for all products containing button cell or coin batteries to be dropped 10 times (consistent with the requirements in UL 4200A for hand-held products to be dropped 10 times) are not appropriate for all products. Staff's revised recommendations would result in hand-held products continuing to be dropped 10 times, consistent with the NPR; portable products would only require 3 drops, and any products that are not hand-held or portable would not be drop tested. This drop test requirement would adequately reduce the risk of injury from dropped consumer products liberating button cell or coin batteries to children that are 6 years of age or younger.

3. Simulated Battery Replacement

The NPR specifies a pre-conditioning requirement in § 1263.3(e)(1)(ii) to repeatedly open and close a battery compartment and remove and replace the battery a total of ten cycles. This requirement intends to simulate the wear and tear of a battery compartment after repeated battery replacements over the course of a product's lifetime. This ensures that when a sample product is subjected to the subsequent use and abuse tests, the sample is representative of a realistic used condition where connection points of enclosures or mechanisms holding batteries in place are in a reasonably weakened state. For enclosures that use fasteners to secure in place, the proposed rule requires the fasteners to be torqued according to Table 20, referenced from UL 60065, *Standard for Audio, Video and Similar Electronic Apparatus – Safety Requirements*.

ITI states that the referenced Table 20 is outdated and is superseded by Table 37 of the *Standard for Safety: Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements*, UL 62368-1. Staff agrees that Table 20 of UL 60065 is superseded by Table 37 of UL 62368-1 and recommends updating the reference table in the final rule. Table 20 specifies torque values based on the screw's diameter and type whereas Table 37 specifies a torque value based on only the screw's diameter regardless of the screw type. Because Table 37 adopts the greatest torque values for screw type II from Table 20 and applies them to all screw fasteners, updating the reference to Table 37 in the final rule will increase the safety and reliability of screw fasteners securing battery compartments.

4. Clarify Test Methods for Performance of Battery Compartment Securement

The proposed rule requires replaceable button cell or coin batteries to be contained within a battery compartment that is secured by an enclosure that meets the performance requirements of § 1263.3(b). These requirements are intended to prevent children from manipulating the mechanisms securing the battery compartment enclosure and gaining access to batteries. The proposed rule requires enclosures to either be secured by a mechanism that requires "a tool, such as a screwdriver or coin, to open" or a mechanism that requires "a minimum of two independent and simultaneous hand movements to open."

In a late filed comment, AWA comments that according to Section 2 of Reese's Law, 15 U.S.C. § 2056e(a), the final consumer product safety standard "shall only contain a performance standard." The commenter argues that the requirements for screws to be held captive to the enclosure, for minimum torque and angle of rotation for enclosures requiring a tool to open, and for multi-action locking mechanisms¹⁴ in § 1263.3(b)(2)(i) and (ii) are design requirements and do not involve any testing; therefore, the commenter states that CPSC lacks the authority to impose these requirements.

Staff disagrees with the commenter and concludes that the referenced requirements are performance requirements, as discussed in the comment responses in Tab A and in further detail in Tab E. Design requirements impose specific designs on products. In contrast, performance requirements define how a

¹⁴ The NPR briefing package used the phrase "double-action lock" as shorthand to describe battery compartments that can be opened with at least two simultaneous and independent actions. Industry frequently refers to these types of locks as "double-action" or "dual action" locks, but this phrasing implies that only two actions can be used to meet the requirement in the rule. The phrase "multi-action lock" more accurately reflects that two *or more* simultaneous and independent actions may be used to meet the requirement in § 1263.3(b)(2)(i) and (ii) of the proposed and draft final rules, which has not been modified based on the comments.

product must function under test conditions. Each of the requirements cited by AWA is a performance requirement that addresses the safety of the battery compartment:

- 1) Use of a tool. The NPR and this Draft Final Rule allow battery compartments to be secured in a manner that requires a tool to open. The rule does not specify what tool is required, or how that tool is to be used to open the battery compartment. Manufacturers can design their products to be opened with any tool, and manufacturers and test labs would have to conduct a test to verify that the battery compartment cannot be opened without a tool. This performance requirement can be met with any number of locking mechanism designs, including screws or fasteners, a pin release, or a small coin slot. This performance requirement is necessary because younger children may lack the required cognitive ability and fine motor coordination to perform the necessary actions to open battery compartments with a tool, as described in the NPR.
- 2) Captive screws. The NPR and this final rule do not require the use of screws or fasteners to secure the battery compartment enclosure. However, if screws or fasteners are used, then their performance must be such that they remain attached to the battery compartment door, cover, or closure. Manufacturers and test labs would test screws or fasteners to ensure they remain attached and the performance requirement is met. This performance requirement does not impose a single design on manufacturers. In addition to the fact that screws or fasteners are not required, even if they are used there are any number of ways to implement a design to retain them, including the use of a retaining washer, a press fit cap, a tether, or other means. This performance requirement is necessary to reduce the likelihood that screws or other fasteners are lost or left off of the compartment, which would allow children to more easily access the battery compartment, as described in the NPR.
- 3) Minimum torque and angle of rotation. The NPR and this final rule do not require battery compartments to be secured using one or more screws or using a twist-on access cover. However, if screws or a twist-on access cover are used, then they must require a minimum torque of 0.5 Nm and a minimum angle of 90 degrees of rotation, or the fastener(s) must engage a minimum of two full threads. Manufacturers and test labs would have to perform a torque and/or a rotation test to verify the torque and rotation angle meet the performance requirement. The requirement does not tell manufacturers how to design the threads or locking mechanism to achieve the required performance. These performance requirements are necessary to address incidents involving stripped screw holes and screws of insufficient length, and the requirements increase the difficulty for children to get into the battery compartment, as described in the NPR.
- 4) A minimum of two independent and simultaneous hand movements. The NPR and this final rule allow battery compartments to be opened using a minimum of two independent and simultaneous hand movements; the hand movements cannot be combinable to a single movement with a single finger or digit. The rule does not specify what the hand movements must be or what specific components of the battery compartment the movements are to engage. Manufacturers and test labs would test to confirm that the battery compartment requires at least two independent and simultaneous hand movements to open. As with tools, children may lack the required cognitive ability and fine motor coordination to open a lock requiring two independent and simultaneous hand movements; moreover, because these locks do not require screws, they afford additional flexibility to manufacturers to design effective child-resistant battery enclosures, as described in the NPR.

Staff have observed numerous consumer products that achieve these performance requirements through a wide variety of designs. Additionally, these performance requirements are based on similar performance requirements found in one or more voluntary standards developed through a consensus process involving manufacturers and other stakeholders. However, to avoid confusion such as that reflected in the comments, staff recommends modifying the requirements in the NPR so that the performance parameters are part of tests to ensure that the designs are adequate. Staff recommends adding test methods under § 1263.3(d)(1) for consumer products with battery compartments enclosures for replaceable button cell or coin batteries:

(1) Consumer products with battery compartments for removeable or replaceable button cell or coin batteries are tested using the following methods:

(i) Use an appropriate tool to open the battery compartment enclosure. For any threaded fastener(s) or twist-on access cover securing the battery compartment enclosure, apply a removal torque over a period of at least 5 seconds. Measure the peak torque and angle of rotation needed to loosen each component and open the battery compartment enclosure.

(ii) Use hand movements to open the battery compartment enclosure. The movements to open cannot be combinable to a single movement with a single finger or digit. Determine the minimum number of independent and simultaneous hand movements required to open the battery compartment enclosure.

Staff also recommends clarifying the appropriate application of these tests and the acceptance criteria in § 1263.3(b)(2):

(i) Secure the battery compartment enclosure so that it requires a tool, such as a screwdriver or coin, to open the battery compartment. Battery compartments secured by one or more screws, or a twist-on access cover, must require a minimum torque of 0.5 Nm (4.4 in-lb) and a minimum angle of 90 degrees of rotation, or the fastener(s) must engage a minimum of two full threads with a minimum angle of 720 degrees of rotation, when tested in accordance with § 1263.3(d)(1)(i). Screws or fasteners used to secure the battery compartment enclosure must remain captive to the compartment door, cover, or closure after testing to § 1263.3(e).

(ii) Secure the battery compartment enclosure so that it requires a minimum of two independent and simultaneous hand movements to open when tested in accordance with 1263.3(d)(1)(ii).

These clarifications of the performance requirements and test methods ensure the performance of the products' battery enclosure systems are evaluated consistently and appropriately.

5. Add Abuse Testing Requirement for Products Containing Accessible Non-Replaceable Batteries

The proposed rule allows in § 1263.3(c) batteries "not intended for removal or replacement" to be made inaccessible by an enclosure that secures the button cell or coin batteries using "soldering, fasteners such as rivets, or equivalent means, that passes the secureness test in § 1263.3(f)." The secureness test applies a test hook to accessible batteries with a force of at least 18 N (4.1 lbf.) on the button cell or coin battery to evaluate how securely fastened the battery is to the product. The Commission based these

requirements in the proposed rule on the requirements from UL 4200A and IEC (UL) 62368-1, which the Commission found to be adequate for application under Reese's Law.

CTA and ITI comment that the NPR incorrectly states that UL 4200A and IEC 62368-1 do not require abuse testing for products with button cell or coin batteries that are secured by soldering, fasteners, or any equivalent means. The commenters explain that UL 62368-1 requires robustness tests for solid safeguards which address accessibility or other hazards such as shock, fire, mechanical, and burn. The commenters state that these requirements are independent of the button cell or coin batteries because they are general requirements for all solid enclosures or barriers.

Staff agrees with the commenters and appreciates their clarification of the interpretation of this requirement. Staff acknowledges that products containing accessible non-removable batteries that are secured by soldering or fasteners will experience foreseeable use and abuse through their lifetime and should not be an exception to the abuse testing requirements. Impacts, drops, or compressions can break the soldering or fasteners attaching the battery to the product thereby freeing the battery and exposing the hazard to children. Staff observes that UL 62368-1 explicitly includes other use and abuse requirements, and UL 4200A implies through its scope that applicable requirements in other standards should be followed. To make these requirements explicit in the Draft Final Rule, and to further address impacts, drops, or compressions that can break the soldering or fasteners securing a permanently attached button cell or coin battery and thereby freeing the battery and exposing the hazard to children, in response to these comments, staff recommends modifying § 1263.3(c)(2) to require compliance with the abuse testing of § 1263.3(e) in addition to the secureness test, § 1263.3(f). Doing so will align the requirement with the commenters' interpretation of the voluntary standards on which it is based, and ensure the mechanical securement of the non-removable battery is adequately robust to withstand foreseeable use and abuse and therefore will increase the safety of these products.

Staff also recommend that consumer products with non-replaceable batteries that become accessible but do not liberate from the product during testing be subject to the secureness test in § 1263.3(f) instead of the compliance accessibility probe test in § 1263.3(e)(3). This ensures that non-replaceable batteries which are accessible by design, or which become accessible through foreseeable use and abuse, cannot be removed from the consumer product and ingested by children.

6. Corrected Minimum Values

The NPR specifies minimum force values using the highest or nominal tolerance from the voluntary standard which served as the basis for the performance requirement rather than specifying a tolerance from a nominal value. For example, the crush test in the proposed rule, which is based on UL 4200A, specifies a force of 335N versus the value in UL 4200A which specifies 330 ± 5N.

ITI and CTA comment that the proposed rule does not include tolerances for specified values and opines that the purpose of tolerances is to provide reasonable allowances (e.g., manufacturability and testability) that will not have a significant impact on test results. The commenters point out that the proposed rule specifies values based on the highest tolerance as delineated in the referenced voluntary standard, which could force unnecessary retesting or could make it impractical to apply the test without custom test equipment. The commenter recommends including tolerances in the final rule that align with those provided in voluntary standards.

Staff acknowledges that the values specified in the Draft Final Rule should be based on the lowest tolerance rather than highest, to represent the lowest acceptable value and recommends modifying the values accordingly. This will reduce the amount of custom equipment needed to conduct the test without compromising the safety of the consumer products. The minimum force requirement does not impose design or production requirements on the manufacturer; and it is the manufacturer's responsibility to have processes in place to ensure each product will meet the proposed requirements.

B. Recommended Marking and Labeling Requirements for Draft Final Rule

The NPR includes proposed marking and labeling requirements in accordance with Reese's Law. The proposed warning labels are based on requirements in ANSI Z535.4. Staff's updated review of voluntary standards concludes that UL 4200A-2023 can be determined to be adequate to meet the warning label requirements for consumer products and consumer product packaging in Reese's Law. UL 4200A-2023 does not address battery package labeling.

Staff recommends changes to the marking and labeling based on public comments. The changes for the Draft Final Rule in accordance with Reese's Law are summarized below. UL 4200A-2023 is consistent with most of the recommended changes, as discussed in Section III.A above.¹⁵

1. Modify General Warning Label Color Requirements

The general requirements in the NPR for warnings and warning labels follow requirements found in ANSI Z535.4 American National Standard Product Safety Signs and Labels, which is the primary voluntary consensus standard providing guidelines for the design of safety signs and labels for application to products. The ANSI standard includes recommendations for the design, application, use, and placement of warning labels, such as having the signal word "WARNING" and the safety alert symbol of an equilateral triangle surrounding an exclamation mark.

Reese's Law includes requirements for the placement and content of warnings, but does not address the warnings' formatting or color. The NPR proposed using the signal word "WARNING" and requiring the word to be in black letters on an orange background. The NPR also proposed that the word "WARNING," when applied directly to the consumer product, be accompanied by the icon representing "Warning: Contains coin battery" which must be in yellow with a black icon. Staff recommended the use of color to make warnings more likely to be noticed quickly.

Several commenters state that the use of color on packaging, instructions, manuals, and on some consumer products would be challenging and, in most cases, add costs to the manufacturing and printing process, particularly to those materials that do not already incorporate color. Commenters also stress that other product safety standards (*e.g.*, ASTM F963, ANSI C18.3, or ANSI Z535 series) do not mandate the use of colors and accept black and white printing or contrasting colors to the background it is printed on. Commenters state, however, that if color is used for the signal panel, colors should conform to ANSI Z535.1 safety colors that correspond to the safety message. Commenters state that the use of color may not be reasonable to print on certain product materials, for example, colored or textured plastics.

¹⁵ It is not consistent only in that it does not add the National Battery Ingestion Hotline phone number to warning labels or make related changes.

Staff agrees that applying color to some materials (*e.g.*, consumer product packaging, manuals, or other collateral material) that do not already contain color may present a burden to some manufacturers. ANSI Z535.4 provides flexibility for special circumstances that limit or preclude the use of colors while preserving the visibility and noticeability of the label by requiring contrasting colors. Staff recommends requiring the use of color when the subject materials will already use printed color processing, otherwise the use of black and white or contrasting colors is acceptable. The use of color is not specified in Reese's Law, thus this recommendation does not conflict with the statutory requirements and staff views this recommendation as safety neutral compared to the NPR proposal, because the label or icon will visually align with other information on the display while ensuring that it is noticeable due to its contrast or color.

2. Clarify On-Product Label Text Size Requirements

Reese's Law requires that consumer products be labeled, where practicable, in a manner that is visible to the consumer upon installation or replacement of the battery, or when the battery is not replaceable, in a manner that is visible to the consumer upon access to the battery compartment. The NPR states that consumer products must be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or coin battery. Product Display Panel is defined in 1263.2(f). Text size must be determined based on Table 1, or if on a sticker label, must meet the minimum size requirements in §1263.4(a)(7).

While reviewing the proposed regulatory text, staff found that the NPR required warnings to be placed on the product consistent with Reese's Law, but the term used to define the appropriate place to put onproduct warning labels, the "product display panel," was not explicitly referenced in the warning label text size requirements. Staff clarifies its understanding that under the NPR and the Draft Final Rule the text size must be dependent on the principal display panel (for labels on battery packaging and consumer product packaging) or the product display panel (for labels on consumer products). This will assist manufacturers in determining what area to measure for the on-product warning label. Alternative onproduct labels can be used in situations where the full label does not fit in the measured product display panel area, as described in the NPR and in the Draft Final Rule.

3. Add National Battery Ingestion Hotline Phone Number

The warning label proposed to be on battery packaging included the bullet "**Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body." Staff received a comment that this statement does not provide the next logical step to get help and requests that CPSC require the addition of the phone number for the National Poison Control Center (NPCC). Staff agrees that adding the appropriate contact number will provide consumers with an actionable step, and recommends that the contact number for the National Battery Ingestion Hotline (NBIH), currently 1-(800) 498-8666, be inserted in the last warning statement, as shown in Figure 3. This provides consumers an actionable step in the case of a battery ingestion.

WARNING

- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested in as little as 2 hours.
- A swallowed button cell or coin battery can cause Internal Chemical Burns.
- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].



Figure 3. Proposed warning of ingestion hazard for battery packaging.

4. Remove Redundant Warning Statements

Because the warning label on battery packaging and consumer product packaging now directly addresses who to contact for treatment information (the National Battery Ingestion Hotline), staff recommends removing the following warning statement from packaging and instructions and manuals:

• "Call a local poison control center for treatment information."

This statement to "Call a local poison control center" is now redundant and should be removed.

5. Alternative Icon and Text for Consumer Product Packaging Warning Labels

The NPR proposed that warning labels for the packaging of consumer products containing button cell or coin batteries include the "Keep Out of Reach" icon to quickly convey the safety message to keep the batteries out of reach of children, and to direct the reader's attention to the label.

Public comments state that the icon on the product packaging can be mistaken to mean that the product itself should be kept away from children, and recommend instead to use the "Warning: Contains coin battery" icon. Staff agrees that the "Keep Out of Reach" icon could be mistaken to mean keep the product out of reach of children; and while this message may be appropriate for some products, it is not appropriate for children's products or other products that may be used by children. For effective communication of safety hazards, people need to notice, read, and heed the warning. If the warning is not believable, people may stop reading the label or disregard it. Having a "Keep out of Reach of Children" icon on a product that is likely to be used by children may give an inaccurate message to consumers, who then may choose to skip the warning content entirely. To eliminate confusion regarding whether the battery or the product should be kept away from children, staff recommends allowing either the "Keep Out of Reach" icon or the "Warning: Contains coin battery" icon to be used, as the responsible firms deem appropriate for the product.

Staff views the effectiveness of either icon safety neutral in this case because both icons require further reading and understanding of the label content to communicate the message accurately. The primary

purpose of the icon is to get the attention of consumers so that they stop and read the text. Therefore, staff concludes that either icon is appropriate and does not conflict with Reese's Law because the label content is identical and communicates the description of the hazard, what to do to avoid the hazard, and to seek medical attention, regardless of what the icon itself communicates.

In addition, one commenter requests flexibility to allow the word "uses" to replace the word "contains" in the first bulleted statement. This is to avoid confusion in circumstances where a consumer must purchase a battery not already installed in or provided with a product, and to prevent the impression of false claims that the battery comes with the product. Staff agrees in some instances the word "contains" may lead to legitimate concerns about misrepresentation and recommends offering alternative wording for manufacturers.

See Figure 4 for an updated proposed warning label with the "Warning: Contains coin battery" icon and showing that the word "uses" can replace the word "contains". This label also includes the NBIH phone number as discussed earlier.

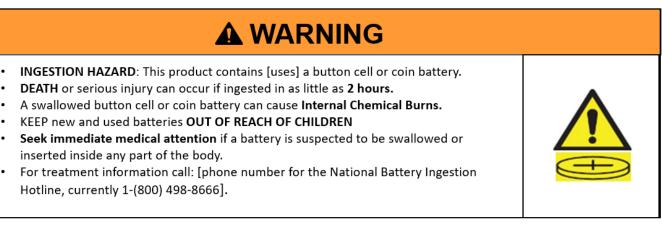


Figure 4. Proposed warning to indicate the presence of a button cell or coin battery and the ingestion hazard for consumer product packaging.

The NPR proposed alternative options to the full warning label if limited packaging size does not permit the use of the full warning label. Based on comments outlined above, staff prepared an example warning label using the "Warning: Contains coin battery" icon for use on the principal display panel (Figure 5) and the remaining statements label for the secondary display panel (Figure 6).

AWARNING

- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours.



A WARNING

- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

Figure 6. Proposed abbreviated warning for the secondary display panel.

Based on the requirements for icon and text size, the warning label shown in Figure 3 will occupy at a minimum about 1.77" (45 mm) width and 0.75" (19 mm) height on the principal display panel of the packaging in its condensed form (Figure 5a). Figure 5b shows a principal display panel of a packaging containing this label. The principal display panel in this case is 1.89" (48 mm) wide and 1.06" (27 mm) tall while also accommodating the product name and a logo. Staff finds that a product packaging slightly exceeding 0.75" x 1.77" can accommodate the minimum required text and icon.

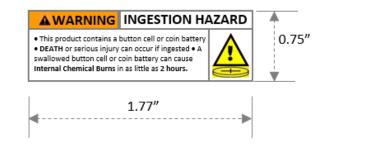


Figure 7a. Proposed abbreviated warning in a condensed form.



Figure 7b. Same label on a package with 1.89" width and 1.06" height

6. Add On-Product Label Permanency Test

The NPR required warning statements or icons to be "clearly visible, prominent, legible, and permanently marked." Commenters requested clarification of the permanency requirement for warning labels printed



on-product or using sticker labels, and one commenter suggested on-product permanency should comply with the test requirements in UL 62368-1.

Staff agrees that the permanency requirement can be clarified. Staff reviewed the recommended warning label permanency test in UL 62368-1 section F.3.10. This test evaluates the legibility of printed or screened markings (1) after a sample is rubbed with a cloth soaked in water, and (2) after a sample is rubbed with a cloth soaked in petroleum spirit (a reagent grade hexane with a minimum 85% n-hexane). The marking must remain legible, and adhesive labels must not curl or be removeable by hand. Staff concludes that this test method, combined with the existing requirements for clearly visible, prominent, and legible warning statements, is appropriate for labels on or near the battery compartments of consumer electronics, and that it addresses labeling methods such as, but not limited to embossing, stamping, etching, or molding. Staff therefore recommend adding the following to the warning label requirements for consumer products that contain button cell or coin batteries:

• Permanency of the label must be tested in accordance with UL 62368-1: F.3.10.

This test method will verify that consumer products containing button cell or coin batteries remain durably and indelibly marked with the required warning labels.

7. Add Warning Statement Addressing Securement of the Battery Compartment

The Toy Association commented that multi-action mechanisms can present a "false positive" where it appears to be closed but is not secure. Staff acknowledges that this scenario may occur in both multi-action enclosures and enclosures secured via screw fasteners. For example, after replacing the battery, consumers may inadvertently neglect to screw the fastener, leaving the enclosure ineffective. To decrease this risk for all products regardless of their enclosure securement design, staff recommends requiring all products with a replaceable button cell or coin batteries to include warnings in product instructions to ensure proper securement of the battery enclosure. Staff's recommended language is shown below:

• For consumer products using replaceable batteries: Always completely secure the battery compartment. If the battery compartment does not close securely stop using the product, remove the batteries, and keep the batteries away from children.

C. Recommended Revisions for a Future Rulemaking

The NPR proposed additional warnings to serve as performance and technical data related to safety at the point of sale under Section 27(e) of the CPSA. Staff has developed changes to the additional warnings based on public comments, on which additional comment could be sought through a SNPR. The preliminary changes for a potential SNPR in accordance with section 27(e) are summarized below. Staff's recommended path for implementation of these changes will differ in the case of a Commission determination that UL 4200A-2023 meets the requirements of Reese's Law, as discussed in section VII of this memorandum.

1. Require Icon for the Button Cell and Coin Battery

The NPR requested comment on whether the rule should require button cell and coin batteries to be durably and indelibly marked with the "Keep out of Reach" icon. After consideration of the comments, staff recommends requiring the "Keep out of Reach" icon be used on button cell or coin batteries that are visible within the packaging, where practicable, as an additional safety warning should the battery be removed from its packaging and not immediately installed in a consumer product. Consumers will see the "Keep out of Reach" icon at the point of sale. The icon will remain visible once the battery is removed from its package but not yet inserted into the consumer product. The goal is to inform the consumer of a hazard and to address incidents associated with batteries loose in the environment so that consumers can take the appropriate action of keeping the battery out of reach of children.

2. Modify Other Battery Safety Information

To protect the public against unreasonable risks of injury associated with button cell and coin batteries, or those consumer products that use such batteries, the NPR proposed other safety information be present on the battery packaging, consumer product packaging, and instructions, if provided. Many of these performance and technical statements proposed under section 27(e), or similar statements, are already found on current retail battery packaging to instruct consumers how to handle batteries safely and avoid foreseen hazards, such as "Keep in original packaging until ready to use" or "Dispose of used batteries promptly." Public comments generally did not support this requirement because battery packaging is already small and unlikely to have space for all the statements recommended. Other public comments point out that some of the recommended warning statements are not applicable to products with non-replaceable batteries. Staff assesses that many of the warning statements can already be found on battery packaging, so space is not likely to be an issue. To the extent that space could be an issue, staff recommends seeking comment on whether QR codes should be allowed as the primary means of displaying these additional warning statements as a means of saving space, so long as the warning statements are also provided in accompanying manuals or literature (see Tab A and section VII of this memorandum). See staff's response to comment Tab A, Issue #14. However, staff agree with commenters that the applicability of the warnings can be clarified. Therefore, staff recommends clarifications to the applicability and content of the warnings on battery packaging, in instructions and manuals, and addressing battery disposal information.

The following statements are applicable only to consumer products with replaceable batteries.

- Ensure the batteries are installed correctly according to polarity (+ and -).
- Remove and immediately discard batteries from equipment not used for an extended period of time.

The following statement is applicable only to consumer products with replaceable batteries that use more than one battery per circuit:

• Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbonzinc, or rechargeable batteries.

The following statement is applicable only to consumer products using replaceable or non-rechargeable batteries:

• Non-rechargeable batteries are not to be recharged.

Staff recommends seeking comment on the applicability of these statements.

3. Battery Disposal Information

Staff received comments from consumer organizations and medical professionals that every use stage of button cell and coin batteries should be addressed, including disposal.

To clarify the steps consumers should take for safe battery disposal, staff recommends adding a statement on battery packaging, product packaging and instructions (or any literature provided) on battery disposal:

• Contact your local hazardous waste authority or find a local recycling center for battery disposal information.

Button cell or coin batteries which are not disposed of properly and promptly can be accessed by children and become an ingestion hazard. Local authorities will be best able to inform consumers on safe ways to dispose of batteries in a manner that meets local regulations. Staff recommends seeking comment on whether the warning statement helps inform consumers on steps to take for battery disposal.

4. Add Insertion Hazard Warning Label for Zinc-Air Batteries

The NPR requested comments on whether zinc air batteries should contain a warning label. Incident data provided in the NPR supports the assessment of a low risk for an ingestion hazard for these batteries, although incident data and comments demonstrate the potential for injury when zinc-air batteries are inserted in the ear and nose. Staff received public comments supporting the exclusion of labels, while those in the medical field expressed concerns about serious injury when inserted into the nose or ear canal.

As discussed in the Directorate for Health Sciences memorandum (see Tab C), staff recommends that zinc-air battery packages carry a warning label regarding insertion into the nose or ear. Figure 8 shows staff's recommended warning label for the final rule, to be added to zinc-air battery packages in lieu of an ingestion hazard warning label. The same format and location requirements for the ingestion hazard warning label.

OS 145

OS 146

A WARNING

- INSERTION HAZARD: Zinc Air batteries inserted in the nose or ear can cause Internal Chemical Burns.
- KEEP new and used batteries OUT OF REACH OF CHILDREN.
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].



Figure 8. Proposed warning label for zinc-air battery packaging

Staff recommends seeking comment on the proposed warning label, as described in section VII of this memorandum.

D. Draft Final Rule Effective Date

The NPR proposed a 180-day effective date for the rule. Multiple manufacturers and trade associations provided comments stating that a longer effective date is required to provide compliant products to the U.S. market. Detailed timelines of the necessary activities include time for product redesign, testing, certification sourcing, supply chain management, and other issues, and range from 12 months to 36 months in total. A commenter also explained that additional time is required to accredit third party laboratories for a large variety of product types.

Staff find the comments credible and of particular significance assess that due to the broad scope of the rule, a large increase in the number of products tested at accredited labs may occur, as discussed in the comment response in Tab A. Based on consideration of the comments, staff concludes that the proposed 180-day effective date is likely insufficient to give affected businesses enough time to design, manufacture, and test consumer products with battery enclosures meeting the rule's requirements. A substantial number of consumer products containing button cell or coin batteries do not meet the requirements of any voluntary standard, and many affected industries will be unfamiliar with all or part of the requirements in the Draft Final Rule. Additionally, staff's recommended warning label requirements include specific language that would require manufacturers to revise or reprint all existing packaging. In the NPR, CPSC proposed a 180-day effective date. Commenters outlined the challenges in doing so, recommending 12-36 months. Based on consideration of these comments, staff is recommending an 18month effective date to provide the time needed for industry to come into compliance including redesign, prototyping and testing as described in Tab A. This seeks to address the consumer need for safer consumer products containing button cell or coin batteries at the earliest time that is reasonably possible. Accordingly, products manufactured or imported 18 months after publication of a final rule would be required to comply with the rule.

V. Certification and Notice of Requirements

A rule for consumer products containing button cell or coin batteries would be a consumer product safety rule that requires testing and certification under section 14(a) of the CPSA. Additionally, as applied to (non-toy) children's products containing button cell or coin batteries, the rule would be a children's product safety rule that requires third party testing by a CPSC-accepted laboratory, and certification of

compliance to the standard. See 16 C.F.R. parts 1110 and 1107. Non-children's products require a General Certificate of Conformity, or GCC, based on a test of each product or a reasonable testing program. See 16 C.F.R. part 1110.

The Commission published Requirements Pertaining to Third Party Conformity Assessment Bodies, 16 C.F.R. part 1112, which establishes the requirements for accreditation of third-party testing laboratories to test for compliance with a children's product safety rule. The Draft Final Rule amends part 1112 to include non-children's consumer products containing button cell or coin batteries.

VI. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. §§ 601 - 612) requires that the agency prepare a final regulatory flexibility analysis that describes the impact that the rule would have on small businesses and other entities. Comments regarding the initial regulatory flexibility analysis are addressed in Tab A.

A. Costs and Impact of Draft Rule for Small Manufacturers

Button cell or coin battery-powered products may require redesign to accommodate the tool lock or a multi-action lock required by the Draft Final Rule. Button cell or coin battery-powered product manufacturers would most likely adopt a tool lock secured with a screw for affected products that currently do not conform to the proposed rule requirements. The potential costs of this rule are, therefore, the incremental cost to incorporate a screw lock, and the one-time research/development and retooling costs associated with the changes to battery compartments. For products that already incorporate a multi-action lock to secure the compartment, staff expects the only cost incurred would be the redesign of the compartment to accommodate the additional requirements from the draft proposed rule.

Estimates of the incremental costs to modify a battery compartment for a screw lock range from \$0.02 to \$0.04 per product, based on an ESMC staff estimate. The estimate of possible research/development and retooling costs equates to \$15,700 per firm. Staff assesses that firms with products or models that require a novel solution to incur an additional \$15,700 cost per product line affected. Firms that choose to meet the requirement using a multi-action lock (and which do not already use a compliant multi-action lock) are only expected to incur research and development costs, as the cost of retooling and modifying the battery compartment are expected to be negligible.

Some additional costs might be incurred from updating and/or adding labels to the product or the packaging of button cell batteries. Generally, the costs associated with modifying/adding warning labels are low because nearly all manufacturers already provide warning labels with their product. Similarly, the cost of upgrading the packaging of button cell batteries is expected to be very low on a per unit basis. Therefore, staff estimates the cost related to the labeling and packaging provisions would be negligible relative to the overall cost of compliance with the Draft Final Rule.

Manufacturers would likely incur additional costs to certify that their button cell or coin battery-powered products meet the requirements of the Draft Final Rule, as required by Section 14 of the CPSA. For general use products, the certification must be based on a test of each product or a reasonable testing program. Manufacturers may complete the testing themselves or use a testing laboratory. Certification of children's products, however, must be completed by a CPSC-accepted, third party conformity

assessment body (third party laboratory). Based on quotes from testing laboratory services for consumer products, the cost of certification testing will range from \$150 to \$460 per product sample.^{16, 17} These third-party testing costs would likely reduce over time as staff expects firms would develop an internal testing program for general use products to ensure these products meet the requirements. Note that the requirement to certify compliance with all product safety rules is a requirement of the CPSA and not of the Draft Final Rule. Certificate content requirements are set forth in section 14(g) of the CPSA and codified in 16 C.F.R. part 1110. A reasonable testing program performed by the manufacturer would meet the requirements for general use (non-children's) products, but children's products are required to be tested and certified based on the third-party testing requirements in 16 C.F.R. part 1107.

To comply with the Draft Final Rule, small manufacturers would incur a one-time redesign and continuous incremental component costs for some product lines that currently do not meet the requirements. Generally, staff considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. Staff does not expect most small manufacturers to suffer a disproportionate cost effect from the Draft Final Rule; but firms that heavily rely on the production of small unique/novel electronic products or high volume-low price products could be adversely affected. Retail prices for button battery-powered products vary widely, with the least expensive on a per-unit basis being mini flashlights at \$1.00.¹⁸ A small manufacturer could incur a significant impact – costs that exceed 1 percent of annual revenue – to comply with the Draft Final Rule if the firm only produced these high-volume low-price or novel electronic products. Also, smaller manufacturers with under \$1,540,000 in annual revenue could incur one-time costs that exceed 1 percent of annual revenue, based on CPSC staff's estimate of the potential research and development costs, which ranged from \$7,700 to \$15,400 per model.

In summary, staff assesses that most small firms would not incur costs that exceed 1 percent of annual revenues and therefore most firms would not be significantly impacted by the proposed rule.

B. Alternatives for Reducing the Adverse Impact on Small Entities

Under section 603(c) of the Regulatory Flexibility Act, a final regulatory flexibility analysis should "contain a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

CPSC staff assessed that the broad scope of Reese's Law does not allow for a significant alternative that would reduce impacts to small businesses, as methods for reducing impacts to small firms, such as limiting scope, providing exemptions, and consumer education in lieu of regulatory action, would not meet Reese's Law requirements. To reduce impact of the rule on small firms, CPSC could remove the additional labeling requirements under section 27(e) of the CPSA, as recommended by staff, that are not required by Reese's Law. However, removing additional labeling would reduce the burden by an inconsequential amount as firms would still have to conform to the other labeling provisions. The *incremental* increase in burden from staff's additional labeling requirements is insignificant.

¹⁶ Based on quotes from firms to conduct product certification tests to the current UL4200A standard.

¹⁷ Staff obtained an additional quote from a CPSC accredited laboratory to perform similar certification tests as completed previously by CPSC staff which amounted to approximately \$460.

¹⁸ Based on staff's review of product offerings on retailer websites and in-store locations.

Another alternative to reduce the potential impact of the rule is an extension of the effective date from 6 months to 12 or 24 months. Staff assesses that due to the broad scope of the rule, a large increase in the number of products tested at accredited laboratories may occur. Manufacturers are not required to third-party test general use products, but due to the diversity of the products subject to the Draft Final Rule, many manufacturers may not be equipped to create a reasonable testing program in 6 months as proposed in the NPR. An effective date of 12 to 24 months would allow manufacturers and labs to acquire the staff and resources needed to perform the required tests.¹⁹ Given the large and extremely diverse set of industries/products affected and the capacity limitations of accredited laboratories, an extension of the effective date may be a reasonable accommodation to ensure availability of the products within the scope of the Draft Final Rule. In addition, a shorter effective date may result in a short run volume increase in lower quality non-compliant products as staff expects total aggregate demand for these products to remain largely unchanged as a result of the rule.²⁰ CPSC staff now recommend an effective date of 18 months to minimize potential disruption in availability of safer *button battery powered products*.

VII. Future Proposed Rulemaking

Section 27(e) of the CPSA (15. U.S.C. 2076(e)) authorizes CPSC to require manufacturers of consumer products to provide, to purchasers and prospective purchasers at the time of sale, notification of performance and technical data related to safety. Staff recommends that the Commission seek additional public comment on the recommended changes to the NPR's proposed requirements for performance and technical data in accordance with section 27(e). Staff's recommended changes include separating these requirements from Reese's Law requirements in the regulation text; adding a new warning label addressing zinc-air batteries inserted into the ear or nose; including a requirement for direct labeling of batteries which was discussed in the previous NPR but was not proposed; and a revised list of warning statements that have been clarified to apply only to consumer products with certain types of batteries or battery compartments. More specifically, staff recommends seeking comments to address the following:

Zinc-Air Battery Warning Label

Based on public comments from physicians, staff recommends labeling zinc-air button cell or coin batteries to address the hazard of these batteries being inserted into the ear or nose. Staff suggest comment on the following:

• Whether the proposed warning label for zinc-air button cell or coin batteries provides sufficient warning of the insertion hazard;

¹⁹ Multiple manufacturers and trade associations submitted detailed timelines concerning required activities to bring products into compliance with the proposed standard. These timelines ranged from18 to 36 months, and frequently cited supply chain and transportation constraints and internal quality and manufacturing verification procedures as leading factors. CPSC staff also interviewed an employee of a CPSC-accepted lab who stated a 12-month lead time is required to acquire the necessary staff and facilities to accommodate the expected increase in product testing volume that may occur as a result of the mandatory standard.

²⁰ One commenter submitted a concern that manufacturers who intend to meet the mandatory standard may lose market share to lower quality foreign producers if the effective date is too soon. Staff found this concern credible but expect this market share loss to be temporary as it is unlikely consumers will alter long-term purchasing habits towards less safe products when both are of comparatively similar cost.

- Whether the proposed warning label for zinc-air button cell or coin batteries should use the signal word CAUTION or WARNING;
- Whether there is an alternative method to inform consumers of the insertion hazard.

Direct Labeling of Batteries

Based on public comments supporting the use of the "Keep Out of Reach" icon directly on batteries, staff recommends that button cell or coin batteries visible within the packaging be required to be durably and indelibly marked with the "Keep Out of Reach" icon, at a diameter of 6 mm or greater, where size permits. Staff recommends seeking comment on the following:

- Whether the proposed requirement should be limited to button cell or coin batteries visible within the packaging based on the authority in section 27(e);
- Whether there is a minimum diameter battery that allows the 6 mm diameter icon and additional safety-related information to be visible and legible, such as battery type and polarity;
- Whether the minimum diameter of 6 mm provides adequate space for the icon.

Additional Warning Statements

Based on public comments requesting more information on proper battery disposal, staff recommends adding a statement that provides consumers with additional battery disposal information. Based on public comments which point out that some of the warning statements only apply to certain types of battery compartments in products, staff recommends clarifying the applicable scenarios for warnings on consumer product packaging and in accompanying literature. Additionally, battery manufacturers commented that the additional warning statements would take up too much space on the packaging and sought to allow the warning statements to be provided via QR code or pictogram. Staff, however, initially concluded in connection with the NPR that space would not be an issue, and that while QR codes or pictograms could be used, they could not adequately replace written warnings. In light of the comments received in response to the NPR, staff urge a request for further public comment on the following:

- Whether the additional disposal information helps inform consumers on steps to take for battery disposal;
- Whether the proposed applicability of the additional warning statements is correct;
- Whether QR codes should be allowed as the primary means of displaying the additional warning statements when space on the packaging does not allow all of the statements to be clearly and legibly printed, and if so, whether written warnings should be required in instructions or manuals when a QR code is used.

Staff, however, welcome comments from the public on all aspects of the staff recommendations.

Staff note that its specific recommendations for a future rulemaking will differ depending on whether the Commission determines that UL 4200A-2023 is adequate to meet Reese's Law. UL 4200A-2023 includes requirements related to additional warning statements on consumer product packaging and in accompanying literature. Staff recommends that a separate briefing package containing recommendations for a future rulemaking be prepared after the Commission approves a rule in accordance with Reese's Law.

VIII.Conclusion

Staff reviewed and considered the comments received in response to the Commission's NPR. In addition, staff reviewed several ballots and revised voluntary standards. Based on the comments and additional staff analysis, staff concludes that UL 4200A-2023 adequately addresses the performance and warning label requirements for consumer products and consumer product packaging in Reese's Law. Staff recommends codifying in a direct final rule UL 4200A-2023 as the mandatory standard for consumer products that contain button cell or coin batteries. Staff also recommends that the Commission issue a final rule to address the warning label requirements for battery packaging in Reese's Law.



Memorandum

TAB A

Staff Briefing Package: Draft FR for Reese's Law | August 31, 2023 | cpsc.gov



Memorandum

TO:The FileDATE: August 31, 2023THROUGH:Duane Boniface, Assistant Executive Director
Office of Hazard Analysis and Reduction (EXHR)Seese's Law EXHR TeamFROM:Reese's Law EXHR TeamSummary of Comments and Staff Responses on the Proposed Rule to Establish a
Safety Standard and Notification Requirements for Button Cell or Coin Batteries and
Consumer Products Containing Such Batteries

I. Introduction

The Consumer Product Safety Commission received 34 comments during the comment period, from February 9 through March 13, 2023. Additionally, CPSC received one late-filed comment from one of the same commenters and one late-filed comment that was out of scope for this rulemaking. Thirty-three commenters support the safety purpose and scope of Reese's Law. Commenters include medical professionals, standards development associations, consumers, consumer advocates, retail and manufacturing associations, and battery and consumer product manufacturers. Commenters note the potential deadly risk of injury associated with ingestion and insertion of button cell and coin batteries and their ubiquitous use in many different types of consumer products that are accessible to young children. Medical professionals state the difficulty in diagnosing an unwitnessed button cell or coin battery ingestion, because the symptoms can mimic other health issues, such as colds or upset stomach, which complicates the necessity of prompt removal to prevent life-threatening esophageal burns and soft tissue damage. Accordingly, commenters generally support the development of strong performance and labeling requirements for consumer products to prevent this hazard, as most of the incidents involve batteries obtained from consumer products.

While supporting Reese's Law, manufacturer comments focus on whether and how various consumer products can meet the requirements of Reese's Law, as proposed in the notice of proposed rulemaking (NPR). Many commenters suggest that the CPSC find one of the reviewed voluntary standards adequate to meet Reese's Law requirements and adopt the voluntary standard. After reviewing and considering the comments, as detailed below, staff recommends retaining the majority of the NPR regulation text but making modifications and clarifications to both the performance and labeling requirements under Reese's Law, while meeting Reese's Law requirements, as well as to performance and technical data under section 27(e) of the CPSA. Additionally, commenters differed in their recommendations for an effective

Staff Briefing Package: Draft FR for Reese's Law | August 31, 2023 | cpsc.gov 48 date, from the proposed 180 days (consumer advocates) to up to 3 years (manufacturer associations). As detailed below, staff recommends an 18-month effective date for the Draft Final Rule. Staff provides a summary of modifications and clarifications in section II.C of the Cover Memorandum.

In addition to the comments described above, CPSC received nine comments in response to the April 11, 2023 *Federal Register* notice requesting comment on the Paperwork Reduction Act (PRA), some of which address the substance of the rule. Staff considers and responds to these comments as well.

Below we provide comment summaries by topic and detailed responses. Comment topics include epidemiological analysis; scope, including exemptions; the adequacy of various voluntary standards; the proposed performance and labeling requirements; costs; effective date; international regulations; and a variety of issues outside the scope of this rulemaking.

A. Comments in Response to Questions on Performance Requirements Posed in the NPR

Issue 1: Whether any consumer products (as opposed to medical devices, such as hearing aids) contain zinc-air button cell or coin batteries, and whether such products should be required to meet the performance requirements for battery compartments on consumer products.

<u>Comments:</u> Other than use in hearing aids, a medical device, no commenters identify any consumer products using zinc-air button cell or coin batteries. An international battery trade association and a coalition of medical and consumer organizations (American Academy of Pediatrics, Consumer Reports, Public Citizen, Consumer Federation of America, Kids In Danger, and U.S. Public Interest Research Group) specifically mention being unaware of any consumer products using zinc-air batteries. The coalition of medical and consumer organizations say the Commission should reserve the ability to take further action.

<u>Response:</u> Because CPSC staff is not aware of any consumer products that contain zinc-air button cell or coin batteries, commenters are also unaware of such products, and such batteries present a low risk of causing an ingestion hazard, as described in Tab C, staff's recommended draft final rule maintains that zinc-air button cell or coin batteries are not subject to the performance requirements in the rule. However, because of the insertion hazard associated with zinc-air batteries (in the ears or nose), staff recommends labeling of packages of zinc-air batteries for the insertion hazard in accordance with section 27(e), as discussed in Tabs C and D, and in response to issue 11 below.

Issue 2: Whether any voluntary standard meets the performance and labeling requirements of Reese's Law.

<u>Comments:</u> Five commenters (The Toy Association, Retail Industry Leaders Association (RILA), Permanent European Horological Committee (CPHE), Federation of the Swiss Watch Industry (FH), and American Watch Association (AWA)) recommend that CPSC accept the voluntary standard ASTM F963 as adequate to address the risk of child ingestion. The commenters generally state that ASTM F963 adequately fulfills the objectives of Reese's Law, and no data suggests that the standard creates an accessibility hazard for products containing button cell or coin batteries that comply with the standard. However, a coalition of medical and consumer organizations recommend that the ASTM toy standard subcommittee incorporate some of

CPSC's proposed requirements, such as improving testing for fastener retention and threading to avoid stripped screw holes and other possible scenarios that might lend access to the batteries.

Five commenters (Garmin International Inc. (Garmin), CPHE, FH, AWA, and TechNet) recommend that CPSC accept the voluntary standard UL 4200A as adequate to address the risk of child ingestion.

Four commenters (Japan Electronics and Information Technology Industries Association (JEITA), Consumer Technology Association (CTA), TechNet, and Information Technology Industry Council (ITI)) state that CPSC should accept IEC 62368-1 or UL 62368-1 as adequate to address the risk of injury for products within the scope of that standard.

The Battery Association of Japan (BAJ), Duracell, Energizer, and National Electrical Manufacturer's Association (NEMA) state that CPSC should accept IEC 60086 or ANSI C18 standards as adequate for battery package labeling requirements.

Finally, the Power Tool Institute says the Commission should work with voluntary standards organizations to improve and codify a voluntary standard.

<u>Response:</u> Reese's Law states that the Commission can rely on any voluntary standard if the Commission determines the following: (A) the voluntary standard meets the requirements for a standard promulgated under subsection (a) with respect to such a product; and (B) the voluntary standard is in effect at the time of the determination, or will be in effect not later than 180 days after August 16, 2022 (February 12, 2023). Based on staff's review of the voluntary standards for the NPR, as well as staff's updated assessment for this final rule, staff recommends that the Commission determine UL 4200A-2023 to be adequate to meet the requirements of Reese's Law or to address the risk of injury from child ingestion. The NPR describes staff's in-depth assessment of ASTM F963, UL 4200A, IEC 62368-1, IEC 60086 parts 4 and 5, and ANSI C18 parts 1 and 3. Tabs D and E discuss updated assessments of the above voluntary standards based on feedback received from public comments, and additionally describe ballots for and updated versions of these standards. Staff conclude that of these standards, only UL 4200A-2023 can be determined to be adequate to meet Reese's Law, and none of the commenters provide sufficient analysis, critique, or justification for the staff to change this recommendation for the other standards.

Issue 3: Whether the requirements for accessibility of battery compartments should incorporate test methods commonly used on toy products, such as the torque and tensile tests for parts of the product that can be gripped by a child's fingers or teeth, or a tensile test for pliable materials.

<u>Comments:</u> Two commenters (Landsdowne Labs and a coalition of medical and consumer organizations) support the incorporation of test methods commonly used on toy products.

<u>Response:</u> Staff agrees with the commenters that incorporating test methods such as torque and tensile tests for parts of the product that can be gripped by a child's fingers or teeth, or a tensile test for pliable materials, will decrease the likelihood of children gaining access to button cell or coin batteries. Staff assess that these test methods in the toy standard and proposed in the NPR are adequate to test the durability and integrity of battery compartments, particularly in products with pliable materials, such as shirts and greeting cards that light up or make sound using batteries. Staff agrees with the commenters and conclude that the proposed requirements

in the NPR will eliminate or adequately reduce the risk of ingestion in pliable products, as required by Reese's Law.

Issue 4: For consumer products that use button cell or coin batteries and have large panel doors, what consumer products have such doors, and should the Commission exclude large panel doors from the requirement for captive screws; why or why not (*i.e.*, why does a large panel door represent a different risk of injury from battery access without using captive screws than a smaller battery compartment door does?).

<u>Comments:</u> Three commenters (UL Solutions, CTA, and ITI) state that the large panel door exception from the captive screw requirement exists for devices where the panel forms part of system enclosure which is not intended to be opened regularly by the consumer. Example devices are desktop computers which commonly use coin batteries on the motherboards to provide backup power. The commenters state that the panels on these devices were unlikely to be left off or screws discarded. ITI opines that typically, large panels form part of the system enclosure which is not intended for consumers to open regularly. They note that UL 62368-1 states that captive screws are for batteries that need to be replaced regularly. CTA additionally demonstrates for a sample desktop computer that several internal components need to be removed in order to reach the battery on one such product. They explain that the exception described in UL 62368-1 is more specific than the exception in UL 4200A, because UL 62368-1 specifies "larger devices which are necessary for the functioning of the equipment and which are not likely to be discarded or left off the equipment."

<u>Response:</u> Staff agrees with the commenters that products containing button cell or coin batteries with large panel doors should be excluded from the captive screw requirement as long as the batteries are not intended to be replaced by the consumer. The intent of the captive screw requirement is to prevent screws securing battery enclosures from being discarded after battery replacement during the product's lifetime. For products requiring battery replacement, consumers foreseeably may discard the screws to make replacing the batteries easier, without appreciating the battery ingestion hazard; or consumers may lose the screw and think the product is safe to use without properly securing the battery compartment. However, if a product's battery is not meant to be replaced, staff advises that consumers are unlikely to open large panel doors to access the battery; therefore, requiring captive screws is not reasonably necessary to address the ingestion hazard in Reese's Law.

Exception 1 in section 5.6 of UL 4200A-2023 provides that captive screws are not required for products containing button cell or coin batteries that are not intended to be replaced by the consumer, and that products containing such batteries that can only be accessed through the removal of multiple enclosures or panels using a tool do not need captive screws. UL 4200A-2023 also requires that to meet the exception, such products must have instructions and warnings that clearly state the battery is not to be replaced by the consumer. Such products must also meet use and abuse testing requirements. Multiple enclosures or panels provide extra safeguards for preventing access to button cell or coin batteries, and staff are unaware of incidents involving access to button cell or coin batteries through multiple enclosures or panels. Staff concludes that the requirements for multiple enclosures in UL 4200A-2023, which can include large panel doors, are adequate to meet the requirements in section 2(a) of Reese's Law.

To address a large panel door exception in the Draft Final Rule, staff recommends modifying §1263.3(c) to require products containing button cell or coin batteries not intended to be replaced by the consumer must be openable with a tool that is not a common household tool,

must have packaging and instructions which state the battery is not to be replaced by the consumer, and must comply with the requirements of §1263.3(e). With this change, products with large panel doors can make their button cell or coin batteries inaccessible by complying with the use and abuse performance requirements or securing the battery using soldering, fasteners such as rivets, or equivalent means, that passes the Secureness Test in §1263.3(f).

Issue 5: Whether a multi-action locking mechanism used to secure battery compartment enclosures, meaning those mechanism that rely on two independent and simultaneous hand movements to open (versus a screw, for example), should be allowed to secure button cell or coin battery compartments.

<u>Comments:</u> Two commenters (RILA and The Toy Association) provide comments on whether multi-action locking mechanisms should be allowed to secure button cell or coin battery compartments. RILA supports including the option for multi-action locking mechanisms, especially for products where it may not be feasible to secure battery compartments with an enclosure that requires a tool. The Toy Association opines that multi-action locking mechanisms are susceptible to be opened by applying forces in a single action or for one or both mechanisms to be disengaged, reducing the safety or efficacy of the mechanism. They also comment that multi-action locking mechanisms may present a "false positive" to the consumer, appearing to be closed but susceptible to opening when the product is operated.

<u>Response:</u> Staff agrees with RILA's comment that multi-action locking mechanisms can be a safe and effective alternative method to securing battery enclosures. Many devices that use button cell or coin batteries are small and sometimes may not have enough space in the design to incorporate a screw to secure the battery enclosure. Therefore, providing multi-action locks as an alternative will provide industry some flexibility for designing their products. Staff's review of consumer products demonstrates a variety of different multi-action locking mechanisms that can be effective. Thus, manufacturers already have a variety of design choices for multi-action locks based on the size and structure of their product, and are free to develop additional methods, as long as those locks meet Reese's Law performance requirements as codified in the rule.

To address incidents involving multi-action locks that could be opened with a single action, the NPR and section 5.5(b) of UL 4200A-2023 supplements the multi-action locking mechanism requirement by specifying that "The movements to open cannot be combinable to a single movement with a single finger or digit." The NPR stated that without this clarification to the multi-action lock requirement, the requirement was not clear and could result in different interpretations by testers, leading to inconsistent and unreliable testing and, ultimately, a risk to children. This clarification in the NPR and UL 4200A-2023 provides further guidance for testers to determine the adequacy of the variety of products' multi-action lock designs.

The NPR addresses the Toy Association's concern. The proposed rule requires multi-action mechanisms to open with a minimum of two independent and simultaneous hand movements. Because the actions must be simultaneous, the first action must be maintained while the second action is completed for the lock to open. This means that the first action must not remain disengaged if the action is released prior to the second action. If the design of the mechanism allows for the first action to remain disengaged, it is poorly designed and does not comply with the requirements of the proposed rule. Therefore, the scenario presented by the Toy Association is prevented if the multi-action locking mechanism is designed per the requirements.

Additionally, regarding the Toy Association's comment on multi-action mechanisms presenting a "false positive" appearing to be closed, staff acknowledges that this scenario may occur in both multi-action enclosures and enclosures secured via screws or other fasteners. After replacing the battery, consumers may inadvertently neglect to screw or retighten a fastener, leaving the enclosure ineffective. To decrease this risk for all products regardless of their enclosure securement design, staff recommends requiring all products with button cell or coin batteries to include warnings in product instructions to ensure proper securement of the battery enclosure, consistent with UL 4200A-2023.

<u>Comments:</u> Four commenters (coalition of medical and consumer organizations, CTA, the Consumer Safety Consultancy (CSC), and Mark Strauch) provide comment on the statement, "The movements to open cannot be combinable to a single movement with a single finger or digit" in the proposed rule. A coalition of medical and consumer organizations recommends adding tests to prove the effectiveness of multi-action locking mechanisms. They express concern that locking mechanisms requiring a push and turn could be opened accidentally. The CTA opines that specifying independent hand movements cannot be combinable to a single movement as redundant, because if the end point of the first movement is the starting point of the second movement, then the movements would not be independent. CSC recommends that the requirement for multi-action locking mechanisms be revised to require independent and sequential motions rather than independent and simultaneous motions as proposed in the NPR. Strauch comments that the additional multi-action lock clarification in the proposed rule is unnecessary and is an enforcement issue rather than an issue with the standard.

Response: Staff considers multi-action locking mechanisms to secure button cell or coin battery compartments as an adequate solution to prevent access to children, so long as the actions cannot be combinable into one single action. Through testing, staff identified multiple products that were designed with the intent of requiring two independent actions to open the battery compartment that could be easily defeated by applying a single force to disengage the lock and expose the battery. The NPR includes the additional clarification specifying, "The movements to open cannot be combinable to a single movement with a single finger or digit," to prevent these types of locking mechanisms. This addition addresses the concerns from the coalition of medical and consumer organizations' comment that locking mechanisms that require a push and turn could be accidentally opened. Moreover, staff does not agree that the requirement should require independent sequential, rather than simultaneous actions, because sequential actions can be achieved more easily than simultaneous actions. The requirement for two independent and simultaneous actions allows for sequential actions, so long as the first action is held by the consumer while the second action occurs. Independent sequential actions would not require that the first action be held by the consumer while the second action occurs for the battery compartment to open, making the scenario of a child accidentally opening the battery compartment more likely.

Because the NPR and UL 4200A-2023 add this clarification, testing laboratories will have a clear criterion for adequacy of multi-action locking mechanisms in what was otherwise previously ambiguous and up for interpretation. Based on staff's testing and the additional clarification of the requirement, an additional test to prove the effectiveness of the lock is unnecessary.

<u>Comments:</u> UL Solutions states they are not aware of designs where a single finger movement could actuate both mechanisms simultaneously and requests information if any such designs were certified compliant to UL 4200A.

<u>Response:</u> Staff provided an example in Tab D of the NPR staff briefing package of a product that employs a multi-action locking mechanism (pull and turn) that could be opened with a single finger movement. Although this sample is not certified compliant with UL 4200A, staff evaluated the sample according to the requirements of UL 4200A and determined that the design of the sample can be interpreted to meet the multi-action locking requirement of UL 4200A. Other example products with this issue include products using a push and turn mechanism. Despite this interpretation, staff identified a method of opening the battery compartment with a single force which effectively combines the two motions required to open the enclosure. By adding the clarification to the proposed rule, products such as these will not be interpreted as meeting the requirement.

Issue 6: Whether the proposed secureness test based on UL 4200A is sufficient to address reasonably foreseeable use and abuse of consumer products containing non-removable batteries.

<u>Comments:</u> ITI asked for clarification on how the secureness test is applied. ITI questions whether the force application per the secureness test is to the exterior battery enclosure or to the battery itself.

<u>Response:</u> Per §1263.3(f) of the proposed and Draft Final Rule, the secureness test is only applicable to button cell or coin batteries that are accessible based on § 1263.3(d), which specifies removing "any part of the battery compartment enclosure that can be opened or removed without a tool or that can be opened or removed with anything less than two independent and simultaneous movements." Section 6.4 in UL 4200A-2023 contains a similar requirement. After removing any components as described above, an accessibility probe is applied to any opening of the battery compartment. If the probe makes contact with any battery, the battery is considered accessible, and the secureness test applies a force, directed outwards, using the test hook on the battery itself at all points where an application of a force is possible to demonstrate that it will not be liberated from the product. For example, if there is sufficient space between the battery and the product to allow for the test hook to be inserted, a force may be applied to pull or pry the battery away from the product.

<u>Comments:</u> The CTA and ITI comment that the NPR incorrectly states that UL 4200A and IEC 62368-1 do not require abuse testing for products with button cell or coin batteries "that are held fully captive by soldering, fasteners, or any equivalent means." The commenters explain that UL 62368-1 requires robustness tests for solid safeguards which address accessibility of other hazards such as shock, fire, mechanical, and burn. The commenters state that these requirements are independent of the button cell or coin batteries because they are general requirements for all solid enclosures or barriers.

<u>Response:</u> Staff agrees with the commenters regarding the assessment of this requirement. UL 62368-1 requires all products containing solid safeguards to comply with the standard's relevant robustness tests which include steady force test (i.e., small surface compression test), drop test, impact test, and other abuse tests based on specific construction materials such as glass or thermoplastic. These tests are required regardless of whether the product contains a button cell or coin battery. Staff considered these comments in its revised appraisal of UL 62368-1 (see the briefing memorandum) and concluded that the securement test was otherwise adequately addressed with other requirements in the standard.

CPSC's proposed rule required products with non-removable button cell or coin batteries that are secured to the product via soldering, fasteners, or equivalent means to comply with the secureness test in §1263.3(f), and not to the abuse testing in § 1263.3(e). UL 4200A requires that button cell or coin batteries held fully captive by the use of soldering, fasteners such as rivets, or equivalent means pass the secureness test in section 6.4 of UL 4200A. This requirement is similar to the NPR and is adequate to meet the requirements in Reese's Law.

Staff observes that UL 62368-1 explicitly includes other use and abuse requirements, and UL 4200A implies through its scope that applicable requirements in other standards should be followed. To make these requirements explicit in the Draft Final Rule, and to further address impacts, drops, or compressions that can break the soldering or fasteners securing a permanently attached button cell or coin battery and thereby freeing the battery and exposing the hazard to children, staff recommends modifying § 1263.3(c)(2) to require compliance with the abuse testing of § 1263.3(e). Doing so will further align the Draft Final Rule with the voluntary standards and ensure the mechanical securement of the non-removable battery is adequately robust to withstand foreseeable use and abuse, and therefore will increase the safety of these products.

Issue 7: Whether Test Probe 11 of the Standard for Protection of Persons and Equipment by Enclosures – Probes for Verification, IEC 61032, is adequate to verify accessibility of a button cell or coin battery in a battery compartment.

<u>Comments:</u> Three commenters (CTA, ITI, and UL Solutions) recommend applying a 45 N force application with Test Probe 11 per UL 62368-1 and UL 4200A to determine whether a battery can be liberated from a consumer product by children up to age 6. CTA and ITI opine that the 50 N force in the proposed rule, which was based on IEC 62115, is intended for a scope of children up to 14 years old, but Reese's law is intended to protect children up to age 6. Furthermore, they state the lack of incidents involving products certified to these requirements is evidence of adequacy. UL Solutions opines that the toy standard, IEC 62115, was developed based on the expectation that toys are continually used by children over its lifetime; whereas UL 4200A was developed assuming that children would likely come into contact with in-scope products, but not continually over the product's lifetime.

Response: For the Draft Final Rule, and consistent with UL 4200A-2023, staff continues to recommend the higher force of 50 N based on requirements in IEC 62115 and on IEC 61032. Although the scope of IEC 62115 is for children up to 14 years old, staff does not have data which supports that the lesser value of 45 N, based on UL 62368-1 and UL 4200A, is adequate to prevent access by children up 6 years old. Furthermore, staff disagrees with UL Solutions' rationale that the test in UL 4200A is adequate because the standard was developed for products that are not continuously used by children over a product's lifetime. The 50N compliance test proposed in the NPR accounts for reasonable, foreseeable use and abuse over the course of a any product's lifetime, presuming that most consumer products are likely to be accessible to children. Indeed, most of the incident data involve batteries liberated from consumer products by children, including products that are not intended for use by children. Accordingly, the rule includes a reasonable safety factor. Staff also observes that IEC 61032, the voluntary standard that serves as the source of the probe, specifies a force of 50 N. Therefore, staff concludes the higher force of 50 N will adequately protect against children accessing button cell or coin batteries from consumer products during reasonably foreseeable use and misuse conditions, as required by Reese's Law.

Issue 8: Whether there are any additional performance requirements that should be considered, either for specific types of products, or in general.

<u>Comments</u>: A coalition of medical and consumer organizations recommends adding a test to prove the effectiveness of multi-action locks. They add that small, disc-shaped products that require a push and turn multi-action can be mimicked by a child putting their hand on the product on the floor and then turning.

<u>Response:</u> As addressed in Issue 5, staff agrees with the commenters that some multi-action locking mechanisms can be defeated by applying a single force, effectively combining the two or more motions of the multi-action. For this reason, staff added the clarification to the multi-action lock requirement that states, "The movements to open cannot be combinable to a single movement with a single finger or digit" to the proposed rule, and retains this requirement for the Draft Final Rule. UL 4200A-2023 also includes this clarification. Based on staff's testing and review of consumer products, staff states that this clarification is adequate for test laboratories to determine effectiveness of multi-action lock designs and that no additional test is necessary.

<u>Comments:</u> Two commenters (a consumer and CTA) provide comment on the requirement for twist-on enclosures requiring a minimum of 90° rotation to remove. The consumer commenter recommended that a 90° rotation is insufficient whereas CTA considers this requirement adequate.

<u>Response:</u> The requirement for minimum rotation angle for twist-on enclosures is based on the voluntary standard UL 4200A. Staff's comparison of all relevant voluntary standards shows that UL 4200A and UL 62368-1 are the only standards to specify a minimum rotation angle for twist-on covers. Based on staff's testing and the lack of more stringent requirements in other standards, staff does not have any data to support a greater rotation angle to prevent children ages 6 years and younger from accessing the button cell or coin battery. Accordingly, staff recommends retaining the 90° rotation angle requirement for the final rule.

Issue 9: Whether one or more performance requirements should be based on IEC 62368-1, in addition to, or instead of, performance requirements based on UL 4200A.

<u>Comments:</u> Two commenters (ITI and Garmin) discuss the fastener torque requirements based on Table 20 of UL 60065. ITI comments that the torque requirements in § 1263.3(e)(1)(ii) for fasteners based on Table 20 of the *Standard for Audio, Video and Similar Electronic Apparatus* – *Safety Requirements*, UL 60065, is outdated and is superseded by Table 37 of the *Standard for Safety: Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements*, UL 62368-1. Garmin comments that the fastener torque requirements from Table 20 of UL 60065 do not consider small fasteners which cannot withstand the specified torque values.

<u>Response:</u> Staff agrees that Table 20 of UL 60065 is superseded by Table 37 of UL 62368-1 and recommends updating the reference table for the Draft Final Rule. Table 20 specifies torque values based on the screw's diameter and type, whereas Table 37 only specifies a torque value based on the screw's diameter, regardless of the screw type. Both tables are adequate to meet the requirements of Reese's Law, but because Table 37 adopts the greatest torque values for screw type II from Table 20, and applies them to all screw fasteners, updating the rule's reference to Table 37 in the final rule will increase the safety and reliability of screw fasteners securing battery compartments. Staff notes that UL 4200A-2023 continues to refer to Table 20 of UL 60065.

Staff disagrees that Table 20 (and similarly Table 37) does not account for small fasteners. The torque values are dependent on the size of the fasteners with the lowest torque requirement of 0.4 Nm for fasteners up to 2.8 mm in diameter. Through staff's testing, discussed in Tab D of the NPR staff briefing package, staff observed that fasteners that did not meet the minimum required torque often failed the preconditioning and abuse tests and therefore were inadequate for reducing the risk to children.

Issue 10: Whether the proposed performance requirements are needed and are likely to eliminate or adequately reduce the ingestion hazard associated with access to button cell or coin batteries from consumer products.

Comments: Three commenters (CPHE, FH, and AWA) opine that watches present a significantly lower risk than other products containing button cell or coin batteries. The commenters recommend imposing different requirements for accessing the battery for products designed to be opened by consumers versus those intended to be opened only by professionals. The commenters state that most watches are intended to be opened by professionals because watches cannot be opened without the use of special tool that is not commercially available; therefore, the risk that screws or the battery cover could be lost or discarded by consumers does not exist. Based on the proposed rule, watches would be required to comply with the requirements of § 1263.3(b) for removable batteries which requires: (1) twist-on covers with minimum torgue of 0.5 Nm to open and a minimum angle of rotation of 90°; or (2) fasteners must engage a minimum of two full threads and be held captive to the closure. The commenters opine that these requirements are not feasible for watches because of the limited space within the product to implement more complex designs. The Switzerland Federal Department of Economic Affairs, Education and Research (Switzerland) asks why the NPR does not differentiate the requirements for the removal or replacement of the button cell or coin batteries by the consumer themselves from removal by professionals.

Response: Staff agrees with the commenters that products containing button cell or coin batteries that are only meant to be replaced by professionals, and that are not routinely replaced by consumers, should have different requirements for battery accessibility. Therefore, staff recommends modifying the Draft Final Rule to exclude from the requirements of § 1263.3(b) any products that are not intended to be opened by consumers. This would apply to any consumer product that cannot be routinely opened by consumers. The performance requirements of § 1263.3(b)(i) intend to prevent children less than 6 years of age from accessing a battery compartment and removing the battery. Specifically for captive screws, this requirement intends to prevent screws that secure battery enclosures from being discarded or lost, thus rendering the battery enclosure ineffective. Because the risk of discarding or losing an enclosure screw is low for products intended to only be opened by professionals, staff advises that it is not reasonably necessary to impose a captive screw/fastener requirement for such products to reduce the risk of injury to young children. However, products intended to be opened by a professional service center may also be opened by consumers, particularly if the products can be opened with a common household tool such as a straight-blade or Philips screwdriver, pliers, or a coin, and adding a captive screw requirement for these products poses minimal inconvenience on service centers. Products that cannot be opened with a common household tool and which have warnings stating that the battery is not to be replaced by the consumer are less likely to be opened by a consumer, and therefore do not need to have captive screws. Additionally, products intended to only be opened by professionals can open and expose a button cell or coin battery through reasonable, foreseeable use and abuse. Accordingly, staff

considers the requirements of § 1263.3(e) reasonably necessary to reduce the risk of children under 6 years old from accessing the battery.

Based on the forgoing, for the final rule, staff recommends modifying the regulation text to exclude from the fastener and captive fastener/screw requirements in § 1263.3(b), products with inaccessible batteries that are intended to be replaced by only professionals. Instead, these products must be openable with a tool that is not a common household tool, have packaging and instructions which state that the product is not to be opened by the consumer, and comply with the performance tests in § 1263.3(e).

Unlike the NPR, UL 4200A-2023 contains different requirements for products with battery compartments only intended to be opened by a professional service center where children are not present. Staff understands UL 4200A-2023 as establishing requirements that effectuate its purpose, so that battery compartments intended to only be opened by a professional service center must have both appropriate labeling and inability for the battery compartment to be opened using a common household tool, such as a straight-blade, a Philips screwdriver, pliers, or a coin. Battery compartments that cannot be opened with a common household tool and have warnings stating that the battery is not to be replaced by the consumer are less likely to be opened by a consumer, and therefore do not need to have captive screws to address the ingestion hazard. At the same time, products intended to only be opened only by professionals can be opened and expose a button cell or coin battery. Accordingly, UL 4200A-2023 reasonably requires use and abuse testing for these products, to reduce the risk of children under six years old from accessing a battery from a battery compartment.

<u>Comments:</u> JEITA requests to exempt from the scope of the rule products that use button cell or coin batteries that are not intended to be replaced by the user or cannot be removed (i.e., user-inaccessible). JEITA explains that IEC 62368-1 does not apply tests and warning label requirements if button cell or coin batteries cannot be removed because such products do not present a battery ingestion risk.

<u>Response:</u> Reese's Law requires CPSC to issue a rule that eliminates or adequately reduces children accessing button cell or coin batteries from consumer products during reasonably foreseeable use and misuse conditions. Accordingly, for the final rule, staff does not recommend removing use and abuse testing for products that use batteries not intended for consumer replacement. Staff disagrees with the commenter that products containing button cell or coin batteries that are not intended to be replaced are not hazardous. Through the life of a product, it may experience a variety of use and abuse that may result in batteries that can become dislodged or become accessible to children, even if the batteries are not intended to be user replaceable. This may be due to poor construction, design, or securement of the non-replaceable batteries that fall apart when dropped.¹ The final rule requirements intend to prevent such poor designs from entering the U.S. market. Staff recommends that all products containing or designed to use button cell or coin batteries, regardless of whether they are replaceable, be included within the scope of the rule and subjected to use and abuse testing.

¹ For example, the narrative for CPSRMS Incident H20C0039A: The consumer reported that they found two button batteries on the carpet and one on the ground, and also they found a tiny light bulb. The consumer discovered that it came from the rubber handle on the device for jumping because it had broken.

<u>Comments:</u> Two commenters (CTA and ITI) recommend that a drop test with three repetitions is adequate for some products. While the commenters state that they agree that ten total drops, as specified in the NPR, is appropriate for hand-held products such as remote controls, they recommend that three drops is adequate for other portable products such as equipment that is transportable but not intended to be held in hand while in use. ITI provides, for example, a desktop computer which uses a coin battery, can be carried and transported, but is intended to be used while sitting on a surface. They opine that this product is not reasonably foreseeable to be dropped ten times over the course of its life.

<u>Response:</u> Staff agrees that requiring ten drops for some portable products is not reasonably necessary to reduce the risk of button battery access to children. Staff acknowledges that not all products are reasonably foreseeable to be dropped up to ten times over the course of their useful life. Staff recommends differentiating the total number of repetitions for the drop test, § 1263.3(e)(2)(i), based on whether the product is considered hand-held or portable. Per UL 4200A-2023's drop test requirements, portable products are dropped three times and hand-held products are dropped ten times, based on the product's weight and foreseeable use and misuse. Staff recommends adding to the Draft Final Rule definitions for portable and hand-held products based on the product's weight and foreseeable use and misuse while being used and/or carried. Accordingly, for the draft final rule, staff recommends requiring three or ten drop repetitions, respectively, based on whether the product type is hand-held (10 drops) or portable (3 drops). To define "handheld" and "portable," staff considered the requirements in Reese's Law, public comments, and the existing requirements in voluntary standards that define such terms. Tab E discusses staff's recommended definitions for product types in more detail.

B. Comments in Response to Questions on Marking and Labeling Requirements Posed in the NPR

Issue 11: Whether the Commission should require ingestion warnings on zinc-air button cell or coin battery packaging.

<u>Comments:</u> Three commenters (Duracell, Energizer, and the National Electrical Manufacturers Association (NEMA)) agree that warning labels on zinc air batteries are not needed regarding the ingestion hazard, citing low risk of injury. Renata SA and AWA propose an exemption from labeling silver oxide button cell batteries as well, because they allegedly also present a low risk of injury. Landsdowne Labs Inc., coalition of medical and consumer organizations, and Dr. Ian Jacobs (Director at the Center for Pediatrics Airway Disorders at the Children's Hospital of Philadelphia) support warning labels on packaging for zinc-air batteries, because they pose an insertion hazard. BAJ states that labeling on zinc-air batteries should be a recommendation, rather than a requirement, and that if zinc-air batteries are labeled, that they should use the word CAUTION instead of WARNING. Dr. Jacobs and Dr. Jatana (Director of Pediatric Otolaryngology in the Department of Otolaryngology Head and Neck Surgery at Nationwide Children's Hospital and Wexner Medical Center at Ohio State University) state that zinc-air batteries pose a risk of injury when inserted into the ear canals and nasal cavities, and should be labeled accordingly.

<u>Response:</u> Based on a literature review and the incident data, staff agrees that labeling of zincair batteries for an ingestion hazard is unnecessary and may cause consumer confusion. However, based on public comments from medical professionals, staff's literature review (see Tab C), and the incident data, staff assesses that zinc-air batteries must be labeled with insertion warnings. Dr. Jacobs explains that zinc-air batteries inserted into the nose or ears can cause septal perforations. Jatana et. al. (2017) found in testing using an animal model that zincair batteries did not cause any damage to esophageal tissue. Researchers opine that the fluid from the moist environment of the esophagus blocked the entrance of oxygen to the battery, and the zinc-air battery was unable to discharge. Therefore, staff agrees that zinc-air batteries do not pose an esophageal ingestion hazard and should not be required to meet the requirements of the performance standard. However, Sancaktar et.al. (2020) showed in animal nasal septal model, that zinc-air batteries did cause necrosis to the tissue. This may be due to the irregular shape and drier environment allowed the zinc-air battery to discharge, causing voltage and tissue damage. Therefore, staff agrees with the commenters that it is appropriate to place warnings on zinc-air battery packaging regarding the insertion hazard. Because Reese's Law is solely related to the ingestion hazard, staff recommends requiring performance and technical data for this insertion-related hazard under section 27(e) of the CPSA, as discussed in Tab C. No consumer products contain or use zinc-air batteries, thus the insertion warning requirements apply solely to packaging and point-of-sale locations for zinc-air batteries. Staff recommend seeking comment on the proposed warning label.

Issue 12: Whether all button cell or coin battery packaging should include the warning on the principal display panel.

Comments:

Several commenters, including the coalition of medical and consumer organizations, BAJ, Energizer, Duracell, Landsdowne Labs, NEMA, and CTA support warning labels on the packaging of button cell and coin battery packaging. The coalition of medical and consumer organizations and Duracell support the use of a conspicuous warning label on the principal display panel, whereas others (BAJ, Energizer, CTA, ITI) request flexibility in the warning label location and the placement of the "KEEP OUT OF REACH" icon, citing limitations of battery packaging size. Seven commenters support the use of warning label placement as found in current voluntary standards, as such standards do not mandate the warning label location. BAJ suggests that the use of the icon accompany the "KEEP OUT OF REACH" text as the icon may not be well known.

Response:

Reese's Law requires warning labels on the packaging of button cell or coin batteries and minimum content requirements. Existing voluntary standards (IEC 60086-4 &-5) do not set forth location requirements, or specify that warnings be on the back of the packaging (ANSI C18.3), which does not clearly identify the hazard of ingestion to consumers looking at the front of the packaging. Existing voluntary standards often do not specify the content of the warning label. While the use of an icon is permissible in voluntary standards, icon use is based on the diameter of the battery. Staff's recommended warning label for the proposed and final rules meet the requirements of Reese's Law. Consistent with Reese's Law and the ANSI standard, the NPR and the Draft Final Rule requires battery packaging to identify the hazard, explain how to avoid the hazard, and requires that warnings be conspicuous on the front of the packaging. The front of the packaging is more desirable for the warning content because this is the first location that a consumer will come into contact. Staff's recommendations include a warning label on all button cell and coin battery packages, regardless of chemistry or battery size. The warnings content also outlines options for a condensed warning label in the form of an icon on the front with additional text to be placed on the back, to accommodate limited space on the battery packaging. While staff does not recommend the "KEEP OUT OF REACH" text be required to accompany the icon, manufacturers may choose to include the text voluntarily to

clarify the icon's meaning. Staff does not recommend any changes to the warning on the front of the battery packaging as a result of these comments.

Issue 13: Whether the requirement for the "Keep Out of Reach" icon to be 20 mm in diameter for visibility purposes, when alone on the front of battery packaging, provides a sufficient warning of the ingestion hazard.

Comments:

Renata SA commented that the 6mm minimum icon size requirements in IEC 60086-4 are adequate. BAJ commented that the icon sizes of minimum 20 mm and minimum 8 mm where proposed are not necessary because "based on the market results so far" a minimum size of 6 mm icon is sufficient.

Response:

Staff does not have the details of the "market results so far" that one commenter references to determine whether the 6-mm icon is sufficiently attention getting for consumers, recognized, and adhered to by industry. Based on an evaluation of existing battery packaging, staff assesses that the recommended sizes of icons in the proposed rule are feasible and are more likely to get the attention of the consumer. After reviewing a number of battery packages, staff assesses that a 20 mm diameter icon is feasible to be on the front of the package while the rest of the label is located on the back side of the package. See examples in Figure 1. The 20 mm diameter icon is sufficiently large to be visible to most consumers, and sufficiently small to fit on existing battery packaging. Staff recommends no changes in response to these comments.



Figure 1. Examples of battery packaging with the 20 mm diameter "Keep Away from Children" icon on the front, to scale with existing battery packaging.

Issue 14: Whether the requirement to provide other information related to the safety of button cell or coin batteries is sufficient to address the risk of ingestion and other hazards associated with button cell or coin batteries.

Comments:

Four commenters (Duracell, Energizer, CTA, ITI and NEMA) do not support the requirements for other safety information on battery packaging; however, NEMA proposes the use of IEC icons that represent the same safety information instead of text.

One battery manufacturer (Renata SA) states that due to the small size of battery packages, having all of the proposed safety statements on the packaging area is challenging. Another manufacturer (Energizer) agrees and states that allowing QR codes and warning icons can provide flexibility to manufacturers. This commenter also states that 27(e) requirements are not directed by Congress. Renata SA recommends having some of the 27(e) statements available digitally and via a QR code on the secondary display panel of the immediate packaging to save space. Energizer also recommends the use of icons and QR codes to save space.

One commenter (Billie Jo Burr) says consumers should be provided with the nationwide poison control center phone number to ease the process of obtaining assistance quickly.

<u>Response</u>: The proposed rule does not prohibit providing digital access to the safety statements. However, given that not all consumers have easy access to the internet, or have the knowledge to use QR codes, staff concludes that to have the intended effect of providing warnings and safety information to consumers, the warnings language must be included physically along with the product in a prominent place on the packaging.

Energizer is correct that Reese's Law does not require performance and technical data. However, CPSC has authority under section 27(e) of the CPSA to require performance and technical data to consumers at the point-of-sale, to address an unreasonable risk of injury. Nothing in Reese's Law precludes the Commission from using its authorities to address consumer safety. Additionally, staff assesses that "other safety information" required under section 27(e) of the CPSA, meaning performance and technical data, is already found on either the principal display (front) or secondary display (rear) of some battery packaging, (e.g., battery type, nominal voltage, keep in original packaging, installation orientation, and risk of leaking or explosion due to high temperature exposure).

Staff agrees with NEMA that some other safety information can be described using icons from international standards, however, U.S. consumers may not be as familiar with its meaning, and if used, recommend text accompany the icon. Staff notes voluntary standards allow for other safety information to be placed on the battery packaging and instructions if the battery packaging size is limited. Staff recommends no changes in response to these comments, but also recommend seeking comment on whether QR codes should be allowed as the primary means of displaying the 27(e) warning statements as a means of saving space on the packaging if the statements are also provided in accompanying manuals or literature.

Staff agrees with Billie Jo Burr that providing consumers with the appropriate contact phone number will provide an actionable step that will ease the process of obtaining assistance quickly. Unlike the poison control phone number, NBIH is dedicated solely to addressing battery ingestions, and is therefore the most immediate and practical resource available to consumers who suspect a battery ingestion. Therefore, staff recommends adding the contact number for the National Battery Ingestion Hotline (NBIH), currently 1-(800) 498-8666, on the

required warning labels for battery packaging, consumer product packaging, and in instructions and manuals. UL 4200A-2023 does not add the NBIH phone number, but still provides advice to "Call a local poison control center for treatment information," which is adequate to meet the requirements of Reese's Law.

Issue 15: For technical and performance data related to the safety of button cell or coin batteries required at the time of purchase, whether the proposed warnings' content and location requirements are adequate to advise consumers who purchase a product online or in-store about the hazards associated with these batteries.

Comments:

Four commenters (NEMA, RILA, Energizer & TechNet) do not support online warning labels.

NEMA, RILA, and Energizer state that the proposed requirement for online sales and advertising to include warning labels for purchases of button cell or coin batteries, and of consumer products containing button cell or coin batteries in a clearly visible, prominent, and legible manner, would generate significant complexities to the online marketing process for manufacturers. In addition, RILA requested a longer lead time to comply with this requirement.

Response:

Staff recommends maintaining the point-of-sale warnings requirements to address the unreasonable risk of injury associated with the ingestion of button cell or coin batteries by children 6 years old and younger. Staff clarifies that "time of original purchase" is applicable to online sales by manufacturers, which includes importers, and to retailers only if they are also manufacturers or importers. To address timing concerns, staff now recommends a longer effective date, as discussed in issue 19 and Tab F.

In the NPR, to ensure that consumers notice the warning, staff recommended that online sales and advertising include the warning in clearly visible, prominent, and legible text next to the product description, near the product image, or near the product price. Staff clarifies that one way to accomplish this is to include the warning label in an image form and display that image along with product photos.

Issue 16: Whether staff's assessment [in V.F of the NPR preamble] that virtually all consumer products can accommodate either the full warning or one of the scaled icons is accurate.

Comments:

Four commenters (The Toy Association, CTA, ITI, and RILA) do not support on-product warning labels citing limitations due to small product size. Other concerns pertain to textured surfaces, product material, or "other" limitations with no explanation on what these may be. The Toy Association asserts that labeling requirements will add significant costs in terms of timing, tooling, and molding. Four commenters (JEITA, CTA, HCPA, and ITI) request exemptions from on-product labeling where button cell or coin batteries are not accessible and not intended to be replaced by the consumer.

Response:

Reese's Law requires that, where practicable, warning labels be placed directly on a consumer product in a manner that is visible to the consumer upon installation or replacement of the battery. Even for products with non-replaceable batteries, Reese's Law requires warning labels to be placed in a manner that is visible upon access to the battery compartment, where practicable. Accordingly, Reese's Law requires on-product warnings. Staff assesses that the options in UL 4200A-2023 and the Draft Final Rule satisfy Reese's Law and provide manufacturers with some flexibility regarding how to inform consumers and size and format requirements to meet the rule and Reese's Law. Staff clarifies its understanding that in cases where the product contains a non-replaceable battery, and the battery compartment itself cannot be accessed with the use of a tool or by opening a multi-action lock, then an alternate part of the product which is preventing access to the battery compartment is to be labeled with the appropriate label or icon.

Issue 17: Whether the rule should require button cell or coin batteries to be durably and indelibly marked with the "Keep Out of Reach" icon where size permits, at a minimum size of 6 mm in diameter, and if so, whether the appropriate legal authority is Reese's Law, section 27(e) of the CPSA, or another statute.

Comments:

Six commenters provided responses on the use of the "Keep Out of Reach" icon on the button cell or coin battery. RILA requests the icon be used on batteries 6mm or greater whereas BAJ supports the icon on button cell and coin batteries 16mm or greater and proposes a 6mm icon be permissible on batteries with a diameter less than 16mm. This aligns with Landsdowne Labs' comment that supports that the icon, to the extent practicable, be applied on all button cell and coin batteries that present a serious hazard. Both NEMA and Duracell agree the use of the icon on the packaging's principal display panel is acceptable but propose this icon be absent if the icon is printed on the button cell or coin battery itself and visible at the point of purchase.

Response:

Given the supportive comments received on this subject, staff recommends requiring the "Keep Out of Reach" icon on the battery itself in conjunction with the warning label on battery packaging. However, the icon on the battery cannot replace the warning requirements pertaining to the battery packaging per Reese's Law. Requiring button cell or coin batteries that are visible within the packaging at the point of sale to have the "Keep Out of Reach" icon will further remind the consumer of the ingestion hazard, and direct attention to the icon and warning label on the battery packaging. Additionally, placing the "Keep Out of Reach" icon on button cell or coin batteries would continue to inform consumers of the ingestion hazard posed by the battery at all stages of its lifecycle, including while it is in battery packaging, when placed in a consumer product, or when loose. Staff recommends seeking comment on the proposed implementation of this requirement.

Issue 18: Whether the internationally recognized safety alert symbol, as shown in yellow color, indicating the presence of a button cell or coin battery, should be required on all consumer products containing such batteries.

Comments:

A coalition of medical and consumer organizations, RILA, and Landsdowne Labs support onproducts alert symbols as some consumers are not aware that the product uses a button cell or coin battery. JEITA and ITI propose products that do not have user accessible batteries be exempt from requiring an alert. Garmin does not support the use of a color for alert symbol on the product.

Response:

Reese's Law requires products containing button cell or coin batteries to have a warning label "as practicable." The proposed rule recommends an alternative to the on-product warning label to increase the visibility that a product contains a button cell or coin battery and likelihood for all products to feature an alert where it otherwise may not be practicable. Staff agrees that the proposed yellow color may not be clear or appropriate in all cases; accordingly, for the Draft Final Rule, in such cases, the safety alert symbol must be clearly visible and contrast to the background on which it is printed. UL 4200A-2023 similarly requires coloring only when more than one color is present on the label, and requires all icons to be prominent legible, easily discernible under normal lighting conditions, and permanently marked.

C. Comments in Response to Questions on Other Topics Posed in the NPR

Issue 19: Whether a later or an earlier effective date would be appropriate to comply with the proposed requirements and to provide specific information to support such a later or an earlier effective date.

<u>Comments</u>: Multiple manufacturers, trade associations, and Switzerland provided comments stating that a longer effective date is required to provide compliant products to the U.S. market. A few commenters provided detailed timelines of the necessary activities (product redesign, testing, certification sourcing, supply chain management, etc.) which ranged from 12 months to 36 months in total.² A commenter also explained that additional time is required to accredit third party laboratories for a large variety of product types. Energizer and NEMA request that battery manufacturers be allowed to sell through existing stock of child-resistant packaging and labels that were purchased to comply with Section 3 of Reese's Law.

<u>Response:</u> Staff assesses that due to the broad scope of the rule, a large increase in the number of products tested at accredited laboratories may occur. Manufacturers are not required to third-party test general use products, but due to the diversity of the products subject to the final rule, many manufacturers of products that are not currently subject to a regulation must now test and certify products and may not be equipped to create a "reasonable testing program" in 6 months. Additionally, many manufacturers will want to verify whether existing product designs meet the requirements of the rule. Staff expect these factors to raise the demand for laboratory testing. CPSC staff agree that an extension of the effective date would allow manufacturers and labs to acquire the staff and resources needed to perform the required tests.³ Given the large and extremely diverse set of industries/products affected and the capacity limitations of accredited laboratories, an extension of the effective date may be a reasonable accommodation to ensure availability of the products within the scope of the final rule. Of the commenters recommending an effective date of 12 to 36 months, most

² An example timeline provided by a commenter (Garmin) included estimates for concept design (9 weeks), prototype design (28 weeks); factory bring Up (23 weeks); manufacturing pilot run (11 weeks) and mass production ramp (6 weeks), for a total of 77 weeks, or approximately 18 months. This timeline is credible for scenarios where the existing product design does not easily accommodate captive screws or a secure double-action locking mechanism. AWA and other commenters have demonstrated such designs in comments.

³ CPSC staff interviewed an employee of a CPSC accredited lab who stated a 12-month lead time is required to acquire the necessary staff and facilities to accommodate the expected increase in product testing volume that may occur as a result of the mandatory standard.

manufacturers recommend an 18-36 month effective date. Battery manufacturers recommended at least a 12-month effective date. Staff recommends an 18-month effective date for the Draft Final Rule, assessing that the extended effective date would provide laboratories sufficient lead time to accommodate the expected demand in testing, and will allow most manufacturers sufficient time to verify existing designs and implement new designs, if necessary. An 18-month effective date also limits consumers' exposure to unsafe products (including knockoffs, counterfeits, and other products which can evade compliance measures) that may result from safe but untested products being removed from the market. CPSC staff recommends an effective date of 18 months to minimize disruption in the marketplace and acknowledge manufacturers' and laboratories' needs for more resources to safely and effectively comply with the rule. This longer effective date also provides battery manufacturers more time to import and sell through battery packaging and labels that were purchased to comply with Section 3 of Reese's Law.

Section 2(e) of Reese's Law states that if the Commission determines that a voluntary standard meets the requirements of Reese's Law, the voluntary standard is treated as a consumer product safety rule as of the date of the Commission's determination. 15 U.S.C. 2056e(d) and (e). If the Commission determines that UL 4200A-2023 meets the requirements of Reese's Law, then in consideration of the public comments on the NPR, staff recommends a transitional period of enforcement discretion for the new requirements of UL 4200A-2023. Additionally, because UL 4200A-2023 does not address battery package labeling, staff recommends the final rule for battery package labeling have an effective date of at least one year after publication in the Federal Register. This is the low end of the time frame sought by commenters on the NPR and is consistent with the timeframe recommended by some battery manufacturers.

Issue 20: In the IRFA, the number of small firms impacted and expected cost impact on small firms (as a percentage of annual revenue) of the proposed rule.

<u>Comments:</u> Nite Ize commented that staff's estimate of the testing cost of \$150 to \$350 is too low and that a quote received by the firm to perform similar tests exceeded staff's estimate by over \$1,650 per sample tested. The firm stated this would pose a substantial burden to the firm as they do not possess the necessary skill set or expertise to mitigate these costs by developing a reasonable testing program in lieu of performing third party testing.

<u>Response:</u> Staff collected an additional quote from an accredited lab and updated the testing cost estimate and revised the estimated cost from \$150 to \$350 per sample to \$150 to \$460 per sample, as presented in Tab F of this package. Staff's revised estimate is still lower than the estimate provided by the firm, which staff does not find credible based on the quotes received by the accredited lab. Staff agrees these testing costs could pose a substantial burden to small firms especially those with a large variety of products that are powered by button or coin batteries. Some portion of these costs can be mitigated/reduced as the manufacturer can certify each product model based on a reasonable testing program, but staff note this is limited only to products defined as "general use." If the cost to create a reasonable testing program exceeds the expected testing costs performed by a third-party then staff expect firms to utilize whichever solution is more cost effective for them. Staff notes that a substantial burden is expected to be placed on some smaller firm as a result of the rule, as noted in Tab E of the NPR staff briefing package and Tab F of this briefing package.

<u>Comments:</u> One firm (Nite Ize) commented that staff failed to account for potential costs related to patent filing and enforcement. The firm expressed concern that current product patents for novel product lines would need new filings to provide robust intellectual property protection.

<u>Response:</u> Staff assume the comment concerns the firm's current product patents and whether they would be rendered obsolete from the rule. Staff note that it is unclear whether current product patents would lose any or all value, or whether a new filing would be required to legally enforce the patents. Also of note, a new filing could provide a longer period of protection which would mitigate some value lost from the previous patent. However, staff cannot determine if a cost is incurred that results in a significant loss for the firm.

Comments: Nite Ize and the Toy Association stated that the cost per product line estimates for research/development and retooling are too low as CPSC failed to account for product lines that require unique solutions.

Response: Commenters did not provide specific alternative cost estimates or justification of their view. CPSC's assessment provided a maximum per firm estimate for redesign/retooling of \$15,700. This estimate is intended to represent costs to most firms supplying these products to the U.S. market. In addition to these costs staff provided a per product line estimate of another \$15,700 for firms that require a novel or unique solutions due to the design of the products (Tab F). Staff expects firms that offer these novel products would incur a larger cost impact that will vary based on the number of novel product lines.

D. Comments Addressing Other Issues

Issue 21: Comments addressing watch data.

<u>Comments:</u> The AWA comments that CPSC does not indicate in the NPR how children gained access to the batteries from watches, and believes data involving watches is limited.

<u>Response:</u> Staff identified 25 NEISS cases⁴ where a *watch* was determined to be the source of an ingested or inserted battery; staff did *not* include every case indicating a "watch battery." In total there are about 260 NEISS cases indicating a "watch battery" was involved or that the battery came from a watch; but staff did not assume that the phrase "watch battery" indicated a watch was the battery source, thereby labeling most as source unspecified. Those 260 cases correspond to an estimate of about 6,000 ingestions or insertions of watch batteries (regardless of battery source). The estimate presented in the NPR of 11,900 BCCB-III (ingestions or insertions of button or coin cell batteries) is based on *496* cases in the NEISS probability sample with sufficient detail for staff to conclude *some* product or device was the source of the button or coin cell battery ingested or inserted. Those 496 cases include batteries determined sourced from medical devices, toys and other products not necessarily intended to be addressed by Reese's law. The NPR states that 237 of these cases (supporting an estimate of 5,300 BCCB-III) specifically indicative of the battery source being some type of consumer product (excluding toys, key fobs and other products or medical devices), which corresponds to the subset of NEISS data known to relate to products (other than batteries themselves) addressable under

⁴ https://www.regulations.gov/document/CPSC-2023-0004-0026

Reese's law. As observed in the NPR, these estimates likely substantially underestimate the actual number of such ingestions/insertions due to the exclusion of many cases for which the battery source was undetermined. However, staff observe that over 10% (25 out of 237) of batteries determined sourced from types of consumers products addressable by Reese's law were sourced specifically from a watch. Staff can alternatively observe that over 5% (25 out of 496) of cases for which the battery was known derived from any medical device or consumer product (including toys) specifically indicate a watch as source. Staff acknowledges there is some uncertainty regarding the exact contribution of watches in comparisons to all other products as a source of button or coin cell battery ingestion or insertion, and also acknowledges that the incident narratives do not describe how the children gained access to batteries from watches. Staff concludes that the draft performance requirements and the performance requirements in UL 4200A-2023 address common hazard patterns leading to the button cell or coin batteries being removed from consumer products; that these performance requirements are necessary to eliminate or reduce the risk of injury to children from button cell or coin battery ingestion; and that watches are a known source of the hazard.

Issue 22: Comments addressing international regulations.

<u>Comments</u>: Garmin and RILA support a review and harmonization with Australia's regulations addressing performance and labeling requirements for products containing button cell or coin batteries.

<u>Response:</u> Staff do not recommend harmonization with Australia's regulations. Reese's Law requires the Commission to promulgate a rule that contains a performance standard that would eliminate or adequately reduce the risk of injury from button cell or coin battery ingestion and warning labels. Reese's Law allows the Commission to rely on voluntary standards if it determines there is a voluntary standard that would eliminate or adequately reduce the risk of injury from the ingestion hazard. The Australia regulation is not a voluntary standard; however, staff reviewed the voluntary standards referenced by the Australia regulation in the NPR, and the Commission preliminarily determined that the standards did not meet the requirements of Reese's Law. This briefing package includes an updated assessment of the voluntary standards (the briefing memorandum and Tabs D and E). Staff conclude that UL 4200A-2023 could be determined to meet the requirements of Reese's Law.

Issue 23: Comments addressing silver-oxide battery chemistries.

<u>Comments:</u> CPHE, FH, AWA and Renata SA state that silver-oxide batteries should be excluded from the rule because of the lack of fatal incident data with these batteries and inability for children to access them from watches. Duracell states that silver-oxide batteries should contain different warnings than lithium batteries because they are lower voltage. Switzerland asks if silver oxide batteries could be excluded from the rule.

<u>Response:</u> Staff recommends that silver-oxide batteries be labeled with ingestion warnings. Jatana et.al. (2017) found in testing using an animal model that silver-oxide button or coin cell batteries caused severe esophageal injuries. These injuries were visible on the tissue within 15 minutes. While lithium batteries induced the most severe visible injury, the lower voltage silveroxide batteries reached the pH of 12 as with the 3V lithium batteries but it took 4 hours longer than the lithium batteries. Therefore, silver-oxide batteries cause severe esophageal injury while it takes longer to achieve than lithium batteries. Non-lithium and lithium batteries have been impacted in the esophagus long enough in many incidents to cause severe esophageal injuries.

While the majority of severe injuries are from 20 mm lithium batteries, researchers have demonstrated that lower voltage non-lithium batteries less than 20 mm (11.6mm – 16mm) can cause severe or fatal outcomes in children under the age of 12 months (Litovitz et.al. 2010). Many silver-oxide batteries are 11.6 mm, and therefore fall within this size range to cause esophageal injury in small children. While it may be difficult for children under the age of 6 to access silver oxide batteries from properly secured products, the batteries can be accessed from packaging or if unknowingly left out after changing the battery. Staff's recommended warnings in the Draft Final Rule and the warnings in UL 4200A-2023 mitigate, but do not eliminate these hazards.

Issue 24: Comments addressing firearm accessories and other household products containing button cell or coin batteries.

<u>Comments:</u> Bushnell states that firearm accessories appear to be subject to the proposed requirements, and that the firearm itself is intended to act as the battery door or cover for these products.

<u>Response:</u> Staff recommends that modular consumer products or component parts containing button cell or coin batteries, like the firearm accessories described by the commenter, must meet the same requirements as other consumer products, independent of their intended use. Reese's Law directs the Commission to promulgate a consumer product safety standard that would eliminate or adequately reduce the risk of injury from ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions. Modular consumer products can be attached to or installed by a consumer on other products to change the host product's design or capabilities. However, it is foreseeable that a modular consumer product could remain unattached from the product(s) for which it is designed to complement. To eliminate or adequately reduce the risk of injury from battery ingestion, these products must be designed in such a way as to prevent unintended access to the battery by children, such as by redesigning the battery compartment so it has a door or cover that meets the draft requirements or the requirements in UL 4200A-2023.

<u>Comments:</u> A consumer safety consultant (Mary Toro) and RILA state that some products containing button cell or coin batteries are made of fragile materials (such as glass or ceramic materials) that are likely to break during the proposed testing protocol. RILA states that the proposed testing is not appropriate for these products, and that alternative test methods should be allowed for such products.

<u>Response:</u> Staff agree that the draft performance requirements are likely to cause products made of materials like glass or ceramic to break. Staff recommends clarifying the test procedure for cases where a previously inaccessible battery compartment becomes accessible during testing. It is reasonably foreseeable that a glass or ceramic product may break due to being knocked to the ground or dropped, and that any button cell or coin battery contained inside may become accessible to a child as a result.⁵ To prevent an ingestion incident in this scenario, the button cell or coin battery could be further contained in a battery compartment that meets the draft requirements or the requirements in UL 4200A-2023. The manufacturer can test its product

⁵ For example, NEISS incident 181117328: 11MOF WAS FOUND LICKING INSIDE LIGHT/BATTERY BOARD OF A BROKEN LAMP. ONLY 1 OF 2 BUTTON BATTERIES FOUND. DX: POSSIBLE BATTERY INGESTION.

to ensure the product meets the requirements of the draft rule or use in its product a battery compartment that has already been certified to the requirements. If performance testing results in a previously inaccessible battery compartment becoming accessible (for instance, as a modular component or a component part of the consumer product), then the battery compartment must meet the performance requirements for consumer products containing button cell or coin batteries that are removable, or the performance requirements for consumer parts of consumer products can be tested and/or certified for use in other consumer products pursuant to 16 C.F.R. part 1109.

Issue 25: Comments addressing "Try Me" buttons.

<u>Comments:</u> A consumer asks for clarification of whether "Try Me" buttons containing button cell or coin batteries used only in stores and not intended for sale are in scope of the rule. UL Solutions states that products can incorporate "Try Me" buttons in retail displays or as part of product packaging, and their disposal should be addressed.

<u>Response:</u> "Try Me" buttons are consumer products that are used by consumers. Purchase of a product is unnecessary to be a "consumer product" under CPSC's jurisdiction, and consumers, including children, are subject to hazards associated with "Try Me" buttons. "Try Me" buttons used for in-store displays or as part of the product packaging pose the same hazards to children as the actual products themselves. Additionally, staff are aware of at least one incident involving a coin battery from a "Try Me" button.⁶ These buttons may experience drops, impacts, and other patterns of use and abuse similar to any other product within the scope of the NPR and staff's recommended rule and therefore should be treated similarly.

Issue 26: Comments addressing the use of color in the requirements for marking and labeling.

<u>Comments:</u> Several commenters (JEITA, Duracell, Gramin, HCPS and CTA) state that the use of color on packing, instructions, or manuals, and on some consumer products would be challenging and, in most cases, add costs to the manufacturing and printing process, particularly to those materials that do not already incorporate color. Duracell and Technet also stress that other product safety standards (*e.g.*, ASTM F963, ANSI C18.3, or ANSI Z535 series) do not mandate the use of colors and accept black and white printing or contrasting colors to the background it is printed on. Commenters state, however, that if color is used for the signal panel, colors should conform to ANSI Z535.1 safety colors that correspond to the safety message. The Toy Association and RILA state that the use of color may not be reasonable to print on certain product materials, for example, colored or textured plastics.

<u>Response:</u> Staff agrees that applying color to some materials (*e.g.*, consumer product packaging, manuals, or other collateral material) that do not already contain color may present a burden to some manufacturers. ANSI Z535.4 provides flexibility for special circumstances that

⁶ IDI 220127HCC3408 narrative summary: ON DECEMBER 21, 2021, A 23-MONTH-OLD MALE INGESTED A COIN BATTERY FROM A CHRISTMAS DECORATION. THE BATTERY HAD BEEN LOCATED IN THE TESTER BUTTON FOR THE DECORATION. THE BATTERY LODGED IN THE VICTIM'S ESOPHAGUS AND REQUIRED ENDOSCOPIC REMOVAL.

limit or preclude the use of colors while preserving the visibility and noticeability of the label by requiring contrasting colors. Staff recommends requiring the use of color when the subject materials will already use printed color processing, otherwise the use of black and white or contrasting colors be acceptable. Staff proposes the icon that represents "Warning: Contains coin battery," when used on consumer products, be in contrasting colors to the background on which it is printed. UL 4200A-2023 similarly requires that instructional safeguards present in more than one color shall be in accordance with the ISO 3864 series (which is similar to the ANSI Z535 series). The use of color is not specified in Reese's Law, thus this recommendation does not conflict with it and staff views this recommendation as a neutral effect on safety because the label or icon will visually align with other information on the display while ensuring that it is noticeable due to its contrast or color.

Issue 27: Comments addressing text size, icons, and alternative symbols for marking and labeling.

<u>Comment</u>: Renata Batteries, ITI, The Toy Association, RILA, BAJ, and Duracell express cost concerns with increased packaging sizes required to accommodate larger warning labels and font sizes, especially for small products. RILA also states that the minimum letter size requirements for packaging warnings may reduce the prominence of other warnings on product packaging.

Response: The NPR proposed that font size requirements for both on-product and onpackaging warning labels be determined based on the size of the principal display panel (e.g., the front face) of the package or the product display panel (e.g., surface area on, near, or in the battery compartment). Reese's Law requires that warning labels clearly identify the hazard of ingestion, and this requirement is met when warning labels are displayed prominently on the principal display panel. Although staff acknowledges that for very large products or packages with principal display panels exceeding 400 inch², the required letter size could be larger than standard font sizes usually referenced in other standards, staff assesses that the required size is relatively proportional to the display panel size and allows easy visibility and noticeability of the label. The minimum letter size is otherwise comparable to font sizes in other standards, and therefore of similar prominence when displayed on the same panel. The largest packaging will have ample room for additional warnings that are of comparable size to the requirements in the NPR. UL 4200A-2023 implements the same font size requirements as the NPR. This level of prominence is appropriate to inform consumers which products contain button cell or coin batteries and to adequately reduce the risk of injury from ingestion. Staff recommends no changes in response to these comments.

<u>Comment</u>: One commenter (consumer, Fo Xu) asked how to determine the size of the text for consumer products and its packaging and whether it is acceptable to use smaller size labels on the consumer products. Energizer requests clarification on whether CPSC will identify the surface size the alternative on-product label can be used, or whether manufacturers can use reasonable judgement.

<u>Response</u>: The NPR states that consumer products must be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or coin battery. Product Display Panel is defined in 1263.2(f). Text size must be determined based on Table 1, or if on a sticker label, must meet the minimum size requirements

in §1263.4(a)(7). While reviewing the proposed regulatory text, staff found that the term used to define the appropriate place to put on-product warning labels, the "product display panel," was not referenced in the warning label text size requirements. Staff recommends clarifying that the text size must be dependent on the principal display panel or the product display panel. This will assist manufacturers in determining what area to measure for the on-product warning label. Alternative on-product labels can be used in situations where the full label does not fit in the measured product display panel area, as described in the NPR, UL 4200A-2023, and the Draft Final Rule.

<u>Comment</u>: The Toy Association recommended that for consumer product packaging and instructions "Keep Out of Reach" icon be changed to the safety alert symbol for coin batteries because the intent of the icon is not to keep the consumer product away from children.

<u>Response</u>: Staff agrees with the commenter and recommends the option of replacing the "Keep Out of Reach" icon on consumer product packaging as well as instructions with the safety alert symbol to indicate "Warning: Contains Coin Battery." UL 4200A-2023 provides this option. See Tab D for a more detailed discussion of this issue.

<u>Comment</u>: CTA states that the proposed symbol for "Warning: Contains Coin Battery" has a different aspect ratio and is rotated farther than the internationally accepted symbols for coin and button cell batteries and that the symbol should match internationally recognized symbols.

<u>Response</u>: Staff's intent on elongating the battery icon was to utilize the available horizontal space to improve its visibility. However, staff acknowledges that internationally recognized symbols have coin battery icons narrower than the width of the safety alert symbol. Staff clarifies that the CPSC-recommended symbol can be replaced with other internationally recognized symbols in ISO 7000-W0001 and IEC 60417-6367 to have consistency.

Issue 28: Comments addressing tolerances for values specified in the proposed rule.

<u>Comment:</u> ITI comments that the proposed rule does not include tolerances for specified values and opines that the purpose is to give reasonable allowances (e.g., manufacturability and testability) that will not have a significant impact on test results. The commenter points out that the proposed rule specifies values based on the highest tolerance of the value based on the referenced voluntary standard. For example, the crush test in the proposed rule which is based on UL 4200A specifies a force of 335N versus the value in UL 4200A which specifies a force of $330 \pm 5N$. The commenter explains that eliminating tolerances could force unnecessary retesting or could make it impractical to apply the test without custom test equipment. The commenter recommends including tolerances in the rule that align with voluntary standards.

<u>Response:</u> The performance requirement does not impose design or production requirements on the manufacturer; and it is the manufacturer's responsibility to have processes in place to ensure each product will meet the proposed requirements. Staff acknowledges that the values specified in the proposed rule should be based on the lowest tolerance rather than highest to represent the lowest acceptable value per the relevant voluntary standard and recommends modifying the values accordingly in the Draft Final Rule. UL 4200A-2023 retains many of the higher minimum values from the NPR.

Issue 29: Comments addressing warning label permanency.

<u>Comment</u>: Staff received comments from RILA stating the permanency requirement for warning labels is unclear. One commenter recommends on-product permanency be tested in accordance with the test requirements in UL 62368-1 section F.3.9.

<u>Response</u>: Staff agrees with the commenter that suggests on-product permanence comply with the test requirements in UL 62368-1: F.3.9. This test evaluates the legibility of printed or screened markings and ensures adhesive labels cannot be easily removeable by hand.

Staff clarifies its understanding that on-product labeling may include, but not limited to: embossed, stamping, etching, or molded markings in addition to an adhesive label. All on-product labeling must be clearly visible, prominent, legible, durable, and indelible; and printed and screened markings must be tested in accordance with UL 62368-1 section F.3.10 (consistent with the requirements in section F.3.9). UL 4200A-2023 also includes a label permanency test consistent with the requirements in UL 62368-1 section F.3.9.

Issue 30: Comments addressing CPSC's statutory authority.

<u>Comments</u>: The AWA filed a late comment stating that parts of the proposed rule constitute design or construction standards, which are not allowed by the CPSA or Reese's Law.

<u>Response</u>: Staff disagree that the performance requirements related to the construction of the battery compartment are design requirements. The performance requirement for access with tool, torque and rotation requirements for screws and twist-on access covers, and a minimum of two independent and simultaneous hand movements are minimum performance specifications needed to prevent children from directly accessing the battery compartment. The performance requirement for captive screws or fasteners is necessary to reduce the likelihood of misplaced screws. These performance requirements do not dictate how the consumer product is to be designed. Moreover, many differing battery compartment designs already used in the marketplace are acceptable, as long as they meet the performance requirements provided in the rule to prevent child access.

To meet these performance requirements, manufacturers may choose to use any type of fastener that requires a tool, also at the manufacturers' choice, or to use a multi-action lock. These performance requirements, which the NPR in shorthand referred to as "construction requirements," describe testing acceptance criteria that must be met to adequately prevent access to the battery compartment of a removeable or replaceable button cell or coin battery. Staff's review of products containing button cell or coin batteries demonstrate that the market already employs many different battery compartment enclosure designs that depend on the size, shape, and materials of the consumer product. For example, remote controls include battery compartments that are either secured with screws or that slide out of the base (and typically require two independent and simultaneous actions to do so); many garage door openers require a tool to open but do not use screws or twist-on access covers; and battery compartments in light-up clothing are frequently stitched into the clothing.

Additionally, the performance requirements specify that battery compartments for replaceable batteries using screws or fasteners are to remain captive to the battery compartment door,

cover, or closure when loosened. This performance requirement does not specify how the manufacturer must design the battery compartment to ensure the screw or fastener remains captive. There are many possible design solutions, including a retaining washer, a press fit cap, a tether, or other means.

The proposed performance requirements address hazards related to accidental release of batteries from poorly constructed products with replaceable batteries. The failure modes of these products are characterized by direct interactions between a child and the replaceable battery compartment, and may not be identified during the other recommended use and abuse tests. Staff does recommend clarifying the test methods used to verify acceptance. The recommended changes are described in further detail in Tab E. UL 4200A-2023 similarly determines compliance through testing.

Issue 31: Comments addressing toy products.

<u>Comments</u>: In response to the April 11, 2023 *Federal Register* notice requesting comment on the Paperwork Reduction Act (PRA) burden associated with non-children's products subject to the proposed rule (88 Fed. Reg. 21,652), Switzerland requests information on why non-children's products containing button cell or coin batteries have to fulfill more stringent requirements than those imposed for toys.

<u>Response</u>: Although this comment was filed in response to the PRA notice, the comment is about the substance of the rule and not about the paperwork burden. Reese's Law specifically exempts "any toy product that is in compliance with the battery accessibility and labeling requirements" of 16 C.F.R. 1250, thus these products are not the subject of this rulemaking. Staff agree with the commenter that the proposed requirements for non-children's products and non-toy children's products are more stringent than those imposed for toys, as addressed in the NPR staff briefing package. Staff sent a letter to the ASTM F15.22 toy subcommittee on March 20, 2023 asking the subcommittee to consider changes to ASTM F963 which would adequately address incidents and hazards involving toys,⁷ and have since been working with ASTM to adopt more stringent standards for toys containing button cell or coin batteries.

E. Comments Addressing the PRA

⁷ Staff's letter to the ASTM F15.22 subcommittee can be found here: <u>https://www.cpsc.gov/s3fs-public/Letter-to-ASTM-F15-22-Reeses-Law-NPR-230320.pdf</u>?VersionId=6ZGPs5nSLhBGIFdoz1IWHF1wo.oOgarH

Issue 32: Whether the proposed collection of information is necessary for the proper performance of CPSC's functions, including whether the information will have practical utility.

<u>Comments</u>: The China National Center of Standards Evaluation and P.R. China believe that there are products with batteries that pose different levels of risk to children, and that there should be product categories assigned to products based upon the risk level they pose to children. Accordingly, the commenters would like for labeling on packaging, including warnings on battery compartments and written materials, such as instructions, manuals, inserts, or hangtags, be limited to products that pose a risk to children.

<u>Response</u>: Although this comment was filed in response to the PRA notice, the comment is about the substance of the rule and not about the paperwork burden. The PRA requirements of the rule apply to non-children's products that pose a risk to children. Staff does not recommend adopting the suggestion to create risk categories based on how frequently a child comes into contact with consumer products, because such an endeavor would not meet the broad requirement of Reese's Law. Reese's Law requires CPSC to promulgate a rule for all consumer products that contain or are designed to use button cell or coin batteries that eliminates or adequately reduces the risk of ingestion to children 6 years old or younger during foreseeable use and misuse conditions. Furthermore, Reese's Law states the Commission should promulgate such regulation within one year after the Act is signed into law, meaning by August 16, 2023. Developing categories of risk based on exposure would require in-depth study of consumer behavior and may be subject to frequent change; indeed, the commenter's own recommended categorization of hearing aids as a product that children hardly come into contact with is undermined by the incident data, which demonstrates hearing aid batteries are frequently ingested by children. Furthermore, the scope of the rule is determined by Reese's Law. The proposed requirements instead address the indestion hazard with performance requirements for consumer products that account for foreseeable use and misuse conditions. For example, the NPR excludes zinc-air batteries from the performance and warning label requirements because (1) zinc-air batteries are not used in consumer products, and (2) zinc-air batteries do not pose an ingestion hazard; zinc-air batteries are not excluded from these requirements due to the incorrect assertion that children "hardly come into contact with" them. The recommendations from the commenter are not supported by the text of Reese's Law or by the incident data.

Issue 33: The accuracy of CPSC's estimate of the burden of the proposed collection of information.

<u>Comments</u>: ITI, CTA, JEITA, AWA, and RILA believe that the CPSC has underestimated the burden of the proposed collection of information. ITI believes that the labor rates used may under-represent the burden cost. ITI and RILA request that CPSC provide additional detail on how the PRA burden estimates were derived. While CTA indicates that it is standard practice within the technology sector to include warnings on product labels, the labeling is different enough that the one hour of burden associated with labeling is appropriate. Relatedly, ITI suggests that product labeling should not be considered "usual and customary" and are within the definition of "PRA burden".

ITI indicates that manufacturers have more than two product families and asserts that 15,363 firms with 2 products each implies that CPSC has incorrectly estimated there are 30,726 unique non-children's products containing coin/button cells on the U.S. market.

<u>Response</u>: Based upon the comments received, staff recommends adjusting the burden estimates upward, as shown in Table 1. Additionally, staff suggest a higher wage rate to represent total compensation costs for private industry workers in goods producing industries.⁸

Though the data provided by commenters is helpful, burden comparisons provided by commenters are generally inappropriate because commenters have compared one-time burden estimates to annual respondent burden calculated by CPSC. For example, one commenter provided the following useful information, estimating that labeling, testing, and recordkeeping would take 4 hours, 48 hours, and approximately 1 hour or more, respectively. Assuming the product that represents these burden estimates is sold for 7 years, in year one total hourly PRA burden needed for the product would be approximately 54 hours. On an annualized basis, hourly burden would be approximately 8 hours (54 hours / 7 years = 7.7 hours per year), and CPSC has estimated annual testing burden of 8 hours for various industry sectors. (See Table 2.) Furthermore, if the product is sold for more than 7 years without major modification, as many products are, then the annualized burden estimate would be lower. Staff assume suppliers will continue to introduce products on a rolling basis, and that up-front costs will diminish over time.

Burden type	Respondents	Frequency of	Hours per	Annual burden	Annual burden
		response	response	(hours)	(costs)
Labeling	15,363	2	1	30,726	\$1,332,586.62
		3	1.25	57,611.25	2,513,002.72
Testing	15,363	2	3	92,178	\$3,997,759.86
		3	3.5	161,311.5	7,036,407.63
Recordkeeping	15,363	2	1	30,726	\$1,332,586.62
		3	1.25	57,611.25	2,513,002.72
Total Burden				153,630	\$6,662,933.10
				276,534	12,062,413.10

Table 1. Estimated Annual Respondent Burden (Revision shown in grey)

Staff do not estimate there are 30,726 unique non-children's products containing coin/button cells on the U.S. Market. The PRA estimates indicate that each year, CPSC expects that approximately 15,300 respondents will respond to labeling, testing, and recordkeeping requirements pertaining to PRA. CPSC staff appreciate the feedback and revises the suggested frequency of response upwards, as shown in Table 1, from 2 to 3 responses annually per respondent, however we note that response frequency will vary.

The estimates provided are based upon data from the U.S. Census Bureau. Burden associated with issuing a GCC is included in these estimates, however burden associated with online warning requirements are no longer required in the final rule and are not included in burden estimates. Establishment data from the U.S. Census Bureau by NAICS code was used to estimate the number of entities with at least one product subject to the proposed rule. Then, weights were assigned to each NAICS sector to estimate both the duration of the required response as well as the estimated average number of responses. (See Table 2.)

⁸ The March 2023 hourly total compensation costs for private industry workers in goods producing industries is \$43.62, according to the U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation (https://www.bls.gov/news.release/archives/ecec_06162023.pdf).

In addition, CPSC staff obtained quotes from testing laboratories on the costs of certification testing. Staff assume that a firm will test in-house, or send the product to a lab for testing, but not both. According to information collected, the cost of third-party testing varies but is consistent with an estimate of \$261.72 per response ($$12,62,413.10 \div 3$ responses $\div 15,363$ respondents = \$261.72).

	Table 2. Estimates by NAICS 3			
NAICS Code		Industry Weight	Estimated PRA Hours	Estimated Number of Responses
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	0.035099	8	4
334290	Other Communications Equipment Manufacturing	0.020788	8	4
334310	Audio and Video Equipment Manufacturing	0.029919	8	4
335210	Small Electrical Appliance Manufacturing	0.003445	8	4
335912	Primary Battery manufacturing	0.005116	8	4
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	0.023391	8	4
339920	Sporting and Athletic Goods Manufacturing	0.061625	2	1
339940	Office Supplies (except Paper) Manufacturing	0.005479	2	1
339999	All Other Miscellaneous Manufacturing	0.037159	2	1
423420	Office Equipment Merchant Wholesalers	0.029336	2	1
423430	Computer and Computer Peripheral Equipment and Software Merchant Wholesalers	0.38266	8	4
423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers	0.131072	4	2
423690	Other Electronic Parts and Equipment Merchant Wholesalers	0.117874	8	4
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	0.060731	2	1
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	0.056308	2	1

Issue 34: Ways to enhance the quality, utility, and clarity of the information the Commission proposes to collect.

<u>Comments</u>: There were no comments received on ways to enhance the quality, utility, and clarity of the information the Commission proposes to collect.

Response: None.

Issue 35: Ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques when appropriate, and other forms of information technology.

<u>Comments</u>: JEITA notes that the new rule would impose requirements different from those of international standards, and that this will burden manufacturers as labeling and testing for products intended for use in the United States would need to be completed separately.

There were no comments received on ways to reduce the burden of the collection of information by using automated collection techniques, or other forms of information technology.

<u>Response</u>: Staff notes that online warning requirements are no longer required in the Draft Final Rule and are not included in burden estimates. Burden associated with testing to international standards, in addition to CPSC standards, are outside the scope of PRA burden estimates for the proposed rule.

Issue 36: The estimated burden hours associated with labels and hang tags, including any alternative estimates.

<u>Comments</u>: ITI, CTA, JEITA, and AWA provided estimates of hourly burden for various industry sectors. A summary of the alternative estimates provided by commenters is provided in Table 3.

CPSC did not receive any detailed estimates on the total number of respondents to which this collection would apply, however data provided by various commenters on the number of firms to which the collection would apply imply that CPSC has likely overestimated the number of respondents.

Commenters provided alternative estimates for the frequency of response based upon the number of product families to which the rule might apply. However, these estimates were not provided at the establishment level and are therefore difficult to compare to CPSC estimates which are based on U.S. Census Bureau establishment data.

Burden Estimate	ITI	CTA	JEITA	AWA
Labeling	3 – 4 hours	No estimate	26 hours	No estimate
		provided		provided
Testing	8 – 48 hours	32 – 48 hours	75 hours	Greater than 80
		(includes		hours
		recordkeeping		
		burden)		
Recordkeeping	Greater than 1	Not provided	8 hours	No estimate
	hour	separately		provided
Approximated	54 hours	50 hours	109 hours	Greater than 80
Total Burden				hours

Table 3. Summary of Burden Estimates Provided by Commenters

<u>Response</u>: CPSC staff note that burden will vary for different industry sectors and by product as pointed out by commenters. Industry sectors with larger impacts likely were more active in responding to the public notice. The estimates provided by commenters generally support average burden calculations provided by CPSC. Preference was given to burden estimates provided by domestic suppliers.

Issue 37: The estimated respondent cost other than burden hour cost.

<u>Comments</u>: JEITA believe that the cost of test samples should be included in the estimated respondent cost other than burden hour cost.

<u>Response</u>: The PRA is a law governing how federal agencies collect information from the American public and does not typically include estimating the cost of the test samples as PRA burden.⁹

F. Comments Addressing Out-of-Scope Issues

The following comments discuss topics that, while generally related to Reese's Law, are not the subject of this particular rulemaking and therefore are not responded to here:

Comments:

- Renata SA, RILA, and an individual employee of a testing and certifying organization state that the test method for battery packaging in IEC 60086 could be used in place of the packaging standards in 16 C.F.R. 1700.15 that are tested in accordance with 16 C.F.R. 1700.20, as described in Section 3 of Reese's Law.
- Varta Microbattery Inc. requests guidance on the applicability of Section 3 of Reese's Law to zinc-air button cell and coin batteries.
- Renata SA and Micropower Battery Company (MBC) states batteries that are processed industrially and are only contacted by professionals should not be subject to child-resistant packaging requirements.
- MBC states delayed enforcement of child resistant battery packaging requirements for silver-oxide and alkaline button cell or coin batteries is arguably more important than for zinc-air batteries.
- A consultant states that the exemption for button cell and coin battery packaging complying with the marking and packaging provisions in ANSI C18.3M is not consistent with the requirements in Section 3 of Reese's Law, as the latter includes the senior adult test while the former does not.
- A consultant states that it would be helpful for staff to provide guidance in the preamble about testing under the PPPA.
- Landsdowne Labs states that a battery-level solution to the ingestion hazard would cost less than the proposed cost of implementation.
- Landsdowne Labs and two consumers state CPSC should implement a path for products containing safer batteries to be exempt from Reese's Law.
- Dr. Jatana states that a safer battery technology is needed to address the hazard, and manufacturers should be encouraged to pursue this.
- Landsdowne Labs states that CPSC should fund testing of safer batteries.
- Reese's Purpose states that it would be encouraging for other federal agencies to adopt safety rulings for products containing button cell or coin batteries not within CPSC's jurisdiction.
- Two consumers and UL Solutions state CPSC should provide or fund public education on the dangers of battery ingestion.
- A consumer states CPSC should require hospitals to report incidents where an individual has swallowed a button battery.

<u>Response</u>: Staff appreciate the comments on the construction and testing of battery packaging, but note that Section 3 of Reese's Law (on child resistant battery packaging requirements) and

⁹ <u>https://pra.digital.gov/about/</u>

battery construction requirements are not a subject of this rulemaking. Guidance on Section 3 of Reese's Law can be found on the CPSC website. While staff agree that safer button cell or coin battery technologies could address the ingestion hazard, Reese's Law does not address the underlying technology of these batteries. Staff therefore considers this issue to be out of scope of this rulemaking. CPSC includes information on the battery ingestion hazard on its website, and can consider further supporting public education, but those activities are outside the scope of this rulemaking. CPSC does not have authority over other federal agencies, and cannot dictate what hospitals must report.





Memorandum

TAB B

Staff Briefing Package: Draft FR for Reese's Law | August 31, 2023 | cpsc.gov

OS 187



Memorandum

TO: Daniel Taxier, Children's Program Manager **DATE:** August 1, 2023 **Division of Mechanical and Combustion Engineering THROUGH:** Ryan Seebruck, **Division Director Division of Hazard Analysis** FROM: John Topping Mathematical Statistician **Division of Hazard Analysis** Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and SUBJECT: Consumer Products Containing Such Batteries: Deaths, Injuries, and non-Injury Incidents Associated with Hazards of Button Cell or Coin Battery Ingestion

I. Introduction

Per Reese's Law, a "button cell or coin battery" includes a single-cell battery with a diameter greater than the height of the battery. Both the proposed rule (NPR) memorandum and this final rule memorandum provide incident data associated with button cell or coin batteries ingested by mouth or inserted into the nose or ears. Staff updated NPR fatality data, which includes an additional 7 deaths reported after the analysis supporting the NPR. Injuries are not updated from the August 2022 NPR, as updated estimates were not available before this final rule briefing package was prepared.

This memorandum uses the abbreviation "BCCB" to cover the combination of <u>B</u>utton <u>C</u>ell or <u>C</u>oin <u>B</u>atteries and focuses on BCCBs entering the body through any of three specific orifices (mouth, nose, or ears), regardless of victim age and intent. However, this memorandum does *not* include any count or assessment of insertions (of which some may result in impactions) in the rectum or genitals. The combination of threats of impaction from BCCBs in the digestive tract (from ingestion), impaction directly by mouth or impaction or insertion into the nose or ears is abbreviated in the NPR and in this memo using the term "III" (for impactions, ingestion, or insertion via the mouth, nose, or ears), which is combined with a previously defined term as "BCCB-III."

II. Fatal BCCB Ingestions Reported in Consumer Product Safety Risk Management System (CPSRMS) For the 11-year period 2011–2021 previously discussed in the NPR, 27 deaths in the United States have been reported to CPSC associated with ingestion of button or coin cell batteries. The NPR only counted 25 deaths for that same period, as it did not include two more recently reported deaths from each of the years 2020 and 2021. Reporting to CPSC through May 1, 2023, indicates another 5 more recent deaths *after* the year 2021 – 3 in the year 2022 and 2 in 2023, between January 2023 and March 2023. Combining all reported deaths since 2011, staff identified 32 reported deaths in the United States from BCCB ingestion for the 12 ¼-year period of January 1, 2011-March 31, 2023. Among the seven additional deaths not already included in the NPR, the earliest occurred in September of 2020 (reported via–death certificate in August 2022) and the most recent occurred in March 2023. The tables that follow present the distribution of deaths separating the "NPR deaths" (25 in total) from the more recently reported "Since NPR Deaths" (7 in total), before adding those columns together to calculate "Combined Deaths" (32 in total). Table 1 presents the distribution by year for the years 2011-2022 or, in the case of the year 2023, for the period of Jan 1, 2023-March 31, 2023.

Year or Period	NPR Deaths	Since NPR Deaths	Combined Deaths	Combined Percent
2011	3	-	3	9
2012	2	-	2	6
2013	6*	-	6	19
2014	1	-	1	3
2015	3	-	3	9
2016	0	-	0	0
2017	3	-	3	9
2018	2	-	2	6
2019	0	-	0	0
2020	4	1	5	16
2021	1	1	2	6
2022	-	3	3	9
2023** (thru March)	-	2	2	6
Total	25	7	32	100

Table 1. Reported Number of BCCB-III Deaths by Year or Period, January 1, 2011- March 31, 2023*.

Source: CPSRMS, CPSC.

*This assessment does not generally cover incidents prior to 2011; however, as already noted in the NPR a late 2010 incident from which a child initially survived until death in 2013 due to the resulting complications is included (as one of 6 deaths in 2013). The remaining combined 31 decedents covered by this assessment died within the same year when they first ingested BCCB.

** Based on reporting as of May 1, 2023, so counting for the year 2023 is incomplete and only includes two deaths known to have occurred between January 2023 and March 2023. Reporting is also incomplete for the years 2021-2022 and counts for those years may increase as additional death certificates are received.

As was true in the NPR, all reported BCCB-related *deaths* in the United States for this period involve ingestion of BCCB by mouth, and therefore, qualify as BCCB-III. Among the reported BCCB-III deaths of which staff is aware during this over 12 ¼-year period, 15 (47%) deaths occurred in the six years 2011-2016 and 17 (53%) deaths occurred during the 6 ¼ years *from Jan 1, 2017-March 2023*. Excluding the partial year of 2023, the six-year period (2017-2022) is associated with 15 reported deaths so far, which is the same number of reported deaths for the prior six-year period (2011-2016). Reporting is particularly incomplete for the years 2021 and afterward, so counts for recent years may increase as CPSC receives additional death certificates.

OS 189

A majority of reported decedents (21 or 66%) were indicated as female. A minority of reported decedents (11 or 34%) were indicated as male.

Victim Sex	NPR Deaths	Since NPR Deaths	Combined Deaths	Combined Percent
Female	16	5	21	66
Male	9	2	11	34
Total	25	7	32	100

Table 2	Reported Number of BCCB-III Deaths	hy Victim Sex	2011 – March 2023
	Reported Multiper of Dood-in Deating		

Source: CPSRMS, CPSC.

Table 3 presents all 32 BCCB ingestion fatalities by initial victim age (*i.e.*, at the time of ingestion). All were under the age of 5 years. For a small number of these incidents, the decedent survived long enough to reach an older age classification than when first ingesting BCCB. Therefore, initial victim age presented in Table 3 may be younger than the decedent's final age upon death. One (3% of 32) indicated initial victim age as 10 months, although that child survived until 3 years of age before death from resulting complications. Most reported deaths, 18 out of 32 (56%), involved BCCB ingested by 1-year-old victims (*i.e.*, 12 months to 23 months at time of ingestion). Seven (22%) decedents were 2 years old at the time of ingestion. No decedents were reported as 3 years old at the time of initial BCCB ingestion. Six (19%) decedents were age 4 years old at the time of ingestion and death. Staff did not identify any decedents *over* the age of 4 years (either upon ingestion or upon death).

Initial Victim Age	NPR Deaths	Since NPR Deaths	Combined Deaths	Combined Percent
0-11 months	1	-	1	3
12-23 months	14	4	18	56
2 years	6	1	7	22
3 years	0	-	0	0
4 years	4	2	6	19
Total	25	7	32	100

Table 3. Reported Number of BCCB-III Deaths by Initial Victim Age, 2011- March 2023.

Source: CPSRMS, CPSC.

Staff could not identify battery chemistry for 14 (44%) of the 32 reported deaths. Staff determined that lithium was the chemistry for at least 18 (56%) of the deaths. Reports did not indicate or infer any other battery chemistry.

Table 4. Reported Number of BCCB-III Deaths by Battery Chemistry, 2011- March 2023.

Battery Chemistry	NPR Deaths	Since NPR Deaths	Combined Deaths	Combined Percent
Lithium	13	5	18	56
Unknown				
Chemistry	12	2	14	44
Total	25	7	32	100

Source: CPSRMS, CPSC.

Sixteen (50%) of the deaths involved batteries of unspecified diameter. These include deaths with descriptors such as "button" or "coin" which may hint at likely relative size without supporting a specific determination of diameter or size classification. The smallest specified diameter applicable to at least one of the deaths was 18 mm. Staff determined a diameter of specifically 20 mm for 13 (41%) of the deaths. One incident indicated medical professionals describing an ingested battery as "about the size of a quarter." Although the size of that battery was not precisely indicated, the size of an actual U.S. guarter would be approximately 24.26 mm. A separate death specifically indicated a 25 mm battery. Combining the above observations, staff concludes that at least 15 (47%) reported deaths involved "Large"-size batteries (20 mm or larger diameter). Only one (the 18 mm battery) staff determined to be "Medium" size (10 mm to 19.9 mm diameter). Staff could not identify batteries to be "Small" size (under 10 mm diameter). However, staff was often assisted by specific reference to an exact battery type (e.g., CR2025 or CR2032) when making battery size determinations, which made it easier to determine larger extracted battery sizes. Battery size may be more likely to be indicated explicitly or implicitly among deaths involving larger size batteries. Conversely, smaller battery size-related BCCB deaths could be less likely to be reported in such a way as to indicate the diameter or size classification of the involved battery. For these and other possible reasons, the 16 deaths related to BCCB of unknown diameter or size classification should not be assumed to have a comparable distribution as observed among the 16 deaths for which battery diameter or size classification could be determined.

Battery Diameter	NPR Deaths	Since NPR Deaths	Combined Deaths	Combined Percent
18 mm	1	-	1	3
20 mm	11	2	13	41
25 mm or "About the size of a quarter"	2	-	2	6
Unknown Diameter	11	5	16	50
Total	25	7	32	100

Table 5. Reported Number of BCCB-III Deaths	by Battery Diameter or Size, 2011- March 202
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Source: CPSRMS, CPSC.

For the majority (78%) of BCCB-III deaths there was not enough information to classify whether the victim found the batteries loose (*e.g.*, stored loosely), from packaging, or removed or liberated from a product. One fatality is inferred to involve a battery found loose by the victim prior to ingestion (if there was an initial product or packaging source, such was unknown).¹ Another death is inferred (unwitnessed) to have involved batteries taken from packaging. Five (16%) deaths were concluded or inferred to have involved batteries removed or liberated from some product prior to ingestion.

¹ The incident narrative describes a button cell or coin battery swept up with other debris and left on the floor.

Battery Source Classification	NPR Deaths	Since NPR Deaths	Combined Deaths	Combined Percent
Loose	1	-	1	3
Packaging	1	-	1	3
Product	5	-	5	16
Unknown Source	18	7	25	78
Total	25	7	32	100

Table 6. Reported Number of BCCB-III Deaths by Battery Source Classification, 2011- March 2023.

Source: CPSRMS, CPSC.

Among the five fatalities classified to be from a "Product" battery source, two deaths were determined to involve batteries extracted from remote controls. One death occurred after a dog chewed a dog collar tracking tag in such a way as to liberate a 20 mm BCCB that fell to the floor undetected before ingestion by a child. In another death, a child was determined to have ingested a battery that came from a tracking device. One death is inferred to have involved a battery from an electronic toy.

III. Conclusion

In the 11 years spanning 2011-2021, at least 27 deaths and, as observed in the NPR memorandum, an estimated 54,300 emergency room visits, were associated with ingested or inserted button cell or coin batteries. Due to the exclusion of cases for which a BCCB-III determination was inconclusive, this may underestimate the actual number of BCCB-III cases treated in U.S. emergency departments during that period. On average, annually, two to three deaths occurred, and an estimated 4,900 BCCB-III cases were treated in U.S. emergency rooms in that period. An estimated 16 percent of BCCB-III resulted in hospitalization (including transfer to another hospital). Young children appear to be at the greatest risk. Four years of age was the maximum age observed among all decedents who had ingested BCCB. A majority of BCCB-III (an estimated 59%) involved children *under* 4 years of age, while an estimated 79 percent of BCCB-III treated in U.S. emergency rooms involved children *under* 7 years. However, victims were observed in all age groups, so the hazards do not appear exclusive to young children.

At least 5 additional deaths *after* the year 2021, have been reported thus far. Among all *reported* incidents (*e.g., excluding NEISS*), staff determined that batteries from out of a product or device compose the majority of incidents (when combining reported nonfatal incidents with or without ingestion as assessed in the NPR with reported deaths).² Among reported ingestions of BCCB, at least a majority (52% or 39 out of 75) involved BCCB removed or liberated from some product battery source.³

² This majority conclusion results regardless of whether the 5 most recently occurring reported deaths are included.
³ The statistic presented in this parenthetical is based on assessment combining all 32 reported ingestion related deaths covered in this memorandum with the 43 nonfatal ingestions previously discussed in the NPR. The reported nonfatal data from the NPR was limited to incident years 2016-2021. Among the 43 reported nonfatal ingestions in that 6-year period, at least 34 (79%) involved BCCB removed or liberated from some product battery source. Limiting reported deaths and nonfatal ingestions to the equivalent timeframe constraints yields a higher percentage majority finding. For example, the NPR identified only 10 deaths within the six-year period of 2016-2021 (excluding deaths more recently reported). Of those 10, the majority did not indicate the source of the battery, but 1 indicated packaging, and two a product source. Combining these reported fatal and nonfatal ingestions subject to comparable reporting and incident timeframe constraints, staff concludes that at least 68% (36 out of these 53 ingestions) involved BCCB removed or liberated from some product battery source.

TAB C

OS 193



Memorandum

TO:	Daniel Taxier, Project Manager, Battery Regulation	DATE: August 31, 2023
THROUGH:	Mary Kelleher, AED, HS Stefanie Marques Ph.D. Division Director, HSPP	
FROM:	Cheryl Scorpio, Ph.D. Pharmacologist, HSPP	
SUBJECT:	Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Toxicity of Batteries	

I. Introduction

The Commission issued a proposed rule (NPR) to establish a safety standard and notification requirements for button cell or coin batteries and consumer products containing such batteries on February 9, 2023. 88 Fed. Reg. 8,692. This memorandum from the Directorate for Health Sciences (HS) supports staff's draft final rule to establish a safety standard for button cell or coin batteries and consumer products containing such batteries. This memorandum discusses the comments received on the NPR regarding the associated hazards, updates injury data from button/coin batteries in the medical literature, discusses updated CPSC data, and data from the National Capital Poison Center or poison.org.

As explained below, research demonstrates that button cell or coin batteries cause serious injury and death when ingested due to impaction (or becoming wedged) in the esophagus, including esophageal burns and perforations, vocal cord paralysis, and fistulas created by burning through the esophagus and surrounding tissues creating a connection between the esophagus and the trachea or blood vessels. Serious injury can also result from button cell or coin batteries inserted into the nose and ear, including septal perforation, decreased structural support of the nose, and hearing loss.

II. Silver Oxide Button or Coin Cell Batteries

Commenters on the NPR stated that silver-oxide batteries should be excluded from the rule and also that they should have different warnings than lithium batteries because of a lack of fatal incidents caused by these batteries.

Staff reviewed the literature on what, if any, hazards are associated with silver oxide button cell or coin batteries and disagrees with the commenters. Jatana *et.al.* (2017) found in testing using an animal model that silver oxide button or coin cell batteries caused severe esophageal injuries. These injuries were visible on the tissue within 15 minutes. While lithium batteries induced the most severe visible injury, the lower voltage silver oxide batteries reached the pH of 12 leading to corrosive tissue damage as with the 3V lithium batteries, but it took 4 hours longer than the lithium batteries. Therefore, silver oxide batteries cause severe esophageal injury, but it takes longer to achieve than lithium batteries. Staff recommends that the performance requirements in the rule should apply to silver oxide button or coin cell batteries because they can cause severe esophageal injury. Although the injury can take longer, batteries have been impacted in the esophagus for the required length of time.

While the majority of severe injuries where the battery size is known are from 20 mm lithium batteries, smaller 1.5V non-lithium batteries less than 20 mm (11.6m – 16mm) can cause severe or fatal outcomes in children aged 22 days to 10 months (Litovitz et.al. 2010). Silver oxide batteries are 11.6 mm, therefore they fall within this size range to cause esophageal injury. Based on this data establishing that silver oxide batteries create the same risk of injury, but may take longer to cause esophageal injury, staff recommends for the final rule that silver oxide batteries be labeled with ingestion warnings.

III. Zinc-Air Button or Coin Cell Batteries

Some NPR commenters agreed with the NPR proposal that warning labels on zinc-air batteries are unnecessary, citing a low risk of injury. Some commenters proposed an exemption from labeling, while others supported warning labels on packaging. Some recommended that the word CAUTION be used instead of WARNING for zinc-air battery package labels. Two doctors state that zinc-air batteries pose a risk of injury when inserted in the ear canals and nasal cavities.

Staff considered the medical literature and incident data associated with zinc-air batteries and recommend that zinc-air batteries not be subject to the performance requirements in the final rule, because zinc-air batteries do not present an ingestion hazard. Jatana et. Al. (2017) found in testing using an animal model that zinc-air batteries did not cause any damage to esophageal tissue. They believe that the fluid from the moist environment of the esophagus blocked the entrance of oxygen to the battery, and the battery was unable to discharge. Based on this research, and the lack of incident data, staff does not recommend performance requirements for zinc-air batteries to be labeled as an ingestion hazard. However, Sancaktar et.al. (2020) showed in animal nasal septal model, that zinc-air batteries did cause necrosis to the tissue. This may be due to the irregular shape and drier environment allowed the zinc-air battery to discharge, causing voltage and tissue damage. Therefore, staff recommends that packages of zinc-air batteries should be labeled with insertion warnings.

IV. National Capital Poison Center or Poison.org Data Update

A. Fatal Cases

The National Capital Poison Center, or Poison.org, a private company, has kept track of button cell or coin battery ingestions that have occurred from 1977 to present. References for these incidents come from the news, medical literature, or from the National Battery Ingestion Hotline.¹ According to the Fatal Button Ingestions, a table online at Poison.org, 69 deaths occurred due to button cell or coin battery ingestion from 1977 to June 2022 (when the NPR was written). Since the NPR, staff found 2 additional deaths reported at Poison.org that occurred due to button or coin battery ingestion from June 2022 to May 2023.² Both deaths were from lithium button or coin cell batteries getting impacted in the esophagus; one battery was 20 mm, and the other was greater than or equal to 20 mm. One battery was impacted for 25 days, the other for 3 days. The children died of hematemesis and sepsis, respectively.

B. Severe Cases

In the Table Nonfatal Button Ingestions with Severe Esophageal or Airway Injury from Poison.org, 267 cases with severe injury occurred from 1982 to June 2022. Since the NPR, 13 additional cases with severe injury were recorded in this Table from June 2022 and May 2023.³ Nine injuries were from lithium batteries, the rest were unknown chemistries. Sources of the batteries were car key fob, novelty tea light candle, remote control (2) and glucometer. Nine of the batteries were 20 mm in diameter or bigger. In four cases, the injury led to vocal cord paralysis. Five led to esophageal burns, and five led to esophageal stricture. Injury reports include two trachealesophageal fistulas, one aortoesophageal fistula, and one tracheo-bronchiesophageal fistula. All incidents required endoscopic or surgical removal of the batteries. Three incidents required surgical esophageal and repair of the fistula, and one required cardiopulmonary bypass and surgical reconstruction of the trachea.

¹ <u>Poison Control Center (batteryingestionhotline.com)</u>. The National Battery Ingestion Hotline transferred from the National Capital Poison Center to the Rocky Mountain Poison Center in 2017, and has not been included in the National Capital Poison Center data since then.

² Fatal Cases (poison.org) Fatal Button Battery Ingestions: 71 Reported Cases (accessed May 2023).

³ Severe Cases (poison.org) Nonfatal Button Battery Ingestions with Severe Esophageal or Airway Injury: 280 Cases. (Accessed May 2023) (Note: the number of cases in the website title is likely to change as additional cases are publicized.)

References

Jatana KR, Rhoades K, Milkovich S, Jacobs. <u>Basic mechanism of button battery ingestion</u> <u>injuries and novel mitigation strategies after diagnosis and removal.</u> Laryngoscope. 2017 Jun;127(6):1276-1282. Doi: 10.1002/lary.26362. Epub 2016 Nov 9. PMID: 27859311

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Sancaktar ME, Bayraktar C, Bakırtaş M. Injury mechanism of button batteries in the nasal cavity and possible mitigation strategies during impaction. Laryngoscope. 2020;130(10):2487-2493. Doi:10.1002/lary.28913

OS 198

TAB D



Memorandum

DATE: August 31, 2023

- **TO:** Daniel Taxier, Project Manager, Button Batteries Rulemaking Division of Mechanical and Combustion Engineering, Directorate for Engineering Sciences
- **THROUGH:** Rana Balci-Sinha, Ph.D., Director, Division of Human Factors, Directorate for Engineering Sciences
- **FROM:** Jill Hurley, Engineering Psychologist, Division of Human Factors, Directorate for Engineering Sciences
- **SUBJECT:** Draft Final Rule to Establish a Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries: Human Factors Assessment

I. Introduction

On February 9, 2023, as required by Reese's Law (15 U.S.C. 2056e), CPSC published a proposed rule (NPR) to establish performance requirements for battery compartments on consumer products that contain, or are designed to use, one or more button cell or coin batteries to eliminate or adequately reduce the risk of injury from ingestion of button cell or coin batteries by children 6 years old and younger. 88 Fed. Reg. 8,692. The NPR also required warning labels on the packaging of button cell or coin batteries, as well as on the packaging, battery compartments, and accompanying instructions and manuals of consumer products containing button cell or coin batteries. In addition to implementing Reese's Law, the proposed rule required manufacturers and importers of button cell or coin batteries, and consumer products containing such batteries, to notify consumers of performance and technical data related to the safety of such batteries at the point of sale, both online and in stores.

In this memorandum, based on the public comments, staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF) provides staff's revised recommendations for marking and labeling requirements for the Draft Final Rule.

CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

II. Background

In the NPR Staff Briefing Package¹ ESHF staff proposed warning labels in accordance with Reese's Law. Warning label requirements specified in Reese's Law include the following:

(A) Warning label to be included on the packaging of button cell or coin batteries and the packaging of a consumer product containing button cell or coin batteries;

(B) Warning label to be included in any literature, such as a user manual, that accompanies a consumer product containing button cell or coin batteries; and

(C) Warning label to be included, as practicable,

(i) directly on a consumer product containing button cell or coin batteries in a manner that is visible to the consumer upon installation or replacement of the button cell or coin battery; or

(ii) in the case of a product for which the battery is not intended to be replaced or installed by the consumer, to be included directly on the consumer product in a manner that is visible to the consumer upon access to the battery compartment, except that if it is impracticable to label the product, this information must be placed on the packaging or instructions.

Reese's Law also states that warning labels must: (1) clearly identify the hazard of ingestion, and (2) instruct consumers, as practicable, to keep new and used batteries out of the reach of children, to seek immediate medical attention if a battery is ingested, and to follow any other consensus medical advice.

In addition to the required warnings specified in Reese's Law, the NPR proposed recommendations to improve safety communication to consumers pursuant to section 27(e) of the CPSA.

III. Staff's Recommended Changes for Marking and Labeling in the Draft Final Rule

CPSC received several comments regarding the marking and labeling proposal in the NPR. Based on these comments, below we list staff's recommended modifications to the warning labels on battery packaging, packaging of the consumer product, consumer product, and instructions/manuals accompanying the consumer product for the draft final rule.

A. Modify Color Requirements in the General Warning Label Requirements

The general requirements in the NPR for warnings and warning labels follow requirements found in ANSI Z535.4 American National Standard Product Safety Signs and Labels, which is the primary voluntary consensus standard providing guidelines for the design of safety signs and

¹ CPSC Staff Briefing Package: Notice of Proposed Rulemaking: Safety Standard and Notification Requirements for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries – Jan 11, 2023: <u>https://cpsc.gov/s3fspublic/NoticeofProposedRulemakingSafetyStandardandNotificationRequirementsforButtonCellorCoinBatteriesandCon</u> <u>sumerProductsContainingSuchBatteries.pdf?VersionId=kDinNeydktkt3T8RRtzN4u1GTXPRjpEl</u>

labels for application to products. The ANSI standard includes recommendations for the design, application, use, and placement of warning labels, such as having the signal word "WARNING" and the safety alert symbol of an equilateral triangle surrounding an exclamation mark.

Reese's Law includes requirements for the placement and content of warnings but does not address warnings formatting or color. The NPR proposed using the signal word "WARNING" and requiring the word to be in black letters on an orange background. The NPR also proposed that the word "WARNING" be accompanied by the icon representing "Warning: Contains coin battery" which must be in yellow with a black icon. The NPR recommended the use of color to make warnings more likely to be noticed quickly.

Several commenters state that the use of color on packing, instructions, or manuals, and on some consumer products would be challenging and, in most cases, add costs to the manufacturing and printing process, particularly to those printed materials that do not already incorporate color. Commenters also stress that other product safety standards (*e.g.*, ASTM F963, ANSI C18.3, or ANSI Z535 series) do not mandate the use of colors and accept black and white printing or contrasting colors to the background it is printed on. Commenters state, however, that if color is used for the signal panel, colors should conform to ANSI Z535.1 safety colors that correspond to the safety message. Commenters state that the use of color may not be reasonable to print on certain product materials, for example, colored or textured plastics.

Staff agrees that applying color to some materials (*e.g.*, colored or textured plastics, consumer product packaging, manuals, or other collateral material) that do not already contain color may present a burden to some manufacturers. ANSI Z535.4 provides flexibility for special circumstances that limit or preclude the use of colors while preserving the visibility and noticeability of the label by requiring contrasting colors. Staff recommends requiring the use of color when the subject materials will already use printed color processing, otherwise the use of black and white or contrasting colors be acceptable. Staff proposes the icon that represents "Warning: Contains Coin Battery," when used on consumer products, be in contrasting colors to the background on which it is printed. The use of color is not specified in Reese's Law, thus this recommendation does not conflict with it and staff views this recommendation neutral because the label or icon will visually align with other information on the display while ensuring that it is noticeable due to its contrast or color.

B. Add Battery Ingestion Hotline Phone Number to Warning Label for the Button Cell or Coin Battery Packaging

The warning label proposed to be on battery packaging included the bullet "**Seek immediate medical attention** if a battery is suspected to be swallowed or inserted inside any part of the body." Staff received a comment that this statement does not provide the next logical step to get help and requests that CPSC require the addition of the phone number for the National Poison Control Center (NPCC). Staff agrees that adding the contact number will provide consumers with an actionable step and recommends that the contact number of the National Battery Ingestion Hotline (NBIH), currently 1-(800) 498-8666, be inserted in the last warning statement. See Figure 1.

- INGESTION HAZARD: DEATH or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

Figure 7. Proposed warning of ingestion hazard for battery packaging.

C. Provide Alternative Icon and Text, limit the required Text Size and add Battery Ingestion Hotline Phone Number in Warning Label for Packaging of the Consumer Product containing Button Cell or Coin Batteries

The NPR proposed that warning labels for the packaging of consumer products containing button cell or coin batteries include the "Keep Out of Reach of Children" icon to quickly convey the safety message to keep the batteries out of reach of children, and to direct the reader's attention to the label.

Public comments state that the icon on the product packaging can be mistaken to mean that the product itself should be kept away from children and recommends instead to use the "Warning: Contains Coin Battery" icon. Staff agrees that the "Keep Out of Reach of Children" icon could be mistaken to mean keep the product out of reach of children; and while this message may be appropriate for some products, it is not appropriate for children's products or other products that may be used by children. For effective communication of safety hazards, people need to notice, read, and heed the warning. If the warning is not believable, people may stop reading the label or disregard it. Having a "Keep Out of Reach of Children" icon on a product that is likely to be used by children may give an inaccurate message to consumers, who then may choose to skip the warning content entirely. To eliminate confusion regarding whether the battery or the product should be kept away from children, staff recommends allowing either the "Keep Out of Reach of Children" icon or the "Warning: Contains Coin Battery" icon to be used, as appropriate for the product.

Staff views the effectiveness of either icon neutral in this case because both require further reading and understanding of the label content to communicate the message accurately, the primary purpose of the icon is to get the attention of consumers so that they stop and read the text. Therefore, staff finds that either icon is appropriate and does not conflict with Reese's Law because the label content is identical and communicates the description of the hazard, what to do to avoid the hazard and seeking medical attention regardless of what the icon itself communicates.

In addition, one commenter requests flexibility to replace the word "uses" rather than "contains" in the first bulleted statement. This is to avoid confusion in circumstances where a consumer must purchase a battery not already installed in or provided with a product, and to prevent false claims that the battery comes with the product. Staff agrees in some instances the word

"contains" may lead to misrepresentation and recommends offering alternative wording for manufacturers.

See Figure 2 for an updated proposed warning label with the "Warning: Contains Coin Battery" icon and showing that the word "uses" can replace the word "contains". This label also includes the Poison Control phone number as discussed earlier.

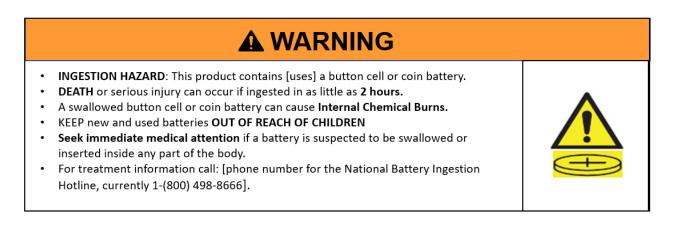


Figure 2. Proposed warning to indicate the presence of a button cell or coin battery and the ingestion hazard for consumer product packaging.

The NPR proposed alternative options to the full warning label if limited packaging size does not permit the use of the full warning label. Based on comments outlined above, staff prepared an example warning label using the "Warning: Contains Coin Battery" icon for use on the principal display panel (Figure 3) and the remaining statements label for the secondary display panel (Figure 4).

- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours.



Figure 3. Proposed abbreviated warning for the principal display panel.

A WARNING

- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

98

Figure 4. Proposed abbreviated warning for the secondary display panel.

Based on the requirements for icon and text size, the warning label shown in Figure 3 will occupy at a minimum about 1.77" (45 mm) width and 0.75" (19 mm) height on the principal display panel of the packaging in its condensed form (Figure 5a). Figure 5b shows a principal display panel of a packaging containing this label. The principal display panel in this case is 1.89" (48 mm) wide and 1.06" (27 mm) tall.

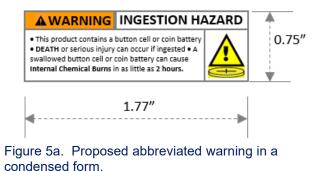




Figure 5b. Same label on a package with 1.89" width and 1.06" height

D. Modify Other Battery Safety Information

To protect the public against unreasonable risks of injury associated with button cell and coin batteries, or those consumer products that use such batteries, the NPR proposed other safety information be present on the battery packaging, consumer product packaging, and instructions, if provided. Many of these performance and technical statements, or similar statements, are already found on current retail battery packaging to instruct consumers how to handle batteries safely and avoid foreseen hazards, such as "Keep in original packaging until ready to use" or "Dispose of used batteries promptly." Public comments generally did not support this requirement because battery packaging is already small and unlikely to have space for all the statements recommended. See staff's response to comment Tab A, Issue #14. In addition, staff recommends clarifications to the applicability and content of the warnings on battery packaging, in instructions and manuals, and addressing battery disposal information.

1. Battery packaging

Staff recommends that the following statement on battery packaging be removed:

• "Call a local poison control center for treatment information."

Staff recommendations include adding specific contact information for the National Battery Ingestion Hotline to the required warning labels on battery packaging and consumer product packaging. This statement to "Call a local poison control center" is now redundant and should be removed.

2. Instructions and manuals, if provided:

Similar to above, staff recommends removing the statement "Call a local poison control center for treatment information" in instructions and manuals.

Regarding the Toy Association's comment on multi-action mechanisms presenting a "false positive" appearing to be closed, staff acknowledges that this scenario may occur in both multi-action enclosures and enclosures secured via screw fasteners. After replacing the battery, consumers may inadvertently neglect to screw the fastener, leaving the enclosure ineffective. In order to decrease this risk for all products regardless of their enclosure securement design, staff recommends requiring all products with a replaceable button cell or coin batteries to include warnings in product instructions to ensure proper securement of the battery enclosure. Staff's recommended language is shown below:

• For consumer products using replaceable batteries: Always completely secure the battery compartment. If the battery compartment does not close securely stop using the product, remove the batteries, and keep the batteries away from children.

E. Other Performance and safety comments

Label Permanency

The NPR required warning statements or icons to be "clearly visible, prominent, legible, and permanently marked." RILA requested clarification of the permanency requirement for warning labels printed on-product or using sticker labels, and one commenter suggested on-product permanency should comply with the test requirements in UL 62368-1.

Staff agrees that the permanency requirement can be clarified. Staff reviewed the recommended warning label permanency test in UL 62368-1 section F.3.10. This test evaluates the legibility of printed or screened markings (1) after a sample is rubbed with a cloth soaked in water, and (2) after a sample is rubbed with a cloth soaked in petroleum spirit (a reagent grade hexane with a minimum 85% n-hexane). The marking must remain legible, and adhesive labels must not curl or be removeable by hand. Staff concludes that this test method is appropriate for labels on or near the battery compartments of consumer electronics, and that it addresses labeling methods such as, but not limited to embossing, stamping, etching, or molding. Staff therefore recommend adding the following to the warning label requirements for consumer products that contain button cell or coin batteries:

• Permanency of the label must be tested in accordance with UL 62368-1: F.3.10.

This test method will verify that consumer products containing button cell or coin batteries remain durably and indelibly marked with the required warning labels.

Text Size Clarification

The NPR states that consumer products must be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or

coin battery. Product Display Panel is defined in 1263.2(f). Text size must be determined based on Table 1, or if on a sticker label, must meet the minimum size requirements in §1263.4(a)(7). While reviewing the proposed regulatory text, staff found that the term used to define the appropriate place to put on-product warning labels, the "product display panel," was not referenced in the warning label text size requirements. Staff clarifies that the text size must be dependent on the principal display panel (for labels on battery packaging and consumer product packaging) or the product display panel (for labels on consumer products). This will assist manufacturers in determining what area to measure for the on-product warning label. Alternative on-product labels can be used in situations where the full label does not fit in the measured product display panel area, as described in the NPR and in the draft final rule.

IV. Staff's Recommendations for Performance and Technical Data in a Future Rulemaking

To protect the public against the unreasonable risk of injury and death to children 6 years old and younger from button cell and coin battery ingestion, the NPR proposed certain performance and technical data be displayed at the point of sale pursuant to section 27(e) of the CPSA. CPSC received several comments regarding the performance and technical data in the NPR. Based on these comments, below we list staff's recommended modifications to the requirements, and recommend seeking additional comment in a future rulemaking.

A. Modify Point of Sale Requirements

To protect the public against the unreasonable risk of injury and death to children 6 years old and younger from button cell and coin battery ingestion, the NPR proposed certain performance and technical data be displayed at the point of sale pursuant to section 27(e) of the CPSA.

1. Require Icon for the Button Cell and Coin Battery

The NPR requested comment on whether the rule should require button cell and coin batteries to be durably and indelibly marked with the "Keep Out of Reach of Children" icon. After consideration of the comments, staff recommends requiring the "Keep Out of Reach of Children" icon be used on button cell or coin batteries that are visible within the packaging, where practicable, as an additional safety warning should the battery be removed from its packaging and not immediately installed in a consumer product. Consumers will see the "Keep Out of Reach of Children" icon at the point of sale. The icon will remain visible once the battery is removed from its package but not yet inserted into the consumer product. The goal is to inform the consumer of a hazard and to address incidents associated with batteries loose in the environment so that consumers can take the appropriate action of keeping the battery out of reach of children.

2. Battery Disposal Information

Staff received positive comments regarding the disposal of button cell and coin batteries to be included. Dr. Ian Jacobs commented that even zinc-air batteries, both new and used, require attention. Consumer organizations (American Academy of Pediatrics, Consumer Federation of America, Consumer Reports, Kids In Danger, Public Citizen, & U.S. Public Interest Research Group) agree that every use stage of battery cell and coin batteries should be addressed, including disposal. UL Solutions requests and supports additional collaboration with voluntary standards to address the practical uses of button cell and coin batteries including household storage and disposal.

To clarify the steps consumers should take for safe battery disposal, staff recommends adding a statement on battery packaging, product packaging and instructions (or any literature provided) on battery disposal.

• Contact your local hazardous waste authority or find a local recycling center for battery disposal information.

Button cell or coin batteries which are not disposed of properly and promptly can be accessed by children and become an ingestion hazard. Local authorities will be best able to inform consumers on safe ways to dispose of batteries in a manner that meets local regulations.

3. Add Insertion Hazard Warning Label for Zinc-Air Batteries

The NPR requested comments on whether zinc air batteries should contain a warning label. Incident data provided in the NPR supports a low risk for an ingestion hazard, although incident data and comments demonstrate the potential for injury when zinc-air batteries are inserted in the ear and nose. Staff received public comments supporting the exclusion of labels, while those in the medical field expressed concerns about serious injury when inserted into the nose or ear canal.

As discussed in the Directorate for Health Sciences memorandum (see Tab C), staff recommends that the zinc-air battery packages carry a warning label regarding insertion into the nose or ear. Figure 6 shows staff's recommended warning label for the final rule, to be added to zinc-air battery packages in lieu of an ingestion hazard warning label. The same format and location requirements for the ingestion hazard warning label apply to this label.

OS 208

- INSERTION HAZARD: Zinc Air batteries inserted in the nose or ear can cause Internal Chemical Burns.
- KEEP new and used batteries OUT OF REACH OF CHILDREN.
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].



Figure 6. Proposed warning label for zinc-air battery packaging

4. Additional Warning Statements on Battery Packaging

Public comments state that some of the proposed warnings appear to be only applicable to replaceable batteries, while others appear to be only applicable to nonreplaceable batteries. Staff agree with the comments, and recommend clarifying the applicability of the warnings:

• For consumer products using replaceable batteries: Ensure the batteries are installed correctly according to polarity (+ and -).

The instruction to install batteries correctly only applies if the battery is accessible and is intended to be replaced by the consumer.

• For consumer products using replaceable batteries: Remove and immediately discard batteries from equipment not used for an extended period of time.

This instruction statement only applies if the batteries are accessible and can be removed from the product. This statement does not need to be included on consumer product packaging, instructions, or collateral materials if inapplicable.

The following statement is applicable only to consumer products with replaceable batteries that use more than one battery per circuit:

• For consumer products using replaceable batteries that use more than one battery per circuit: Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries.

Consumer products powered by one battery will not present a risk for mixing batteries.

The following statement is applicable only to consumer products using non-rechargeable batteries:

• For consumer products using replaceable or non-rechargeable batteries: Non-rechargeable batteries are not to be recharged.

This sentence explains that non rechargeable batteries should not be recharged. This statement does not apply to non-replaceable rechargeable batteries.

V. Staff's Assessment of UL 62368-1

Several commenters (JEITA, HCPA, Tech Net, CTA, ITI) requested that CPSC consider the requirements in UL 62368 -1 Audio/video, Information and Communication Technology Equipment -Part 1: Safety Requirements to be sufficient to meet Reese's Law. Below staff assesses the General Requirements in UL 62368-1.

Labeling requirements for products subject to UL 62368 -1 that contain button cell and coin batteries are limited to products likely to be accessible to children and include button or coin batteries with a diameter of 32 mm or less. Products with button cell or coin batteries that are not intended to be replaced or are only accessible after damaging the equipment do not require labeling.

On-product

Labeling requirements, described as instructional safeguards, must identify the nature and classification of the hazardous energy source. The following statements are required and may include symbols and text,

• "Do not ingest battery, Chemical Burn Hazzard" or equivalent,

Text must be preceded by the word "Warning" or "Caution" or similar wording.

- "[The remote control supplied with] This product contains a coin/button cell battery. If the coin/button cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death."
- "Keep new and used batteries away from children."
- "If the battery compartment does not close securely, stop using the product and keep it away from children."
- "If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention."

Instructions

When on-product labeling is required, the safety information must also be provided in accompanying installation or instructional materials.

Battery

The standard does not include requirements associated with safety information for individual batteries; however, it does require compliance with relevant IEC standards such as IEC 60086-4 (Safety Standard for lithium batteries) and IEC 60086-5 (Safety Standard for aqueous batteries).

Packaging

The standard does not include requirements associated with safety information for product packaging.

Staff Evaluation

Staff finds the warning content aligns with Reese's Law in that it identifies the ingestion hazard, to keep batteries away from children, and to seek medical attention. The standards does not address the labeling required for consumer product packaging or labeling products regardless of whether the battery is accessible or not. Staff does not find UL 62368-1 adequate to address Reese's Law.

VI. Staff's Assessment of UL 4200A Ballots

On April 28, 2023, UL balloted a proposal to revise UL 4200A in response to CPSC's proposed rule. The marking and labeling sections of the ballot largely align with the NPR. One difference between the ballot and the NPR is the color requirements. As discussed above, after considering the comments, for the final rule staff recommends requiring the use of color when the subject materials will already use color processing, and otherwise that the use of black and white or contrasting colors be acceptable. Another difference identified by UL is to require markings in the native language(s) of the country in which the product is sold given the international nature of the standard and the products covered. The draft final rule requires labels to be in English. The third difference is on the "Warning: Contains coin battery" icon to be used in lieu of "Keep out of reach of children" icon on the packaging of consumer products. As discussed above, after considering the comments, the draft final rule allows for the use of either icon, determined by the manufacturer, on consumer product packages. The UL ballot also proposes specific requirements to evaluate marking permanency. The NPR required that the labels be permanent but did not specify the method to determine permanency. For the final rule, staff recommends that labeling permanency incorporate by references testing in accordance with UL 62368-1 section F.3.9.

The UL balloted marking and labeling sections meet the requirements of Reese's Law in that it requires a warning label to identify an ingestion hazard, instruct consumers to keep new & used batteries away from children, and seek medical attention if a battery is ingested. The ballot also will require a warning label on the consumer product, packaging, and any accompanying literature.

Reese's Law requires, as practicable, the on-product warning label to be visible in a manner that it can be seen by the consumer when installing or replacing a battery. The UL ballot requires labels on the product's principal display however, principal display is not defined. The lack of a clear requirement for the placement of the warning labels in the ballot could result in warning labels being placed in a manner that do not meet Reese's Law. For this reason, staff does not find the April 28 balloted revision adequate to meet Reese's Law.

UL submitted a recirculation ballot on July 7, 2023 in response to comments on the April 28 ballot. The language requirement was revised to be in the official language(s) of the country

where the product is sold or in English if there is no official language(s). The July 7 recirculation Ballot included a choice on use of either the "Warning: Contains coin battery" or the "Keep out of reach of children" icon on the packaging of consumer products, consistent with the draft final rule. And UL added definitions to the July 7 ballot for the principal display panel, secondary display panel, and product display panel, which addressed staff's concerns that on-product warning labels could be placed in a manner not visible to the consumer when installing or replacing a battery. The contents of this recirculation ballot were published on August 30, 2023 as UL 4200A-2023. Therefore, staff concludes UL 4200A-2023 is adequate meet Reese's Law.

VII. Conclusion

ESHF staff reviewed and considered the public comments and UL's ballot to revise UL 4200. For the final rule, staff recommends modifications related to the use of color on battery, consumer product packaging, and instructions or collateral materials, if included. Additionally, staff recommends changes in the language on the warning label, replacing the "Keep Out of Reach" icon with "warning contains battery" on product packaging, including an insertion warning label on zinc-air batteries, the keep out of reach icon directly on batteries, and other safety information on battery packaging, product packaging, instructions if provided, and online. Staff's recommended warnings language for the final rule is included in Tab G.

107



TAB E

108



MEMORANDUM

то:	Daniel Taxier, Project Manager Division of Mechanical and Combustion Engineering Directorate of Engineering Sciences	DATE : August 31, 2023	
THROUGH:	Caroleene Paul, Director Division of Mechanical and Combustion Engineering Directorate of Engineering Sciences		
FROM:	Frederick deGrano, Mechanical Engineer, Division of Mechanical and Combustion Engineering Directorate of Engineering Sciences		
SUBJECT:	Draft Final Rule to Establish a Safety Standard for Button Cell or Co and Consumer Products Containing Such Batteries: Voluntary Stand Assessment and Modifications to the Final Rule	ntaining Such Batteries: Voluntary Standards	

I. Introduction

On February 9, 2023, as required by Reese's Law (15 U.S.C. 2056e), the U.S. Consumer Product Safety Commission published a proposed rule (NPR) to establish performance requirements for battery compartments on consumer products that contain, or are designed to use, one or more button cell or coin batteries to eliminate or adequately reduce the risk of injury from ingestion of button cell or coin batteries by children 6 years old and younger. 88 Fed. Reg. 8,692. As required by Reese's Law, the NPR requirements apply to all consumer products within CPSC's jurisdiction, including remote controls, portable lights, wearable accessories, location trackers, and kitchen products. However, the NPR excluded toys that are within the scope of 16 C.F.R. 1250, which incorporates by reference American Society for Testing and Materials (ASTM) F963-17, *Standard Consumer Safety Specification for Toy Safety*, as well as other products that are not within the Commission's jurisdiction under section 3 of the Consumer Product Safety Act (CPSA), such as medical devices like hearing aids and thermometers.

In this memorandum, staff provides the following information:

- Updated assessment of current voluntary standards
- Recommendations for modifications to the Draft Final Rule

II. Voluntary Standards

In the NPR, the Commission reviewed the following voluntary standards that address hazards associated with button cell and coin battery accessibility:

- UL 4200A-2020, Standard for Safety for Products Incorporating Button or Coin Cell Batteries of Lithium Technologies
- ASTM F963 Standard Consumer Safety Specification for Toy Safety
- Voluntary standards referenced by Australian F2020L01656, including:
 - IEC 62368-1 Audio/video, information and communication technology equipment-Part 1: Safety requirements
 - o IEC 62115 International Standard for Electric Toys Safety
 - AS/NZS 60065:2018 Audio, video and similar electronic apparatus-Safety requirements
 - o AS/NZS 60598.1:2017 Luminaires Part 1: General requirements and tests

One standard, IEC 62368-1, had a new edition (Edition 4, or IEC 62368-1:2023) published in May 2023. Additionally, UL balloted and published a revised version of UL 4200A (UL 4200A-2023), and ASTM balloted a revision to the battery compartment construction requirements in ASTM F963. The following provides the Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering (ESMC) staff's evaluation of the published and balloted revisions to the performance requirements of the respective voluntary standards. Furthermore, several public comments to the NPR address the Commission's preliminary assessment of these standards. Staff recommends updating the previous assessment of voluntary standards based on information received in the public comments.

A. UL 4200A

In the NPR, the Commission detailed their assessment of UL 4200A and found that it was not adequate in addressing all of the ingestion hazards associated with child access to button cell and coin batteries in consumer products. The NPR proposed a rule based on the provisions of several existing voluntary standards, including UL 4200A-2020, IEC 62368-1, and ASTM F963-17 (as codified in 16 C.F.R. part 1250). On April 28, 2023, UL balloted revisions to UL 4200A in response to CPSC's NPR, including revisions to the below requirements. Additionally, on July 7, 2023, UL issued a recirculation ballot with revisions in response to comments on the April 28 ballot. These revisions were later published on August 30, 2023 as UL 4200A-2023. This section provides ESMC staff's evaluation of the proposed revisions to the performance requirements in UL 4200A. Tab D provides Human Factor's evaluation of the proposed revisions to the marking and instructions requirements.

- Scope
- Tension test for seams
- Captive screw exceptions
- Multi-action lock mechanisms
- Drop test
- Compression test (small surface area)
- Torque and tension tests
- Compliance test

- Markings (see Tab D)
- Instructions (see Tab D)

1. Scope

UL's ballot would revise UL 4200A's scope to align with CPSC's proposed rule. The proposed rule provides two exemptions from the scope for toy products that comply with the mandatory *Safety Standard Mandating ASTM F963 for Toys*, 16 C.F.R. 1250, and products containing zincair button cell or coin batteries. Section 4 of Reese's Law specifically exempts the requirements for any toy products, but other children's products that contain button cell or coin batteries as a power source, such as children's apparel that light up, are required to meet the requirements of the proposed rule. Moreover, staff considered the risk for button or coin cell batteries with zincair chemistries to be low because they need air for current to flow, which reduces the likelihood of chemical burns in the esophagus if swallowed. Zinc-air batteries are primarily used in hearing aids which are not under CPSC's jurisdiction; therefore, the proposed rule exempted these batteries from the performance requirements and sought comment.

UL 4200A's scope currently exempts batteries "other than lithium button or coin cells" from the standard. UL's April 28 ballot revises the scope to specifically exempt batteries of zinc-air chemistries rather than generally stating chemistries other than lithium. Additionally, the ballot proposes an additional exemption for "toy products that comply with battery accessibility and labeling requirements of ASTM F963, *Safety Standard for Toys.*"

Staff concludes that the proposed revisions to the scope of UL 4200A would better align UL 4200A with the NPR and with Reese's Law. Moreover, staff is not recommending any changes to the scope of the NPR based on comments received.

2. Tension test for seams

CPSC's proposed rule includes a tension test for products containing button cell or coin battery enclosures that are covered by soft, pliable materials such as textile, gel, or paper. The proposed requirement is based on the Tension Test for Seams in Stuffed Toys and Beanbag-Type Toys performance requirement from ASTM F963-17. The NPR stated that UL 4200A did not adequately address the ingestion hazard for these types of products. In response, UL's ballot would add a tension test similar to ASTM F963-17. Staff considers this addition adequate for Reese's Law because it simulates foreseeable interactions such as when a child grasps a part of a product made with pliable materials with fingers or teeth and pulls, potentially exposing internal button cell or coin batteries.

Based on public comments, for the final rule, staff recommends modifying the magnitude of the applied force in the proposed rule to account for the tolerance specified in ASTM F963-17 (see section III.D below for more detail). Therefore, the revision proposed in UL's April 28 ballot will no longer align with CPSC's proposed rule, should the Commission agree with staff's recommended modification. However, staff concludes that the addition of this test is adequate to address the risk of children obtaining button cell or coin batteries from consumer products made from soft, pliable materials, as the test uses the same force as in the NPR and greater force than staff currently recommend.

3. Captive screw exception

UL 4200A includes an exception from the requirement for fasteners to remain captive to the battery enclosure for large panel doors on large devices which are not likely to be discarded or left off the equipment. The Commission did not include such captive screw exception in the NPR and stated that the products to which such an exception would apply is unclear. The NPR requested comment on the large panel door captive screw exception.

UL's April 28 ballot would clarify the large panel door captive screw exception by defining two different exceptions. The first exception would apply to products where "access to the coin/button cell battery is only through the removal of the equipment's enclosure or side panels which are a required enclosure part and which both are needed to be replaced for normal and safe operation of the equipment (such as desktop computer enclosures)." Furthermore, UL's balloted revision would clarify that a required enclosure part is "needed to comply with the requirements to reduce the risk of fire, electric shock or injury to persons or reduce risk of mechanical damage to internal parts." UL's second balloted exception would apply to "products that are only to be opened by a professional service center (where children are not present)."

UL's first balloted exception applies to any enclosure that reduces the risk of fire, electric shock, or injury to persons, or mechanical damage to internal parts. Staff is concerned about this wording, because all battery enclosures are intended for these purposes, and therefore, the exception could be applicable to all products. Additionally, staff disagrees that the captive screw exception should apply to products with large panel doors containing button cell or coin batteries that are intended to be user replaceable. The intent of the captive screw requirement is to prevent screws securing battery enclosures from being discarded, especially after repeated battery replacement through the product's lifetime by the consumer. Products with large panels may be frequently opened by consumers to replace the button cell or coin battery and therefore, consumers are more likely to discard the screws securing the enclosure thereby rendering the enclosure ineffective from preventing access to children. Staff concludes that UL's balloted language with regard to the captive screw exception is inadequate to address the risk of children obtaining button cell or coin batteries from consumer products with large panel doors and consumer-replaceable batteries.

4. Multi-action lock mechanisms

The NPR discussed products with multi-action locking mechanisms securing the battery compartment that could easily be opened with a single action. To address this inadequacy, the NPR included clarification to the multi-action requirement, stating that the "movements to open cannot be combinable to a single movement with a single finger or digit." UL's April 28 ballot would add this same clarification to UL 4200A.

Staff concludes that the balloted revision would clarify the requirement for multi-action locking mechanisms and would align UL 4200A with CPSC's proposed rule. For the final rule, staff does not recommend any changes to the multi-action locking requirement in the NPR.

5. Drop test

To address the liberation of button cell or coin batteries from consumer products, UL 4200A performance requirements subject portable products to be dropped a total of three cycles and hand-held products a total of 10 cycles. However, a lack of clarity exists in UL 4200A for what defines a "hand-held product" and "portable device." In the NPR, the Commission stated that the 10-cycle drop test for handheld items in UL 4200A is adequate to address and prevent incidents of breaking consumer products or battery compartments. The NPR proposed to require all products within the scope of the rule to be subject to the drop test performance requirements, meaning that every consumer product would require a total of 10 drop cycles.

UL's April 28 ballot would add a definition for "hand-held product" and revise the existing definition for "portable" products, while keeping the requirements for the drop test (section 6.3.2) as it is currently stated. The ballot would define "hand-held product" as "a product that is intended to be used while being held in one or both hands," which is similar to the definition in UL 62368-1. Moreover, the ballot would revise the definition for "portable device" to "a device that is intended to be routinely carried but not operated during transit." Currently, UL 4200A defines these products as "easily carried with mass not exceeding 18 kg (39.7 lb)."

UL's ballot provides a rationale that the proposed definition for hand-held products specifically targets remote controls, because the UL task group generally believes that these products are more likely to be dropped ten times through their lifetime, whereas three drops are appropriate for other portable products. UL's definitions differentiate between handheld and portable products primarily by their intended utility and removes the criterion of weight; thus, UL defines hand-held products as those used while held in hand while portable products are those used while sitting on a surface. Per these definitions, products such as remote controls, tracking devices, and flashlights, among others, would be subjected to ten total drops, and products such as laptop computers, desktop computers, audio/visual equipment, and bathroom scales, among others, would be subject to three drops.

Staff assesses that UL's proposed definitions are too vague and subject to different interpretations by test laboratories. Because the proposed definitions are based primarily on the product's utility (i.e., whether or not they intended to be used while in hand), staff concludes that some devices can be interpreted differently based on how an individual commonly uses those products. For example, the core feature of laptop computers is for them to be portable and carried around, but laptops are typically used while sitting on a surface. However, it is reasonably foreseeable that some users may use laptops while holding them in hand. Some consumers could, for example, use a laptop while standing on a train during a commute to work, or while walking around a consumer's household.

Based on laptop construction, staff considers the risk of a button cell or coin battery in a laptop from becoming accessible relatively low compared to other hand-held products, because the battery is non-replaceable and mounted on the computer's motherboard which is often surrounded by many other internal components. Therefore, a laptop would likely need to be completely disassembled during the abuse testing for the battery to become accessible. However, staff recommends that the number of drops during testing should be based on the likely frequency in which a product would reasonably and foreseeably be dropped through the course of its life, rather than the risk of a battery becoming accessible based on the product's construction. The abuse tests intend to simulate real world scenarios of products regardless of their risk. Because a laptop computer is often carried by hand, it may be subjected to more frequent drops as opposed to a desktop computer, which mostly sits on a surface and may rarely be carried or dropped. Therefore, staff concludes that UL's balloted definitions would inaccurately assign laptops as portable products subject to three drops, rather than as handheld products subject to ten drops.

Another example product would be flameless candles, otherwise known as "tea lights." Based on UL's balloted definitions, tea lights would be classified as portable products subject to only three drops, because they are typically not operated while held in hand and often sit on a surface during use. However, staff assesses that tea lights are small enough to be carried frequently or played with by a small child, therefore this type of product may experience a higher frequency of drops throughout its useful lifetime.

Staff recommends that definitions for "handheld" and "portable" be specific and measurable. For example, handheld and portable products could be defined using the weight of products. Definitions based solely on the manufacturer's intended use does not account for the consumers reasonable and foreseeable use and misuse of consumer products. Section III.A. below discusses in more detail staff's recommended changes to the drop test performance requirements.

6. Compression test (small surface area)

In the NPR, the Commission preliminarily determined that UL 4200A was inadequate because it did not include a compression test for battery compartments that were recessed due the product's shape and therefore are not accessible to flat surface contact during the drop, impact, or crush abuse tests. CPSC's proposed rule included a compression test for little surface areas based on the compression test from ASTM F963-17 to address these types of battery enclosures.

UL's April 28 ballot would add to UL 4200A the same compression test as in the NPR, referencing ASTM F963-17. UL's ballot would also add that an equivalent test can substitute the compression test from ASTM F963-17.

Based on public comments, for the final rule, staff recommends modifying the magnitude of the applied force in the small surface area compression test to account for the tolerance specified in ASTM F963-17 (see section III.D below for more detail). Therefore, UL's balloted revision would not align with the draft final rule, though it would be a greater force. Furthermore, if adopted as a regulation, allowing for an "equivalent test" would be difficult to enforce and would have limited applicability because manufacturers would need to prove equivalency to be proven to be accepted.

7. Torque and tension tests

In the NPR, the Commission stated that UL 4200A did not address torque and tension forces on battery compartment enclosures. These forces would simulate a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth. CPSC's proposed rule includes torque and tension tests based on ASTM F963-17 to account for these

common child use and misuse interactions with products. UL's ballot would add to UL 4200A the same torque and tension tests referencing ASTM F963-17.

Based on public comments, for the final rule, staff recommends modifying the magnitude of the applied force for the torque and tension tests to account for the tolerance specified in ASTM F963-17 (see section III.D below for more detail). Therefore, UL's April 28 balloted revision does not align with staff's recommended draft final rule. However, aside from the changes to the magnitude of the applied force, staff concludes that the addition of this test is adequate to simulate a child grabbing and twisting or pulling on parts of the battery enclosure or tearing apart soft goods with fingers or teeth.

8. Compliance test

UL 4200A contains an Accessibility Probe Compliance Test that specifies applying a force of 45 N using the accessibility probe. Similarly, IEC 62115 contains a compliance test but specifies a force of 50 N, which the Commission found to be adequate to address the hazard in the NPR. UL's ballot would increase the required force in UL 4200A from 45 N to 50 N and also revise the requirement for minor clarifications.

Staff concludes that UL's April 28 ballot to increase the required force for the compliance test aligns with CPSC's proposed rule and is adequate for addressing the hazard. Staff does not recommend any changes to compliance tests based on comments received on the NPR.

9. Recirculation ballot

TC 4200 met on June 22, 2023 to discuss all of the comments on the April 28 ballot and revised the ballot language. This recirculation ballot was published on July 7, 2023. Revisions included the captive screw exceptions, the definitions for "hand-held product" and "portable device" used to determine the number of drops in the drop test, and the compression test.

Captive Screw Exceptions

Both exceptions to the requirement for captive screws were revised to apply only to products containing button cell or coin batteries not intended to be replaced by the consumer and require instructions and warnings that clearly state the battery is not to be replaced by the consumer. Additionally, the first exception was revised to apply to products containing button cell or coin batteries "that can only be accessed through the removal of multiple enclosures or panels using a tool." The second exception for "products only to be opened by a professional service center (where children are not present)" remains unchanged except as noted above.

Products designed and labeled not to have the battery replaced by the consumer provide the consumer with less incentive or need to access the battery. Additionally, multiple enclosures or panels will provide an extra layer of protection that prevents immediate access to button cell or coin batteries, even if screws to those panels are lost or discarded. Some products that might fit into the first exception include desktop and laptop computers; these products have button cell or coin batteries in their motherboards that often require multiple panels and components to be removed before the battery can be accessed, and the battery frequently lasts longer than the product itself, so has no need to be replaced. There are no known incidents involving access to button cell or coin batteries through multiple enclosures. Products only to be opened by a

professional service center will lack features that allow consumers to access the battery with a common household tool such as a straight-blade or Phillips screwdriver, pliers, or a coin. Some secure watches which require a special tool will fall into this category, and would not require captive screws; however, watches secured only with straight blade or Phillips screws would not fall into this category, and thus would be required to have captive screws. This interpretation of the exception is not explicit in the UL standard, and a manufacturer or test lab could alternatively interpret that a consumer product with a battery compartment that is easily openable by a consumer with a simple household tool only needs a label stating that the battery is to be replaced at a professional service center for the product not to have captive screws. If a consumer ignores the label, which is foreseeable, such screws could be easily discarded or lost and cause the battery compartment to be easily accessible by a child. However, staff assesses that with appropriate guidance in place, this interpretation of the exception would be unlikely to occur. Staff therefore conclude these exceptions would be adequate to meet Reese's Law if published with appropriate guidance from the Commission.

Drop Test

The definition for "hand-held product" was revised to mean products that are "reasonably foreseeable to be used or misused when being held in one or both hands. Products specifically designed to be carried easily, with a mass not exceeding 4.5 kg (10 lbs)." This revision aligns closely with staff's own recommended definition for hand-held products (discussed in Section III.A of this memorandum, below).

The definition for "portable device" was revised to mean a "device that is reasonably foreseeable to be routinely carried or lifted as part of its use or misuse but not operated during transit with a mass not exceeding 18 kg (39.7 lb)." This is a narrower definition than that recommended by staff (discussed in Section III.A of this memorandum, below), as the phrase "routinely carried" could exclude some products, such as heavy desktop computers or some televisions, from a required drop test. The phrase "routinely carried" is subjective and could result in different manufacturers or test labs subjecting different tests to otherwise similar products. However, staff are not aware of any incidents involving access to batteries from these definitions are adequate to meet Reese's Law.

Compression Test

The recirculation ballot removed the language that would allow an "equivalent test" to substitute the compression test from ASTM F963-17 but kept the greater force requirement. Therefore, the revision does not align with staff's recommended draft final rule only in that it uses the greater force from the NPR (*i.e.*, is more stringent than the draft final rule). Staff concludes that the addition of this test is adequate for Reese's Law.

10. Summary and Publication

TC 4200 met on August 11, 2023 to discuss comments on the July 7 recirculation ballot. The TC decided not to ballot further changes. As a result, all but one of the proposed changes in the April 28 ballot with the changes in the July 7 recirculation ballot were published in ANSI/UL 4200-2023 on August 15, 2023. Due to ANSI/UL balloting protocol, the proposal to add the small surface area compression test, based on the test in ASTM F963, was recirculated for additional comments and was published on August 30, 2023. Staff assesses that the August 30, 2023 version of UL 4200A-2023 is adequate to meet Reese's Law.

B. ASTM F963

ASTM released a ballot item on January 12, 2023, F15(23-02) item 3, which would strengthen requirements for toys containing batteries:

- Toys containing batteries that fit within the small parts cylinder (including button cell and coin batteries) intended for children 8 years and older would be subject to drop testing. Previously, only toys for children less than 8 years old were subject to drop testing.
- 2. For toys that use a fastener to secure the battery compartment, the fastener must remain attached to the toy or battery compartment cover. This effectively adds a captive screw requirement.

Staff expects this ballot item to be published in the next version of ASTM F963. Staff commented on the ballot with concerns that the revision, which would allow specialty fasteners to be used (such as hex or torx), could contribute to hazards which may not have been mitigated. Staff assesses that caregivers may lose the tool and can no longer access the compartment which may lead to battery leakage if not removed after a long period of time. Staff is also concerned that such tools may not be included with the toy for secondhand use. Lastly, staff is concerned that if a specialty tool is included with the toy, children may gain access to the tool and thereby may access the button cell or coin battery. However, staff is working with ASTM to address staff's concerns and believe that the ballot item is overall an improvement to safety.

Staff revises the assessment of the performance requirements in ASTM F963 assuming that this ballot item is published. Staff concludes the captive screw requirement is adequate and aligns with the requirements of the NPR. Furthermore, the drop test relies on user age to determine the drop height, the maximum weight of products to be tested, and the maximum number of drops. These restrictions are not appropriate for non-toy products, which are likely to be interacted with by a variety of age groups. Therefore, staff concludes the drop test requirements are inadequate for the purpose of Reese's Law, and staff recommends no change to the proposed rule based on this comment.

C. UL 62368-1

1. Compression test (small surface area)

For the NPR, the Commission reviewed a compression test for little surface areas from the voluntary standard ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety*. The test in ASTM F963 applies compression to any area of the surface of a toy that is

accessible to a child, and inaccessible to a flat surface contact during the impact test. For products within scope of the NPR, the Commission found this test effective for testing the robustness of battery compartment enclosures that are inaccessible to flat surface contact during the proposed drop or crush abuse testing. The Commission determined that this small surface compression test was effective especially for products where the battery compartment is recessed due to the shape of the product. The Commission concluded that this test is adequate to simulate foreseeable interactions such as a child pressing on a small area of the product that may house a button cell or coin battery. The Commission also concluded that UL 4200A and IEC 62368-1 do not contain performance requirements to address this risk. However, CTA provided comment stating that section 4.4.3 of UL 62368-1, which is the equivalent voluntary standard to IEC 62368-1 for the United States, contains general robustness requirements that subject an enclosure or barrier to a steady force test.

UL 62368-1's steady force test applies a compressive force on a surface of a product based on the type of safeguard an enclosure is intended to provide. For most products within the scope of this rulemaking, the test subjects a steady force of 100 N \pm 10 N (22.5lbf \pm 2.2 lbf) over a circular plane surface 30 mm (1.2 inches) in diameter for 5 seconds.¹ The test repeats to the top, bottom, and sides of the product. UL 62368-1 specifies compliance criteria for the general robustness tests, only requiring that "safeguards shall remain effective." Staff assesses that the compression test in UL 62368-1 would be applied more frequently than the test in ASTM F963, because the UL test is not restricted to surfaces not contacted during the drop test. However, the average pressure (defined as force over area) of 2.05 N/mm² applied during the ASTM F963 compression test is 47% greater than the average pressure of 1.40 N/mm² applied during the UL 62368-1 steady force test. Staff assesses that the ASTM F963 compression test, based on 16 C.F.R. part 1500.50, adequately prevents hazardous small parts from being created and ingested, and that the pressure applied during the UL 62368-1 steady force test is substantially lower and may not reach the levels necessary to prevent hazardous small parts. Therefore, staff assesses the UL 62368-1 steady force test is inadequate to address the ingestion hazard, and staff recommends no change to the proposed rule based on this comment.

2. Impact test

In the NPR, the Commission stated that the required impact energy for the impact test in IEC 62368-1 was dependent on the type of product: 0.5 J impact for 3D glasses and 2 J for all other products. Public comments point out that the equivalent US voluntary standard, UL 62368-1, deviates from the international IEC version by deleting the 0.5 J requirement for 3D glasses, and therefore requires 2 J of impact energy for all products. This effectively makes the impact test performance requirement in UL 62368-1 the same as UL 4200A and CPSC's proposed rule. Although this corrects information stated in the NPR, staff recommends no change to the proposed rule based on this comment.

¹ Some product enclosures are subject to a steady force of 250 N \pm 10 N; however, the lower force of 100 N \pm 10 N is applied to transportable equipment, hand-held equipment, and direct plug-in equipment, which are more likely to contain button cell or coin batteries and be interacted with by children.

D. IEC 62368-1:2023

Staff's review of IEC 62368-1:2023 identified differences in the general requirements and construction performance requirements for equipment containing button cell or coin batteries. All other aspects remain substantively similar to the previous version of the standard, and staff's assessment of those aspects remains the same.²

1. General Requirements

The previous version of IEC 62368-1 included exceptions to some of the specific performance requirements for products using button cell or coin batteries.³ The exceptions included professional equipment, equipment for use in locations where it is unlikely that children will be present, and equipment containing button cell or coin batteries that are soldered in place. In IEC 62368-1:2023, these exceptions remain the same, and an additional exception is added:

• Equipment for which it is unlikely that the coin or button cell battery will be removed by children due to location of the battery within the equipment; in such cases, the instructional safeguard still applies.

This exception may exclude certain products from the construction performance requirements and the specific test sequence for products containing button cell or coin batteries, like laptops or desktop computers which have the coin battery buried under internal components or panels. However, a manufacturer might argue that a series of panels that are openable by hand with a single action or a non-replaceable button battery in an easily broken plastic compartment meets the criterion for the exception. Other use and abuse tests in the standard are not likely to be as rigorous or address other hazards than those specifically for products containing button cell or coin batteries. The exception is subjective and difficult to enforce. Staff considers this exception inadequate to meet Reese's Law.

2. Battery Compartment Securement Performance Requirements

IEC 62368-1:2023 includes construction performance options that either require the use of a tool or a series of hand movements, like the previous version of the standard. The options are more specific than the previous version, and a total of five options are available:

- If a tool is required to open or remove the battery compartment, door or cover, any of the following options may be used:
 - If one or more screws or similar fasteners is used to secure the compartment, door or cover, a minimum of two full rotations of the screw or fastener are required to open or remove the coin or button cell battery compartment, door or cover. The screw or fastener shall be captive to the coin or button cell battery compartment, door, cover, or to the equipment; or

² Staff's original assessment of IEC 62368-1 can be found in the NPR staff briefing package; staff's assessment of the compression test, warning labels and instructions for UL 62368-1 in this briefing package also apply to IEC 62368-1.

³ The exceptions do not mean that these products are not tested, as other performance and labeling requirements in the standard still apply, including similar tests. However, construction performance requirements and (in some cases) instructional safeguards would not apply.

- for a cover which is required to be rotated to be opened, a minimum torque of 0.5 Nm shall be required to unlock the cover and start its rotation. A minimum rotation of 90° shall be required to remove the cover; or
- $_{\odot}$ for a cover which is secured by one or more latches, a minimum torque of 0.5 Nm is required to release the latches.
- If no tool is required to remove the button cell or coin battery compartment door or cover, either of the following options for opening by hand shall apply:
 - The application of a minimum of two different and interdependent movements; or
 - The application of simultaneous movements to engage two mechanisms requiring the use of multiple fingers.

The options requiring the use of a tool are similar to those proposed in the NPR,⁴ with a specific performance requirement added that latches require a minimum torque of 0.5 Nm. The NPR proposes a performance requirement for battery compartments to open with a torque greater than 0.5 Nm, and the latch performance requirement is consistent with this requirement. Staff considers the construction performance requirements adequate to meet Reese's Law.

The first option not requiring a tool is the application of a minimum of two different and interdependent movements, or at least two different movements that are dependent on each other. Because the different and interdependent movements are not clearly required to be simultaneous (or, because the movements can apparently occur sequentially), a scenario can occur in which a user may perform the first movement, and then a child may later perform the second movement, and easily access the battery compartment. This requirement is not adequate to meet Reese's Law.

The second option not requiring a tool is the application of simultaneous movements to engage two mechanisms requiring the use of multiple fingers. This option requires two simultaneous and independent movements with multiple fingers, thus would meet the requirement proposed in the NPR. This option therefore is adequate to meet Reese's Law.

Staff assesses that four of the options for construction performance are adequate to meet Reese's law, while one is not adequate. Staff also assesses that the exception added to the general requirements for products using button cell or coin batteries is overly subjective and does not meet Reese's Law. The rest of IEC 62368-1:2023 is substantively similar to the previous version, which staff assessed as not adequate to meet Reese's Law. Staff concludes IEC 62368-1:2023 is not adequate to meet Reese's Law.

E. Comparison of voluntary standards

Table 1 compares how the above standards address the battery ingestion hazard with requirements that are intended to minimize the risk of children removing batteries from the consumer product. This table updates the table from the NPR to reflect changes in UL 4200A-

⁴ "Secure the battery compartment enclosure so that it requires a minimum of two independent and simultaneous hand movements to open. The movements to open cannot be combinable to a single movement with a single finger or digit."

2023 and the steady force test (herein referred to as small surface compression test for comparison) from IEC 62368-1 and UL 62368-1.

Standard	Scope	Action to Open Battery	Abuse Testing
		Compartment	
UL 4200A- 2023	Household type products that incorporate or may use button cell or coin batteries	 (1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand. The movements to open cannot be combinable to a single action. 	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test –74 lbf. over 38 square inches for 10s in positions likely to produce the most adverse results (4) Small surface compression test –30.6 lbf over 1 square inch for 10 seconds (5) Torque test – 4.4 in-lbs. of torque over 10 seconds (6) Tension test – 16.2 lbs. of tension over 10 seconds
ASTM F963	Toys intended for use by children under 14 years of age	Coin, screwdriver, or other common household tool required to open battery compartment	 (1) Drop test – maximum 10 times at 4.5 ft in random orientation; minimum of 4 times at 3 ft in random orientation (2) Torque test – 2-4 in-lbs. of torque over 10 seconds (3) Tension test – 10-15 lbs. of tension over 10 seconds (4) Tension test for pliable materials – 10-15 lbs. of tension over 10 seconds (5) Small surface compression test – 20-30 lbf over 1 square inch for 10 seconds
IEC 62368-1 ed. 3 (US equiv. UL 62368-1)	Electrical and electronic equipment within the field of audio, video, information and communication technology, and business and office machines with a rated voltage not exceeding 600 V	 (1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR (2) The battery compartment door or cover requires the application of a minimum of two independent and simultaneous movements to open by hand 	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests: (1) Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure (2) Impact test – 3 impacts by steel sphere imparting 2-J of energy (3) Crush test – apply 74 lbf. for 10s in positions likely to produce the most adverse results (4) Small surface compression test – 100 N ± 10 N (22.5lbf) over 30 mm diameter area for 5 seconds
IEC 62368- 1:2023	Electrical and electronic equipment within the field of audio, video, information and	(1) A tool, such as a screwdriver or coin, is required to open the battery compartment, screw fasteners must be captive; OR	Preconditioning: (1) 7 hours of pre-conditioning in oven at 70°C (158°F) (2) Open/close and remove/install battery 10 times Abuse Tests:

Table 1. Summary of Voluntary Standards

Standard	Scope	Action to Open Battery Compartment	Abuse Testing
	communication technology, and business and office machines with a rated voltage not exceeding 600 V	(2) The battery compartment door or cover requires the application of a minimum of two different and interdependent movements to open by hand, or the application of simultaneous movements to engage two mechanisms requiring the use of multiple fingers	 Drop test – maximum 10 times at 3.3 ft in positions likely to produce the maximum force on the battery compartment or enclosure Impact test – 3 impacts by steel sphere imparting 2-J of energy Crush test – apply 74 lbf. for 10s in positions likely to produce the most adverse results Small surface compression test – 100 N ± 10 N (22.5lbf) over 30 mm diameter area for 5 seconds
IEC 62115	Electric toys being any product designed or intended for use in play by children under 14 years of age	Batteries that fit wholly within the small parts cylinder shall not be removable without the aid of a tool, screw fasteners must be captive.	(1) Screw test – Remove/replace screws 10 times with torque applied (2) Drop test – maximum 10 times at 93 cm \pm 5 cm (36.6 in.) in random orientation; minimum 4 times at 93 cm \pm 5 cm (36.6 in.) in random orientation (3) Impact test – 3 impacts by hammer imparting 0.5-J of energy (4) Tension test – 70 N \pm 2 N (15.7 lbs.) of tension over 10 seconds (5) Tension test – 70 N \pm 2 N (15.7 lbs.) tension force on a textile seam over 10 seconds

Both UL 62368-1 and ASTM F963 specify a compression test for small surface areas. Both tests intend to ensure robustness of construction for localized areas, but while the test in ASTM F963 addresses areas which are inaccessible to flat surface contact that would otherwise be impacted during the drop test, the test in UL 62368-1 addresses the strength of the enclosure regardless of flat surface contact. Both compression tests apply a similar magnitude of compressive force, with ASTM F963 applying 20 to 30 lbf. depending on the age range intended for the product, and UL 62368-1 applying approximately 22.5 lbf. for all in-scope products. ASTM F963 specifies a loading device as a rigid metal disk measuring 1.125 inches in diameter and 0.375-inch thickness. ASTM F963 further describes the loading device as having a perimeter rounded to a radius of 1/32 in. (0.8 mm), to eliminate an irregular edge, and attached to a compression scale having an accuracy of ±0.5 lbf. (2 N). UL 62368-1 is less descriptive with the loading device by only specifying it as a circular plane surface 1.181 inches (30 mm) in diameter with no thickness defined. ASTM F963's test procedure specifies that the compressive force shall be applied evenly within 5 seconds and maintained for an additional 10 seconds. The procedure defines the force application by stating that the disk shall be positioned so that the flat contact surface is parallel to the surface under test. UL 62368-1's test procedure only specifies that the compressive force is applied with a duration of 5 seconds, but does not describe how the force should be applied to the sample area.

F. Recommendation for Performance Requirement

The Commission's proposed rule includes a small surface area compression test that references the test from ASTM F963-17 while specifying a force magnitude of at least 30.6 lbf. Upon staff's review of a comparable small surface area compression test from UL 62368-1, staff recommends maintaining the original performance requirement proposed in the NPR. The original performance requirement applies a greater force of 30.6 lbf. compared to UL 62368-1's maximum nominal force of 22.5 lbf. Considering the force magnitude of each test and their

respective loading devices, the ASTM F963-17 test applies approximately 2.05 N/mm² of pressure on the battery compartment versus UL 62368-1's test applying 1.40 N/mm² of pressure; therefore, ASTM F963-17's test applies 47% more pressure. ASTM F963 also maintains the force for a longer duration of 10 seconds versus UL 62368-1 which only applies the force for 5 seconds. Also, ASTM F963 provides a more descriptive test procedure than UL 62368-1 by specifying the size, shape, and material of the loading device, a required accuracy for the force gauge attached to the loading device, and an orientation of the loading device relative to the test sample's surface area. Because UL 62368-1 only defines the loading device as a circular plane with a 30 mm diameter, with no additional detail, staff concludes that there is too much uncertainty performing this test, which could lead different test laboratories to test products in a different manner and lead to varying results for the same or similar products. Because the test method is more defined and repeatable, staff recommends that maintaining the small surface compression test set forth in ASTM F963 for the final rule will lead to safer products that reduce the risk of children accessing button cell or coin batteries.

III. Staff-Recommended Modifications to the Draft Final Rule

ESMC staff assessed comments related to the performance requirements for products containing button cell or coin batteries, and Tab A of this briefing package includes staff's responses. Based on public comments on the NPR, staff recommends changes to the definitions and requirements for the draft final rule. The changes will:

- Apply different drop test requirements based on the type of product;
- Exclude captive screw requirements for products containing button cell or coin batteries not intended to be replaced by the consumer;
- Update the referenced table for minimum required torques for fasteners securing battery compartment enclosures;
- Modify the performance requirements for compartment enclosures to include testing;
- Add requirement for abuse testing for non-removable button cell or coin batteries; and
- Correct specified values in the proposed rule to incorporate lower bound tolerances.

A. Apply different drop test requirements based on the type of product

The proposed rule requires products to be subject to drop tests based on requirements from UL 4200A. Staff considered comparable drop tests from UL 4200A, ASTM F963, IEC 62368-1, and IEC 62115. Ultimately, staff decided to base the proposed rule's drop test on UL 4200A. However, this standard required a different number of drops depending on whether the product is classified as portable or hand-held with three or ten drops respectively. Staff observed that the term "hand-held" is undefined in UL 4200A and therefore can be subjective, which may lead to a product being subjected to a different number of drops by different testers. To avoid this confusion, staff recommended subjecting all products in scope to the greater number of ten drops, as a more severe test is better able to address allowing access to button cell or coin batteries and is therefore more adequate to address the risk of injury.

Two commenters (Consumer Technology Association and Information Technology Industry Council (ITI)) recommend that a drop test with three repetitions is adequate for some products. While the commenters state that they agree that ten total drops as specified in the NPR is appropriate for hand-held products such as remote controls, they recommend that three drops is adequate for other portable products such as equipment that is transportable but not intended to be held in hand while in use. ITI provides for example a desktop computer which uses a coin battery, can be carried and transported, but is intended to be used while sitting on a surface. They opine that this product is not reasonably foreseeable to be dropped ten times over the course of its life.

Staff agrees that requiring ten drops for some portable products is not reasonably necessary to reduce the risk to children. Staff acknowledges that not all products are reasonably foreseeable to be dropped up to ten times over the course of their life. Staff recommends differentiating the total number of repetitions for the drop test, § 1263.3(e)(2)(i), based on whether the product is considered hand-held or portable. Because UL 4200A does not specify any definition for "hand-held" and only defines "portable" as "Products specifically designed to be carried easily, with mass not exceeding 18 kg (39.7 lb)," for the final rule, staff recommends adding definitions for "portable" and "hand-held" products and requiring three or ten drop repetitions, respectively, based on the product type.

Staff recommends that the number of times a product must be dropped should be based on the likely frequency a product may be dropped over the course of its lifetime. Staff considers the product's weight as the primary determining factor for drop frequency. Products that are lighter are more often carried by hand or often operated while in hand; therefore, there are more opportunities for these products to be inadvertently dropped. This is especially true for lightweight products that young children may be able to lift and carry and possibly play with. On the other hand, heavier objects tend to be carried less frequently and are often operated while sitting on a surface such as a tabletop. Additionally, young children are less able to lift or play with these heavier products. Therefore, these products are less likely to be dropped over the course of their lifetime but are still possible to be dropped if moved to another location, and therefore, the potential for liberating a button cell or coin battery must be tested.

ASTM F963-17 specifies a drop test for toys based on weight and intended age range in section 8.7.1. The ASTM standard requires toys less than 10 lb. \pm 0.01 lb. (4.5 kg) intended for children younger than 96 months (8 years) old to be subject to the drop test. Based on this weight criteria, because children are more likely to carry, use, and potentially drop such objects, staff recommends defining a "hand-held" product as any product that is reasonably foreseeable to be held by hand during use that has a mass less than 4.54 kg (10 lb.). Handheld products must be drop tested ten times. Based on the definition from UL 4200A, staff recommends defining a "portable" product as a consumer product or component part that is routinely, easily, or foreseeably carried and having a mass less than 18 kg (40 lb.). Per these definitions, products such as remote controls, tracking devices, flashlights, flameless candles, and most laptops, among others, will be subjected to ten total drops. Such products are commonly carried by hand by both adults and children, and therefore are more likely to be dropped frequently over the course of their lifetime. Moreover, products such as desktop computers and audio/visual equipment, among others, would be considered portable products because they can be lifted and transported but are most commonly sitting on a surface when in use, and therefore are likely to be dropped less frequently over the course of their lifetime. Staff concludes that

products weighing greater than 40 lb. are not considered to be routinely, easily, or foreseeably carried and are less likely to experience drop through the course of their lifetime; therefore, staff recommends that it is not reasonably necessary for these products to be subject to the drop test. This performance requirement would adequately reduce the risk of injury from dropped consumer products liberating button cell or coin batteries to children that are 6 years of age or younger.

B. Add exceptions for captive screw requirements for products containing button cell or coin batteries not intended to be replaced by the consumer

The proposed rule requires products containing non-removable button cell or coin batteries to comply with requirements pertaining to accessibility of batteries. The rule states that batteries shall be made inaccessible by either: (1) using an enclosure that requires a tool to open via fasteners held captive to the enclosure or twist-on access cover or using an enclosure that requires two independent and simultaneous hand movements to open (§ 1263.3(b)); or (2) securing the button cell or coin battery, if accessible, using soldering, fasteners such as rivets, or equivalent means, that passes the Secureness Test. The proposed rule effectively requires products containing non-removable button cell or coin batteries that are inaccessible to comply with the same performance requirements as products containing batteries that are intended to be replaced by the consumer.

Three watch associations (CPHE, FH, and American Watch Association) submitted comments opining that watches present a significantly lower risk than other products containing button cell or coin batteries. They recommend imposing different requirements for accessing the battery for products designed to be opened by consumers versus those only opened by professionals. Commenters state that some watches are intended to be opened by professionals only because those watches cannot be opened without the use of special tool that is typically not commercially available; therefore, the risk that screws or the battery cover could be lost or discarded by consumers does not exist. The commenters opine that the proposed requirements for battery accessibility are not feasible for watches because of the limited space within the product to implement more complex designs.

Staff agrees with the commenters that products containing button cell or coin batteries that cannot be replaced by consumers and only by professionals should have different requirements for battery accessibility. The performance requirements of § 1263.3(b) intend to prevent children less than 6 years of age from removing the battery enclosure and gaining access to the battery by specifying requirements for the design battery compartment enclosures and how they are secured. Specifically for captive screws, this requirement intends to prevent screws that secure battery enclosures from being discarded or lost, thus rendering the battery enclosure ineffective. Because the risk of discarding or losing an enclosure screw is low for products that can only be opened by professionals, staff concludes that it is not reasonably necessary to impose this requirement for such products to reduce the risk of injury to young children. Furthermore, for twist-on access covers, removal of the enclosure should not be possible without the aid of a specialized tool by a professional, and therefore, staff recommends that it is not reasonably necessary to impose this requirement for such products. However, staff assesses that products intended to only be opened by professionals can open and expose a button cell or coin battery through reasonable, foreseeable use and abuse, and therefore staff considers the use and abuse testing requirements of § 1263.3(e) reasonably necessary to reduce the risk of children

under 6 years old from accessing the battery. Additionally, products with battery compartments that are openable using common household tools, such as a Phillips or straight blade screwdriver, pliers, or coins, are reasonably foreseeable to be opened by consumers, regardless of whether this behavior is intended by the manufacturer. For the final rule, staff recommends excepting products from the requirements in § 1263.3(b) if they cannot be opened using common household tools such as a screwdriver (Philips or straight blade), pliers, or coins, and which have warnings stating that the battery is not to be replaced by the consumer, but maintaining use and abuse testing for these products, to ensure that the battery does not become liberated.

Additionally, three commenters (UL Solutions, CTA, and ITI) state that the large panel door exception in UL 4200A exists for products where the panel door forms part of system enclosure that is not intended to be opened regularly by the consumer. An example product is a desktop computer., Desktop computers use large panel doors to house the hard drive that commonly contain coin batteries on the motherboards to provide backup power. The commenters state that the panel doors on these devices are unlikely to be left off or screws discarded. ITI opines that typically large panels form part of the system enclosure which is not intended to be opened regularly. They note that UL 62368-1 states that captive screws are for batteries that need to be replaced regularly. CTA demonstrates for a sample desktop computer that several internal components need to be removed to reach the battery on one such product. Furthermore, CTA that the exception described in UL 62368-1 is more specific than the exception in UL 4200A, because UL 62368-1 specifies that the captive screw exception only applies to "larger devices which are necessary for the functioning of the equipment and which are not likely to be discarded or left off the equipment."

Staff agrees with the commenters that products containing button cell or coin batteries with large panel doors should also be exempt from the captive screw requirement so long as the batteries are not intended to be replaced by the consumer. The intent of the captive screw requirement is to prevent screws securing battery enclosures from being discarded by the consumer, especially after repeated battery replacement through the product's lifetime. However, if a product's battery is not meant to be replaced, and is difficult to access, staff assesses that these large panel doors are not expected to be opened frequently; therefore, it is not reasonably necessary to require the screws to be held captive.

For the final rule, staff recommends modifying § 1263.3(c) to only require products with batteries that are not intended to be removed or replaced by consumers to be excluded from § 1263.3(b) requirements, and only comply with the performance requirements of § 1263.3(e), including use and abuse testing, to ensure the batteries do not liberate from the product. Furthermore, staff recommends adding to § 1263.3(c)(1) that the battery compartment enclosure must require a tool to open that is not a common household tool, as described above. These changes will ensure that battery compartments of products containing non-replaceable button cell or coin batteries are secured in a manner that would eliminate or adequately reduce the risk of injury without unnecessarily restricting the design of these products.

C. Update the referenced table for minimum required torques for fasteners securing battery compartment enclosures

The proposed rule specifies a pre-conditioning requirement in § 1263.3(e)(1)(ii) to repeatedly open and close a battery compartment and remove and replace the battery a total of ten cycles. This requirement intends to simulate the wear and tear of a battery compartment after repeated battery replacements over the course of a product's lifetime. This ensures that when a sample product is subjected to the subsequent use and abuse tests that the sample is representative of a realistic used condition where connection points of enclosures or mechanisms holding batteries in place are in a reasonably weakened state. For enclosures that use fasteners to secure in place, the proposed rule requires the fasteners to be torqued according to Table 20, referenced from UL 60065, *Standard for Audio, Video and Similar Electronic Apparatus – Safety Requirements*.

A commenter states that the referenced Table 20 is outdated and is superseded by Table 37 of the *Standard for Safety: Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements*, UL 62368-1. Staff agrees that Table 20 of UL 60065 is superseded by Table 37 of UL 62368-1 and recommends updating the reference table in the final rule. Table 20 specifies torque values based on the screw's diameter and type whereas Table 37 only specifies a torque value based on the screw's diameter regardless of the screw type. Because Table 37 adopts the greatest torque values for screw type II from Table 20 and applies them to all screw fasteners, updating the reference to Table 37 in the final rule will increase the safety and reliability of screw fasteners securing battery compartments.

D. Modify the performance requirements for compartment enclosures to include testing

The proposed rule requires replaceable button cell or coin batteries to be contained within a battery compartment that is secured by an enclosure that meets the performance requirements of § 1263.3(b). These requirements intend to prevent children from manipulating the mechanisms securing the battery compartment enclosure and gaining access to batteries. The proposed rule requires enclosures to either be secured by a mechanism that requires "a tool, such as a screwdriver or coin, to open" or a mechanism that requires "a minimum of two independent and simultaneous hand movements to open."

The American Watch Association comments that according to Section 2 of Reese's Law, the final consumer product safety standard "shall only contain a performance standard." The commenter alleges that § 1263.3(b)(2)(i) and (ii) of the proposed rule constitute design or construction requirements and are not performance-based requirements because they require specific designs to secure battery compartment enclosures. The commenter argues that the requirements for screws to be held captive to the enclosure, for minimum torque and angle of rotation for enclosures requiring a tool to open, and for multi-action locking mechanisms are design requirements and do not involve any testing; therefore, the commenter states that CPSC lacks the authority to impose these requirements.

Staff disagrees with the commenter that the referenced requirements are design requirements. § 1263.3(b)(2)(i) requires enclosures to be secured so that it requires a tool to open and gain access to the battery. The requirement provides examples of tools such as a screwdriver or coin but does not limit the design of the locking mechanism to any specific tool. Therefore, manufacturers have the freedom to design their locking mechanisms to utilize any tool that may be used to manipulate the enclosure such as pliers, paper clips, or hair clips among others. The requirement further requires that the fasteners or twist-on covers have a minimum torque and minimum angle of rotation in order to open the enclosure, thus setting a minimum required performance of the enclosure to ensure children under the age of 6 years old cannot access the battery under foreseeable use. Furthermore, § 1263.3(b)(2)(ii) requires enclosures to be secured so that it requires a minimum of two independent and simultaneous hand movements to open, otherwise referred to as multi-action. The requirement does not require any specific design which satisfies the requirement, allowing for manufacturers to innovate designs that will safely prevent access to children younger than 6 years old. Rather, the requirement only establishes the minimum number of simultaneous actions to perform to release locking mechanisms. Tab D of the NPR describes many different designs from samples tested implementing various multi-action locking mechanisms that the Commission deemed satisfying the proposed rule.

To the extent that § 1263.3(b)(2) can be construed as design or construction requirements, staff recommends adding tests to the final rule that will evaluate products for compliance to the specified performance requirements. Staff recommends adding a test under § 1263.3(d) for battery compartment enclosures that require a tool to open. The test shall specify using a tool that is appropriate for the design of the enclosure and apply a torque to remove the component. The peak torque and total angle of rotation to remove the component shall be measured. This test shall determine if the performance requirement is met if the minimum torque to remove the component is no less than 0.5 Nm (4.4 in-lb) and a minimum angle of rotation to remove the component is no less than 90 degrees, or the fastener(s) engages a minimum of two full threads with a minimum angle of 720 degrees of rotation. Secondly, staff recommends adding a test for battery compartment enclosures that require manipulation by hand in which the minimum number of independent and simultaneous hand movements required to open the battery compartment enclosure is determined. This test shall determine if the performance requirement is met if the enclosure requires at least two independent and simultaneous hand movements to open. Adding these tests will increase clarity for laboratories for evaluating the performance of the products' battery enclosure system.

E. Add requirement for abuse testing for accessible non-removable button cell or coin batteries

The proposed rule specifies accessibility requirements for non-removable button cell or coin batteries in § 1263.3(c). The requirement states that batteries "not intended for removal or replacement must be made inaccessible" by an enclosure that: (1) complies with the same accessibility requirements as replaceable batteries in § 1263.3(b), including the abuse testing of § 1263.3(e), or (2) securing the button cell or coin batteries using "soldering, fasteners such as rivets, or equivalent means, that passes the secureness test in § 1263.3(f)." The secureness test applies a test hook with a force of at least 18 N (4.1 lbf.) on the button cell or coin battery to evaluate how securely fastened the battery is to the product. The Commission based these requirements in the proposed rule on the requirements from UL 4200A and IEC (UL) 62368-1 which the Commission found to be adequate for Reese's Law.

The CTA and ITI comment that the NPR incorrectly states that UL 4200A and IEC 62368-1 do not require abuse testing for products with button cell or coin batteries that are secured by soldering, fasteners, or any equivalent means.

Staff agrees with the commenters and acknowledge the error made in the assessment of this requirement, as described in Tab A. As mentioned above, the proposed rule currently only requires non-removable button cell or coin batteries that are secured to the product via soldering, fasteners, or equivalent means to only comply with the secureness test in § 1263.3(f) and are therefore not subject to the abuse testing of § 1263.3(e). Staff acknowledges that products containing non-removable batteries that are secured by soldering or fasteners will experience foreseeable use and abuse through their lifetime and should not be an exception to the abuse testing requirements. Impacts, drops, or compressions can break the soldering or fasteners attaching the battery to the product thereby freeing the battery and exposing the hazard to children. Staff recommends modifying § 1263.3(c)(2) to require compliance with the abuse testing of § 1263.3(e) in addition to the secureness test, § 1263.3(f). Doing so will ensure the mechanical securement of the non-removable battery is adequately robust to withstand foreseeable use and abuse and therefore will increase the safety of these products.

F. Correct specified values in the proposed rule to incorporate lower bound tolerances

The proposed rule specifies values using the highest tolerance from the voluntary standard which served as the basis for the performance requirement rather than specifying a tolerance from a nominal value. For example, the crush test in the proposed rule, which is based on UL 4200A, specifies a force of 335 N versus the value in UL 4200A which specifies 330 ± 5 N.

ITI and CTA comment that the proposed rule does not include tolerances for specified values and opines that the purpose of tolerances is to provide reasonable allowances (e.g., manufacturability and testability) that will not have a significant impact on test results. The commenter points out that the proposed rule specifies values based on the highest tolerance of the value based on the referenced voluntary standard. The commenter explains that eliminating tolerances could force unnecessary retesting or could make it impractical to apply the test without custom test equipment. The commenter recommends including tolerances in the final rule that align with those provided in voluntary standards.

Staff acknowledges that the values specified in the proposed rule should be based on the lowest tolerance rather than highest, to represent the lowest acceptable value to ensure safety and recommends modifying the values accordingly.

IV. Conclusion

The Commission issued an NPR with performance requirements based on UL 4200A, ASTM F963-17, IEC 62115, and UL 62368-1, with modifications, which would result in consumer products with secure child-resistant battery enclosures as required by Reese's Law, that will adequately reduce the risk of injury from button or coin cell battery ingestion by children that are 6 years of age or younger during reasonably foreseeable use or misuse conditions. Based on ESMC staff's review of the comments received regarding the NPR, for the final rule, staff

recommends modifications for the: drop test, abuse tests, accessibility performance requirements for products intended only to be opened by professionals, captive screw requirements for products with large panel doors, corrections to reference tables, and specified values with respect to tolerances.

TAB F

OS 237



Final Regulatory Flexibility Analysis

Draft Final Rule: Safety Standard for Button Cell or Coin Batteries and Consumer Products Containing Such Batteries

August 31, 2023

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This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

I. Introduction

Pursuant to the passage of Reese's Law, staff of the Consumer Product Safety Commission (CPSC) is submitting a draft final rule for Commission consideration that would establish a mandatory safety standard for button cell or coin batteries and consumer products containing such batteries. These products, referred to throughout this report as *button battery powered products*, include, but are not limited to, remote controls, portable lights, and other consumer products; but exclude toys (under 16 C.F.R. 1250) and medical devices, such as hearing aids and digital thermometers.

Whenever an agency publishes a final rule, the Regulatory Flexibility Act (5 U.S.C. § 601 – 612) requires that the agency prepare a final regulatory flexibility analysis (FRFA) that describes the impact the rule would have on small businesses and other entities. The FRFA must contain:

- 1. a statement of the need for, and objectives of, the rule;
- 2. a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- 3. the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- 4. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- 5. a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- 6. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected;

This report provides an FRFA describing the potential impact of the draft final rule on small businesses and other small entities.

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II. Reason for Agency Action

The draft final rule addresses the ingestion hazard to children 6 years and younger involving button cell or coin batteries, as required by Reese's Law. The Directorate for Epidemiology, Division of Hazard Analysis (EPHA), identified an average of 2.4 button/coin battery ingestion fatalities reported annually from 2011 to 2022 (Tab B Topping). Additionally, EPHA estimates that from 2011 to 2021 an annual average of 4,900 non-fatal ingestions or insertions involving button or coin batteries were treated in hospital emergency departments across the U.S. Among these non-fatal ingestions or insertions, 82 percent were treated and released from the emergency department.

III. Objectives of and Legal Basis for the Rule

The objective of the rule is to adequately reduce or eliminate the risk of serious injury or death related to ingestion of button cell or coin batteries in children six years old and younger. The final rule would be issued under the authority of Reese's Law, which authorizes the Commission to conduct notice and comment rulemaking under 5 U.S.C. section 553 to establish a safety standard for child-resistant battery compartments on consumer products and warnings on such products, and on button cell and coin battery packaging, and pursuant to section 27(e) of the Consumer Product Safety Act.

IV. Comments of the Chief Council for Advocacy, SBA

The Office of Advocacy of the SBA (SBAA) submitted no comments on the NPR.

V. Significant Economic Issues Raised by the Public

These are discussed in Tab A of this package. A few commenters provided specific details concerning cost estimates and effects on small businesses which staff found credible and incorporated into the FRFA.

VI. Small Entities to Which the Rule Will Apply

The North American Industry Classification System (NAICS) defines product codes for U.S. firms. Firms that manufacture *button battery powered products* are likely listed under a large variety of NAICS codes as a wide variety of consumer products use button batteries. However, a majority of these firms likely fall under NAICS codes 334118 Computer Terminal and Other Computer Peripheral Equipment Manufacturing, 334310 Audio and Video Equipment

134

Manufacturing, 335999 All Other Miscellaneous Electrical Equipment and Component Manufacturing, and 339920 Sporting and Athletic Goods Manufacturing. Battery manufacturers (producers of button and coin cell batteries) are listed under NAICS code 33591. Importers of *button battery powered products* are also listed under various NAICS codes, either as wholesalers or retailers. Staff expects that a majority of the wholesalers fall under NAICS codes: 423620 Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers, 423430 Computer and Computer Peripheral Equipment and Software Merchant Wholesalers, and 423690 Other Electronic Parts and Equipment Merchant Wholesalers. With respect to retailers – either large "big box" retailers or smaller specialized firms – nearly every NAICS code listed under retail trade (44, 45) may sell a product within the scope of the final rule. Staff expects that a majority of these products are sold by firms listed in NAICS codes 443140 Electronics and Appliance Retailers, 455219 All Other General Merchandise Retailers, 459420, Gift, Novelty, and Souvenir Retailers, 452000 General Merchandise Stores, and 459110 Sporting Goods Retailers.

Staff notes that the NAICS codes listed in the previous paragraph for manufacturers, wholesalers, and retailers are not meant to be all inclusive, as the scope of the rule is wide and includes products ranging from, but not limited to, lighting, safety, audio, entertainment, health, cooking, and sport devices. The wide scope of products subject to the draft final rule could affect a much greater number of firms than those listed under the NAICS codes above.

Under Small Business Administration guidelines, a manufacturer, wholesaler, or retailer of *button battery powered products* is categorized as small based on the associated NAICS code. Generally, manufacturers and wholesalers are categorized as small by the number of employees, while retailers are assessed based on annual revenues. Based on 2017 data from U.S. Census Bureau, and a sample of retailers' estimated revenues, staff estimated the number of firms classified as small for each NAICS code listed above (Census Bureau, 2020).¹ The tables below provide the estimates of number of small firms by each code.

NAICS Code	Description	SBA Size Standard for Manufacturers/Importers (# of Employees)	Number of firms that meet or are below the size standard
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000	509
334290	Other Communications Equipment Manufacturing	750	305
334310	Audio and Video Equipment Manufacturing	750	453
335210	Small Electrical Appliance Manufacturing	1,500	119

Table 1. Estimate of Number of Small Manufacturers and Wholesalers

¹ Staff reviewed a small sample of retailers within NAICS codes 443140, 455219, 459420, 452000, and 459110. Annual revenue estimates were obtained for the sample from Dun and Bradstreet commercial data.

NAICS Code	Description	SBA Size Standard for Manufacturers/Importers (# of Employees)	Number of firms that meet or are below the size standard
335999	All Other Miscellaneous Electrical Equipment and Component Manufacturing	500	734
339920	Sporting and Athletic Goods Manufacturing	750	1,564
339940	Office Supplies (except Paper) Manufacturing	750	412
339999	All Other Miscellaneous Manufacturing	500	5,714
423420	Office Equipment Merchant Wholesalers	200	2,197
423430	Computer and Computer Peripheral Equipment and Software Merchant Wholesalers	250	5,743
423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant Wholesalers	225	1,956
423690	Other Electronic Parts and Equipment Merchant Wholesalers	250	8,826
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	100	4,521
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100	8,350
335910	Battery Manufacturing	1,250	18

NAICS Code	Description	SBA Size Standard for Retailers (Annual Revenue) \$millions	Number of firms that meet or are below the size standard
444110	Home Centers	\$41.50	1,526
444130	Hardware Retailers	\$14.50	9,623
444240	Nursery, Garden Center, and Farm Supply Retailers	\$19.00	13,228
443140	Electronics and Appliance Retailers	\$35.00	18,906
455110	Department Stores	\$35.00	11
455211	Warehouse Clubs and Supercenters	\$41.50	3
455219	All Other General Merchandise Retailers	\$35.00	7,812
456110	Pharmacies and Drug Retailers	\$33.00	18,912
459110	Sporting Goods Retailers	\$23.50	16,123
459410	Office Supplies and Stationery Retailers	\$35.00	2,646
459420	Gift, Novelty, and Souvenir Retailers	\$12.00	15,264
459999	All Other Miscellaneous Retailers	\$10.00	36,225
452000	General Merchandise Stores	\$35.00	7,832

Table 2.	Estimate of N	umber of Small Retailers
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VII. Compliance Requirements of the Final Rule, Including Reporting and Recordkeeping Requirements

The draft final rule would establish a performance standard for *button battery powered products* as stated in Tab D and labeling/packaging requirements as stated in Tab C of this package.

Under section 14 of the CPSA, *button battery powered product* manufacturers or importers of general use products would be required to certify, based on a test of each product or upon a reasonable testing program, that their products comply with the requirements of the draft final rule. Each certificate of compliance must meet the certificate requirements in 15 U.S.C. 2063(a)(1) and (g), as codified in 16 C.F.R. part 1110, including identification of the manufacturer or importer issuing the certificate and any manufacturer, firm, or third-party conformity assessment body on whose testing the certificate depends. Children's products must be certified based on testing performed by a third-party conformity assessment body whose accreditation to perform the required tests has been accepted by CPSC. The certificate must be legible and in English, and it must also include the date and place of manufacture, the

date and place where the product was tested, including the full mailing address and telephone number for each party, and the contact information for the person responsible for maintaining records of the test results. The certificates may be in electronic format and must be provided to each distributor or retailer of the product. Upon request, the certificates must also be provided to the CPSC.

VIII.Costs of Final Rule

Noncompliant *button battery powered products* may need to be redesigned to accommodate a screw lock or a multi-action lock, as required by the draft final rule. Staff assesses that manufacturers would most likely adopt a screw lock solution to bring noncompliant models into compliance. The potential costs of this draft final rule are therefore the incremental cost to incorporate a screw lock, and the one-time research/development and retooling costs associated with the changes to battery compartments. For noncompliant products that currently incorporate a multi-action lock without the specified additional safety elements (detailed on pg.4-5 of the briefing memo) required by the draft final rule, staff expects that manufacturers would only incur the cost of redesigning the compartment to accommodate the additional elements required by the draft final rule.²

Estimates of the incremental costs to modify a battery compartment for a screw lock range from \$0.02 to \$0.04 per product based on an ESMC staff estimate.³ Staff also estimated a range of 1 to 2 months of labor by an electrical engineer is required for research, design, validation, and retooling. Data from the Bureau of Labor Statistics (BLS) reports the median hourly wage of an electrical engineer in the U.S. is \$48.93. (BLS 2022) Staff expects firms would be able to incorporate updated battery compartment designs across most product lines the manufacturer offers. A small number of product lines may require additional effort or novel solutions to ensure the security of the battery compartment. Staff estimates this additional cost equates to approximately 2 months of additional labor by an electrical engineer for each specific product line requiring a novel solution. This equates to \$7,800 to \$15,700 in potential research/development and retooling costs for most firms.⁴ For the purpose of this FRFA, staff uses the higher-end estimate of \$15,700 cost per product line affected for a novel solution. Staff expects that firms that choose to meet the requirements of the draft final rule through the use of multi-action locks only incur research and development costs, as the cost of retooling and modifying the battery compartment are expected to be negligible.

² Double-action locks may require an additional plastic tray or stronger locks, but the cost of the additional plastic required is expected to be near \$0.00.

³ Cost estimate based on a review of prices for a #2 and #6 machine screw along with required lock washers for each.

⁴ These estimates are towards the high-end of the distribution, as they are based on US labor rates. Lower costs would be expected for firms utilizing engineering labor in low-cost countries, such as China and India.

Battery Compartment Type	Labor Months [Col. 1]	Labor Hours Per Month [Col.2]	Electrical Engineer Wage Rate [Col. 3]	R/D & Retooling Costs [Col. 4] (Col 1 x 2 x 3)
Standard	2	160	\$48.93	\$15,700
Novel/Unique	2			\$15,700
Total for firm only requiring standard design	2			\$15,700
Total for firm with at least 1 novel product line	4			\$31,400

Table 3	Estimate of Res	search Develop	oment, and Retooli	na Costs
	Loundle of Rea	scarch, bevelop	ment, and Retoon	ng oosis

Some additional costs might be incurred related to updating and/or adding labels to the product or the packaging of button cell batteries. Generally, the costs associated with modifying/adding warning labels are low because nearly all manufacturers already provide warning labels with their product. Similarly, staff expects the cost of upgrading the packaging of button cell batteries to be very low on a per unit basis. Therefore, staff estimates the cost related to the labeling and packaging provisions would be negligible relative to the overall cost of compliance with the final rule.

Manufacturers would likely incur additional costs to certify that their *button battery powered products* meet the requirements of the final rule, as required by Section 14 of the CPSA.⁵ For general use products, the certification must be based on a test of each model or a reasonable testing program.⁶ Manufacturers may complete the testing themselves or use a testing laboratory. Certification of children's products, however, must be completed by a CPSC-accepted third-party conformity assessment body (or third-party laboratory). Based on quotes from testing laboratory services for consumer products, the cost of the certification testing will range from \$150 to \$460 per product sample.^{7, 8} These third-party testing costs would likely reduce over time as staff expects firms would develop an internal testing program for general use products to ensure these products meet the requirements.

IX. Impact on Small Manufacturers

Generally, staff considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. As described below, CPSC staff expects a potentially significant impact on some small firms which manufacture *button battery powered products.*⁹ Based on the relatively low cost of compliance, staff assesses that most small firms are not expected to incur costs that

⁵ Note that the requirement to certify compliance with all product safety rules is a requirement of the CPSA and not of the final rule. Certificate content requirements are set forth in 16 C.F.R. part 1110.

⁶ A reasonable testing program performed by the manufacturer would meet the requirements for general use (nonchildren's) products, but children's products are required to be tested and certified based on the third-party testing requirements in 16 C.F.R. part 1107.

⁷ Based on quotes from firms to conduct product certification tests to the current UL4200A standard.

⁸ Staff obtained an additional quote from a CPSC accredited laboratory to perform similar certification tests as completed previously by CPSC staff which amounted to approximately \$460.

⁹ One small business interviewed by CPSC staff indicated that a rule concerning battery compartments would result in significant costs and potential reductions to product offerings.

exceed 1 percent of annual revenues and therefore, most firms would not be significantly impacted by the final rule. Public comments submitted to the Commission stated that some small firms would be significantly impacted by the final rule. These comments were considered in assessing the potential impact on firms. (See Tab A for responses.)

To comply with the final rule, small manufacturers of noncompliant products would likely incur a one-time redesign cost and recurrent incremental costs. Staff does not expect most small manufacturers to suffer a disproportionate cost impact from the draft final rule. However, firms that rely heavily on the production of small unique/novel electronic products or on high-volume, low-price products could be adversely affected. Retail prices for *button battery powered products* vary widely with the least expensive on a per unit basis being mini flashlights of \$1.00.¹⁰ A small manufacturer of \$1.00 mini flashlights would incur costs that exceed 1 percent of annual revenue if the cost to comply with the draft final rule is above one cent per product (high-volume, low-price). Similarly, the redesign cost of novel electronic products or models (roughly \$31,400 as shown in Table 3 would exceed 1 percent of annual sales revenue for firms selling under \$3.14 million per year. Also, smaller manufacturers with under \$1.54 million in annual revenue may incur a significant impact based on CPSC staff's estimate of the potential research and development costs, which range from \$7,800 to \$15,700 per model.

X. Federal Rules which may Duplicate, Overlap, or Conflict with the Final Rule

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the final rule.

XI. Agency Actions for Reducing the Adverse Impact on Small Entities

Under section 603(c) of the Regulatory Flexibility Act, a final regulatory flexibility analysis should "contain a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected".

CPSC staff assessed that the broad scope of Reese's Law does not allow for a significant alternative that would reduce impacts to small businesses, as methods for reducing impacts to small firms, such as limiting scope, providing exemptions, and consumer education in lieu of regulatory action, would not meet the Reese's Law requirements. To reduce impact of the rule on small firms, CPSC could remove the additional labeling requirements under section 27(e) of the CPSA, which are recommended by staff, but not required by Reese's Law.¹¹ The

¹⁰ Based on staff's review of product offerings on retailer websites and in-store locations. Some lighting and decorative products can be purchased in large quantities at lower prices per unit.

¹¹ These additional requirements can be found in Tab C section V subsections D, E, and section VI.

incremental increase in burden from the additional labeling requirements under section 27(e) are insignificant and removal of these additional requirements would not significantly reduce the burden to small businesses.

Another alternative to reduce the potential impact of the rule is an extension of the effective date from 6 months to 12 or 24 months. Staff assesses that due to the broad scope of the rule, a large increase in the number of products tested at accredited laboratories may occur. Manufacturers are not required to third-party test general use products, but due to the diversity of the products subject to the final rule, many manufacturers may not be equipped to create a reasonable testing program in 6 months. An effective date of 12 to 24 months would allow manufacturers and labs to acquire the staff and resources needed to perform the required tests.¹² Given the large and extremely diverse set of industries/products affected and the capacity limitations of accredited laboratories, an extension of the effective date may be a reasonable accommodation to ensure availability of the products within the scope of the final rule.

In addition, a shorter effective date may result in a short run volume increase in lower quality non-compliant products as staff expects total aggregate demand for these products to remain largely unchanged as a result of the rule.¹³ CPSC staff recommends an effective date of at least 18 months to minimize potential disruption in availability of safer *button battery powered products.*

¹² Multiple manufacturers and trade associations submitted detailed timelines concerning required activities to bring products into compliance with the proposed standard. These timelines ranged from18 to 36 months, and frequently cited supply chain and transportation constraints and internal quality and manufacturing verification procedures as leading factors. CPSC staff also interviewed an employee of a CPSC-accepted lab who stated a 12-month lead time is required to acquire the necessary staff and facilities to accommodate the expected increase in product testing volume that may occur as a result of the mandatory standard.

¹³ One commenter submitted a concern that manufacturers who intend to meet the mandatory standard may lose market share to lower quality foreign producers. Staff found this concern credible but expect this market share loss to be temporary as it is unlikely consumers will alter long-term purchasing habits towards less safe products when both are of comparatively similar cost.

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143

TAB G

OS 249

OS 250



Memorandum

TO:	The File	DATE: August 31, 2023
THROUGH:	Duane Boniface, Assistant Executive Director, Office of Hazard Analysis and Reduction (EXHR)	
FROM:	Reese's Law Rulemaking Team	
SUBJECT:		andard for Button Cell or Coin Batteries and atteries: Recommended Regulatory Text

I. Introduction

This memorandum provides staff's recommended regulatory text for the Draft Final Rule to establish a safety standard for button cell or coin batteries and consumer products containing such batteries. Based on commenters on the NPR, this regulatory text contains several revisions, as explained in the cover memorandum and redlined below, and includes general provisions, such as scope and definitions, as well as the recommended performance requirements for products containing button and coin cell batteries, and warning label requirements for packaging containing button cell or coin batteries and consumer products containing such batteries. Finally, as proposed, staff recommends the final rule require point of sale performance and technical data authorized under section 27(e) of the Consumer Product Safety Act (CPSA), to assist in educating caregivers about the unreasonable risk of injury to young children who obtain button batteries and swallow them.

II. Recommended Regulatory Text

16 C.F.R. part 1263: Safety Standard for Child-Resistant Button Cell or Coin Battery Compartments on Consumer Products

§ 1263.1 Scope, Purpose, Effective Date, Units, and Exemption

(a) Scope and purpose. As required by Reese's Law (15 U.S.C. § 2056e, Public Law 117-171), this part establishes performance requirements for child-resistant button cell or coin battery compartments on consumer products during reasonably foreseeable use and misuse of the consumer product, to address the risk of injury and death to children 6 years old and younger from ingesting these batteries. This part also establishes warning label requirements for packaging containing button cell or coin batteries, and packaging of consumer products containing such batteries, as well as point of sale performance and technical data pursuant to section 27(e) of the Consumer Product Safety Act (15 U.S.C. 2076(e).

(b) Effective Date. Except as provided in paragraph (d) of this section, all consumer products and packaging containing button cell or coin batteries that are manufactured or imported after [INSERT 18 MONTHS AFTER PUBLICATION IN THE FEDERAL REGISTER] are subject to the requirements of this part.

(c) Units. In this part, values stated without parentheses are the requirement. Values in parentheses are approximate information.

(d) *Exemption*. Any object designed, manufactured, or marketed as a plaything for children under 14 years of age that is in compliance with the battery accessibility and labeling requirements of 16 C.F.R. part 1250, Safety Standard Mandating ASTM F963 for Toys, is exempt from the requirements of this part.

(e) *Batteries that Do Not Present an Ingestion Risk.* Button cell or coin batteries that the Commission has determined do not present an ingestion risk are not subject to § 1263.3 or § 1263.4. These are: zinc-air button cell or coin batteries.

§ 1263.2 Definitions

In addition to the definitions given in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052), the following definitions apply for purposes of this part:

Accessibility probe means Test Probe 11 in IEC 61032 Protection of Persons and Equipment by Enclosures - Probes for Verification.

Accessible means able to be contacted by the accessibility probe.

Button cell or coin battery means (1) a single cell battery with a diameter greater than the height of the battery; or (2) any other battery, regardless of the technology used to produce an electrical charge, that is determined by the Commission to pose an ingestion hazard.

Hand-held product means a consumer product that is reasonably foreseeable to be held by hand during use or misuse and that is 4.54 kg (10.0 lb) or less in mass.

Ingestion hazard means a hazard caused by swallowing a button cell or coin battery whereby (1) the button cell or coin battery can become lodged in the digestive tract or airways, and (2) can potentially cause death or serious injury through choking, generation of hazardous chemicals, leaking of hazardous chemicals, electrical burns, pressure necrosis, or other means.

Principal display panel means the display panel for a retail package of button cell or coin batteries or retail package of consumer product containing such batteries that is most likely to be displayed, shown, presented, or examined under normal or customary conditions of display for retail sale. The principal display panel is typically the front of the package.

Portable product means a consumer product that requires lifting or handling as part of its reasonably foreseeable use or misuse and that is 18 kg (40 lb) or less in mass.

Product display panel means the surface area on, near, or in the battery compartment of a consumer product containing button cell or coin batteries. For consumer products with replaceable button cell or coin batteries, the product display panel is visible while a consumer installs or replaces any button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel is visible while a consumer installs or replaces any button cell or coin battery. For consumer products with nonreplaceable button cell or coin batteries, the product display panel is visible upon access to the battery compartment.

Secondary display panel means a display panel for a retail package of button cell or coin batteries or retail package of a consumer product containing such batteries that is opposite or next to the principal display panel. The secondary display panel is typically the rear or side panels of the package.

§ 1263.3 Requirements for Consumer Products Containing Button Cell or Coin Batteries

(a) *General*. Consumer products that contain button cell or coin batteries must meet the performance and labeling requirements in this part to minimize the risk of children accessing and ingesting button cell or coin batteries. Consumer products that allow consumers to remove or replace a button cell or coin battery must comply with the performance requirements of § 1263.3(b). Consumer products that do not allow for the removal or replacement of button cell or coin batteries must comply with the performance right or coin batteries must comply with the performance requirements in \$ 1263.3(c).

(b) *Performance requirements for removable button cell or coin batteries*. (1) A removable or replaceable button cell or coin battery in a consumer product must not be made accessible when tested pursuant to § 1263.3(d).

(2) Battery compartments for removable or replaceable button cell or coin batteries must meet the requirements in § 1263.3(e) and be secured using at least one of the following methods:

(i) Secure the battery compartment enclosure so that it requires a tool, such as a screwdriver or coin, to open the battery compartment. Battery compartments secured by one or more screws, or a twist-on access cover, must require a minimum torque of 0.5 Nm (4.4 in-lb) and a minimum angle of 90 degrees of rotation, or the fastener(s) must engage a minimum of two full threads with a minimum angle of 720 degrees of rotation, when tested in accordance with § 1263.3(d)(1)(i). Screws or fasteners used to secure the battery compartment enclosure must remain captive to the compartment door, cover, or closure after testing to § 1263.3(e).

(ii) Secure the battery compartment enclosure so that it requires a minimum of two independent and simultaneous hand movements to open when tested in accordance with § 1263.3(d)(1)(ii).

(c) Performance requirements for consumer products containing non-replaceable button cell or coin batteries. Consumer products that contain button cell or coin batteries not intended for removal or replacement by the consumer must be made inaccessible by (1) using a battery compartment enclosure that requires a tool that is not a common household tool, such as a screwdriver (Philips or straight blade), pliers, or coin to open and complies with the performance requirements of § 1263.3(e), or (2) securing the button cell or coin battery using soldering, fasteners such as rivets, or equivalent means, that complies with the performance requirements Test in § 1263.3(f).

(d) Accessibility test method. This test assesses whether a child can access a button cell or coin battery installed in a consumer product by determining whether the accessibility probe can contact a button cell or coin battery.

(1) Consumer products with battery compartments for removeable or replaceable button cell or coin batteries are tested using the following methods:

(i) Use an appropriate tool to open the battery compartment enclosure. For any threaded fastener(s) or twist-on access cover securing the battery compartment enclosure, apply a removal torque. Measure the peak torque and angle of rotation needed to loosen each component and open the battery compartment enclosure.

(ii) Use hand movements to open the battery compartment enclosure. The movements to open cannot be combinable to a single movement with a single finger or digit. Determine the minimum number of independent and simultaneous hand movements required to open the battery compartment enclosure.

(2) To determine whether a button cell or coin battery is accessible, first open and remove any part of the battery compartment enclosure that can be opened or removed without a tool or that can be opened or removed with anything less than two independent and simultaneous movements (for example, a zipper or hook and loop).

(3) If a part of the battery compartment enclosure is protected by pliable material such as fabric, paper, foam, or vinyl, or a pliable material with a seam, apply the *Tension Test for Seams in Stuffed Toys and Beanbag-Type Toys* test in 16 C.F.R. 1250 to determine whether the battery compartment enclosure can become exposed or accessible, using a force of at least 68.0 N (15.3 lbf). If a new part of the battery compartment enclosure becomes exposed or accessible, repeat the preceding step (1) and this step (2) until no new part of the battery compartment becomes exposed or accessible, and then conduct the test in § 1263.3(d)(3).

(4) Insert or apply the accessibility probe to any depth that a battery compartment opening will permit, and rotate or angle the accessibility probe before, during, and after insertion or application through the battery compartment opening to any position that is necessary to determine whether the probe can contact the button cell or coin battery. This test is not intended to judge the strength of the material comprising the

battery compartment. Use the minimum force necessary in determining whether the probe can contact a button cell or coin battery.

(e) Performance tests for consumer products containing button cell or coin batteries. After preconditioning in § 1263.3(e)(1), consumer products containing a button cell or coin battery must pass the performance requirements in § 1263.3(e)(2) or § 1263.3(f) in the order presented, as applicable.

(1) Pre-conditioning. Subject each test sample consumer product to applicable pre-conditioning:

(i) Stress relief. Subject each sample consumer product with a battery compartment enclosure, door/cover, or door/cover opening mechanism that is made from molded or formed thermoplastic materials to a stress relief test. Place each test sample consumer product in a circulating air oven for at least 7 hours, using an oven temperature of the higher of at least 70°C (158°F) or at least 10°C (18°F) higher than the maximum temperature of thermoplastic battery compartment enclosures, doors/covers, or door/cover opening mechanisms during the most stringent normal operation of the consumer product. Allow the sample consumer product to cool to room temperature after removal from the oven.

(ii) *Battery replacement*. This step only applies to consumer products with button cell or coin batteries intended to be removable or replaceable. Open the battery compartment enclosure, remove and replace the button cell or coin battery, and close the battery compartment enclosure for a total of ten cycles. This test is intended to simulate replacing the button cell or coin battery 10 times per the manufacturer's instructions. For battery compartment enclosures that are secured with a screw(s), the screw(s) must be loosened and then tightened using a suitable screwdriver, applying a continuous linear torque according to the Torque to be Applied to Screws table, Table 37, of the Standard for Safety – Audio/Video, Information and Communication Technology Equipment – Part 1: Safety Requirements, UL 62368-1. If the screw(s) do not meet the specified torque requirements during this step, remove the screw(s) and repeat the test in § 1263.3(d).

(2) Abuse tests. Subject each test sample consumer product to the following abuse tests, performed sequentially, as applicable. Check compliance of the sample using § 1263(e)(3). If the consumer product contains button cell or coin batteries that are not intended for removal or replacement, and that are accessible based on § 1263.3(d), then the consumer product must be tested under § 1263.3(f).

(i) *Drop test.* Portable products and hand-held products are subject to this test. Drop each sample portable product three times; drop each sample hand-held product ten times. Each sample product must be dropped from a height of at least 1.0 m (39.4 in) onto a horizontal hardwood surface in positions likely to produce the maximum force on the battery compartment enclosure. The hardwood surface must be at least 13 mm (0.5 in) thick, mounted on two layers of nominal 19 mm (0.75 in) thick plywood, and placed on a concrete or equivalent non-resilient surface.

(ii) *Impact test*. Subject the battery compartment enclosure door or cover on each sample consumer product to three, at least 2-J (1.5-ft·lbf) impacts. Produce the impact by dropping a steel sphere, approximately 50.8 mm (2 in) in diameter, and weighing approximately 0.5 kg (1.1 lb) from the height required to produce the specified impact, as shown in Figure 1 to this paragraph (e)(2)(ii), or suspend the steel sphere by a cord and swing as a pendulum, dropping through the vertical distance required to cause the steel sphere to strike the battery compartment enclosure door or cover with the specified impact, as shown in Figure 2 to this paragraph (e)(2)(ii). The steel sphere must strike the battery compartment enclosure door or cover perpendicular to the surface of the battery compartment enclosure. The minimum height or vertical distance should be approximately 408 mm (16.1 in).

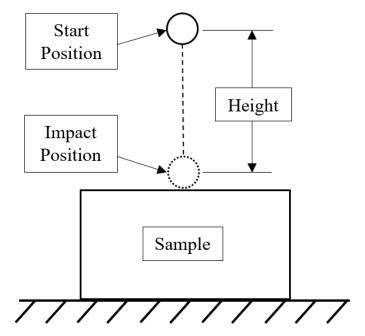


Figure 1 to Paragraph (e)(2)(ii). Example impact test with a dropped steel sphere.

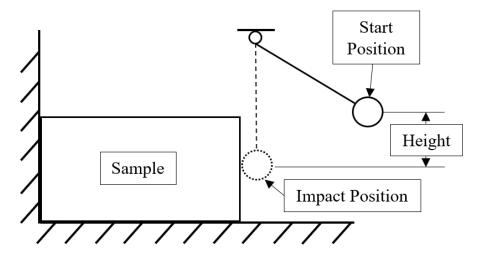


Figure 2 to Paragraph (e)(2)(ii). Impact Test with a swinging steel sphere.

(iii) *Crush test*. Support each sample consumer product by a fixed rigid supporting surface, in positions likely to produce the most adverse results as long as the position of the consumer product is self-supported. Apply a crushing force of at least 325 N (73.1 lbf) to the exposed surface for a period of 10 seconds. Apply the force using a flat surface measuring approximately 100 by 250 mm (3.9 by 9.8 in).

(iv) *Compression test*. If any surface of the battery compartment enclosure is accessible to a child and inaccessible to flat surface contact during the drop test, apply the *Compression Test* from 16 C.F.R. part 1250 to that surface, using a force of at least 131 N (29.5 lbf).

(v) *Torque test.* If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth,

149

apply the *Torque Test for Removal of Components* from 16 C.F.R. part 1250 to the battery compartment enclosure, using a torque of at least 0.50 Nm (4.4 in.-lbf).

(vi) *Tension test*. If a child can grasp any part of the battery compartment enclosure on a sample consumer product, including the door or cover, with at least the thumb and forefinger, or using teeth, apply the *Tension Test for Removal of Components* from 16 C.F.R. part 1250 to the battery compartment enclosure, using a force of at least 68.0 N (15.3 lbf).

(3) *Compliance*. If a button cell or coin battery becomes accessible or liberates from a consumer product as a result of any of the abuse tests in \$1263.3(e)(2), the consumer product is non-compliant and fails testing. Additionally, after completing all abuse testing, apply a force of at least 50 N (11.2 lbf) for 10 seconds to the battery compartment enclosure door or cover using the accessibility probe. Apply the accessibility probe at the most unfavorable position(s) on the battery compartment enclosure, and in the most unfavorable direction(s). Apply a force in only one direction at a time. If the battery compartment enclosure door or cover using the accessible, the consumer product is non-compliant and fails testing. Button cell or coin batteries installed in a consumer product that are not intended for removal or replacement, and that become accessible based on \$ 1263.3(d) or as a result any of the abuse tests \$1263.3(e)(2) but do not liberate from the consumer product, are not subject to this test and must pass the test in \$1263.3(f).

(f) Secureness test. Button cell or coin batteries installed in a consumer product that are not intended for removal or replacement, and that are accessible based on § 1263.3(d), must be tested by applying a test hook, as shown in Figure 3 to this paragraph (f), using a force of at least 18 N (4.1 lbf), directed outwards, applied for 10 seconds at all points where application of a force is possible. To pass the test, the button cell or coin battery cannot liberate from the consumer product during testing.

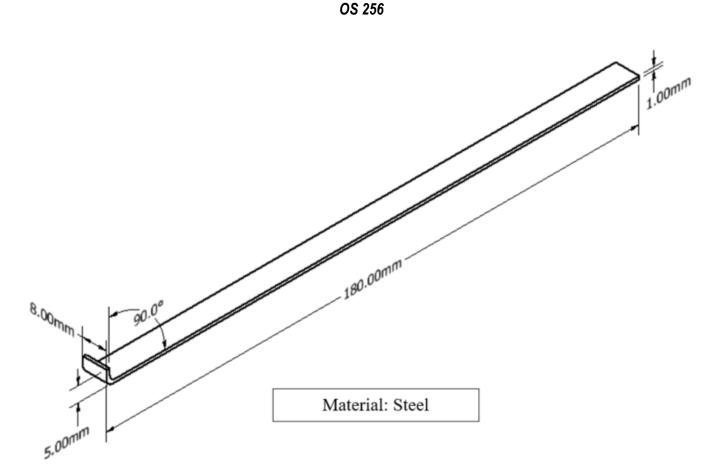


Figure 3 to Paragraph (f). Secureness test hook for consumer products with accessible button cell or coin batteries not intended for removal or replacement.

§ 1263.4 Requirements for Marking and Labeling

(a) *General Requirements*. (1) All warning statements must be clearly visible, prominent, legible, and permanently marked.

(2) Warning statements must be in contrasting color to the background onto which the warning statement is printed.

(3) Warning statements must be in English.

(4) The safety alert symbol, an exclamation mark in a triangle, when used with the signal word, must precede the signal word. The base of the safety alert symbol must be on the same horizontal line as the base of the letters of the signal word. The height of the safety alert symbol must equal or exceed the signal word letter height.

(5) The signal word "WARNING" and safety alert symbol must be in black letters on an orange background unless this would conflict with §1263.4(a)(1)-(2) or only one color is present, in which case, signal word and safety alert symbol must contrast to the background on which they are printed. The signal word must appear in sans serif letters in upper case only.

(6) Certain text in the message panel must be in bold and in capital letters as shown in the example warning labels to get the attention of the reader.

(7) For labels that are provided on a sticker, hang tag, instructions or manual, the safety alert symbol and the signal word "WARNING" must be at least 0.2 in. (5 mm) high. The remainder of the text must be in characters whose upper case must be at least 0.1 in. (2.5 mm), except where otherwise specified.

(8) For labels that are required to be on the packaging of button cell and coin batteries, the packaging of consumer products containing such batteries, and directly on consumer products, text size must be

dependent on the area of the principal display panel or the product display panel. Text size must be determined based on Table 1 to this paragraph (a)(8).

[Information based on 16 C.F.R. part 1500.19(d)(7).]									
Letter size measurements in inches									
Display Area: Inches ²	0–2	+2–5	+5–10	+10–15	+15–30	+30–100	+100–400	+400	
Signal word (WARNING)	3/64	1/16	3/32	7/64	1/8	5/32	1/4	1/2	
Statement of Hazard	3/64	3/64	1/16	3/32	3/32	7/64	5/32	1/4	
Other Text	1/32	3/64	1/16	1/16	5/64	3/32	7/64	5/32	
Letter size measurements in cm (for reference only)									
Display Area: cm ²	0-13	+13-32	+32-65	+65-97	+97-194	+194-645	+645-2,581	+2,581	
Signal word (WARNING)	0.119	0.159	0.238	0.278	0.318	0.397	0.635	1.270	
Statement of Hazard	0.119	0.119	0.159	0.238	0.238	0.278	0.397	0.635	
Other Text	0.079	0.119	0.159	0.159	0.198	0.238	0.278	0.397	

Table 1 to Paragraph (a)(8)—Letter size for recommended warning labels. [Information based on 16 C.F.R. part 1500.19(d)(7).]

(b) Warning label requirements for button cell or coin battery packaging. (1) The principal display panel of the packaging must include the warning label in Figure 4 to this paragraph (b)(1). The icon must be at least 8 mm (0.3 inches) in diameter. The text must state the following warnings as shown on Figure 4 to this paragraph (b)(1).

- INGESTION HAZARD: DEATH or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.
- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

Figure 4 to Paragraph (b)(1)

(2) If space prohibits (see Table 1) the full warning label shown in Figure 4 to paragraph (b)(1), place the icon shown in Figure 5 to this paragraph (b)(2) on the principal display panel with the text shown in Figure 6 to this paragraph (b)(2) on the secondary display panel. The icon must be at least 20 mm in diameter. The text must state the following warnings as shown on Figure 6 to this paragraph (b)(2):





▲WARNING INGESTION HAZARD ● DEATH or serious injury can occur ● A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours ● KEEP new and used batteries OUT OF REACH OF CHILDREN ● Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body ● For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

Figure 6 to Paragraph (b)(2)

(3) The following safety-related statements must be addressed on the principal display panel or secondary display panel:

- i. Keep in original package until ready to use.
- ii. Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash.

(4) For button cell or coin battery packaging included separately with a consumer product, only paragraphs (b)(1) and (2) of this section apply.

(b) Warning label requirements for packaging of consumer products containing button cell or coin batteries. (1) The principal display panel must contain the warning label in Figure 7 to this paragraph (c)(1). The icon must be either the internationally recognized "Keep Out of Reach of Children" icon shown in Figure 5 to paragraph (b)(2), or the internationally recognized "Warning: Contains Coin Battery" icon shown in Figure 11 to paragraph (d)(2). The "Keep Out of Reach of Children" icon must be at least 8 mm in diameter. The "Warning: Contains Coin Battery" icon must be at least 7 mm in width and 9 mm in height. The text must state the following as shown in Figure 7 to this paragraph (c)(1):

WARNING

- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested in as little as 2 hours.
- A swallowed button cell or coin battery can cause Internal Chemical Burns.
- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].



WARNING

- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested in as little as 2 hours.
- A swallowed button cell or coin battery can cause Internal Chemical Burns.
- KEEP new and used batteries OUT OF REACH OF CHILDREN
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

Figure 7 to Paragraph (c)(1)

(2) Consumer products that are not contained in packaging must have the warning label in Figure 7 to paragraph (c)(1) affixed to the consumer product with a hang tag or a sticker label.

(3) If space on the principal display panel of the consumer product packaging does not permit the warning label in Figure 7 in paragraph (c)(1), the principal display panel must include the warning in Figure 8 to this paragraph (c)(3) in a conspicuous location. The icon must be at least 8 mm in diameter. The remaining warning statements must be on a secondary display panel, as shown in Figure 9 to this paragraph (c)(3). The text must state the following on the principal display panel as shown in Figure 8 to this paragraph (c)(3).

AWARNING

- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause **Internal Chemical Burns** in as little as **2 hours**.



- INGESTION HAZARD: This product contains [uses] a button cell or coin battery.
- DEATH or serious injury can occur if ingested.
- A swallowed button cell or coin battery can cause Internal Chemical Burns in as little as 2 hours.



Figure 8 to Paragraph (c)(3)



Figure 9 to Paragraph (c)(3)

(4) The text must state the following on the secondary display panel as shown in Figure 9 to paragraph (c)(3).

(5) The principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must include the following:

i. For products with non-replaceable batteries, include a statement indicating the product contains batteries not to be replaced by the consumer.

(d) *Warning label requirements for consumer products that contain button cell or coin batteries.* (1) Consumer products must be durably and indelibly marked with a warning label on the product display panel that alerts the consumer of the presence of a button cell or coin battery. Permanency of printed and screened labels must be tested in accordance with UL 62368-1 section F.3.10. The warning text must include the safety alert symbol, signal word, and text, as shown in Figure 10 to this paragraph (d)(1).



Figure 10 to Paragraph (d)(1)

(2) If space on the product is limited, use the internationally recognized "Warning: contains coin battery" icon shown in Figure 11 to this paragraph (d)(2), without text. The icon must be at least 7 mm in width and 9 mm in height and must be on the product display panel as shown in Figure 11 to this paragraph (d)(2). The icon must be defined in accompanying printed materials such as instructions, manual, insert, or hangtag.



Figure 11 to Paragraph (d)(2)

(3) If the product itself is too small to include the warning with text in Figure 10 to paragraph (d)(1) or the icon in Figure 11 to paragraph (d)(2), the product must:

(i) Have packaging containing the warning label following the requirements in § 1263.4(c), or

(ii) Contain a hangtag or sticker label with the full warning label using requirements for the packaging of consumer products containing batteries in § 1263.4(c).

(e) Instructions/Manuals accompanying consumer products containing button cell and coin batteries. (1) Instructions and manuals, including printed inserts, if provided, must include the warning label shown in Figure 7.

(2) Instructions and manuals must address the following warning statements:

- i. Immediately dispose of used batteries and keep away from children. Do NOT dispose of batteries in household trash.
- ii. Even used batteries may cause severe injury or death.
- iii. For consumer products using replaceable batteries: Always completely secure the battery compartment. If the battery compartment does not close securely, stop using the product, remove the batteries, and keep the batteries away from children.
- iv. For products with non-replaceable batteries, include a statement indicating the product contains batteries not to be replaced by the consumer.

(3) If instructions and manuals are not provided, the warning statements in § 1263.4(e)(2) must be present on the principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label.

§ 1263.5 Requirements for Performance and Technical Data

(a) *General Requirements*. The requirements in § 1263.4(a) also apply to this section unless otherwise stated.

(b) *Warning label requirements for zinc-air battery packaging.* 1) The principal display panel of the packaging must include the warning label in Figure 12 to this paragraph (b)(1). The icon must be at least 8 mm (0.3 inches) in diameter. The text must state the following as shown in Figure 12 to this paragraph (b)(1):

- INSERTION HAZARD: Zinc Air batteries inserted in the nose or ear can cause Internal Chemical Burns.
- KEEP new and used batteries OUT OF REACH OF CHILDREN.
- Seek immediate medical attention if a battery is suspected to be swallowed or inserted inside any part of the body.
- For treatment information call: [phone number for the National Battery Ingestion Hotline, currently 1-(800) 498-8666].

Figure 12 to Paragraph (b)(1)

(c) *Icon requirements for button cell or coin batteries*. Button cell or coin batteries that are visible within the packaging must be durably and indelibly marked with the "Keep Out of Reach of Children" icon where size permits, at a minimum size of 6 mm in diameter.

(d) *Additional warning statements.* (1) Battery packaging must address the following safety-related statements on the principal display panel or secondary display panel:

- i. Battery type (*e.g.*, LR44, CR2032)
- ii. Battery chemistry (e.g., silver oxide or lithium)
- iii. Nominal voltage
- iv. Year and month or week of manufacture or expiration date
- v. Name or trademark of the manufacturer or supplier
- vi. Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbonzinc, or rechargeable batteries.
- vii. Ensure the batteries are installed correctly according to polarity (+ and -).
- viii. Remove and immediately discard batteries from equipment not used for an extended period of time.
- ix. Contact your local hazardous waste authority or find a local recycling center for battery disposal information.
- x. Non-rechargeable batteries are not to be recharged.
- xi. Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns.

(2) The principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label, must address the following:

- i. Battery type (e.g., LR44, CR2032)
- ii. Nominal voltage
- iii. For consumer products using replaceable batteries: Contact your local hazardous waste authority or find a local recycling center for battery disposal information.

(3) Instructions and manuals, if provided, must address the following safety-related statements, as applicable:

- i. Compatible battery type (e.g., LR44, CR2032)
- ii. Nominal voltage



- iii. For consumer products using replaceable batteries and that use more than one battery per circuit: Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries.
- iv. For consumer products using replaceable batteries: Ensure the batteries are installed correctly according to polarity (+ and -).
- v. For consumer products using replaceable batteries: Remove and immediately discard batteries from equipment not used for an extended period of time.
- vi. For consumer products using replaceable or non-rechargeable batteries: Non-rechargeable batteries are not to be recharged.
- vii. Do not force discharge, recharge, disassemble, heat above (manufacturer's specified temperature rating) or incinerate. Doing so may result in injury due to venting, leakage or explosion resulting in chemical burns.
- viii. For consumer products using replaceable batteries: Contact your local hazardous waste authority or find a local recycling center for battery disposal information.

(4) If instructions and manuals are not provided, the warning statements in § 1263.5(d)(3) must be present on the principal display panel or secondary display panel of the consumer product packaging, or if there is no consumer product packaging, the accompanying hang tag or sticker label.

(e) *Online information*. Manufacturers, including importers, shall include, in a manner that is clearly visible, prominent, and legible (either next to the product description, the product image, or the product price):

(1) in their online materials that enable consumers to purchase button cell or coin batteries, the warning in Figure 4 to § 1263.4(b)(1); and

(2) in their online materials that enable consumers to purchase products containing button cell or coin batteries, the warning in Figure 7 to 1263.4(c)(1).

TAB H



Small Business Economic Analysis

Final Rule: Warning Label Requirements for Button Cell or Coin Batteries Packaging

August 31, 2023

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THIS DOCUMENT HAS NOT BEEN REVIEWED OR ACCEPTED BY THE COMMISSION CLEARED FOR PUBLIC RELEASE UNDER CPSA 6(b)(1)

I. Introduction

Pursuant to the passage of Reese's Law, Public Law 117-171, staff of the Consumer Product Safety Commission (CPSC) is submitting a draft final rule for Commission consideration that would establish mandatory warning label requirements for button cell or coin battery packaging.

Whenever an agency publishes a final rule, the Regulatory Flexibility Act (5 USC 601 - 612) requires that the agency prepare a final regulatory flexibility analysis (FRFA) that describes the impact the rule would have on small businesses and other entities. An agency does not have to prepare a FRFA, however, "if the head of the agency certifies that rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b).

If an agency prepares a FRFA, it must contain:

- 7. a statement of the need for, and objectives of, the rule;
- 8. a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- 9. the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA) in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments;
- 10. a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- 11. a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- 12. a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

Based on staff's analysis, the Commission may certify that the rule will not have a significant economic impact on a substantial number of small entities. This report provides an economic analysis describing the potential impact of the final rule on small businesses and other small entities to support such a determination.

II. Reason for Agency Action

The draft final rule addresses the ingestion hazard to children 6 years and younger involving button cell or coin batteries, as required by Reese's Law. The Directorate for Epidemiology, Division of Hazard Analysis (EPHA), identified an average of 2.4 button/coin battery ingestion fatalities reported annually from 2011 to 2022 (Topping, 2023). Additionally, EPHA estimates that from 2011 to 2021, an

annual average of 4,900 non-fatal ingestions or insertions involving button or coin batteries were treated in hospital emergency departments across the U.S. Among these non-fatal ingestions or insertions, 82 percent were treated and released from the emergency department.

III. Objectives of and Legal Basis for the Rule

The objective of the rule is to adequately reduce or eliminate the risk of serious injury or death related to ingestion of button cell or coin batteries in children six years old and younger. The final rule would be issued under the authority of Reese's Law, Public Law 117-171, which authorizes the Commission to conduct notice and comment rulemaking under 5 U.S.C. section 553 to establish warnings on button cell and coin battery packaging.

IV. Public comments in response to the IRFA

CPSC received substantive public comments regarding the initial regulatory flexibility analysis (IRFA). Staff's responses to these comments are in Tab A of this briefing package.

V. Response to comments from SBA

CPSC did not receive any comments from the Chief Counsel for Advocacy of the SBA.

VI. Small Entities to Which the Rule Will Apply

The North American Industry Classification System (NAICS) defines product codes for U.S. firms. Firms that manufacture button/coin battery powered products are listed under NAICS code 33591. With respect to retailers – either large "big box" retailers or smaller specialized firms – nearly every NAICS code listed under retail trade (44, 45) may include firms that sell a product within the scope of the final rule. Staff expects that a majority of these products are sold by firms listed in NAICS codes 443140 Electronics and Appliance Retailers, 455219 All Other General Merchandise Retailers, 459420, Gift, Novelty, and Souvenir Retailers, 452000 General Merchandise Stores, and 459110 Sporting Goods Retailers.

Under Small Business Administration guidelines, a manufacturer, wholesaler, or retailer of button/coin battery powered products is categorized as small based on the associated NAICS code. Generally, manufacturers are categorized as small by the number of employees, while retailers are assessed based on annual revenues. Based on 2017 data from U.S. Census Bureau, and a sample of retailers' estimated revenues, staff estimated the number of firms classified as small for each NAICS code listed above (Census Bureau, 2020). Battery manufacturers are classified as a small business if they have less than 1,250 employees. Based on the Statistics of U.S. Businesses published by the Census Bureau, there are 18 manufacturers that are classified as small. For retailers, the table below provides the estimates of number of firms that meet the size standard to be considered small by each code.

NAICS	Description	SBA Size Standard	Number of firms
Code		for Retailers	that meet size
		(Annual Revenue)	standard
		\$millions	
444110	Home Centers	\$41.50	1,526
444130	Hardware Retailers	\$14.50	9,623
444240	Nursery, Garden Center, and Farm Supply Retailers	\$19.00	13,228
443140	Electronics and Appliance Retailers	\$35.00	18,906
455110	Department Stores	\$35.00	11
455211	Warehouse Clubs and Supercenters	\$41.50	3
455219	All Other General Merchandise Retailers	\$35.00	7,812
456110	Pharmacies and Drug Retailers	\$33.00	18,912
459110	Sporting Goods Retailers	\$23.50	16,123
459410	Office Supplies and Stationery Retailers	\$35.00	2,646
459420	Gift, Novelty, and Souvenir Retailers	\$12.00	15,264
459999	All Other Miscellaneous Retailers	\$10.00	36,225
452000	General Merchandise Stores	\$35.00	7,832

Table 1. Estimate of Number of Small Retailers

VII. Compliance Requirements of the Final Rule, Including Reporting and Recordkeeping Requirements

The final rule would establish labeling/packaging requirements as stated in Tab D of this package.

VIII.Costs of Final Rule

Some costs might be incurred related to updating and/or adding labels to the packaging of button cell or coin batteries. Generally, the costs associated with modifying/adding warning labels are low because nearly all battery manufacturers already provide warning labels with their product. Similarly, the cost of upgrading the packaging of button cell or coin batteries is expected to be very low on a per unit basis as the change is a one-time cost that will be spread across millions of units. Burden estimates

related to labeling and product packaging submitted to CPSC indicate an hourly burden range of 4 to 26 labor hours per model to update/upgrade the labels and/or packaging. Applying the manufacturing industry hourly compensation value for professional occupations published by the Bureau of Labor Statistics in March (\$70.55) results in a higher end, one-time cost equal to \$1,834.30 per model (\$70.55 x 26). Per unit retail prices of these products ranges from \$0.20 to \$3.00. As these button cell and coin batteries are high volume products, staff expects these costs to be spread across millions of retail units. Therefore, staff estimates the cost related to the labeling and packaging provisions would be negligible on a per unit basis.

IX. Impact on Small Manufacturers

Generally, staff considers an impact to be potentially significant if it exceeds 1 percent of a firm's revenue. CPSC staff does not expect a potentially significant impact on small firms which manufacture button and coin batteries, as the per unit costs are far less than 1 percent of retail prices for these products. Small firms are not expected to incur costs that exceed 1 percent of annual revenues and therefore will not be significantly impacted by the final rule. Therefore, the Commission may certify that the rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C § 605(b).

X. Federal Rules which may Duplicate, Overlap, or Conflict with the Final Rule

CPSC staff has not identified any other Federal rules that duplicate, overlap, or conflict with the final rule.

XI. Agency Actions for Reducing the Adverse Impact on Small Entities

Under section 603(c) of the Regulatory Flexibility Act, a final regulatory flexibility analysis should "contain a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

CPSC staff assessed that the broad scope of Reese's Law does not allow for a significant alternative that would reduce impacts to small businesses, as typical methods for reducing impacts to small firms—such as limiting scope, providing exemptions, and consumer education in lieu of regulatory action—would not meet the requirements of the statute.

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