1375 Broadway • Suite 1001 • New York, NY 10018
t. 212.675.1141 • e. info@toyassociation.org

August 11, 2025

The Honorable Peter Feldman
Acting Chair
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

RE: Request for Information on Reducing Regulatory Burdens (CPSC Docket No. CPSC-2025-0009)

Dear Acting Chair Feldman,

Thank you for the opportunity to submit comments regarding the Request for Information on Reducing Regulatory Burdens. These comments are provided on behalf of The Toy Association (TA) and its 900+ members, representing manufacturers, importers, designers, retailers, inventors, and toy safety testing labs, all working to ensure safe play for children and families.

Toy safety is our number one priority, and we have been global leaders in advancing physical and chemical toy safety for decades. ASTM F963, as incorporated in 16 CFR 1250 pursuant to the Consumer Product Safety Improvement Act (CPSIA), is recognized as one of the world's premier toy safety standards. Its comprehensive requirements have been emulated globally for toys and several non-toy categories, and its consensus process ensures consideration of stakeholder viewpoints, innovation in product design and data-supported emerging hazards.

Our comments address opportunities for CPSC to reduce burden and costs, without impacting safety, in three areas: (1) current regulations (eFiling[1], phthalates[2], and infant support cushions[3], (2) proposed regulations (button & coin cell batteries in toys[4], water beads[5], and neck floats[6]), and (3) recent changes in enforcement and regulatory practices by CPSC staff and Commissioners (recall procedures and deviations from established rulemaking processes).

A. Current Rules & Regulations

1. **The eFiling final rule, while a potentially beneficial update to the certification process, is an unfinished and unproven 'one-size-fits-all' framework that will create significant administrative burden and cost.**

   The eFiling rule, while incorporating some amendments in response to public comments filed, still presents opportunities needing to be addressed by CPSC: (1) unduly complex and unnecessary multiple identifiers for Children's Product Certificates (CPCs) and

[1] FR Vol 90, No. 5, p 1800
[2] 16 CFR 1307
[3] FR Vol 89, No. 213, p 87467
[4] FR Vol 89, No. 156, p 65791
[5] FR Vol 89, No. 174, p 73024
[6] FR Vol 89, No. 224, p 91586

General Certificates of Conformity (GCCs), when only a single identifier should be required; (2) leaves manufacturers to have to find ways to address variations between CPSC's approach and retailers' systems; (3) limited alpha & beta testing has been conducted, without a disaster recovery plan, and (4) inadequate data privacy & security for users of the platform.

While the eFiling rule did incorporate some adjustments since the Supplemental Notice of Proposed Rulemaking (SNPR)[7] which have reduced some of the potential burden (such as no longer requiring certification for exempted testing or treating replacement parts as discrete and separate products, as well as extending the enforcement period from 120 days to 18 months), it did not address or resolve a number of the concerns relating to regulatory burdens impacting the affected entities.

Outstanding concerns include:

- Each individual CPC or GCC is currently required to contain three separate, distinct identifiers that have to be individually managed. To reduce administrative burden and complexity for manufacturers and importers of record, a single identifier for each discrete CPC (or GCC) should replace the current multiple identifier format.
- Manufacturers need to provide eFiling information for retailer Direct Import through various methods of data input, multiplying the administrative burden. In addition, a single shipment may include multiple version IDs of the same product, requiring manufacturers to implement processes that ensure all relevant IDs are supplied with the certification information, further increasing the administrative complexity and costs. Failure to comply will result in shipments being disrupted.
- The July 8, 2026 effective date applies to all products covered by CPSC certification requirements (except those in US Free Trade Zones). As yet, only limited Alpha and Beta testing with small numbers of participants have been conducted. While these limited programs have helped identify some potential pain points (including several that remain unaddressed), the programs are not able to predict or ensure that the system will function correctly at the time of eFiling launch, when all certification requirements are intended to be managed therein. Further, there appears to be no disaster recovery plan in the event of a system failure. Without such a plan, manufacturers/importers of record would face potentially crippling delays in timely importation of goods, significantly disrupting commerce and supply chains.
- The lack of a data security process and firewalling within the eFiling system remains of significant concern, as described by numerous businesses in public comments filed. Entities granted access to the Product Registry are given open access, including the ability to access confidential business data relating to other entities within the same area. For example, if a retailer gives access to company A within the Product Registry, companies B – Z who also have that access will be able to view that proprietary information. While this has been acknowledged by CPSC staff as an issue, firewalling and data privacy remain areas to be addressed prior to the effective date.
- CPSA requires that certification is made to applicable "…rules, bans, standards or regulations…"[8]. The eFiling rule changes the certification for toys and only toys, by requiring certification to *each subsection* of ASTM F963, layering on an

[7] Including The Toy Association comments https://www.regulations.gov/comment/CPSC-2013-0017-0097
[8] 15 USC §2063

unnecessary level of complexity beyond what is required by statute[9]. This change, while appearing to be subtle, adds a significant additional burden to the generation of CPCs for toys by requiring manufacturers to manage and track every applicable subsection for each product instead of the rule itself.

- The eFiling rulemaking includes inaccurate cost/benefit analyses to the detriment of manufacturers and importers of record as described in Section C below.

Opportunities to reduce burdens and costs related to the eFiling Rule:

- *Implement unique, single identifiers for individual CPCs and GCCs in place of multiple identifiers.*

- *Implement a staggered implementation period and a disaster recovery plan to ensure an orderly, systematic roll-out of the eFiling Rule and to avoid disruptions and delays in product shipments.*

- *Ensure data privacy and security for confidential business information (CBI) prior to the rule's effective date.*

- *Remove the additional requirement for toys to certify to individual sections of ASTM F963, as this is not a requirement of CPSA nor in previous certification requirements for toys.*

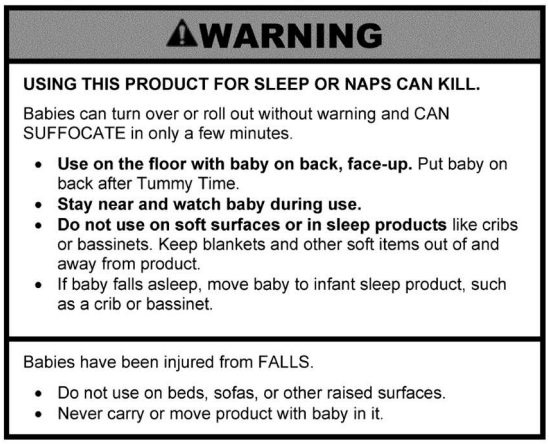
2. **The Infant Support Cushions Final Rule[10] has been implemented with an overly broad scope encompassing product categories, including some toys that have no causal relation to the incident data leading to the rule**.

   The final rule for Infant Support Cushions took effect on May 5, 2025. The Toy Association submitted comments in response to the NPR[11], outlining concerns related to the overly broad scope proposed (and subsequently implemented) by CPSC, which encompassed product categories that bore no direct relation to the original products leading to the rule being promulgated.[12]

   The final rule defines infant support cushion[13] so broadly that many types of products - including toys - that would otherwise be out of scope *and are unrelated to any causal data relating to infant suffocation cases*, are subject to an unnecessary and burdensome regulation. For toys, this includes any and all playmats and 'tummy time' toys, intended for play versus sleep or other forms of childcare.

[9] *Id.* While the CPSC webpage previously recommended, as recently as December 2024 (https://web.archive.org/web/20241214194404/https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Lab-Accreditation/Rules-Requiring-Third-Party-Testing), that CPCs "…**should** also include the individual sections…" (emphasis added), the same web page now makes the section certification appear to be mandatory in that a CPC "…**must** include the individual sections…" (emphasis added) (https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/Lab-Accreditation/Rules-Requiring-Third-Party-Testing).
[10] FR Vol 89, No. 213, p 87467
[11] Docket # CPSC-2023-0047-0001 https://www.regulations.gov/comment/CPSC-2023-0047-0013
[12] FR Vol 89, No. 79, p 30295
[13] "…an infant product that is filled with or comprised of resilient material such as foam, fibrous batting, or granular material or with a gel, liquid, or gas, and which is marketed, designed, or intended to support an infant's weight or any portion of an infant while reclining or in a supine, prone or recumbent position."

In addition to the significant compliance and testing costs associated with the rule, such products intended for 'tummy time' play are also subjected to an overly prescriptive and inaccurate mandatory warning statement to be placed on the product:



⚠WARNING

USING THIS PRODUCT FOR SLEEP OR NAPS CAN KILL.

Babies can turn over or roll out without warning and CAN SUFFOCATE in only a few minutes.

- **Use on the floor with baby on back, face-up.** Put baby on back after Tummy Time.
- **Stay near and watch baby during use.**
- **Do not use on soft surfaces or in sleep products** like cribs or bassinets. Keep blankets and other soft items out of and away from product.
- If baby falls asleep, move baby to infant sleep product, such as a crib or bassinet.

Babies have been injured from FALLS.

- Do not use on beds, sofas, or other raised surfaces.
- Never carry or move product with baby in it.

This mandatory warning statement directs the consumer to use the product in a manner contrary to the intended 'tummy time' use (on floor with baby on back) and contrary to advice of medical and child development experts who advise 'tummy time' play as important to support a baby's growth and development[14]. It also requires inclusion of alarming and unsupported language to consumers, that use of the product can kill -- without applicable data for these product types or to support such a statement.

Further, the rule unnecessarily requires that the entire perimeter of warning labels must be attached to the fabric of the product[15] by being sewn onto the fabric on all sides, even though sew-in labels (SILs) are regularly attached by one side only and are recognized as being permanently attached to the product. The issue becomes more acute when considering that products are often made for multiple markets, as well as for multilingual markets; when the warning is required to be present in more than one language, the area taken up by the warning label at least doubles when language parity requirements are considered. Additionally, the rule requires that all warnings be 'conspicuous and permanent'[16], including "…visible, when the product is in each manufacturer's recommended use position"[17]. Toy items such as 'tummy time' playmats can and often do have more than one 'right' side ('face') intended for use, meaning that the large warning label is required to be repeated on the second face, since in each use it is required to be affixed around the entire perimeter. If the warning label were permitted to be affixed in a permanent manner along one edge only along a seam (as is the case for SILs), the same label could be applied off of the play area and, double-sided, visible in either orientation. Additionally, this would allow for the warning, even if in more than one language, to be present in a safe, permanent and visible manner without the burden of taking up the (play) area of the product itself.

Opportunities to reduce burdens and costs related to Infant Support Cushions:

- *Review and revise the definition to focus on the product type(s) actually associated with causal-based incident data.*

[14] https://www.uclahealth.org/sites/default/files/documents/Tummy-Time-Brochure.pdf
[15] 16 CFR 1243.3(f)(4)
[16] 16 CFR 1243.6(d)(3)
[17] 16 CFR 1243.2

- *Accordingly, products designed for 'tummy time' play should not be forced to carry statements that advise consumers to use the product contrary to the proper manner of play, nor unsupported statements that are unduly alarmist and unsupported by data.*

- *Revise the on-product warning label requirement for all defined products to allow the use of labels that are permanently attached to the product but not necessarily sewn down on all sides, e.g., utilizing a side seam (SIL).*

3. The CPSIA Phthalates Testing requirement continues to require manufacturers to repeatedly test product and material categories that do not contain phthalates.

The Consumer Product Safety Act (CPSA)[18] as amended following CPSIA[19], established requirements for specified phthalates in toys and childcare articles, and CPSC issued a Final Rule for phthalates[20], effective April 2018, including rules for mandatory third-party testing.

In response to concerns regarding repeated and unnecessary testing resulting from the phthalate requirement at the time, and since numerous materials/material types do not include phthalates, while some others cannot function properly *with* their inclusion, CPSC's Phthalates Testing rules[21] exempt from third-party laboratory testing certain materials recognized to be unlikely to present phthalates at levels exceeding the federal requirements. The thresholds for including specific material types (and conditions), however, are limited in scope and, in effect, some materials that are not likely to include phthalates are still required to be tested (such as EVA, nylon and polycarbonate). Additionally, since the testing relief applies only to unfinished or untreated versions of the material categories (wood/engineered wood products/fibers), the burden relief provided is limited since *any treatment or finishing* can be considered to invalidate the exemption.

The burden of unnecessary testing is exacerbated by the fact that the basic costs associated with phthalate testing are already more expensive than other tests. This fact has been recognized by CPSC[22], although actual costs are largely underestimated by the agency. Nonetheless, the sizable burden is then compounded after the required initial phthalate testing of components and materials by repeated testing for the same material as part of the regular annual re-testing.

Importantly, neither CPSIA nor 16 CFR 1307 provide clarity on what would be considered to be a 'plasticized component part of a children's toy' and without a framework for assessment of what would and would not fall under the term 'plasticized', all plastic items not specifically exempt must then also be considered to fall under the scope and burden of otherwise unnecessary testing, with test laboratories having to take the most conservative position absent clear direction.

Opportunities to reduce burdens and costs related to the existing phthalates rules:

[18] 15 USC §§ 2051 - 2089
[19] CPSIA Section 108, 15 USC §2057c
[20] 16 CFR 1307
[21] 16 CFR 1308, 16 CFR 1252, 16 CFR 1253
[22] FR Vol 85, No. 105, p 33019, at $125 to $350 per component tested.

- *Clearly define what is a 'plasticized component part' to ensure non-plasticized materials are not needlessly tested.*

- *Implement a new review cycle to identify an expanded list of materials and material types that can be excluded from phthalate testing and extending the exemption beyond untreated/unfinished materials.*

B. Recent CPSC-Proposed Rules & Regulations

4. Recent CPSC NPRs bypass the consensus-based standards development process, without valid incident data to support that the proposed rules are appropriate or reasonable.

CPSC currently has three published NPRs that would impact toys (button and coin cell batteries in toys[23]; water beads[24], and neck floats[25]) even though the products in the latter case are not sold as toys.

Among the burdens posed by these NPRs, are that they each propose new unilateral requirements to be applied directly to 16 CFR 1250 instead of following the consensus review process and approval within ASTM F963, as directed by Congress under CPSIA, All three are also examples where CPSC-proposed actions appear inconsistent with the science- and consensus-based regulatory development process that has been a hallmark of the US regulatory approach for toys. Instead, the NPRs demonstrate an apparent change in practice by the Commission and CPSC staff in a manner that attempts to bypass or disregard ongoing standards activity, impose unilateral requirements developed in isolation and which appear to support pre-determined positions, ignore stakeholder input and misrepresent or misapply incident data. These proposed requirements threaten significant new regulatory burdens on manufacturers by unnecessarily imposing redundant test requirements and excessive labeling and warnings that ignore proven and effective requirements.

Regulatory burden concerns specific to these NPRs are outlined in this section. Additional process concerns that are applicable across various CPSC actions are listed in Part C of this document.

Button and coin cell batteries

Congress passed Reese's Law[26] in 2022, regarding hazards associated with button and coin cell batteries in consumer products and requiring CPSC to promulgate rulemaking to address the identified hazards across a range of consumer products, however, in doing so, Congress recognized that batteries in toys were already effectively protected under ASTM F963 *and expressly exempted toys from the scope of the law and subsequent rulemaking.*

CPSC implemented Reese's Law with rulemaking, expediting the publication through a Direct Final Rule, at 16 CFR 1263, in September 2023, incorporating by reference a newly published consensus standard, UL 4200A-23. It is important to note that this UL

[23] FR Vol 89, No. 156, p 65791
[24] FR Vol 89, No. 174, p 73024
[25] FR Vol 89, No. 224, p 91586
[26] Pub. L. 117-171, § 5, Aug. 16, 2022, 136 Stat. 2096

standard had only just been revised one month prior to incorporate the NPR's proposed test and labeling provisions (which themselves were compiled from pulling individual 'most strict' requirements a number of other standards without applying a scientific analysis for redundancy or applicability), and so UL 4200A-23 was not peer-reviewed, subject to stakeholder comment, or yet in common use. Even though the rulemaking for Reese's Law expressly exempted toys, The Toy Association provided comments on the NPR[27], identifying areas of concern related to misrepresentation of data and assertions made by CPSC staff as well as the manner of the determination of test requirements made therein.

Disregarding the express exemption for toys under Reese's Law, CPSC published an NPR for button and coin cell batteries in toys[28] on August 14, 2024, proposing to extend its regulations for non-toy button and coin cell batteries to toys. The Toy Association submitted comments[29], identifying a number of concerns related both to the accuracy of the information presented in the NPR (including that products in the dataset provided by CPSC are not actually toys by definition) as well as the redundancy of the new and more onerous requirements being proposed on a product category without regard to the existing and effective mandatory requirements for toys (or the fact that ASTM F963 was updated in 2023 and approved by the Commission and incorporated by reference in 16 CFR 1250). CPSC staff's view that it can amend such mandatory standards based on its own view of stringency, while disregarding contrary, specific exemptions set forth directly by Congress in the more recently adopted Reese's Law, cannot be supported as justifiable. Use of this NPR as a regulatory process to bypass express congressional intent, under the guise of amending the existing toy standard, cannot stand. Furthermore, taken as a whole, the proposed design, testing and labeling requirements, instead introduce significant design, production and testing costs without improving safety.

Under its continual review process, the ASTM F15.22 Subcommittee on Toy Safety, via its designated task group on batteries, has continued to work to determine which of CPSC's proposed revisions are supported by verified data, are relevant and appropriate, unnecessarily burdensome or redundant. Unvalidated information being used as the basis for the proposed rulemaking does not meet the thresholds needed, nor the scientific basis, for changes in most instances. Unfortunately, CPSC staff is moving to bypass the scientific consensus process by instead imposing its own unilateral requirements which ignore the existing requirements related to battery accessibility as agreed by consensus within the ASTM process.

Water Beads in toys

Water beads are a sub-category of expanding materials that expand in size when exposed to liquid such as water. The hazard of expanding materials has been recognized and requirements incorporated in ASTM F963 since the 2016 edition of the standard[30] including Commission approval with each new version. Water beads are inherently small parts, which by definition are not suitable for children under three years of age and must be labeled accordingly. Even with this in mind, the existing expanding materials requirement in ASTM F963 applies an additional safety margin to avoid a

[27] https://www.regulations.gov/comment/CPSC-2023-0004-0054
[28] FR Vol 89, No 156, p65791
[29] https://www.regulations.gov/comment/CPSC-2024-0023-0041
[30] ASTM F963-16

potential intestinal blockage (the primary hazard condition as determined in the incident data and the prevailing medical and CPSC staff opinion at the time) for a fifth percentile 18-month-old child.

It bears noting that water bead technology is also present in non-toy applications, including floral design & horticultural, crafts, medical & health items and these non-toy water beads may be commonplace in the home environment. However, similar to the scenario observed by Congress for button and coin cell batteries, of all the consumer uses for this product category, only water beads included in toys have had requirements, mandatory or otherwise. Further, despite the fact that these products are not appropriate for children under three years of age, of the injury data provided by CPSC to the F15.22 task group[31] and accompanying the NPR, *only children aged younger than 18 months* experienced intestinal obstruction injuries from toy water beads[32]. Intestinal obstructions observed in children older than this age occurred with products that were not "toys" and not subject to compliance with the toy standard.

Based on information from CPSC staff, the ASTM F15.22 water beads work group has been working to develop and propose an additional layer of safety specifically for water beads including potential additional test requirements to address the intestinal obstruction hazard even for younger children (below 18 months of age) and labeling requirements for other potential hazard conditions. Despite the ongoing work to update the ASTM F963 toy standard, with the NPR CPSC has moved instead to promulgate requirements that are unsupported by the data available.

The Toy Association submitted comments on the water beads NPR[33], detailing areas of concern. Notably, the NPR creates a *de-facto* ban[34] on toy water beads (only), by setting requirements that are technically unachievable. By extracting a critical element of the globally recognized *definition* of an expanding material (that it expands by more than 50 % in any dimension), CPSC has, without evidence to support the assertion of appropriateness or effectiveness, instead applied it as a *performance requirement* (i.e., that water beads shall not expand by more than 50 %). Not only does this introduce an inherent contradiction (that an expanding material *shall not expand to the extent that it actually becomes an 'expanding material', by definition)* but it is not possible to meet this requirement with the materials used for water beads. CPSA outlines a process for CPSC to implement a ban of a consumer product[35], however CPSC appears to truncate that process. CPSC is aware of the impact from this proposed requirement[36], but in lieu of offering an economic feasibility assessment of such a ban on companies, instead recommends repurposing product for non-toy applications[37]. In effect, CPSC inexplicably offers an alternative, presumably without assessing the potential safety implications of repurposing product the agency appears to be aiming to 'ban' and redirecting it to other

[31] https://www.cpsc.gov/s3fs-public/Letter-to-ASTM-on-Expanding-Water-Beads-6-20-23.pdf?VersionId=r3ozcmlQnxz74Gp.FXx2PngBYTykjCRc
[32] Toy Association comments https://www.regulations.gov/comment/CPSC-2024-0027-0129 p 3
[33] https://www.regulations.gov/comment/CPSC-2024-0027-0129
[34] FR Vol 89, No. 174, p 73044 "However, the 50 percent growth limitation requirement is expected to result in all or nearly all water bead toys needing to be redesigned."
[35] 15 USC §2058
[36] FR Vol 89, No. 174, p 70343-70344 "The Commission assess it is likely that a substantial number of firms will incur significant costs from redesign, retooling, loss of sales, or the purchase and installation of new components. […] CPSC staff has not identified water bead products that currently conform to the 50-percent-or-less growth limitation specified on the proposed rule." and "Due to the uncertainty related to redesigning these products, CPSC staff cannot generate an estimate of the potential costs of the proposed rule."
[37] *Id.,* "... instead as agricultural or decorative home products.."

items that might be common in consumers' homes and a child's environment. If CPSC has determined that these products are not safe for children's toys, it is unclear how they would then be safe for other uses in homes.

Despite the presence of acrylamide monomer in common foods, CPSC has also unilaterally decided that acrylamide monomer, used as a building block in materials used in *some* water beads and which may be present at residual levels as an unreacted monomer during the polymerization process, needs to be tested using a novel method developed by CPSC without review or assessment by any other entity, to a threshold level that appears to be significantly lower than can be present naturally within foods[38], and which is able to be readily metabolized by the body[39]. This novel testing would introduce significant testing burdens, including test requirements for water bead materials that are not likely to have residual acrylamide monomer (i.e., those made from polymers that do not have acrylamide as a raw material). Further, CPSC has not established that residual levels of acrylamide monomer are present at a level that would support a test requirement. Indeed, data provided by CPSC illustrated that the overwhelming majority of samples evaluated *did not present elevated levels of acrylamide monomer*; and of all the samples in CPSC's test, only two larger bead types were nominally deemed by CPSC to have levels 'of concern'. Notably however, water beads of such size would not be permitted for sale as toys using either the water bead size under consideration by the ASTM task group or the size proposed in the NPR, invalidating the relevance of those samples with hypothetical levels 'of concern' to CPSC.

As with other matters, it is important to only seek regulations within 16 CFR 1250 that specifically and clearly fall within the scope of ASTM F963 for defined toys.

Neck Floats

In 2021, CPSC staff notified ASTM F15.22 of concerns related to certain 'bath toys' as described by CPSC). However, as incident information was eventually made available, it became apparent that the products of CPSC's concern were specific to infant neck floats, which are inherently not toys, since they are designed not as playthings with which a child interacts, but to provide buoyancy for an infant in water, under an adult's supervision (and, thereby, intended to aid in the care of a child, rather than to engage a child in play). This was discussed with CPSC staff over several meetings, and the determination that these were *not toys* was supported by three leading CPSC-approved third-party test laboratories, via informal outreach, as well as CPSC's own characterization of such items as 'infant flotation rings' [40] in a 2022 CPSC notice to consumers about the products; notably, the term 'toy' was not used anywhere in that warning. Similarly, CPSC's Regulatory Robot[41] on the CPSC website identified that 'Children's Bathing and Feeding Products' was a suitable classification for this product type; and a new ASTM committee tasked with developing standards for buoyancy aids including a broad range of products intended for use in water, has arrived at the same

[38] Toy Association comments, https://www.regulations.gov/comment/CPSC-2024-0027-0129, page 7
[39] https://link.springer.com/article/10.1007/s00204-024-03798-z
[40] November 2022 CPSC Warning to Consumers https://www.cpsc.gov/Warnings/2023/CPSC-Warning-Stop-Using-Otteroo-LUMI-and-MINI-Infant-Flotation-Rings-Due-to-Drowning-Hazard-One-Infant-Death-Reported
[41] https://business.cpsc.gov/robot/decision

conclusion -- that the infant neck float product category does not fall under the definition of 'toy'[42].

Despite the weight of evidence and undeterred, CPSC staff have arbitrarily made the assertion that ASTM F963 is deficient since it does not cover such products and proceeded to publish an NPR to add requirements for infant neck floats directly to the mandatory toy standards at 16 CFR 1250. CPSC is asserting that, because children play in the bath or pool, anything used in (the play) environment is a *toy*. The closest analogue to these flotation items in the infant environment may be infant bath seats, in which an infant may also 'play' in the aquatic environment (under adult supervision), however the intent of the product is to facilitate an adult's care of the child. Accordingly, bath seats are regulated as infant products, not toys. The Toy Association again submitted comments on the NPR[43], detailing these concerns.

Opportunities to reduce burdens and costs related to proposed rulemaking:

- *Revisit NPRs which threaten to impose extensive and highly disruptive design, manufacture, labeling and shipping costs (in some cases impossible to meet) on product categories that are demonstrably safe (button and coin cell batteries in toys), already under review within the consensus standards process with risk-based standards being considered (water beads in toys), and/or are not toys (neck floats)*.

- *Empower CPSC to return to active and collaborative engagement within the consensus standards community, as appropriate (ASTM F15.22 for button & coin cell batteries and water beads, F15.07 for Buoyancy Aids for Children).*

C. Changes in CPSC Regulatory Practice

This section details the concerns affecting the toy industry related to new or emerging regulatory practices that have been observed in recent years from CPSC and which present increasingly onerous regulatory burdens.

CPSC's previously applied data-driven and risk-based analyses have been replaced by a lack of verified data and scientific risk assessment, resulting in data referenced by CPSC that is often not accurate or applicable to the arguments being made.

An increasing concern through recent CPSC regulatory activity (whether or not relating to toys) is that that the data used by CPSC to support proposed and implemented actions are in many cases inaccurate to the specific product categories, not applicable to the hazard conditions cited, and/or misrepresented by being treated as causative when the data cohorts such as the National Electronic Injury Surveillance System (NEISS) are inherently associative. A significant number of comments submitted in response to NPRs in recent years identify these inconsistencies and concerns, including those of the Toy Association,[44] for toys as well as those for the Reese's Law NPR[45], however this practice continues to underly much of the agency's recent rulemakings. Examples include recall

[42] ASTM F15.07 Buoyancy Aids for Children
[43] https://www.regulations.gov/comment/CPSC-2024-0039-0146
[44] https://www.regulations.gov/comment/CPSC-2024-0023-0041, https://www.regulations.gov/comment/CPSC-2024-0027-0129, https://www.regulations.gov/comment/CPSC-2024-0039-0146
[45] https://www.regulations.gov/comment/CPSC-2023-0004-0054

information related to non-toy items (per CPSC's own recall database) cited in the assessment of button and coin cell toy recalls [46] as well as misrepresentation of existing ASTM F963 requirements for button and coin cell battery toys[47] and water beads[48].

Additionally, CPSC staff have significantly underestimated the cost of implementing the proposed rulemakings across various NPRs, usually by orders of magnitude and often accompanied by erroneous or demonstrably incorrect assertions and assumptions. Where cost estimates are provided, they lack the technical and financial background or assessment to adequately estimate the real-world financial and logistical burdens associated with implementation of the applicable rulemaking.

For eFiling, CPSC's analysis estimates for the total burden projects a cost estimate of $43.70 per company, achievable in a *total* of 1.3 hours work, based on an estimated average of 36 seconds work per CPC[49]. Even without taking into consideration recognized factors within the rule (such as Application Programming Interface (API) development, implementation and maintenance, ongoing management of CPC requests from Importers of Record, training of staff and other associated costs), this estimate bears no resemblance to actual costs of implementation.

Labeling costs are repeatedly listed by CPSC staff as being $0.01 per unit of product sold[50]. This value does not even represent the *material cost* alone for a label to be applied onto an existing package ('overlabel') which can be around $0.05 per label and another $0.05 cost to apply, plus added costs related to design, labor, rework and warehousing, among others. Further, an overlabel is a short-term solution only; actual labeling changes include re-design of packaging layout (including potential changes to the sizes to accommodate the new label area), as well as new printing and dies, wastage of existing printed package and logistical costs to manage new versions in the supply chain. These are significant costs imposed on manufacturers of any size, yet comments provided to CPSC have flagged these misrepresentations[51], to no avail.

As noted for water beads previously in this document, in at least one instance, CPSC staff has also declined to provide *any* cost analysis and by withholding even this level of review, further increases the regulatory burden on impacted manufacturers.

CPSC has long recognized that regulatory effectiveness includes active engagement in the consensus standards process (as directed by Congress under CPSIA) and incorporating stakeholder input. Recent rulemakings however bypass these opportunities, pushing instead for pre-determined conclusions based on the concept that 'the most' strict is the minimum level of acceptance, and disregarding existing standards or equivalencies.

CPSIA Section 106[52] recognized ASTM F963 as appropriately protective for toys, and specifically directed CPSC to incorporate it as a mandatory consumer product safety rule, and outlined a regulatory process under which future updates to the standard could be considered and adopted. However, CPSC has on recent occasion employed an

[46] https://www.regulations.gov/comment/CPSC-2024-0023-0041, p 7
[47] *Id.,* p 8
[48] https://www.regulations.gov/comment/CPSC-2024-0027-0129, p2
[49] Toy Association comments, https://www.regulations.gov/comment/CPSC-2013-0017-0097 p 9
[50] *Id.,* FR Vol 89, No. 224, p 91610 as examples
[51] Toy Association comments, https://www.regulations.gov/comment/CPSC-2024-0027-0129 p 14 as example
[52] 15 USC §2056b

approach instead that bypasses the consensus standards process (and disregards existing or in-development consensus-based standards) to support pre-determined CPSC staff-recommended changes. In these cases, staff have cited a novel interpretation and application of CPSIA Sections 104 and 106, as rationale for an approach that considers only (changes) they have deemed to be the most strict or strongest.

Further, CPSC now appears to use the term 'feasible' to be analogous to 'possible' when applying the CPSIA phrasing of reviewing ASTM F963 for the "…highest level of safety for such products that is feasible."[53], rather than considering relevant factors, including cost, relative effectiveness, that do not necessarily hinge on maxima as the basis for effectiveness. This position is being taken despite the empirical evidence of the effectiveness of existing regulatory provisions that are not at the newly directed 'maximum' level that CPSC now applies. This ideological position disregards the equivalence of standards, which recognizes that different standards do not have to be identical in order to provide an effective and equivalent level of protection, by instead taking the position that any example of an individual requirement being 'stricter' than the other makes the other requirements or standards 'inadequate'.

The impact of this change in CPSC practice can be seen in the agency's approach to labeling of products (discussed separately below) as well as other examples of the regulatory burden it creates including:

- Citing a minor difference in (one) test method, CPSC has determined that the existing requirements for button and coin cell batteries in toys (e.g., ASTM F963, 16 CFR 1500.50 – 53) are 'inadequate,' without consideration that these comprehensive and protective test parameters that already exist for toys, are effectively protecting against a multitude of potential hazard conditions (e.g., small parts, sharp points, sharp edges, internal components becoming accessible during use).
- Pulling individual test requirements from available standards (whether or not relevant to the product category) in isolation and out of context with existing requirements, and layering new requirements in, without assessment for relevance or redundancy. (e.g., applying infant sleep product requirements applicable for cribs to toys reasonably intended for toddlers during supervised play).
- While the consumer product safety community holds a wealth of expertise, CPSC staff have recently taken to developing test requirements in isolation, utilizing CPSC's own interpretation of 'feasible' and without stakeholder involvement. Such test requirements, once 'proposed' in a published NPR, are treated as 'final' and not open for peer review or the incorporation of public comment from the NPR (e.g., for Infant Support Cushions[54]).

Recent **changes to labeling requirements** are an example in which CPSC has asserted the approach of recognizing only the *largest* existing regulated sizing as adequate for packaging labeling (and in some cases, on-product labeling as well). As an example, CPSC is extracting coloration and formatting *options* from the non-normative ANSI Z535.4 guidance document, and mandating those. This approach forces companies to only apply the prescriptive, mandated formatting when other potential coloration, format or sizing options could and do provide equally effective conveyance of

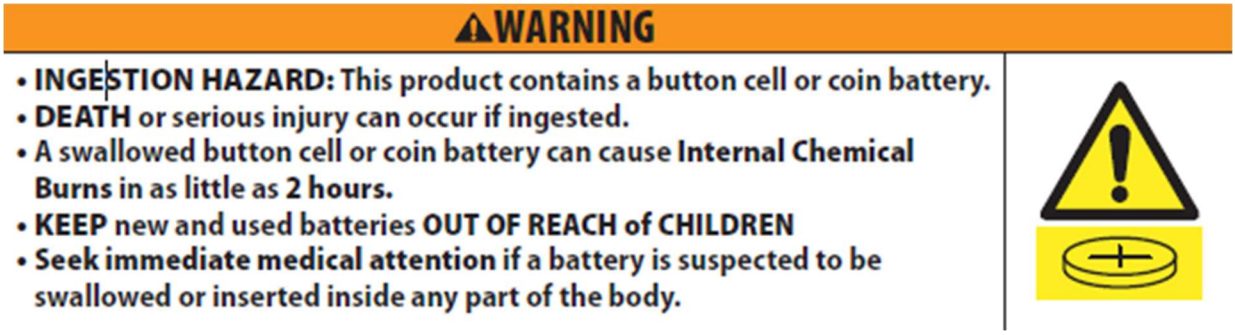
[53] *Id.*
[54] FR Vol 89, No.10, p 2551 & FR Vol. 89, No. 213, p 87467

the cautionary or advisory information. These excessive requirements run counter to existing warning statements and approaches, such as the Code of Federal Regulations 16 CFR 1500.19 which does not require specific coloration and permits flexibility relative to the product or package, for example; or ASTM F963 section 5.3 which, while it does specify minimum size text, does not require specific formatting nor text sizing to be equivalent to that of the small parts warning

Compounding the size and formatting issue, recent cautionary and advisory statements being mandated by CPSC are increasingly becoming longer (increasing the footprint of the warning statement) and compelled to carry mandatory wording that is alarmist and either questionable in accuracy[55] or outright inaccurate[56].

For example, compare the Federal Small Parts Warning statement, placed on the Principal Display Panel (PDP) of the packaging (i.e., main display panel), as shown below, to the Reese's Law Warning statement that follows it in the depiction below (using the same text height requirements):

⚠ WARNING:
CHOKING HAZARD—Small parts.
Not for children under 3 yrs.



As can be seen, the text alone for the battery warning statement, even without considering the space required for the additional symbol, requires a significantly larger area than the small parts warning. This is more pressing for smaller packages — even without considering when multiple warnings are required (such as a product that has button or coin cell batteries as well as other non-battery small parts so that both warnings are required), or multiple language and comparable size and format requirements. In many cases, especially for smaller packages that are common for toys, the packaging is simply not large enough to accommodate all of the mandatory statements without having to be redesigned and potentially increased in size (resulting in costs for change, wastage and increased shipping). For example, for a 30 square inch PDP (e.g. 5" x 6"), the button and coin cell battery statement alone will require over 10 square inches for placement[57]. For packages that include blister card or other formats to

[55] FR Vol 89, No. 10 'Using this product for sleep or naps can kill' on tummy time play mats.
[56] FR Vol 89, No. 174 "Children have DIED after swallowing water beads because beads blocked their intestines. Your child can die too.' For water beads that will not be large enough to cause an obstruction in the intestine due to mandatory size limitations.
[57] Toy Association comments https://www.regulations.gov/comment/CPSC-2024-0023-0041, page 11 and Appendix A

view the product as part of the selling face, placement becomes more difficult, if not impossible, without changing the size and layout of the package. The costs incurred to revise and enlarge packaging contribute to more expensive products without improving safety to consumers.

A change in CPSC practice relating to **compressed regulatory timelines** has also been observed and is creating new regulatory burdens, without a demonstrable increase in safety. Shortened timelines have included the minimum time to implement and enforce new regulations, whether by applying the minimum enforcement period permitted by statute, or when no mandate is present, by unrealistic and impossible to meet timelines.

As an example, in the implementation of the Final Rule for Reese's Law[58], even with CPSC staff *recommending* an 18-month 'enforcement discretion' period reflecting industry assessment of the time needed to effectively implement the significant changes to the product designs and supply chain[59], the Commission overrode the requested change and mandated a 180-day enforcement period. Additionally, the Rule was expedited using the 'Direct Final Rule' process, which under the Administrative Procedure Act is to be reserved for non-controversial regulatory change and withdrawn if 'significant adverse comments' are received within a certain timeframe[60]. While significant adverse comments were submitted in the Federal Register[61], these were disregarded by CPSC and no withdrawal occurred.

In the NPR on water beads, CPSC is proposing a 90-day effective date after being published in the Federal Register[62]. Even without considering that there is a *de-facto* ban within the NPR based on the changes that would need to be applied, it is simply not possible to implement the proposed changes within this time period, even if only for a labeling change.

Mis-categorizing non-toy products as 'toys', applying an overly broad interpretation of 'toy' inconsistent with the established scope.

CPSC has increasingly been seen to deviate from established and widely accepted definitions for product categories including, and specifically, toys. Incident and product data provided by CPSC for toy categories in recent rulemakings has included products that are not, or may not be, toys, such as fidget spinners and other novelty or non-toy items and has disregarded even CPSC's own determinations[63] and even citing such products in incident data as toy-related[64].

In addition to the mis-classification of infant neck floats detailed elsewhere in this document, recent examples of other changes in CPSC practice related to product categorization have included an assertion that color can be used to determine whether a product is a toy, even though it has already been shown that coloration that *may be*

[58] FR Vol 88, No. 182, p 65274
[59] https://www.cpsc.gov/s3fs-public/Reeses-Law-Implementation-Commission-Determination-Regarding-UL-4200A-2023-and-Draft-DFR-for-Button-Cell-or-Coin-Batteries-and-2-Draft-FR-to-Amend-Part-1263--Labeling-Requirmnts-for-Button-Cell-or-Coin-Batte.pdf?VersionId=PyTbnom1OemA3BWl9Z1lONzTlyqbcthW
[60] https://www.acus.gov/sites/default/files/documents/1995-04%20Pt.2%20Procedures%20for%20Noncontroversial%20and%20Expedited%20Rulemaking.pdf
[61] https://www.regulations.gov/document/CPSC-2023-0004-0088/comment
[62] FR Vol 89, No. 174, p 73042
[63] https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Fidget-Spinners
[64] Toy Association comments https://www.regulations.gov/comment/CPSC-2024-0023-0041 p 7

attractive to children does not necessarily determine whether a product (or category of product) is a toy[65]; and while this has been well-established within CPSC practice and understanding previously, CPSC has requested information to support the opposite assertion that coloration could be used to determine 'toy' applicability for water beads.[66]

Following due process requirements in enforcement.

U.S. manufacturers and brand owners should be afforded due process by agency staff, before issuance of unilateral stop sales, safety, or recall notices to their distributors/retailers or customers[67].

In addition, safeguards should be established to assure that parties subject to CPSC investigatory process can avail themselves of the right to a hearing, prior to unilateral, *ex parte* actions by agency staff against a US business or its products. Notwithstanding adherence to such existing requirements, the Commission should also establish an enhanced process to assure the material accuracy of public statements. Under the law, CPSC has an obligation to make sure that public safety information is not inaccurate or misleading regardless of whether or not the manufacturer is identified[68]. Disclosure responsibilities under CPSA apply to the CPSC, individual CPSC Commissioners, as well as CPSC employees, agents, and representatives. The public disclosure procedure "…shall apply whenever information is to be disclosed by the [CPSC], any member of the [CPSC], or any employee, agent, or representative of the Commission in an official capacity."[69]. The power to make a final determination as to whether a violation has occurred and whether to pursue enforcement rests with the Commission itself, not its Compliance Office which lacks authority to issue binding decisions on behalf of the agency[70].

Opportunities to reduce burdens and costs of practices:

- *Verified and accurate data underpins a reliable and responsible regulatory process. As a science-based agency, CPSC should recommit to a risk-based, scientific approach to regulation, incorporating a process of verifying incident data for applicability, accuracy and veracity prior to use in regulatory activity, including input from all stakeholders.*

- *Regulations can take differing approaches while providing comparably effective protection of consumers; this is an integral element of efficient regulation and reduces unnecessary regulatory burden. Prioritize a practice of assessing and recognizing equivalency of existing standards that may differ in approach, test parameters and/or the specifics of requirements, but provide comparable levels of effectiveness and protection.*

- *Accurate cost-benefit analyses ensure that potential rulemaking is effectively and transparently considered. Review all in-process and future rulemaking cost*

[65] Liquid laundry packets are colorful and acknowledged to be attractive to children, but are not considered to be toys.
[66] FR Vol No. 89, No. 174, p 73046
[67] See July 25, 2024, and May 22, 2025, correspondence from Roger Williams, Chairman of the House Committee on Small Business expressing concerns about unilateral actions that threatened the ability of some small businesses to continue operating alleging CPSC personnel violated the Consumer Product Safety Act.
[68] 15 U.S.C. § 2055(b)(6)
[69] 15 U.S.C. § 2055(d)(2)
[70] 15 U.S.C. §§ 1274(a)–(b), 2064(c)

estimates, to include input from impacted stakeholders, in order to ensure that relevant costs are estimated and assessed prior to regulatory implementation.

- *Clear and concise safety labeling ensures that important information is effectively conveyed to consumers. Review proposed warning statements and labeling for conciseness, accuracy and appropriateness.*
  Examples include:
  - *Use of clear, empirical and factual statements as opposed to speculative and alarmist statements,*
  - *Restoring application of ANSI Z535.4 to its intended "guidance" purpose as opposed to a prescriptive, mandatory format,*
  - *Incorporating scalable requirements such as sizing other than the largest established size available, and alternative placement in cases where there is insufficient space.*

- *Good regulatory practice recognizes appropriate timeframes in which to implement effective change. Conversely, unrealistic and constrained implementation timelines can increase cost and other burdens of compliance. While incremental or de-minimis changes can realistically and effectively be implemented in less than 18 months, larger changes that require design & tooling changes (product and/or package) as well as testing and supply chain management cannot be implemented without significant disruption, costs and exposure to potential punitive enforcement in the proposed timelines despite best intent to comply.*

Conclusion

We respectfully request that CPSC consider the points raised in this document in order to ease unnecessary burdens and costs that do not enhance safety. As recognized in the FR Notice of request for information, such regulatory burdens also threaten to "...restrict consumer choice, or reduce competition, entrepreneurship, and innovation—and thereby restrain the American economy…"[71] and should be addressed accordingly.

We offer these comments to assist the Commission in its effort to identify opportunities to reduce unnecessary burdens and to more efficiently focus agency resources, without impacting safety,[72] and in the agency's ongoing mission to protect the public from unreasonable risks from consumer products.

The Toy Association welcomes the opportunity for continued collaboration on regulatory policy, in *our shared goal of toy safety*. Please do not hesitate to reach out to discuss further.

Sincerely,

Jos Huxley
Senior Vice President of Technical Affairs
The Toy Association
jhuxley@toyassociation.org

[71] FR Vol 90, No.112, p 24792
[72] *Id.*

About The Toy Association and the toy industry:

The Toy Association is the North America-based trade association; our membership includes more than 800 businesses, from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs, and all members are involved in bringing safe & fun toys and games to children. The toy sector is a global industry of more than US $90 billion worldwide annually, and our members account for more than half of this amount.

Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard that has been adopted as a mandatory toy safety standard for all toys sold in the U.S. under the Consumer Product Safety Improvement Act (CPSIA) in 2008. It also serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children. The 2023 revision to ASTM F963 was accepted by the Commission and came into force in April 2024. The Toy Association continues to work with medical experts, government, consumers and industry to provide technical input to ensure that toy safety standards keep pace with innovation and potential emerging issues.
The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.