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

RE: Notice of Proposed Rulemaking - Safety Standard for Toys: Requirements for Neck Floats (Docket Number CPSC-2024-0039)

This letter is being submitted in response to the Notice of Proposed Rulemaking (NPR) relating to neck floats. These comments are provided on behalf of The Toy Association and its 900+ members, representing manufacturers, importers, designers, retailers, inventors, and toy safety testing labs, all working to ensure safe and fun play for families. Toy safety is the number one priority for the industry, as evidenced by the fact that the industry and The Toy Association have been global leaders in advancing toy safety for decades.

The Toy Association recognizes the benefit of the process of reviewing existing standards, updating the requirements as supporting documents are revised, and introducing new standards as and when safety data identifies potential hazards that are not addressed by existing standards. We also recognize that stakeholder input is an integral part of the rule process and appreciate the opportunity to provide these comments for consideration. As such, we welcome the opportunity to provide the following input related to the proposed rulemaking regarding infant neck floats, as published in the Federal Register¹.

The Toy Association does not dispute, per se, the need for additional requirements to be developed for the product category of infant flotation devices ('neck floats'). However, as outlined in this document, we believe that CPSC has inappropriately categorized these products as 'toys' when they are not. With this approach, CPSC has proposed to bypass the consensus-based, scientific process by applying the pre-supposed (but unsupported) position that this product category falls under the definition of 'toy' and, following on this faulty premise, proposes unilateral requirements directly to the toy regulations at 16 CFR 1250.

There are significant concerns presented by this novel approach including, most critically, the concern that such action would be misleading to consumers, and while the NPR aims to make these infant flotation products safer, this approach risks an opposite effect instead.

We underscore this most critical concern within these comments and the likely unintended consequences of the regulation, as proposed. Additionally, these comments outline both

¹ FR Vol. 89, No. 224, p 91586

procedural and technical concerns, among them a series of statements that are neither correct nor accurate with regard to ASTM F963, aquatic toys and/or neck floats.

The Toy Association is respectfully requesting CPSC to reassess the determinations and intended actions outlined in the NPR accordingly.

Infant Neck Floats are not Toys²

The NPR states from the outset that the products it intends to regulate are within the definition of ‘toy’ and within the scope of the existing toy standard ASTM F963. We do not agree with this fundamental premise put forth by CPSC – the agency’s determination that infant neck floats are ‘toys’ and upon which CPSC bases its entire proposed rule, nor do we believe there is logical support for this position.

While footnote #2 of the NPR includes the definition of ‘toy’ per the existing and federally mandated ASTM F963³, it leaves out other relevant and determinative guidance from that standard (and elsewhere), and instead makes the presumptive determination that neck floats are toys. Importantly, this differs from numerous other determinations that neck floats (as described in the NPR) are not toys, including, among others⁴, relevant ASTM consensus committees, independent third-party labs (accredited for toy testing by CPSC) as well as extensive prior communication and discussion with CPSC staff on this topic.

Even CPSC’s own characterization of these products over time has been inconsistent. A November 2022 CPSC-issued “Warning” to consumers regarding a brand of neck float⁵ (similar to products described in the NPR) specifically referred to the items as ‘infant flotation rings’, as opposed to ‘toys’. Similarly, Commissioner Trumka’s accompanying statement specifically referred to these items as ‘baby products’,⁶ with neither document making any mention of ‘toy’ in their warning to consumers about the products. We also understand that the manufacturer of the product in question had reached out to the Small Business Ombudsman at CPSC prior to manufacturing the product, and was advised that the product as described (and subsequently marketed) would not be considered to be a toy. Indeed, the CPSC website currently suggests via its Regulatory Robot tool ‘Children’s Bathing and Feeding Products’ as a likely more suitable categorization for these products⁷.

The ASTM consensus community has been engaged with CPSC for some time in discussions related to products intended for use by children in water. While the NPR states that “...since August 2021, CPSC staff has been corresponding with the relevant ASTM Subcommittee and task group to discuss hazards associated with neck floats...”⁸, it is important to note that the subject of the CPSC correspondence⁹ cited was actually described as ‘bath toys’, without images of the products of concern to CPSC at that time. The technical working group convened under ASTM F15.22 Subcommittee on Toy Safety in response to that correspondence and,

² For additional information related to the definition of “toy” and scope of the toy safety standards and regulations (ASTM F963 and 16 CFR 1250, respectively), see also appended to this document, Responses of The Toy Association to CPSC Questions (A and B).

³ “Any object designed, manufactured, or marketed as a plaything for children under 14 years of age.”

⁴ U.S. Food & Drug Admin., Do Not Use Baby Neck Floats Due to the Risk of Death or Injury: FDA Safety Communication (June 28, 2022), available at <https://www.fda.gov/medical-devices/safetycommunications/do-not-use-baby-neck-floats-duerisk-death-or-injury-fda-safety-communication>.

⁵ <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>

⁶ <https://www.cpsc.gov/About-CPSC/Commissioner/Richard-Trumka/Statement/Otteroo-Infant-Neck-Floaties-Pose-Drowning-Hazard>

⁷ <https://business.cpsc.gov/robot/decision>

⁸ FR Vol 89, No. 224, p 91587

⁹ ‘8-4-2021 Letter to ASTM Bath Toys’ and ‘8-11-22 Letter to ASTM Bath Toys II’

without product evidence to the contrary, took the assumption that the products of concern were indeed toys and engaged with CPSC accordingly.

In good faith, and based on input from CPSC, the technical working group continued to be engaged with CPSC for some time. Following numerous discussions and work (including even a proposed initial draft that attempted to address ‘aquatic toys’ as the task group understood at the time) a March 2023, ASTM F15.22 aquatic toys work group meeting, however, revealed there was conflicting information from CPSC staff and that there did not appear to be agreement or common understanding as to scope of the work. Subsequent to that meeting, CPSC staff confirmed that the products of concern related to neck flotation devices used with children under 4 years of age.

With that clarity, and upon further review, it was identified that this specific group of products *only* provided a means of flotation for use by adults in their care of infants, and the principal exemplar provided (similar in design to Otteroo products related to the November 2022 CPSC-issued “Warning”) are not marketed as toys. As such, while these items may be used when playing in water, the items themselves were not intended to entertain or engage a child in play (with the item itself) and therefore, under the ASTM F963 standard, would be outside the scope of the ‘toy’ definition and the toy standard.

This determination was discussed in a meeting between CPSC staff and the ASTM task group chair in December 2023¹⁰. As an example, it was noted that infant neck floats are comparable to other items that are used while playing in water but are not intrinsically toys, such as infant bath seats¹¹ and other items.

In the course of ASTM work on this subject, informal outreach was made to three major testing labs (all are CPSC-accredited for toys and children’s products¹²) specifically related to neck floats; notably, all three labs indicated that neck floats would not be considered toys under ASTM F963. Some labs elaborated further, indicating that infant neck floats are not toys as they do not contain an element of play, play features, or play value, and, as such, would not be subject to the toy standards but would be considered children’s products instead. It was appropriately noted however, that if a toy feature were included, such as a squirt gun attached to and sold as part of a float, then the toy standard (and definition of ‘toy’) would apply to those feature(s). Further, ASTM F32 has standards covering items that fall within requirements set up by the US Coast Guard (USCG) and refer to several CFR codes. Water wings and neck floats are not deemed to fall under the definition of personal flotation device as a ‘life saving device’.

An EU guidance document for water use items¹³ that provides examples of what are considered to be ‘toy’ or ‘non-toy’ items under the European regulatory framework is also inconsistent with the CPSC opinion. Ironically, the guidance document was among the references specifically cited and recommended by CPSC as an exemplar during the ASTM standards work, and while CPSC staff indicated a willingness to align with the EU guidance,¹⁴ that guidance is directly contrary to what CPSC has proposed in the NPR in that the EU guidance document explicitly

¹⁰ In-person meeting held at CPSC Rockville, MD facility, December 5th, 2023

¹¹ ASTM F1967-19 Standard Consumer Specification for Infant Bath Seats.

Scope 1.1 This consumer safety specification establishes performance requirements, test methods, and labeling requirements to promote the safe use of infant bath seats. Products commonly referred to as bath rings also are included in the scope of this specification. Traditional infant bath tubs that are used to bathe an infant are not within the scope of this standard.

¹² [List of CPSC-Accepted Testing Laboratories | CPSC.gov](#)

¹³ Guidance Document No.7 on the Application of Directive 2009/48/EC on the Safety of toys
<https://ec.europa.eu/docsroom/documents/57194>

¹⁴ Email correspondence from B. Mordecai to J. Huxley 12/7/2023 and 12/12/2023

states that neck rings, as well as other items such as water wings, are not considered to be toys.

Of course, not all products are ‘children’s products’ by definition; nor are all ‘children’s products’ necessarily toys. It also follows that there are numerous items intended for ‘aquatic’ use, which may colloquially be referred to as ‘toys’, that do not qualify as toys under the federally mandated definitions and scope of the toy standard (at ASTM F963 section 3.1.91 et. al.), and as such, would be outside the purview of the toy standard. Importantly, additional factors, among others, in determining whether an item is a ‘toy’ are whether it is “...intended primarily for children...” (from the definition of ‘children’s product’ in federal regulations¹⁵, under which toys are one subgroup); and its intended use as ‘a plaything’ which indicates an item with which the child *actively* plays, rather than an item that simply is present or used during the process of play.

Infant neck floats are more akin to baby bath seats, infant bath tubs, and infant car seats or carriers, which are all items intended to be used by a caregiver in the care of a child. Notably, these products are actually aimed at adults as the primary consumer and caregiver, to facilitate the care of infants and young children (versus aimed directly at the child themselves as the sole user).

These items aid a caregiver in the care of an infant, but that does not make them “toys” by definition. Each of these examples are subject to their own safety standards outside the scope of the ASTM toy standard and 16 CFR 1250. Consistent with this, CPSC’s Regulatory Robot tool categorizes such product categories as children’s products and the respective standards that apply. The tool treats ‘Children’s Bathing and Feeding Products’ separately from ‘Toys’ and lists the applicable requirements for each; importantly, the toy safety standards and regulations are not listed as requirements for ‘Children’s Bathing and Feeding Products’.

Why this matters

These concerns are not merely a matter of semantics. The crux of our concern focuses on the unintended risk this approach likely introduces. Mischaracterizing neck floats as a ‘toy’ is not merely a technicality, but may present a serious, unintended safety risk, directly counter to the intent of the proposed regulation.

The aim of the NPR is to increase the safety of these products and of users. Key elements to making them safer, in addition to design considerations, include the raising of awareness and clear understanding amongst adult consumers of both the inherent concern related to drowning risk and the importance of proper use for these products (uninterrupted and hands-on parental supervision, age of the occupant, etc.). In calling these items ‘toys’, however, CPSC sends a conflicting message which will be confusing and misleading to consumers; one that implies that these are for children as the primary user -- rather than for the adults caring for a young child.

This risks creating a false sense of security for consumers. Characterizing infant neck floats as toys sends a message that these are primarily children’s products and safe for children, like other children’s ‘toys’, rather than properly emphasizing the unique risks and how the product should be safely used, i.e., only under direct and full-on supervision of an adult, and constant vigilance. Consumers may hear ‘toy’ and lower their guard towards drowning risk.

¹⁵ 16 CFR 1200 Definition of Children’s Product under the Consumer Product Safety Act

In effect, by taking the position that these items are ‘toys’, CPSC risks negating the NPR’s aim to reduce drowning risk and make these products safer – and may leave consumers at continued risk.

Additional concerns

In addition to the concerns and potential risk described above, CPSC appears to be taking the position that anything that may be present in a play environment or associated with potential play by a child is automatically classified as a toy. This position does not align with the established framework for ‘toys’, ‘children’s products’ and ‘general use’ products. We have noted above that the primary use of these products is by caregivers in the care of a child (in a water environment). The possible ancillary function that flotation may entertain or amuse the child and/or allows the child to play in water, does not make infant neck floats toys. However, by taking this novel position, the NPR is disregarding established precedence whereby a non-toy product, if it also has an intended play function, would additionally be subject to the toy standard as well as one or more other appropriate standards. The position taken in the NPR also would remove the clear determinations of the existing assessment framework since, following this concept, any item that may be played with by a child could be arbitrarily considered by CPSC to be a toy and subject to the mandatory toy standard, even if evidently not intended as such. This is not a logical or sustainable approach, nor would it necessarily make any product safer.

Existing ASTM F963 requirements for toys

The NPR erroneously states that “[ASTM F963] sets forth only minimal labeling requirements for aquatic toys such as neck floats.”¹⁶ While the mischaracterization of neck floats as toys has been detailed elsewhere in this document, this statement is in error by stating that ASTM F963 mandates ‘only minimal labeling requirements’. All toys that fall under the scope of ASTM F963 are subject to the requirements of the standard, and while the labeling requirements in Section 5.4 are the only requirements specific to ‘aquatic toys’ as defined in ASTM F963¹⁷, compliance with all applicable sections of the standard is required, not just the sections specifically cited for specific types of toys. CPSC knows this fact and enforces it on a daily basis; it is misleading to consumers and readers of the NPR to imply otherwise.

As has been communicated to CPSC previously and summarized in this document, the definition of ‘toy’ (and the pursuant definition of ‘aquatic toy’) in ASTM F963 does not support the position that a device that solely provides buoyancy support would be classified as a toy. While the NPR is factually correct in stating that ASTM F963 does not establish performance requirements or ‘adequate’ warning statements that would address potential hazard conditions associated with neck floats¹⁸, the statement is not relevant since such items do not fall under the scope of the standard in the first place.

The Consensus Standards Process

In addition to the work conducted in the technical task group under ASTM F15,22, and the subsequent determination by that task group that neck floats are not toys, the topic of neck floats has been discussed elsewhere within ASTM. Recognizing that such items are outside the scope of the ASTM toy standard, ASTM has been determining the appropriate standards

¹⁶ FR Vol 89, No. 224, p 91586

¹⁷ ASTM F963 section 3.1.4

¹⁸ FR Vol. 89 No. 224, p 91595

committee forum (and corresponding regulatory framework) for these products. As of the time of the writing of this document, ASTM F15 is in the process of forming a separate technical task group with the intent to consider and develop an ASTM standard to encompass non-USCG buoyancy/flotation devices intended for children under 14 years of age, and which would include infant neck floats under a broader scope than is currently proposed in the NPR.¹⁹ As such, we recommend that CPSC pause its work related to the NPR on neck floats and invest its resources in the work being undertaken on the newly formed ASTM work item in the designated consensus forum.

Conclusions

The Toy Association does not dispute (and in fact, agrees with) the need for requirements to be developed for this product category but the toy standard is not the appropriate channel to regulate this product category. We do not believe these products have been appropriately categorized as ‘toys’ by CPSC, nor do they belong in the toy standard or in toy regulations at 16 CFR 1250, as proposed, for the reasons stated herein.

The novel approach proposed by CPSC in the NPR poses numerous concerns, with one of the most troubling being the idea that CPSC is proposing an approach that is counterintuitive and may actually add potential risk for consumers, contradictory to the aim of the NPR. Among the actions needed to improve the safety of these products is ensuring that users understand the potential risks and instructions for proper usage (including the fact that these are intended for use by adults in the care of a child, and that continuous, hands-on, adult supervision is needed). However, mis-categorizing these items as ‘toys’ implies they are primarily for children and sends a mixed message to consumers that undermines the necessary caution needed with these products.

We support CPSC’s intent to enhance the safety of these products, but regulating these as toys is not a logical way to do this, nor would it be the most effective. The CPSC does not need to call them ‘toys’ (and add requirements for them into 16 CFR 1250) in order to take steps to make them safer, and doing so may actually have an opposite effect. There are other regulatory approaches and scenarios that could be employed which would more effectively address identified safety concerns.

We note that the potential hazard conditions are not isolated to the specific products that the NPR is intended to regulate; ASTM has identified a broader group of products offering a similar function to neck floats but also not covered by USCG regulations, and ASTM is in the process of assembling a body of stakeholder experts to develop consensus-based standards for neck floats as well as other non-USCG & non-toy flotation devices. The Toy Association respectfully requests that CPSC recognizes the larger category of products (which are demonstrably not toys unless play features are incorporated into specific product designs), and refocuses agency resources on this multi-stakeholder consensus-based standards development process.

We thank you for your attention to these comments. If you would like to further discuss any of the issues raised, please do not hesitate to contact me, or my colleague Joan Lawrence, senior vice president of Standards & Regulatory Affairs (jlawrence@toyassociation.org).

¹⁹ An exploratory meeting was held in December 2024 and a follow-up meeting in January 2025; current CPSC staff are involved and among the technical experts who have volunteered to help launch the initiative is former CPSC Standards Coordinator Patricia Edwards.

Regards,



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About The Toy Association and the toy industry:

The Toy Association is the North America-based trade association; our membership includes more than 900 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 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.

Toy Association responses to specific CPSC Questions

A. Neck Float Definition

1. *The proposed rule defines a “neck float” as “an article, whether inflatable or not, that encircles the neck, supports the weight of the child by securing around the neck (such as by fastening, tightening, or other methods), and is used as an instrument of play in water environments including sinks, baths, paddling pools and swimming pools, and is intended for use by children up to and including 4 years of age.” Should the proposed rule use a different definition of neck floats?*

Response – The sub-clause “as an instrument of play” is not an accurate determinant of scope, is far too narrow, and should be removed from the proposed definition. The products in question only provide flotation support for the infant, separate from any subsidiary play that might occur.

Further, as stated more fully in the comments submitted by The Toy Association on this matter, neck floats are not toys. Adults – not children -- are the primary users of these products, in their care of children. To suggest otherwise would be seriously misleading to consumers, at best, and potentially poses increased risk of these products, contrary to the purpose of the NPR. For many of these products, children would not have the developmental ability to be the primary users, to properly inflate and don the product alone, or to use it in water safely.

As such, infant neck floats, are more akin to infant bath seats, bathtubs, child car seats and other childcare items, than they are to “toys”. The regulatory model for these types of products is a more appropriate exemplar for infant neck floats.

B. NPR Scope

1. *Are there any other products that should be included within the scope of this NPR as neck floats?*

Response – Please see the comments of The Toy Association regarding current and ongoing ASTM activity to develop a standard for a wider range of product types than what is proposed in the NPR.

2. *Based on FDA’s warning about the risk of death due to suffocation, strain, and injury to a baby’s neck, should the Commission strengthen the proposed performance requirements to address other hazards, or should the Commission promulgate alternative performance requirements?*

Response – The Toy Association respectfully recommends that the Commission works with ASTM and other relevant stakeholders on the promulgation of a more comprehensive standard for flotation devices, and to halt the intended mis-characterization of these products as toys.
