

December 6, 2024

Division of the Secretary U.S. Consumer Product Safety Commission 4330 East-West Highway Bethesda, MD 20814

Submitted via www.regulations.gov

Comments of Consumer Reports to the Consumer Product Safety Commission on the Notice of Proposed Rulemaking: "Safety Standard for Toys: Requirements for Water Beads" Docket No. CPSC-2024-0027

I. Introduction

Consumer Reports (CR), the independent, non-profit member organization,¹ welcomes the opportunity to submit the following comments to the Consumer Product Safety Commission (CPSC) regarding its notice of proposed rulemaking (NPR) to add requirements for water beads to the federal safety standard for toys. CR strongly supports the CPSC's proposed standard, which builds on elements of multiple existing voluntary standards.

Water beads, which are often marketed as sensory toys to children,² are associated with thousands of emergency department visits every year. Already banned from being sold as toys in Italy and Malaysia, water beads have also been the subject of governmental safety warnings to parents by agencies in Canada, Ireland, and New Zealand.³ In the United States, a number of retailers have voluntarily stopped the sale of water beads marketed for children.⁴ While CR

¹ Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to more than 5 million members across the United States.

² CR, "Parents Urged to Throw Away Water Beads Made by Jangostor and Tuladuo" (updated March 20, 2024) (online at: <u>www.consumerreports.org/babies-kids/toys/cpsc-safety-warnings-jangostor-and-tuladuo-water-beads-a1154425579</u>).

³ CR, "Nobody Should Lose Their Child Over a Toy" (updated Nov. 21, 2023) (online at: <u>www.consumer</u> reports.org/babies-kids/toys/water-beads-pose-a-serious-safety-risk-to-children-a6431187819).

⁴ CR, "Amazon, Target, and Walmart Announce They Will Stop Selling Water Beads Marketed for Children" (Jan. 8, 2024) (online at: <u>www.consumerreports.org/babies-kids/toys/amazon-to-stop-selling-water-bead-toys-a233261526</u>).

applauds the companies that have taken action in the interest of child safety, others have yet to take similar steps, leaving countless children at risk for serious injury or death. It is clear that a strong, mandatory safety standard for water beads is necessary to better protect children.

II. Risks of Exposure and Hazard Patterns

Water beads are made of absorbent polymers and expand dramatically when soaked in liquid. They are often marketed as toys appropriate for children; yet, emergency room data, medical literature, incident data reported by consumers and doctors, and devastating firsthand accounts from parents have made clear the serious, even lethal, risks posed to children by these products.⁵

Water beads can be bouncy and come in packages of thousands, and they can easily scatter and become hidden in carpets, grooves of hardwood floors, areas under furniture, and elsewhere. Even with adult supervision and precautions taken to prevent babies and younger children from accessing them, water beads can go undetected for extended periods of time due to these beads' small size when dehydrated. They can be enticingly rainbow-colored and nearly indistinguishable from cupcake sprinkles or candy in their pre-expanded state, leading infants and toddlers – who explore their environment by putting objects in their mouths – to be particularly likely to ingest them or insert them into their noses and ears. Ingestion, nasal and ear insertion, choking, and aspiration can all occur within seconds, and may go unnoticed by caretakers.⁶ In addition, pellet guns that use water beads, sometimes called "water bead gel blasters," have been linked to eye injuries, including hyphema, inflammation in the eye or the iris, and herpetic keratitis.⁷

The CPSC estimates that about 6,300 water bead-related injuries were treated in U.S. emergency departments from 2017 to 2022.⁸ Concerningly, researchers from the Center for Injury Research and Policy at Nationwide Children's Hospital found that water bead-related emergency department visits increased by more than 130% from 2021 to 2022.⁹ Children as young as nine months are known to have ingested water beads, and children have died after swallowing them. In July 2023, unbeknownst to her parents, 10-month-old Esther Jo Bethard ingested at least one water bead that had been purchased for her older sibling. She began to display symptoms identical to a stomach bug, and was found deceased in her crib the following morning.¹⁰

⁵ Supra note 3.

⁶ CPSC, Notice of Proposed Rulemaking: "Safety Standard for Toys: Requirements for Water Beads" (Sept. 9, 2024) (Docket No. CPSC-024-0027) (online at: <u>www.govinfo.gov/content/pkg/FR-2024-09-09/pdf/2024-19286.pdf</u>).

⁷ Clark, Cherly, MedPage Today, "AMA Delegates Dive Into Water Bead Injuries; Patients' 'Scanxiety' Over Test Results" (Nov. 10, 2024) (online at: <u>www.medpagetoday.com/meetingcoverage/ama/112829</u>).

⁸ CPSC, "Water Beads" (online at: <u>www.cpsc.gov/Safety-Education/Safety-Education-Centers/Water-Beads-Information-Center</u>).

⁹ Nationwide Children's, "Study Finds Emergency Department Visits by Children Associated with Water Beads More Than Doubled from 2021 to 2022" (Aug. 13, 2024) (online at: <u>www.nationwidechildrens.org/newsroom/news-releases/2024/08/waterbeads_cirp</u>).

¹⁰ *Supra* note 3.

Misdiagnoses or delayed treatment for water bead ingestion or with ear or nose insertion occurs because many of the symptoms, including vomiting, lethargy, loss of appetite, fever, abdominal pain, and nasal congestion are ambiguous and can be mistaken for other common conditions. This may be especially true if caregivers do not witness a child swallowing a water bead or inserting it into their ear or nose. Treatment for ingestion may also be delayed due to a medical professional's lack of awareness of the serious risks, including bowel obstructions, or because water beads can go undetected by routine X-rays due to their radiolucent nature. As noted in the proposed rule, a delay between the time a caregiver or medical provider discovers that a child has swallowed a water bead and the time when the child receives appropriate medical care may increase the risk of severe injury or death.¹¹

Consumer Reports is also concerned about the potential effects of exposure to certain chemicals that may be found in water beads. The CPSC found that two brands the agency tested, Tuladuo and Jangostor, contained levels of acrylamide in violation of the Federal Hazardous Substances Act (FHSA).¹² A suspected carcinogen, acrylamide can be harmful to the nervous system, reproductive system, and brain. Consumer Reports' lab tests of several popular brands of water beads found that several brands, including Jangostor, contained bisphenol A (BPA), an endocrine disruptor, further challenging the validity of the "non-toxic" label frequently seen on the toy's packaging.¹³ One incident highlights the potential dangers associated with the chemical composition of water beads. Several years after one documented ingestion case involving 13-month-old Kipley Haugen, the child's pediatrician diagnosed her with toxic encephalopathy – a brain injury – stating that it was likely due to toxic ingredients in the water beads, which had been labeled as non-toxic.¹⁴

III. Scope

We agree with the scope of the proposed rule, which applies to water bead toys, and toys that contain water beads that are designed, manufactured, or marketed as a plaything for children under 14 years old, including toy squeeze/sensory balls filled with water beads and toy water pellet guns. However, we have concerns that manufacturers or retailers of water beads that were previously marketed as toys or for use by children may attempt to evade the proposed rule by remarketing their products, such as for decorative or agricultural purposes. If these remarketed water beads continue to include images of children or descriptive language such as "bouncy," "slippery," "squishy," "fun," "play," "magic," or similar, it could be mistaken by a caregiver as a

¹¹ *Supra* note 6 at 73029.

¹² CPSC, "CPSC Warns Consumers to Immediately Stop Using Jangostor Water Beads Due to Chemical Toxicity Hazard, Violation of Federal Ban of Hazardous Substances; Sold on Amazon.com" (Mar. 19, 2024) (online at: https://www.cpsc.gov/Newsroom/News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Jangostor-Water-Beads-Due-to-Chemical-Toxicity-Hazard-Violation-of-Federal-Ban-of-Hazardous-Substances-Sold-on-Amazon-com); CPSC, "CPSC Warns Consumers to Immediately Stop Using Tuladuo Water Bead Sets Due to Chemical Toxicity Hazard, Violation of Federal Ban of Hazardous Substances; Sold on Amazon.com" (Mar. 19, 2024) (online at: <a href="https://www.cpsc.gov/Newsroom/News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-Using-Tuladuo-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-News-Releases/2024/CPSC-Warns-Consumers-to-Immediately-Stop-News-Releases/202

Water-Bead-Sets-Due-to-Chemical-Toxicity-Hazard-Violation-of-Federal-Ban-of-Hazardous-Substances-Sold-on-Amazon-com).

¹³ Supra note 2.

¹⁴ Supra note 3.

product suitable for use by children. We therefore urge the agency to carefully monitor how water bead products are marketed, including evaluating the use of images, colors, language, and product placement.

The CPSC should also factor in the colors of water beads, and product descriptions related to colors, to determine whether they may be toys within the scope of the proposed rule. Bright and colorful design schemes are often used for children's products, and the use of colors across the spectrum, especially bold and bright colors, may reasonably lead a consumer to believe that a product is intended for use as a toy. At the same time, the CPSC should recognize that water beads can be designed, manufactured, or marketed as a plaything for children regardless of their color, and it is important for the agency to account for the full context. Finally, given that the scope of the rule applies only to products that are designed, manufactured, or marketed to children under the age of 14, the CPSC should monitor the marketing of water beads to older children, and evaluate whether such marketing is age-appropriate.

IV. Consideration of Voluntary Standards and Proposed Testing and Performance Requirements

ASTM F963-23, *Standard Consumer Safety Specification for Toy Safety*, and EN 71-1, *Safety of Toys—Part 1: Mechanical and Physical Properties*, are inadequate as standalone standards to address the severe hazards posed by water beads. However, we find the incorporation of certain elements of these voluntary standards into the proposed rule to be reasonable, together with the proposed modifications and additional requirements necessary to ensure children are better protected against water beads' hazards.

Performance Requirements To Address Ingestion, Choking, Aspiration, and Insertion Hazards

We agree with the CPSC's proposal to limit a water bead expansion to not more than 50 percent in any direction, while also requiring a maximum expanded diameter of 9.0 mm. Under the CPSC's proposal, a water bead must remain whole while passing through a 9.0 mm (+0.0/-0.1 mm) diameter funnel test gauge under its own weight. Compared to the test method of the current ASTM F962-23 standard and the proposed revisions to the ASTM standard, which prescribe the use of a rod to apply force to determine whether a water bead can pass through a funnel test gauge, this approach would more realistically replicate the lower range of the compression forces a water bead would experience while passing through a child's gastrointestinal tract. The approach taken under the ASTM standard can also cause a water bead to fragment, which would be considered a "pass" under the standards. However, incident data show that water beads typically remain whole after being swallowed, and expand in a child's digestive track, leading to blockages.

Section 4.40 of ASTM F963-23 specifies that toys and removable components of toys made of expanding materials must, after expansion, pass through a 20.0 mm diameter test gauge, while the ASTM draft proposal states that a water bead must pass through a 12.0 mm diameter (+0.0/-0.1 mm) funnel test gauge. However, incident data indicate that water beads smaller than 12.0 mm can pose serious hazards, and therefore we agree with the CPSC's assessment that a smaller test gauge size is appropriate. We agree with the preliminary decision by the CPSC to

adopt the EN 71-1 standard's expansion limit of not more than 50 percent in any direction when used in conjunction with requiring a maximum water bead expanded diameter of 9.0 mm. Critically, the proposed 9.0 mm expansion limit would also reduce the hazards associated with the insertion of water beads into many children's noses and ears.

We agree with the CPSC's decision to incorporate the ASTM F963-23 requirement that water beads must be small enough to fit entirely inside the small parts cylinder, as specified in 16 CFR 1501.4, as well as the "Expanding Materials" test method from ASTM Section 8.30 for conditioning and immersing water beads. We also agree with the proposed modification that if a water bead is partially expanded, or is contained within a toy and partially expanded, it must be removed and dehydrated prior to testing, to simulate the real-world situation that can occur when a bead dislodges from the product and then dehydrates, and also so that compliance with the expansion limit of 50 percent can be assessed. These requirements would help to ensure that water beads do not cause a bowel obstruction or blockage if ingested or inserted.

Acrylamide and BPA Limits and Testing

Exposure to a sufficiently high concentration of acrylamide monomer can be harmful to the nervous system, even for short periods or one-time exposures,¹⁵ and it is necessary to include an acrylamide limit that adequately safeguards children from these harms. CPSC staff detected acrylamide monomers in several water bead products, including at levels that violate the FHSA. In addition, incident data includes several cases in which children have swallowed multiple small beads, potentially exposing them to greater amounts of this compound, and further necessitating an acrylamide limit that accounts for such scenarios. Accordingly, we support the proposed limit of 65 micrograms (μ g) extractable from either 100 small water beads or one large water bead, tested in accordance with the test procedure specified in the proposed 16 CFR 1250.4(c)(2).

The CPSC should also consider whether limits for BPA, a known endocrine disruptor that has been linked to certain cancers and fertility issues, ought to be included in the final rule. The violative level would have to be determined in order to be included. In 2023, CR tested several brands of water beads for known toxic chemicals, including lead, phthalates, and BPA, and found BPA in six brands of water beads.

Marking, Labeling, and Instructional Literature Requirements

CR supports the CPSC's proposals for marking, warning, labeling, and instructional literature that would apply to water beads and all products within the scope of this NPR. ASTM F963-23's general labeling requirements, applicable to toys, including water beads or toys containing water beads, are not specifically referenced in the ASTM standard's Expanding Materials section, nor does the Expanding Materials section specifically address the risk of severe injury or death related to water beads ingestion or insertion. The ASTM draft revisions also do not include labeling requirements specific to water beads.

Because the hazards associated with water beads are unique, severe, and potentially lethal, it is critical that warning labels explicitly address these products' dangers. Taylor Bethard,

¹⁵ *Supra* note 6 at 73038.

the mother of Esther Jo Bethard, told CR, "If I had known of the risks, I would've never allowed my older kids to play with them. They would've never been in my house."¹⁶ To improve the likelihood that potential buyers become aware of the consequences of exposure, it is imperative that warning labels be as clear and conspicuous as possible. We agree with the Commission's proposal to require toys containing water beads that are not individually packaged, such as multiple squeeze balls sold in a bin or box, to have a hangtag or sticker label with the proposed warning language affixed to each individual product. If such a bin or box was purchased, for example, for distribution among a group of children, each individual product should carry the proposed warning label language.

In CR's investigation of water beads, we found that product packages and online descriptions commonly describe water beads as "non-toxic." Such claims are potentially misleading to consumers, given the results of the CPSC's findings on acrylamide in multiple brands of water beads, and CR's lab tests which found BPA in six brands.¹⁷ Even with the proposed warning labels, parents and caregivers may reasonably believe that water bead products labeled as "non-toxic" do not pose certain health risks. The CPSC should consider whether restricting the use of this term may be appropriate, or whether warning label language should explicitly state that such claims may be inaccurate.

V. Technical and Economic Feasibility of the Proposed Rule

According to our assessment of the information presented by the CPSC, we consider the proposed rule to be both technically and economically feasible. The proposed compliance testing procedure, in which a water bead must pass through a 9.0 mm funnel test gauge under its own weight, does not require the use of tools, such as a push rod.¹⁸ As staff notes, several of the tools that are required to perform compliance testing under the NPR, including a small parts cylinder, are derived from the ASTM F963 standard, or are already required by other relevant CPSC standards, and are commercially available. Regarding the economic feasibility of the rule, companies that manufacture water beads can either redesign the products to meet compliance requirements or repurpose the beads for various non-toy uses, including decorative or agricultural purposes. Taking these steps would be a small price to pay to achieve a significant reduction in preventable serious injuries and medical procedures that would result from the rule.

VI. Considered Alternatives to the Proposed Rule and Effective Date

We find compelling the CPSC's determination that none of the considered alternatives to the proposed rule, including not establishing a mandatory standard, establishing an information and educational campaign, or setting a later effective date, would adequately address the associated hazards and reduce fatal and non-fatal injuries. It is clear that a mandatory standard is necessary to reduce harm to children. While an information campaign may help educate consumers about the serious dangers associated with water beads, it would not do nearly enough to prevent injuries or deaths from occurring. Hazard patterns demonstrate that children's access

¹⁶ *Supra* note 3.

¹⁷ CR, "'Non-Toxic' Labels on Water Beads Are Meaningless'" (Dec. 1, 2023) (online at: <u>www.consumer</u> reports.org/babies-kids/toys/non-toxic-labels-on-water-beads-are-meaningless-a7507892565/).

¹⁸ Supra note 6 at 73041.

to water beads is often undetected by parents and caretakers, due to the small nature of dehydrated water beads that can easily become hidden around the home. In many instances, caretakers have reported taking various measures to prevent a child from encountering a water bead, but ingestion still occurs. The CPSC first issued a warning about water bead ingestions through a product recall in 2012. According to the American Academy of Pediatrics (AAP), over the past decade, the number of cases of children swallowing water beads and experiencing intestinal blockage has increased.¹⁹

As previously stated, water bead-related incidents have escalated dramatically in recent years. Due to the sharp increase in water bead-related injuries and the severity of a number of incidents, an effective date later than the proposed 90 days would be inappropriate. Water beads present a clear danger to children and strong rules should be implemented urgently. The proposed test methods and equipment are not unique to the proposed rule, and they do not present an undue burden or require more time for manufacturers to come into compliance. Additionally, the 90-day effective date enables the proposed requirements to coincide with the third-party testing requirements for children's products under section 14(a)(3) of the CPSA, as a notice of requirements (NOR) date must be no later than 90 days before such rules or revisions take place.²⁰

VII. Conclusion

As the evidence shows, children who ingest, aspirate, and choke on water beads, or insert them into the nose or ear, can subsequently suffer injury or death. Water bead-related emergency department visits have increased dramatically in recent years, and in the absence of a strong, mandatory safety standard, it is foreseeable that severe injuries and fatalities will continue. In the interest of child safety, we urge the CPSC to finalize the proposed rule expeditiously. Thank you for your consideration of our comments.

Respectfully submitted,

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William Wallace Director, Safety Advocacy

Gabe Knight Senior Safety Policy Analyst

¹⁹ AAP, "Water-absorbing Beads Pose Increasing Hazard for Young Children; Researchers Test Methods on How to Shrink Them" (Sept. 27, 2024) (online at: <u>www.aap.org/en/news-room/news-releases-from-aap-conferences/water-absorbing-beads-pose-increasing-hazard-for-young-children-researchers-test-methods-on-how-to-shrink-them/?srsltid=AfmBOorwb1IBqi89dmkhXwzBzM_jL9BEI227yM92rNVj0bZ1pt6HkTtg).</u>

²⁰ *Supra* note 6 at 73042.