



Date December 08, 2024

The Honorable Alexander Hoehn-Saric  
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 Water Beads (Docket Number CPSC-2024-0027)**

This letter is being submitted in response to the Notice of Proposed Rulemaking (NPR) relating to toys containing water beads. 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.

ASTM F963 is well-recognized internationally as one of the world's premier toy safety standards and its comprehensive requirements have been emulated globally for toys, as well as for several non-toy categories. Its credibility comes, in part, from the consensus process that ensures that multiple stakeholder viewpoints are considered. The standard is also respected because it is driven by solid, validated data and because it (and the F15.22 Subcommittee which manages it) is responsive to real, identified hazards and is often the first to identify and address an emerging issue, well ahead of other standards or regulations. Congress mandated the ASTM F963 consensus standard under CPSIA, and provided a mechanism whereby revisions to the standard, as adopted by the consensus committee and process, could also be accepted by the Commission. The 2023 revision to ASTM F963 was accepted by the Commission and came into force in April 2024.

In 2023, CPSC staff raised the topic of water beads to ASTM<sup>1</sup>, and ASTM F15.22 currently has a technical working group reviewing the topic with the participation of CPSC, with the intent to formulate revisions to the toy standard in order to address new incident data.

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<sup>1</sup> [2-7-23 Letter to ASTM Expanding Materials](#)

In the NPR however, CPSC is proposing to bypass the consensus-based, scientific process by applying the proposed requirements directly to 16 CFR 1250. There are significant areas of concern presented by this novel approach, and our comments include both procedural and technical concerns related to the NPR which are outlined in this document.

## **Incident Data**

Although comments related to specific incident data will follow in subsequent sections of this document, there are a number of areas of concern relating to the potential hazard conditions and the incidents associated with them that are separate from the topics listed later, and are detailed here.

### **Aspiration:**

The second example presented for water bead aspiration incidents does not support the position taken in the NPR<sup>2</sup>. For IDI 201130CCC3196 (listed in the data packet as 11303196), the aspiration occurred *after* the child vomited beads that were in the stomach. This hazard potential is not specific to water beads, and relates to any object, including food and other matter, since aspiration from vomiting is a known hazard in any situation.

### **Choking:**

The IDI listed as an example for the hazard pattern for choking, IDI 180104CBB1236 (listed in the data packet as 01041236) relates to a nasal obstruction instead of a choking incident. The NPR itself does not identify the "...one reported incident..."<sup>3</sup> that it cites. Additionally, the NPR goes on to outline the hazard associated with "Large, expanded water beads..."<sup>4</sup> without addressing whether or not these would conform to the existing ASTM F963 requirement or not. If such beads would not comply, it would be an indication that the existing standard already addressed the issue and therefore does not merit a change to the requirements, nor would the data be relevant to this NPR. Furthermore, no such incident data regarding "large, expanded water beads" was provided by CPSC to the ASTM F15.22 work group.

### **Clumping:**

CPSC staff makes the statement that they have "...not identified evidence of water beads sticking together once fully expanded within the gastrointestinal tract to form a congealed water bead mass that is more difficult to pass than individual beads."<sup>5</sup> This statement is supported by all of the incident and supporting data provided by CPSC staff which has detailed obstruction resulting from individual beads, even when multiple beads have been ingested and either result in blockage from the original bead, or separate obstructions. We are also not aware of any circumstances associated with water bead toys that resulted in an agglomeration of beads or of pieces of broken beads, in alignment with what CPSC staff has also observed.

## **ASTM F963**

In the analysis of the current expanding materials requirement in ASTM F963, the NPR incorrectly asserts several points about the toy standard. Among these incorrect assertions, the NPR states that "Most water bead products are intended for children older than 36 months of age, however, and therefore *are not subject to requirements in section 4.6.1* of ASTM F963-

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<sup>2</sup> FR Vol. 89, No. 174, p 73030

<sup>3</sup> FR Vol. 89, No. 174, p 73031

<sup>4</sup> *Id.*

<sup>5</sup> FR Vol. 89, No. 174, p 73029

23.”<sup>6</sup> (emphasis added), since section 4.6.1 is based on requirements for children under 36 months of age. In actuality, while section 4.6.1 *itself* relates to products intended for children under 36 months, it is misleading and inaccurate to suggest that products for children three years of age and older are not subject to the requirement. In fact, several sections of F963 apply the small part requirements of section 4.6.1 and the small parts gauge to specific items or product categories intended for older children, including the requirements for magnets<sup>7</sup>, the small part warning requirement for products appropriate for children between 36 and 72 months<sup>8</sup>, and projectiles<sup>9</sup>, for example. Importantly, since the expanding materials section of ASTM F963 section 4.38 explicitly refers to the small part cylinder from the small part requirement, it does apply to water beads and other expanding materials.

The NPR provides images of what it refers to as water bead toys, however the last image shown, listed as a ‘water bead pellet gun’ is incorrectly classified in the NPR as a toy<sup>10</sup>, since this type of product utilizes stored energy and, as such, would be outside the scope of, and not in conformance with, ASTM F963, which stipulates that this type of projectile cannot be a small part. These items are recognized as being appropriate and age graded for ages 14 years and older (14+), making them, by definition, *not toys*. Further, as CPSC staff are aware, such products are addressed separately by ASTM F08.27 and CPSC staff participate on that technical subcommittee.

The NPR is also misleading in stating that “ASTM F963 does not specifically mandate testing for hazardous chemicals.”<sup>11</sup>, inferring that a testing mandate is required. While the Federal Hazardous Substances Act (FHSA) does not itself mandate testing specifically, it does mandate that materials are compliant with the requirements, and this is reflected in ASTM F963. As such, the statement that such a mandate is *missing* is not a basis for arguing a need for the proposed acrylamide test (cf. the Acrylamide section in this document).

### **Activity within the ASTM Consensus Standards Process**

The requirements for expanding materials in ASTM F963 were originally added in the 2016 edition in response to ingestion incidents, and are based on information and advice provided by pediatric experts on the size of the pyloric sphincter for a 5<sup>th</sup> percentile 18 month old, (the pyloric sphincter having been advised to be the critical dimension for obstruction); in doing so, the ASTM consensus committee took the approach that, while these products are intended for children 3 years and older, utilizing the age of 18 months (and a 5<sup>th</sup> percentile sizing) added additional safety factors. According to the NPR, there were alternative positions posited for the smallest dimension when the requirements were developed but the consensus position applied was the pyloric sphincter.<sup>12</sup> The incident data on water bead toys provided by CPSC to the ASTM F15.22 work group in 2023 and 2024 related to intestinal obstructions in children younger than 18 months old and the work group determination has been to extend the age applicability below the 18 month threshold to incorporate the younger children that the incident data relates to, in order to address the new information.

Although the NPR details some of the ongoing ASTM F15.22 water bead work group activity leading up to the 2024 balloted proposed revision to include a specific test methodology for

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<sup>6</sup> FR Vol. 89, No. 174, p 73034

<sup>7</sup> ASTM F963-23 section 4.38

<sup>8</sup> ASTM F963-23 section 4.6.3

<sup>9</sup> ASTM F963-23 section 4.21.2.1

<sup>10</sup> FR Vol. 89, No. 174, p 73027

<sup>11</sup> FR Vol. 89, No. 174, p 73034

<sup>12</sup> *Id.*

water beads<sup>13</sup>, it misrepresents the basis for the 12 mm diameter threshold in the 2024 balloted revision by stating that proposed diameter in the ASTM ballot is "...in consideration of **one** incident..."<sup>14</sup> (emphasis added). In actuality, this value was the lowest confirmed size of a water bead that resulted in an intestinal obstruction based on all of the incident data provided by CPSC relating to water bead toys. The basis for the proposed size was also extensively discussed in the ASTM F15.22 water bead work group meetings that CPSC staff attended and was documented in the rationale for the balloted text.

It is also important to stress that the 2024 ASTM ballot was a preliminary action to work toward consensus on (a) including specific requirements for water beads and (b) establish a starting position for the sizing requirement to be applied to such items to address the intestinal obstruction potential, with the ballot seeking input from the ASTM F15.22 subcommittee on toy safety. Further work, including consideration for warning statements remains outstanding before a subsequent ballot would be finalized and presented to the full ASTM F15. Nose and ear insertion hazards were discussed but as there is no data or consensus on scientific-based test requirements that would be applicable to address this potential. The principal hazard was recognized to be intestinal obstruction,<sup>15</sup> which has actionable data to support a test requirement; ear and nose insertion hazard potential would also be reduced once the size limitation for water beads in toys would be implemented, since making only the smaller beads being able to be present for toys instead of the larger ones currently available, the potential for ear or nose pressure/blockage would be reduced in parallel. This approach would be supported by a cautionary statement about the potential for ear and nose insertion since these potential hazards would not be addressed by scientifically-based test requirements (unlike the intestinal obstruction hazard).

### **9 mm Maximum Diameter**

The basis for the proposed maximum water bead size requirement in the NPR is described as being based on IDI 230707CBB1698<sup>16</sup> (listed as #07071698 in the data packet). Firstly, this incident did not result in an intestinal obstruction (and relates to a 3-year-old child); although an enema was prophylactically applied since the child intentionally ingested a large number of beads, it is not clear whether this was needed to pass the beads. Secondly, and in the absence of any scientific basis for the determination, CPSC staff is applying the smallest recorded size of water bead in a *set where all beads (up to 15 mm diameter) passed through the child's intestinal tract without obstruction*. Thirdly, since the 9 mm diameter is based on the smallest bead in this set, the value observed could have been any value which can and will depend on the variation in the product assessed versus *any other* set obtained (i.e., the set could have had beads down to 10 mm, 11 mm or any other diameter up to and including values higher than the smallest confirmed diameter of 13 mm). There is no scientific basis for selecting this value, nor for making the assertion that this would provide the "...highest level of safety feasible..."<sup>17</sup>. This contrasts with the consensus-based ASTM process whereby the information provided by CPSC was assessed for validity, and once that was ascertained, a preliminary value below the *lowest observed diameter* of toy water bead to have resulted in an intestinal obstruction was applied.

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<sup>13</sup> FR Vol. 89, No. 174, p 73035

<sup>14</sup> *Id.*

<sup>15</sup> NCPCC 'Are water beads dangerous?' <https://www.poison.org/articles/are-water-beads-toxic>

<sup>16</sup> FR Vol. 89, No. 174, p 73036

<sup>17</sup> *Id.*

## 50 % Expansion

The NPR proposes a test methodology for water beads<sup>18</sup> that appears to intentionally disregard the well-established<sup>19</sup> parameter for the definition of an expanding material within ASTM F963. The accepted definition of "expanding material" in ASTM F963 is "any material used in a toy which expands greater than 50 % in any dimension..."<sup>20</sup> Regardless, and in the absence of validated data to support the positioning, the NPR proposes that water beads (which are, by definition an expanding material), according to the NPR would now be incorrectly and paradoxically categorized as not being expanding materials instead of a subset of expanding material products (i.e., water beads, under the requirements proposed in the NPR would no longer be classified as an expanding material in any of the established standards around the world, making the proposed requirement out of alignment with other standards since they would not be permitted to expand more than 50 % in any dimension).

It is also important to note that there is no minimum size threshold listed in the definition proposed in the NPR. Indeed, using the proposed definition, a water bead with a 1 mm diameter that expands to more than 1.5 mm diameter would fail, *without any basis or determination* that that an article of this size, regardless of expansion potential, would present the perceived hazard condition in the first place.

Such a change in the categorization of water bead expanding materials is arbitrary, contradicts CPSC's own prior positions<sup>21</sup>, and is not supported by valid data; The NPR offers only an unsubstantiated statement as a possible rationale; that a maximum 50 % expansion would be "...a beneficial additional safety provision..."<sup>22</sup>, that "...reduces the potential damage..."<sup>23</sup> of ear and nose insertion incidents.

Further, the NPR also states that CPSC has made a preliminary determination that the current 50 % expansion requirement in EN71-1 (the European Toy Safety Standard) is "...inadequate as a stand-alone requirement."<sup>24</sup>, apparently on the basis that a (theoretical) water bead that expands less than 50 % would present an obstruction hazard since it could expand to 13.5 mm diameter and then "...likely cause a gastrointestinal block if a child ingested it."<sup>25</sup>, while apparently not considering that the same would be true of *any other non-expanding material* that has a diameter of 13 mm or greater. CPSC's assertion is also made in the absence of data to support the supposed inadequacy.

It also bears mentioning that in this section, the NPR recognizes the smallest confirmed diameter of a water bead that resulted in an intestinal obstruction was 13 mm, based on the data that CPSC has provided<sup>26</sup>. See also additional comments on the water bead diameter elsewhere in this document and in response to the questions posed by CPSC.

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<sup>18</sup> FR Vol. 89, No. 174, p 73048

<sup>19</sup> ASTM F963-23 section 3.1.28, EN71-1 2014 + A1 2018 section 4.6, ISO 8124-1 2022 section 5.21

<sup>20</sup> ASTM F963-23 section 1.2.28

<sup>21</sup> CPSC approved ASTM F963 and the definitions developed for expanding materials in the 2016, 2017 and 2023 versions, and CPSC staff in ASTM F15.22 meetings have consistently referred to water beads as a type of expanding material product.

<sup>22</sup> FR No. 89, No. 174, p 37035

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

## Inaccessible Water Beads

The NPR would require that all water beads, even those “contained within a toy”<sup>27</sup> meet the performance requirements of 16 CFR 1250.4(c). This approach is absent any assessment of availability or inaccessibility and is a stark departure from CPSC’s established approach to performance requirements for inaccessible components of toys. It is also overly burdensome and unnecessary for addressing the potential hazards associated with water beads, as there are existing longstanding and effective methods for effectively eliminating hazards by ensuring the inaccessibility of potentially hazardous components of toys.

The preamble to the NPR describes the potential hazards presented by water beads including ingestion, insertion in the ear or nose, choking, aspiration, and potential chemical hazards. In short, the hazards outlined are either physical or chemical and arise if children have access to the water beads. Existing CPSC standards for products that pose similar hazards rely on ensuring inaccessibility *as a primary safeguard*. CPSC has not provided any reason why maintaining inaccessibility cannot be an effective requirement here. Inaccessibility can be designed and manufactured into products to serve as a barrier to children gaining access to an interior component. Inaccessibility is also a longstanding approach for protecting children from mechanical & physical as well as chemical hazards in toys and children’s products.

Similar to water beads, high powered magnets and button and coin cell batteries pose specific hazards if ingested. The harm caused by ingested high powered magnets and button and coin cell batteries is unlike the hazard posed by other objects that may be ingested. Additionally, it is difficult to diagnose ingestion of high-powered magnets and button and coin cell batteries, which further compounds the risks they may present. Both product categories have been associated with a significant number of deaths and serious injuries.

Yet, in both cases, CPSC and relevant, respected standards apply inaccessibility, along with a means of testing for accessibility, as an effective means of safeguarding children. For example, whether for non-toy products per Reese’s Law, or toys per ASTM F963-23, button and coin cell batteries are allowed in products intended for children, so long as the product ensures and passes the inaccessibility requirements and use and abuse tests in the relevant requirements.

Similarly, magnets that are inaccessible do not need to meet the flux and size requirements of 16 CFR Part 1262. Only “loose and separable” magnets must either be too big to fit in the small parts cylinder or have a flux index less than 50.<sup>28</sup> The ASTM F963 Toy Safety Standard also allows high powered magnets in toys, so long as these magnets are not loose and are not liberated through use and abuse<sup>29</sup>. The same approach should apply to water beads. If a toy contains *inaccessible* water beads, there is no reason to impose any performance requirements for those beads, as long as they remain inaccessible during reasonably foreseeable use and abuse.

For the risk of chemical exposure associated with phthalates, Congress, in Section 108 of the Consumer Product Safety Improvement Act (CPSIA), specifically exempts inaccessible parts of toys or childcare articles that are “not accessible to a child through normal and reasonably foreseeable use and abuse of such product.”<sup>30</sup> CPSC added a regulation consistent with the statute in 16 C.F.R. Part 1199. Similarly, in Section 101 (b)(2) of the CPSIA, Congress provides

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<sup>27</sup> FR Vol. 89, No. 174, p 730336

<sup>28</sup> 16 CFR 1262.3

<sup>29</sup> ASTM F963-23, § 4.38

<sup>30</sup> 15 U.S.C. §2057c(d)

that the lead limits do not apply to component parts of a product that are not accessible to a child. This section specifies that a component part is not accessible if it is not physically exposed by reason of a sealed covering or casing and does not become physically exposed through reasonably foreseeable use and abuse of the product including swallowing, mouthing, breaking, or other children's activities, and the aging of the product. CPSC's regulation at 16 C.F.R. 1500.87 formalizes this statutory requirement for inaccessibility related to lead content. Similarly, the Toy Safety Standard in 16 C.F.R. Part 1250 only imposes limitations on lead on components of toys that are accessible.<sup>31</sup>

The risks posed by physical hazards as well as by lead, other heavy elements and prohibited phthalates are well documented. If the law and regulations allow for these physical characteristics or chemicals to be present in inaccessible parts of toys, there is no justification to restrict the size or characteristics of contained water beads that are inaccessible in toys or components of toys.

The NPR also presents an implicit argument that interior components of toys containing water beads may become accessible by a child biting into the product and liberating the water beads. There is however no explanation as to why this risk is any different from that posed if a high-powered magnet, button or coin cell battery, or chemically hazardous component would be released, marking a starkly different approach for water beads. Indeed, this idea is already accounted for within the CPSC's established 16 CFR Part 1500 use and abuse tests<sup>32</sup>. To the degree to which biting (and ingestion) may be a risk, the burden rests with the CPSC to explain why the established use and abuse testing, effectively used for other types of hazards, is not adequate here for water beads.

CPSC cannot simply assume that such a risk exists. As an example, within the NPR data packet, IDI 230613CBB1591 presents a circumstance relating to an intestinal obstruction resulting after water beads were released from a '...ball, similar to a stress ball.'<sup>33</sup> received from a party goodie bag and which was described by CPSC as being "...expected to be used as a toy."<sup>34</sup> Without information to confirm whether the product associated with the incident was actually designed, intended, marketed and sold as a toy or not, it is not reliable to assume that the product was actually a toy, which would affect the crucial assessment of whether compliance to ASTM F963 was applicable and had been applied.

## Acrylamide

While the NPR acknowledges that section 4.3 of ASTM F963 requires that all toys must comply with the Federal Hazardous Substances Act (FHSA) for toxicity and hazardous substances<sup>35</sup>, it then in the same paragraph goes on to claim that this provision somehow leaves out toys made with expanding materials, since the overarching FHSA requirement is not explicitly (and redundantly) required in this section<sup>36</sup>, concluding that "...therefore, the current ASTM standard is inadequate to provide the highest level of safety feasible to ensure that the chemicals in water

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<sup>31</sup> ASTM F963-23 §4.3.5.2

<sup>32</sup> While Federal requirements do include a bite test at 16 CFR 1500.52, in 1974, however, a federal court ruled against the CPSC's use and abuse bite test then in-effect as not being supported by adequate science. See *Clever Idea Co., Inc. v. Consumer Products Safety Commission*, 385 F. Supp. 688 (E.D. N.Y. 1974). The CPSC has taken no regulatory actions in the ensuing 50 years to address such a risk, which largely indicates that it has come to view the existing use and abuse testing as adequate to the task.

<sup>33</sup> IDI 230613CBB1591, 06131591

<sup>34</sup> *Id.*

<sup>35</sup> FR Vol. 89, No. 174, p 73034

<sup>36</sup> *Id.*

beads are non-toxic.”<sup>37</sup>. The follow-on statement “Because water beads containing high levels of acrylamide monomer are toxic, the NPR proposes to establish content limits and test methods to address the toxicity hazard.”<sup>38</sup> that the NPR uses to justify the addition of an acrylamide requirement for water beads is spurious since any toy that contains a high level of acrylamide monomer (or any other substance) sufficient to be considered ‘toxic’ would fall under the overarching requirement laid down in section 4.3 of ASTM F963. As such, the statements made in the NPR do not support the provision for the proposed novel acrylamide test.

Superabsorbent polymers (SAP) are usually either polyacrylate, polyacrylamide, or a combination (copolymer) of the two. While the NPR acknowledges that both types can be present in water beads, and continues by noting that acrylamide monomer may be present in an unreacted form since it is a catalyst for the polymerization process, it omits several important considerations. Firstly, there is no mention that unreacted monomers present a small percentage of the resulting polymer (typically at very low levels) which are bound within the non-soluble polymer matrix (even lower levels when the SAP is present as a copolymer), and secondly, while polyacrylate is a common material for water beads, its polymerization process used *does not utilize acrylamide monomer*<sup>39</sup>. As such, it is not acknowledged in the NPR that a significant proportion of water beads either do not have acrylamide monomer present as a contaminant at all, or have it present at an even lower threshold than would be present for polyacrylamide SAP.

The NPR considers EN71 Part 9: Organic Chemicals Requirement<sup>40</sup> as it includes an acrylamide concentration limit, however the NPR does not take into account that the referenced standard was (previously) considered to be voluntary since it was never harmonized under the EU framework, as well as the fact that it has been subsequently withdrawn altogether as of August 2022<sup>41</sup>.

Although the NPR lists US Food and Drug Administration (FDA) limits for residual acrylamide monomer allowed in polyacrylamide used in food production, and that guidance has been published for *reducing* the amount of acrylamide in foods (as opposed to *removing* acrylamide)<sup>42</sup>, the NPR does not mention the equally important and relevant fact provided in the FDA guidance document<sup>43</sup> that acrylamide is present in many foods, as a result of the Maillard reaction<sup>44</sup> which naturally *results in* acrylamide being present in food as a part of the cooking process, and as such, humans are exposed to this chemical throughout their natural life. Also relevant is that the FDA guidance on reducing acrylamide in food expressly states that “FDA is not suggesting maximum recommended levels for acrylamide...”<sup>45</sup> and that “...acrylamide can vary significantly between identically prepared products...”<sup>46</sup>. Indeed, one of the papers cited in the Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for Acrylamide<sup>47</sup> links the presence in breast milk samples taken from mothers who had eaten potato chips<sup>48</sup>. The generation of acrylamide in the diet is present from a wide range of

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<sup>37</sup> *Id.*

<sup>38</sup> FR Vol. 89, No. 174, p 73034

<sup>39</sup> <https://cosmetics.specialchem.com/inci-ingredients/sodium-polyacrylate>

<sup>40</sup> FR Vol. 89, No. 174, p 73032

<sup>41</sup> [https://standards.iteh.ai/catalog/standards/cen/8c56bca5-e4ce-412a-aa77-91572f489fc0/en-71-9-2005a1-2007?srltid=AfmBOoq6MW0RATKeY15rP4SI\\_CZpIHnmG2N7RYhV6AJvTb5F5CoXnmzu](https://standards.iteh.ai/catalog/standards/cen/8c56bca5-e4ce-412a-aa77-91572f489fc0/en-71-9-2005a1-2007?srltid=AfmBOoq6MW0RATKeY15rP4SI_CZpIHnmG2N7RYhV6AJvTb5F5CoXnmzu)

<sup>42</sup> FR Vol. 89, No. 174, p 73038

<sup>43</sup> <https://www.fda.gov/media/87150/download>

<sup>44</sup> <https://home.sandiego.edu/~josephprovost/Acrylamide%20is%20formed%20in%20Maillard%20Reaction.pdf>

<sup>45</sup> <https://www.fda.gov/media/87150/download>, p 5

<sup>46</sup> *Id.*

<sup>47</sup> <https://www.atsdr.cdc.gov/ToxProfiles/tp203.pdf>

<sup>48</sup> Sörgel et. al., 2002, <https://www.atsdr.cdc.gov/ToxProfiles/tp203.pdf>, p163

foodstuffs, including those such as cereals and potatoes (commonly used in infant foods)<sup>49</sup>, as well as cocoa, cooked meats and coffee.

Further, the National Capital Poison Center (NCPC) clearly states “Because it is so common in the world around us, most people are exposed to low levels of acrylamide every day.”<sup>50</sup> and goes on to state “But to put the risk of acrylamide toxicity from water beads in perspective, a cup of french fries likely contains more acrylamide than the amount released from 100 of the *high-level* acrylamide-containing water beads that are in the stomach for 24 hours.”<sup>51</sup> (emphasis added). Note also that this time period is consistent with the proposed 24-hour time period for acrylamide testing in the NPR<sup>52</sup>.

Comparing the CPSC-proposed 65 µg acrylamide against the levels in food cited in Table 6-2 of the ATSDR Toxicological Profile for Acrylamide<sup>53</sup>:

**Table 6-2. Acrylamide Levels in Different Food and Food Product Groups from Norway, Sweden, Switzerland, the United Kingdom, and the United States**

Food/product group	Acrylamide levels (µg/kg) <sup>a</sup>			Number of Samples
	Mean <sup>b</sup>	Median <sup>2</sup>	Minimum-Maximum	
Crisps, potato/sweet potato <sup>c</sup>	1,312	1,343	170–2,287	38
Chips, potato <sup>d</sup>	537	330	<50–3,500	39
Batter based products	36	36	<30–42	2
Bakery products	112	<50	<50–450	19
Biscuits, crackers, toast, bread crisps	423	142	<30–3,200	58
Breakfast cereals	298	150	<30–1346	29
Crisps, corn	218	167	34–416	7
Bread, soft	50	30	<30–162	41
Fish and seafood products, crumbled, battered	35	35	30–39	4
Poultry or game, crumbed, battered	52	52	39–64	2
Instant malt drinks	50	50	<50–70	3
Chocolate powder	75	75	<50–100	2
Coffee powder	200	200	170–230	3
Beer	<30	<30	<30	1

<sup>a</sup>The limits of detection and quantification varied among laboratories; values reported as less than a value are below the limit reported by the laboratory.

<sup>b</sup>Mean and median values were calculated where individual data were available; sample sizes were extremely small, particularly for some food categories; where the mean and median are different, it reflects the skewed distribution of the underlying data that were collected in different countries and may represent different food items within the larger category.

<sup>c</sup>Products that are thinly sliced and fried (such as potato chips).

<sup>d</sup>Products that are more thickly sliced (such as French fries).

Source: WHO 2002

<sup>49</sup> <https://home.sandiego.edu/~josephprovost/Acrylamide%20is%20formed%20in%20Maillard%20Reaction.pdf>

“The almost exclusive formation of acrylamide from asparagine could explain the occurrence of acrylamide in cooked plant-based foods, such as cereals and potato, which are rich in this particular amino acid.

In potato used for the manufacture of potato crisps, the dominant free amino acid is asparagine (940 mg kg, representing 40 % of the total amino-acid content); in wheat flour it is present at 167 mg kg, corresponding to 14 % of the total free amino acids (our unpublished results), and a high-protein rye variety contains 173 mg kg (18 % of the total free amino acids).”

<sup>50</sup> <https://www.poison.org/articles/are-water-beads-toxic>

<sup>51</sup> *Id.*

<sup>52</sup> FR Vol. 89, No. 174, p73039

<sup>53</sup> <https://www.atsdr.cdc.gov/ToxProfiles/tp203.pdf>, p 203

Assuming a standard bag of potato chips @ 32.5 g (single serving) and the maximum acrylamide level @ 3,500 µg/kg for potato chips per the table above, the acrylamide level would be

$$(32.5 \div 1000) \times 3500 = 113.75 \mu\text{g}$$

This alone is nearly twice the proposed threshold for 100 small water beads. It is also worth noting that the highest concentration listed in the above table is by no means an absolute maximum; in the accompanying table that follows in the ATSDR document (Table 6-3 Acrylamide in Potato Products)<sup>54</sup>, the maximum acrylamide recorded for potato chips was 9,670 µg/kg, nearly 3 times the level in the calculation above.

Taking into account the cumulative amount potentially ingested over a day, even for small children, the proposed 65 µg threshold for what the NPR classifies as a single-dose consideration can be concluded to be overly conservative. Further, the NPR states that “CPSC has not yet received data demonstrating chronic exposure to acrylamide from water beads.”<sup>55</sup>. The briefing package is more explicit, stating that “...staff does not have incident data reflecting acrylamide poisoning from water beads...”<sup>56</sup> and no data relating to acute poisoning is present in the data package provided by CPSC to accompany the NPR.

The NPR does not provide evidence of (a) the level of acrylamide monomer in water beads if and when it is present, (b) any consideration for water beads that are composed of materials that either have no unreacted acrylamide monomer present or are copolymers that would present even less acrylamide monomer than an polyacrylamide SAP material, or (c) an assessment of the actual residual monomer level against the weight of each (unhydrated) water bead (generally 1-4 mg per bead in the sizes that expand to the 7–13 mm diameter expanded state)<sup>57</sup>.

The NPR is mistakenly using ATSDR’s derived acute-duration exposure limit of 0.01 mg/kg-bw/day. The agency then multiplies this by the 5<sup>th</sup> percentile body mass of a 6-to-8-month-old female of 6.5 kg, to arrive at a maximum daily acute exposure limit of 0.065 mg/day, or 65µg/day. Additionally, it is important to note however, that among other problems with the CPSC calculation, ATSDR defines acute exposure as “Exposure to a chemical for a duration of 14 days or less, as specified in the Toxicological Profiles” (emphasis added)<sup>58</sup>. This is compared to the assessment in the NPR that exposure to water bead ingestion “...would likely be a single, infrequent event (possibly including multiple beads in a single event).<sup>59</sup>

However, several studies have dosed humans at up to 3 mg/kg-bw as a single oral dose with no ill effects observed<sup>60</sup>. This is submitted as a more representative threshold for a potential hazard scenario (i.e., one single oral exposure). As such, a threshold of 3 mg/day (possibly more) is a more appropriate limit.

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<sup>54</sup> <https://www.atsdr.cdc.gov/ToxProfiles/tp203.pdf>, p 204

<sup>55</sup> FR Vol. 89, No 174, p 73038

<sup>56</sup> <https://www.cpsc.gov/s3fs-public/Notice-of-Proposed-Rulemaking-Requirements-for-Water-Beads.pdf?VersionId=3kxvgzeMplRHJaKQ3knA4G36gVZ6EySi>, p OS 88

<sup>57</sup> Based on calculations of net weight/# of beads listed on e-commerce pages.

<sup>58</sup> <https://www.atsdr.cdc.gov/ToxProfiles/tp203.pdf>, p 259

<sup>59</sup> FR Vol. 89, No. 174, p 73038

<sup>60</sup> Fennell and Friedman “Comparison of acrylamide metabolism in humans and rodents” Adv Exp Med Biol 2005:561:109-16. doi: 10.1007/0-387-24980-X\_9

Another relevant consideration is that ATSDR's exposure limit is based on rodent studies<sup>61</sup>, but acrylamide metabolism differs significantly between rodents and humans. Specifically, rodents metabolize acrylamide largely via the CYP 2E1 oxidation pathway to glycidamide (mutagenic in the Ames Salmonella test) compared with humans, who metabolize acrylamide via conjugation with glutathione to a much greater extent.<sup>62</sup>

Beyond the information listed above, another consideration that does not appear have been taken into account is that there is also evidence that a significant amount of acrylamide is endogenously produced by the body itself. The German Federal Institute for Risk Assessment (BfR) has studied this issue, and found that up to 48 % (blood) and 25 % (urine) of C<sup>13</sup>-labeled acrylamide metabolites are generated by the body itself.<sup>63</sup>

### CPSC's Acrylamide Testing of Water Beads

In November 2023 CPSC staff provided a letter to the ASTM F15. 22 Emerging Hazards work group concerning the agency's investigative activity on acrylamide in water beads using a test methodology devised by CPSC<sup>64</sup>, and citing a 'concerning' level of acrylamide monomer in certain water beads<sup>65</sup>. CPSC staff were asked to provide information related to the test methodology and the test results for review in order to determine whether the novel test and resulting data supported a change to the ASTM standard, however over the course of several months and numerous conversations and meetings, the request for information was repeatedly denied by CPSC staff.

On April 23, 2024, a Freedom of Information Act (FOIA) request was submitted to CPSC, with the additional request for expedited processing on the basis of CPSC staff's characterization of the presumed acrylamide monomer presence as an 'acute' hazard<sup>66 67</sup>. The request for expedited processing was denied on April 25, 2024, on the basis that the request had "...not demonstrated that the failure to obtain the requested records on an expedited basis could reasonably be expected to pose and imminent threat to the life or physical safety of an individual [...] or that there is an urgency to inform the public..."<sup>68</sup> despite CPSC staff's own characterization of the concern as an "acute" hazard, not meriting a CHAP. This denial was followed on June 13, 2024 with a "final" denial of the FOIA request, stating that "Your request seeks record(s) that will be made available to the public outside of the FOIA process in a Notice

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<sup>61</sup> In deriving an acute exposure limit (Minimal Risk Level, or MRL), ATSDR relied almost entirely on data from one study, Sublet, et al. (1989) [Sublet VH, Zenick H, Smith MK. 1989: Factors associated with reduced fertility and implantation rates in females mated to acrylamide-treated rats. Toxicology 55:53-67]. These data involve feeding of male Long-Evans hooded rats by gastric lavage, dosed in distilled water for 5 days at doses of 0, 30, 45, and 60 mg/kg-bw/day in one experimental run, and 0, 5, and 15 mg/kg-bw/day in a second run. These males were then allowed to mate with untreated females, which were sacrificed at 15 days and the fetuses histologically examined for developmental and implantation anomalies, a toxic endpoint that, while likely chosen as the most sensitive, has limited applicability to children. The raw data was then fed into a PBPK (Physiologically Based Pharmacokinetic) model developed by Sweeney, et al. (2010) [Sweeney LM, Kirman CR, Gargas ML, et al. 2010: Development of a PBPK of acrylamide and glycidamide [glycidamide is the primary metabolite of acrylamide via CYP 2E1] in rats and humans. Food Chem Toxicol 48(2):668-685] to estimate blood levels. This derivation utilized uncertainty factors of 3 for extrapolation from animals to humans with dosimetric adjustment and 10 for human variability, which collectively have the effect of reducing the MRL by a factor of 30.

<sup>62</sup> Fennell and Friedman "Comparison of acrylamide metabolism in humans and rodents" Adv Exp Med Biol 2005:561:109-16. doi: 10.1007/0-387-24980-X\_9

<sup>63</sup> <https://link.springer.com/article/10.1007/s00204-024-03798-z>

<sup>64</sup> <https://www.cpsc.gov/s3fs-public/Water-Bead-Letter-to-ASTM.pdf?VersionId=CDUhf2.4wIE8vc0XTaHZQAziBXhELY>

<sup>65</sup> *Id.* "The two large, soft beads released concerning levels of acrylamide within the first 26 hours of extractions."

<sup>66</sup> FOIA request #24-F-00409

<sup>67</sup> Acrylamide monomer is categorized as a carcinogen, and a CHAP is required when assessing such. CPSC staff however defined the acrylamide as having an acute hazard potential, which does not trigger a CHAP.

<sup>68</sup> 24-F-00409 Expedite Denied Letter, Appendix A to this document

of Data Availability (NOA). CPSC's Office of Executive Director, Office of Hazard Identification and Reduction (EXHR) will provide this information in the NOA associated with the proposed rule. Processing this record under the FOIA would be duplicative of EXHR's efforts to make them publicly available, and unduly burdensome.<sup>69</sup>

Once this NPR was published, The Toy Association requested the link to the supporting information provided and received access on September 10, 2024. Upon review of the information, there was no data related to CPSC's testing of acrylamide in water beads. On the same day, and understanding the time constraints due to the 60-day comment period, we reached out to CPSC staff to request an update on when this information would be made available. As a result of the conversation, CPSC staff advised that they were looking into the matter. On September 23, 2024, CPSC staff advised by email that the NPR data would not include the acrylamide information. On the same day, we responded by email, pointing out that their determination directly contradicted the FOIA denial regarding the requested information. Following this exchange, CPSC reopened the FOIA request on September 25, 2024 and on October 7, 2024 links were provided to the FOIA newsroom with the previously-denied information<sup>70</sup>. The link to the NPR data, however, had not been updated to include this information, and without this, commenters would not have been provided with ready access to all of the necessary information related to the NPR for consideration during the full comment period.

On October 21, 2024, The Toy Association requested an extension of the comment period in order to allow for time needed by the public to review the data that has not been provided in the NPR data packet. On November 4, 2024, CPSC staff notified The Toy Association that Commission had voted on November 1 to approve a 30-day extension to the comment period (to December 8, 2024), and the acrylamide test information had also been added to the NPR data packet.

Based on the information received, and independent of the points raised in the previous section related to the proposed acrylamide requirement in the NPR, even if the testing is taken as necessary and appropriate, the only samples that were deemed by CPSC to be 'of concern' or presented what could be termed as elevated results are water beads of a size and form that would not be approved as toys in the first place, whether the 9 mm proposed in the NPR or 12 mm proposed in the ASTM draft.<sup>71</sup> As such, and again independent of the other points raised previously, if the outlier large beads are removed from consideration, the test data itself, even if including 'medium' sized beads that also would not meet either proposed gauge, does not support the assertion in the NPR that a test for all water beads is would be necessary or appropriate.

## Labeling

Since the physical testing proposed in the NPR is intended to prevent the potential of an intestinal blockage (as are the test parameters proposed by ASTM 15.22 for inclusion in ASTM F963), the proposed warning statement stating that "Children have DIED after swallowing water beads because beads block their intestines. Your child can die too."<sup>72</sup> is neither appropriate nor accurate, and will misinform the consumer to a hazard that will not be present. The first sentence relates to products that would no longer be allowed following adoption of the NPR (or

<sup>69</sup> 24-F-00409 Final Response, Appendix A to this document

<sup>70</sup> [https://www.cpsc.gov/Newsroom/FOIA/ReportList?month=all&year=all&nfr\\_type=All&title=24-F-00409](https://www.cpsc.gov/Newsroom/FOIA/ReportList?month=all&year=all&nfr_type=All&title=24-F-00409)

<sup>71</sup> Per CPSC 's size assessment on bead size examples per FR Vol 89, No. 174, p 73025

<sup>72</sup> FR Vol 89, No. 174, p 73040

a similar change to ASTM F963) and thereby would be misleading to consumers, at best, once proposed rulemaking comes into effect since the hazard is intended to be addressed by the requirements themselves; i.e., water beads would only be permitted if they meet the physical size requirement that is below the lowest diameter confirmed to have resulted in an intestinal obstruction for toys (13.0 mm per data provided by CPSC). The second statement, while also designed to alarm consumers, is *wrong*, since water beads that conform to the physical size requirements of either the proposed ASTM or the NPR requirements for expanded diameter will not be large enough to present the intestinal obstruction hazard.

Separate from the intestinal obstruction wording presented above, the potential for ear and nose insertion does remain present (as for any items of a similar physical size), but with the additional aspect of potential expansion, a cautionary statement relating to potential ear and nose insertion hazards would be appropriate for advisement to consumers. As stated previously, the proposed 50 % expansion limit has no basis for efficacy and may or may not prevent occurrence of such incidents (the likelihood of which will likely be reduced as a result of the physical size limitation proposed by either the NPR or the ASTM proposed testing). Such statements are advisory and, consistent with other such statements, could appropriately be addressed with the signal word 'Caution' and be presented along with the instructions for use as opposed to being present on the principal display panel of the package at point of sale. Although labeling statements were not included in the ASTM F15.22 work group ballot related to water beads as of this date as has been observed in the NPR<sup>73</sup>, the intention remains to address these and ballot any such revisions within the workgroup prior to an update to the full standard.

## Feasibility

The proposed 50 % maximum expansion for water beads in the NPR is also not feasible as presented. As well as making a product category that is classified as an expanding material (because it expands by more than 50 %, as stipulated in toy safety standards around the world<sup>74</sup>, as described earlier in these comments) into a product that would then not be classified as such, it also presents an unachievable requirement on the materials used for water beads. Since the chemical properties of the SAP materials themselves result in an expansion at a level far greater than this threshold, it will not be possible to manufacture water beads that meet the conflicting requirements of a maximum 9 mm diameter *and* less than 50 % expansion when hydrated. This belies the NPR's assertion (without supporting information) that "...there *should* be multiple means of producing and packaging water bead toys that expand by less than 50 %<sup>75</sup> (emphasis added). This assertion is also contradicted by a later statement in the NPR that "...CPSC staff has not identified water bead products that currently conform to the 50-percent-or-less growth limitation specified in the proposed rule."<sup>76</sup>

The statement that "Staff estimates that water beads over the size limit are less than 5 percent of the market based on the range of sizes from [the descriptions for 'popular' water bead products] and an assumed distribution."<sup>77</sup> appears to be incorrect, since a significant portion of the hydrated water beads are over the proposed 9 mm diameter. The statement appears to conflate the unhydrated diameter (smaller than 9 mm) with the limit for the hydrated water beads. A cursory review of water bead products on e-commerce sites illustrates water beads that are stated to expand to a size larger than the proposed 9 mm threshold.

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<sup>73</sup> FR Vol. 89, No. 174, p 73035

<sup>74</sup> ASTM F963-23, EN71-1 2014 + A1 2018, ISO 8124-1 2022

<sup>75</sup> FR Vol. 89, No. 174, p 73041

<sup>76</sup> FR Vol. 89, No. 174, p 73043

<sup>77</sup> FR Vol. 89, No. 174, p 73044

The NPR also acknowledges that "...the 50 percent growth limitation requirement is expected to result in all or nearly all water bead toys needing to be redesigned."<sup>78</sup> When also considering the fact that it is not likely to be possible to redesign the water beads to meet the proposed requirement (as previously stated in this document), it becomes increasingly evident that the proposed NPR is, to all intents and purposes, applying a *de-facto* ban on water beads as toys, instead of a performance standard.

The assertion that firms 'might' incur a "...small one-time additional cost from updating existing labels and/or adding labels."<sup>79</sup> is both factually incorrect and misleading. While the incremental cost estimated in the NPR for an *overlabel* (separately applied stick-on label) might, in reality, be at or close to the estimated cost for the application only (not including generation & printing costs), CPSC staff's estimates do not take into account the very real costs associated with having to redesign the packaging to accommodate the additional label footprint, as well as the scrap costs for packaging already printed (either in the component part form or already used to contain product) above and beyond the overlabel rework for product that is already contained in the previous packaging version. Stating that "...all manufacturers of children's products are already required to provide labels with their product pursuant to section 14(a)(5) of the CPSA."<sup>80</sup> is also misleading, since the 'labels' being referenced are not separate components as CPSC staff appear to be implying, but instead integrated *labelling elements* incorporated into the design and positioning of the printed packaging layouts. Any such change requires a redesign to re-align and re-arrange all of the packaging layout elements, especially when the new label is large and in such cases, the entire sizing of the package layout may well need to be enlarged to accommodate the label, resulting in additional scrap costs as well as increased shipment costs since the physical volume of the packages increase accordingly.

### **Effective Date**

The NPR is proposing that the final rule would become effective 90-days after being published in the Federal Register<sup>81</sup>. This proposed timeline is simply unfeasible in order to make any changes relating to physical composition or labeling, even if the existing materials could meet the proposed requirements. The disruption to the supply chain for water beads will be significant since 'manufactured date' is applied as being the date of importation for foreign-manufactured product, meaning that product in the process of being shipped on the date of the Final Rule would potentially be banned on arrival in the US, and all production would have to cease while the resulting changes are addressed. The proposed timeline makes no allowance for the investigation needed to even begin to start the work necessary to investigate how to develop and manufacture an SAP material with properties that can meet the proposed maximum diameter and non-expanding toy expansion rate.

As such, this unachievable proposed effective date further highlights that CPSC is intending not for the safety of products to be improved, but knowing that it is likely that "...all or nearly all water bead toys need[...] to be redesigned..." they are intending for this to be a *de facto* ban on water beads in toys instead.

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<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> FR Vol. 89, No. 174, p 73042

## CPSC Questions

### A. Water Bead Definition

*The proposed rule defines “water bead(s)” as “various shaped, water absorbent polymers, such as, but not limited to polyacrylamides and polyacrylates, which expand when soaked in water.” Should the proposed rule use a different definition of water beads?*

**Response** – The definition is missing the parameter for expansion that is used for the defined term ‘expanding materials’ in ASTM F963<sup>82</sup>. Without reference to it, and as described previously in this document, the proposed definition conflicts with established and commonly applied definitions for all expanding materials (in addition to the NPR proposal effectively requiring that the expanding material does not expand in a manner consistent with expanding materials). The use of ‘various shaped’ is appropriate, as it has been established that there are non-spherical items available.

### B. NPR Scope

*1. Which, if any, water pellet guns designed to shoot water bead projectiles are not children’s toys within the scope of the NPR? Please provide rationale supporting your comment.*

**Response** – Water bead launchers are intended to be played with in a manner similar to airsoft and paintball products (including needing protective eyewear which is inconsistent with play patterns for toys), and are not appropriate for children under 14 years. Under CPSIA, toys are a sub-category of children’s products and defined as being appropriate for children 12 years of age and younger<sup>83</sup>; and ASTM F963, as recognized by Congress when it was incorporated by reference as a mandatory standard<sup>84</sup>, applies to toys age graded under 14 years of age. Water pellet guns designed to shoot water bead projectiles are not considered toys, as the products themselves do not meet the prevailing toy definitions (nor do they meet the projectiles requirement of ASTM F963, as mentioned earlier in this document). Such products are recognized as being separate and discrete from toys, and category-specific (non-toy) ASTM standards are in the process of being developed for this category under ASTM F08.27.

*2. How, if at all, should color(s) of the water beads factor into the determination of whether they are toys, and therefore within the scope of the proposed rule? Please provide support for your recommendation.*

**Response** – Color is not a determinant of whether or not a product is a toy and does not play into the definition of toys. Many products, whether intended for children or not, are colorful. For example, consider CPSC’s handling of the issue of liquid laundry detergent packets (‘Tide pods’). Even though they are colorful and can be attractive to children, CPSC recognized that they are not toys<sup>85</sup>. In that situation, CPSC worked with ASTM to develop ASTM F 3159-15 Standard Safety Specification for Liquid Laundry Packets<sup>86</sup>.

### C. Proposed Requirements to Address Ingestion Hazards

*1. Are the proposed 9.0 mm diameter funnel test gauge and the 50 percent expansion limit adequate to address the hazards associated with ingestion of the product? If 9.0 mm diameter*

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<sup>82</sup> ASTM F963 section 3.1.28 “any material used in a toy which expands greater than 50 % in any dimension from its as-received state”

<sup>83</sup> [15 USC 2052 \(a\)\(2\)](#)

<sup>84</sup> [https://www.cpsc.gov/s3fs-public/pdfs/blk\\_media\\_cpsia.pdf](https://www.cpsc.gov/s3fs-public/pdfs/blk_media_cpsia.pdf)

<sup>85</sup> <https://www.cpsc.gov/s3fs-public/390%20Laundry%20Packets.pdf>

<sup>86</sup> <https://www.astm.org/f3159-15r22.html>

*is not adequate, what size is adequate and why? If a 50 percent expansion limit is not adequate, what expansion limit is adequate and why?*

**Response** – Both parameters are demonstrated not to be supported by data showing relevance to the respective hazards within this document. The 9 mm diameter is derived from data that is not related to the size of a water bead that results in intestinal obstruction, while the proposed 12 mm in the ASTM ballot is derived from a diameter that is a measured level less than the diameter derived from the smallest recorded size of a water bead that resulted in an intestinal obstruction in a very young child. The 50 % expansion limit has no supporting data to demonstrate effectiveness related to nose or ear insertion. The expansion value is the internationally recognized parameter used to determine whether or not an item is an expanding material, and is not appropriate as a restrictive requirement (effectively requiring an expanding material not to be such). Together, these two proposed requirements effectively ban ALL water beads in toys.

*2. Are there any other performance requirements CPSC should consider to address the hazards associated with water bead ingestion?*

**Response** – This is being addressed by ASTM F15.22 work group activity.

#### D. Proposed Requirements to Address Ear Insertion Hazards

*1. Is the proposed 9.0 mm diameter funnel test gauge along with the 50 percent expansion limit adequate to address the hazards associated with ear insertion? If 9.0 mm diameter is not adequate, what size is adequate and why? If a 50 percent expansion limit is not adequate, what percentage is adequate and why?*

**Response** – As previously stated, the 50 % expansion limit has no supporting data to demonstrate effectiveness related to nose or ear insertion. The expansion value is the internationally recognized parameter used to determine whether or not an item is or is not an expanding material, and is not appropriate as a restrictive requirement (effectively requiring an expanding material not to be such).

*2. What size dehydrated bead is most attractive to children regarding the risk of ear insertions and why?*

**Response** – We are not aware of any information that could address this question.

*3. Are there any other performance requirements CPSC should consider to address the hazards associated with ear insertion?*

**Response** – The 50 % expansion requirement has been proposed without any scientific basis; instead the NPR provides only an unsupported statement that “...this expansion limit will address potential damage to nasal and ear cavities...”<sup>87</sup>. This also ignores the fact that both the proposed ASTM and proposed NPR maximum water bead diameters would remove the larger water beads from toys, thus presenting only smaller water beads that might be inserted in the ear or nose, expanding to a smaller maximum size. As stated in this document, in addition to the maximum diameter, since any small item (whether or not a water bead) is able to be inserted into the ear or nose, this is an appropriate application for a cautionary statement to the consumer.

#### E. Proposed Requirements to Address Nose Insertion Hazards

*1. Is the proposed 9.0 mm diameter funnel test gauge along with the 50 percent expansion limit adequate to address the hazards associated with nose insertion? If 9.0 mm diameter is not*

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<sup>87</sup> FR Vol. 89, No. 174, p 73037

*adequate, what size is adequate and why? If a 50 percent expansion limit is not adequate, what percentage is adequate and why?*

**Response** – See previous responses related to the 9 mm diameter and 50 % expansion rate.

*2. What size dehydrated bead is most attractive to children regarding the risk of nose insertions and why?*

**Response** – We are not aware of any information that could address this question.

*3. Are there any other performance requirements CPSC should consider to address the hazards associated with nose insertion?*

**Response** – We are not aware of any additional information that could address this question.

#### F. Proposed Requirements to Address Aspiration Hazards

*1. Is the proposed 9.0 mm diameter funnel test gauge along with the 50 percent expansion limit adequate to address the hazards associated with aspiration of the product? If the 9.0 mm diameter is not adequate, what size is adequate and why? If a limit of 50 percent expansion is not adequate, what percentage is adequate and why?*

**Response** – Neither proposed requirement is supported by data to demonstrate any effectiveness in addressing potential aspiration hazards by water beads (either alone or in comparison with any other product or material).

*2. Are there any other performance requirements CPSC should consider to address the hazards associated with water bead aspiration?*

**Response** – This is covered by wording in the proposed warning statement.

#### G. Water Beads Sticking Together

*1. Is there evidence of water beads sticking together or are there specific water bead products that have tendency to stick together before, during, or after expansion? If so, please provide further details.*

**Response** – No data has been determined to demonstrate that water beads stick together, either in relation to intestinal obstruction incidents or ingestion & passage through the intestinal tract incidents.

*2. Is there an environment or scenario that has successfully caused expanded water beads to aggregate with themselves and/or any other substances, like food or mucus, to cause an obstruction? If so, please provide details.*

**Response** – We are not aware of any such instances.

#### H. Proposed Acrylamide Limit and Test Method

*1. Is the proposed limit of 65 mg (sic.) extractable acrylamide monomer from 100 small water beads or from one large water bead appropriate to adequately address the hazard of acute toxicity for children who ingest water beads?*

**Response** – Note typo: '65 mg' should read '65 µg'. This proposed limit is not appropriate, as detailed previously in this document.

*2. The 4.0 mm demarcation between the “small” and “large” designations for water beads was selected based on CPSC staff’s observations of water bead samples prior to hydration, which tended to have diameters of equal to or less than 3.0 mm, or equal to or greater than 5.0 mm. Is another metric or method more appropriate to distinguish small and large water beads?*

**Response** – Based on information received from the water bead manufacturers it is not possible to have a water bead using SAP that will expand less than 50 %. As such, this question is moot.

*3. Is there an alternative, more appropriate, acute oral toxicity reference value than ATSDR's the acute-duration oral minimal risk level that is based on valid test methods, relevant health endpoint(s), and appropriate safety factors?*

**Response** – See comments provided previously in this document.

*4. The chosen test value of 100 small water beads when testing for extractable acrylamide was within the range noted in incident case reports of children ingesting water beads. Is another test value for small water beads more appropriate?*

**Response** – Based on the information available & provided by CPSC, it is highly unlikely for younger children of the age used for the body weight (6-8 months) to be physically or developmentally able to obtain such a large number of water beads in one instance (especially related to the observed instances that individual or small numbers of beads were misplaced and discovered in the child's environment). The 100-bead value relates more to incidents involving older children who are able to access and manipulate containers of the water beads and is not appropriate in conjunction with the selected body weight value.

*5. Is CPSC's acrylamide limit test method sufficient to evaluate extractable acrylamide in water beads? Are there other tests methods that CPSC should consider?*

**Response** – As demonstrated in this document, the proposed acrylamide test and associated limit has not been shown to be appropriate or relevant to this product category. From the testing that CPSC carried out, the only types of water beads that exhibited 'concerning' results are of a type that would not be permitted under the test gauges as proposed per ASTM F963 (balloted update) and the NPR.

## I. Proposed Warning Label Requirements for Water Beads

*1. Are the proposed warnings adequate to address hazards associated with water beads? Should other warnings be considered? Should other warning formats be considered?*

**Response** – As presented in this document, warning statements are not appropriate or required when either the design or the test requirements prevent the identified hazard potential. Warnings about ingestion and death are not appropriate since the requirements (whether in this NPR or as proposed in the ASTM ballot) are designed to prevent intestinal obstruction. Separately, cautionary statements about the potential for ear or nose insertion are appropriate, however these are not required for point-of-purchase notification and should be permitted to be present on instructional material (or on package if separate instructions are not provided).

*2. Regarding the proposed warning for toys that contain water beads, will consumers know what "water beads" are when warned of the dangers of "water beads" that became dislodged from the toy? Is there another term aside from "water bead" that would help consumers better identify what part of the toy is a water bead?*

**Response** – 'Water beads' is an appropriate descriptor for this product category.

*3. Regarding the proposed warning for toys that contain water beads, will consumers know what the warning "Discard if beads are coming out" means? Is there another term aside from "coming out" that would help consumers understand the warning?*

**Response** – As presented elsewhere in this document, if the product meets the use and abuse testing to ensure that inaccessible components remain contained in the toy, the proposed warning is not appropriate or relevant.

#### J. Initial Regulatory Flexibility Analysis and Other Topics

1. *Significant impact. Is CPSC's estimated cost of redesign to achieve compliance accurate? If not, please provide additional information and support for your proposed correction. Also, do the estimated costs represent more than one percent of annual revenue for individual small U.S. manufacturers and importers?*

**Response** – The estimated costs are not accurate and do not properly reflect the effective ban proposed in this NPR.

2. *Testing costs. Will third-party testing costs for water beads increase as a result of the requirements in this NPR, and if so, by how much? Are test labs that are currently accredited to test for ASTM F963–23 equipped to use LC–MS–MS to test for acrylamide in water beads? What other analytical test methods and equipment are appropriate for quantifying acrylamide content in the levels discussed in the NPR?*

**Response** – As demonstrated in this document, the proposed acrylamide test and associated limit has not been shown to be appropriate or relevant to this product category. From the testing that CPSC carried out, the only types of water beads that exhibited 'concerning' results are of a type that would not be permitted under the test gauges as proposed per ASTM F963 (balloted update) and the NPR.

3. *Effective date. How much time is required to come into compliance with a final rule (including product compliance and third-party testing), particularly for small businesses? Please provide supporting data with your comment.*

**Response** – Even if it were possible to re-engineer the materials to comply, a 90-day period from the publish date of a Final Rule is not achievable. Without the proposed 50 % expansion requirement, it would be possible to revise product and labeling/packaging, however, as has been advised to CPSC on other similar re-engineering and re-labeling instances would require a significantly greater time period to carry out even if all production ceased on the publish date of the FR (12 months has been provided as a more realistic timeline. Timelines below this level significantly increase financial burdens as any changeover results in extended periods of non-shipment while the revised product designs are made, implemented, tested and shipped.

4. *Alternatives to reduce the impact on small businesses. Are there any alternatives to the rule that could reduce the impact on small businesses without reducing safety? Please provide supporting data with your comment, particularly addressing small businesses.*

**Response** – Recognizing ASTM's actions to update ASTM F963 through the consensus process would constitute less impact than the de-facto ban proposed in the NPR.

#### K. Feasibility

*Are the proposed requirements in this NPR feasible, both technically and economically?*

**Response** – As presented in this document, the proposed requirements are a de-facto ban and are not feasible as-presented.

#### L. Water Bead Manufacturing

*Are manufacturers able to limit the growth of water beads to a specific diameter or specific percentage of growth? If so, what is the process of adjusting growth potential?*

**Response** – Information received from water bead manufacturers demonstrate that the proposed expansion limit in the NPR is not technically feasible. SAP materials exhibit around a

200 % expansion (with a variance range), based on the material properties of the polymers used.

## **Conclusions**

As noted earlier, an ASTM technical working group has been considering the issue of water beads within the consensus standards process and with direct participation from CPSC staff, for some time. This NPR, however, appears to bypass or forgo that ongoing multi-stakeholder effort. As illustrated throughout this document, the proposed requirements are presented using partial or misleading information, and as a result, are not based on science- or data-driven, and the combination of requirements is, in effect, a ban on water bead toys, presented as a product safety standard.

The proposed definition is unduly broad by having no minimum size and also ignores the established parameters for expanding materials by removing the 50 % expansion threshold from the definition and instead applies it as an unattainable performance parameter by adding the expansion rate to the maximum size instead. Paradoxically, this requires that water beads, which are universally recognized to be expanding materials (to a definition that has been approved and accepted by CPSC when approving the updates to ASTM F963 that incorporated the expanding materials requirements), would have to not be expanding materials in order to pass the proposed requirement in the NPR.

The proposed acrylamide test itself is unnecessary and burdensome. CPSC does not consider:

- (a) that many water beads do not have acrylamide monomer present,
- (b) any data about the actual acrylamide monomer levels in polyacrylamide water beads,
- (c) that from CPSC's own testing, only the large beads exhibited 'concerning' levels and those beads would no longer be present due to the proposed size limitation (whether per the NPR or proposed ASTM testing),
- (d) that acrylamide is commonly present in foodstuffs at potential levels greatly exceeding the proposed limit, and
- (e) that requiring a test contradicts other government agencies' assessment of acrylamide risk.

Once the information relating to the test methodology developed by CPSC and used to assert acrylamide risk potential was provided for review, the extension to the comment period of 30 days was appreciated but only provided a limited window of opportunity for peer review of the information made available. Even after the acrylamide test information was released, it does not demonstrate a need for the test, especially considering that the characteristics of the examples that were listed to be of concern to CPSC are of a size that would not be permitted for toys, whether per the requirements proposed in the NPR or as is currently being proposed in ASTM F15.22 for inclusion in ASTM F963.

Contributing to the assessment that the NPR as-proposed is a ban on water beads in toys, despite being aware that the 50 % expansion parameter is a determinant of assessing whether or not a material is classified as being an expanding material, CPSC staff instead took the expansion property out of consideration for the classification determination and instead, without any basis in fact to support the change other than opining that it must be better, applied the 50 % expansion as a pass/fail parameter. It is important to stress that the NPR recognizes that CPSC staff are not aware of any product currently on the market that can meet this requirement, as well as the likelihood that it will not be possible to engineer a compliant version of SAP. In the same instance, an enforcement window of only 90 days after the final rule is published in the Federal Register is proposed, with no basis in the reality of the typical production cycle for toys,

and making it all but impossible for any manufacturer to attempt to reengineer the product (including needing to take into account manufacturing tolerances as well as material variability to ensure consistent compliance).

The proposed warning label statement and approach *contradicts* the established hazard remediation process in that a warning is warranted if and where a hazard cannot be addressed through design and/or test requirements. In this instance, the NPR both proposes (excessive and not scientifically-based) physical test requirements that are intended to prevent any chance of intestinal obstruction, and at the same time proposing a warning statement that is designed to incorporate an alarmist message for a hazard that, to the NPR's own stated intent, *precludes the intestinal obstruction hazard from being present in the first place*.

Ensuring that potentially hazardous components and materials in toys and children's products are inaccessible is a long-established and effective statutory and regulatory approach. This has been done with physical hazards like ingestion, as well as chemical hazards. There are established tools and test methods designed to ensure that a component is not accessible and will not become accessible during normal use and abuse of a product. CPSC has not provided a data-driven reason to impose new performance requirements on water beads contained in toys if such water beads are not accessible and do not otherwise become accessible during normal use and abuse. CPSC has not provided any data or information that suggests that water beads contained within toys cannot be made inaccessible nor, if water beads contained within a toy are inaccessible, how they could pose a choking, ingestion, aspiration, insertion, or chemical hazard. For these reasons, the NPR should be amended to recognize inaccessibility performance requirements for water beads contained within toys, and to exclude water beads that are demonstrably inaccessible to the child.

The Toy Association respectfully requests that CPSC reconsider the proposed position of overlaying unilateral requirements that are verifiably misleading or incorrect, and which contradict established and commonly applied consensus-based and scientific definitions.

If the intent is to ban this product category, this is unquestionably within CPSC's domain, but such an action is required to be applied using the proper process and procedure, instead of through CPSIA section 106. If CPSC's intent is to institute a reasoned and appropriate product safety standard, utilizing the consensus standards process to effectively address the actual risk parameters of the product category, we stand ready to assist in this 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.

Regards,



Jos Huxley  
Senior Vice President of Technical Affairs  
The Toy Association  
[jhuxley@toyassociation.org](mailto:jhuxley@toyassociation.org)

About The Toy Association and the toy industry:

The Toy Association is the North American 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 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.

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## Appendix A

### 24-F-00409 Expedite Denied Letter



United States  
Consumer Product Safety Commission

April 26, 2024

**Via Email**

Joan Lawrence  
1375 Broadway  
New York, New York 10018  
[jlawrence@tovassociation.org](mailto:jlawrence@tovassociation.org)

**RE:** Freedom of Information Act Request #24-F-00409: Requesting information related to CPSC testing of water bead products, as described in the attached document.

Dear Ms. Lawrence:

This is an interim response to your Freedom of Information Act (FOIA) request to U.S. Consumer Product Safety Commission (CPSC or Commission) that seeks, *inter alia*, expedited processing. You state that your request for expedited processing is being made because "Given the position taken by CPSC staff of a potential acute toxicity issue of certain such products, and the expressed urgency by CPSC in its communications to revise the toy standard. An expedited request is appropriate and warranted in fulfilling this FOIA request in order for the ASTM technical working group to have full and transparent information from the commission in order to review and assess the information upon which the commission is basing its assertions and publicly stated position."

Your statement does not set forth a claim that a "compelling need" exists for expedited processing under Commission regulations, *i.e.*, you have not demonstrated that the failure to obtain the requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual or that there is an urgency to inform the public concerning actual or alleged Federal Government activity. See 16 C.F.R. § 1015.5(g)(1). We are, therefore, denying your request for expedited processing. Please be assured, however, that our office is processing your FOIA request and will provide you with all releasable material at the earliest possible date.

*Right to appeal.* According to the Commission's regulations at 16 C.F.R. § 1015.5(g)(4), a denial of a request for expedited processing may be appealed. If you are not satisfied with the response to this request, you may administratively appeal in writing, addressed to FOIA APPEAL, Office of the General Counsel, ATTN: Division of Information Access, U.S. Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, MD 20814-4408. Your appeal must be postmarked or electronically transmitted ([cpscfoiarequests@cpsc.gov](mailto:cpscfoiarequests@cpsc.gov)) within 90 days of the date of the response to your request. You can also fax your appeal to 301-504-0127. You can contact us Monday – Friday from 8:00AM – 4:30PM ET by telephone at 1-800-638-2772, by fax to 301-504-0127, or by email to

U.S. Consumer Product  
Safety Commission  
4330 East-West Highway  
Bethesda, MD 20814  
[cpsc.gov](http://cpsc.gov)

National Product Testing  
& Evaluation Center  
5 Research Place  
Rockville, MD 20850

## 24-F-00409 Final Response



United States  
Consumer Product Safety Commission

June 13, 2024

### Via Email

Joan Lawrence  
The Toy Association  
1375 Broadway  
New York, New York 10018  
[jlawrence@toyassociation.org](mailto:jlawrence@toyassociation.org)

RE: Freedom of Information Act Request #24-F-00409: Requesting information related to CPSC testing of water bead products, as described in the attached document.

Dear Ms. Lawrence:

The Consumer Product Safety Commission (Commission or CPSC) is in receipt of your request for information pursuant to the Freedom of Information Act (FOIA), filed on April 12, 2024.

In your request, you seek documents related to the testing of water beads.

The Commission directed staff to complete a notice of proposed rulemaking regarding water beads this fiscal year. The Commission makes rulemaking documents available as required by law, when it issues a Notice of Proposed Rulemaking. Your request seeks record(s) that will be made available to the public outside of the FOIA process in a Notice of Data Availability (NOA). CPSC's Office of Executive Director, Office of Hazard Identification and Reduction (EXHR) will provide this information in the NOA associated with the proposed rule. Processing this record under the FOIA would be duplicative of EXHR's efforts to make them publicly available, and unduly burdensome. Accordingly, we are closing this request. If you have any questions about this rulemaking, please contact Andrew Stadnik, the Associate Executive Director for Laboratory Sciences, at [ASTadnik@cpsc.gov](mailto:ASTadnik@cpsc.gov).

### FOIA Administrative Procedures

*Right to appeal.* If you are not satisfied with the response to this request, you may administratively appeal in writing, addressed to: FOIA APPEAL, Office of the General Counsel, ATTN: Division of Information Access, U.S. Consumer Product Safety Commission, 4330 East West Highway, Room 820, Bethesda, MD 20814-4408. Your appeal must be postmarked or electronically transmitted ([cpscfoiarequests@cpsc.gov](mailto:cpscfoiarequests@cpsc.gov)) within 90 days of the date of the response to your request. You may also fax your appeal to 301-504-0127. You may contact us Monday – Friday from 8:00AM – 4:30PM ET, by telephone at 1-800-638-2772, by fax to 301-504-0127, or by email to [cpsc-foia@cpsc.gov](mailto:cpsc-foia@cpsc.gov).

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