UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: **May 10, 2010**

TO : Robert J. Howell, Assistant Executive Director
Office of Hazard Identification and Reduction

THROUGH: Hugh McLaurin, Associate Executive Director
Directorate for Engineering Sciences

FROM : Jonathan D. Midgett, Ph.D.
Office of Hazard Identification and Reduction

SUBJECT : Evaluation of the Toy Standard for Section 106 of the CPSIA

On August 14, 2008, the Consumer Product Safety Improvement Act (hereafter referred to as the "Act" or the "CPSIA") was signed into law [Public Law 110-314]. Section 106(b)(1) of the Act directs the Commission, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, to examine and assess the effectiveness of ASTM F963-07e1 or its successor standard (except for section 4.2 and Annex 4), as it relates to safety requirements, safety labeling requirements, and test methods related to—

(A) internal harm or injury hazards caused by the ingestion or inhalation of magnets in children's products;
(B) toxic substances;
(C) toys with spherical ends;
(D) hemispheric-shaped objects;
(E) cords, straps, and elastics; and
(F) battery-operated toys.

To address this mandate, CPSC staff consulted with the representatives of the required groups at ASTM meetings on 9/16/2008, 3/3/2009 and 9/17/2009. The following list of concerns voiced by industry and consumer stakeholders and CPSC staff was generated by agency staff for use when setting priorities.[1] All of the concerns expressed by interested parties listed below were included on this list for consideration only. Inclusion on this list should not be interpreted as being an assigned task for ASTM or the Commission. This analysis is for discussion only.

The concerns are listed according to the numerical sections of the ASTM F 963 toy standard.

Section	Topic	Concerns

[1] The statute directs that "[w]ithin 1 year after the completion of the assessment required by paragraph 1, the Commission shall promulgate rules in accordance with section 553 of title 5, United States Code, that (1) take into account other children's products safety rules; and (2) are more stringent than such standards, if the Commission determines that more stringent standards would further reduce the risk of injury of such toys." Section 106 (b)(2).

3.1.33	—a magnet which has a flux index >50 (refer to test method in 8.25.1) and which is a small object (refer to 4.6 and Fig.3)	Flux index may not adequately represent the key hazardous characteristics of all shapes and kinds of magnets, particularly "high energy product" magnets of irregular shape or very small size. The flux index threshold of 50 kG^2mm^2 is derived from inferences made from the strength of a small sample of magnets involved in incidents, but the flux index approach has not been independently evaluated. More study of the effects of clamping forces on human tissues is needed before confidence is placed on the current required flux index limit of 50 kG^2mm^2. It is unknown whether or not magnets with a flux index slightly below 50 kG^2mm^2 could cause injury in some areas of the intestines. More research is warranted on this and on the effects of different magnet materials and magnet shape on magnet strength and how this relates to injuries caused by clamping forces exerted on human tissues.
3.1.34	*hazardous magnet component*—any part of a toy that is a small object (refer to 4.6 and Fig. 3) and which contains an attached or imbedded magnet which has a flux density >50 as determined in accordance with the test method in 8.24.1.	Change "flux density" to "flux index." The flux index approach and prescribed threshold of 50 kG^2mm^2 requires more science-based evaluation and refinement, especially with regard to stacking of disc magnets noted in incident reports. Stacking magnets may sometimes increase flux index depending on various factors thereby turning two or more magnets with a flux index less than 50 kG^2mm^2 into a composite object with a flux index greater than 50 kG^2mm^2.
4.2	4.2 *Flammability*—Materials other than textiles (excluding paper) used in toys shall not be flammable, as defined under 16 CFR 1500.3 (c) (6) (vi) under the Federal Hazardous Substances Act (FHSA) (see 16 CFR 1500). For testing purposes, any textile fabrics used in toys should comply with 16 CFR 1610. A test procedure for testing flammability of toys, which is an interpretation of 16 CFR 1500.44, is contained in Annex A4. A procedure for testing the	Industry representatives believe that the information in Annex A4 and A5 represent the state of the art in safety test methods. Many of the details in these Annexes clarify portions of the CFR that have historically been confusing to test laboratories. Consider updating the CFR to reflect the accumulated testing experiences reflected in F 963's methodology.

	flammability of fabrics is contained in Annex A5.	
4.3.1	*Hazardous Substances*: Toys or materials used in toys shall conform to the FHSA and to the regulations promulgated under that act. Exemptions to this act for certain types of toys are given in 16 CFR 1500.85. The regulations define limits for substances that are toxic, corrosive, an irritant, sensitizer or pressure generating, and radioactive, flammable, and combustible materials. Testing references for hazardous substance content are given in 8.2. It should be noted that specific states may have hazardous substances regulations that are more restrictive than the Federal regulations.	Section 8.2 will be reviewed for changes and updates. Consumer groups believe that the approach to injury prevention involving toxic substances should account for cumulative exposures from all sources.
4.3.2	*Manufacturing and Packaging of Food*: All food products supplied with toys shall be manufactured and pack- aged in compliance with 21 CFR 110, which is concerned with the sanitation practices for the manufacture, processing, packaging, or holding of human food.	Potentially overlapping jurisdiction between CPSC and FDA. Determine FDA's intentions to revise regulations and how to navigate overlapping jurisdictions. FDA requirements would typically be more restrictive and supersede CPSC packaging requirements, regardless of conflict. This issue recurs repeatedly in F 963, especially in section 4, with every mention of FDA requirements.
4.3.5.2	In addition, surface-coating materials shall not contain compounds of antimony, arsenic, barium, cadmium, chromium, lead, mercury, or selenium, of which the metal content of the *soluble* material is in excess of the levels by weight of the contained solids (including pigments, film solids, and driers) given in Table 1. The analytical results obtained should be adjusted in accordance with the test method in 8.3.4.3 prior to	A CPSC contractor is conducting a toxicity review of the seven (7) metals identified in section 4.3.5.2 of the F963. In addition, the European Union has made significant changes to their Toy Safety Directive, EN-71-3, which the Toxicology section of the F963 is modeled after. These changes will be reviewed and considered for harmonization.

	comparing them to the values in Table 1 to determine conformance. The soluble level shall be determined by dissolving the contained solids (dried film including pigments, film solids, and driers) as specified in 8.3.	
4.3.6	*Cosmetics, Liquids, Pastes Putties Gels, and Powders*: The purpose of this requirement is to minimize the risk associated with the lack of cleanliness, shelf life, and contamination of cosmetics, liquids, pastes, putties, gels, and powders used in toys (excluding art materials). It sets standards for cleanliness and the ability to withstand extended shelf life or contamination, or both, during use without microbiological degradation.	Consider a review for potentially updating and improving this section.
4.3.6.1	Water used in the manufacturing and filling of toys shall be prepared according to the bacteriological standards for USP Purified Water. (**Warning—**The various methods for producing purified water each present different potentials for contaminating the final product. Purified water produced by distillation is sterile, provided that the production equipment is suitable and sterile. On the other hand, ion-exchange columns and reverse osmosis units require special attention in that they afford sites for microorganisms to foul the system and contaminate the effluent. Frequent monitoring may thus be called for, particularly with the use of these units following periods of shutdown of more than a few hours.)	Effective May 2009, US Pharmacopeia (USP) requires compliance with two test methods, USP 61, a preparatory test, and USP 62, for specific microorganisms. Previously, both tests were done under USP 61. Changes were made in the microbes evaluated and the testing protocol, including the loss of testing for pathogens *E. coli* and *Salmonella* under the preparatory test, the addition of testing for *Candida albicans* (a yeast) and *Aspergillus niger* (a fungus) and *Bacillus subtilis* under the preparatory test, and reduction of pass/fail limits. Loss of testing for such important pathogens creates the need for compliance with both USP 61 and 62 or compliance with another testing protocol that includes pathogen testing. HS review of the changes in these methods suggests that both 61 and 62 are preferred. The Office of the General Counsel (OGC) states that under the current language, both the old and the new versions must be allowed. Clarification of the preferred method is required with the addition of the appropriate legal wording about successor standards.

4.3.8	*DEHP (DOP)*: Pacifiers, rattles, and teethers shall not intentionally contain DI (2-ethylhexyl) phthalate (also known as dioctyl phthalate). To prevent trace amounts of DEHP (DOP) from affecting analysis, up to 3 % of total solid content will be accepted in the result, when tested in accordance with Practice D 3421.	Regarding the test practice in ASTM D 3421: This standard has been withdrawn by ASTM, but continues to be referenced by F 963 (F 963 footnotes that D3421 has been withdrawn.) CPSC's method for testing phthalates is on the web: CPSC-CH-C1001-09.2 – *Standard Operation Procedure for Determination of Phthalates*, July 27, 2009 This method also includes by reference other methods which can be used, including ASTM D 7083, which itself, by reference requires the use of ASTM D 2124 as a preparatory step. Depending on comments and rulemakings, some of the agency's interpretations of CPSIA Section 108 may change, and these would be reflected in amendments or revisions of CPSC-CH-C1001-09.2. The major issues include the definitions of DINP and DIDP. Additionally, the testing community would like us to consider other changes for ease-of-testing or harmonization with the EU. Consider the risks presented by BPA, PBDEs, nanoengineered materials and formaldehyde in toys.
4.14.1	*Cords, Straps, and Elastics in Toys*: Cords or elastics included with or attached to toys intended for children less than 18 months of age (excluding pull toys, see 4.14.3) shall be less than 12 in. (300 mm) long when measured to the maximum length in a free state and under a load of 5 lb (2.25 kg). If cords/straps/elastics or multiple cords/straps/elastics can tangle or form a loop in connection with any part of the toy, including beads or other attachments on the ends of cords/	Does the incident data still support the age limit of 18 months? Pull toys apply to 36 months. How do laboratories test "if they can tangle to form a loop"? Should this have a repeatable method? Does the incident data support a need to be concerned with this potential injury scenario? The CPSC toy testing manual has a recommended method for loop formation.

	straps/elastics, the loop shall not permit the passage of the head probe (Fig. 11) when tested in accordance with 8.23. Specifically, the loop shall not allow the head probe to be inserted so deep that it admits the base of the probe. The configuration of the loop shall be determined by using all components that make up the loop. For example, the configuration of the loop for the product illustrated in Fig. 12 is comprised of Cord 1, Cord 2, and the toy part.	
4.14.1.1	*Cords, Straps, and Elastics Containing a Break- away Feature:* Cords, straps, and elastics on toys that have loops that admit the base of the head probe shall contain a functional breakaway feature that prevents entanglement by releasing at a force less than 5.0 lbf (22.2 N) when tested in accordance with 8.23.3. The free length of the individual released cord, strap, or elastic should not exceed a maximum length of 12 in. (300 mm). The breakaway feature shall be capable of being reattached without altering the characteristics of the attachment.	Change "should" to "shall." In general, the language of the standard should be harmonized with the style and vocabulary of other federal regulations if possible.
4.14.3	*Pull Toys*: Cords, straps, and elastics greater than 12 in. (300 mm) long for pull toys intended for children under 36 months of age shall not be provided with beads or other attachments that could tangle to form a loop.	Should this be "beads and/or any other attachment?" Does this include *knots* in the end of a string? Does the incident data show knots causing injuries?
4.14.5	*Cords on Toy Bags Intended for Children Up to 18 Months*: Toy bags made of impermeable material with an opening perimeter greater than 14 in. (360	What is considered an "impermeable" material? Can this be clarified with the packaging film test? Are there other standard methods for determining permeability?

	mm) shall not have a drawstring or cord as a means of closing.	
4.25.8	No condition shall occur that would cause the toy to fail the temperature requirements of 4.25.7 or present a combustion hazard as described in 4.25.	Since November 2007, CPSC has received over 40 of reports of remote-controlled helicopters igniting while being charged and one incident of a helicopter that ignited while flying. Numerous other incidents have resulted in overheating, smoke, thermal burn hazards, acoustic trauma noise hazards, and minor property damage. Since November of 2006, there have been eleven recalls associated with the charging or use of high energy rechargeable batteries. These recalls involved over 1,300,000 toy helicopters and games. In order to reduce the number of incidents associated with high energy rechargeable batteries, the CPSC staff believes that new requirements should be added to ASTM F 963. (1) Consumer Alert: Fire Hazard with Remote-Controlled Helicopters and Airplanes – CPSC link: http://www.cpsc.gov/CPSCPUB/PREREL/prhtml08/08189.html (2) CPSC staff letter to ASTM F15.22 Subcommittee Chair, - CPSC link: http://www.cpsc.gov/volstd/toys/astm02252008.pdf (3) Risk of Explosion and Hearing Damage Prompts Recall of Remote Control Airplanes—CPSC link: http://www.cpsc.gov/cpscpub/prerel/prhtml07/07250.html A working group at ASTM has been formed to address the issues with CPSC support to refine the requirements.
4.25.9	Battery-operated toys shall meet the requirements of 6.6 for instructions on safe battery usage. Toys which use non-replaceable batteries as the only source of power are not subject to 6.6.	Explosion of battery operated toys can occur during use or charging when battery compartments are sealed and certain batteries are used. This section needs improvement. A working group at ASTM has been formed to address the issues with CPSC support.
4.32.1	Toys intended for children up to the age of 18 months, having a total weight less than 1.1 lb (0.5 kg) incorporating spherical,	Consider addressing the seeming convergence of test methods for rattles, small figures, and impaction hazards. Is simplification across these similar hazard patterns possible?

	hemispherical, or circular flared ends and which are attached to a shaft, handle, or support that has a smaller cross section, shall be so designed that such ends are not capable of entering and penetrating past the full depth of the cavity of the supplemental test fixture shown in Fig. 17. A toy shall meet this requirement when tested under the force only of its own weight and in a noncompressed state. Exclusion—The requirement of 4.33.1 shall not apply to soft-filled (stuffed) toys or soft-filled parts of toys or parts of fabric.	Consider expanding the size of the test fixture which was designed for use with children under 18 months of age. By age 4 years, children's oral anatomy has grown, potentially indicating the need to use a larger diameter test fixture, such as the 1.75 inch small ball standard to prevent impaction incidents. Consider increasing the force of the test so that the product is subjected to more representative forces, such as the weight of a toddler falling, rather than testing under its own weight. Consider expanding exclusions to toys made of other materials or those having a different construction, such as balls on springs or very flexible shafts that would not cause an impaction due to being too soft.
4.32.2	Additionally, in toys intended for children between the ages of 18 and 48 months, nail, screw, and bolt shapes that weigh less than 1.1 lb (0.5 kg) and incorporate spherical or hemispherical ends attached to a shaft or handle (see Fig. 17) shall be so designed that such ends are not capable of entering and penetrating past the full depth of the cavity of the supplemental test fixture shown in Fig. 16. A toy shall meet this requirement when tested under the force only of its own weight and in a noncompressed state.	Staff supports this new section to F 963-08.
4.32.2.1	Exclusions—The requirements of 4.32.2 do not apply to the following nail, screw, and bolt shapes: (1) Soft-filled shapes and fabric shapes. (2) Shapes with an overall length less than 2.25 in. (57.1 mm). (3) Shapes whose spherical or	Staff supports this new section to F 963-08.

	hemispherical ends are less than 0.6 in. (15 mm) in diameter, as shown in Fig. 18. (4) Shapes with flexible ends. (5) Shapes where the distance to the undercut is greater than 1.75 in. (44.4 mm) as shown in Fig. 18.	
4.32.3.1	Preschool play figures intended for children under three years of age shall be designed so that their rounded ends are not capable of entering and penetrating to the full depth of the cavity in the Supplemental Test Fixture illustrated in Fig. 17. Test the play figure under the force of its own weight.	Consider addressing the seeming convergence of test methods for rattles, small figures, and impaction hazards. Is simplification across these similar hazard patterns possible?
5.16	Magnets—The packaging and instructions of hobby and crafts items and science kit-type items for children over 8 years of age which contain a loose as-received hazardous magnet or a loose as-received hazardous magnetic component shall carry safety labeling in accordance with 5.3. ...	Concerns have been expressed by the American Academy of Pediatrics (AAP) that the warning label wording is not clear and should be tested. The warning label was never validated with consumers and may need refinement if difficulties with consumer understanding of the hazard are discovered. Consider requiring the warning label on any magnetic toys with magnets that can be swallowed, regardless of the size of components. Consider better defining science and craft kits to prevent repackaging of toys with hazardous magnets.
8.4.1	*Cleanliness of Materials*—The cleanliness of cosmetics, liquids, pastes, putties, gels, and powders used in toys (excluding art materials) shall be determined using the methods in USP 24 <61> Microbial Limits Tests or the most current edition of the U.S. Pharmacopeia.10 Another method may be substituted provided it has been properly validated as giving equivalent or better results, as specified in USP	The test method in USP 24 has been updated in USP 32, but the requirements in <61> have been separated into <61> and <62> and also expanded to include a number of new microbials that significantly increase the time needed for the entire test. The Office of the General Counsel (OGC) believes the wording requires the CPSC to use either USP 24 or the most current edition rather than requiring the CPSC to replace USP 24 with each new edition. This means that the state of the art USP methods are allowed, but not required. Health Sciences (HS) believes the newest USP version is better than USP 24 and that the use of

	24 <61> or the most current edition of the U.S. Pharmacopeia. In conjunction with the chosen test method, the limits for determining the cleanliness of materials will consist of the most current guidelines for cosmetics set forth by the Cosmetic, Toiletry, and Fragrance Association (CTFA).	the new tests should be encouraged. Consider updating this wording to mean that successor standards actually replace prior standards. Determine the accessibility of the CTFA guidelines to the industry and their schedule of revision.
8.4.2	*Preservative Effectiveness*—The formulations of cosmetics used in toys shall be evaluated for the potential microbiological degradation, or they shall be tested for microbial control and preservative effectiveness using the methods and limits in USP 24 <51> Antimicrobial Effectiveness Testing or the most current edition of the U.S. Pharmacopeia.	Another potential FDA issue; update wording to mean that successor standards actually replace prior standards.
8.5	*Normal Use Testing*—These tests are intended to simulate normal use conditions so as to ensure that hazards are not generated through normal wear and deterioration. The object of these tests shall be to simulate the normal play mode of the toy, and the tests are therefore unrelated to the reasonably foreseeable abuse tests of 8.6-8.13. The tests are intended to uncover hazards rather than to demonstrate the reliability of the toy. The fact that a mechanism or material of a toy fails during testing is relevant only if the failure creates a potential hazard. Toys shall be subject to appropriate tests to simulate the expected mode of use of the particular toy. For example, levers, wheels, catches, triggers, strings, wires, chains, and so on,	This test is often not performed by test labs due to the difficulty of defining foreseeable use and misuse. The problem is identifying a "normal play mode" and giving this requirement some testing consistency across labs. The CPSC toy testing manual provides an interpretation of this section. How does a toy manufacturer estimate the lifetime of a toy? Is more guidance needed for this?

	that are intended to be actuated by a child shall be operated repeatedly. Spring or power-operated devices shall be tested similarly. The tests shall be conducted in an expected use environment. For example, toys intended for use in the bathtub shall be tested in soapy water, and toys intended for use in the sandbox shall be exposed to sand during testing. It is recognized that no specific requirements are defined here; it would not be possible in view of the wide range of toys covered by this specification. However, the manufacturer or distributor must do enough testing to satisfy himself that normal use during the estimated lifetime of the toy is being simulated. The toy shall be inspected after such tests, and hazards such as points, sharp edges, and release of small parts shall be evaluated in accordance with the relevant requirements listed in Section 4.	
8.20.2.4	(3) Measurements of Impulsive Sounds—Measure the C-weighted peak sound pressure level, LCpeak, of impulsive sounds in each microphone position. Perform a total of three measurements of impulsive sounds in each microphone position. Perform a total of three measurements. For pass-by tests, measure the C-weighted peak sound pressure level. Measure twice on each side.	This change was made to harmonize with the ISO toy standard. A-weighted measurements simulate human perception while C-weighted measurements are more accurate to the physical properties associated with sound pressure. Basically, humans may not actually hear all the damage they are receiving, making the C-weighted curve preferable. For measurement of impulsive noise (fast-rise, short-lived in nature), most authorities recommend use of either C-weighted sound pressure level peaks or the very similar unweighted peak sound pressure level. The A-weighted measurement is more appropriate for noises composed of continuous sounds or a mix of continuous and impulsive noises up to 115 dBA. Health Canada opposed the addition of the last two

		sentences to this section with an extensive negative vote on this ballot item that was found non-persuasive by the subcommittee. For push-pull toys only**,** Health Canada opposed the change from the F963-07 that used a continuous dBA noise exposure limit for pass-by tests, to the use in F963-08 of C-weighted peak impulsive noise limits for pass -by tests. In part, Health Canada contested ASTM's rationale for the change and reasoned that the type of noise exposure during normal play with push-pull toys is more accurately considered continuous or mixed in nature, meaning that A-weighted measurements are most appropriate. The pass-by test is also used for hand-activated, spring-propelled toys. This may suggest a need for a separate test method for push-pull toys.
8.23.1	Anchor or secure the toy. Place the head probe (Fig. 11) in the loop/opening formed by the cord/s, tapered end first, with the plane of its base parallel to the plane of the opening. Rotate the probe to any orientation about its own axis while keeping its base parallel to the plane of the opening; apply 10 bf (45 N) while attempting to push the probe through the opening.	This can be a difficult test to perform with a flexible cord. Is an easier method warranted? Consider a tolerance on force. In general, tolerances on forces and probes could be re-evaluated throughout the standard.
Annex A4 and A5	*Flammability Testing Procedures*	This section was expressly omitted in the CPSIA. Industry experts express concerns that the flammability test methods in the CFR need clarification and that the guidance in the F 963 toy standard reflects state-of-the-art procedures.

Conclusion

Staff believes that the preceding concerns should be addressed in future revisions of the toy standard.