

■ 2. Supplement No. 1 to Part 738 is amended by revising the entry for “Venezuela” to read as follows:

SUPPLEMENT NO. 1 TO PART 738—COMMERCE COUNTRY CHART
[Reason for control]

Countries	Chemical and biological weapons			Nuclear non-proliferation		National security		Missile tech	Regional stability		Firearms convention	Crime control			Anti-terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
Venezuela	X	X	X	X	X	X	X	X	X	X	X	X		X		

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PART 740—LICENSE EXCEPTIONS

■ 3. The authority citation for part 740 is revised to read as follows:

Authority: Pub. L. 115–232, 132 Stat. 2208 (50 U.S.C. 4801 *et seq.*); 50 U.S.C. 4601 *et*

seq.; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2018, 83 FR 39871 (August 13, 2018).

■ 4. Supplement No. 1 to Part 740 is amended by:

■ a. Removing Venezuela from the table labeled “Country Group B—Countries;” and

■ b. Revising the entry for “Venezuela” under “Country Group D” to read as follows:

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SUPPLEMENT NO. 1 TO PART 740—COUNTRY GROUPS
[Country Group D]

Country	[D: 1] National security	[D: 2] Nuclear	[D: 3] Chemical and biological	[D: 4] Missile technology	[D: 5] U.S. arms embargoed countries ¹
Venezuela	X	X	X	X	X

¹ **Note to Country Group D:5:** Countries subject to U.S. arms embargoes are identified by the State Department through notices published in the **Federal Register**. The list of arms embargoed destinations in this paragraph is drawn from 22 CFR 126.1 and State Department **Federal Register** notices related to arms embargoes (compiled at http://www.pmdc.state.gov/embargoed_countries/index.html) and will be amended when the State Department publishes subsequent notices. If there are any discrepancies between the list of countries in this paragraph and the countries identified by the State Department as subject to a U.S. arms embargo (in the **Federal Register**), the State Department’s list of countries subject to U.S. arms embargoes shall be controlling.

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Dated: May 17, 2019.

Richard E. Ashooh,
Assistant Secretary for Export Administration.

[FR Doc. 2019–11034 Filed 5–22–19; 4:15 pm]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 181219999–8999–01]

RIN 0694–AH72

Addition of Certain Entities to the Entity List, Revision of an Entry on the Entity List, and Removal of an Entity From the Entity List

Correction

In rule document 2019–09945, appearing on pages 21233 through

21238, in the issue of Tuesday, May 14, 2019, make the following correction:

PART 744 [CORRECTED]

On page 21236, in the table labeled “Supplement No. 4 to Part 744—Entity List”, in the second column, in the third entry “Multi-Mart Electronics Technology Co, Ltd.,” in the second line, “S/F” should read “5/F”.

[FR Doc. C1–2019–09945 Filed 5–23–19; 8:45 am]

BILLING CODE 1301–00–D

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1450

[Docket No. CPSC–2019–0012]

Virginia Graeme Baker Pool and Spa Safety Act; Incorporation by Reference of Successor Standard

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: The Virginia Graeme Baker Pool and Spa Act (VGBA, or Act) requires that drain covers must comply with entrapment protection requirements specified by the joint American Society of Mechanical Engineers (ASME) and American National Standards Institute (ANSI) ASME/ANSI A112.19.8 performance standard, or any successor standard. The Consumer Product Safety Commission incorporates sections of APSP–16 2017 as the successor drain cover standard.

DATES: The rule is effective November 24, 2020, unless we receive significant adverse comment by June 24, 2019. If we receive timely significant adverse comments, we will publish notification in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is

approved by the Director of the Federal Register as of November 24, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2019–0012, by any of the following methods:

Electronic Submissions: Submit electronic comments in the following way: Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. To ensure timely processing of comments, please submit all electronic (email) comments through www.regulations.gov rather than to CPSC. CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments in the following way: Mail/Hand delivery/Courier (for paper, disk or CD–ROM submissions), preferably in five copies, to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change to <http://www.regulations.gov>, including any personal identifiers, contact information, or other personal information provided. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted by mail/hand delivery/courier.

Docket: For access to the docket to read background documents or comments received, go to: <http://www.regulations.gov>, insert docket number CPSC–2019–0012 into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Troy Whitfield, Lead Compliance Officer, Directorate for Compliance Regulatory Enforcement, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301–504–7548; email: twhitfield@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The VGBA, 15 U.S.C. 8001 *et seq.*, took effect on December 19, 2008. The VGBA’s purpose is to prevent drain entrapment and child drowning in swimming pools and spas. In part, the Act requires that drain covers must comply with entrapment protection requirements specified by the joint ASME/ANSI A112.19.8 performance

standard, or any successor standard. The VGBA also states that public pools¹ must be equipped with drain covers that meet the requirements of the ASME/ANSI or any successor standard. The VGBA provides that if a successor standard to ASME/ANSI/A112.19.8 is proposed and the Commission determines the successor standard is in the public interest, the Commission must incorporate the revision into the mandatory drain cover standard.

On August 5, 2011, the Commission recognized the Association of Pool and Spa Professionals (APSP)² standard APSP–16 2011, *Suction Fittings for Use in Swimming Pools, Wading Pools, Spas, and Hot Tubs*, as the successor standard to ASME/ANSI A112.19.8. The Commission incorporated by reference APSP–16 2011 into 16 CFR part 1450.76 FR 47436 (Aug. 5, 2011). ASME/ANSI A112.19.8 and its successor standard, APSP–16 2011, contain requirements that address hair entrapment,³ body entrapment,⁴ and, in a limited way, limb entrapment.⁵

On March 27, 2018, APSP notified the Commission of the publication of a successor pool drain cover standard to APSP–16 2011, in conjunction with ANSI and the International Code Council (ICC), ANSI/APSP/ICC–16 2017 (APSP–16 2017).

II. APSP–16 2017

APSP–16 2017 establishes materials, testing, use, installation, and marketing requirements for new or replacement bather-accessible suction outlet fitting assemblies, other than maintenance drains, that are designed to be fully submerged for use in any pool. APSP–16 2017 contains a new effective date for the standard, changes to physical testing requirements, new definitions, and new labeling requirements for the drain cover. These changes are

¹ The Act defines the term “pool” to mean any outdoor or indoor structure intended for swimming or recreational bathing, including in-ground and above ground structures, and includes hot tubs, spas, portable spas, and non-portable wading pools.

² On April 1, 2019, the Association of Pool and Spa Professionals changed its name to the Pool & Hot Tub Alliance (PHTA).

³ Hair entrapment typically occurs when water flowing into the suction outlet carries a person’s hair through and behind the openings in the drain cover, where it becomes so entangled that it prevents escape.

⁴ Body entrapment typically occurs on drains that are not unblockable and are served by direct-suction pumps when a person’s body forms a seal around the perimeter of a drain, and they are thus held against the drain by the pump suction.

⁵ Limb entrapment typically occurs on drain covers when a cover is broken and a person gets a limb stuck in the broken portion of the cover; or when the cover is completely missing and a person gets a limb stuck in the suction outlet, or other geometry that is within the sump.

discussed in section III of this preamble. APSP–16 2017 also contains new requirements that apply to the installation of the drain cover, to pools, to the operation of pools, and to pool owners. These changes are discussed in section IV of this preamble. As explained in section IV.A, the Commission does not have the authority to impose these requirements under section 1404(b) of the VGBA.

III. Changes to APSP–16 2017 That Are Within the Commission’s Authority

A. Effective Date

The VGBA does not specify an effective date for implementing successor standards. The Commission expects drain covers that meet APSP–16 2011 to be able to meet APSP–16 2017 with minimal changes to the drain covers. The changes necessary for the product to comply with the revised standard are limited to minor changes in on-product markings and new requirements for what must be included in the documentation accompanying the product. Product instructions and on-product markings are already required; thus, costs are limited to altering the content of these items. The APSP–16 2017 standard states that it will take effect 18 months after its adoption by CPSC.

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. 553(d)). Because of the low rate of injuries under APSP–16 2011,⁶ and because the APA does not prohibit an 18-month effective date, accelerated adoption of the new standard is not warranted. Therefore, unless the Commission receives timely significant adverse comments, CPSC’s revised standard will take effect 18 months after publication of this **Federal Register** notice incorporating APSP–16 2017 as the successor standard.

B. Changes to Physical Testing Requirements

The APSP–16 technical committee considered many possible changes to physical testing requirements when it was developing the 2017 version of the APSP–16 standard. Ultimately, CPSC staff found only two changes to physical testing requirements that maintain or increase the level of safety afforded by APSP–16 2011. These are the changes to the hair test approach time (section 5.9.5.5 of APSP–16 2017), and changes

⁶ There were two fatalities and nine injuries between 2013 and 2017. <https://www.cpsc.gov/s3fs-public/2018-Circulation-Entrapment.pdf?36TkV6OzJPzZPvRvC5IBnB5YhD1qkOPT>.

to hair testing at specific ports in suction outlet fitting assemblies (section 1.3.7.1 of APSP-16 2017).

1. Changes to Hair Test Approach Time

For three of the most significant tests specified in the 2011 version of APSP-16, the test results are given as a flow rating of gallons per minute of water through the drain cover. These three tests are the pony tail hair test, the full head of hair test, and the body-blocking test. The highest flow rate at which the drain cover meets the performance criteria of all three tests is the maximum allowable flow rate of water for which the drain cover may be certified. Drain cover manufacturers seek the highest possible flow rating. A higher flow rating increases the number of applications for which the drain cover is suitable.

The hair and body-blocking tests are conducted in a simulated pool installation. The test technician selects an initial water flow rate for testing through the drain cover, and then increases the test flow rate until the test requirements are no longer met for the hair or body tests. The test technician records the maximum flow rate for each of the tests where the drain cover meets the standard. The lower of the flow rates from the pony tail or full head of hair tests is considered to be the hair test result. The flow rating of the cover is the

highest flow rating at which the drain cover meets the requirements for the hair and body-blocking tests.

The pony tail and full head of hair tests begin with the free ends of hair two inches away from the drain cover. APSP-16 2011 specified that the head and ponytail fixtures are moved in a side-to-side motion as they are lowered over a period of 60 seconds toward the drain cover during their respective tests. The hair ends move in response to, or generally opposite to, these motions, until the flow of water draws the hair into the drain cover. Due to the iterative nature of the tests, coupled with the dual requirement for the drain cover to meet two types of hair test requirements, it can take numerous tests to determine a hair flow rating.

To reduce the time required to perform the hair tests, and therefore, to lower the cost of testing, APSP-16 2017 decreases the hair test approach time from 60 seconds to 30 seconds. CPSC staff studied the change in hair approach time extensively. Staff explained the results of its testing in a detailed letter to APSP.⁷ Staff's test experiences indicate that most of the time spent moving hair the full 60 seconds is unnecessary, because the hair is effectively drawn to the target area within a few seconds. Moreover, too much movement can lead to the hair being self-entangled above the drain and

not within the drain, thus producing inaccurate results. The Commission concludes that the change to 30 seconds in section 5.9.5.5 of APSP-16 2017 is in the public interest because it is at least as protective as the 60 seconds specified in APSP-16 2011; it may minimize the risk of the hair being self-entangled above the drain; and it reduces the cost of performing the testing that is required to meet the standard because it reduces the time necessary to perform the tests.

2. Changes to Hair Testing To Include all Suction Outlet Fittings

To ease product installation, many SOFA manufacturers include more than one suction outlet on their products. Suction outlets may be located on one or more sides of the SOFA, on the bottom, or on a combination of these locations. For SOFAs with multiple suction outlets, APSP-16 2011, and before it, ASME/ANSI A112.19.8, only required that the hair and body-blocking element tests be performed on the drain cover while water was flowing through one of the suction outlets. The standards did not require testing the drain cover using the additional suction outlets, when present.

The introduction of channel drains, whose length is much longer than their width, provided a new scenario for entrapment. Figure 1 shows an example of a channel drain.

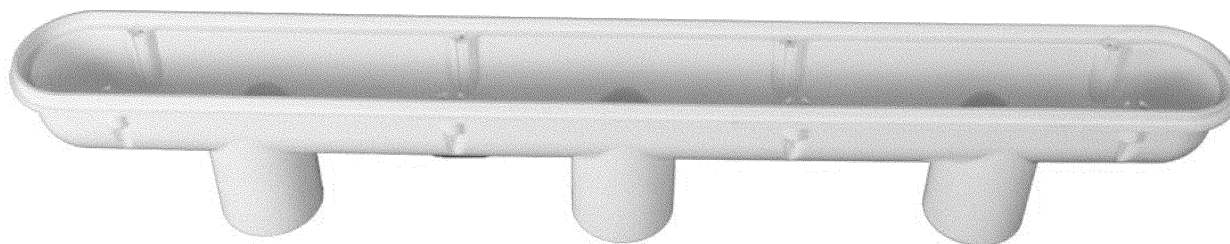


Figure 1. A commercially available channel drain, shown without a drain cover.

Like traditional SOFAs, channel drains are often equipped with multiple suction outlets, not all of which must necessarily be connected during installation. However, because channel drains have very narrow widths compared to their lengths, their design potentially concentrates the low-pressure area underneath the portion of the drain cover that is closest to the suction outlet. Because there was no previous requirement to test SOFAs using every suction outlet as the water source for the pump, it was possible that

a channel drain could be tested using only the suction outlet that yielded the highest flow rating, *i.e.*, the suction outlet least likely to produce entrapment for a given flow rate. However, channel SOFAs could be installed using a different suction outlet than the one that was used during testing; thus, this could potentially expose bathers to conditions that exceed what is allowed by the standard. To ensure that channel-type SOFAs did not receive an improper flow rating, the committee initially proposed that

channel drains must meet the hair and body-block tests when each suction outlet was tested. Due to the wide variety of styles and suction outlet configurations available on traditional, non-channel-type SOFAs, and because all types of SOFAs could be subject to differing flow through the drain cover that are dependent on the suction outlet location, the committee decided that the new requirement to test at all suction outlets on channel drains should also apply to all types of SOFAs.

⁷ https://www.cpsc.gov/s3fs-public/pdfs/blk_media_CPSCCommentstoRevisionAPSP162011.pdf.

The additional requirement to perform hair tests at all suction outlets for all types of SOFAs will increase the testing burden because it increases the number of tests that are required to be performed. However, the possible increase in testing burden will be offset by other changes to the testing requirements. Under the revised standard, if the hair cannot reach the suction outlet, there is no need to test that outlet. Thus, APSP-17 2017 provides that the requirement to test at each suction outlet, which is included in section 5.7.2, only applies to suction outlets that have a “flow path length” (*i.e.*, the distance between the drain cover the suction outlet) of less than 16 inches, which is the maximum length of hair used in the hair tests. Furthermore, as discussed above, the 2017 standard reduced the hair approach time from 60 seconds to 30 seconds. The additional testing required to evaluate all of the suction outlets on a SOFA is offset by the reduction in hair test approach time discussed in Section II.A.2.a.

The requirement in APSP-16 2017 to test at every suction outlet reachable by the hair test specimen will increase the safety of bathers because it precludes the chance of a SOFA being installed in a manner that is different from the way it was tested, serves to clarify prior practice, and is supported by laboratory testing. Accordingly, the Commission determines that testing of SOFAs at every suction outlet is in the public interest.

C. Definition of “Unblockable Drain”

The 2011 version of the APSP standard did not define “unblockable drain” or “unblockable SOFA.” The definitions section of APSP-16 2017 includes the following definition of “Unblockable SOFA”:

A suction outlet fitting assembly that, when installed according to the manufacturer’s instructions, cannot be shadowed by an 18” x 23” Body Blocking Element, and has a rated flow through the remaining open area beyond the shadowed portion that cannot create a suction force in excess of the force calculated in equation 2.

Pool drain professionals have essentially been using this definition to determine whether a SOFA is unblockable since a similar version was first published as an interpretive rule by CPSC on April 27, 2010.⁸ At least 149 state and local building codes now reference the 18” x 23” dimension and the pull-off force requirements

originally found in Table 1 of A112.19.8, which are consistent with the definition of “unblockable” in APSP-16 2017. Other state and local codes reference slight variations of this definition of “unblockable.” Because this is an accepted definition among pool professionals, the Commission believes including this definition in its mandatory standard is in the public interest.

D. Labeling Requirements

Section 8.4 of APSP-16 2017 contains requirements for the labelling of a SOFA, requiring identifying information, such as the manufacturer name and cover/grate part number, and date of the installation of the cover/grate. Section 8.5.1 of APSP-16 2017 contains labeling requirements for Registered Design Professional (RDP) SOFAs. Section 9.3 of APSP-16 2017 adds provisions regarding a General Certificate of Conformity (GCC) that are consistent with the Consumer Product Safety Act and VGBA. These requirements identify the product, the manufacturer, and the test lab that performed the analysis, as well as state the standard to which the product was tested, and when and where it was tested. Because the presence of this information makes it easy to identify relevant safety information about the product, the Commission finds these requirements are in the public interest.

IV. Changes to APSP-16 2017 That Exceed the Commission’s Authority

A. The Commission’s Authority Under the VGBA

Section 1404(b) of the VGBA specifies a standard for drain covers. It states “each swimming pool or spa drain cover manufactured, distributed, or entered into commerce in the United States shall conform to the entrapment protection standards of [the drain cover performance standard].” Section 1404(a) of the VGBA states that the requirements of section 1404(b) shall be treated as a consumer product safety rule under the CPSA. Thus, the drain cover must be in compliance with the drain cover standard at the time of manufacture of the cover, distribution of the cover, or when the cover is entered into commerce. This indicates that the drain cover standard is a standard for the drain cover, as a discrete product.

Section 1404(b) requires the Commission to assess any successor drain cover standard to determine whether the changes in the standard are in the public interest, before incorporating the successor standard.

CPSC’s Office of Compliance enforces section 1404(b) by determining whether the drain cover, as a discrete product, at the time of manufacture, distribution, or entrance into commerce, complies with the drain cover standard.

Separately, section 1404(c) of the VGBA requires that public pools and spas in the United States:

- Have drain covers that comply with the standard specified in section 1404(b) or a successor standard; and
- if the public pool or spa does not have an unblockable drain, it must be equipped with one or more of the secondary systems specified in section 1404(c)(1)(A)(ii).

Thus, section 1404(c) gives the CPSC authority to determine and enforce these requirements for public pools and spas, and it gives the CPSC the authority to inspect these public facilities for the presence of drain covers and secondary systems and to enforce those requirements. In summary, section 1404(b) of the VGBA is the drain cover standard, which is to be treated as a consumer product safety rule. The VGBA authorizes a product safety standard for that product—drain covers (or SOFAs). The authority for the Commission to incorporate by reference the APSP drain cover standard is in section 1404(b) of the VGBA. Separately, section 1404(c) of the VGBA requires public pools and spas to have certain specified equipment, and it gives the Commission authority to check that the equipment is installed in public pools and spas.

B. Specific Sections of APSP-16 2017 That Exceed Commission Authority

APSP-16 2017 contains many changes that extend beyond the requirements for the drain cover or SOFA itself, and thus, exceed CPSC’s authority under section 1404(b) of the VGBA. The voluntary standard can have such provisions. However, the Commission does not have authority to enforce them as mandatory standard provisions. The changes include requirements that can be separated into the following categories:

- Installation of the SOFA;
- Requirements applicable to pools;
- Activities of pool owners;
- Changes to statutory definitions in the VGBA.

The changes specific to each category are detailed in Tables 1 through 4.

⁸ <https://www.federalregister.gov/documents/2010/04/27/2010-8160/virginia-graeme-baker-pool-and-spa-safety-act-interpretation-of-unblockable-drain>.

TABLE 1—SECTIONS OF APSP–16 2017 THAT ARE BEYOND THE AUTHORITY OF CPSC BECAUSE THEY ESTABLISH REQUIREMENTS FOR THE INSTALLATION OF THE SOFA

Section No.	Summary of topic(s) covered
1.3.3.2	Drain covers can only be installed on SOFAs deemed suitable by the drain cover manufacturer.
3.5.1	Drain covers shall only be installed on sumps in configurations authorized by the drain cover manufacturer's installation instructions, and at a specific flow rating.
3.6.1	A SOFA must be installed per the manufacturer's instructions.
3.6.3.2	Compliance with the standard requires selecting and installing a SOFA or combination of SOFAs such that the flow rating of the SOFAs is greater than the maximum system flow of the pool.
3.6.4.2	The flow rating for existing pools with blockable SOFAs is the flow rating of the SOFA, when also installed in conjunction with an additional device or system designed to prevent suction entrapment ("secondary anti-entrapment system"). A single, blockable SOFA installed in existing pools with no secondary anti-entrapment system results in a flow rating of zero.
3.7.2	Blockable SOFAs installed in existing pools must also be installed with a secondary anti-entrapment system.
3.7.3	Covers or grates marked unblockable may be installed in pools with multiple SOFA systems. Covers or grates marked unblockable may also be installed in pools with single SOFA systems when this use is authorized by the cover/grate manufacturer.
9.4.1	Blockable covers may only be installed in multiple-SOFA systems, or in pools that are also equipped with one or more secondary anti-entrapment systems.

The provisions mentioned in Table 1 set forth requirements for how to install the SOFA. The 2011 version of the APSP standard addressed installation by requiring that certain information about installation be provided in labels and

instructions. In contrast, the provisions referenced in Table 1 require that the installer or pool owner/operator take certain actions. These are not provisions for the drain cover. A drain cover manufacturer has the ability to provide

labels and instructions with the product. A drain cover manufacturer does not control how the product is installed.

TABLE 2—SECTIONS OF APSP–16 2017 THAT ARE BEYOND THE AUTHORITY OF CPSC BECAUSE THEY ESTABLISH REQUIREMENTS FOR POOLS

Section No.	Summary of topic(s) covered
1.3.3.1	A pool's system suction flow must not exceed the rating of the installed SOFA(s). A pool with SOFA(s) that were not installed per the manufacturer's instructions is not in compliance with the standard.
3.6.3.1	A pool's system flow ratings cannot exceed the SOFA flow rating while the pool is open to bathers.
3.6.4.1	For multiple blockable SOFA systems, the maximum system flow rating for the pool is determined by subtracting the flow rating of the largest SOFA.
3.6.4.3	The system flow rating for pools with unblockable SOFA(s) shall be determined by combining the flow rating of all SOFA(s).
3.7.1	In new pool construction, the use of a single blockable SOFA is not permitted.

The provisions mentioned in Table 2 set forth requirements for pools, not for drain covers. Several of the provisions set requirements for the pool's flow

rating. The 2011 version of the APSP standard required markings and instructions regarding operation at an appropriate flow rating. However, the

revised standard states requirements for the pool; these are requirements the drain cover manufacturer lacks the ability to fulfill.

TABLE 3—SECTIONS OF APSP–16 2017 THAT ARE BEYOND THE AUTHORITY OF CPSC BECAUSE THEY REQUIRE ACTIONS OF POOL OWNERS

Section No.	Summary of topic(s) covered
1.1.3	Drain covers must be replaced at the end of their stated service life.
3.6.2	No modifications to SOFAs or the SOFA flow paths are permitted unless they are subsequently re-tested.

The provisions mentioned in Table 3 require pool owners to take certain actions. The 2011 version of the APSP standard required that components of drain covers be marked to state the

component's life span. In contrast, the revised standard requires that drain cover components be replaced at the end of their service life. This change makes the requirement apply to the pool

owner, not the drain cover manufacturer. Similarly, a requirement prohibiting modifications to installed SOFAs applies to the pool owner, not the drain cover.

TABLE 4—SECTIONS OF APSP–16 2017 THAT SET INSTANTATION REQUIREMENTS REGARDING SECONDARY SYSTEMS

Section No.	Summary of topic(s) covered
9.4.1	Requires that blockable SOFAs have installation instructions stating that SOFAs shall be installed only in multiple SOFA systems or instructions shall state that the installer shall include one or more of the following devices or systems
9.4.1.1	Provides a definition of safety vacuum relief system (SVRS).
9.4.1.2	Provides a definition of suction-limiting vent system (SVLS).

TABLE 4—SECTIONS OF APSP–16 2017 THAT SET INSTAALLATION REQUIREMENTS REGARDING SECONDARY SYSTEMS—Continued

Section No.	Summary of topic(s) covered
9.4.1.3	Provides a definition of gravity drainage system.
9.4.1.4	Provides a definition of automatic pump shut-off system.
9.4.1.5	Provides a definition of drain disablement.
9.4.1.6	Provides a definition of other secondary anti-entrapment systems.

The provisions listed in Table 4 set forth what seem to be requirements for instructions. As is stated above, CPSC standards can include requirements for instructions. However, the instructions specified in section 9.4 actually establish requirements for pools and for secondary devices and systems designed to prevent suction entrapment. All of section 9.4 exceeds the Commission’s authority under Section 1404(a) of the VGBA because the instructions require secondary systems on *all* pools. The VGBA only requires secondary systems for *public* pools. In addition, this section provides definitions of the secondary systems that differ from the statutory definitions in the VGBA.

C. Section That Should Not Be Included Because of an Error

Section 3.2.4 requires SOFAs to be designated in their installation manual as “blockable” or “unblockable.” This requirement does fall within the enforcement authority of CPSC. However, the definition in APSP–16 2017 contains an error. As discussed, APSP–16 2017 provides a definition of “unblockable.” That definition has two parts: Unblockable SOFAs must meet a minimum size requirement, and they must meet the body-blocking element maximum pull-off force requirement. Due to a printing error, section 3.2.4 omitted the pull-off force requirement. Thus, the Commission will not adopt section 3.2.4 of APSP–16 2017.

V. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to the final rule, ways that the materials the agency incorporates by reference are reasonably available to interested person and how interested parties can obtain the materials. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR’s requirements, section II of this preamble summarizes the major provisions of the APSP–16 2017 standard that the Commission incorporates by reference into 16 CFR 1450.3. The standard is

reasonably available to interested parties, and interested parties may purchase a copy of the standard from The Association of Pool & Spa Professionals. A copy of the standard can also be inspected at CPSC’s Office of the Secretary.

VI. Direct Final Rule Process

The APA generally requires that agencies use notice and comment rulemaking when issuing a rule. 5 U.S.C. 553. The Commission is adopting as a mandatory standard a voluntary standard that was developed through the consensus process. The voluntary standard is noncontroversial and receives widespread support. In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite promulgation of rules that are noncontroversial and that are not expected to generate significant adverse comment. See 60 FR 43108 (August 18, 1995). The Commission believes it is very unlikely that there will be adverse comments to this rule. Consistent with the ACUS recommendation, the Commission is satisfying the notice and comment procedure by publishing this rule as a direct final rule and providing that, unless adverse comment is received within 30 days, the rule will become effective as a final rule.

VII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires that when agencies are required to issue a notice of proposed rulemaking they must review the rulemaking’s potential economic impact on small entities, including small businesses. Section 603 of the RFA requires the Commission to prepare and make available for public comment an Initial Regulatory Flexibility Analysis (IRFA) describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. However, under Section 605 of the RFA, if an agency certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities, an IRFA is not required, provided that the

agency publishes the certification in the **Federal Register**, along with a statement providing the factual basis for the certification.

As discussed in section III.B of this preamble, the revised standard includes two changes to the testing procedures in ANSI/APSP/ICC–16: Hair test approach time and hair testing at specific ports in channel SOFAs. In addition to these two changes in hair tests from the current standard, ANSI/APSP/ICC–16 2017 specifies additional editorial changes, which are intended to clarify existing wording. Clarifying language pertaining to installation and maintenance instructions to be provided with the covers/grates for SOFAs was also added to the standard. Also, manufacturers are required to make minor changes to the information that is provided in permanent markings of compliant covers and grates.

Overall, the changes in testing requirements in the standard revision should have minimal impacts on small businesses, either in costs of testing, or in product modifications necessitated to comply with the revised testing provisions. The revisions that this rule would require in the information that must be provided in installation and maintenance instructions, and the changes in the permanent markings required for covers, and grates should also not impose significant costs on small cover and grate manufacturers. Because small firms should only experience minimal increases in compliance costs or other burdens associated with this rule, the Commission certifies that referencing the revised standard, ANSI/APSP/ICC–16–2017, as the successor standard under the VGBA will not be likely to have significant economic impact on a substantial number of small businesses or other entities.

VIII. Paperwork Reduction Act

This rule does not impose any information collection requirements. Accordingly, this rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

IX. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

X. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a "consumer product safety standard under [the Consumer Product Safety Act (CPSA)]" is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury, unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption in certain circumstances.

Section 1404(a) of the VGBA specifies that a rule issued under section 1404(b) of the VGBA shall be treated as a consumer product safety standard under the CPSA, thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, this rule will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

List of Subjects in 16 CFR Part 1450

Consumer protection, Incorporation by reference, Infants and children, Law enforcement.

For the reasons stated above, the Commission amends part 1450 of title 16 of the Code of the Federal Regulations as follows:

PART 1450—VIRGINIA GRAEME BAKER POOL AND SPA SAFETY ACT REGULATIONS

- 1. The authority citation for part 1450 continues to read as follows:

Authority: 15 U.S.C. 2051–2089, 86 Stat. 1207; 15 U.S.C. 8001–8008, 121 Stat. 1794.

- 2. Revise § 1450.3 to read as follows:

§ 1450.3 Incorporation by reference.

(a) Except as provided in paragraph (b) of this section, each swimming pool or spa drain cover manufactured, distributed, or entered into commerce in the United States shall conform to the

entrapment protection standards of ANSI/APSP/ICC–16 2017, American National Standard for *Suction Outlet Fitting Assemblies (SOFA) for Use in Pools, Spas and Hot Tubs*, approved on August 18, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Pool & Hot Tub Alliance (formerly known as the Association of Pool & Spa Professionals), 2111 Eisenhower Avenue, Alexandria, Virginia 22314; <http://www.apsp.org>, telephone 703–838–0083. You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(b) The CPSC standard does not require compliance with the following provisions:

(1) Section 1.1.3 of ANSI/APSP/ICC–16 2017.

(2) Sections 1.3.3.1 through 1.3.3.2 of ANSI/APSP/ICC–16 2017.

(3) Section 3.2.4 of ANSI/APSP/ICC–16 2017.

(4) Section 3.5.1 of ANSI/APSP/ICC–16 2017.

(5) Sections 3.6.1 through 3.6.4.3 of ANSI/APSP/ICC–16 2017.

(6) Section 3.7 of ANSI/APSP/ICC–16 2017.

(7) Section 9.4 of ANSI/APSP/ICC–16 2017.

Abioye E. Mosheim,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2019–10845 Filed 5–23–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA–2019–D–2011]

Section 503A Bulks List Final Rule Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled "Section 503A Bulks List Final Rule Questions and Answers—Small Entity Compliance Guide." The small entity compliance guide (SECG) is intended to help small entities comply with the final rule establishing the list of bulk drug substances that can be used in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on May 24, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."