

# Rules and Regulations

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## CONSUMER PRODUCT SAFETY COMMISSION

### 16 CFR Part 1238

[Docket No. CPSC–2018–0015]

### Safety Standard for Stationary Activity Centers

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Direct final rule.

**SUMMARY:** In June 2019, the U.S. Consumer Product Safety Commission (CPSC or Commission) published a consumer product safety standard for stationary activity centers pursuant to section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The Commission's mandatory standard incorporates by reference ASTM F2012–18<sup>e1</sup>, *Standard Consumer Safety Performance Specification for Stationary Activity Centers*. The CPSIA sets forth a process for updating mandatory standards for durable infant or toddler products that are based on a voluntary standard, when a voluntary standards organization revises the standard. In November 2024, ASTM published a revised voluntary standard. This direct final rule updates the mandatory standard for stationary activity centers to incorporate by reference the 2024 version of ASTM F2012, which the Commission has allowed to become the mandatory standard under section 104. The purpose of the direct final rule is to conform the Code of Federal Regulations (CFR) to the correct version of ASTM F2012 to provide an accurate reference to the standard that will be enforced as a mandatory rule.

**DATES:** The rule is effective on July 5, 2025, unless the Commission receives a significant adverse comment by April 28, 2025. If the Commission receives such a comment, it will publish a notice 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 July 5, 2025.

**ADDRESSES:** You can submit comments, identified by Docket No. CPSC–2018–0015, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by email, except as described below.

*Mail/Hand Delivery/Courier/Confidential Written Submissions:* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

*Instructions:* All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit to this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

*Docket:* For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, and insert the docket number, CPSC–2018–0015, into the “Search” box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Bradley Gordon, Project Manager, Division of Mechanical and Combustion Engineering, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2099; email: [bgordon@cpsc.gov](mailto:bgordon@cpsc.gov).

## SUPPLEMENTARY INFORMATION:

### I. Statutory Authority and Background

#### A. Statutory Authority

Section 104(b) of the CPSIA requires the Commission to assess the effectiveness of voluntary standards for durable infant or toddler products<sup>1</sup> and adopt mandatory standards for these products. 15 U.S.C. 2056a(b)(1). Mandatory standards must be “substantially the same as” applicable voluntary standards, or they may be “more stringent” than the voluntary standards if the Commission determines that more stringent requirements would further reduce the risk of injury associated with the products. *Id.* Accordingly, mandatory standards may be based, in whole or in part, on a voluntary standard.

Section 104(b)(4)(B) of the CPSIA specifies the process for when a voluntary standards organization revises a standard the Commission has incorporated by reference under section 104(b)(1). 15 U.S.C. 2056a(b)(4)(B). First, the voluntary standards organization must notify the Commission of the revision. Once the Commission receives this notification, the Commission may reject or accept the revised standard. To reject a revised standard, the Commission must notify the voluntary standards organization within 90 days of receiving the notice of revision that the Commission has determined that the revised standard does not improve the safety of the consumer product and that CPSC is retaining the existing standard. If the Commission does not take this action, then the revised voluntary standard will be considered a consumer product safety standard issued under section 9 of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2058), effective 180 days after the Commission received notification of the revision (or a later date specified by the Commission in the **Federal Register**). 15 U.S.C. 2056a(b)(4)(B).

#### B. Safety Standard for Stationary Activity Centers

On June 18, 2019, under section 104 of the CPSIA, the Commission published the first stationary activity centers rule that incorporated by reference ASTM F2012–18<sup>e1</sup>, *Standard*

<sup>1</sup> Section 104(f)(2)(G) of the CPSIA lists stationary activity centers as a durable infant or toddler product. 15 U.S.C. 2056a(f)(2)(G).

*Consumer Safety Performance Specification for Stationary Activity Centers*, as the mandatory standard. 84 FR 28205.

The ASTM standard incorporated by CPSC defines a stationary activity center as “a freestanding product intended to remain stationary that enables a sitting or standing occupant whose torso is completely surrounded by the product to walk, rock, play, spin or bounce, or all of these, within a limited range of motion.” Section 3.1.12, ASTM F2012–18<sup>e1</sup>; see 16 CFR 1238.2.

On January 6, 2025, ASTM notified the Commission that it had approved and published a newly revised version of the voluntary standard, ASTM F2012–24. The revision includes a change to update the requirements for assessing the permanency of warning labels attached to the product. The Commission determines that this change improves the safety of stationary activity centers, because it provides improved requirements for permanent attachment of labels and improved testing consistency of label permanency.

The revision to the standard also adds example warning labels that manufacturers can use on stationary activity centers, and it also includes several editorial changes. The Commission determines that these changes are safety-neutral and do not reduce the safety of stationary activity centers because they do not change any requirements in the standard.

On January 21, 2025, the Commission published in the **Federal Register** a Notice of Availability, requesting comment on whether the 2024 revision improves the safety of stationary activity

centers. 90 FR 6844. CPSC received one anonymous comment, discussed below, addressing the new example warning labels.

Based on staff’s evaluation of ASTM F2012–24 and consideration of the comment received, the Commission will allow ASTM F2012–24 to become the new consumer product safety standard for stationary activity centers because it improves safety. Pursuant to CPSIA section 104, the revised voluntary standard will take effect as the new mandatory standard for stationary activity centers on July 5, 2025. 15 U.S.C. 2056a(b)(4)(B). This direct final rule updates 16 CFR part 1238 to incorporate by reference the applicable provisions of the revised voluntary standard, ASTM F2012–24.<sup>2</sup>

## II. Description of ASTM F2012–24 Related to Stationary Activity Centers

The ASTM standard for stationary activity centers includes performance requirements, test methods, and requirements for marking, labeling, and instructional literature, to address hazards to children associated with stationary activity centers. The 2024 revision to the voluntary standard, ASTM F2012, includes updated requirements for assessing the permanency of attaching warning labels, updated warning label examples, and editorial changes.

### A. Updated Requirements for Assessing Warning Label Permanency

In section 7.5.3 of ASTM F2012–24, ASTM revised the requirement to assess the permanency of attaching a warning label by a seam. In ASTM F2012–18<sup>e1</sup>,

section 7.5.3 includes instructions to test whether a warning label is permanent, which require clamping the label and applying a specified pull force in *any direction*. In ASTM F2012–24, ASTM revised the test requirements to specify that (1) the same pull force specified in ASTM F2012–18<sup>e1</sup> must be applied in the direction most likely to cause failure, rather than in any direction, and (2) the pull force must be applied gradually within a period of 5 seconds and then maintained for an additional 10 seconds. The direction most likely to cause failure can be determined by applying pull forces to the label in different directions until separation from the product, to identify the direction with the lowest pull force. These changes are consistent with recommendations of the Ad Hoc Language task group. The Commission determines that the updated requirements are an improvement in safety because: (1) the requirement to pull the warning label in the direction most likely to cause failure represents the worst-case scenario and thus will better ensure the permanency of the label; and (2) the addition of a specific test duration will provide better consistency across test labs.

### B. Updated Warning Labels

In ASTM F2012–18<sup>e1</sup>, section 8.4.7 provides one example of a warning label that meets the formatting requirements for a warning label’s message panel text layout in section 8.4.6. This figure, shown in Figure 1, continues to be provided in section 8.4.7 in ASTM F2012–24.

**BILLING CODE 6355–01–P**

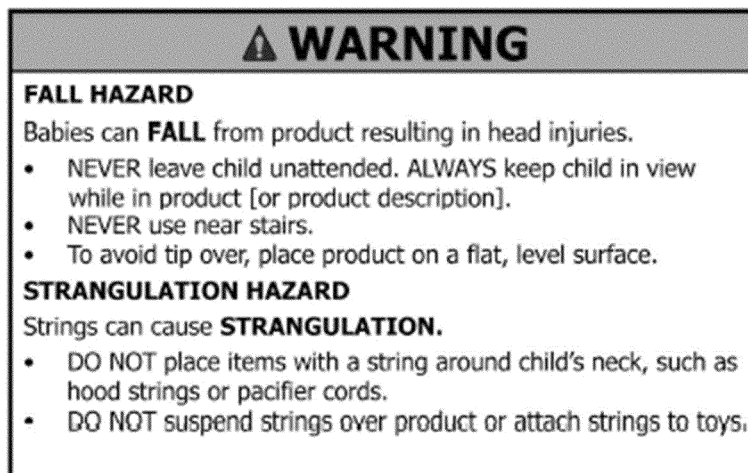


Figure 1. Warning Example<sup>3</sup>

<sup>2</sup> On March 18, 2025, the Commission voted (4–1) to publish this direct final rule.

The 2024 version of ASTM F2012, however, updates the language in section 8.4.7 from “an example

warning” to “[e]xample warnings” to refer to four other example warning

labels that are added to ASTM F2012, shown in Figure 2.

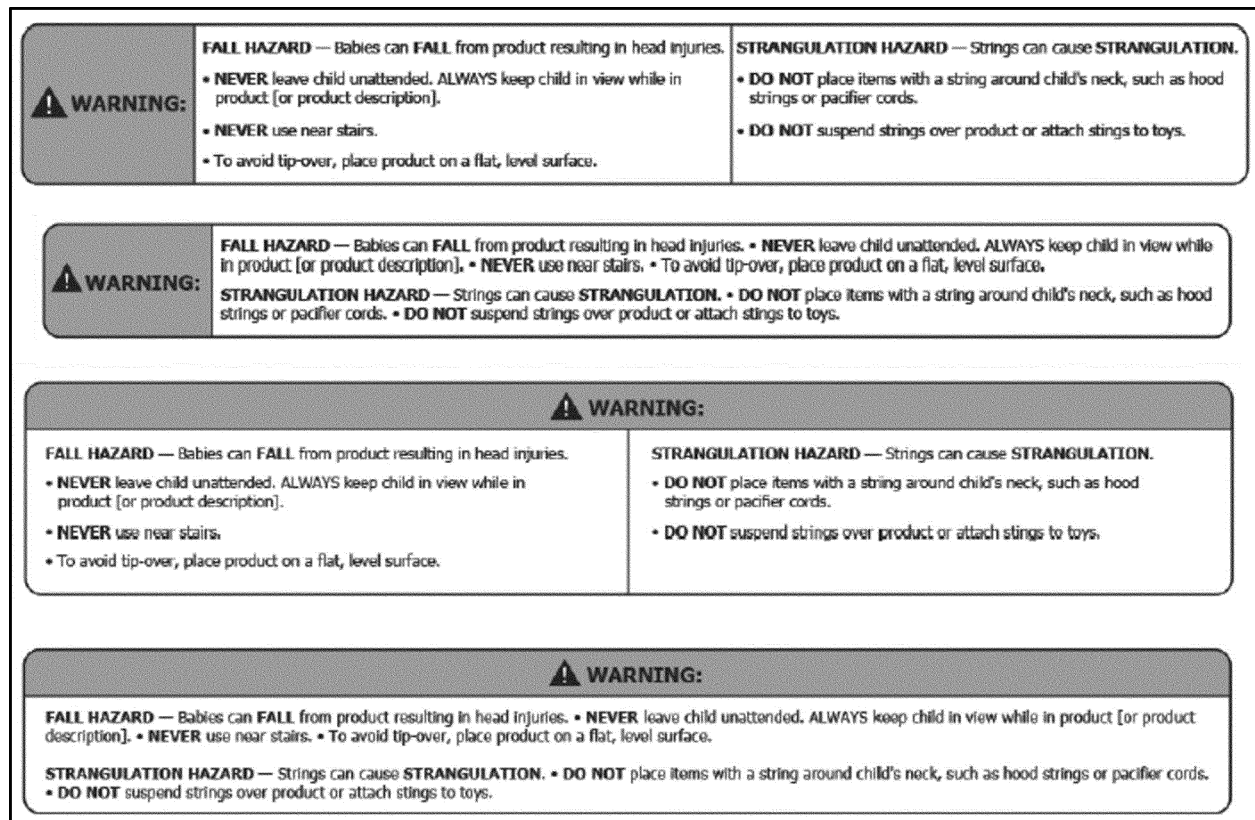


Figure 2. Four Added Example Warnings<sup>4</sup>

#### BILLING CODE 6355-01-C

The content in the four additional example warning labels is the same as content in the initial example warning label. However, the arrangement of the text, the layout of the text relative to the signal word panel, and the overall dimensions of the warnings have been modified. The new example warning labels are wider and shorter than the initial example warning. Variations in the exterior dimensions of these warning labels allow for their placement on a wider range of product components, which provides manufacturers with more flexibility for label placement. The Commission determines that this revision is safety-neutral and does not reduce the safety of stationary activity centers.

The Commission notes that the four additional sample warnings contain two formatting errors, as identified by the anonymous commenter. The safety alert

symbol (exclamation mark in a triangle) in the examples, in Figure 2, should appear as an orange exclamation point rather than a white exclamation point. Section 8.4.4 of ASTM F2012–24 requires that the warnings shall conform to ANSI Z535.4–2011, *American National Standard for Product Safety Signs and Labels*, sections 6.1–6.4, 7.2–7.6.3, and 8.1. Section 7.2.6 of ANSI Z535.4–2011 requires the solid triangle portion to be the same color as the signal word lettering, and the exclamation mark portion to be the same color as the signal word panel background.

Additionally, the base of the triangle in the warning symbols should be aligned with the base of the signal word “WARNING” as required by section 8.4.4 of ASTM F2012–24. Section 6.3 of ANSI Z534.4–2011 specifies that the base of the safety alert symbol must be

on the same horizontal line as the base of the letters of the signal word and the height of the safety alert symbol must be equal or exceed the signal word letter height.

These formatting errors are minor deviations from the applicable voluntary standards that do not impact the effectiveness of the warning labels. Commission staff has requested that ASTM correct these formatting errors in the next revision of ASTM F2012.

#### C. Editorial Changes

ASTM F2012–24 also includes revisions that are primarily editorial changes to language that do not materially change the requirements for stationary activity centers. The changes include correcting typos, adding missing units, and hyphenating certain words. The changes also include rephrased wording to delete unnecessary text to reduce redundancy

<sup>3</sup> Reprinted, with permission, from ASTM F2012–24, *Standard Consumer Safety Performance Specification for Stationary Activity Centers*, copyright ASTM International. A copy of the complete standard may be obtained for downloading from [www.astm.org](http://www.astm.org). The standard

may be viewed at no charge as explained in § 1238.2 of the rule.

<sup>4</sup> Reprinted, with permission, from ASTM F2012–24, *Standard Consumer Safety Performance Specification for Stationary Activity Centers*,

copyright ASTM International. A copy of the complete standard may be obtained for downloading from [www.astm.org](http://www.astm.org). The standard may be viewed at no charge as explained in § 1238.2 of the rule.

and to modify text to clarify the characterization of certain requirements. The Commission determines that these changes are safety-neutral and do not reduce the safety of stationary activity centers.

#### D. Public Comments

The Commission requested public comment on how the revisions to ASTM F2012–24 affect the safety of stationary activity centers and received one anonymous comment. As discussed in Section II.B. in this preamble, the commenter pointed out that newly added example warnings in ASTM F2012–24, shown in Figure 2 of this preamble, fail to comply with the formatting requirements incorporated by section 8.4.4 of the standard in minor respects, which Commission staff has requested that ASTM address in the voluntary standards process.

#### E. Summary of Assessment of ASTM F2012–24

Under CPSIA section 104(b)(4)(B), unless the Commission determines that ASTM's revision to a voluntary standard that is referenced in a mandatory standard "does not improve the safety of the consumer product covered by the standard," the revised voluntary standard becomes the new mandatory standard. The Commission concludes that F2012–24 improves the safety of stationary activity centers.

#### III. Incorporation by Reference

Section 1238.2 of the direct final rule incorporates by reference ASTM F2012–24. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to a final rule, ways in which material the agency incorporates by reference is reasonably available to interested parties, and how interested parties can obtain the material. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR regulations, Section II. of this preamble summarizes the revised provisions of ASTM F2012–24 that the Commission incorporates by reference into 16 CFR part 1238. The standard is reasonably available to interested parties in several ways. Until the direct final rule takes effect, a read-only copy of ASTM F2012–24 is available for viewing on ASTM's website at: <https://www.astm.org/CPSC.htm>. Once the rule takes effect, a read-only copy of the standard will be available for viewing on the ASTM website at: <https://www.astm.org/READINGLIBRARY/>.

Additionally, interested parties can purchase a copy of ASTM F406–24 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; [www.astm.org](http://www.astm.org). Finally, interested parties can schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, telephone: 301–504–7479; email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov).

#### IV. Testing and Certification

Section 14(a) of the CPSA (15 U.S.C. 2051–2089) requires manufacturers, including importers, of products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, to certify that the products comply with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or, for children's products, on tests of a sufficient number of samples by a third party conformity assessment body accredited by CPSC to test according to the applicable requirements. As noted in Section I.A. of this preamble, standards issued under section 104(b)(1)(B) of the CPSIA are "consumer product safety standards." Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Additionally, because stationary activity centers are children's products, a CPSC-accepted third party conformity assessment body must test samples of the products for compliance with 16 CFR part 1238. Products subject to part 1238 also must be compliant with all other applicable CPSC requirements,<sup>5 6</sup> including the lead content requirements in section 101 of the CPSIA,<sup>7</sup> and the phthalates prohibitions in section 108 of the CPSIA<sup>8</sup> and 16 CFR 1307. In accordance with section 14(a)(3)(B)(vi) of the CPSIA, the Commission previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies (*i.e.*, third party laboratories) for testing stationary activity centers, and codified the requirement at 16 CFR 1112.15(b)(48).

The modifications to assess warning label permanency in ASTM F2012–24 specify the direction and timing to

conduct an existing test. These changes will not require laboratories to obtain additional test equipment or new training. The Commission considers third party labs that are currently CPSC-accepted for 16 CFR part 1238 to have demonstrated competence to test stationary activity centers to the revised ASTM F2012–24, as incorporated into part 1238. Accordingly, the existing accreditations that the Commission has accepted for testing to this standard will cover testing to the revised standard. The existing NOR for the Safety Standard for Stationary Activity Centers will remain in place, and CPSC-accepted third party labs are expected to update the scope of their accreditations to reflect the revised stationary activity center standard in the normal course of renewing their accreditations.

#### V. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA; 5 U.S.C. 551–559) generally requires agencies to provide notice of a rule and an opportunity for interested parties to comment on it, section 553 of the APA provides an exception when the agency "for good cause finds" that notice and comment are "impracticable, unnecessary, or contrary to the public interest." *Id.* 553(b)(4)(B).

The purpose of this direct final rule is to update the reference in the CFR so that it reflects the version of the ASTM standard that takes effect by statute. Under the terms of the CPSIA, ASTM F2012–24 takes effect as the new CPSC standard for stationary activity centers even if the Commission does not issue this direct final rule. Thus, the purpose of the direct final rule is to conform the CFR to the updated ASTM F2012 standard to provide an accurate reference to the standard that will be enforced as a mandatory rule. Consequently, public comments would not lead to substantive changes to the standard or to the effect of the revised standard as a consumer product safety rule under section 104(b) of the CPSIA. Under these circumstances, notice and comment are unnecessary.

In Recommendation 2024–6, the Administrative Conference of the United States (ACUS) endorses direct final rulemaking as an appropriate procedure to expedite rules that are unlikely to elicit any significant adverse comments. *See* 89 FR 106406 (Dec. 30, 2024). ACUS recommends that agencies use the direct final rule process when they act under the "unnecessary" prong of the good cause exemption in 5 U.S.C. 553(b)(4)(B). 89 FR 106406, 106409. ACUS also explains that notice and

<sup>5</sup> 15 U.S.C. 2063(a)(5).

<sup>6</sup> 15 U.S.C. 2056a(d).

<sup>7</sup> 15 U.S.C. 1278a.

<sup>8</sup> 15 U.S.C. 2057c.

comment may be “unnecessary” when the agency lacks discretion regarding the substance of the rule. *Id.* at 106408. As noted, this rule updates a reference in the CFR to reflect a change that occurs by statute. Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule, because CPSC does not expect any significant adverse comments.

Unless CPSC receives a significant adverse comment within 30 days of this notification, the rule will become effective on July 5, 2025. In accordance with ACUS’s recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why the rule “would be inappropriate,” including an assertion challenging “the rule’s underlying premise or approach,” or a claim that the rule “would be ineffective or unacceptable without a change.” 89 FR 106409.

If the Commission receives a significant adverse comment, the Commission will withdraw this direct final rule. Depending on the comment and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

#### VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612) generally requires agencies to review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603–604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. 5 U.S.C. 601–612. As discussed in Section V. of this preamble regarding the Direct Final Rule Process, the Commission has determined that notice and the opportunity to comment are unnecessary for this rule. Therefore, the RFA does not apply. The Commission also notes the limited nature of this document, which updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

#### VII. Paperwork Reduction Act

The current mandatory standard for stationary activity centers includes labeling requirements that constitute a “collection of information,” as defined in the Paperwork Reduction Act (PRA; 44 U.S.C. 3501–3521). The revised mandatory standard for stationary activity centers does not alter these

requirements. The Commission took the steps required by the PRA for information collections when it adopted 16 CFR part 1238, including obtaining approval and a control number. Because the information collection is unchanged, the revision does not affect the information collection requirements or approval related to the standard.

#### VIII. Environmental Considerations

The Commission’s regulations provide for a categorical exclusion from any requirement to prepare an environmental assessment or an environmental impact statement where 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.

#### IX. Preemption

Section 26(a) of the CPSA provides that where a consumer product safety standard 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. 15 U.S.C. 2075(a). Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued under that provision “consumer product safety standards.” Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

#### X. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standards organization revises a standard that the Commission adopted as a mandatory standard, the revision becomes the CPSC standard 180 days after notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. 15 U.S.C. 2056a(b)(4)(B). The Commission is taking neither of those actions with respect to the revised standard for stationary activity centers. Therefore, ASTM F2012–24 automatically will take effect as the new mandatory standard for stationary activity centers on July 5, 2025, 180 days after the Commission

received notice of the revision. As a direct final rule, unless the Commission receives a significant adverse comment within 30 days of this notice, the rule will become effective on July 5, 2025.

#### XI. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a “major rule.” The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a “major rule.”

Pursuant to the CRA, OIRA has determined that this rule does not qualify as a “major rule,” as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

#### List of Subjects in 16 CFR Part 1238

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, Safety, and Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

#### PART 1238—SAFETY STANDARD FOR STATIONARY ACTIVITY CENTERS

■ 1. The authority citation for part 1238 continues to read as follows:

**Authority:** 15 U.S.C. 2056a.

■ 2. Revise § 1238.2 to read as follows:

#### § 1238.2 Requirements for stationary activity centers.

Each stationary activity center shall comply with all applicable provisions of ASTM F2012–24, *Standard Consumer Safety Performance Specification for Stationary Activity Centers*, approved on November 1, 2024. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 16 CFR part 51. This material is available for inspection at the U.S. Consumer Product Safety Commission (CPSC) and at the National Archives and Records Administration (NARA). Contact the U.S. Consumer Product Safety Commission at: Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, telephone (301) 504–7479, email: [cpsc-os@cpsc.gov](mailto:cpsc-os@cpsc.gov). For

information on the availability of this material at NARA, email [fr.inspection@nara.gov](mailto:fr.inspection@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html). A free, read-only copy of the standard is available for viewing on the ASTM website at <https://www.astm.org/READINGLIBRARY/>. You may also obtain a copy from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959; phone: (610) 832-9585; [www.astm.org](http://www.astm.org).

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2025-05239 Filed 3-26-25; 8:45 am]

BILLING CODE 6355-01-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2023-0503; FRL-12664-01-OCSPP]

#### ***Pseudomonas Oryzihabitans* Strain SYM23945; Exemption From the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of *Pseudomonas oryzihabitans* strain SYM23945 in or on all food commodities when used in accordance with label directions and good agricultural practices. Indigo Ag, Inc. submitted a petition to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Pseudomonas oryzihabitans* strain SYM23945 under FFDCA when used in accordance with this exemption.

**DATES:** This regulation is effective March 27, 2025. Objections and requests for hearings must be received on or before May 27, 2025 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2023-0503, is available at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the

docket in-person, is available at <https://www.epa.gov/dockets>.

#### **FOR FURTHER INFORMATION CONTACT:**

Madison H. Le, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (202) 566-1400; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### *B. What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." FFDCA section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of

infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue." Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

###### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by the EPA, you must identify docket ID number EPA-HQ-OPP-2023-0503 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before May 27, 2025.

EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at <https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf>. Although EPA's regulations require submission via U.S. Mail or hand delivery, EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at [https://yosemite.epa.gov/OA/EAB/EAB-ALJ\\_upload.nsf](https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket