



**Billing Code 6355-01-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Part 1500**

**[CPSC Docket No. CPSC-2012-0036]**

**Hazardous Substances and Articles; Administration and Enforcement Regulations:**

**Corrections to Animal Testing Regulations**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Direct final rule.

**SUMMARY:** The Consumer Product Safety Commission (CPSC or Commission) is issuing a direct final rule to correct its animal testing regulations under the Federal Hazardous Substances Act (FHSA). The rule reinserts text that was inadvertently omitted and corrects references.

**DATES:** The rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, unless we receive significant adverse comment by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. If we receive timely significant adverse comment, we will publish notification in the *Federal Register*, withdrawing this direct final rule before its effective date.

**ADDRESSES:** You may submit comments, identified by Docket No. CPSC-2012-0036, by any of the following methods:

*Electronic Submissions:* Submit electronic comments to the Federal eRulemaking Portal at: [www.regulations.gov](http://www.regulations.gov). Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (e-mail), except through [www.regulations.gov](http://www.regulations.gov). The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

*Written Submissions:* Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, 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, including any personal identifiers, contact information, or other personal information provided, to: [www.regulations.gov](http://www.regulations.gov). 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 in writing.

*Docket:* For access to the docket to read background documents or comments received, go to: [www.regulations.gov](http://www.regulations.gov), and insert the docket number CPSC-2012-0036, into the “Search” box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Alice Thaler, Associate Executive Director for Health Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987-2240; [athaler@cpsc.gov](mailto:athaler@cpsc.gov).

**SUPPLEMENTARY INFORMATION:**

**A. Background**

The Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261–1278, requires appropriate cautionary labeling on certain hazardous household substances to alert consumers to the potential hazards that a product may present. Among the hazards addressed by the FHSA are products that are toxic, corrosive, irritants, flammable, combustible, or strong sensitizers. The FHSA and the Commission’s regulations at 16 CFR part 1500 provide the definitions and test methods used to determine whether a substance is “hazardous” under the FHSA. Specifically, §

1500.3(b) of these regulations restates the statutory definitions that are in the FHSA. Section 1500.3(c) interprets, supplements, or provide alternatives to the statutory definitions. Section 1500.40 provides the method of testing toxic substances.

On December 10, 2012, the CPSC amended and updated regulations on the CPSC's animal testing methods under the FHSA (77 FR 73289). Among other things, the amendment to 16 CFR 1500.3 explained that alternative test methods exist that avoid, reduce, or refine animal testing to determine toxicity. At the same time, the CPSC codified its statement of policy on animal testing to reflect new test methods accepted by the scientific community, including recommendations of the Interagency Coordinating Committee on the Validation of Alternative Methods in a new section, 16 CFR 1500.232. (77 FR 73286). Sections 1500.3(c) and 1500.232 cross-reference each other.

CPSC staff recently reviewed the animal testing regulations. Staff's review showed that when CPSC revised the animal testing regulations, the definitions in 16 CFR 1500.3(c)(2)(i), inadvertently removed the definition of "acute toxicity" (oral, dermal, and inhalation). Before the 2012 amendment, this definition appeared at § 1500.3(c)(2)(i)(A) through (C). We are amending § 1500.3(c)(2)(i) to restore the "acute toxicity" definition. In addition, staff found that two other corrections are needed. As explained below, we are reinserting a sentence into the definition of "corrosive" in § 1500.3, and we are correcting a reference that appears in the regulation on method of testing toxic substances at § 1500.40.

## **B. Amendments**

### **1. Definition of "Toxic"**

The FHSA defines the term "toxic." 15 U.S.C. 1261(f). The Commission has issued regulations that supplement the FHSA's statutory definition under 16 CFR 1500.3(c). Before

2012, the regulatory definitions included a definition of “acute toxicity,” which provided guidance on the toxicity of substances falling in different toxicity ranges for oral, dermal, and inhalation exposures. The Commission intended to retain those paragraphs in the CFR under § 1500.3(c)(2)(i) when it amended the animal testing regulations. 77 FR 73293. However, the subsequent versions of the CFR omitted those subparagraphs. These provisions are necessary because they give specificity to the definition of “toxic.” The paragraphs that were omitted included guidance on when a substance might be considered for exemption from some or all of the labeling requirements of the FHSA. In addition, the omitted provisions provided guidance on the toxicity of substances falling within the toxicity range of 500 mg and 5 grams per kilogram of body weight. Without this text in the CFR, the CPSC cannot reference the testing criteria that help to determine acute toxicity. The animal testing policy under 16 CFR 1500.232(b)(1)(i) also refers to these paragraphs (16 CFR 1500.3(c)(1) and (2)) to describe the traditional animal testing methods.

Accordingly, the Commission amends § 1500.3(c)(2)(i) to reinstate the omitted paragraphs to give specificity to the definition of “toxic.”

## **2. Interpretation of “Corrosive”**

Section 1500.3(c)(3) provides a regulatory definition of “corrosive” that supplements the statutory definition of “corrosive” under the FHSA. Before the 2012 amendment of the animal testing regulations, 16 CFR 1500.3(c)(3) included a citation to the relevant section of the FHSA that defined the term “corrosive,” 15 U.S.C. 1261(h)(2)(i), and a cross-reference to 16 CFR 1500.3(b)(7), which restated the statutory definition of “corrosive.” However, that text was removed in the subsequent editions of the CFR. The Commission believes that reinserting that sentence in § 1500.3(c)(3) will help clarify what is meant by “corrosive” by providing the

references to the statutory definition under the FHSA. Accordingly, the Commission amends § 1500.3(c)(3) to reference the definition of “corrosive” under 15 U.S.C. 1261(h)(2)(i), as cross-referenced in 16 CFR 1500.3(b)(7).

### **3. Method of Testing Toxic Substances**

The method of testing toxic substances for acute dermal toxicity is set forth in 16 CFR 1500.40. Currently, the method of testing the toxic substances references “§ 1500.3(c)(1)(ii)(C) and (c)(2)(iii).” However, § 1500.3(c)(2)(iii) does not exist. Accordingly, the Commission is amending § 1500.40 to correct the references for testing toxic substances, which are § 1500.3(c)(1) and (2).

### **C. Direct Final Rule Process**

The Commission is issuing this rule as a direct final rule. The Administrative Procedure Act (APA) generally requires notice and comment rulemaking. 5 U.S.C. 553. The direct final rule process is an appropriate process for expediting the issuance of non-controversial rules. In Recommendation 95-4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite promulgating rules that are noncontroversial and that are not expected to generate significant adverse comment. *See* 60 FR 43108 (August 18, 1995). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule because we believe the corrections will not be controversial. The rule will not impose any new obligations, but rather, will reinstate text that was inadvertently omitted and correct references. Therefore, the Commission believes this rulemaking is a non-controversial matter that is not likely to engender any significant comments.

Unless we receive a significant adverse comment within 30 days, the rule will take effect on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL**

**REGISTER]**. 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 change.

Should the Commission receive significant adverse comment, the Commission would withdraw this direct final rule. Depending on the comments 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.

#### **D. Regulatory Flexibility Act**

The Regulatory Flexibility Act (RFA) generally requires that agencies 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 and 604. When CPSC issued the animal testing regulations in December 2012, staff assessed the potential effect the regulations would have on small businesses, and the Commission certified that the rule would not have a significant impact on a substantial number of small entities. 77 FR 73293. The corrections to the regulations do not make any substantive changes. Therefore, the Commission certifies that the direct final rule will not have a significant impact on a substantial number of small entities.

#### **E. Paperwork Reduction Act**

This rule would not impose any information collection or disclosure requirements. Accordingly, the rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501-3520.

#### **F. Environmental Considerations**

This rule makes corrections to regulatory definitions and references. As such, the rule will not affect the human environment. See 16 CFR 1021.5.

**List of Subjects in 16 CFR Part 1500**

Consumer protection, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Reporting and recordkeeping requirements, Toys.

Accordingly, 16 CFR part 1500 is amended as follows:

**PART 1500—[AMENDED]**

- 1. The authority citation for part 1500 is revised to reads as follows:

**Authority:** 15 U.S.C. 1261–1278.

- 2. Amend § 1500.3 by:
  - a. Revising paragraph (c)(2)(i); and
  - b. Adding a sentence to the beginning of paragraph (c)(3).

The revision and addition read as follows:

**§ 1500.3 Definitions.**

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(i) *Acute toxicity. Toxic* means any substance that produces death within 14 days in half or more than half of a group of:

(A) White rats (each weighing between 200 and 300 grams) when a single dose of from 50 milligrams to 5 grams per kilogram of body weight is administered orally. Substances falling in the toxicity range between 500 milligrams and 5 grams per kilogram of body weight will be considered for exemption from some or all of the labeling requirements of the act, under § 1500.82, upon a showing that such labeling is not needed because of the physical form of the

substances (solid, a thick plastic, emulsion, etc.), the size or closure of the container, human experience with the article, or any other relevant factors;

(B) White rats (each weighing between 200 and 300 grams) when an atmospheric concentration of more than 200 parts per million but not more than 20,000 parts per million by volume of gas or vapor, or more than 2 but not more than 200 milligrams per liter by volume of mist or dust, is inhaled continuously for 1 hour or less, if such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; and/or

(C) Rabbits (each weighing between 2.3 and 3.0 kilograms) when a dosage of more than 200 milligrams but not more than 2 grams per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours by the method described in § 1500.40.

(D) The number of animals tested shall be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices. *Toxic* also applies to any substance that can be labeled as such, based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in § 1500.232, including data from *in vitro* or *in silico* test methods that the Commission has approved; or a validated weight-of-evidence analysis comprising all of the following that are available: existing human and animal data, structure activity relationships, physicochemical properties, and chemical reactivity data.

\* \* \* \* \*

(3) The definition of corrosive in section 2(i) of the act (restated in paragraph (b)(7) of this section) is interpreted to also mean the following: \* \* \*

\* \* \* \* \*

**§ 1500.40 [Amended]**

3. Amend the last sentence of the introductory text of § 1500.40 by removing the citation “§ 1500.3(c)(1)(ii)(C) and (c)(2)(iii)” and adding in its place “§ 1500.3(c)(1) and (2).”

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Alberta E. Mills, Secretary,  
Consumer Product Safety Commission.

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