UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved and signed.

DATE: February 14, 2018

BALLOT VOTE SHEET

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Patricia H. Adkins, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT: Direct Final Rule: *Hazardous Substances and Articles; Administration and Enforcement Regulations: Corrections to Animal Testing Regulations*

BALLOT VOTE DUE: Wednesday, February 21, 2018

Staff is forwarding to the Commission a memorandum recommending that the Commission issue a direct final rule (DFR) to make corrections to the CPSC's animal testing regulations. The DFR reinserts sections that were omitted erroneously and updates references in the Code of Federal Regulations. The Office of the General Counsel is providing for the Commission's consideration the attached draft DFR for publication in the *Federal Register*.

Please indicate your vote on the following options:

I. Approve publication of the document in the *Federal Register,* as drafted.

_____ _____
(Signature) (Date)

II. Approve publication of the document in the *Federal Register,* with changes. (Please specify.)

_____ _____
(Signature) (Date)

III. Do not approve publication of the document in the *Federal Register*.

_____ _____

(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment: Draft Direct Final Rule: *Hazardous Substances and Articles; Administration and Enforcement Regulations: Corrections to Animal Testing Regulations*

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC-2012-0036]

16 CFR Part 1500

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 publication in the FEDERAL REGISTER**], unless we receive significant adverse comment by [**insert date 30 days after 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.

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.

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, section 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 section 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 sections in the CFR under section 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 sections 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 sections (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 sections 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 section 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 (2)(iii)." However, section 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 sections 1500.3(c)(1) and (c)(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 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 DFR 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, and Toys.

Accordingly, 16 CFR part 1500 is amended as follows:

PART 1500—[AMENDED]

1. The authority citation for part 1500 continues 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 revisions 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.

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 16 CFR 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.

(ii) * * *

(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. Method of testing toxic substances. [Amended]

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

* * * * *

Dated: _____

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

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

This document has been electronically approved and signed.

MEMORANDUM

DATE: February 14, 2018

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: Patricia M. Hanz, General Counsel
Patricia H. Adkins, Executive Director

FROM: George A. Borlase, Ph.D., P.E., Assistant Executive Director
Office of Hazard Identification and Reduction

Alice M. Thaler, Associate Executive Director
Directorate for Health Sciences

SUBJECT: Direct Final Rule: Corrections to Animal Testing Regulations

Background

The Federal Hazardous Substances Act (FHSA) establishes requirements for, and authorizes the Consumer Product Safety Commission (Commission or CPSC) to take certain actions, regarding "hazardous substances" as defined in the FHSA. The FHSA regulations at 16 C.F.R § 1500.3 provide definitions for terms used in the FHSA. Section 1500.3(b) of these regulations restates the definitions that are in the FHSA. Section 1500.3(c) states regulatory definitions which provide the Commission's interpretation of the statutory terms. In 2012, the CPSC issued a final rule that amended and updated regulations on the CPSC's animal testing methods under the FHSA[1]. Among other things, the amendment to 16 C.F.R. § 1500.3 explained that alternative test methods exist that avoid, reduce, or refine animal testing to determine toxicity. (77 FR 73289). 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 C.F.R. § 1500.232. (77 FR 73286). Sections 1500.3(c) and 1500.232 cross-reference each other.

Health Sciences staff recently reviewed 16 C.F.R. § 1500.3(c) and found that, when CPSC revised the animal testing regulations, the definition of "acute toxicity" (oral, dermal and inhalation) at §§ 1500.3(c)(2)(i)(A) through (C) was inadvertently omitted. In addition, staff found additional references in the animal testing regulations that need to be updated to the interpretation of "corrosive" and to the method of testing toxic substances in 16 C.F.R. §

[1] The staff briefing package is available at https://www.cpsc.gov/s3fs-public/pdfs/foia_animalrule.pdf

1500.40. Staff recommends that the Commission issue a direct final rule to add the text that was inadvertently removed in these three FHSA regulations.

Definition of acute toxicity

The FHSA defines the term "toxic." 15 U.S.C. § 1261(f). The Commission has issued regulations that supplement the FHSA's statutory definition. 16 C.F.R. § 1500.3(c). Before the 2012 final rule, the regulatory definitions included a definition of "acute toxicity." *Id.* § 1500.3(c)(2). In the final rule amending the animal testing rule, staff intended to include all of the criteria for determining the definition of "toxic." Although the animal testing rule signaled for those sections to be retained in the codification, 77 FR 73293, the subsequent version of the Code of Federal Regulations (C.F.R.) omitted those subparagraphs. Recently, staff discovered the omission when a stakeholder sought information regarding the definition of "toxic substances." These provisions are important because they give specificity to the definition of "toxic."

The text that was 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 those specific references, staff cannot reference the animal testing criteria that help to determine acute toxicity. The animal testing policy also refers to these sections (16 C.F.R. § 1500.3(c)(1) and (2)) to describe the traditional animal testing methods under 16 C.F.R. § 1500.232(b)(1)(i).

Accordingly, Health Sciences staff recommends that the Commission amend 16 C.F.R. § 1500.3(c)(2) to reinstate the missing provisions that were inadvertently omitted (text to be reinserted is italicized):

> (2) To give specificity to the definition of "toxic" in section 2(g) of the act (and restated in paragraph (b)(5) of this section), the following supplements that definition. "Toxic" applies to any substance that is "toxic" (but not "highly toxic") on the basis of human experience. The following categories are not intended to be inclusive.
>
> *(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.

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 16 C.F.R. § 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.

Interpretation of "Corrosive"

In addition, staff found another editorial change that should be made to clarify the regulation. Section 1500.3(c)(3) provides a regulatory definition of "corrosive." The regulatory definition provides the Commission's interpretation of the statutory term. In the 2012 edition of the C.F.R., § 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 C.F.R. § 1500.3(b)(7), which restated the statutory definition of "corrosive." That sentence was removed for no discernable reason. Staff believes that reinserting that sentence will help clarify what is meant by "corrosive" by providing the references to the statutory definition, as follows (text to be reinserted is italicized):

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: Corrosive means a substance that causes visible destruction or irreversible alterations in the tissue at the site of contact. A test for a corrosive substance is whether, by human experience, such tissue destruction occurs at the site of application. A substance would be considered corrosive to the skin if a weight-of-evidence analysis suggests that it is corrosive, or validated in vitro test method suggests that

it is corrosive, or if, when tested by the in vivo technique described in § 1500.41, the structure of the tissue at the site of contact is destroyed or changed irreversibly in 24 hours or less. Other appropriate tests should be applied when contact of the substance with other than skin tissue is being considered. A substance could also be labeled corrosive based on the outcome of any of the approved test methods described in the CPSC's animal testing policy set forth in 16 C.F.R. § 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.

Method of Testing Toxic Substances

Finally, staff's review showed that there is an incorrect reference in 16 C.F.R. § 1500.40 regarding the method of testing toxic substances. 16 C.F.R. § 1500.40 contains details for preparing test animals and applying substances to their skin in order to determine if contact results in acute dermal toxicity. That section states: "The reference for the method of testing the toxic substances was referred to in § 1500.3(c)(1)(ii)(C) and (2)(iii)." Section 1500.3(c)(2)(iii) does not exist. Accordingly, staff believes that the Commission should modify that section to reflect the current applicable sections as follows (text to be modified is in italics).

> Guidelines for testing the toxicity of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 C.F.R. 1500.232. A weight-of-evidence analysis, including any of the following: existing human and animal data, structure activity relationships, physicochemical properties; and chemical reactivity, or validated in vitro or in silico testing are recommended to evaluate existing information before in vivo tests are considered. If in vivo testing is conducted, a sequential testing strategy is recommended to reduce the number of test animals. *The method of testing the toxic substances referred to in § 1500.3(c)(1) and (c)(2) is as follows:*

Regulatory Flexibility Act - The draft direct final rule does not add any new requirements on small businesses or any other entity. Rather, the direct final rule simply reinserts and corrects, the information that was in the FHSA regulations before the 2012 animal testing rule.