[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: Notice of Proposed Rulemaking; Revisions to Animal Testing Regulations

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Consumer Product Safety Commission (CPSC or Commission) proposes to amend and to update regulations on the CPSC's animal testing methods under the Federal Hazardous Substances Act (FHSA).

DATES: Written comments must be received by **[insert date that is 75 days after publication in the Federal Register**].

ADDRESSES: You may submit comments identified by Docket No. CPSC-2012-0036, 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, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, 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 proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Leslie E. Patton, Ph.D., Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7848; lpatton@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 products 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 regulations at 16

CFR part 1500 provide certain test methods related to testing on animals to determine the existence of the hazards addressed by the FHSA.

On May 30, 1984, the Commission adopted an animal testing policy that minimized the number of test animals required for toxicity testing and clarified when animal testing might be needed (1984 Policy) (49 FR 22522). These guidelines advised product manufacturers to use alternatives to animal testing whenever possible, including: (1) prior human experience, (2) existing animal or limited human test results, and (3) expert opinion. The 1984 Policy stated:

> it is important to keep in mind that neither the FHSA nor the Commission's regulations require any firm to perform animal tests. The statute and its implementing regulations only require that a product be labeled to reflect the hazards associated with that product. While animal testing may be necessary in some cases, Commission policy supports limiting such tests to the lowest feasible number and taking every feasible step to eliminate or reduce the pain or discomfort that can be associated with such tests….The Commission resorts to animal testing only when the other information sources have been exhausted. Furthermore, the FHSA regulations, at 16 CFR 1500.4, clearly state that reliable human experience shall take precedence over different results from animal data.

Id. at 22523. The 1984 Policy also stated that if non-animal test systems for prediction of toxicity and irritancy are accepted by the scientific community as adjuncts or alternatives to whole-animal testing, "[The CPSC Directorate for] Health Sciences will incorporate the techniques into the Commission's compliance program to the extent feasible and will recommend any changes to the Commission's statutes or regulations that may become appropriate as the result of advances in testing methods that are developed." *Id.*

Since the 1984 Policy, there have been new methods accepted by the scientific community as replacements or adjuncts to animal tests for predictions of toxicity and irritancy. Such developments in testing have been made in recent years, particularly

since the National Institutes of Health Revitalization Act was passed in 1993 (Public Law 103-43, Section 1301), directing the National Institute of Environmental Health Sciences (NIEHS) to establish a method and criteria for the validation and regulatory acceptance of alternative testing methods. The NIEHS created the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM; http://iccvam.niehs.nih.gov/home.htm), which was made permanent by the ICCVAM Authorization Act of 2000, Public Law 106-545. The duties of ICCVAM are to review, optimize, and validate new, revised, or alternative test methods that encourage the reduction, refinement, or replacement of the use of animals in testing. ICCVAM has representatives from 15 federal regulatory and research agencies, including the CPSC. These agencies generate, use, or provide information from toxicity test methods for risk assessment purposes. In addition, ICCVAM provides test recommendations to federal agencies and other stakeholders to facilitate appropriate interagency and international harmonization of toxicological test protocols.

ICCVAM submits recommendations for a test method to federal agencies that require or recommend acute or chronic toxicological testing. According to Public Law 106-545, these agencies should promote and encourage the development and use of alternatives to animal test methods for regulatory purposes, and ensure that any new or revised acute or chronic toxicity test method is valid for its proposed use. Federal agencies have 180 days from the time of submission to identify any relevant test methods for which the ICCVAM test recommendations may be added or substituted, review such test recommendations, and notify ICCVAM if they will adopt the ICCVAM test recommendations. Since 2003, the Commission has approved, where applicable, the

recommendations made by ICCVAM to reduce and refine animal testing applicable to test methods under the FHSA. In order to make the ICCVAM recommendations and Commission's animal testing policy more accessible and transparent to interested parties, the Commission proposes to codify its updated animal testing policy at 16 CFR 1500.232, published elsewhere in this *Federal Register,* and establish a Web page on the CPSC's website at http://www.cpsc.gov/businfo/animaltesting.html regarding the ICCVAM recommendations and new developments in test methods that further reduce or refine animal testing.

In addition, to reflect more accurately the ICCVAM recommendations and updated test methods approved by the Commission, this proposed rule amends the Commission's regulations that interpret, supplement, or provide alternatives to definitions on animal test methods used to aid in the classification of hazardous substances under the FHSA.

B. Proposed Amendments

All of the proposed amendments to 16 CFR part 1500 clarify or add language to explain that alternative test methods exist that avoid or reduce animal testing, which have been approved by the Commission.

1. *Definition of highly toxic.* Currently, the test methods in section 1500.3(c)(1)(ii) A–C, used in the definitions of oral, inhalation, and dermal toxicity, respectively, each describe a method for defining a substance as *highly toxic.* The definition of highly toxic is:

> (i) A substance determined by the Commission to be highly toxic on the basis of human experience; and/or (ii) A 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 50 milligrams or less per kilogram of body

> weight is administered orally; (B) White rats (each weighing between 200 and 300 grams) when a concentration of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter by volume or less 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 200 milligrams or less per kilogram of body weight is administered by continuous contact with the bare skin for 24 hours or less by the method described in §1500.40. The number of animals tested must be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

The proposed amendment makes clear that the animal tests are not the only means to test or define a product's toxicity under the FHSA, nor are they the only methods used by the CPSC to assess product toxicity. Because there are other Commission-approved test methods that may be used by CPSC staff or the public for toxicity testing and defining a substance as highly toxic, as reflected in the ICCVAM recommendations and outlined in the CPSC'statement of policy on animal testing published elsewhere in this *Federal Register*, the proposed rule adds language under new section1500.3(c)(1)(iii) as follows : A substance that produces a result of 'highly toxic' in any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.

2. *Definition of toxic.* Currently, the test methods in section 1500.3(c)(2)(i) A–C, used in the definitions of oral, inhalation, and dermal toxicity, respectively, each describe a method for defining a substance as *toxic.* The definition of toxic is:

> (i) 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 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; and/or (B) White rats (each weighing between 200 and 300 grams) when a 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 must be sufficient to give a statistically significant result and shall be in conformity with good pharmacological practices.

The proposed amendment makes clear that the animal tests are not the only means to test or define a product's toxicity under the FHSA, nor are they the only methods used by the CPSC to assess product toxicity. Because there are other Commission-approved test methods that may be used by CPSC staff or the public for toxicity testing and defining a substance as *toxic,* as reflected in the ICCVAM recommendations, and outlined in the CPSC's statement of policy on animal testing published elsewhere in this *Federal Register*, the proposed rule adds language under new section 1500.3(c)(2)(iii) as follows : *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.

3. *Definition of corrosive.* 16 CFR 1500.3(c)(3) currently states that: 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, when tested on the intact skin of the albino rabbit by the 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.

The method of testing described in §1500.41 is a test for acute dermal toxicity. The proposed rule amends this definition to make explicit that the animal testing is not the only testing method used or accepted by the CPSC, or the preferred method. Accordingly, the proposed rule adds the following text (in underline) to section 16 CFR 1500.3(c)(3):

> 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 <u>if a weight-of-evidence analysis suggests that it is corrosive or if, when tested by the *in vivo*</u> 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. <u>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 CFR 1500.232.</u>

4. *Definition of irritant, primary irritant, and eye irritant.* Currently, 16 CFR 1500.3(c)(4) provides that the test methods for *irritant*, *primary irritant*, and *eye irritant* reference 16 CFR 1500.41 and 1500.42, which each describe a specific animal test method and outcome. For example, 16 CFR 1500.41 states that primary irritation to the skin is measured by a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. A minimum of six subjects are used in the skin tests. To test for eye irritants, 16 CFR 1500.42 requires the use of six albino rabbits. Such tests require the test material be placed in one eye of each animal, while the other eye remains untreated, to serve as a control to assess the grade of ocular reaction.

The proposed rule clarifies that the method for testing for irritant substances should not be based solely on these specific animal tests because there are other scientifically valid ways of testing for irritants, including methods that do not use animals.

Accordingly, the proposed rule adds the following text (in underline) to section 1500.3(c)(4):

> The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in 1500.41; and/or a substance that can be considered a primary irritant 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. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or means a substance for which a positive test is obtained when tested by the method described in 1500.42; and/or means a substance that can be considered an eye irritant 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.

5. *Method of Testing Toxic Substances*

The method of testing toxic substances is set forth under 16 CFR 1500.40. This method details an acute dermal toxicity assay using rabbits. The method is referenced in § 1500.3(c)(1)(ii)(C) and §1500.3(c)(2)(C). Although the method described in §1500.40 is one way of assessing a substance's acute dermal toxicity, this method is not mandatory, and it is not the only or preferred method for evaluating dermal toxicity. Accordingly, the proposed rule adds the following text (in underline) to § 1500.40 immediately after the heading titled, "Method of testing toxic substances":

> 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 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis, when deemed necessary to carry out, should include any of the following: existing human and animal data, *in vitro* data, structure activity relationships, physicochemical properties, and chemical reactivity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals.

6. *Method of Testing Primary Irritant Substances*

The method of testing primary irritant substances is set forth under 16 CFR 1500.41. This method details an acute dermal toxicity assay using rabbits. The method is referenced in §§ 1500.3(c)(3) and 1500.3(c)(4). Although the method described in §1500.41 is one way of assessing a substance's dermal irritation/corrosivity, this method is not mandatory, and it is not the only or preferred method for evaluating a substance's dermal irritation/corrosivity. Accordingly, the proposed rule adds the following text (in underline) to §1500.41 immediately after the heading titled, "Method of testing primary irritant substances":

> Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include all of the following that are available: human and animal data, structure activity relationships, physicochemical properties, and dermal toxicity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the dermal corrosivity and primary irritation of substances referred to in §§1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair…

7. *Test for Eye Irritants*

Section 1500.42 of 16 CFR provides a detailed animal test for eye irritation. The method is referenced in §1500.3(c)(4), which defines *irritation*. Although the method described in §1500.42 is one way of assessing a substance's properties of ocular irritation, this method is not mandatory, and it is not the only or preferred method of assessing a substance's properties of ocular irritation. Accordingly, the proposed rule adds the following text (in underline) to § 1500.42 immediately after the heading titled, "Test for eye irritants":

> Guidelines for *in vivo* and *in vitro* testing of ocular irritation of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include any of the following: existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize pain and distress in ocular safety testing is recommended.
> (a)(1) In the method of testing the ocular irritation of a substance referred to in §1500.3(c)(4), six albino rabbits are used for each test substance…

8. *Editorial changes.*

The proposed rule eliminates the reference in §1500.42(c) to the "Illustrated Guide for Grading Eye Irritation by Hazardous Substances," and the accompanying note. The referenced guide is out of print, and photocopies are rare. Instead, the proposed rule amends §1500.42(c) to reference guidelines from the U.S. Environmental Protection Agency (EPA) and the Organisation for Economic Co-operation and Development (OECD) as follows:

> To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at http://www.cpsc.gov/businfo/animaltesting.html will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation[1] or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.[2]

C. Impact on Small Businesses

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the

[1] EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712- C-98-195. Washington, DC: U.S. Environmental Protection Agency. (Available: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf)

[2] OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf)

impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities.

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of amending the regulations on animal testing. That assessment found that there would be little or no effect on small businesses and other entities because the proposed amendments will not result in product modifications in order to comply, and they will not result in additional testing or recordkeeping burdens. Based on the foregoing assessment, the Commission preliminarily finds that the proposed rule would not have a significant impact on a substantial number of small entities.

D. Environmental Considerations

Generally, CPSC rules are considered to "have little or no potential for affecting the human environment," and environmental assessments and environmental impact statements are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). The Commission does not expect the proposed rule to have any adverse impact on the environment under this categorical exclusion.

E. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. The preemptive effect of regulations such as this proposed rule is stated in section 18 of the FHSA. 15 U.S.C. 1261n.

F. Paperwork Reduction Act

This rule would not impose any information collection requirements.

Accordingly, this rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

G. Effective Date

The Administrative Procedure Act generally requires that a substantive rule be published not less than 30 days before its effective date, unless the agency finds, for good cause shown, that a lesser time period is required. 5 U.S.C. 553(d)(3). We propose that the rule would take effect 30 days after publication of a final rule in the *Federal Register*.

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 proposed to be 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, 122 Stat. 3016; the Consumer Product Safety Improvement Act of 2008, Pub. L. 110–314, §104, 122 Stat. 3016 (August 14, 2008).

2. Amend section 1500.3 by adding a new paragraphs (c)(1)(iii) and (c)(2)(iii) and revise paragraphs (c)(3) and (c)(4), to read as follows:

§ 1500.3 Definitions

* * * * *

(c) * * *

(1) * * *

(iii) A substance that produces a result of 'highly toxic' in any of the approved test methods described in the CPSC's animal testing policy set forth in 16 CFR 1500.232.

(2) * * *

(iii) *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.

(3) 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 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 CFR 1500.232.

(4) The definition of irritant in section 2(j) of the act (restated in paragraph (b)(8) of this section) is supplemented by the following: *Irritant* includes primary irritant to the skin, as well as substances irritant to the eye or to the mucous membranes. *Primary irritant* means a substance that is not corrosive and that human experience data indicate is a primary irritant; and/or means a substance that results in an empirical score of five or more when tested by the method described in §1500.41; and/or a substance that can be considered a primary irritant 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. *Eye irritant* means a substance that human experience data indicate is an irritant to the eye; and/or

means a substance for which a positive test is obtained when tested by the method described in §1500.42; and/or means a substance that can be considered an eye irritant 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.

* * * * *

3. Amend section 1500.40 by revising the introductory text to read as follows:

§ 1500.40 Method of testing toxic substances.

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 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis, when deemed necessary to carry out, should include any of the following: existing human and animal data, *in vitro* data, structure activity relationships, physicochemical properties, and chemical reactivity. When *in vivo* testing is necessary, 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)(ii)(C) and (2)(iii) is as follows:

* * * * *

4. In § 1500.41, add five sentences at the start of the introductory text to read as follows::

§ 1500.41 Method of testing primary irritant substances.

Guidelines for testing the dermal irritation and corrosivity properties of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is

recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include all of the following that are available: human and animal data, structure activity relationships, physicochemical properties, and dermal toxicity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. The method of testing the dermal corrosivity and primary irritation of substances referred to in §§1500.3(c)(3) and (4), respectively, is a patch-test technique on the abraded and intact skin of the albino rabbit, clipped free of hair. * * *

5. Amend section 1500.42 by adding introductory text, adding a sentence at the beginning of paragraph (a)(1), and revising paragraph (c) to read as follows:

§ 1500.42 Test for eye irritants.

Guidelines for *in vivo* and *in vitro* testing of ocular irritation of substances, including testing that does not require animals, are presented in the CPSC's animal testing policy set forth in 16 CFR 1500.232. A weight-of-evidence analysis is recommended to evaluate existing information before *in vivo* tests are considered. This analysis should include any of the following: existing human and animal data on ocular or dermal irritation, structure activity relationships, physicochemical properties, and chemical reactivity. When *in vivo* testing is necessary, a sequential testing strategy is recommended to reduce the number of test animals. Additionally, the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid or minimize pain and distress in ocular safety testing is recommended.

(a)(1) In the method of testing the ocular irritation of a substance referred to in §1500.3(c)(4), six albino rabbits are used for each test substance * * *

* * * * *

(c) To assist testing laboratories and others interested in interpreting ocular irritation test results, the CPSC animal testing policy Web page at http://www.cpsc.gov/businfo/animaltesting.html will contain the scoring system defined in the U.S. EPA's Test Guideline, OPPTS 870.2400: Acute Eye Irritation[3] or the OECD Test Guideline 405: Acute Eye Irritation/Corrosion.[4]

Dated: June 25, 2012

Todd A. Stevenson, Secretary
U.S. Consumer Product Safety Commission

[FR Doc. 2012-15882 Filed 06/28/2012 at 8:45 am; Publication Date: 06/29/2012]

[3] EPA. 1998. Health Effects Test Guidelines, OPPTS 870.2400 Acute Eye Irritation. EPA 712- C-98-195. Washington, DC: U.S. Environmental Protection Agency. (Available: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/EPA/EPA_870_2400.pdf)

[4] OECD. 2002. OECD Guideline for the Testing of Chemicals 405: Acute Eye Irritation/Corrosion. Paris: Organisation for Economic Co-operation and Development. (Available: http://iccvam.niehs.nih.gov/SuppDocs/FedDocs/OECD/OECDtg405.pdf)