



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 BETHESDA, MARYLAND 20814

BALLOT VOTE SHEET

DATE: MAY - 9 2006

TO: The Commission
 Todd A. Stevenson, Secretary

FROM: Page C. Faulk, General Counsel

PCF

SUBJECT: Proposed Revisions to 16 C.F.R. Part 1115

MAY 16 2006

BALLOT VOTE DUE: _____

Attached is a Federal Register notice announcing proposed revisions to Commission regulations on Substantial Product Hazard Reports at 16 C.F.R. Part 1115: a revision to the definition of "defect" at 16 C.F.R. § 1115.4 adding four new factors for consideration, a proposed revision to 16 C.F.R. § 1115.12(g)(1)(ii) adding a factor to be considered by the Commission when determining the number of defective products distributed in commerce, and a proposed new section at 16 C.F.R. § 1115.8 adding guidance on compliance with voluntary and mandatory product safety standards. Although not required because it is interpretative guidance, these attached draft revisions, if approved by the Commission, would be published in the Federal Register for notice and comment for 30 days pursuant to the Administrative Procedure Act, 5 U.S.C. § 552, et seq.

Please indicate your vote:

I. Approve the attached revisions to 16 C.F.R. Part 1115 as drafted.

 Signature

 Date

II. Approve the attached revisions to 16 C.F.R. Part 1115 with changes (please specify).

 Signature

 Date

NOTE: This document has not been reviewed or accepted by the Commission. CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: <http://www.cpsc.gov>

Initial PCF Date 5/9/06

SEARCHED INDEXED
 SERIALIZED FILED
 MAY 9 2006
 FEDERAL BUREAU OF INVESTIGATION
 U.S. DEPARTMENT OF JUSTICE
 — EXCEPTED FROM AUTOMATIC DECLASSIFICATION
 — WITH PORTAL IS RENOV/2006

III. Do not approve the attached draft revisions to 16 C.F.R. Part 1115.

Signature

Date

Attachment: 1.) Draft Fed. Reg. notice on revisions to 16 C.F.R. Part 1115

DRAFT

BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1115

Substantial Product Hazard Reports

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed revision to interpretative rule.

SUMMARY: Section 15(b) of the Consumer Product Safety Act, 15 U.S.C. 2064(b), requires manufacturers, distributors, and retailers of consumer products to report potential product hazards to the Consumer Product Safety Commission. The Commission publishes proposed revisions to its interpretative rule advising manufacturers, distributors, and retailers how to comply with the requirements of section 15(b). The proposed revisions identify certain factors the Commission and staff consider when assessing whether a product is defective or not. The proposed revisions also clarify that compliance with voluntary or mandatory product safety standards may be considered by the Commission in making certain determinations under section 15(b). In addition, the Commission may consider the adoption of an interpretative regulation related to the statutory factors for the assessment of civil penalties pursuant to section 20, CPSA (15 U.S.C. 2069(b),(c)). A

DRAFT

separate Federal Register notice, if approved, will be issued for public comment.

DATES: The Office of the Secretary must receive written comments not later than [**insert date that is 30 days after publication in the Federal Register**].

ADDRESSES: Written comments should be captioned "Substantial Product Hazard Reports" and e-mailed to the Office of the Secretary at cpssc-os@cpssc.gov. Written comments may also be sent to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814 or by facsimile at (301) 504-0127.

FOR FURTHER INFORMATION CONTACT: John Gibson Mullan, Assistant Executive Director, Compliance and Field Operations at (301) 504-7626.

SUPPLEMENTARY INFORMATION: To provide further guidance, clarity and transparency to the regulated community on reporting obligations under section 15(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2064(b), the Commission proposes revisions to its interpretative rules regarding reporting of possible substantial product hazards. Section 15 (b) of the CPSA requires that every manufacturer (including an importer), distributor or retailer of a consumer product who obtains information which reasonably supports the conclusion that its product fails to comply with an applicable consumer product safety

DRAFT

rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, or contains a defect which could create a substantial product hazard as defined in section 15(a)(2) of the CPSA, or creates an unreasonable risk of serious injury or death, shall immediately inform the Commission of such failure to comply, of such defect, or of such risk, unless the manufacturer, distributor or retailer has actual knowledge that the Commission has been adequately informed. In 1978, the Commission first published an interpretative rule, 16 CFR Part 1115, which explained the section 15(b) reporting requirement and provided guidance on filing section 15(b) reports. In this notice the Commission proposes revisions to the interpretative rule to clarify factors relevant to section 15(b) reporting determinations.

A. Section 1115.4 Defect

The first revision clarifies the Commission's definition of "defect" by adding four additional criteria Commission staff use to evaluate whether a risk of injury is the type of risk that will render a product defective, thus possibly triggering a reporting obligation under section 15(b). The rule currently states that in determining whether the risk of injury associated with a product is the type of risk which will render a product

DRAFT

defective, the Commission and staff consider, as appropriate: the utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination. The proposed revision adds the following factors: the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product, and the foreseeability of such misuse.

The determination of whether a product presents a risk of injury that would render it defective is a threshold issue in evaluating reporting obligations under section 15(b) of the CPSA and is one of the most critical determinations a company is required to make under the CPSA. A firm must report if it obtains information which reasonably supports the conclusion that a product it manufactures and/or distributes contains a defect which could create a substantial product hazard. 15 U.S.C. 2064(b)(2). In determining whether a product contains a defect that presents a substantial risk of injury, the

DRAFT

Commission has explained that certain products may not be defective although they present a risk of injury because that risk is outweighed by the usefulness of the product and its ability to function properly. The classic example is a knife.

The regulatory criteria for evaluating whether a product presents a risk of injury that may render it defective have been in effect since 1978. In the more than twenty years since then, the Commission and staff have evaluated hundreds of products using, as appropriate, these criteria. The Commission has concluded, based on experience and practice in applying the criteria, that the four proposed additional factors - the obviousness of such risk; the adequacy of warning and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse - will enable a better analysis of whether the risk of injury associated with a product is the type of risk which will render the product defective.

B. Section 1115.12(g)(1)(ii) Number of defective products distributed in commerce.

The Commission also clarifies that in evaluating the substantial risk of injury involving a particular consumer product, it recognizes that the risk of injury from a

DRAFT

product may decline over time as the number of products being used by consumers decreases. While there may be other factors unique to a particular product which influence the rate of the reduction, if any, of injury risk, Commission staff believes that this factor is reasonable and appropriate to consider when evaluating the impact of the number of defective products distributed in commerce, authorized by 16 C.F.R. 1115.12(g)(1)(ii), when undertaking a substantial product hazard determination.

C. § 1115.8 Compliance with Product Safety Standards

The proposed revisions also add a new section § 1115.8, "Compliance with Product Safety Standards." This section is intended to further explain how the Commission views compliance with applicable voluntary or mandatory standards, particularly in the context of decisions under section 15(b) of the CPSA.

The Commission strongly encourages all firms to comply with voluntary consumer product safety standards and advises that where appropriate, compliance or non-compliance with such standards may be considered by the Commission and staff in exercising its authority under the CPSA, including when making determinations under section 15. The section also provides that compliance or non-compliance with applicable mandatory consumer product

DRAFT

safety standards may be considered by the Commission and staff in making relevant determinations and exercising relevant federal authorities under the CPSA and other federal statutes including when making corrective action determinations under section 15 of the CPSA.

The Commission is providing this guidance to emphasize that compliance with voluntary or mandatory standards are relevant considerations to the exercise of its authorities, particularly in evaluating section 15(b) obligations. The provision on voluntary standards is added to emphasize that when the Commission staff preliminarily determines whether a product presents a substantial product hazard under section 15(b) of the CPSA, the Commission staff will consider compliance with any relevant voluntary standard as part of that determination. Therefore, by this provision the Commission urges firms to consider compliance with voluntary standards in evaluating whether or not a substantial product hazard should be reported to the Commission.

In the context of mandatory standards, the Commission emphasizes that the Commission will consider such compliance when making relevant determinations and exercising relevant authorities under the CPSA and other federal statutes. In particular, a product's compliance

DRAFT

with a mandatory standard will be considered in determining whether and to what extent corrective action is necessary. This policy statement is not intended to reduce the volume of reporting to the Office of Compliance.

List of Subjects in 16 CFR PART 1115

Administrative practice and procedure, Business and Industry, Consumer protection, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 1115 is proposed to be amended as follows:

PART 1115- SUBSTANTIAL PRODUCT HAZARD REPORTS

1. The authority citation for part 1115 continues to read as follows:

AUTHORITY: 15 U.S.C. 2061, 2064, 2065, 2066(a), 2068, 2070, 2071, 2073, 2076, 2079 and 2084.

2. Revise part 1115 to read as follows:

PART 1115-SUBSTANTIAL PRODUCT HAZARD REPORTS

Subpart A-General Interpretation

Sec.

1115.1 Purpose.

1115.2 Scope and finding.

1115.3 Definitions.

1115.4 Defect.

DRAFT

1115.5 Reporting of failures to comply with a voluntary consumer product safety standard relied upon by the Commission under section 9 of the CPSA.

1115.6 Reporting of unreasonable risk of serious injury or death.

1115.7 Relation to other provisions.

1115.8 Compliance with product safety standards.

1115.9 [Reserved]

1115.10 Persons who must report and where to report.

1115.11 Imputed knowledge.

1115.12 Information which should be reported; evaluating substantial product hazard.

1115.13 Content and form of reports; delegations of authority.

1115.14 Time computations.

1115.15 Confidentiality and disclosure of data.

3. Revise section 1115.4 to read as follows:

§ 1115.4 Defect.

In § 1115.4, in the last paragraph after the phrase, "the population exposed to the product and its risk of injury;" add "the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse;" * * *

DRAFT

4. Section 1115.8 is added to read as follows:

§ 1115.8 Compliance with Product Safety Standards.

(a) *Voluntary Standards.* The CPSA and other federal statutes administered by the Commission generally encourage the private sector development of, and compliance with voluntary consumer product safety standards to help protect the public from unreasonable risks of injury associated with consumer products. To support the development of such consensus standards, Commission staff participates in many voluntary standards committees and other activities. The Commission also strongly encourages all firms to comply with voluntary consumer product safety standards and considers, where appropriate, compliance or non-compliance with such standards in exercising its authorities under the CPSA and other federal statutes, including when making determinations under section 15 of the CPSA. Thus, for example, whether a product is in compliance with applicable voluntary safety standards may be relevant to the Commission staff's preliminary determination of whether that product presents a substantial product hazard under section 15 of the CPSA.

(b) *Mandatory Standards.* The CPSA requires that firms comply with all applicable mandatory consumer product safety standards and to report to the Commission any

DRAFT

products which do not comply with either mandatory standards or voluntary standards upon which the Commission has relied. As is the case with voluntary consumer product safety standards, compliance or non-compliance with applicable mandatory safety standards may be considered by the Commission and staff in making relevant determinations and exercising relevant authorities under the CPSA and other federal statutes. Thus, for example, while compliance with a relevant mandatory product safety standard may not, of itself, relieve a firm from the need to report to the Commission a product defect that creates a substantial product hazard under section 15 of the CPSA, it will be considered by staff in making the determination of whether and what type of corrective action may be required.

5. Revise section 1115.12(g)(1)(ii) to read as follows:

§ 1115.12 Information which should be reported; evaluating substantial product hazard.

In section 1115.12 (g) (1) (ii), after the last sentence, add, "The Commission also recognizes that the risk of injury from a product may decline over time as the number of products being used by consumers decreases."

* * * * *