



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

BALLOT VOTE SHEET

Date: July 7, 2006

TO : The Commission
 Todd A. Stevenson, Secretary

FROM : Page C. Faulk, General Counsel **PCF**

SUBJECT : Draft Federal Register Notice Issuing a Final Interpretative Rule and
 Responding to Public Comment on Proposed Revisions to Section 15

BALLOT VOTE Due: JUL 13 2006

On May 26, 2006, the Commission solicited comments on proposed revisions to its interpretative rule advising manufacturers, distributors and retailers how to comply with the requirements of section 15(b) of the Consumer Product Safety Act, 15 U.S.C. § 2064(b). Attached is a draft *Federal Register* notice issuing a final interpretative rule that responds to the comments received on the proposed revisions. The response represents the view of the Office of Compliance and the General Counsel's Office. The attached preamble and regulation, if approved by the Commission, is a final interpretative rule and would be effective on the date of publication in the *Federal Register* pursuant to the Administrative Procedure Act, 5 U.S.C. § 552, *et seq.*

Please indicate your vote on the following options.

- I. Approve publication of the attached draft Federal Register notice issuing a final interpretative rule on section 15.

 Signature

 Date

CPSA 5000-100 PUBLIC
 NO MEMORANDUMS OR
 PRODUCTS IDENTIFIED
 7/17/06
 PREPARED BY: PETTITON
 REGULATING ADMIN. PROCOS
 WITH PORTIONS REMOVED:

NOTE: This document has not been reviewed or accepted by the Commission.
 Initial: [Signature] Date: 7/1/06

II. Approve publication of the attached draft Federal Register notice issuing a final interpretative rule on section 15 with changes (please specify).

Signature

Date

III. Do not approve publication of the attached draft Federal Register notice issuing a final interpretative rule on section 15.

Signature

Date

IV. Take other action (please specify):

Signature

Date

Attachment: Draft *Federal Register* notice issuing final interpretative rule on Section 15.

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BILLING CODE 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1115

Substantial Product Hazard Reports

AGENCY: Consumer Product Safety Commission.

ACTION: Final 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. On May 26, 2006, the Commission solicited comments on proposed revisions to its interpretative rule advising manufacturers, distributors, and retailers how to comply with the requirements of section 15(b). The proposed revisions identified additional factors the Commission and staff consider when assessing whether a product is defective or not. The proposed revisions also clarified that compliance with voluntary or mandatory product safety standards may be considered by the Commission in making certain determinations under section 15. After considering public comments, the Commission issues the accompanying final rule.

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DATE: This final rule becomes effective on [insert date of publication in the Federal Register].

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

SUPPLEMENTARY INFORMATION:

A. Background

To provide further guidance, clarity and transparency on reporting obligations under section 15(b) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2064(b), the Commission, on May 26, 2006 (71 FR 30350) proposed 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 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

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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 finalizes revisions to the interpretative rule to clarify factors relevant to section 15(b) reporting determinations. These revisions are not intended to reduce the number of reports to the Office of Compliance, to reduce or change the types of information reported, or to suggest a diminished need to report.

The Commission received 14 comments in response to the proposed revisions. Joint comments were submitted by four ATV companies (Kawaski Motors Corp., USA; American Honda Motor Co., Inc.; Polaris Industries Inc., and Yamaha Motor Corporation, U.S.A.). Joint comments were also submitted by four consumer groups (Consumers Union, Consumer Federation of America, Kids In Danger, and U.S. Public Interest Research Group.) Eight commenters supported the revisions; two of the eight suggested clarifications to certain provisions. Six commenters opposed the revisions; five of the six suggested that the Commission not adopt the revisions and one of the six suggested that the Commission keep the record open. The Commission received a number of

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comments in support of a regulation related to the assessment of civil penalties pursuant to section 20 of the CPSA, 15 U.S.C. 2069 (b), (c). A separate Federal Register notice is being issued for public comment on this issue.

The Commission received a number of comments that went beyond the scope of the proposed revisions. These included a suggestion for a new appeal process for preliminary determinations relating to substantial product hazards, issues concerning the hazards presented by counterfeit products, more widespread notice about the Fast Track recall process, General Counsel review of recommendations of proposed administrative complaints, and provisions in the adjudicative rules for joinder and intervention. The Commission is not incorporating any of these suggestions since they were not part of the proposed revisions.

A summary of the comments on the proposed revisions and our responses appear below.

B. Section 1115.4 Defect

The first revision clarifies the Commission's discussion of "defect" by adding 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

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whether the risk of injury associated with a product is the type of risk which will render a product 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 Commission proposed to add the following factors as considerations: 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 commenters who opposed the revisions suggested that inclusion of these additional factors does not clarify a firm's reporting obligations but weakens the intent of the original regulation by giving firms additional factors upon which to argue that a particular product is not defective and thereby avoid reporting. Several commenters also suggested that a firm could rely on just one of the factors - like consumer misuse - to negate a reporting obligation.

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The Commission's intent in adopting this revision is to give further guidance to firms about reporting defects in their products. The determination of whether a product is 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). 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 nearly 30 years since then, the Commission and staff have evaluated thousands of products using many criteria, including, as appropriate, the criteria now being adopted. The Commission has concluded, based on experience and practice in applying the criteria, that the 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 - help clarify the existing factors in the regulation and enable a better analysis of whether the risk of injury associated with a product is the type of risk which will render it defective.

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This regulation contemplates consideration of a number of appropriate factors in making such a determination.

Reliance on one factor alone cannot negate a reporting obligation if other factors, as applied, reasonably support the conclusion that a defect exists.

The Commission staff already considers the proposed factors in making decisions about potential defects. The current defect regulation specifies that the Commission and staff will, as appropriate, consider the case law in the area of product liability. Two commenters pointed out that the case law in the product liability area, as reflected in the Restatement of Torts, uses all of the additional criteria proposed. Thus, the regulation only makes explicit what was already implicit in the Commission's regulation.

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

The Commission proposed adding the following statement to an evaluation of the number of defective products distributed in commerce when making a substantial product hazard determination: "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."

Three commenters objected to this provision. One commenter contended that the proposed regulatory change is

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untrue because the individual risk to a user from a defective product bears no relationship to the number of products in use. Commenters opposed to the provision also stated that the proposal gave manufacturers an incentive to wait to report and to hide problems until a product is older.

The Commission has clarified the language of this provision in response to comments. By this provision, the Commission is merely recognizing that the number of products remaining in consumers hands at any given time is relevant to a substantial product hazard determination and that determination can be influenced by a decline over time in the number of products remaining in use. The current regulation can be misleading because it suggests that the number of products originally distributed is the only relevant number in deciding whether a defective product presents a substantial risk of injury. When a potential hazard first appears long after a product was sold, however, the more relevant number is not the number of products originally sold but the number still with consumers. A firm may still have a reporting obligation in such circumstances. The Commission stresses that firms should never delay reporting in anticipation of, or because of, a decrease in the number of products in use. Firms that delay reporting

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for such reasons will be subject to civil penalties. The final regulation is reworded to avoid use of the term "risk" which generated some confusion.

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 of the CPSA. Three of the commenters raised the objection that this new provision creates a safe harbor for companies by negating a reporting obligation when a product complies with a voluntary or mandatory standard.

Voluntary Standards. The opposing commenters mistake the scope and intent of this provision. It provides no safe harbor from a reporting obligation. The text of the rule states that compliance with voluntary standards "may be relevant" to preliminary determinations. This language clearly does not foreclose the possibility that the staff may make a preliminary determination that a product presents a substantial product hazard notwithstanding compliance with all applicable voluntary standards. Although the Commission strongly supports voluntary standards, such standards are not always adequate. In some cases, a defect may involve a

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product characteristic or aspect of performance not addressed by a standard that is adequate in other respects, or a product that meets voluntary standards by design may be taken out of compliance by a manufacturing defect. In short, if a voluntary standard exists and addresses a product hazard, and the product complies with such a standard, then that compliance may be relevant to considering whether a product preliminarily presents a substantial product hazard. Compliance with a voluntary standard does not preclude a determination that a substantial product hazard exists, nor will it relieve a firm of the requirement to report when a substantial product hazard may exist. Firms must not treat compliance with standards as an excuse not to report. They should report if a substantial product hazard may exist and allow the staff to consider the significance of the standard. In the past, the Commission has sought recalls for products that have complied with voluntary standards as well as products that did not comply. Compliance with an applicable voluntary standard, as stated in the final regulation, is merely one factor in this evaluation.

Mandatory Standards. For reasons similar to those stated above, the Commission's provision for mandatory standards does not negate a reporting obligation nor provide

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safe harbor for the failure to report. There have been a number of occasions in the experience of the Commission staff when a product is determined to contain a defect that could create a substantial product hazard even though such product complies with a mandatory standard. The statute and regulations contemplate a report in such a circumstance. In fact, reports are especially important in such cases because they may be the Commission's only indication that the mandatory standards are in need of revision. At the same time, the Commission appreciates that it is generally inappropriate to hold firms to a higher standard for products retroactively. As stated in the regulation, which is slightly reworded in the final text, compliance with a mandatory standard should play a role in the staff's determination as to whether a corrective action is necessary.

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 amended as follows:

PART 1115- SUBSTANTIAL PRODUCT HAZARD REPORTS

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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. In § 1115.4, amend the concluding text by adding a new phrase after the phrase, "the population exposed to the product and its risk of injury;" to read as follows:

§ 1115.4 Defect.

* * * 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;" * * *

3. 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

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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 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 does not, of itself, relieve a firm from the need to report to the Commission a product defect that creates a substantial

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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.

4. Section 1115.12 is amended by adding a new sentence at the end of paragraph (g)(1)(ii) to read as follows:

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

* * * * *

(g) * * *

(1) * * *

(ii) * * * The Commission also recognizes that the number of products remaining with consumers is a relevant consideration.

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Dated:

Todd A. Stevenson, Secretary
Consumer Product Safety Commission