

Consumer Product Safety Commission

§ 1115.12

Prevention Packaging Act, and Refrigerator Safety Act as well as products subject to regulation under the CPSA.

(e) A distributor or retailer of a consumer product (who is neither a manufacturer nor an importer of that product) is subject to the reporting requirements of section 15(b) of the CPSA but may satisfy them by following the procedure detailed in §1115.13(b).

(f) A manufacturer (including an importer), distributor, or retailer need not inform the Commission under section 15(b) of the CPSA if that person has actual knowledge that the Commission has been adequately informed of the defect or failure to comply. (See section 15(b) of the CPSA.)

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992; 62 FR 46667, Sept. 4, 1997]

§ 1115.11 Imputed knowledge.

(a) In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information. (See §1115.14(b).)

(b) In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to know what a reasonable person acting in the circumstances in which the firm finds itself would know. Thus, the subject firm shall be deemed to know what it would have known if it had exercised due care to ascertain the truth of complaints or other representations. This includes the knowledge a firm would have if it conducted a reasonably expeditious investigation in order to evaluate the reportability of a death or grievous bodily injury or other information. (See §1115.14.)

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

(a) *General.* Subject firms should not delay reporting in order to determine to a certainty the existence of a reportable noncompliance, defect or unreasonable risk. The obligation to report arises upon receipt of information from which one could reasonably conclude

the existence of a reportable noncompliance, defect which could create a substantial product hazard, or unreasonable risk of serious injury or death. Thus, an obligation to report may arise when a subject firm received the first information regarding a potential hazard, noncompliance or risk. (See §1115.14(c).) A subject firm in its report to the Commission need not admit, or may specifically deny, that the information it submits reasonably supports the conclusion that its consumer product is noncomplying, contains a defect which could create a substantial product hazard within the meaning of section 15(b) of the CPSA, or creates an unreasonable risk of serious injury or death. After receiving the report, the staff may conduct further investigation and will preliminarily determine whether the product reported upon presents a substantial product hazard. This determination can be based on information supplied by a subject firm or from any other source. If the matter is adjudicated, the Commission will ultimately make the decision as to substantial product hazard or will seek to have a court make the decision as to imminent product hazard.

(b) *Failure to comply.* A subject firm must report information indicating that a consumer product which it has distributed in commerce does not comply with an applicable consumer product safety standard or ban issued under the CPSA, or a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA.

(c) *Unreasonable risk of serious injury or death.* A subject firm must report when it obtains information indicating that a consumer product which it has distributed in commerce creates an unreasonable risk of serious injury or death.

(d) *Death or grievous bodily injury.* Information indicating that a noncompliance or a defect in a consumer product has caused, may have caused, or contributed to the causing, or could cause or contribute to the causing of a death or grievous bodily injury (e.g., mutilation, amputation/dismemberment, disfigurement, loss of important bodily functions, debilitating internal disorders, severe burns, severe electrical

§ 1115.12

16 CFR Ch. II (1–1–14 Edition)

shocks, and injuries likely to require extended hospitalization) must be reported, unless the subject firm has investigated and determined that the information is not reportable.

(e) *Other information indicating a defect or noncompliance.* Even if there are no reports of a potential for or an actual death or grievous bodily injury, other information may indicate a reportable defect or noncompliance. In evaluating whether or when a subject firm should have reported, the Commission will deem a subject firm to know what a reasonable and prudent manufacturer (including an importer), distributor, or retailer would know. (See § 1115.11.)

(f) *Information which should be studied and evaluated.* Paragraphs (f)(1) through (7) of this section are examples of information which a subject firm should study and evaluate in order to determine whether it is obligated to report under section 15(b) of the CPSA. Such information may include information that a firm has obtained, or reasonably should have obtained in accordance with § 1115.11, about product use, experience, performance, design, or manufacture outside the United States that is relevant to products sold or distributed in the United States. All information should be evaluated to determine whether it suggests the existence of a noncompliance, a defect, or an unreasonable risk of serious injury or death:

(1) Information about engineering, quality control, or production data.

(2) Information about safety-related production or design change(s).

(3) Product liability suits and/or claims for personal injury or damage.

(4) Information from an independent testing laboratory.

(5) Complaints from a consumer or consumer group.

(6) Information received from the Commission or other governmental agency.

(7) Information received from other firms, including requests to return a product or for replacement or credit. This includes both requests made by distributors and retailers to the manufacturer and requests from the manufacturer that products be returned.

(g) *Evaluating substantial risk of injury.* Information which should be or has been reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect or noncompliance exists and whether it results in a substantial risk of injury to the public. In deciding whether to report, subject firms may be guided by the following criteria the staff and the Commission use in determining whether a substantial product hazard exists:

(1) *Hazard created by defect.* Section 15(a)(2) of the CPSA lists factors to be considered in determining whether a defect creates a substantial risk of injury. These factors are set forth in the disjunctive. Therefore, the existence of any one of the factors could create a substantial product hazard. The Commission and the staff will consider some or all of the following factors, as appropriate, in determining the substantiality of a hazard created by a product defect:

(i) *Pattern of defect.* The Commission and the staff will consider whether the defect arises from the design, composition, contents, construction, finish, packaging, warnings, or instructions of the product or from some other cause and will consider the conditions under which the defect manifests itself.

(ii) *Number of defective products distributed in commerce.* Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination under section 15 of the CPSA if the injury which might occur is serious and/or if the injury is likely to occur. However, a few defective products with no potential for causing serious injury and little likelihood of injuring even in a minor way will not ordinarily provide a proper basis for a substantial product hazard determination. The Commission also recognizes that the number of products remaining with consumers is a relevant consideration.

(iii) *Severity of the risk.* A risk is severe if the injury which might occur is serious and/or if the injury is likely to occur. In considering the likelihood of any injury the Commission and the

Consumer Product Safety Commission

§ 1115.13

staff will consider the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (e.g., children, elderly, handicapped).

(iv) *Other considerations.* The Commission and the staff will consider all other relevant factors.

(2) *Hazard presented by noncompliance.* Section 15(a)(1) of the CPSA states that a substantial product hazard exists when a failure to comply with an applicable consumer product safety rule creates a substantial risk of injury to the public. Therefore, the Commission and staff will consider whether the non-compliance is likely to result in injury when determining whether the non-compliance creates a substantial product hazard. As appropriate, the Commission and staff may consider some or all of the factors set forth in paragraph (f)(1) of this section in reaching the substantial product hazard determination.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992; 66 FR 54925, Oct. 31, 2001; 71 FR 42031, July 25, 2006]

§ 1115.13 Content and form of reports; delegations of authority.

(a) *Written reports.* The chief executive officer of the subject firm should sign any written reports to the Commission under section 15(b) of the CPSA unless this responsibility has been delegated by filing a written delegation of authority with the Commission's Office of Compliance and Enforcement, Division of Corrective Actions. Delegations of authority filed with the Commission under §1115.9 of the previous regulations interpreting section 15 of the CPSA will remain in effect until revoked by the chief executive officer of the subject firm. The delegation may be in the following form:

DELEGATION OF AUTHORITY

(Name of company) _____

I _____ hereby certify that I am Chief Executive Officer of the above-named company and that as such I am authorized to sign documents and to certify on behalf of said company the accuracy and completeness of information in such documents.

Pursuant to the power vested in me, I hereby delegate all or, to the extent indicated

below, a portion of that authority to the person listed below.

This delegation is effective until revoked in writing. Authority delegated to:

(Name) _____

(Address) _____

(Title) _____

Extent of authority: _____

Signed:

(Name) _____

(Address) _____

(Title) _____

(b) *Distributors and retailers.* A distributor or retailer of a product (who is neither a manufacturer nor an importer of that product) satisfies the initial reporting requirements either by telephoning or writing the Office of Compliance and Enforcement, Division of Corrective Actions, Consumer Product Safety Commission, Washington, DC 20207, phone 301-504-0608; by sending a letter describing the noncompliance, defect or risk of injury to the manufacturer (or importer) of the product and sending a copy of the letter to the Commission's Division of Corrective Actions; or by forwarding to the Commission's Division of Corrective Actions reportable information received from another firm. A distributor or retailer who receives reportable information from a manufacturer (or importer) shall report to the Commission unless the manufacturer (or importer) informs the distributor or retailer that a report has been made to the Commission. A report under this paragraph should contain the information detailed in paragraph (c) of this section insofar as it is known to the distributor or retailer. Unless further information is requested by the staff, this action will constitute a sufficient report insofar as the distributor or retailer is concerned.

(c) *Initial report.* Immediately after a subject firm has obtained information which reasonably supports the conclusion that a product fails to comply with an applicable consumer product safety rule or a voluntary standard, contains a defect which could create a substantial risk of serious injury or death, the subject firm should provide the Division of Corrective Actions, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207 (telephone: 301-504-0608), with an initial report containing the information listed in paragraphs (c) (1) through (6) of this section. This initial report