U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, or by electronic mail to: *cpsc-os@cpsc.gov*.

(ii) All appeals must be in writing, and must be in English.

(iii) All appeals must explain the nature of the issues appealed from in the Final Decision, and must describe in detail the reasons why the third party conformity assessment body believes that no ground(s) for adverse action exist.

§ 1112.53 Can the CPSC immediately withdraw its acceptance of the accreditation of a third party conformity assessment body?

(a) When it is in the public interest to protect health and safety, and notwithstanding any other provision of this part, the CPSC may withdraw immediately and temporarily its acceptance of a third party conformity assessment body's accreditation for any portion of its CPSC scope while the CPSC pursues an investigation and potential adverse action under §1112.51.

(1) For purposes of this part, ''in the public interest to protect health and safety'' means that the CPSC has credible evidence that:

(i) The integrity of test(s) being conducted under a scope for which the CPSC has accepted the third party conformity assessment body's accreditation, have been affected by undue influence or otherwise interfered with or compromised; and

(ii) The scope for which the CPSC has accepted the third party conformity assessment body's accreditation involve a product(s) which, if noncompliant with CPSC rules, bans, standards, and/or regulations, constitutes an imminently hazardous consumer product under section 12 of the CPSA.

(2) When presented with an allegation that, if credible, would result in immediate and temporary withdrawal of CPSC acceptance of a third party conformity assessment body's accreditation, the investigation and adverse action procedures described in §1112.51 apply, except that instead of the timeframes described in §1112.51, the following timeframes will apply when the CPSC pursues immediate and temporary withdrawal:

(i) The Initial Notice will generally inform the third party conformity assessment body that it has 7 calendar days to respond.

(ii) An administrative appeal of a Final Notice of immediate and temporary withdrawal will be timely if filed within 7 calendar days of the date of the Final Notice.

(b) If the third party conformity assessment body is already the subject of an investigation or adverse action process under §1112.51, the immediate and temporary withdrawal will remain in effect until: the agency communicates in writing that the immediate and temporary withdrawal has been lifted; the investigation concludes and the agency does not propose an adverse action; or the adverse action process concludes with denial, suspension, or withdrawal.

(c) If the third party conformity assessment body is not already the subject of an investigation or adverse action process under §1112.51, an investigation under §1112.51(a) will be launched based on the same information that justified the immediate and temporary withdrawal.

§ 1112.55 Will the CPSC publish adverse actions?

Immediately following a final adverse action, the CPSC may publish the fact of a final adverse action, the text of a final adverse action, or a summary of the substance of a final adverse action. After issuance of a final adverse action, the CPSC will amend its Web site listing of CPSC-accepted third party conformity assessment bodies to reflect the nature and scope of such adverse action.

PART 1115—SUBSTANTIAL PRODUCT HAZARD REPORTS

Subpart A—General Interpretation

Sec.

AUTHORITY: 15 U.S.C. 2061, 2064, 2065, 2066(a), 2068, 2069, 2070, 2071, 2073, 2076, 2079 and 2084.

SOURCE: 43 FR 34998, Aug. 7, 1978, unless otherwise noted.

Subpart A—General Interpretation

§ 1115.1 Purpose.

The purpose of this part 1115 is to set forth the Consumer Product Safety Commission's (Commission's) interpretation of the reporting requirements imposed on manufacturers (including importers), distributors, and retailers by section 15(b) of the Consumer Product Safety Act, as amended (CPSA) (15 U.S.C. 2064(b)) and to indicate the actions and sanctions which the Commission may require or impose to protect the public from substantial product hazards, as that term is defined in section 15(a) of the CPSA.

§ 1115.2 Scope and finding.

(a) Section 15(a) of the CPSA (15 U.S.C. 2064(a)) defines *substantial product hazard* as either:

(1) A failure to comply with an applicable consumer product safety rule, which failure creates a substantial risk of injury to the public, or

(2) A product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

(b) Section 15(b) of the CPSA requires every manufacturer (including an importer), distributor, and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that the product fails to comply with an applicable consumer product safety rule, fails to comply with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, contains a defect which could create a substantial product hazard described in subsection 15(a)(2) of the CPSA, or creates an unreasonable risk of serious injury or death, immediately to inform the Commission, unless the manufacturer (including an importer), distributor or retailer has actual knowledge that the Commission has been adequately informed of such failure to comply, defect, or risk. This provision indicates that a broad spectrum of safety related information should be reported under section 15(b) of the CPSA.

(c) Sections 15 (c) and (d) of the CPSA, (15 U.S.C. 2064(c) and (d)), empower the Commission to order a manufacturer (including an importer), distributor, or retailer of a consumer product distributed in commerce that presents a substantial product hazard to give various forms of notice to the public of the defect or the failure to comply and/or to order the subject firm to elect either to repair, to replace, or to refund the purchase price of such product. However, information which should be reported under section 15(b) of the CPSA does not automatically indicate the presence of a substantial product hazard, because what must be reported under section 15(b) are failures to comply with consumer product

safety rules or voluntary standards upon which the Commission has relied under section 9, defects that could create a substantial product hazard, and products which create an unreasonable risk of serious injury or death. (See § 1115.12.)

(d) The provisions of this part 1115 deal with all consumer products (including imports) subject to regulation under the Consumer Product Safety Act, as amended (15 U.S.C. 2051–2081) (CPSA), and the Refrigerator Safety Act (15 U.S.C. 1211–1214) (RSA). In addition, the Commission has found that risks of injury to the public from consumer products subject to regulation under the Flammable Fabrics Act (15 U.S.C. 1191–1204) (FFA), the Federal Hazardous Substances Act (15 U.S.C. 1261–1274) (FHSA), and the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471–1476) (PPPA) cannot be eliminated or reduced to a sufficient extent in a timely fashion under those acts. Therefore, pursuant to section 30(d) of the CPSA (15 U.S.C. 2079(d)), manufacturers (including importers), distributors, and retailers of consumer products which are subject to regulation under provisions of the FFA, FHSA, and PPPA must comply with the reporting requirements of section 15(b).

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34227, Aug. 4, 1992]

§ 1115.3 Definitions.

In addition to the definitions given in section 3 of the CPSA (15 U.S.C. 2052), the following definitions apply:

(a) *Adequately informed* under section 15(b) of the CPSA means that the Commission staff has received the information requested under §§ 1115.12 and/or 1115.13 of this part insofar as it is reasonably available and applicable or that the staff has informed the subject firm that the staff is adequately informed.

(b) *Commission meeting* means the joint deliberations of at least a majority of the Commission where such deliberations determine or result in the conduct or disposition of official Commission business. This term is synonymous with ''Commission meeting'' as defined in the Commission's regulation issued under the Government in the Sunshine Act, 16 CFR part 1012.

(c) *Noncompliance* means the failure of a consumer product 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.

(d) A *person* means a corporation, company, association, firm, partnership, society, joint stock company, or individual.

(e) *Staff* means the staff of the Consumer Product Safety Commission unless otherwise stated.

(f) *Subject firm* means any manufacturer (including an importer), distributor, or retailer of a consumer product.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34227, Aug. 4, 1992]

§ 1115.4 Defect.

Section 15(b)(2) of the CPSA requires every manufacturer (including an importer), distributor, and retailer of a consumer product who obtains information which reasonably supports the conclusion that the product contains a defect which could create a substantial product hazard to inform the Commission of such defect. Thus, whether the information available reasonably suggests a defect is the first determination which a subject firm must make in deciding whether it has obtained information which must be reported to the Commission. In determining whether it has obtained information which reasonably supports the conclusion that its consumer product contains a defect, a subject firm may be guided by the criteria the Commission and staff use in determining whether a defect exists. At a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect, for example, may be the result of a manufacturing or production error; that is, the consumer product as manufactured is not in the form intended by, or fails to perform in accordance with, its design. In addition, the design of and the materials used in a consumer product may also result in a defect. Thus, a product

may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public. A design defect may also be present if the risk of injury occurs as a result of the operation or use of the product or the failure of the product to operate as intended. A defect can also occur in a product's contents, construction, finish, packaging, warnings, and/or instructions. With respect to instructions, a consumer product may contain a defect if the instructions for assembly or use could allow the product, otherwise safely designed and manufactured, to present a risk of injury. To assist subject firms in understanding the concept of defect as used in the CPSA, the following examples are offered:

(a) An electric appliance presents a shock hazard because, through a manufacturing error, its casing can be electrically charged by full-line voltage. This product contains a defect as a result of manufacturing or production error.

(b) Shoes labeled and marketed for long-distance running are so designed that they might cause or contribute to the causing of muscle or tendon injury if used for long-distance running. The shoes are defective due to the labeling and marketing.

(c) A kite made of electrically conductive material presents a risk of electrocution if it is long enough to become entangled in power lines and be within reach from the ground. The electrically conductive material contributes both to the beauty of the kite and the hazard it presents. The kite contains a design defect.

(d) A power tool is not accompanied by adequate instructions and safety warnings. Reasonably foreseeable consumer use or misuse, based in part on the lack of adequate instructions and safety warnings, could result in injury. Although there are no reports of injury, the product contains a defect because of the inadequate warnings and instructions.

(e) An exhaust fan for home garages is advertised as activating when carbon monoxide fumes reach a dangerous level but does not exhaust when fumes have reached the dangerous level. Although the cause of the failure to exhaust is not known, the exhaust fan is defective because users rely on the fan to remove the fumes and the fan does not do so.

However, not all products which present a risk of injury are defective. For example, a knife has a sharp blade and is capable of seriously injuring someone. This very sharpness, however, is necessary if the knife is to function adequately. The knife does not contain a defect insofar as the sharpness of its blade is concerned, despite its potential for causing injury, because the risk of injury is outweighed by the usefulness of the product which is made possible by the same aspect which presents the risk of injury. In determining whether the risk of injury associated with a product is the type of risk which will render the product defective, the Commission and staff will 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 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 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. If the information available to a subject firm does not reasonably support the conclusion that a defect exists, the subject firm need not report. However, if the information does reasonably support the conclusion that a defect exists, the subject firm must then consider whether that defect could create a substantial product hazard. (See §1115.12(f) for factors to be assessed in determining whether a substantial product hazard could exist.) If the subject firm determines that the defect could create a substantial product hazard, the subject firm must report to the Commission. Most defects could present a substantial product hazard if the public is exposed to significant numbers of defective products or if the possible injury is serious or is

likely to occur. Since the extent of public exposure and/or the likelihood or seriousness of injury are ordinarily not known at the time a defect first manifests itself, subject firms are urged to report if in doubt as to whether a defect could present a substantial product hazard. On a case-by-case basis the Commission and the staff will determine whether a defect within the meaning of section 15 of the CPSA does, in fact, exist and whether that defect presents a substantial product hazard. Since a consumer product may be defective even if it is designed, manufactured, and marketed exactly as intended by a subject firm, subject firms should report if in doubt as to whether a defect exists. Defect, as discussed in this section and as used by the Commission and staff, pertains only to interpreting and enforcing the Consumer Product Safety Act. The criteria and discussion in this section are not intended to apply to any other area of the law.

[43 FR 34998, Aug. 7, 1978, as amended at 71 FR 42030, July 25, 2006]

§ 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.

(a) *General provision.* Under the CPSA, the Commission may rely on voluntary standards in lieu of developing mandatory ones. In recognition of the role of voluntary standards under the CPSA, section 15(b)(1) requires reports if a product fails to comply with a voluntary standard ''upon which the Commission has relied under section 9'' of the CPSA. The Commission has relied upon a voluntary consumer product safety standard under section 9 of the CPSA if, since August 13, 1981 it has terminated a rulemaking proceeding or withdrawn an existing consumer product safety rule because it explicitly determined that an existing voluntary standard, or portion(s) thereof, is likely to result in an adequate reduction of the risk of injury and it is likely there will be substantial compliance with that voluntary standard. (See appendix to this part 1115 for a list of such voluntary standards.) This provision applies only when the Commission relies upon a voluntary standard in a rulemaking proceeding under section 9 of the CPSA. In evaluating whether or not to rely upon an existing voluntary standard, the Commission shall adhere to all the procedural safeguards currently required under the provisions of the CPSA, including publication in the FEDERAL REGISTER of the Commission's intent to rely upon a voluntary standard in order to provide the public with a fair opportunity to comment upon such proposed action.

(b) *Reporting requirement.* A firm must report under this section if it has distributed in commerce, subsequent to the effective date of the Consumer Product Safety Improvement Act of 1990 (November 16, 1990), a product that does not conform to a voluntary standard or portion(s) of a voluntary standard relied upon by the Commission since August 13, 1981. If the Commission relied upon only a portion(s) of a voluntary standard, a firm must report under this section only nonconformance with the portion(s) of the voluntary standard relied upon by the Commission. Pursuant to section 7(b)(2) of the CPSA, the Commission shall monitor any modifications of a voluntary standard upon which it has relied and determine, as a matter of policy, at the time any substantive safety related modification is adopted, whether it shall continue to rely upon the former standard or whether it shall rely, subsequently, upon the modified standard. The Commission shall publish such decisions in the FEDERAL REGISTER. Until the Commission makes such a decision, subject firms need not report under this provision a product which complies with either the original version of the voluntary standard relied upon by the Commission or the new version of the standard. A firm must continue to evaluate whether deviations from other portions of a voluntary standard, or other voluntary standards not relied upon by the Commission, either constitute a defect which could create a substantial product hazard or create an unreasonable risk of serious injury or death.

[57 FR 34228, Aug. 4, 1992; 57 FR 39597, Sept. 1, 1992]

§ 1115.6 Reporting of unreasonable risk of serious injury or death.

(a) *General provision.* Every manufacturer, distributor, and retailer of a consumer product distributed in commerce who obtains information which reasonably supports the conclusion that its product creates an unreasonable risk of serious injury or death is required to notify the Commission immediately. 15 U.S.C. 2064(b)(3). The requirement that notification occur when a responsible party ''obtains information which reasonably supports the conclusion that'' its product creates an unreasonable risk of serious injury or death is intended to require firms to report even when no final determination of the risk is possible. Firms must carefully analyze the information they obtain to determine whether such information ''reasonably supports'' a determination that the product creates an unreasonable risk of serious injury or death. (See §1115.12(f) for a discussion of the kinds of information that firms must study and evaluate to determine whether they have an obligation to report.) Firms that obtain information indicating that their products present an unreasonable risk of serious injury or death should not wait for such serious injury or death to actually occur before reporting. Such information can include reports from experts, test reports, product liability lawsuits or claims, consumer or customer complaints, quality control data, scientific or epidemiological studies, reports of injury, information from other firms or governmental entities, and other relevant information. While such information shall not trigger a *per se* reporting requirement, in its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA, the Commission shall attach considerable significance if such firm learns that a court or jury has determined that one of its products has caused a serious injury or death and a reasonable person could conclude based on the lawsuit and other information obtained by the firm that the product creates an unreasonable risk of serious injury or death.

(b) *Unreasonable risk.* The use of the term ''unreasonable risk'' suggests that the risk of injury presented by a product should be evaluated to determine if that risk is a reasonable one. In determining whether a product presents an unreasonable risk, the firm should examine the utility of the product, or the utility of the aspect of the product that causes the risk, the level of exposure of consumers to the risk, the nature and severity of the hazard presented, and the likelihood of resulting serious injury or death. In its analysis, the firm should also evaluate the state of the manufacturing or scientific art, the availability of alternative designs or products, and the feasibility of eliminating the risk. The Commission expects firms to report if a reasonable person could conclude given the information available that a product creates an unreasonable risk of serious injury or death. In its evaluation of whether a subject firm is required to file a report under the provisions of section 15 of the CPSA the Commission shall, as a practical matter, attach considerable significance if such firm obtains information which reasonably supports the conclusion that its product violates a standard or ban promulgated under the FHSA, FFA, PPPA or RSA and the violation could result in serious injury or death.

(c) *Serious injury or death.* The term ''serious injury'' is not defined in the CPSA. The Commission believes that the term includes not only the concept of ''grievous bodily injury,'' defined at §1115.12(d), but also any other significant injury. Injuries necessitating hospitalization which require actual medical or surgical treatment, fractures, lacerations requiring sutures, concussions, injuries to the eye, ear, or internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day are examples of situations in which the Commission shall presume that such a serious injury has occurred. To determine whether an unreasonable risk of serious injury or death exists, the firm should evaluate chronic or long term health effects as well as immediate injuries.

[57 FR 34228, Aug. 4, 1992]

§ 1115.7 Relation to other provisions.

The reporting requirements of section 37 of the CPSA (15 U.S.C. 2084) are

in addition to the requirement in section 15 of the CPSA. Section 37 requires a product manufacturer to report certain kinds of lawsuit information. It is intended as a supplement to, not a substitute for, the requirements of section 15(b) of the CPSA. Whether or not a firm has an obligation to provide information under section 37, it must consider whether it has obtained information which reasonably supports the conclusion that its product violates a consumer product safety rule, does not comply with a voluntary safety standard upon which the Commission has relied under section 9, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. If a firm has obtained such information, it must report under section 15(b) of the CPSA, whether or not it is required to report under section 37. Further, in many cases the Commission would expect to receive reports under section 15(b) long before the obligation to report under section 37 arises since firms have frequently obtained reportable information before settlements or judgments in their product liability lawsuits.

[57 FR 34229, Aug. 4, 1992]

§ 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 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 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.

[71 FR 42030, July 25, 2006]

§ 1115.9 [Reserved]

§ 1115.10 Persons who must report and where to report.

(a) Every manufacturer (including importer), distributor, or retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product contains a defect which could create a substantial risk of injury to the public shall immediately notify the Office of Compliance, Division of Corrective Actions, Consumer Product Safety Commission, Washington, DC 20207 (telephone: 301–504–0608), or such other persons as may be designated. Manufacturers (including importers), distributors, and retailers of consumer products subject to regulation by the Commission under provisions of the FFA, FHSA, PPPA, as well as consumer products subject to regulation under the CPSA and RSA, must comply with this requirement.

(b) Every manufacturer (including importer), distributor, or retailer of a

consumer product that has been distributed in commerce who obtains information that such consumer product fails to comply with an applicable consumer product safety standard or ban issued under the CPSA shall immediately notify the Commission's Office of Compliance and Enforcement, Division of Corrective Actions or such other persons as may be designated. A subject firm need not report a failure to comply with a standard or regulation issued under the provisions of the RSA, FFA, FHSA, or PPPA unless it can be reasonably concluded that the failure to comply results in a defect which could create a substantial product hazard. (See paragraph (a) of this section.)

(c) Every manufacturer (including importer), distributor, and retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product fails to comply with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, shall immediately notify the Commission's Office of Compliance and Enforcement, Division of Corrective Actions or such other persons as may be designated.

(d) Every manufacturer (including importer), distributor, and retailer of a consumer product that has been distributed in commerce who obtains information that such consumer product creates an unreasonable risk of serious injury or death shall immediately notify the Commission's Office of Compliance and Enforcement, Division of Corrective Actions or such other persons as may be designated. This obligation applies to manufacturers, distributors and retailers of consumer products subject to regulation by the Commission under the Flammable Fabrics Act, Federal Hazardous Substances Act, Poison 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 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 exist- ence 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 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 noncompliance is likely to result in injury when determining whether the noncompliance 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 defecat 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 may be made by any means, but if it is not in writing, it should be confirmed in writing within 48 hours of the initial report. (See § 1115.14 for time computations.) The initial report should contain, insofar as is reasonably available and/or applicable:

(1) An identification and description of the product.

(2) The name and address of the manufacturer (or importer) or, if the manufacturer or importer is not known, the names and addresses of all known distributors and retailers of the product.

(3) The nature and extent of the possible defect, the failure to comply, or the risk.

(4) The nature and extent of the injury or risk of injury associated with the product.

(5) The name and address of the person informing the Commission.

(6) To the extent such information is then reasonably available, the data specified in § 1115.13(d).

(d) *Full report.* Subject firms which file initial reports are required to file full reports in accordance with this paragraph. Retailers and distributors may satisfy their reporting obligations in accordance with § 1115.13(b). At any time after an initial report, the staff may modify the requirements detailed in this section with respect to any subject firm. If the staff preliminarily determines that there is no substantial product hazard, it may inform the firm that its reporting obligation has been fulfilled. However, a subject firm would be required to report if it later became aware of new information indicating a reportable defect, noncompliance, or risk, whether the new information related to the same or another consumer product. Unless modified by staff action, the following information, to the extent that it is reasonably available and/or applicable, constitutes a ''full report,'' must be submitted to the staff, and must be supplemented or corrected as new or different information becomes known:

(1) The name, address, and title of the person submitting the ''full report'' to the Commission.

(2) The name and address of the manufacturer (or importer) of the product and the addresses of the manufacturing plants for that product.

(3) An identification and description of the product(s). Give retail prices, model numbers, serial numbers, and date codes. Describe any identifying marks and their location on the product. Provide a picture or a sample of the product.

(4) A description of the nature of the defect, failure to comply, or risk. If technical drawings, test results, schematics, diagrams, blueprints, or other

graphic depictions are available, attach copies.

(5) The nature of the injury or the possible injury associated with the product defect, failure to comply, or risk.

(6) The manner in which and the date when the information about the defect, noncompliance, or risk (e.g., complaints, reported injuries, quality control testing) was obtained. If any complaints related to the safety of the product or any allegations or reports of injuries associated with the product have been received, copies of such complaints or reports (or a summary thereof) shall be attached. Give a chronological account of facts or events leading to the report under section 15(b) of the CPSA, beginning with receipt of the first information which ultimately led to the report. Also included may be an analysis of these facts or events.

(7) The total number of products and units involved.

(8) The dates when products and units were manufactured, imported, distributed, and sold at retail.

(9) The number of products and units in each of the following: in the possession of the manufacturer or importer, in the possession of private labelers, in the possession of distributors, in the possession of retailers, and in the possession of consumers.

(10) An explanation of any changes (e.g., designs, adjustments, and additional parts, quality control, testing) that have been or will be effected to correct the defect, failure to comply, or risk and of the steps that have been or will be taken to prevent similar occurrences in the future together with the timetable for implementing such changes and steps.

(11) Information that has been or will be given to purchasers, including consumers, about the defect, noncompliance, or risk with a description of how this information has been or will be communicated. This shall include copies or drafts of any letters, press releases, warning labels, or other written information that has been or will be given to purchasers, including consumers.

(12) The details of and schedule for any contemplated refund, replacement, or repair actions, including plans for disposing of returned products (e.g., repair, destroy, return to foreign manufacturer).

(13) A detailed explanation and description of the marketing and distribution of the product from the manufacturer (including importer) to the consumer (e.g., use of sales representatives, independent contractors, and/or jobbers; installation of the product, if any, and by whom).

(14) Upon request, the names and addresses of all distributors, retailers, and purchasers, including consumers.

(15) Such further information necessary or appropriate to the functions of the Commission as is requested by the staff.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34229, Aug. 4, 1992]

§ 1115.14 Time computations.

(a) *General.* Weekends and holidays are excluded from the computation of the time periods in this part.

(b) *Imputing knowledge.* In evaluating whether or when a firm should have reported, the Commission shall impute to the subject firm knowledge of product safety related information received by an official or employee of a subject firm capable of appreciating the significance of the information. Under ordinary circumstances, 5 days should be the maximum reasonable time for information to reach the Chief Executive Officer or the official or employee responsible for complying with the reporting requirements of section 15(b) of the CPSA. The Commission will impute knowledge possessed by the Chief Executive Officer or by the official or employee responsible for complying with the reporting requirements of section 15(b) of the CPSA simultaneously to the subject firm.

(c) *Time when obligation to report arises.* The obligation to report under section 15(b) of the CPSA may arise upon receipt by a subject firm of the first information regarding a noncompliance, or a potential hazard presented by a product defect, or an unreasonable risk. Information giving rise to a reporting obligation may include, but is not limited to, complaints, injury reports, quality control and engineering data. A subject firm should not await complete or accurate

risk estimates before reporting under section 15(b) of CPSA. However, if information is not clearly reportable, a subject firm may spend a reasonable time for investigation and evaluation. (See § 1115.14(d).)

(d) *Time for investigation and evaluation.* A subject firm may conduct a reasonably expeditious investigation in order to evaluate the reportability of a death or grievous bodily injury or other information. This investigation and evaluation should not exceed 10 days unless a firm can demonstrate that a longer period is reasonable. The Commission will deem that, at the end of 10 days, a subject firm has received and considered all information which would have been available to it had a reasonable, expeditious, and diligent investigation been undertaken.

(e) *Time to report.* Immediately, that is, within 24 hours, after a subject firm has obtained information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or voluntary consumer product safety standard, contains a defect which could create a substantial risk of injury to the public, or creates an unreasonable risk of serious injury or death, the firm should report. (See § 1115.13.) If a firm elects to conduct an investigation in order to evaluate the existence of reportable information, the 24-hour period begins when the firm has information which reasonably supports the conclusion that its consumer product fails to comply with an applicable consumer product safety rule or voluntary consumer product safety standard upon which the Commission has relied under section 9, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. Thus, a firm could report to the Commission before the conclusion of a reasonably expeditious investigation and evaluation if the reportable information becomes known during the course of the investigation. In lieu of the investigation, the firm may report the information immediately.

[43 FR 34998, Aug. 7, 1978, as amended at 57 FR 34230, Aug. 4, 1992]

§ 1115.15 Confidentiality and disclosure of data.

(a) *General.* The Commission does not routinely make reports available to the public until the staff has made a preliminary hazard determination. Copies of reports will not be available to the public in the Commission's public reading room, and information contained in reports will not ordinarily be disclosed to the public in the absence of a formal request.

(b) *Freedom of Information Act.* Any person who submits information to the Commission who believes that any portion of the information is entitled to exemption from public disclosure under the provisions of the Freedom of Information Act, as amended (15 U.S.C. 552(b)), of the CPSA, as amended, or of another Federal statute must accompany the submission with a written request that the information be considered exempt from disclosure or indicate that a written request will be submitted within 10 working days of the submission. The request shall (1) identify the portions of the information for which exemption is claimed, which may include the identity of the reporting firm and the fact that it is making a report, and (2) state the facts and reasons which support the claimed exemption. After the staff has made its preliminary hazard determination, and regardless of whether or not the staff preliminarily determines that a product presents a substantial product hazard, the Commission will no longer honor requests for exempt status for the identity of the reporting firm, the identity of the consumer product, and the nature of the reported alleged defect or noncompliance. This information, together with the staff's preliminary hazard determination, will be made available to the public in the Commission's public reading room. Information for which exempt status is claimed (such as alleged trade secrets, confidential commercial or financial information, or information the disclosure of which would constitute an unwarranted invasion of personal privacy) shall not be released to the public except in accordance with the applicable statute or the Commission's Freedom of Information Act regulations (16 CFR part 1015).

(c) *Section 6(b) of the CPSA.* The Commission believes that the first two sentences in section 6(b)(1) of the CPSA (15 U.S.C. 2055(b)(1)) apply to affirmative dissemination of information by the Commission (such as press releases or fact sheets distributed to the public) from which the public may ascertain readily the identity of the product's manufacturer and/or private labeler. Manufacturers and private labelers will ordinarily be given 30 days' notice before the Commission makes such affirmative disseminations. However, this 30-day notice will not apply if the Commission finds that a lesser notice period is required in the interest of public health and safety.

Subpart B—Remedial Actions and Sanctions

§ 1115.20 Voluntary remedial actions.

As appropriate, the Commission will attempt to protect the public from substantial product hazards by seeking one or more of the following voluntary remedies:

(a) *Corrective action plans.* A corrective action plan is a document, signed by a subject firm, which sets forth the remedial action which the firm will voluntarily undertake to protect the public, but which has no legally binding effect. The Commission reserves the right to seek broader corrective action if it becomes aware of new facts or if the corrective action plan does not sufficiently protect the public.

(1) Corrective action plans shall include, as appropriate:

(i) A statement of the nature of the alleged hazard associated with the product, including the nature of the alleged defect or noncompliance and type(s) of injury or potential injury presented.

(ii) A detailed statement of the means to be employed to notify the public of the alleged product hazard (e.g., letter, press release, advertising), including an identification of the classes of persons who will receive such notice and a copy or copies of the notice or notices to be used.

(iii) A specification of model number and/or other appropriate descriptions of the product.

(iv) Any necessary instructions regarding use or handling of the product pending correction.

(v) An explanation of the specific cause of the alleged substantial product hazard, if known.

(vi) A statement of the corrective action which will be or has been taken to eliminate the alleged substantial product hazard. The firm should indicate whether it is repairing or replacing the product or refunding its purchase price. If products are to be returned to a subject firm, the corrective action plan should indicate their disposition (e.g., reworked, destroyed, returned to foreign manufacturer). Samples of replacement products and relevant drawings and test data for repairs or replacements should be available.

(vii) A statement of the steps that will be, or have been, taken to reasonably prevent recurrence of the alleged substantial product hazard in the future.

(viii) A statement of the action which will be undertaken to correct product units in the distribution chain, including a timetable and specific information about the number and location of such units.

(ix) The signatures of representatives of the subject firm.

(x) An acknowledgment by the subject firm that the Commission may monitor the corrective action and that the firm will furnish necessary information, including customer lists.

(xi) An agreement that the Commission may publicize the terms of the plan to the extent necessary to inform the public of the nature and extent of the alleged substantial product hazard and of the actions being undertaken to correct the alleged hazard presented.

(xii) Additional points of agreement, as appropriate.

(xiii) If desired by the subject firm, the following statement or its equivalent: ''The submission of this corrective action plan does not constitute an admission by (the subject firm) that either reportable information or a substantial product hazard exists.''

(xiv) An acknowledgment that the corrective action plan becomes effective only upon its final acceptance by the Commission.

(2) In determining whether to recommend to the Commission acceptance of a corrective action plan, the staff shall consider favorably both the promptness of the subject firm's reporting and any remedial actions taken by the subject firm in the interest of public safety. The staff also shall consider, insofar as possible, prior involvement by the subject firm in corrective action plans and Commission orders if such involvement bears on the likelihood that the firm will comply fully with the terms of the corrective action plan.

(3) Upon receipt of a corrective action plan and staff recommendation, the Commission may:

(i) Approve the plan;

(ii) Reject the plan and issue a complaint (in which case an administrative and/or judicial proceeding will be commenced); or

(iii) Take any other action necessary to insure that the plan is adequate.

(4) When time permits and where practicable in the interest of protecting the public, a summary of the plan shall be published in the Commission's Public Calendar. Those portions of the plan that are not restricted will be made available to the public in the Commission's public reading room as much in advance of the Commission meeting as practicable. Any interested person wishing to comment on the plan must file a Notice of Intent to Comment at least forty-eight (48) hours prior to the commencement of the Commission meeting during which the plan will be discussed. If no notices of intent are received, the Commission may take final action on the plan. If such notice is received within the time limits detailed above, the plan will, if practicable, be docketed for the following week's agenda. All comments must be in writing, and final written comments must be submitted at least forty-eight (48) hours before that session.

(b) *Consent order agreements under section 15 of CPSA.* The consent order agreement (agreement) is a document executed by a subject firm (Consenting Party) and a Commission staff representative which incorporates both a proposed complaint setting forth the staff's charges and a proposed order by which such charges are resolved.

(1) Consent order agreements shall include, as appropriate:

(i) An admission of all jurisdictional facts by the Consenting Party.

(ii) A waiver of any rights to an administrative or judicial hearing and of any other procedural steps, including any rights to seek judicial review or otherwise challenge or contest the validity of the Commission's Order.

(iii) A statement that the agreement is in settlement of the staff's charges.

(iv) A statement that the Commission's Order is issued under section 15 of the CPSA (15 U.S.C. 2064) and that a violation is a prohibited act within the meaning of section 19(a)(5) of the CPSA (15 U.S.C. 2068(a)(5)) and may subject a violator to civil and/or criminal penalties under sections 20 and 21 of the CPSA (15 U.S.C. 2069 and 2070).

(v) An acknowledgment that the Commission reserves its right to seek sanctions for any violations of the reporting obligations of section 15(b) of CPSA (15 U.S.C. 2064(b)) and its right to take other appropriate legal action.

(vi) An acknowledgment that the agreement becomes effective only upon its final acceptance by the Commission and its service upon the Consenting Party.

(vii) An acknowledgment that the Commission may disclose terms of the consent order agreement to the public.

(viii) A listing of the acts or practices from which the Consenting Party will refrain.

(ix) A statement that the Consenting Party shall perform certain acts and practices pursuant to the agreement.

(x) An acknowledgment that any interested person may bring an action pursuant to section 24 of the CPSA (15 U.S.C. 2073) in any U.S. district court for the district in which the Consenting Party is found or transacts business to enforce the order and to obtain appropriate injunctive relief.

(xi) A description of the alleged substantial product hazard.

(xii) If desired by the Consenting Party, the following statement or its equivalent: ''The signing of this consent order agreement does not constitute an admission by (the Consenting Party) that either reportable

information or a substantial product hazard exists.''

(xiii) The elements of a corrective action plan as set forth in §1115.20(a).

(2) At any time in the course of an investigation, the staff may propose to a subject firm which is being investigated that some or all of the allegations be resolved by a consent order agreement. Additionally, such a proposal may be made to the staff by a subject firm.

(3) Upon receiving an executed agreement, the Commission may:

(i) Provisionally accept it;

(ii) Reject it and issue a complaint (in which case an administrative and/or judicial proceeding will be commenced); or

(iii) Take such other action as it may deem appropriate.

(4) If the consent order agreement is provisionally accepted, the Commission shall place the agreement on the public record and shall announce provisional acceptance of the agreement in the Commission's public calendar and in the FEDERAL REGISTER. Any interested person may request the Commission not to accept the agreement by filing a written request in the Office of the Secretary. Such written request must be received in the Office of the Secretary no later than the close of business of the fifteenth (15th) calendar day following the date of announcement in the FEDERAL REGISTER.

(5) If the Commission does not receive any requests not to accept the agreement within the time period specified above, the consent order agreement shall be deemed finally accepted by the Commission on the twentieth (20th) calendar day after the date of announcement in the FEDERAL REGISTER, unless the Commission determines otherwise. However, if the Commission does receive a request not to accept the consent order agreement, then it will consider such request and vote on the acceptability of such agreement or the desirability of further action. After the consent order agreement is finally accepted, the Commission may then issue its complaint and order in such form as the circumstances may require. The order is a final order in disposition of the proceeding and is effective immediately upon its service upon the Consenting Party pursuant to the Commission's Rules of Practice for Adjudicative Proceedings (16 CFR part 1025). The Consenting Party shall thereafter be bound by and take immediate action in accordance with such final order.

(6) If the Commission does not accept the consent order agreement on a final basis, it shall so notify the Consenting Party. Such notification constitutes withdrawal of the Commission's provisional acceptance unless the Commission orders otherwise. The Commission then may:

(i) Issue a complaint, in which case an administrative and/or judicial proceeding will be commenced;

(ii) Order further investigation; or

(iii) Take such other action as it may deem appropriate.

§ 1115.21 Compulsory remedial actions.

As appropriate, the Commission will attempt to protect the public from hazards presented by consumer products by seeking one or more of the following:

(a) *Adjudicated Commission Order.* An adjudicated Commission Order under section 15 (c) or (d) of the CPSA may be issued after parties and interested persons have had an opportunity for a hearing in accordance with section 554 of title 5, United States Code, and with section 15(f) of the CPSA. This hearing is governed by the Commission's Rules of Practice for Adjudicative Proceedings (16 CFR part 1025).

(b) *Injunctive relief.* The Commission may apply to a U.S. district court in accordance with the provisions of section 15(g) of the CPSA for a preliminary injunction to restrain the distribution in commerce of a product it has reason to believe presents a substantial product hazard. The Commission may seek enforcement of its orders issued under sections 15 (c) and (d) of the CPSA in accordance with provisions of sections 22 and 27(b)(7) of the CPSA (15 U.S.C. 2071 and 2076(b)(7)).

(c) *Judicial determination of imminent hazard.* The Commission may file a complaint in a U.S. district court in accordance with the provisions of section 12 of the CPSA (15 U.S.C. 2061).

(d) *Orders of the Secretary of the Treasury.* The Commission staff may inform

the Secretary of the Treasury that a consumer product offered for importation into the customs territory of the United States fails to comply with an applicable consumer product safety rule and/or has a product defect which constitutes a substantial product hazard. The Commission may request the Secretary of the Treasury under section 17 of the CPSA (15 U.S.C. 2066) to refuse admission to any such consumer product.

§ 1115.22 Prohibited acts and sanctions.

(a) *Statements generally.* Whoever knowingly and willfully falsifies, or conceals a material fact in a report under the CPSA and rules thereunder, is subject to criminal penalties under 18 U.S.C. 1001.

(b) *Timeliness and adequacy of reporting.* A failure to inform the Commission immediately and adequately, as required by section 15(b) of the CPSA, is a prohibited act within section 19(a)(4) of the CPSA (15 U.S.C. 2068(a)(4)).

(c) *Failure to make reports.* The failure or refusal to make reports or provide information as required under the CPSA is a prohibited act within the meaning of section 19(a)(3) of the CPSA (15 U.S.C. 2068(a)(3)).

(d) *Noncomplying products.* The manufacture for sale, offering for sale, distribution in commerce, and/or importation into the United States of a consumer product which is not in conformity with an applicable consumer product safety rule under CPSA is a prohibited act within the meaning of sections 19 (a)(1) and (a)(2) of the CPSA (15 U.S.C. 2068 (a)(1) and (a)(2)).

(e) *Orders issued under section 15 (c) and/or (d).* The failure to comply with an order issued under section 15 (c) and/or (d) of the CPSA is a prohibited act within the meaning of section 19(a)(5) of the CPSA (15 U.S.C. 2068(a)(5)).

(f) *Consequences of engaging in prohibited acts.* A knowing violation of section 19(a) of the CPSA subjects the violator to a civil penalty in accordance with section 20 of the CPSA (15 U.S.C. 2069). ''Knowing,'' as defined in section 20(c) of the CPSA (15 U.S.C. 2069(c)), means the having of actual knowledge or the presumed having of knowledge deemed to be possessed by a reasonable person who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. A knowing and willful violation of section 19(a), after the violator has received notice of noncompliance, subjects the violator to criminal penalties in accordance with section 21 of the CPSA (15 U.S.C. 2070).

Subpart C—Guidelines and Requirements for Mandatory Recall Notices

SOURCE: 75 FR 3371, Jan. 21, 2010, unless otherwise noted.

§ 1115.23 Purpose.

(a) The Commission establishes these guidelines and requirements for recall notices as required by section 15(i) of the Consumer Product Safety Act, as amended (CPSA) (15 U.S.C. 2064(i)). The guidelines and requirements set forth the information to be included in a notice required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)). Unless otherwise ordered by the Commission under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or by a United States district court under section 12 of the CPSA (15 U.S.C. 2061), the content information required in this subpart must be included in every such notice.

(b) The Commission establishes these guidelines and requirements to ensure that every recall notice effectively helps consumers and other persons to:

(1) Identify the specific product to which the recall notice pertains;

(2) Understand the product's actual or potential hazards to which the recall notice pertains, and information relating to such hazards; and

(3) Understand all remedies available to consumers concerning the product to which the recall notice pertains.

§ 1115.24 Applicability.

This subpart applies to manufacturers (including importers), retailers, and distributors of consumer products as those terms are defined herein and in the CPSA.

§ 1115.25 Definitions.

In addition to the definitions given in section 3 of the CPSA (15 U.S.C. 2052), the following definitions apply:

(a) *Recall* means any one or more of the actions required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)).

(b) *Recall notice* means a notification required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)).

(c) *Direct recall notice* means a notification required by an order under sections 12, 15(c), or 15(d) of the CPSA (15 U.S.C. 2061, 2064(c), or 2064(d)), that is sent directly to specifically-identified consumers.

(d) *Firm* means a manufacturer (including an importer), retailer, or distributor as those terms are defined in the CPSA.

(e) *Other persons* means, but is not limited to, consumer safety advocacy organizations, public interest groups, trade associations, industry advocacy organizations, other State, local, and Federal government agencies, and the media.

§ 1115.26 Guidelines and policies.

(a) *General.* (1) A recall notice should provide sufficient information and motivation for consumers and other persons to identify the product and its actual or potential hazards, and to respond and take the stated action. A recall notice should clearly and concisely state the potential for injury or death.

(2) A recall notice should be written in language designed for, and readily understood by, the targeted consumers or other persons. The language should be simple and should avoid or minimize the use of highly technical or legal terminology.

(3) A recall notice should be targeted and tailored to the specific product and circumstances. In determining the form and content of a recall notice, the manner in which the product was advertised and marketed should be considered.

(4) A direct recall notice is the most effective form of a recall notice.

(5) At least two of the recall notice forms listed in subsection (b) should be used.

(b) *Form of recall notice*—(1) *Possible forms.* A recall notice may be written, electronic, audio, visual, or in any other form ordered by the Commission in an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or by a United States district court under section 12 of the CPSA (15 U.S.C. 2061). The forms of, and means for communicating, recall notices include, but are not limited to:

(i) Letter, Web site posting, electronic mail, RSS feed, or text message;

(ii) Computer, radio, television, or other electronic transmission or medium;

(iii) Video news release, press release, recall alert, Web stream, or other form of news release;

(iv) Newspaper, magazine, catalog, or other publication; and

(v) Advertisement, newsletter, and service bulletin.

(2) *Direct recall notice.* A direct recall notice should be used for each consumer for whom a firm has direct contact information, or when such information is obtainable, regardless of whether the information was collected for product registration, sales records, catalog orders, billing records, marketing purposes, warranty information, loyal purchaser clubs, or other such purposes. Direct contact information includes, but is not limited to, name and address, telephone number, and electronic mail address. Forms of direct recall notice include, but are not limited to, United States mail, electronic mail, and telephone calls. A direct recall notice should prominently show its importance over other consumer notices or mail by including ''Safety Recall'' or other appropriate terms in an electronic mail subject line, and, in large bold red typeface, on the front of an envelope and in the body of a recall notice.

(3) *Web site recall notice.* A Web site recall notice should be on a Web site's first entry point such as a home page, should be clear and prominent, and should be interactive by permitting consumers and other persons to obtain recall information and request a remedy directly on the Web site.

(c) *Languages.* Where the Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C.

2064(c) or (d)), or a United States district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), determines that it is necessary or appropriate to adequately inform and protect the public, a recall notice may be required to be in languages in addition to English. For example, it may be necessary or appropriate to require a recall notice be in a language in addition to English when a product label is in a language in addition to English, when a product is marketed in a language in addition to English, or when a product is marketed or available in a geographic location where English is not the predominant language.

§ 1115.27 Recall notice content requirements.

Except as provided in §1115.29, every recall notice must include the information set forth below:

(a) *Terms.* A recall notice must include the word ''recall'' in the heading and text.

(b) *Date.* A recall notice must include its date of release, issuance, posting, or publication.

(c) *Description of product.* A recall notice must include a clear and concise statement of the information that will enable consumers and other persons to readily and accurately identify the specific product and distinguish it from similar products. The information must enable consumers to readily determine whether or not they have, or may be exposed to, the product. To the extent applicable to a product, descriptive information that must appear on a recall notice includes, but is not limited to:

(1) The product's names, including informal and abbreviated names, by which consumers and other persons should know or recognize the product;

(2) The product's intended or targeted use population (*e.g.*, infants, children, or adults);

(3) The product's colors and sizes;

(4) The product's model numbers, serial numbers, date codes, stock keeping unit (SKU) numbers, and tracking labels, including their exact locations on the product;

(5) Identification and exact locations of product tags, labels, and other identifying parts, and a statement of the specific identifying information found on each part; and

(6) Product photographs. A firm must provide photographs. Each photograph must be electronic or digital, in color, of high resolution and quality, and in a format readily transferable with high quality to a Web site or other appropriate medium. As needed for effective notification, multiple photographs and photograph angles may be required.

(d) *Description of action being taken.* A recall notice must contain a clear and concise statement of the actions that a firm is taking concerning the product. These actions may include, but are not limited to, one or more of the following: Stop sale and distribution in commerce; recall to the distributor, retailer, or consumer level; repair; request return and provide a replacement; and request return and provide a refund.

(e) *Statement of number of product units.* A recall notice must state the approximate number of product units covered by the recall, including all product units manufactured, imported, and/or distributed in commerce.

(f) *Description of substantial product hazard.* A recall notice must contain a clear and concise description of the product's actual or potential hazards that result from the product condition or circumstances giving rise to the recall. The description must enable consumers and other persons to readily identify the reasons that a firm is conducting a recall. The description must also enable consumers and other persons to readily identify and understand the risks and potential injuries or deaths associated with the product conditions and circumstances giving rise to the recall. The description must include:

(1) The product defect, fault, failure, flaw, and/or problem giving rise to the recall; and

(2) The type of hazard or risk, including, by way of example only, burn, fall, choking, laceration, entrapment, and/or death.

(g) *Identification of recalling firm.* A recall notice must identify the firm conducting the recall by stating the firm's legal name and commonly known trade name, and the city and state of its headquarters. The notice

must state whether the recalling firm is a manufacturer (including importer), retailer, or distributor.

(h) *Identification of manufacturers.* A recall notice must identify each manufacturer (including importer) of the product and the country of manufacture. Under the definition in section 3(a)(11) of the CPSA (15 U.S.C. 2052(a)(11)), a manufacturer means ''any person who manufactures or imports a consumer product.'' If a product has been manufactured outside of the United States, a recall notice must identify the foreign manufacturer and the United States importer. A recall notice must identify the manufacturer by stating the manufacturer's legal name and the city and state of its headquarters, or, if a foreign manufacturer, the foreign manufacturer's legal name and the city and country of its headquarters.

(i) *Identification of significant retailers.* A recall notice must identify each significant retailer of the product. A recall notice must identify such a retailer by stating the retailer's commonly known trade name. Under the definition in section 3(a)(13) of the CPSA (15 U.S.C. 2052(a)(13)), a retailer means ''a person to whom a consumer product is delivered or sold for purposes of sale or distribution by such person to a consumer.'' A product's retailer is ''significant'' if, upon the Commission's information and belief, and in the sole discretion of the Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or in the sole discretion of a United States district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), any one or more of the circumstances set forth below is present (the Commission may require manufacturers (including importers), retailers, and distributors to provide information relating to these circumstances):

(1) The retailer was the exclusive retailer of the product;

(2) The retailer was an importer of the product;

(3) The retailer has stores nationwide or regionally-located;

(4) The retailer sold, or held for purposes of sale or distribution in commerce, a significant number of the total manufactured, imported, or distributed units of the product; or

(5) Identification of the retailer is in the public interest.

(j) *Region.* Where necessary or appropriate to assist consumers in determining whether they have the product at issue, a description of the region where the product was sold, or held for purposes of sale or distribution in commerce, must be provided.

(k) *Dates of manufacture and sale.* A recall notice must state the month and year in which the manufacture of the product began and ended, and the month and year in which the retail sales of the product began and ended. These dates must be included for each make and model of the product.

(l) *Price.* A recall notice must state the approximate retail price or price range of the product.

(m) *Description of incidents, injuries, and deaths.* A recall notice must contain a clear and concise summary description of all incidents (including, but not limited to, property damage), injuries, and deaths associated with the product conditions or circumstances giving rise to the recall, as well as a statement of the number of such incidents, injuries, and deaths. The description must enable consumers and other persons to readily understand the nature and extent of the incidents and injuries. A recall notice must state the ages of all persons injured and killed. A recall notice must state the dates or range of dates on which the Commission received information about injuries and deaths.

(n) *Description of remedy.* A recall notice must contain a clear and concise statement, readily understandable by consumers and other persons, of:

(1) Each remedy available to a consumer for the product conditions or circumstances giving rise to the recall. Remedies include, but are not limited to, refunds, product repairs, product replacements, rebates, coupons, gifts, premiums, and other incentives.

(2) All specific actions that a consumer must take to obtain each remedy, including, but not limited to, instructions on how to participate in the recall. These actions may include, but are not limited to, contacting a firm,

removing the product from use, discarding the product, returning part or all of the product, or removing or disabling part of the product.

(3) All specific information that a consumer needs in order to obtain each remedy and to obtain all information about each remedy. This information may include, but is not limited to, the following: Manufacturer, retailer, and distributor contact information (such as name, address, telephone and facsimile numbers, e-mail address, and Web site address); whether telephone calls will be toll-free or collect; and telephone number days and hours of operation including time zone.

(o) *Other information.* A recall notice must contain such other information as the Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or a United States district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), deems appropriate and orders.

§ 1115.28 Multiple products or models.

For each product or model covered by a recall notice, the notice must meet the requirements of this subpart.

§ 1115.29 Final determination regarding form and content.

(a) *Commission or court discretion.* The recall notice content required by this subpart must be included in a recall notice whether or not the firm admits the existence of a defect or of an actual or potential hazard, and whether or not the firm concedes the accuracy or applicability of all of the information contained in the recall notice. The Commission will make the final determination as to the form and content of the recall notice for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), and a United States district court will make the final determination as to the form and content of a recall notice for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061).

(b) *Recall notice exceptions.* The Commission for purposes of an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), or a United States district court for purposes of an order under section 12 of the CPSA (15 U.S.C. 2061), may determine that one or more of the recall notice requirements set forth in this subpart is not required, and will not be included, in a recall notice.

(c) *Commission approval.* Before a firm may publish, broadcast, or otherwise disseminate a recall notice to be issued pursuant to an order under section 15(c) or (d) of the CPSA (15 U.S.C. 2064(c) or (d)), the Commission must review and agree in writing to all aspects of the notice.

Appendix to Part 1115—Voluntary Standards on Which the Commission Has Relied Under Section 9 of the Consumer Product Safety Act

The following are the voluntary standards on which the Commission has relied under section 9 of the Consumer Product Safety Act:

1. American National Standard for Power Tools—Gasoline-Powered Chain Saws—Safety Regulations, ANSI B175.1–1985 sections 4.9.4, 4.12, 4.15, 7 and 8, or the current version: ANSI B175.1–1991 sections 5.9.4, 5.12, 5.15, 8 and 9.

2. American National Standard for Gas-Fired Room Heaters, Volume II, Unvented Room Heaters, ANSI Z21.11.2–1989 and addenda ANSI Z21.11.2 a and b- 1991), sections 1.8, 1.20.9, and 2.9.

[57 FR 34230, Aug. 4, 1992]

PART 1116—REPORTS SUBMITTED PURSUANT TO SECTION 37 OF THE CONSUMER PRODUCT SAFETY ACT

Sec.

AUTHORITY: 15 U.S.C. 2055(e), 2084.

SOURCE: 57 FR 34239, Aug. 4, 1992, unless otherwise noted.