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]

§§ 1115.8–1115.9 [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.