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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.

§ 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