

(b) *Violation* means a violation committed knowingly, as the term “knowingly” is defined in section 19 of the CPSA, section 4 of the FHSA, or section 5 of the FFA.

(c) *Person* means any manufacturer (including importer), distributor, or retailer, as those terms are defined in the CPSA, FHSA, or FFA, and any other legally responsible party.

**§ 1119.4 Factors considered in determining civil penalties.**

(a) *Statutory Factors.* (1) Section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA, specify factors considered by the Commission in determining the amount of a civil penalty to be sought upon commencing an action for knowing violations of each act. These factors are:

(i) *CPSA (15 U.S.C. 2069(b)).* The nature, circumstances, extent, and gravity of the violation, including:

- (A) The nature of the product defect;
- (B) The severity of the risk of injury;
- (C) The occurrence or absence of injury;
- (D) The number of defective products distributed;

(E) The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and

(F) Such other factors as appropriate.

(ii) *FHSA (15 U.S.C. 1264 (c)(3)).* The nature, circumstances, extent, and gravity of the violation, including:

- (A) The nature of the substance;
- (B) Severity of the risk of injury;
- (C) The occurrence or absence of injury;
- (D) The amount of substance distributed;

(E) The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and

(F) Such other factors as appropriate.

(iii) *FFA (15 U.S.C. 1194 (e)(2)).* The nature, circumstances, extent, and gravity of the violations:

- (A) The severity of the risk of injury;
- (B) The occurrence or absence of injury;

(C) The appropriateness of such penalty in relation to the size of the business of the person charged; and

(D) Such other factors as appropriate.

(2) *The nature, circumstances, extent, and gravity of the violation.* Under this factor, the Commission will consider the totality of the circumstances and all other facts concerning a violation. The Commission will consider the enumerated statutory factors, as well as the factors described in paragraph (b) of this section.

(3) *Nature of the product defect.* The Commission will consider the nature of the product defect associated with a CPSA violation. This consideration will include, for example, whether the defect arises from the product’s design, composition, contents, construction, manufacture, packaging, warnings, or instructions, and will include consideration of conditions or circumstances in which the defect arises. The Commission will also consider the nature of the substance associated with an FHSA violation. Two of the statutory factors in the CPSA civil penalty factors include the terms “product defect” or “defective products.” However, certain violations of the CPSA, for example, failing to supply a required certificate that the product complies with an applicable consumer product safety rule, do not necessarily require that there be a product defect or defective product. The terms “product defect” or “defective products” would not apply to such situation. In such cases, however, the other civil penalty factors would still be considered.

(4) *Severity of the risk of injury.* Consistent with its discussion of severity of the risk at 16 CFR 1115.12, the Commission will consider, among other factors, the potential for serious injury, illness, or death (and whether any injury or illness required medical treatment including hospitalization or surgery); the likelihood of injury; the intended or reasonably foreseeable use or misuse of the product; and the population at risk (including vulnerable populations such as children, the elderly, or those with disabilities).

(5) *The occurrence or absence of injury.* The Commission will consider whether injuries, illnesses, or deaths have or

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have not occurred with respect to any product or substance associated with a violation, and, if so, the number and nature of injuries, illnesses, or deaths. Both acute illnesses and the likelihood of chronic illnesses will be considered.

(6) *The number of defective products distributed.* The Commission will consider the number of defective products or amount of substance distributed in commerce. The statutory language makes no distinction between those defective products distributed in commerce that consumers received and those defective products distributed in commerce that consumers have not received. Therefore both could be considered in appropriate cases. This factor will not be used to penalize a person's decision to conduct a wider-than-necessary recall out of an abundance of caution. This would not include situations where such a recall is conducted due to a person's uncertainty concerning how many or which products may need to be recalled.

(7) The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses.

(i) The Commission is required to consider the size of the business of the person charged in relation to the amount of the penalty. This factor reflects the relationship between the size of a business and the policies behind, and purposes of, a penalty (as noted above in § 1119.1). In considering business size, the Commission may look to several factors including, but not limited to, the number of employees, net worth, and annual sales. A business's size and a business's ability to pay a penalty are separate considerations. In some cases for small businesses, however, these two considerations may relate to each other. The Commission will be guided, where appropriate, by relevant financial factors to determine a small business's ability to pay a penalty, including, but not limited to, liquidity, solvency, and profitability. The burden to present clear, reliable, relevant, and sufficient evidence relating to a business's size and ability to pay rests on the business.

(ii) The statute requires the Commission to consider how to mitigate the

adverse economic impacts on small businesses only if those impacts would be undue. What the Commission considers in determining what is undue may include, but is not limited to, the business's size and financial factors relating to its ability to pay. When considering how to mitigate undue adverse economic impacts, the Commission will, as appropriate, also follow its Small Business Enforcement Policy set forth at § 1020.5.

(b) *Other factors as appropriate.* In determining the amount of any civil penalty to be sought for a violation of the CPSA, FHSA, or FFA, the Commission may consider, as appropriate, such other factors in addition to those listed in the statutes. Both the Commission and a person may raise any factors they believe are relevant in determining an appropriate penalty amount. A person will be notified of any factors beyond those enumerated in the statutes that the Commission relies on as aggravating factors for purposes of determining a civil penalty amount. Additional factors that may be considered in a case include, but are not limited to, the following:

(1) *Safety/compliance program and/or system relating to a violation.* The Commission may consider, when a safety/compliance program and/or system as established is relevant to a violation, whether a person had at the time of the violation a reasonable and effective program or system for collecting and analyzing information related to safety issues. Examples of such information would include incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns. The Commission may also consider whether a person conducted adequate and relevant premarket and production testing of the product at issue; had a program in place for continued compliance with all relevant mandatory and voluntary safety standards; and other factors as the Commission deems appropriate. The burden to present clear, reliable, relevant, and sufficient evidence of such program, system, or testing rests on the person seeking consideration of this factor.

(2) *History of noncompliance.* The Commission may consider whether or not a person's history of noncompliance with

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the CPSA, FHSA, FFA, and other laws that the CPSC enforces, and the regulations thereunder, should increase the amount of the penalty. A person's history of noncompliance may be indicated by, for example, multiple violations of one or more laws or regulations that the CPSC enforces, including repeated violations of the same law or regulation. History of noncompliance may include the number of previous violations or how recently a previous violation occurred.

(3) *Economic gain from noncompliance.* The Commission may consider whether a person benefitted economically from a failure to comply, including a delay in complying, with the CPSA, FHSA, FFA, and other laws that the CPSC enforces, and the regulations thereunder.

(4) *Failure to respond in a timely and complete fashion to the Commission's requests for information or remedial action.* The Commission may consider whether a person's failure to respond in a timely and complete fashion to requests from the Commission for information or for remedial action should increase a penalty. This factor is intended to address a person's dilatory and egregious conduct in responding to written requests for information or remedial action sought by the Commission, but not to impede any person's lawful rights.

### § 1119.5 Enforcement notification.

A person will be informed in writing if it is believed that the person has violated the law and if the Commission intends to seek a civil penalty. Any person who receives such a writing will have an opportunity to submit evidence and arguments that it should not pay a penalty or should not pay a penalty in the amount sought by the Commission.

## PART 1120—SUBSTANTIAL PRODUCT HAZARD LIST

Sec.

1120.1 Authority.

1120.2 Definitions.

1120.3 Products deemed to be substantial product hazards.

AUTHORITY: 15 U.S.C. 2064(j).

SOURCE: 76 FR 37640, June 28, 2011, unless otherwise noted.

## 16 CFR Ch. II (1–1–13 Edition)

### § 1120.1 Authority.

Under the authority of section 15(j) of the Consumer Product Safety Act (CPSA), the Commission determines that consumer products or classes of consumer products listed in § 1120.3 of this part have characteristics whose existence or absence present a substantial product hazard under section 15(a)(2) of the CPSA. The Commission has determined that the listed products have characteristics that are readily observable and have been addressed by a voluntary standard, that the voluntary standard has been effective, and that there is substantial compliance with the voluntary standard. The listed products are subject to the reporting requirements of section 15(b) of the CPSA and to the recall provisions of section 15(c) and (d) of the CPSA, and shall be refused entry into the United States under section 17(a)(4) of the CPSA.

### § 1120.2 Definitions.

The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this part 1120.

(a) *Substantial product hazard* means 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) *Hand-supported hair dryer* means an electrical appliance, intended to be held with one hand during use, which creates a flow of air over or through a self-contained heating element for the purpose of drying hair.

(c) *Drawstring* means a non-retractable cord, ribbon, or tape of any material to pull together parts of upper outerwear to provide for closure.

[76 FR 37640, June 28, 2011, as amended at 76 FR 42507, July 19, 2011]

### § 1120.3 Products deemed to be substantial product hazards.

The following products or class of products shall be deemed to be substantial product hazards under section 15(a)(2) of the CPSA: