

## § 12.1

## 19 CFR Ch. I (4–1–23 Edition)

FOOD, DRUGS, AND COSMETICS, ECONOMIC POISONS, HAZARDOUS SUBSTANCES, AND DANGEROUS CAUSTIC OR CORROSIVE SUBSTANCES

### § 12.1 Cooperation with certain agencies; joint regulations.

(a) *Federal Food, Drug, and Cosmetic Act.* The importation into the United States of food, drugs, devices, cosmetics, and tobacco products as defined in section 201 (f), (g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (f), (g), (h), (i)) is governed by section 801 of the Act, as amended (21 U.S.C. 381) and regulations issued under authority of section 701(b) of the Act (21 U.S.C. 371(b)) by the Secretary of Health and Human Services and the Secretary of the Treasury (21 CFR 1.83 through 1.99).

(b) *Federal Insecticide, Fungicide, and Rodenticide Act.* The importation of pesticides and devices is governed by section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136o(c)), and regulations issued under the authority of section 17(e) of that Act (7 U.S.C. 1360(e)) by the Secretary of the Treasury, in consultation with the Administrator of the Environmental Protection Agency, as set forth below (§12.110 *et seq.*).

(c) *Federal Hazardous Substances Act.* The importation of hazardous substances, misbranded hazardous substances, or banned hazardous substances as defined in section 2 of the Federal Hazardous Substances Act, as amended (15 U.S.C. 1261), is governed by regulations issued under the authority of sections 10(b) and 14 of the Act, as amended (15 U.S.C. 1269, 1273), by the Consumer Product Safety Commission (16 CFR 1500.265 through 1500.272).

[T.D. 68–191, 33 FR 11019, Aug. 2, 1968, as amended by T.D. 75–194, 40 FR 32321, Aug. 1, 1975; T.D. 82–145, 47 FR 35475, Aug. 16, 1982; CBP Dec. 10–29, 75 FR 52450, Aug. 26, 2010]

### § 12.3 Release under bond; liquidated damages.

(a) *Release.* No food, drug, device, cosmetic, tobacco product, pesticide, hazardous substance or dangerous caustic or corrosive substance that is the subject of §12.1 will be released except in accordance with the laws and regulations applicable to the merchandise.

When any merchandise that is the subject of §12.1 is to be released under bond pursuant to regulations applicable to that merchandise, a bond on Customs Form 301, containing the bond conditions set forth in §113.62 of this chapter, will be required.

(b) *Bond amount.* The bond referred to in paragraph (a) of this section must be in a specific amount prescribed by the port director based on the circumstances of the particular case that is either:

(1) Equal to the domestic value (see §162.43(a) of this chapter) of the merchandise at the time of release as if the merchandise were admissible and otherwise in compliance; or

(2) Equal to three times the value of the merchandise as provided in §113.62(n)(1) of this chapter.

(c) *Liquidated damages.* Whenever liquidated damages arise with regard to any food, drug, device or cosmetic subject to §12.1(a) for failure to redeliver merchandise into Customs custody or for failure to rectify any noncompliance with the applicable provisions of admission, including the failure to export or destroy the merchandise within the time period prescribed by law after the merchandise has been refused admission pursuant to the provisions of the Food, Drug and Cosmetic Act, those liquidated damages will be assessed pursuant to §113.62(n)(1) of this chapter in the amount of the bond prescribed under paragraph (b) of this section.

[T.D. 01–26, 66 FR 16853, Mar. 28, 2001; CBP Dec. 08–46, 73 FR 71780, Nov. 25, 2008; CBP Dec. 10–29, 75 FR 52451, Aug. 26, 2010; CBP Dec. 18–05, 83 FR 27404, June 12, 2018]

### § 12.4 Exportation.

The exportation of merchandise, the subject of §12.1, refused admission into the United States in accordance with regulations applicable thereto shall be under Customs supervision in accordance with the regulations set forth in §§18.25 and 18.26 of this chapter.

[T.D. 68–191, 33 FR 11019, Aug. 2, 1968]

### § 12.5 Shipment to other ports.

When imported merchandise, the subject of §12.1, is shipped to another port for reconditioning or exportation, such