

§ 325.9

the Federal Food, Drug, and Cosmetic Act.

[43 FR 43445, Sept. 26, 1978]

§ 325.9 [Reserved]

§ 325.10 Handling of products which may have become adulterated or misbranded; authorization and other requirements.

(a) When it is claimed that any inspected and passed product, marked with an inspection legend, has become adulterated or misbranded after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the area supervisor of the area in which that official establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of officially determining if the product has become adulterated or misbranded and making the appropriate disposition. The area supervisor shall make a record of the authorization and such other information which will effectively identify the shipment and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(b) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by a Program inspector, and if it is found that the article is not adulterated, the same may be received into the establishment; but if the article is found to be adulterated, it shall at once be stamped "U.S. inspected and condemned" and disposed of in accordance with part 314 of this subchapter, and if it is found to be misbranded, it shall be handled in accordance with § 318.2(d) of this subchapter: *Provided*, That when a product is found to be affected with one of the correctable conditions specified in § 318.2(d) of this subchapter, in respect to which rehandling is permitted, it may be transported from the official establishment to an-

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other official establishment for such rehandling as is necessary to assure that the product is not adulterated or misbranded when finally released. The transportation of such a product from an official establishment shall be done in a manner prescribed in each specific case by the Administrator.

[35 FR 15605, Oct. 3, 1970, as amended at 47 FR 17274, Apr. 22, 1982]

§ 325.11 Inedible articles: denaturing and other means of identification; exceptions.

(a) Except as provided in § 325.8 and § 325.10, no carcass, part of a carcass, rendered grease, tallow, or other fat derived from the carcasses of livestock, or other meat food product, that has not been inspected and passed at an official establishment under the provisions of this subchapter and is not exempted from such inspection, and no carcass, part of a carcass, fat or other meat food product that is adulterated or misbranded, shall be offered for transportation in commerce by any person unless it is handled in accordance with paragraph (b), (c), (d), or (e) of this section or is denatured or otherwise identified as prescribed in § 325.13, § 314.1, § 314.3, § 314.9, § 314.10, or § 314.11 of this subchapter.

(b) Inedible rendered animal fats from official or other establishments in the United States having the physical characteristics of a meat food product fit for human food may be transported in commerce without denaturing, if the following conditions are met:

(1) Such inedible rendered fat shall not be bought, sold, transported, or offered for sale or offered for transportation in commerce, or imported, except by rendering companies, dealers, brokers, or others who obtain a numbered permit for such activities from the Regional Director.

(2) Such inedible rendered animal fat may be so distributed only if consigned to a domestic manufacturer of technical articles other than for human food or to an export terminal for exportation or storage for exportation as an inedible article, and provided, in the case of such fat consigned to a domestic manufacturer, the product is for use

solely by the consignee for manufacturing purposes of nonhuman food articles and may not be further sold or shipped without first receiving approval of the Regional Director: *And provided further*, That such fat intended for export and stored at a terminal point prior to export will be subject to review by Program employees to assure that it is exported as inedible.

(3) When transported in commerce, or imported, such inedible rendered fat shall be marked conspicuously with the words "technical animal fat not intended for human food" on the ends of the shipping containers, in letters not less than 2 inches high; in the case of shipping containers such as drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks. All shipping containers shall have both ends painted with a durable paint, if necessary, to provide a contrasting background for the required marking.

(4) Such inedible rendered fat shall be transported only in sealed shipping containers bearing unofficial seals applied by the shipper, which shall include the identification number assigned by said Director for the permit holder. The number shall appear on the bill of lading or other transportation documents for the shipment. The consignees in the United States must retain the seals in their records as prescribed in part 320 of this subchapter.

(5) Any diversion or effort to divert inedible rendered fat contrary to the provisions of this paragraph (b) or other violation of the provisions of this section may result in the revocation of the permit for shipment of technical animal fat at the discretion of the Administrator.

(c) Inedible rendered animal fat derived from condemned or other inedible materials at official or other establishments in the United States may be transported in commerce if mixed with low grade offal or other materials which render the fat readily distinguishable from an article of human food, and if the outside container bears the word "inedible."

(d)(1) Except as provided in paragraphs (d)(2), (3), and (4) of this section, or in §§314.10 and 314.11 of this subchapter, no animal food prepared, in

whole or in part, from materials derived from the carcasses of livestock in an official establishment or elsewhere, shall be bought, sold, transported, offered for sale or transportation, or received for transportation, in commerce, or imported, unless:

(i) It is properly identified as animal food;

(ii) It is not represented as being a human food; and

(iii) It has been denatured as prescribed in §325.13(a)(2) so as to be readily distinguishable from an article of human food.

(2) Notwithstanding the provisions of paragraph (d)(1) of this section, an animal food that consists of less than 5 percent of parts or products of the carcasses of livestock and that is not represented by labeling or appearance or otherwise as being a human food or as a product of the meat food industry need not be denatured in accordance with §325.13(a)(2).

(3) Notwithstanding the provisions of paragraph (d)(1) of this section, animal food packed in hermetically sealed, retort processed, conventional retail-size containers, and retail-size packages of semi-moist animal food need not be denatured in accordance with §325.13(a)(2) if the name of the article clearly conveys the article's intended use for animal food and appeared on the label in a conspicuous manner.

(i) Except as provided in paragraph (ii) of paragraph (d)(3), the name of the article must be stated on the label as "Animal Food," "Pet Food," or "(name of species) Food" (e.g., "Dog Food" or "Cat Food"). To be considered conspicuous, the name of the article, wherever it appears on the label, must be in letters at least twice as high, wide, and thick as the letters indicating the presence in the article of any ingredients derived from the carcasses of livestock.

(ii) Notwithstanding the provisions of paragraph (i) of this paragraph (d)(3), the article's name may be stated on the label to show that it is or contains livestock-source material and that the article is for animals; e.g., "Horsemeat for Pets" or "Beef Stew for Dogs": *Provided*, That the entire name of the article is stated, wherever it appears on the label, as an individual, contiguous

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unit, whether stated on a single line or more than one line, and the letters denoting the article's intended use for animal food are at least as high, wide, and thick as the letters indicating the presence of material derived from any livestock carcass. However, when the label bears on its principal display panel a vignette which pictures, in clearly recognizable form and size, one or more animals of the species for which the article's name indicates the article is intended, the letters used to state the article's intended use shall be at least one-half as high, wide, and thick as the letters used in the article's name or other letters indicating the presence of material derived from any livestock carcass, but shall not be less than $\frac{1}{8}$ inches high. The letters used to state the article's intended use may be separated from the article's name by the vignette.

(iii) Letters used to denote the intended use of the article must contrast as markedly with their background as the letters indicating the presence in the article of livestock carcass-source material contrast with their background.

(4) The requirements of this part do not apply to livestock or poultry feeds manufactured from processed livestock byproducts (such as meat meal tankage, meat and bone meal, blood meal, and feed grade animal fat), or to processed dry animal food.

(e) Except for inedible rendered animal fats and lungs or lung lobes, inedible products (including condemned products only if condemned for causes specified in §314.11 of this subchapter) which were prepared at any official establishment, or at any State inspected establishment in any State not listed in §331.2 of this subchapter, and which have the physical characteristics of a product fit for human food, may be transported from an official establishment or in commerce, without denaturing as required by this subchapter, if the following conditions are met:

(1) The shipper must have obtained a numbered permit for such activity from the appropriate Regional Director, as identified in §301.2 of this subchapter. Such permit may be obtained upon written application to the appropriate Regional Director and his deter-

mination that the proposed transportation would be authorized under this paragraph (e). The application shall state the name and address of the applicant, a description of the type of his business operations, and the purpose of making such application.

(2) Such inedible products may be transported under this paragraph (e) only if consigned to a manufacturer in the United States of articles other than for human food and if the product is for use solely by the consignee for manufacturing articles not for human food. Such products may not be transported in commerce to any consignee other than the one to which they were originally shipped unless prior notice of the diversion is given to the appropriate Regional Director and a record identifying the new consignee is maintained by the shipper as required by §320.1 of this subchapter.

(3) When transported from an official establishment or in commerce under this paragraph (e), the outside container of such inedible products shall be marked conspicuously with the words "Inedible—Not Intended for Human Food" in letters not less than 2 inches high, in the case of containers, such as cartons, drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks used to transport such products not in other containers.

(4) Such inedible products shall be transported from an official establishment or in commerce under this paragraph (e) only in railroad cars, trucks, or containers which bear unofficial seals applied by the shipper, which shall include the identification number assigned to the permit holder and an individual seal serial number assigned by the shipper; and the product so transported shall be accompanied by an invoice or bill of lading specifying the permit holder's identification number. The consignee in the United States must retain a record of the identification and serial numbers shown on the seals in his records as prescribed in part 320 of this subchapter.

(5) Any diversion, or effort to divert, unadorned, inedible product contrary to the provisions of this paragraph (e) or other violation of the provisions of

this section may result in the revocation of the permit for shipment of inedible products under this paragraph (e), at the discretion of the Administrator.

[47 FR 17274, Apr. 22, 1982, as amended at 49 FR 47478, Dec. 5, 1984]

§ 325.12 [Reserved]

§ 325.13 Denaturing procedures.

(a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this paragraph shall be considered denatured for the purposes of the regulations in this part, except as otherwise provided in part 314 of this subchapter for articles condemned at official establishments.

(1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under part 314 of this subchapter if they were at an official establishment: Crude carbolic acid; cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases.³

(2) Except as provided in paragraphs (a)(3), (4), and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases.³

(3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring;

(4) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and

(5) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(6) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4 inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a)(1) or (2) of this section to the outer surface of molds or blocks of boneless meat, meat byproducts, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with all of the material to be denatured, and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.

(7) Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91).¹

³Information as to approval of any proprietary denaturing substance may be obtained from the Technical Services, Meat and Poultry Inspection, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

¹Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the

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