be taken into official establishments and be mixed with or added to any product in such establishments which has been inspected and passed therein.

(c) Imported product which has been inspected, passed, and marked under this part may be transported in the course of importation or subsequently in commerce only upon compliance with part 325 of this subchapter.

[35 FR 15610, Oct. 3, 1970, as amended at 41 FR 18089, Apr. 30, 1976; 54 FR 41049, Oct. 5, 1989]

§ 327.19 Specimens for laboratory examination and similar purposes.

The provisions in this part do not apply to specimens of products for laboratory examination, research, or similar purposes when authorized importation by the Administrator under conditions specified by him in specific cases, including requirements of denaturing or other identification to deter their use for human food. Authorization will not be given for the importation of any products contrary to the provisions of part 94 of this chapter.

§ 327.20 Importation of foreign inedible fats.

No inedible grease, inedible tallow, or other inedible rendered fat shall be imported into the United States unless it has been first denatured as prescribed in § 327.25 of this part and the containers marked as prescribed by § 316.15 of this subchapter or unless it is identified and handled as prescribed by § 325.11 (b) or (c) of this subchapter.

[54 FR 41049, Oct. 5, 1989]

§ 327.21 Inspection procedures for chilled fresh and frozen boneless manufacturing meat.

(a) *Definitions; sampling; standards.* (1) Frozen boneless manufacturing meat is meat, frozen in the fresh state from cattle, sheep, swine, goats, horses, mules, or other equines that has all bone removed and is cut into pieces or trimmings, frozen into a compact block of any shape and suitable for slicing or chopping in the manufacturing of meat food products. As used in this section, the term ''frozen'' includes ''chilled fresh,'' and ''lot'' means any amount of frozen boneless manufacturing meat of one species, similarly packaged, shipped from one establishment, and offered for import inspection under one or more foreign inspection certificates.

(2) Imported frozen boneless manufacturing meat shall be sampled as required by § 327.6(a) of this part, and the samples defrosted for inspection. The Program import inspector, or in the case of Canadian product subject to procedures described in § 327.5(d)(1), the Canadian representative will select from a lot the appropriate number of cartons specified by the table of sampling plans. The total sample for inspection will consist of the necessary number of 12-pound units drawn from these cartons. The 12-pound units selected will be completely defrosted and examined.

(b) *Lots refused entry.* Reinspection (including resampling) will be provided for any lot of frozen boneless manufacturing meat which was refused entry under this section on the basis of the original evaluation of the sample thereof, upon appeal from the inspector's initial decision.

[35 FR 15610, Oct. 3, 1970, as amended at 49 FR 36819, Sept. 20, 1984; 51 FR 44901, Dec. 15, 1986; 54 FR 275, Jan. 5, 1989; 57 FR 27906, June 23, 1992]

§ 327.22 [Reserved]

§ 327.23 Compliance procedure for cured pork products offered for entry.

(a) *Definitions.* For the purposes of this section:

(1) A *Product* is that cured pork article which is contained within one Group as defined in paragraph (a)(2) of this section and which purports to meet the criteria for a single product designated under the heading ''Product Name and Qualifying Statements'' in the chart in § 319.104 or § 319.105 of this subchapter.

(2) A *Product Group* or a *Group* means one of the following:

(i) Group I, consisting of cured pork products which have been cooked while imperviously encased. Any product that fits into the Group shall be placed in this Group regardless of any other considerations.

(ii) Group II, consisting of cured pork products which have been water cooked. Any product that does not fit

into Group I but does fit into Group II shall be placed into Group II regardless of any other considerations.

(iii) Group III, consisting of boneless, smokehouse heated cured pork products. Any boneless product that does not fit into Group I or II shall be placed in Group III.

(iv) Group IV, consisting of bone-in or semi-boneless smokehouse heated cured pork products. Any product that is not completely boneless or still contains all the bone which is traditional for bone-in product and does not fit into Group I, II, or III shall be placed in this Group.

(3) *Protein Fat-Free Percentage, Protein Fat-Free Content, PFF Percentage, PFF Content or PFF* of a product means the meat protein (indigenous to the raw, unprocessed pork cut) content expressed as a percent of the non-fat portion of the finished product.

(4) A *PFF Standardized Difference* is the PFF of the sample minus the minimum PFF requirement, set forth in § 319.104 and § 319.105 of this subchapter, for the product being analyzed, divided by the Appropriate Standard Deviation for the product group.

(5) The *Absolute Minimum PFF Requirement* is that no laboratory result of an individual sample for PFF content be below the applicable minimum requirement of § 319.104 or § 319.105 of this subchapter by 2.3 or more percentage points for a Group I or II product or 2.7 or more percentage points for a Group III or IV product.

(6) A *PFF Standardized Arithmetic Average of the Country's Products* is the arithmetic average of PFF Standardized Differences from either 36 or 100 consecutively sampled lots of product entering the United States from a given producing country.

(7) A *PFF Standardized Weighted Average of the Country's Products* is an estimate of the average of the PFF Standardized Differences from either 36 or 100 consecutively sampled lots, adjusted for the size of the lot, of different types of cured pork product entering the United States from a given producing country. A Standardized Weighted Average is computed by multiplying the PFF Standardized Difference calculated for each lot by the number of pounds of product in each lot, adding those results together, and dividing the sum by the total weight of product from all the lots making up the average.

(8) The *Appropriate Standard Deviation* is based on within lot variability. That assigned to Groups I and II = 0.75 percent PFF and that assigned to Groups III and IV = 0.91 percent PFF.

(9) A *Lot* is all product of one type from one establishment presented by an importer as the unit for inspection at the Port of Entry.

(b) *Normal monitoring procedures.* Except for product imported from Canada, the Department shall collect sample(s) of cured pork product on a random basis from lots offered for entry at the Port of Entry and, after analyzing the sample for fat and indigenous protein content, calculate the PFF percentage. The product shall not be held pending laboratory results during the monitoring phase. The PFF percentage for each sample shall be considered along with the cumulative results of prior samples to assess the effectiveness of a country's overall compliance program and to determine the course of action for subsequent lots of product.

(1) Factors determining whether a country's inspection system is functioning adequately:

(i) The PFF percentage for each sample must not be below the minimum PFF requirement by 2.3 percentage points for cured pork products in Groups I and II or 2.7 percentage points for cured pork products in Groups III and IV.

(ii) Both of the PFF Standardized Averages, Arithmetic and Weighted, for the last 100 consecutive lots of all cured pork products from the country must be equal to or greater than zero. The count for the 100 consecutive lots starts with the lots arriving from that country after April 15, 1985.

(iii) Both of the PFF Standardized Averages, Arithmetic and Weighted, for the last 36 consecutive lots of all cured pork products from the country must be above the lowest 5 percent of the Normal distribution. This minimum value is minus 0.28 (−0.28) for the Arithmetic Average and depends on the production volume for the Weighted Average.

(2) Actions when calculations indicate that processing procedures in a country are out-of-compliance:

(i) If the PFF level of a sample taken during normal monitoring procedures is found to be as low as the Absolute Minimum PFF Requirement, the country of origin shall be notified; the lot involved shall be retained if still available in an official establishment or subject to detention or other actions pursuant to the Act; and all subsequently presented lots of that cured pork product from the same foreign establishment shall be held under retention until the provisions of paragraph (c) are satisfied.

(ii) If either of the PFF Standardized Averages, Arithmetic or Weighted, for the last 100 consecutive lots falls below zero or either of the PFF Standardized Averages for the last 36 consecutive lots falls below the upper 95 percent of the Normal distribution, all available cured pork product from the foreign country shall be subject to administrative retention and all subsequently presented lots of cured pork product from the foreign country shall be held under retention until the provisions of paragraph (c) are satisfied. The country of origin shall be notified, and shall be subject to other actions pursuant to the Act.

(c) *Retention.* When lots of cured pork product are under retention they shall be refused entry and reexported in accordance with § 327.13 of this subchapter unless they can be released in accordance with the provisions of paragraph (c)(1), establishments may be returned to normal monitoring procedures in accordance with paragraph (c)(2), and countries may be returned to normal monitoring procedures in accordance with paragraph (c)(3).

(1) If a lot is subject to retention procedures under this section, the Department shall collect five randomly selected sample units from each lot and determine the PFF of each sample unit. The lot may be released into commerce if:

(i) The average PFF percentage of the five randomly selected sample units is equal to or greater than the applicable minimum PFF percentage required by § 319.104 or § 319.105 of this subchapter, or

(ii) The product is relabeled under the supervision of a program employee so that it conforms to the provisions of § 319.104 or § 319.105 of this subchapter.

(2) If product from a foreign establishment is subject to retention procedures under this section, the foreign establishment may be returned to normal monitoring procedures when:

(i) Ten consecutively presented lots of that cured pork product from that establishment have been sampled as provided in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (50 in all) is above the Absolute Minimum PFF Percentage.

(3) If a country is subject to retention procedures under this section, the country shall be returned to normal monitoring procedures when:

(i) Twenty-five consecutively presented lots of cured pork product have been sampled as required in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (125 in all) is above the Absolute Minimum PFF Percentage; and

(iii) Both of the PFF Standardized Averages for 36 consecutive lots are in the required percentage of the Normal distribution; and

(iv) Both of the PFF Standardized Averages for 100 consecutive lots are zero or higher.

(4) The sample units collected under retention procedures as provided in paragraph (c)(2) of this section will not be included in the PFF standardized averages for 36 and 100 consecutive lots.

(d) *Adulterated and Misbranded Products.* Products not meeting specified PFF requirements, determined according to procedures set forth in this section, may be deemed adulterated under section 1(m)(8) of the Act (21 U.S.C. 601(m)(8)) and misbranded under section 1(n) of the Act (21 U.S.C. 601(n)).

(e) Activities requiring additional inspectional supervision, such as relabeling, shall be at the importer's expense. In addition, if the importer wishes, he or she may have samples analyzed at an accredited laboratory.

[50 FR 9792, Mar. 12, 1985, as amended at 54 FR 41049, Oct. 5, 1989]

§ 327.24 Appeals; how made.

Any appeal from a decision of any program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

[51 FR 37707, Oct. 24, 1986, as amended at 60 FR 67456, Dec. 29, 1995]

§ 327.25 Disposition procedures for product condemned or ordered destroyed under import inspection.

(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 section 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 or at official import inspection 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 or at an official import inspection 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.[1]

(2) 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 except as provided in paragraphs (a) (3) 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.[1] 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).[2]

(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) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard done, 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.

(5) 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

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

[2] Copies 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 Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register Library.