§ 327.22 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 regardless of any other considerations.

(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.

(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 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)).

(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

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1Information 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.