produced using processes ensuring that the products meet the following performance standards:

(1) Lethality. A 6.5-log₁₀ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum*, and no more than 1-log₁₀ multiplication of *Clostridium perfringens* within the product.

(b) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file and available to FSIS, a process schedule, as defined in §301.2 of this chapter. Each process schedule must be approved in writing by a process authority. An establishment must have access to the process schedule in order to evaluate and approve the safety and efficacy of each process schedule.

(c) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(64 FR 74, Jan. 6, 1999)

§ 318.18 Handling of certain material for mechanical processing.

Material to be processed into “Mechanically Separated (Species)” shall be so processed within 1 hour from the time it is cut or separated from carcasses or parts of carcasses, except that such product may be held for no more than 72 hours at 40 °F. (4 °C.) or less, or held indefinitely at 4 °F. (−18 °C.) or less. “Mechanically Separated (Species)” shall, directly after being processed, be used as an ingredient in a meat food product except that it may be held prior to such use for no more than 72 hours at 40 °F. (4 °C.) or less or indefinitely at 0 °F. (−18 °C.) or less.

(43 FR 26423, June 20, 1978, as amended at 47 FR 26256, June 29, 1982)

§ 318.19 Compliance procedure for cured pork products.

(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 the chart in §319.105.

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

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

Group II, consisting of cured pork products which have been water cooked. Any product which does not fit into Group I but does fit into Group II will be placed into Group II regardless of any other considerations.

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

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, Group II, or Group III shall be placed in this Group.

(3) A lot is that product from one production shift.

(4) A production rate is frequency of production, expressed in days per week.

(5) Protein fat free content, protein fat free percentage, PFF, 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.

(b) Normal Compliance Procedures. The Department shall collect samples of cured pork products and analyze them.
for their PFF content. Analyses shall be conducted in accordance with the “Official Methods of Analysis of the Association of Official Analytical Chemists §§§950.46, and 928.08 (Chapter 39). The “Official Methods of Analysis of the Association of Official Analytical Chemists,” 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each analytical result shall be recorded and evaluated to determine whether future sampling of product Groups within an official establishment shall be periodic or daily under the provisions of paragraph (b)(1) of this section, and if the affected lot and subsequent production of like product shall be U.S. retained, or administratively detained, as appropriate, as provided in paragraph (b)(2) of this section.\(^1\)


\(^2\) Rules for Rounding:

1. Laboratory results for percent meat protein and fat will be reported to the second decimal place (hundredths).
   
2. PFF and Sample Values for charting purposes will be calculated from the reported laboratory results to the second decimal place. Rounding of calculations to reach two decimal places will be done by the following rule:
   
   All values of five-thousandths (0.005) or more will be rounded up to the nearest hundredth. All values of less than five-thousandths (0.005) will be dropped.
   
3. For compliance with the Absolute Minimum PFF requirements, the PFF will be rounded to the first decimal place (tenths). Rounding of calculations to reach one decimal place will be done by the following rule:
   
   All PFF values of five-hundredths (0.05) or more will be rounded up to the nearest tenth. All PFF values of less than five-hundredths (0.05) will be dropped.
   
4. For product disposition (pass-fail of a minimum PFF standard for retained product) the average PFF calculation will be rounded to the first decimal place. Individual PFF Values will be calculated to the nearest hundredth as in (2) above. The average, however, will be rounded to the nearest tenth as in (3) above.

(1) Criteria to determine sampling frequency of Product Groups. For each official plant preparing cured pork products, Product Groups shall be sampled periodically or daily. Analytical results shall be evaluated and the sampling frequency determined as follows:

(i) Determine the difference between the individual PFF analysis and the applicable minimum PFF percentage requirement of §319.104 or §319.105. The resulting figure shall be negative when the individual sample result is less than the applicable minimum PFF percentage requirement and shall be positive when the individual sample result is greater than the applicable minimum PFF percentage requirement.

(ii) Divide the resulting number by the standard deviation assigned to the Product Group represented by the sample to find the Standardized Difference. The standard deviation assigned to Groups I and II is .75 and to Groups III and IV is .91.

(iii) Add 0.25 to the Standardized Difference to find the Adjusted Standardized Difference.

(iv) Use the lesser of 1.90 and the Adjusted Standardized Difference as the Sample Value.

(v) Cumulatively total Sample Values to determine the Group Value. The first Sample Value in a Group shall be the Group Value, and each succeeding Group Value shall be determined by adding the most recent Sample Value to the existing Group Value; provided, however, that in no event shall the Group Value exceed 1.00. When calculation of a Group Value results in a figure greater than 1.00, the Group Value shall be 1.00 and all previous Sample Values shall be ignored in determining future Group Values.

(vi) The frequency of sampling of a Group shall be periodic when the Group Value is greater than 1.40 (e.g., −1.39, −1.14, 0, 0.50, etc.) and shall be daily when the Group Value is −1.40 or less (e.g., −1.40, −1.45, −1.50, etc.); provided, however, that once daily sampling has been initiated, it shall continue until the Group Value is 0.00 or greater, and each of the last seven Sample Values is −1.65 or greater (e.g., −1.63, −1.50, etc.), and there is no other product within the affected Group being U.S. retained as produced.
under provisions of paragraph (b)(2) or (c).

(2) Criteria for U.S. retention or administrative detention of cured pork products for further analysis. Cured pork products shall be U.S. retained, or administratively detained, as appropriate, when prescribed by paragraphs (b)(2) (i) or (ii) of this section as follows:

(i) Absolute Minimum PFF Requirement. In the event that an analysis of an individual sample indicates a PFF content below the applicable minimum requirement of §319.104 or §319.105 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, the lot from which the sample was collected shall be U.S. retained if in an official establishment and shall be subject to administrative detention if not in an official establishment unless returned to an official establishment and there U.S. retained. Any subsequently produced lots of like product and any lots of like product for which production dates cannot be established shall be U.S. retained or subject to administrative detention. Such administratively detained product shall be handled in accordance with part 329 of this subchapter, or shall be returned to an official establishment and subject to the provisions of paragraph (c)(1) (i) or (ii) of this section, or shall be relabeled in compliance with the applicable standard, under the supervision of a program employee, at the expense of the product owner. Disposition of such U.S. retained product shall be in accord with paragraph (c) of this section.

(ii) Product Value requirement. The Department shall maintain, for each product prepared in an official establishment, a Product Value. Except as provided in paragraph (c)(1) (i) or (ii) of this section, and its use to determine if a product shall be U.S. retained shall be as follows:

(A) Determine the difference between the individual PFF analysis and applicable minimum PFF percentage requirement of §319.104 and §319.105. The resulting figure shall be negative when the individual sample result is less than the applicable minimum PFF percentage requirement and shall be positive when the individual sample result is greater than the applicable minimum PFF percentage requirement.

(B) Divide the difference determined in paragraph (b)(2)(ii)(A) of this section by the standard deviation assigned to the product’s Group in paragraph (b)(1)(ii) of this section to find the standardized difference.

(C) Use the lesser of 1.65 and the standardized difference as the Sample Value.

(D) Cumulatively total Sample Values to determine the Product Value. The first Sample Value of a product shall be the Product Value, and each succeeding Product Value shall be determined by adding the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When calculation of a Product Value results in a figure greater than 1.15, the Product Value shall be 1.15, and all previous Sample Values shall be ignored in determining future Product Values.

(E) Provided daily group sampling is in effect pursuant to the provisions of paragraph (b)(1) of this section, and provided further the Product Value is $1.65 or less (e.g., $1.66), the affected lot (if within the official establishment) and all subsequent lots of like product prepared by and still within the official establishment shall be U.S. retained and further evaluated under paragraph (c) of this section. Except for release of individual lot pursuant to paragraph (c)(1), subsequently produced lots of like product shall continue to be U.S. retained until discontinued pursuant to paragraph (c)(2) of this section.

(c) Compliance procedure during product retention. When a product lot is U.S. retained under the provisions of paragraph (b)(2) of this section, the Department shall collect three randomly selected samples from each such lot and analyze them individually for PFF content. The PFF content of the three samples shall be evaluated to determine disposition of the lot as provided in paragraph (c)(1) of this section and the action to be taken on subsequently
produced lots of like product as provided in paragraph (c)(2) of this section.³

(1) A product lot which is U.S. retained under the provisions of paragraph (b)(2) of this section may be released for entry into commerce provided one of the following conditions is met:

(i) The average PFF content of the three samples randomly selected from the lot is equal to or greater than the applicable minimum PFF percentage required by §319.104 or §319.105. Further processing to remove moisture for the purpose of meeting this provision is permissible. In lieu of further analysis to determine the effects of such processing, each 0.37 percent weight reduction due to moisture loss resulting from the processing may be considered the equivalent of a 0.1 percent PFF gain.

(ii) The lot of the product is relabeled to conform to the provisions of §319.104 or §319.105, under the supervision of a program employee.

(iii) The lot is one that has been prepared subsequent to preparation of the lot which, under the provisions of paragraph (c)(2) of this section, resulted in discontinuance of U.S. retention of new lots of like product. Such lot may be released for entry into commerce prior to receipt of analytical results for which sampling has been conducted. Upon receipt of such results, they shall be subjected to the provisions of paragraphs (b)(2)(i) and (c)(2) of this section.

(2) The PFF content of three randomly selected samples from each U.S. retained lot shall be used to maintain the Product Value described in paragraph (c)(2)(ii). The manner and effect of such maintenance shall be as follows: (i) Find the average PFF content of the three samples.

(ii) Determine the difference between that average and the applicable minimum PFF percentage requirement of §319.104 or §319.105. The resulting figure shall be negative when the average of the sample results is less than the applicable minimum PFF percentage requirement and shall be positive when the average of the sample results is greater than the applicable minimum PFF requirements.

(iii) Divide the resulting figure by the standard deviation assigned to the product’s Group in paragraph (b)(1)(ii) of this section, to find the standardized difference.

(iv) Use the lesser of 1.30 and the standardized difference as the Sample Value.

(v) Add the first Sample Value thus calculated to the latest Product Value calculated under the provisions of paragraph (c)(2)(ii) of this section to find the new Product Value. To find each succeeding Product Value, add the most recent Sample Value to the existing Product Value; provided, however, that in no event shall the Product Value exceed 1.15. When the addition of a Sample Value to an existing Product Value results in a figure greater than 1.15, the Product Value shall be 1.15 and all previous Sample Values shall be ignored in determining future Product Values.

(vi) New lots of like product shall continue to be retained pending disposition in accordance with paragraph (c)(1) of this section until, after 5 days of production, the Product Value is 0.00 or greater, and the PFF content of no individual sample from a U.S. retained lot is less than the Absolute Minimum PFF requirement specified in paragraph (b)(2)(i) of this section. Should an individual sample fail to meet its Absolute Minimum PFF requirement, the 5-day count shall begin anew.

(vii) When U.S. retention of new lots is discontinued under the above provisions, maintenance of the Product Value shall revert to the provisions of paragraph (b)(2)(ii) of this section.

(3) For purposes of this section, the plant owner or operator shall have the option of temporarily removing a product from its Product Group, provided product lots are being U.S. retained, as produced, and provided further that the average production rate of the product, over the 8-week period preceding the
§ 318.22 Determination of added water in cooked sausages.

(a) For purposes of this section, the following definitions apply.

(1) Cooked sausage. Cooked sausage is any product described in §319.140 and §§319.180–319.182 of this chapter.

(2) Group 1 Protein-Contributing Ingredients. Ingredients of livestock or poultry origin from muscle tissue which is skeletal or which is found in the edible organs, with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing; meat byproducts; mechanically separated (species); and poultry products; except those ingredients processed by hydrolysis, extraction, concentrating or drying.

(3) Group 2 Protein-Contributing Ingredients. Ingredients from Group 1 protein-contributing ingredients processed by hydrolysis, extraction, concentrating, or drying, or any other ingredient which contributes protein.

(b) The amount of added water in cooked sausage is calculated by:

(1) Determining by laboratory analysis the total percentage of water contained in the cooked sausage; and

(2) Determining by laboratory analysis the total percentage of protein contained in the cooked sausage; and

(3) Calculating the percentage of protein in the cooked sausage contributed by the Group 2 protein-contributing ingredients; and

(4) Subtracting one percent from the total percentage of protein calculated in (b)(3)); and

(5) Subtracting the remaining percentage of protein calculated in (b)(3) from the total protein content determined in (b)(2)); and

(6) Calculating the percentage of indigenous water in the cooked sausage by multiplying the percentage of protein determined in (b)(5) by 4. (This amount is the percentage of water attributable to Group 1 protein-contributing ingredients and one percent of Group 2 protein-contributing ingredients in a cooked sausage.); and