

meeting the performance standards established for the product in question. A process authority must have access to the establishment 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 744, 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 0 °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 28256, 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 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.

(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).<sup>1</sup> 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.<sup>2</sup>

<sup>1</sup>A copy of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

<sup>2</sup>Rules for Rounding:

*Continued*

(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 0.75 and to Groups III and IV is 0.91.

(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.

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 next highest 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 next highest 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.

(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 subjected to the provisions of paragraph (c)(1) (i) or (ii) of this section, or shall be re-labeled 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 accordance 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)(2) of this section, calculation of the Product Value 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.<sup>3</sup>

(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

<sup>3</sup>If the processor does not wish to have the product evaluated in this manner, alternate sampling plans may be used provided such plans have been formulated by the processor and approved by the Administrator prior to evaluation by the three-sample criteria, and provided the analyses specified in such plans are performed at the expense of the processor.

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 week in which the first U.S. retained lot was prepared, is not greater than 20 percent of the production rate of its Group. When a product is thus removed from its Group, analytical results of product samples shall not cause daily sampling of the Group. When pursuant to paragraph (c)(2)(vi) of this section, new lots of the product are no longer being U.S. retained, the product shall again be considered with its Group.

(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) *Quality control.* Cured pork products bearing on their labeling the statement "X% of Weight is Added Ingredients" shall be prepared only under a quality control system or program in accordance with §318.4 of this subchapter. With respect to any other cured pork product, official establishments may institute quality control procedures under §318.4 of this subchapter. Cured pork products produced in such establishments may be exempt from the requirements of this section,

provided in plant quality control procedures are shown to attain the same or higher degree of compliance as the procedures set forth in this section; provided, however, that all cured pork products produced shall be subject to the applicable Absolute Minimum PFF content requirement, regardless of any quality control procedures in effect.

[49 FR 14877, Apr. 13, 1984; 49 FR 33434, Aug. 23, 1984, as amended at 59 FR 33642, June 30, 1994; 60 FR 10304, Feb. 24, 1995; 62 FR 45025, Aug. 25, 1997]

#### § 318.20 Use of animal drugs.

Animal drug residues are permitted in meat and meat food products if such residues are from drugs which have been approved by the Food and Drug Administration and any such drug residues are within tolerance levels approved by the Food and Drug Administration, unless otherwise determined by the Administrator and listed herein.

[50 FR 32165, Aug. 9, 1985]

#### § 318.21 Accreditation of chemistry laboratories.

(a) *Definitions—Accredited laboratory*—A non-Federal analytical laboratory that has met the requirements for accreditation specified in this section and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of official samples is to be made by the establishment using the accredited laboratory.

*Accreditation*—Determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and part 381 of this chapter for the presence and amount of all four food chemistry analytes (protein, moisture, fat, and salt); or a determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and part 381 of this chapter for the presence and amount of one of several classes of chemical residue, in accordance with the requirements of the Accredited Laboratory Program. Accreditations are granted separately for the food chemistry analysis of official samples and for the analysis of such samples for any one of the several classes

of chemical residue. A laboratory may hold more than one accreditation.

*AOAC methods*—Methods of chemical analysis, Chapter 39, Association of Official Analytical Chemists (AOAC), published in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990.<sup>1</sup> 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.

*Chemical residue misidentification*—see "correct chemical residue identification" definition.

*Coefficient of variation (CV)*—The standard deviation of a distribution of analytical values multiplied by 100, and divided by the mean of those values.

*Comparison Mean*—The average, for a sample, of all accredited and FSIS laboratories' average results, each of which has a large deviation measure of zero, except when only two laboratories perform the analysis, as in the case of split sample analysis by both an accredited laboratory and an FSIS laboratory. In the latter case, the comparison mean is the average of the two laboratories' results. For food chemistry, a result for a laboratory is the obtained analytical value; for chemical residues, a result is the logarithmic transformation of the obtained analytical value.

*Correct chemical residue identification*—Correct identification by a laboratory of a chemical residue whose concentration, in a sample, is equal to or greater than the minimum reporting level for that residue, as determined by the median of all positive analytical values obtained by laboratories analyzing the sample. Failure of a laboratory to report the presence such a chemical residue is considered a misidentification. In addition, reporting the presence of a residue at a level

<sup>1</sup>A copy of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 15th edition, 1990, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.