

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #2

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2010 JUN 14 PM 1:44

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Department of Agriculture TITLE NUMBER: 61

RULE TYPE: Legislative CITE AUTHORITY: WV Code 19-2B-3X

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 16

TITLE OF RULE BEING AMENDED: Inspection of Meat and Poultry

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON July 14, 2010 AT 4:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

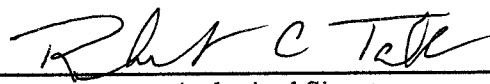
West Virginia Department of Agriculture

Meat and Poultry Inspection Division
Attn: Robert E. Pitts, DVM

State Capitol
1900 Kanawha Blvd., East

Charleston, WV 25305

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.



Authorized Signature

Deputy Commissioner
June 14 2010

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL



State of West Virginia
DEPARTMENT OF AGRICULTURE
Gus R. Douglass, Commissioner

Janet L. Fisher
Deputy Commissioner

Bob Tabb
Deputy Commissioner

SUMMARY OF THE PROPOSED RULE

The intent of the proposed revisions to the existing rules is to update the rules to conform to Federal requirements. They are intended to incorporate by reference the applicable changes to USDA mandatory meat and poultry inspection regulations promulgated in the *Federal Register* between May 1, 2007 and June 1, 2010. Two regulations under "Deleted Regulations" were eliminated since they no longer exist in the Federal regulations. The revisions also eliminated four federal documents which are no longer produced by FSIS or have been eliminated from reference.



State of West Virginia
DEPARTMENT OF AGRICULTURE
Gus R. Douglass, Commissioner

Janet L. Fisher
Deputy Commissioner

Bob Tabb
Deputy Commissioner

STATEMENT OF CIRCUMSTANCES

Rules on Inspection of
Meat and Poultry
Title 61, Series 1C

The Federal Meat Inspection Act and the Poultry Products Inspection Act require a State meat and poultry inspection program in terms of law, regulations, inspection procedures, etc be "at least equal to" the Federal program.

Periodical updates to our rules are needed in order to maintain the equivalency of the State inspection program and continuation of the Federal 50% funding for the program (approximately \$774,000 per year).

§61-16-2. Incorporation by Reference of Federal Meat and Poultry Inspection Regulations.

Change requested to update the adoption of new regulations that have been implemented between May 1, 2007 and June 1, 2010.

§61-16-3. Deleted Regulations.

MPID recommends the reversing of the deletion of 303.1(d)(2)(l)(c) for two reasons. One is that such section does not exist. The intended regulation is 303.1(d)(2)(i)(c) which still is recommended for removal from deletions. This would follow more closely the federal recommendations for allowing the exemption from inspection at retail stores and restaurants of "Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;"

MPID recommends the removal of 381.19(a)(2) which no longer is in the federal regulations.

MPID recommends the removal of "and (4)" from the following statement: "In 9CFR 381.123(b)(2) and (4) the words "and accompanied by the prefix 'P' are deleted". This portion had been previously deleted in the list of deleted regulations.

§61-16-5. The United States Department of Agriculture's Guidelines and Procedures Applicable to the West Virginia Department of Agriculture.

MPID recommends the removal of:

- (2) "The Meat and Poultry Inspection Manual";
- (3) "Sanitation Handbook for Meat and Poultry Inspectors";
- (4) "Accepted Meat and Poultry Equipment" MPI-2;
- (5) "List of Proprietary Substances and Nonfood Compounds", Miscellaneous Publication Number 1419;

These documents have not been in print for several years and have been replaced by previously adopted regulations.

§61-16-6. Licensing.

In section 6.2.1.1. "A current certificate from the local health authority certifying the water potability at the establishment and approval of the sewage disposal system of the establishment." MPID recommends inserting the words "or state" after health and before authority since some sewage disposal systems are now approved by the DEP.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Inspection of Meat and Poultry

Rule Title: _____

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Department of Agriculture

Address: State Capitol, 1900 Kanawha Blvd., East
Charleston, WV 25305-0170

Phone Number: 304-558-2206 Email: rpitts@ag.state.wv.us

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The agency approved rule will have no economic impact on costs and revenues of State government.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services			
Current Expenses			
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: Inspection of Meat and Poultry

Rule Title: _____

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

N/A

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The proposed rules will only slightly modify inspection techniques and procedures but will have no fiscal impact.

Date: JUNE 14 2010

Signature of Agency Head or Authorized Representative

Rhett C. Telle
Deputy Commissioner

**TITLE 61
LEGISLATIVE RULE
DEPARTMENT OF AGRICULTURE**

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**SERIES 16
INSPECTION OF MEAT AND POULTRY**

OFFICE WEST VIRGINIA
SECRETARY OF STATE**§61-16-1. General.**

1.1. Scope. -- This rule is established in order to implement the requirements of W. Va. Code §19-2B-1 et seq. Inspection of Meat and Poultry, and to maintain and administer an effective State-Federal Cooperative Meat and Poultry Inspection Program in the State of West Virginia by establishing requirements which equal those imposed by the applicable provisions of the Federal Meat Inspection Act (34 Stat. 1260) as amended by the Wholesome Meat Act (81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, U.S.C., Sec. 601 et seq.), and the Poultry Products Inspection Act (71 Stat. 441), as amended by the Wholesome Poultry Products Act (82 Stat. 791; U.S.C. 451 et seq.). This rule establishes general operating procedures, requirements and standards in the West Virginia Department of Agriculture, Meat and Poultry Inspection Division.

1.2. Authority. -- W. Va. Code §19-2B-3.

1.3. Filing Date. -- ~~April 8, 2008.~~

1.4. Effective Date. -- ~~July 1, 2008.~~

§61-16-2. Incorporation by Reference of Federal Meat and Poultry Inspection Regulations.

The Mandatory Meat Inspection Regulations (9 CFR, Parts 301 et seq.) the Mandatory Poultry Products Inspection Regulations (9 CFR, Part 381) and Regulatory Requirements Under the Federal Meat Inspection Act and the Poultry Products Inspection Act (9 CFR, Parts 416, 417, 424, 430 and 441) of the United States Department of Agriculture, promulgated in the Federal Register prior to ~~May 1, 2007~~ June 1, 2010 are hereby adopted in their entirety with the exception of the deleted regulations specified in section 3 of this rule.

§61-16-3. Deleted Regulations.

The following sections of the Federal regulations governing the mandatory meat inspection (9 CFR, Part 301 et seq.) and the mandatory poultry products inspection (9 CFR, Part 381) of the United States Department of Agriculture incorporated by reference under section 2 of this rule are deleted and are not rules of the West Virginia Department of Agriculture: 302.2; 303.1 (c); ~~303.1 (d)(2)(f)(e)~~; 304; 305.2 (b); 307.5; 307.6; 312; 316.12; 316.13 (c); 317.7; 317.9; 318.8; 321; 322; 327; 329.6; 329.7; 329.8; 329.9; 331; 335; 381.6; 381.10 (a)(2), (5), (6), and (7); 381.10 (b); 381.13 (b); 381.16; 381.17; ~~381.19 (a)(2)~~; 381.30; 381.31; 381.38; 381.39; 381.96, 381.98, 381.104 through 381.112; 381.123 (b)(1) and (4); 381.179; 381.185; 381.186; 381.195 through 381.236.

In 9CFR 381.10(a) (3) and (4) the words "and the statement 'Exempt - P. L. 90-492'" are deleted.

In 9CFR 381.123(b) (2) ~~and (4)~~ the words "and accompanied by the prefix 'P' are deleted".

§61-16-4. Definitions.

4.1. All terms used in this rule are those defined in W. Va. Code §19-2B-2, except for the terms defined in this section.

4.2. Definitions in the incorporated parts of the Federal regulations on mandatory meat inspection (9 CFR, Part 301 et seq.) and mandatory poultry products inspection (9 CFR, Part 381) of the United States Department of Agriculture are amended to read as follows:

4.2.1. "The Act" means W. Va. Code §19-2B-1 et seq.

4.2.2. "The United States Department

of Agriculture" and "Department" means the West Virginia Department of Agriculture. For brevity, the acronym WVDA for the West Virginia Department of Agriculture is used in this rule.

4.2.3. "Secretary" means the Commissioner of Agriculture.

4.2.4. "Administrator", "Regional Director", and "Area Supervisor" mean the Director, Meat and Poultry Inspection Division, WVDA.

4.2.5. "Federal Meat Inspection", "Program", "Federal Inspection", "Federal Poultry Inspection", "Meat and Poultry Inspection Program", "Inspection Service", "Standards and Labeling Division", "Meat and Poultry Inspection", "Technical Services", and "Agency" mean the Meat and Poultry Inspection Division, WVDA.

4.2.6. "Federal" means State.

4.2.7. "Food Inspector", "Inspection Service Employee", "USDA Inspector", "USDA Program Official", and "Program Inspector" mean Inspector, Meat and Poultry Inspection Division, WVDA.

4.2.8. "Inspection Service Supervisor", "Veterinary Inspector", and "Circuit Supervisor" mean Veterinary Supervisor, Meat and Poultry Inspection Division, WVDA.

4.2.9. "Food Safety and Inspection Service" means the Meat and Poultry Inspection Division, WVDA.

4.2.10. "USDA Inspection Legend" and "Official Inspection Legend" mean WVDA Inspection Legend.

4.2.11. "Federally Inspected and Passed", "U.S. Inspected and Passed", "U.S. Inspected for Wholesomeness", and "Federally Inspected for Wholesomeness" mean WVDA Inspected and Passed.

4.2.12. "U.S. Passed for Cooking" means WVDA Passed for Cooking.

4.2.13. "U.S. Passed for Refrigeration" means WVDA Passed for Refrigeration.

4.2.14. "U.S. Inspected and Condemned" means WVDA Inspected and Condemned.

4.2.15. "U.S. Retained" or "U.S. Detained" means WVDA Retained.

4.2.16. "U.S. Rejected" means WVDA Rejected.

4.2.17. "U.S. Suspect" means WVDA Suspect.

4.2.18. "U.S. Condemned" means WVDA Condemned.

4.2.19. "U.S. Government Seals" means WVDA Seals.

4.3. Whenever an official form, certificate, or seal is designated by Federal regulations, the appropriate WVDA form, certificate, or seal shall be substituted.

§61-16-5. The United States Department of Agriculture's Guidelines and Procedures Applicable to the West Virginia Department of Agriculture.

The following publications prepared and approved by the United States Department of Agriculture are applicable to the West Virginia Department of Agriculture, as determined by the Commissioner of Agriculture:

(1) "U.S. Inspected Meat and Poultry Packing Plants: A Guide to Construction and Layout", Agriculture Handbook 570;

~~(2) "The Meat and Poultry Inspection Manual";~~

~~(3) "Sanitation Handbook for Meat and Poultry Inspectors";~~

~~(4) "Accepted Meat and Poultry Equipment" MPI-2;~~

~~(5) "List of Proprietary Substances and Nonfood Compounds", Miscellaneous~~

~~Publication Number 1419;~~

(62) "Standards and Labeling Policy Book"; and

(73) Food Safety and Inspection Service's Directives, Notices, and Bulletins.

§61-16-6. Licensing.

6.1. Application for license and inspection - Every commercial slaughterer, custom slaughterer, commercial processor, custom processor, or distributor shall obtain a license from the Commissioner.

6.1.1. An applicant for a license shall make application on an official form furnished by the Commissioner and shall complete the application to include all information requested. Only the applicant named in the application may conduct operations at the establishment for which the license is granted.

6.1.2. The licensee shall apply for a new license when ownership or the location of the business changes.

6.2. Drawings and specification to be furnished.

6.2.1. Each applicant for the license shall submit to the Director, Meat and Poultry Inspection Division; WVDA;

6.2.1.1. Three (3) sets of complete drawings containing a plot plan showing the limits of the establishment's premises, locations in outline of buildings on the premises, cardinal points of the compass, and roads and railroads serving the establishment; the floor plans of the establishment for which inspection is requested, showing the locations of principal pieces of equipment, floor drains, principal drainage lines, handwashing basins and hose connections for cleanup purposes; and a room schedule showing the finish of walls, floors, and ceilings of all rooms in the establishments;

6.2.1.2. Three (3) sets of specifications which shall include statements, describing water supply, plumbing, drainage, refrigeration, equipment, lighting, and

operations to be performed at the establishment; and

6.2.1.3. A current certificate from the local or state health authority certifying the water potability at the establishment and approval of the sewage disposal system of the establishment.

§61-16-7. Official Inspection Marks and Devices.

7.1. General - The inspection marks and devices, prescribed or referenced in this section are official marks and devices, for purposes of the W. Va. Code §19-2B-6 and shall be used in accordance with the provisions of this section and the United States Department of Agriculture regulations governing meat and poultry inspection as incorporated in this rule.

7.2. The inspection marks shall be affixed by the establishment under the oversight of the inspectors of the Meat and Poultry Inspection Division, WVDA.

7.3. Inspection legends on animal carcasses and parts of carcasses.

7.3.1. The inspection legend to identify WV inspected and passed animal carcasses, primal cuts, beef livers, beef tongues, beef hearts, and smoked meats not in casings and for application to materials that enclose carcasses or parts of carcasses, is as shown in this subdivision. The establishment number shall be placed in the inspection legend by the establishment where the three zeros appear. The size of the inspection legend shall be 1-7/8"x2".



7.3.2. The inspection legend may be proportionally reduced in size, provided it shall not be smaller than 7/8"x1". for application to the loins and ribs of pork, beef tails, and

sausages in animal casings.

7.4. Inspection legends on labels.

7.4.1. The inspection legend required to be shown on all labels for inspected and passed products of cattle, sheep, swine, goats, and poultry shall be in the form as shown in subdivision 7.3.1 of this rule, except that it need not be of the size illustrated, provided that it is of a sufficient size and of such color as to be conspicuously displayed and readily legible and the same proportions of letter size and boldness are maintained. The establishment number shall be placed in the inspection legend where the three zeros appear, and it may be preceded by the abbreviation "EST."

7.4.2. The inspection legend shall be applied on labels by mechanical means and shall not be applied by a hand stamp.

7.4.3. The inspection legend described in subdivision 7.3.1 of this section may also be used on shipping containers, band labels, artificial casings, and other articles with the approval of the Director, Meat and Poultry Inspection Division, WVDA.

7.5. Any brand, stamp, label, or other device approved by the Director, Meat and Poultry Inspection Division, WVDA, and bearing any inspection legend presented in this section is an official device for purposes of the W. Va. Code §19-2B-6.

7.6. Custom stamps and devices to identify custom slaughtered animals or custom prepared product.

7.6.1. An establishment licensed for custom slaughter, custom processing operations, or both shall identify all custom carcasses, carcass parts, and custom meats with:

7.6.1.1. A custom stamp as provided for in subdivision 7.6.2 of this rule and a custom stamp with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height applied to the animal carcass immediately after slaughter;

7.6.1.2. A custom stamp with the words "NOT FOR SALE" in uppercase letters at

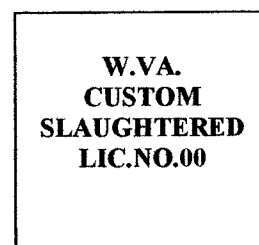
least 3/8" in height applied immediately upon receipt of a carcass or carcass parts which were slaughtered at a location other than the receiving licensed establishment;

7.6.1.3. A tag made from a material that is nontoxic and waterproof, that identifies the name of the owner or a number which identifies the owner of the meat, which must be placed on the carcass immediately after slaughter or on the carcass or carcass parts upon receipt. The tag may be omitted if the identification number is legibly applied directly on the meat or poultry by an approved marking pencil;

7.6.1.4. A stamp or legible printing or pressure sensitive tape with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height on all custom wrapped or packaged meats or poultry immediately after final preparation. All custom meat or poultry must remain so identified while on the establishment's premises; and

7.6.1.5. A stamp, legible printing or pressure sensitive tape or tag attached with the words "NOT FOR SALE" in uppercase letters at least 3/8" in height on closed containers when utilized for packing unwrapped, wrapped, or packaged custom meats or poultry. All custom meat or poultry must remain so identified immediately after packing the containers and while on the establishment's premises.

7.6.2. The official custom stamp (brass faced) required to identify animal carcasses or parts of carcasses resulting from custom establishment slaughter is as shown in this subdivision. The size of the stamp shall be 2"X2" with uppercase letters 3/8" in height.



§61-16-8. Overtime and Holiday Inspection Service.

8.1. The management of a licensed establishment shall reimburse WVDA for the cost of inspection service furnished on any holiday as specified in subsection 8.3 of this Section, or for providing inspection services for more than eight (8) hours on any day or more than forty (40) hours in any administrative workweek, Saturday through Friday.

8.2. When a licensed establishment requires an inspection service on a holiday or for more than eight (8) hours on any other day, it shall request the veterinary supervisor to furnish inspection during that period. The request shall be made at least seven (7) days before the holiday and at least two (2) days in advance of planned overtime.

8.3. Holidays are those specified in W. Va. Code §2-2-1.

8.4. The Commissioner shall determine from time to time the rate for overtime and holiday services.

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Title 9: Animals and Animal Products

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PART 303—EXEMPTIONS

Section Contents

[§ 303.1 Exemptions.](#)

[§ 303.2 Experimentation: Intensity of inspection coverage.](#)

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§ 303.1 Exemptions.



(a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:

(1) The slaughtering by any individual of livestock of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock exclusively for use by him and members of his household and his nonpaying guests and employees;

(2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of his own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided*, That the following requirements are met by such custom operator;

(i) Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§416.1 through 416.6, except for: §416.2(g)(2) through (6) of this chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter of shall apply to those operations.

(ii) If the custom operator prepares or handles any products for sale, they are kept separate and apart from the custom prepared products at all times while the latter are in his custody;

(iii) The custom prepared products are plainly marked "Not for Sale" as provided in §316.16 of this subchapter, immediately after being prepared and are kept so identified until delivered to the owner; and

(iv) If exempted custom slaughtering or other preparation of products is conducted in an official establishment, all facilities and equipment in the official establishment used for such custom operations shall be thoroughly cleaned and sanitized before they are used for preparing any products for sale.

(b)(1) The exempted custom prepared products shall be prepared and handled in accordance with the provisions of §§318.5, 318.6, 318.7, 318.10, and 318.300 through 318.311 of this subchapter and shall not be adulterated as defined in paragraph 1(m) of the Act. *Provided*, That the provisions of §§318.5, 318.6, 318.10, and 318.300 through 318.311 relating to inspection or supervision of specified activities or other action by a Program inspector, and the provisions of §318.6(b)(9) and (10), shall not apply to the preparation and handling of such exempted products.

(2) The exempted custom prepared products shall comply with the requirements of §§316.16 and 317.16 of this subchapter.

(3) The custom operators claiming exemption under paragraph (a)(2) of this section shall keep records, in addition to records otherwise required by part 320 of this subchapter, showing the numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products.

(4) Articles capable of use as human food, resulting from the exempted custom slaughter or other preparation of products shall be promptly denatured or otherwise identified in accordance with §325.13 of this subchapter and not removed from the establishment where the custom operations are conducted until so identified, unless they are delivered to the owner of the articles for use in accordance with paragraph (a)(2) of this section.

(c) It has been determined that it is impracticable to provide inspection of the preparation of products at establishments in any unorganized Territory at which livestock are slaughtered or their products are prepared for distribution solely within such jurisdiction and that exempting such establishments from requirements of the Act for such inspections under the conditions stated in this section will otherwise facilitate enforcement of the Act. Therefore, such inspection requirements of the Act and of the regulations in this subchapter shall not apply at such establishments if they are operated in accordance with the regulations in part 416, §§416.1 through 416.5 of this chapter. However, the Administrator may refuse, withdraw, or modify any exemption under this paragraph when he determines in any specific case in accordance with the applicable rules of practice that such action is necessary to effectuate the purposes of this Act.

(d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:

(a) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;

(b) Grinding and freezing products made from meat;

(c) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;

(d) Breaking bulk shipments of products;

(e) Wrapping or rewrapping products.

(ii) Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to

be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

	One-half carcass pounds
Cattle	300
Calves	37.5
Sheep	27.5
Swine	100
Goats	25

(iii) A retail store is any place of business where:

(a) The sales of product are made to consumers only;

(b) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds \$500. Notice of the adjusted dollar limitation will be published in the Federal Register.¹

¹ The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food and Safety Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447-3219.

(c) Only federally or State inspected and passed product is handled or used in the preparation of any product, except that product resulting from the custom slaughter or custom preparation of product may be handled or used in accordance with paragraph (a)(2) and (b) of this section but not for sale;

(d) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section;

(e) The preparation of products for sale to household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section; and

(f) The preparation of products for sale to other than household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) (a), (b), (d), and (e) of this section. (A retail store at which custom slaughtering or preparation of products is conducted is not thereby disqualified from exemption as a retail store under this paragraph (d).)

(iv) *Restaurants.* (a) A restaurant is any establishment where:

(1) Product is prepared only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(2) Only federally or State inspected and passed product or such product prepared at a retail store exempted under paragraph (d)(2)(iii) of this section is handled or used in the preparation of any product;

(3) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(4) The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(b) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(c) For purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirements of this paragraph: *Provided*, That the requirements of §§320.1 through 320.4 of this subchapter apply to such facility. *Provided further*, That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary, if the Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) Similar retail-type establishment: Any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraphs (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) Consumer: Any household consumer, hotel, restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail store claiming exemption under this paragraph (d), in any designated State or organized Territory that is identified under section 205 of the Act (as one that does not have or is not exercising adequate authority with respect to recordkeeping requirements) has been operated in violation of the conditions prescribed in this section for exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail store and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator still has reason to believe that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail store would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of total monthly purchases and of total monthly sales of meat, meat byproducts, and meat food products, in terms of dollar values of the products involved. Such records shall separately show total sales to household consumers and total sales to other consumers and shall be maintained for the period prescribed in §320.3 of this subchapter. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to meat pizzas containing meat food product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the meat pizzas are to be served in public or private nonprofit institutions, provided that the meat pizzas are ready-to-eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1-102, except 1-102(z) and the provisions of Chapters 2 through 8, except sections 2-102(a) and (b), 2-302(d), 2-403(a), 2-403(c), 2-404, 2-405, 2-407, 2-502 through 2-506, 2-508, 2-509, 4-105, 4-201(c), 4-208, 5-101(a), 5-103, 5-104, 5-202(c), 5-203, and 6-105, part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78-2081, which is incorporated by reference, shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/fibr_locations.html.

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) *Manual cleaning and sanitizing.* (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(1) Sinks shall be cleaned prior to use.

(2) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(3) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(4) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (1) through (4) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(1) Immersion for at least 1/2 minute in clean, hot water at a temperature of at least 170 °F; or

(2) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(3) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(4) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(5) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(6) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(4) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(1) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(2) A numerically scaled indicating thermometer, accurate to ± 3 °F, convenient to the sink for frequent checks of water temperature; and

(3) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.* (A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair.

Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A 1/4-inch IPS valve shall be provided immediately up stream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ± 3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: *Provided, That,*

(1) The temperature of the wash water shall not be less than 120 °F.

(2) The wash water shall be kept clean.

(3) Chemicals added for sanitization purposes shall be automatically dispensed.

(4) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(5) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(6) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(7) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(1) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature 150 °F Final rinse temperature 180 °F

(2) Single-tank, stationary-rack, single-temperature machine:

Wash temperature 165 °F Final rinse temperature 165 °F

(3) Single-tank, conveyor machine:

Wash temperature 160 °F Final rinse temperature 180 °F

(4) Multitank, conveyor machine:

Wash temperature 150 °F Pumped rinse temperature 160 °F Final rinse temperature 180 °F

(5) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature 140 °F Final rinse temperature 180 °F

(l) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) *Steam.* Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term "private nonprofit institution" means "a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office."

(5) The Administrator may withdraw or modify the exemption set forth in §303.1(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect ending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(f) The adulteration and misbranding provisions of the Act and the regulations in this subchapter, other than the requirement of the official inspection legend, apply to articles which are exempted from inspection or not required to be inspected under this section. This includes the requirement that any pork and any product containing pork be prepared only in compliance with any applicable requirement for the destruction of trichina as provided in §318.10 of this subchapter.

(g) The Administrator may extend the requirements of titles I and IV of the Act to any establishment in any State or organized Territory at which products are prepared for distribution solely within such

jurisdiction, if he determines in accordance with the provisions of paragraph 301(c)(1) of the Act that it is producing adulterated products which would clearly endanger the public health.

(h) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements: *Provided*, That such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Act.

(Approved by the Office of Management and Budget under control number 0583-0015)

[35 FR 15558, Oct. 3, 1970, as amended at 36 FR 12002, 12004, June 24, 1971; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 18, 1981; 47 FR 746, Jan. 7, 1982; 51 FR 29909, Aug. 21, 1986; 52 FR 10032, Mar. 30, 1987; 52 FR 48091, Dec. 18, 1987; 53 FR 24679, June 30, 1988; 57 FR 34182, Aug. 3, 1992; 64 FR 56415, Oct. 20, 1999]

§ 303.2 Experimentation: Intensity of inspection coverage.



(a) Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (Pub. L. 99-641), in establishments preparing products at which inspection under the Act and regulations is required, the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(b) The determinations referred to in paragraph (a) of this section shall be made by the program and shall reflect evaluations of the performance and the characteristics and such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person conducting operations at such establishment or by anyone responsibly connected with the business conducting operations at such establishment, as "responsibly connected" is defined in section 401(g) of the Act,

(ii) The competence of the person conducting operations at such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Program employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

- (ii) The frequency with which each such operation is conducted at such establishment,
- (iii) The volume of product resulting from each such operation at such establishment,
- (iv) Whether and to what extent slaughter operations also are conducted at such establishment,
- (v) What, if any, food products not regulated under this Act or the Poultry Products Inspection Act also are prepared at such establishment, and
- (vi) The size of such establishment.

(c)(1) For the period of experimentation described in paragraph (a) of this section, the frequency of inspection by Program employees of operations other than slaughter may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (b)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (b)(2) of this section,¹

¹ These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Program employees.

(ii) To the extent that such frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this subchapter, the Administrator will waive such provisions for the period of experimentation, in accordance with §303.1(g) of this subchapter.

[52 FR 10032, Mar. 30, 1987 and 52 FR 48091, Dec. 18, 1987]

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§ 381.20 Survey and grant of inspection.

(a) Before inspection is granted, FSIS shall survey the establishment to determine if the construction and facilities of the establishment are in accordance with the regulations. FSIS will grant inspection, subject to §381.21, when these requirements are met.

(b) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

[62 FR 45026, Aug. 25, 1997]

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§ 381.18 Authority of applicant.

Any person applying for inspection service may be required at the discretion of the Administrator to demonstrate that the operator of the establishment authorized him to do so.

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