

of operations other than slaughter and evisceration 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 (d)(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 (d)(2) of this section,<sup>1</sup>

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

(C) The availability of Inspection Service employees.

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

[37 FR 9706, May 16, 1972, as amended at 52 FR 10033, Mar. 30, 1987; 69 FR 255, Jan. 5, 2004]

**§ 381.4 Inspection in accordance with methods prescribed or approved.**

Inspection of poultry products shall be rendered pursuant to the regula-

<sup>1</sup>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.

tions and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

**§ 381.5 Publications.**

Publications under the Act and the regulations shall be made in the FEDERAL REGISTER and in such other media as the Administrator may designate.

**§ 381.6 Establishments requiring inspection.**

Inspection under the regulations is required at:

(a) Every establishment, except as provided in § 381.10 (a) and (b) or § 381.11, in which any poultry is slaughtered for transportation or sale in commerce, or in which any poultry products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food;

(b) Every establishment, except as provided in § 381.10 (a) and (b), (c), or (d), or § 381.11, within any State or organized territory which is designated in § 381.221 pursuant to section 5(c) of the Act, at which any poultry is slaughtered or any poultry products are processed, for use as human food solely for distribution within such jurisdiction; and

(c) Except as provided in § 381.10 (a) and (b), or (c), or § 381.11, every establishment designated by the Administrator pursuant to section 5(c) of the Act as one producing adulterated poultry products which would clearly endanger the public health.

**§ 381.7 Coverage of all poultry and poultry products processed in official establishments.**

All poultry and poultry products processed in an official establishment shall be inspected, handled, processed, marked, and labeled as required by the regulations.

**Subpart C—Exemptions**

**§ 381.10 Exemptions for specified operations.**

(a) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products shall not apply to:

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(1) Any retail dealer with respect to poultry products sold in commerce directly to consumers in an individual retail store, if the only processing operation performed by such retail dealer is the cutting up of poultry products on the premises where such sales to consumers are made: *Provided*, That such operation is conducted under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further*, That the poultry products sold in commerce are derived from poultry inspected and passed under the Act and such poultry products are not adulterated or misbranded at the time of sale (except that the official inspection legend shall not be used). (For the purposes of this subparagraph, a retail dealer is any person who sells poultry products directly to consumers as defined in paragraph (d)(2)(vi) of this section and whose sales of poultry products to household consumers constitute, in terms of dollar value, at least 75 percent of his total sales of poultry products.)

(2) The slaughter of poultry, and the processing of poultry products, by any person in any territory not organized with a legislative body, solely for distribution within such territory: *Provided*, That such poultry is sound and healthy and is slaughtered under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further*, That the poultry products are not adulterated or misbranded when so distributed (except that the official inspection legend shall not be used).

(3) The slaughtering by any person of poultry of his own raising, and the processing by him and transportation in commerce of the poultry products exclusively for use by him and members of his household and his non-paying guests and employees: *Provided*, That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food, and the shipping con-

tainers of such poultry products bear the producer's name and address and the statement "Exempted—P.L. 90-492."

(4) The custom slaughter by any person of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of such owner, by him and members of his household and his non-paying guests and the employees: *Provided*, That such custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food: *And provided further*, That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean and fit for human food, and the shipping containers of such poultry products bear the owner's name and address and the statement "Exempted—P.L. 90-492."

(5) The slaughtering of sound and healthy poultry and processing of poultry products therefrom in any State or territory or the District of Columbia by any poultry producer on his own premises with respect to poultry raised on his premises, and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations: *Provided*, That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when so distributed; (ii) such poultry products when so distributed, bear (in lieu of labeling that would otherwise be required) the producer's name and address and the statement "Exempted—P.L. 90-492" and such poultry products are not otherwise misbranded; (iii) such producer and distributor do not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (5) or (6) of

this section; and (iv) neither such producer or distributor slaughters or processes the products of more poultry than allowed by paragraph (b) of this section.

(6) The slaughtering of sound and healthy poultry or the processing of poultry products of such poultry in any State or territory or the District of Columbia by any poultry producer or other person for distribution by him solely within such jurisdiction directly to household consumers, restaurants, hotels, and boardinghouses, for use in their own dining rooms, or in the preparation of meals for sales direct to consumers: *Provided*, That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when distributed by such processor; (ii) such poultry products when so distributed bear (in lieu of labeling that would otherwise be required) the processor's name and address and the statement "Exempted—P.L. 90-492" and such poultry products are not otherwise misbranded; (iii) such processor does not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (6) or (5) of this section; and (iv) such processor does not exceed the volume limitation prescribed in paragraph (b) of this section.

(7) The operations and products of small enterprises (including poultry producers) not exempted under paragraphs (a) (1) through (6) of this section that are engaged in any State or territory or the District of Columbia in slaughtering and/or cutting up poultry for distribution as carcasses or parts thereof solely for distribution within such jurisdiction; *Provided*, That (i) such poultry is sound and healthy when slaughtered and is slaughtered and/or cut up and handled under such sanitary standards, practices and procedures as result in the preparation of poultry products that are not adulterated when so distributed; and (ii) when so distributed, such poultry products are not

misbranded (except that the official inspection legend shall not be used).

(b) No person qualifies for any exemption specified in paragraph (a)(5), (6), or (7) of this section if, in the current calendar year, such person:

(1) Slaughters or processes the products of more than 20,000 poultry, or

(2) Slaughters or processes poultry products at a facility used for slaughtering or processing poultry products by any other person, except when the Administrator grants such exemption after determining, upon review of a person's application, that such an exemption will not impair effectuating the purposes of the Act.

(c) The provisions of the Act and the regulations do not apply to any poultry producer with respect to poultry, of his own raising on his own farm, which he slaughters if:

(1) Such producer slaughters not more than 1,000 poultry during the calendar year for which this exemption is being determined;

(2) Such poultry producer does not engage in buying or selling poultry products other than those produced from poultry raised on his own farm; and

(3) None of such poultry moves in "commerce" (as defined in §381.1).

(d)(1) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry 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 the purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants include any processing of poultry products except canning of poultry products and except slaughtering of poultry unless such slaughtering is conducted at a retail store with respect to live poultry purchased by the consumer at the retail store and processed by the retail store operator in accordance with the consumer's instructions.

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(ii) A normal retail quantity is any quantity of a poultry product purchased by a household consumer from a retail supplier that in the aggregate does not exceed 75 pounds. A normal retail quantity sold by a retail supplier to other than a household consumer is any quantity that in the aggregate does not exceed 150 pounds.

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

(a) The sales of poultry products 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.<sup>1</sup>

(c) Only federally or State inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

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

(e) The processing of poultry products for sale is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

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

(1) Poultry products are processed only for sale or service in meals or as

entrees directly to individual consumers at such establishments;

(2) Only federally inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

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

(4) The processing of poultry products 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 as a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares poultry 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 requirement of this paragraph: *Provided*, That the requirements of §§ 381.175 through 381.178 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 poultry products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central

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

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) A similar retail-type establishment is 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 paragraph (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) A consumer is any household consumer, hotel, or 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 establishment or restaurant claiming exemption under this paragraph (d) in any designated State or organized territory listed in §381.221 that is also identified in §381.224 as a jurisdiction 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 paragraph (d) for such 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 establishment or restaurant and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator determines that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail establishment or restaurant would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of his total monthly purchases and of his total monthly sales of poultry and poultry products. 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 §381.177. 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.

(4) The adulteration and misbranding provisions of the Act and the regulations other than the requirement of the official inspection legend, apply to articles which are exempted from inspection under this paragraph (d).

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to poultry pizzas containing poultry 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 poultry pizzas are to be served in public or private nonprofit institutions, provided that the poultry 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

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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/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_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 ½ 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 ¼-inch IPS valve shall be provided immediately upstream 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  $\pm 3$  °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:

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(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

(I) 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 §381.10(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 pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(6) The adulteration and misbranding provisions of the Act and the regulations apply to articles which are exempted from inspection under §381.10(e).

[37 FR 9706, May 16, 1972, as amended at 38 FR 16991, June 28, 1973; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 16, 1981; 48 FR 2959, Jan. 24, 1983; 51 FR 29909, Aug. 21, 1986; 53 FR 24679, June 30, 1988; 57 FR 34184, Aug. 3, 1992]