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, is 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 knowlege 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]

(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

[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.

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]

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

Sec.

304.1 Application for inspection.
304.2 Information to be furnished; grant or refusal of inspection.
304.3 Conditions for receiving inspection.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§304.1 Application for inspection.

(a) Before the inspection is granted, each person conducting operations at an establishment subject to the Act, whether tenant, subsidiary, or landlord, shall make application therefor to the Administrator as provided for in this part.

(b) Every application under this section shall be made on an official form furnished by the Program, available from any Regional Director identified in §301.2(kkk) of this subchapter, and shall be completed to include all information requested. Trade names of the applicant for labeling purposes, shall be inserted in the appropriate blank in the application. Each applicant for inspection will be held responsible for compliance with the Act and the regulations in this subchapter if inspection is granted. Preparation of product and other operations at the establishment for which inspection is granted may be conducted only by the applicant named in the application.

(c) In cases of change of ownership or location, a new application shall be made.

[40 FR 2575, Jan. 14, 1975, as amended at 53 FR 49848, Dec. 12, 1988]

§304.2 Information to be furnished; grant or refusal of inspection.

(a) 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.

(b) The Administrator is authorized to grant inspection upon his determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if he determines that it does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§416.1 through 416.6 of this chapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

(c)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency or the Secretary of the Interior to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request).

(2) However, certification is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification and meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.