

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,<sup>1</sup>

(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]

## 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.

<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.

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 of this subchapter. 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.

Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

[35 FR 15558, Oct. 3, 1970, as amended at 41 FR 4889, Feb. 3, 1976; 44 FR 68813, Nov. 30, 1979; 62 FR 45024, Aug. 25, 1997; 64 FR 56415, Oct. 20, 1999; 64 FR 66545, Nov. 29, 1999; 65 FR 2284, Jan. 14, 2000]

EFFECTIVE DATE NOTES: 1. At 64 FR 56415, Oct. 20, 1999, §304.2(b) was amended by removing the phrase "308" in the first sentence, and adding the phrase "Part 416,

§§416.1 through 416.6 of this chapter" in its place, effective Jan. 25, 2000.

2. At 64 FR 66545, Nov. 29, 1999, §304.2 section heading and the last sentence in paragraph (b) were revised, paragraphs (c) and (e) were removed and paragraph (d) was redesignated as (c), effective Jan. 25, 2000. For the convenience of the user, the superseded text is set forth as follows:

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

\* \* \* \* \*

(b) \* \* \* When inspection is refused for any reason, the applicant shall be informed of the action and the reasons therefor and afforded an opportunity to present his views.

(c) Inspection may also be refused in accordance with section 401 of the Act and the applicable rules of practice.

\* \* \* \* \*

(e) Inspection may be refused in accordance with humane slaughter and handling provisions of the Act (21 U.S.C. 603(b)) and the applicable rules of practice.

3. At 65 FR 2284, Jan. 14, 2000, §304.2, the first sentence of paragraph (b) was amended by removing the phrase "of this subchapter" after the phrase "parts 305, 307, and 416, §§416.1 through 416.6 of this chapter", effective Jan. 25, 2000.

**§304.3 Conditions for receiving inspection.**

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with §417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP

plan, in accordance with §417.4 of this chapter.

[61 FR 38864, July 25, 1996]

**PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION**

Sec.

- 305.1 Official numbers; subsidiaries and tenants.
- 305.2 Separation of official establishments.
- 305.3 Sanitation and adequate facilities.
- 305.4 Inauguration of inspection.
- 305.5 Withdrawal of inspection; statement of policy.
- 305.6 Reports of violations.

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

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

**§305.1 Official numbers; subsidiaries and tenants.**

(a) An official number shall be assigned to each establishment granted inspection. Such number shall be used to identify all inspected and passed products prepared in the establishment. More than one number shall not be assigned to an establishment.

(b) Two or more official establishments under the same ownership or control may be granted the same official number, provided a serial letter is added in each case to identify each establishment and the products thereof.

(c) When inspection has been granted to any applicant at an establishment, it shall not be granted to any other person at the same establishment. However, persons operating as separate entities in the same building or structure may operate separate establishments therein only under their own grant of inspection. All such persons operating separate establishments in the same building or structure shall be responsible for compliance with the Act and regulations in their own establishments, which shall include common areas, e.g., hallways, stairways, and elevators.

[35 FR 15559, Oct. 3, 1970, as amended at 40 FR 2576, Jan. 14, 1975]

**§305.2 Separation of official establishments.**

(a) Each official establishment shall be separate and distinct from any unofficial establishment except a poultry products processing establishment operated under Federal inspection under the Poultry Products Inspection Act or under State inspection.

(b) The slaughter or other preparation of products of horses, mules, or other equines required to be conducted under inspection pursuant to the regulations in this subchapter shall be done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared.

(c) Inspection shall not be inaugurated in any building, any part of which is used as living quarters, unless the part for which inspection is requested is separated from such quarters by floors, walls, and ceilings of solid concrete, brick, wood, or similar material, and the floors, walls, and ceilings are without openings that directly or indirectly communicate with any part of the building used as living quarters.

**§305.3 Sanitation and adequate facilities.**

Inspection shall not be inaugurated if an establishment is not in a sanitary condition nor unless the establishment agrees to maintain a sanitary condition and provides adequate facilities for conducting such inspection.

**§305.4 Inauguration of inspection.**

When inspection is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the operator of the establishment of the requirements of the regulations in this subchapter. If the establishment, at the time inspection is inaugurated, contains any product which has not theretofore been inspected, passed, and marked in compliance with the regulations in this subchapter, the identity of the same shall be maintained, and it shall not be distributed in commerce, or otherwise subject to the requirements of such regulations, or dealt with as inspected and passed under the regulations. The establishment shall