

## Food Safety and Inspection Service, USDA

## § 381.21

to the requirements of the Federal Food, Drug, and Cosmetic Act.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55982, Nov. 3, 1995]

### Subpart D—Application for Inspection; Grant or Refusal of Inspection

#### § 381.16 How application shall be made.

The operator of each establishment of the kind required by § 381.6 to have inspection shall make application to the Administrator for inspection service. In cases of change of name, ownership, or location, a new application shall be made.

#### § 381.17 Filing of application.

Every application for inspection at any establishment shall be made by the operator on a form furnished by the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and shall include all information called for by that form, including the name of any subsidiary corporation that will prepare any poultry product or conduct any other operation at the establishment for which inspection is requested. The applicant for inspection will be held responsible for compliance by all its subsidiaries with the requirements of the regulations at such establishments if inspection is granted. Processing of poultry products and other operations at the establishment for which inspection is granted may be conducted only by the applicant, except that such a subsidiary of the grantee, may conduct such operations at such establishment.

#### § 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.

#### § 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 accord-

ance 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]

#### § 381.21 Refusal of inspection.

(a) Any application for inspection in accordance with this part may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(b)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters of the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended, 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 Administrator of the Environmental Protection Agency to act on a request for certification within 1 year after receipt of such request. Further, upon receipt of an application for inspection and a certification as required by subsection 21(b) of the Federal Water Pollution Control Act, the Administrator (as defined in § 381.1) is required by paragraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that paragraph. No grant of inspection can be made until the requirements of said paragraph (2) have been met.

(2) However, certification under subsection 21(b) of the Federal Water Pollution Control Act 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

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certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification or to 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.

(3) 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.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

[37 FR 9706, May 16, 1972, as amended at 64 FR 66545, Nov. 29, 1999]

## § 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, in accordance with 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, in accordance with §§ 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

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plan, in accordance with § 417.4 of this chapter.

[61 FR 38866, July 25, 1996]

## Subpart E—Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

### § 381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

### § 381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

### § 381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under subpart C and comply with all requirements of said subpart.