

part or the regulations in parts 305, 307, and 308 of this subchapter 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. 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.

(d)(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.

(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.

[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]

§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.