

**§ 108.35**

**21 CFR Ch. I (4-1-04 Edition)**

for import has complied with the requirements of this section and that the food is not injurious to health. To assist the Commissioner in making this determination, a duly authorized employee of the Food and Drug Administration shall be permitted to inspect the commercial processor's manufacturing, processing, and packing facilities.

(k) The following information submitted to the Food and Drug Administration under this section is not available for public disclosure unless it has been previously disclosed to the public as defined in §20.81 of this chapter or it relates to a product or ingredient that has been abandoned and no longer represents a trade secret or confidential commercial or financial information as defined in §20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar information, except that any compilation of the information aggregated and prepared in a way that does not reveal information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

[44 FR 16207, Mar. 16, 1979, as amended at 54 FR 24891, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

**§ 108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.**

(a) Inadequate or improper manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers may result in the distribution in interstate commerce of processed foods that may be injurious to health. The harmful nature of such foods cannot be adequately determined after these foods have entered into interstate commerce. The Commissioner of Food and Drugs therefore finds that, in order to protect the public health, it may be necessary to require any commercial processor, in any establishment engaged in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers, to ob-

tain and hold a temporary emergency permit provided for under section 404 of the Federal Food, Drug, and Cosmetic Act. Such a permit may be required whenever the Commissioner finds, after investigation, that the commercial processor has failed to fulfill all the requirements of this section, including registration and the filing of process information, and the mandatory portions of part 113 of this chapter. These requirements are intended to ensure safe manufacture, processing, and packing procedures and to permit the Food and Drug Administration to verify that these procedures are being followed. Such failure shall constitute a prima facie basis for the immediate application of the emergency permit control provisions of section 404 of the act to that establishment, pursuant to the procedures established in subpart A of this part.

(b) The definitions in §113.3 of this chapter are applicable when such terms are used in this section.

(c) *Registration and process filing*—(1) *Registration.* A commercial processor when first engaging in the manufacture, processing, or packing of thermally processed low-acid foods in hermetically sealed containers in any state, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register with the Food and Drug Administration on Form FDA 2541 (food canning establishment registration) information including (but not limited to) his name, principal place of business, the location of each establishment in which such processing is carried on, the processing method in terms of the type of processing equipment employed, and a list of the low-acid foods so processed in each such establishment. These forms are available from the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form shall be submitted to the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park,

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MD 20740. Commercial processors presently so engaged shall register not later than July 13, 1973. Commercial processors duly registered in accordance with this section shall notify the Food and Drug Administration not later than 90 days after such commercial processor ceases or discontinues the manufacture, processing, or packing of thermally processed foods in any establishment: *Provided*, That such notification shall not be required as to the temporary cessation necessitated by the seasonal character of the particular establishment's production or caused by temporary conditions including but not limited to strikes, lockouts, fire, or acts of God.

(2) *Process filing.* A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall, not later than 60 days after registration and prior to the packing of a new product, provide the Food and Drug Administration information as to the scheduled processes including but not limited to the processing method, type of retort or other thermal processing equipment employed, minimum initial temperatures, times and temperatures of processing, sterilizing value (Fo), or other equivalent scientific evidence of process adequacy, critical control factors affecting heat penetration, and source and date of the establishment of the process, for each such low-acid food in each container size: *Provided*, That the filing of such information does not constitute approval of the information by the Food and Drug Administration, and that information concerning processes and other data so filed shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905. This information shall be submitted on the following forms as appropriate: Form FDA 2541a (food canning establishment process filing for all methods except aseptic), or Form FDA 2541c (food canning establishment process filing for aseptic systems). These forms are available from the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at any Food and Drug Administration district of-

vice. The completed form(s) shall be submitted to the LACF Registration Coordinator (HFS-618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(i) If all the necessary information is not available for existing products, the processor shall, at the time the existing information is provided to the Food and Drug Administration request in writing an extension of time for submission of such information, specifying what additional information is to be supplied and the date by which it is to be submitted. Within 30 working days after receipt of such request the Food and Drug Administration shall either grant or deny such request in writing.

(ii) If a packer intentionally makes a change in a previously filed scheduled process by reducing the initial temperature or retort temperature, reducing the time of processing, or changing the product formulation, the container, or any other condition basic to the adequacy of scheduled process, he shall prior to using such changed process obtain substantiation by qualified scientific authority as to its adequacy. Such substantiation may be obtained by telephone, telegram, or other media, but must be promptly recorded, verified in writing by the authority, and contained in the packer's files for review by the Food and Drug Administration. Within 30 days after first use, the packer shall submit to the Center for Food Safety and Applied Nutrition (HFS-617), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740 a complete description of the modifications made and utilized, together with a copy of his file record showing prior substantiation by a qualified scientific authority as to the safety of the changed process. Any intentional change of a previously filed scheduled process or modification thereof in which the change consists solely of a higher initial temperature, a higher retort temperature, or a longer processing time, shall not be considered a change subject to this paragraph, but if that modification is thereafter to be regularly scheduled, the modified process shall be promptly

filed as a scheduled process, accompanied by full information on the specified forms as provided in this paragraph.

(iii) Many packers employ an "operating" process in which retort operators are instructed to use retort temperatures and/or processing times slightly in excess of those specified in the scheduled process as a safety factor to compensate for minor fluctuations in temperature or time to assure that the minimum times and temperatures in the scheduled process are always met. This would not constitute a modification of the scheduled process.

(3) *Process adherence and information.*

(i) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers in any registered establishment shall process each low-acid food in each container size in conformity with at least the scheduled processes and modifications filed pursuant to paragraph (c)(2) of this section.

(ii) *Process information availability:* When requested by the Food and Drug Administration in writing, a commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers shall provide the Food and Drug Administration with any information concerning processes and procedures which is deemed necessary by the Food and Drug Administration to determine the adequacy of the process: *Provided*, That the furnishing of such information does not constitute approval of the information by the Food and Drug Administration, and that the information concerning processes and other data so furnished shall be regarded as trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905.

(d) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall promptly report to the Food and Drug Administration any instance of spoilage or process deviation the nature of which indicates potential health significance where any lot of such food has in whole or in part entered distribution.

(e) A commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed con-

tainers shall promptly report to the Food and Drug Administration any instance wherein any lot of such food, which may be injurious to health by reason of contamination with microorganisms, has in whole or in part entered distribution.

(f) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall have prepared and in his files a current procedure which he will use for products under his control and which he will ask his distributor to follow, including plans for effecting recalls of any product that may be injurious to health; for identifying, collecting, warehousing, and controlling the product; for determining the effectiveness of such recall; for notifying the Food and Drug Administration of any such recall; and for implementing such recall program.

(g) All operators of retorts, thermal processing systems, aseptic processing and packaging systems, or other thermal processing systems, and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, aseptic processing and packaging systems operations or other thermal processing systems operations, and container closure inspections, and has satisfactorily completed the prescribed course of instruction: *Provided*, That this requirement shall not apply in the State of California as listed in paragraph (j) of this section. The Commissioner will not withhold approval of any school qualified to give such instruction.

(h) A commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers shall prepare, review, and retain at the processing plant for a period of not less than one year, and at the processing plant or other reasonably accessible location for an additional two years, all records of processing, deviations in processing, container closure inspections, and other records specified in part 113 of this chapter. If during the first year of the three-year record retention period the processing plant is closed for a prolonged period between seasonal packs,

the records may be transferred to some other reasonably accessible location at the end of the seasonal pack. Upon written demand during the course of a factory inspection pursuant to section 704 of the act by a duly authorized employee of the Food and Drug Administration, a commercial processor shall permit the inspection and copying by such employee of these records to verify the adequacy of processing, the integrity of container closures, and the coding of the products.

(i) This section shall not apply to the commercial processing of any food processed under the continuous inspection of the meat and poultry inspection program of the Animal and Plant Health Inspection Service of the Department of Agriculture under the Federal Meat Inspection Act (34 Stat. 1256, as amended by 81 Stat. 584 (21 U.S.C. 601 *et seq.*)) and the Poultry Products Inspection Act (71 Stat. 441, as amended by 82 Stat. 791 (21 U.S.C. 451 *et seq.*)).

(j) Compliance with State regulations: (1) Wherever the Commissioner finds that any State regulates the commercial thermal processing of low-acid foods in accordance with effective regulations specifying at least the requirements of part 113 of this chapter, he shall issue a notice stating that compliance with such State regulations shall constitute compliance with part 113 of this chapter. However, the provisions of this section shall remain applicable to the commercial processing of low-acid foods in any such State, except that, either the State through its regulatory agency or each processor of low-acid foods in such State shall file with the Center for Food Safety and Applied Nutrition the registration information and the processing information prescribed in paragraph (c) of this section.

(2) The Commissioner finds that the regulations adopted by the State of California under the laws relating to cannery inspections governing thermal processing of low-acid foods packaged in hermetically sealed containers satisfy the requirements of part 113 of this chapter.

Accordingly, processors, who under the laws relating to cannery inspections are licensed by the State of California and who comply with such state regu-

lations, shall be deemed to comply with the requirements of part 113 of this chapter.

(k) *Imports:* (1) This section shall apply to any foreign commercial processor engaged in the thermal processing of low-acid foods packaged in hermetically sealed containers and offering such foods for import into the United States except that, in lieu of providing for the issuance of an emergency permit under paragraph (a) of this section, the Commissioner will request the Secretary of the Treasury to refuse admission into the United States, pursuant to section 801 of the act, of any such low-acid foods which the Commissioner determines, after investigation, may result in the distribution in interstate commerce of processed foods that may be injurious to health as set forth in paragraph (a) of this section.

(2) Any such food refused admission shall not be admitted until such time as the Commissioner may determine that the commercial processor offering the food for import is in compliance with the requirements and conditions of this section and that such food is not injurious to health. For the purpose of making such determination, the Commissioner reserves the right for a duly authorized employee of the Food and Drug Administration to inspect the commercial processor's manufacturing, processing, and packing facilities.

(1) The following data and information submitted to the Food and Drug Administration pursuant to this section are not available for public disclosure unless they have been previously disclosed to the public as defined in §20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §20.81 of this chapter:

(1) Manufacturing methods or processes, including quality control information.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this

provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

[42 FR 14334, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977; 54 FR 24891, June 12, 1989; 61 FR 14480, Apr. 2, 1996; 66 FR 56035, Nov. 6, 2001]

## PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

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AUTHORITY: 21 U.S.C. 321, 336, 342, 346, 346a, 348, 371.

SOURCE: 42 FR 52819, Sept. 30, 1977, unless otherwise noted.

### Subpart A—General Provisions

#### § 109.3 Definitions and interpretations.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms contained in section 201 of the act are applicable to such terms when used in this part unless modified in this section.

(c) A *naturally occurring poisonous or deleterious substance* is a poisonous or deleterious substance that is an inherent natural constituent of a food and is

not the result of environmental, agricultural, industrial, or other contamination.

(d) An *added poisonous or deleterious substance* is a poisonous or deleterious substance that is not a naturally occurring poisonous or deleterious substance. When a naturally occurring poisonous or deleterious substance is increased to abnormal levels through mishandling or other intervening acts, it is an added poisonous or deleterious substance to the extent of such increase.

(e) *Food* includes human food and substances migrating to food from food-contact articles.

#### § 109.4 Establishment of tolerances, regulatory limits, and action levels.

(a) When appropriate under the criteria of § 109.6, a tolerance for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart B of this part under the provisions of section 406 of the act. A tolerance may prohibit any detectable amount of the substance in food.

(b) When appropriate under the criteria of § 109.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of § 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the FEDERAL REGISTER as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Division of Dockets Management before the notice