Code of Federal Regulations
Chapter 21 -- Subchapter B -- Part 108
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EMERGENCY PERMIT CONTROL

OUTLINE:

Subpart A – General Provisions
Purposely Omitted from this Reprint

Subpart B--Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

108.25 Acidified foods.
108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers.

Authority:

Secs. 402, 404, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 344, 371).

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Subpart B--Specific Requirements and Conditions for Exemption From or Compliance With an Emergency Permit

Section 108.25 Acidified foods.

(a) Inadequate or improper manufacture, processing, or packing of acidified foods 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, 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 acidified foods, to obtain 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 filing of process information, and the mandatory portions of Sec.14.10, 114.80(a) (1) and (2), and (b), 114.83, 114.89, and 114.100 (b), (c), and (d) of this chapter as they relate to acidified foods. These requirements are intended to ensure safe manufacturing, processing, and packing processes and to permit the Food and Drug Administration to verify that these processes are being followed. Failure to meet these requirements 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, under the procedures established in Subpart A of this part.

(b) The definitions in Sec. 114.3 of this chapter are applicable when those terms are used in this section.

(c)

(1) Registration. A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods in any State, as defined in section 201(a)(1) of the act, shall, not later than 10 days after first so engaging, register and file with the Food and Drug Administration on Form FDA 2541 (food canning establishment registration) information including, but not limited to, the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method in terms of acidity and pH control, and a list of foods so processed in each establishment. These forms are available from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator (HFF-233), 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration

district office. The completed form shall be submitted to the Food and Drug Administration, Bureau of Foods, Industry Guidance Branch (HFF-342), 200 C St. SW., Washington, DC 20204. Commercial processors presently so engaged shall register within 120 days after the effective date of this regulation.

Foreign processors shall register within 120 days after the effective date of this regulation or before any offering of foods for import into the United States, whichever is later. Commercial processors duly registered under this section shall notify the Food and Drug Administration not later than 90 days after the commercial processor ceases or discontinues the manufacture, processing, or packing of the foods in any establishment, except that this notification shall not be required for temporary cessation due to the seasonal character of an establishment's production or by temporary conditions including, but not limited to, labor disputes, fire, or acts of God.

(2) Process filing. A commercial processor engaged in the processing of acidified foods shall, not later than 60 days after registration, and before packing any new product, provide the Food and Drug Administration information on the scheduled processes including, as necessary, conditions for heat processing and control of pH, salt, sugar, and preservative levels and source and date of the establishment of the process, for each acidified food in each container size. Filing of this information does not constitute approval of the information by the Food and Drug Administration, and 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 form FDA 2541a (food canning establishment process filing form for all methods except aseptic). Forms are available from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator (HFF-233), 200 C St. SW., Washington, DC 20204, or at Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator (HFF-233), 200 C St. SW., Washington, DC 20204.

(3) Process adherence and information -

(i) Scheduling. A commercial processor engaged in processing acidified foods in any registered establishment shall process each food in conformity with at least the scheduled processes filed under paragraph (c)(2) of this section.

(ii) Process and pH information availability. When requested by the Food and Drug Administration in writing, a commercial processor engaged in the processing of acidified foods shall provide the Food and Drug Administration with any process and procedure information that the Food and Drug Administration deems necessary to determine the adequacy of the process. Furnishing of this information does not constitute approval by the Food and Drug Administration of the content of the information filed, and the information concerning processes and other data so furnished shall be considered trade secrets within the meaning of 21 U.S.C. 331(j) and 18 U.S.C. 1905 (to the extent that they qualify under those provisions).

(d) A commercial processor engaged in the processing of acidified foods shall promptly report to the Food and Drug Administration any instance of spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance, where any lot of such food has in whole or in part entered distribution in commerce.

(e) A commercial processor engaged in the processing of acidified foods shall prepare and maintain files on a current procedure for use for products under the processor's control, which that processor will ask the distributor to follow, including plans for recalling products that may be injurious to health; for identifying, collecting, warehousing, and controlling products; for determining the effectiveness of recalls; for notifying the Food and Drug Administration of any recalls; and for implementing recall programs.

(f) All plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food protection principles, personal hygiene, plant sanitation practices, pH controls, and critical factors in acidification, and who has satisfactorily completed the prescribed course of instruction. The Commissioner will consider students who have satisfactorily completed the required portions of the courses presented under Sec. 108.35 and Part 113 of this chapter before March 16, 1979, as having satisfactorily completed the prescribed course of instruction under this section and Part 114 of this chapter. The Commissioner will not withhold approval of any school qualified to give such instruction.

(g) A commercial processor engaged in the processing of acidified foods shall prepare, review, and retain at the processing plant or other reasonably accessible

location for a period of 3 years from the date of manufacture, all records of processing, deviations in processing, pH, and other records specified in Part 114 of this chapter. Upon written demand during the course of a factory inspection under 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 that employee of these records to verify the pH and the adequacy of processing.

(h) 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 Food Safety and 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.)).

(i) Wherever the Commissioner finds that any State regulates the commercial processing of acidified foods under effective regulations specifying at least the requirements of Part 114 of this chapter, the Commissioner shall issue a notice stating that compliance with
such State regulations shall constitute compliance with this section, if the State through its regulatory agency or each processor of acidified foods in the State files with the Food and Drug Administration the registration information and the processing information prescribed in paragraph (c) of this section.

(j) Imports:

(1) This section applies to any foreign commercial processor engaged in the processing of acidified foods and offering those 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, under section 801 of the act, to any acidified 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 acidified food so refused admission shall not be admitted until the Commissioner determines that the commercial processor offering the food 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 Sec. 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 Sec. 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 R 24891, June 12, 1989]

Section 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 obtain 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 Sec.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 Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator HFF-233, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator HFF-233, 200 C St. SW., Washington, DC 20204. 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 Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator, HFF-233, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form(s) shall be submitted to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, LACF Registration Coordinator, HFF-233, 200 C St. SW., Washington, DC 20204.

(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 Food and Drug Administration, Center for Food

Safety and Applied Nutrition, DFCT, HFF-414, 200 C St. SW., Washington, DC 20204 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 21U.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 partnered distribution.

(e) A commercial processor engaged in thermal processing of low-acid foods packaged in hermetically sealed containers 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 and shall not apply until March 25, 1975 in any other State. 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 regulations, 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.

(l) 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 Sec. 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 Sec. 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.

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