FDA's own audits or from other sources, demonstrating that the recall has not been effective. The agency may conclude that a recall has not been effective if:

(a) The recalling firm's distributors have failed to retrieve the recalled infant formula; or

(b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.

[54 FR 4008, Jan. 27, 1989, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17359, Mar. 30, 2001]

§ 107.260 Revision of an infant formula recall.

If after a review of the recalling firm's recall strategy or periodic reports or other monitoring of the recall, the Food and Drug Administration concludes that the actions of the recalling firm are deficient, the agency shall notify the recalling firm of any serious deficiency. The agency may require the firm to:

(a) Change the extent of the recall, if the agency concludes on the basis of available data that the depth of the recall is not adequate in light of the risk to human health presented by the infant formula.

(b) Carry out additional effectiveness checks, if the agency's audits, or other information, demonstrate that the recall has not been effective.

(c) Issue additional notifications to the firm's direct accounts, if the agency's audits, or other information demonstrate that the original notifications were not received, or were disregarded in a significant number of cases.

§ 107.270 Compliance with this subpart.

A recalling firm may satisfy the requirements of this subpart by any means reasonable calculated to meet the obligations set forth in this Subpart E. The recall guidance in subpart C of part 7 of this chapter specify procedures that may be useful to a recalling firm in determining how to comply with these regulations.

[54 FR 4008, Jan. 27, 1989, as amended at 65 FR 56479, Sept. 19, 2000]

§ 107.280 Records retention.

Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

(Collection of information requirements in this section were approved by the Office of Management and Budget under OMB control number 0910–0188)

PART 108—EMERGENCY PERMIT CONTROL

Subpart A—General Provisions

Sec.

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

AUTHORITY: 21 U.S.C. 342, 344, 371.

SOURCE: 42 FR 14334, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 108.3 Definitions.

(a) The definitions contained in section 201 of the Federal Food, Drug, and Cosmetic Act are applicable to such terms when used in this part.

(b) *Commissioner* means the Commissioner of Food and Drugs.

(c) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended.

(d) *Permit* means an emergency permit issued by the Commissioner pursuant to section 404 of the act for such temporary period of time as may be necessary to protect the public health.

(e) *Manufacture, processing, or packing of food in any locality* means activities conducted in a single plant or establishment, a series of plants under a single management, or all plants in an industry or region, by a manufacturer, processor, or packer.

§ 108.5 Determination of the need for a permit.

(a) Whenever the Commissioner determines after investigation that a manufacturer, processor, or packer of a food for which a regulation has been promulgated in subpart B of this part does not meet the mandatory conditions and requirements established in such regulation, he shall issue to such manufacturer, processor, or packer an order determining that a permit shall be required before the food may be introduced or delivered for introduction into interstate commerce by that person. The order shall specify the mandatory conditions and requirements with which there is a lack of compliance.

(1) The manufacturer, processor, or packer shall have 3 working days after receipt of such order within which to file objections. Such objections may be filed by telegram, telex, or any other mode of written communication addressed to the Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS–605), 200 C St. SW., Washington, DC 20204. If such objections are filed, the determination is stayed pending a hearing to be held within 5 working days after the filing of objections on the issues involved unless the Commissioner determines that the objections raise no genuine and substantial issue of fact to justify a hearing.

(2) If the Commissioner finds that there is an imminent hazard to health, the order shall contain this finding and the reasons therefor, and shall state that the determination of the need for a permit is effective immediately pending an expedited hearing.

(b) A hearing under this section shall be conducted by the Commissioner or his designee at a location agreed upon by the objector and the Commissioner or, if such agreement cannot be reached, at a location designated by the Commissioner. The manufacturer, processor, or packer shall have the right to cross-examine the Food and Drug Administration's witnesses and to present witnesses on his own behalf.

(c) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether a permit is required and shall so inform the manufacturer, processor, or packer in writing, with the reasons for his decision.

(d) The Commissioner's determination of the need for a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay a determination of the need for a permit pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

[42 FR 14334, Mar. 15, 1977, as amended at 54 FR 24891, June 12, 1989; 61 FR 14479, Apr. 2, 1996]

§ 108.6 Revocation of determination of need for permit.

(a) A permit shall be required only during such temporary period as is necessary to protect the public health.

(b) Whenever the Commissioner has reason to believe that a permit holder is in compliance with the mandatory requirements and conditions established in subpart B of this part and is likely to remain in compliance, he shall, on his own initiative or on the application of the permit holder, revoke both the determination of need for a permit and the permit that had been issued. If denied, the applicant shall, upon request, be afforded a hearing conducted in accordance with § 108.5 (b) and (c) as soon as practicable. Such revocation is without prejudice to the initiation of further permit proceedings with respect to the same manufacturer, processor, or packer should later information again show the need for a permit.

§ 108.7 Issuance or denial of permit.

(a) After a determination and notification by the Commissioner in accordance with the provisions of § 108.5 that

a manufacturer, processor, or packer requires a permit, such manufacturer, processor, or packer may not thereafter introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by him unless he holds a permit issued by the Commissioner or obtains advance written approval of the Food and Drug Administration pursuant to § 108.12(a).

(b) Any manufacturer, processor, or packer for whom the Commissioner has made a determination that a permit is necessary may apply to the Commissioner for the issuance of such a permit. The application shall contain such data and information as is necessary to show that all mandatory requirements and conditions for the manufacturer, processing or packing of a food for which regulations are established in subpart B of this part are met and, in particular, shall show that the deviations specified in the Commissioner's determination of the need for a permit have been corrected or suitable interim measures established. Within 10 working days after receipt of such application, (except that the Commissioner may extend such time an additional 10 working days where necessary), the Commissioner shall issue a permit, deny the permit, or offer the applicant a hearing conducted in accordance with § 108.5 (b) and (c) as to whether the permit should be issued. The Commissioner shall issue such a permit to which shall be attached, in addition to the mandatory requirements and conditions of subpart B of this part, any additional requirements or conditions which may be necessary to protect the public health if he finds that all mandatory requirements and conditions of subpart B of this part are met or suitable interim measures are established.

(c) Denial of a permit constitutes final agency action from which appeal lies to the courts. The Commissioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 108.10 Suspension and reinstatement of permit.

(a) Whenever the Commissioner finds that a permit holder is not in compliance with the mandatory requirements and conditions established by the permit, he shall immediately suspend the permit and so inform the permit holder, with the reasons for the suspension.

(b) Upon application for reinstatement of a permit, the Commissioner shall, within 10 working days, reinstate the permit if he finds that the person is in compliance with the mandatory requirements and conditions established by the permit or deny the application.

(c) Any person whose permit has been suspended or whose application for reinstatement has been denied may request a hearing. The hearing shall be conducted by the Commissioner or his designee within 5 working days of receipt of the request at a location agreed upon by the objector and the Commissioner or, if an agreement cannot be reached, at a location designated by the Commissioner. The permit holder shall have the right to present witnesses on his own behalf and to cross-examine the Food and Drug Administration's witnesses.

(d) Within 5 working days after the hearing, and based on the evidence presented at the hearing, the Commissioner shall determine whether the permit shall be reinstated and shall so inform the permit holder, with the reasons for his decision.

(e) Denial of an application for reinstatement of a permit constitutes final agency action from which appeal lies to the courts. The Commisioner will not stay such denial pending court appeal except in unusual circumstances, but will participate in expediting any such appeal.

§ 108.12 Manufacturing, processing, or packing without a permit, or in violation of a permit.

(a) A manufacturer, processor, or packer may continue at his own risk to manufacture, process, or pack without a permit a food for which the Commissioner has determined that a permit is required. All food so manufactured, processed, or packed during such period without a permit shall be retained by the manufacturer, processor, or packer and may not be introduced or delivered

for introduction into interstate commerce without the advance written approval of the Food and Drug Administration. Such approval may be granted only upon an adequate showing that such food is free from microorganisms of public health significance. The manufacturer, processor, or packer may provide to the Commissioner, for his consideration in making any such determination, an evaluation of the potential public health significance of such food by a competent authority in accordance with procedures recognized as being adequate to detect any potential hazard to public health. Within 20 working days after receipt of a written request for such written approval the Food and Drug Administration shall either issue such written approval or deny the request. If the request is denied, the applicant shall, upon request, be afforded a prompt hearing conducted in accordance with §108.5 (b) and (c).

(b) Except as provided in paragraph (a) of this section, no manufacturer, processor, or packer may introduce or deliver for introduction into interstate commerce without a permit or in violation of a permit a food for which the Commissioner has determined that a permit is required. Where a manufacturer, processor, or packer utilizes a consolidation warehouse or other storage facility under his control, interstate shipment of any such food from the point of production to that warehouse or storage facility shall not violate this paragraph, provided that no further introduction or delivery for introduction into interstate commerce is made from that consolidated warehouse or storage facility except as provided in paragraph (a) of this section.

§ 108.19 Establishment of requirements for exemption from section 404 of the act.

(a) Whenever the Commissioner finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with microorganisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he shall promulgate regulations in Subpart B of this part establishing requirements and conditions governing the manufacture, processing, or packing of the food necessary to protect the public health. Such regulations may be proposed by the Commissioner on his own initiative or in response to a petition from any interested person pursuant to part 10 of this chapter.

(b) A manufacturer, processor, or packer of a food for which a regulation has been promulgated in subpart B of this part shall be exempt from the requirement for a permit only if he meets all of the mandatory requirements and conditions established in that regulation.

[42 FR 14334, Mar. 15, 1977, as amended at 42 FR 15673, Mar. 22, 1977]

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

§ 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 commericial 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 §§114.10, 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 §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 LACF Registration Coordinator (HFS–618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or at any Food and Drug Administration district office. The completed form shall be submitted to the Center for Food Safety and Applied Nutrition (HFS–565), Food and Drug Administration, 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 cessations 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 LACF Registration Coordinator (HFS–618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or at 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, 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 §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 § 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]

§ 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 § 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, 200 C St. SW., Washington, DC 20204, 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, 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 LACF Registration Coordinator (HFS–618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 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 LACF Registration Coordinator (HFS–618), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 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 Center for Food Safety and Applied Nutrition (HFS–617), Food and Drug Administration, 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 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 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. 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 §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]

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

Subpart A—General Provisions

Subpart B—Tolerances for Unavoidable Poisonous or Deleterious Substances

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances [Reserved]

Subpart D—Naturally Occurring Poisonous or Deleterious Substances [Reserved]

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 Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.