

Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act: Guidance for Industry

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Table of Contents

- I. Introduction
- II. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (CGMP & PC Regulation)
- III. Foreign Supplier Verification Program (FSVP Regulation)
- IV. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Regulation)
- V. Mitigation Strategies to Protect Food Against Intentional Adulteration (IA Regulation)
- VI. Sanitary Transportation of Human and Animal Food (ST Regulation)

Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act: Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting the form available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

I. Introduction

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables the FDA to better protect public health by helping to ensure the safety and security of the food supply. It requires FDA to promulgate food safety rules that focus on preventing food safety issues rather than relying on detecting issues and reacting to them after they occur.

FSMA recognizes that FDA has previously established a regulation that addresses biological hazards unique to low-acid foods packaged in hermetically sealed containers (i.e., "low-acid canned foods," hereinafter referred to as LACF)² (Title 21, Code of Federal Regulations (21 CFR) part 113). See FSMA §§ 103(a), 103(f), 105(d), and 301 (§§ 418(j) and 805(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 350g(j), 350g note, 350h note, and 384a(e))).

Importantly, several of the regulations that FDA has issued under FSMA provide exemptions that are related to the LACF requirements in part 113. This guidance addresses those

¹ This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as 'cans,' the term "low-acid canned foods" has been used for decades as a shorthand description for "thermally processed low-acid foods packaged in hermetically sealed containers," and we continue to use that term and its abbreviation, LACF, for the purposes of this document.

exemptions,³ and also provides information about the LACF regulation in part 113 in connection with the following FSMA regulations:

- 21 CFR part 117, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (the CGMP & PC Regulation)
- 21 CFR 1, subpart L, Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (the FSVP Regulation)
- 21 CFR 112, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the PS Regulation)
- 21 CFR part 121, Mitigation Strategies To Protect Food Against Intentional Adulteration (the IA Regulation)
- 21 CFR 1, subpart O, Sanitary Transportation of Human and Animal Food (the ST Regulation)

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

The CGMP & PC regulation contains 7 subparts which address key areas associated with a comprehensive food safety program. Below is a brief summary of the content of each subpart:

Subpart A: General Provisions

This subpart provides definitions, identifies exemptions, defines applicability of subparts, and specifies training requirements.

Subpart B: Current Good Manufacturing Practice

Subpart B contains most of the provisions previously in 21 CFR part 110. The changes include modifications that either delete or make previously recommended practices into requirements and provide explicit regulatory text to address allergen cross-contact.

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

Subpart C describes the requirements for a food safety plan, including hazard analyses and preventive controls for facilities subject to this subpart.

Subpart D: Modified Requirements

³ Acidified foods subject to Title 21, Code of Federal Regulations (21 CFR part 114) are subject to the FSVP regulation, the CGMP & PC regulation, and the IA regulation.

Subpart D describes the modified requirements for qualified facilities and facilities solely engaged in the storage of unexposed packaged food (for food that requires time/temperature control for safety).

Subpart E: Withdrawal of a Qualified Facility Exemption

Subpart E addresses the withdrawal of a qualified facility exemption and the appeal and reinstatement procedures.

Subpart F: Requirements Applying to Records that must be Established and Maintained

Subpart F establishes the requirements that apply to all subparts for the records required to be kept.

Subpart G: Supply-Chain Program

Subpart G requires the establishment of written risk-based supply-chain programs for receiving facilities (manufacturers/processors) for raw materials and other ingredients when a hazard associated with the raw material or other ingredient has been controlled before receipt. It further describes the requirements for supply-chain programs, supplier verification activities, and recordkeeping for those programs.

Subpart A – General Provisions

1. Are manufacturers of LACF subject to the Current Good Manufacturing Practice and Preventive Controls Regulation (21 CFR Part 117)?

Manufacturers of low-acid canned foods must meet the requirements of specific subparts of the CGMP & PC Regulation. The exemption in 21 CFR 117.5(d) of subpart A applies to the activities that are subject to 21 CFR part 113. 21 CFR 117.5(d) specifically exempts the processing activities of processors of low-acid canned foods from the requirements of part 117 subpart C, *Hazard Analysis and Risk-Based Preventive Controls*, and subpart G, *Supply-Chain Program* for biological hazards and their controls, if the processor of low-acid canned foods is in compliance with 21 CFR part 113. Low-acid canned food processors still must meet the requirements of part 117 subparts A, B, and F (for the records required by subpart A). In contrast to manufacturers of low-acid canned foods, food processors subject to 21 CFR part 114, Acidified Foods, are not specifically exempt from any provisions of 21 CFR part 117 and must comply with all applicable sections.

Note that manufacturers subject to 21 CFR part 123, Fish and Fishery Products or 21 CFR part 120, Hazard Analysis and Critical Control Point (HACCP) Systems (Juice HACCP) may also be subject to the LACF regulation in 21 CFR part 113.

2. What if the facility is not in compliance with 21 CFR part 113?

We expect that situations in which enforcement actions to ensure compliance with 21 CFR part 113 are insufficient to correct problems, and lead to a facility losing its exemption from the requirements of subparts C and G, will be rare and will depend on very specific circumstances.

In general the appropriate action for us to take when a facility is out of compliance with the LACF regulation in 21 CFR part 113 will be to employ existing enforcement tools to bring the facility into compliance with that regulation.

However, there may be circumstances where an added food safety benefit could be achieved by requiring compliance with the CGMP & PC regulation when a facility does not comply with the LACF regulation in 21 CFR part 113.

3. Which definitions apply to manufacturers of LACF?

With respect to any microbiological hazard and its corresponding control, the definitions found in 21 CFR part 113 apply. Definitions found in 21 CFR part 117 apply to all other relevant requirements of that regulation.

4. What additional training requirements apply to manufacturers of LACF under 21 CFR part 117?

Manufacturers of LACF are required to comply with the new training requirements in 21 CFR 117.4, which requires that individuals engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) and the supervisors who oversee their activities (1) be a qualified individual as defined in 21 CFR 117.3, i.e., have the combination of education, training, and/or experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties (21 CFR 117.4(b)(1)); and (2) receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility, and the individual's assigned duties (21 CFR 117.4(b)(2)). Manufacturers of LACF must establish and maintain records that document training required in the principles of food hygiene and food safety in accordance with requirements in 21 CFR part 117 subpart F (21 CFR 117.4(d)).

In addition to the above requirements, the LACF regulation (21 CFR 113.10) contains a training requirement applicable to a person providing operating supervision under the LACF regulation.

5. When do I need to comply with the relevant provisions in 21 CFR part 117 that apply to me, including the records requirements?

Compliance dates for businesses are staggered over several years.

- Very small businesses, which means, for purposes of part 117, a business (including any subsidiaries and affiliates) averaging less than \$1,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee), must be compliant by September 17, 2018.

(This is also the compliance date for grade “A” milk and milk products covered by the Pasteurized Milk Ordinance.)

- Small businesses, which means, for the purposes of part 117, a business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees, must be compliant by September 18, 2017.
- All other businesses must be compliant by September 19, 2016.

For the purpose of determining your compliance date for the CGMPs in subpart B and the training requirements in subpart A, the definitions of “small business” and “very small business” established in 21 CFR part 117 apply.

Subpart B – Current Good Manufacturing Practices

6. Are the Current Good Manufacturing Practices provisions in 21 CFR part 117 different from those in 21 CFR part 110?

The CGMP requirements in 21 CFR part 117 (mostly in subpart B) generally align with the requirements of 21 CFR part 110, with the non-binding provisions in 21 CFR part 110 removed or made binding. In addition, 21 CFR part 117 subpart B addresses allergen cross-contact explicitly in the regulatory text. In addition, training, which was recommended in 21 CFR part 110, is now mandated in 21 CFR part 117 subpart A (refer to question 4).

7. What procedures and controls does FDA require manufacturers of LACF to have and implement to control allergen cross-contact?

Food allergens, which are considered chemical hazards and thus are not covered by the LACF exemption at 21 CFR 117.5(d), are specifically addressed in 21 CFR part 117 Subpart C as a hazard that must be addressed in the food safety plan (21 CFR 117.135). If a low acid canned food processor identifies food allergens as a hazard they must establish preventive controls (21 CFR 117.135(c)(2)).

Subpart C – Hazard Analysis and Risk-Based Preventive Controls

8. Does 21 CFR part 117 require manufacturers of LACF to have written sanitation controls?

Written sanitation controls for microbiological hazards are not required because manufacturers of LACF are exempt from subpart C with regard to microbiological hazards regulated under part 113 (21 CFR 117.5(d)). However, sanitation controls may be required to prevent cross contact if the firm has identified food allergen hazards.

9. Are manufacturers of LACF required to collect and test environmental samples?

No. Manufacturers of LACF are not required to do environmental monitoring because they are exempt from subpart C with regard to microbiological hazards that are regulated under part 113 (21 CFR 117.5(d)).

Subparts D and E – Modified Requirements and Withdrawal of a Qualified Facility Exemption

10. Can manufacturers of LACF be a “qualified facility”?

Yes, if a manufacturer of LACF has identified chemical or physical hazards and they meet the requirements for a “qualified facility” then the “qualified facility exemption” in 21 CFR 117.5(a) may apply; they would be subject to the modified requirements in 21 CFR 117.201. Any applicable exemption in part 117 does not relieve a manufacturer from compliance with 21 CFR part 113.

Subpart F - Requirements Applying to Records that must be Established and Maintained

11. Do the records requirements listed in 21 CFR part 117 subpart F apply to manufacturers of LACF?

Yes, the record keeping requirements in 21 CFR part 117 subpart F apply to manufacturers of LACF with respect to applicable preventive controls (physical and chemical hazards), as well as to training records required by 21 CFR 117.4(d)(2).

Subpart G – Supply-Chain Program

12. Does subpart G apply to manufacturers of LACF raw materials and ingredients?

If a manufacturer of LACF identifies non-biological (i.e., chemical or physical) hazards associated with raw materials and ingredients received by the facility and the hazards are controlled by the supplier, the manufacturer would be subject to the requirements for a supply-chain program as required by subpart G.

III. Foreign Supplier Verification Program (FSVP)

The, *Foreign Supplier Verification Programs for Food Importers of Foods for Humans and Animals* (FSVP) regulation, is in subpart L of part 1 of FDA’s regulations (21 CFR 1.500-1.514). The FSVP regulation requires importers to create and follow procedures to ensure the safety of the food they import.

13. How does FSVP impact my importation of LACF?

Importers of LACF not subject to further manufacturing and processing, and subject to 21 CFR part 113, are subject to the FSVP Regulation (21 CFR part 1, subpart L (21 CFR 1.500-1.514)). See 21 CFR 1.502(b)(1).

With respect to microbiological hazards that are controlled by part 113, importers of LACF must verify that their suppliers produced the LACF products in accordance with part 113. With respect to non-biological hazards (i.e., chemical and physical hazards) in these products, importers of LACF must have an FSVP in accordance with the FSVP regulation.

14. How does FSVP affect my importation of raw materials or other ingredients used in LACF?

With respect to microbiological hazards that are controlled by part 113, importers are not required to comply with the FSVP regulation for raw materials or other ingredients that the importer uses in the manufacturing or processing of LACF provided that the importer is in compliance with part 113 with respect to the LACF manufactured or processed from the imported raw materials or other ingredients. See 21 CFR 1.502(b)(2). With respect to all hazards other than microbiological hazards, the importer must have an FSVP for the imported raw materials and other ingredients that the importer uses in the manufacture or processing of LACF. Thus, if an importer of raw materials used in the production of LACF complies with part 113 in making LACF products using the imported raw materials, the importer must have an FSVP for the chemical or physical hazards associated with the raw materials or other ingredients, but the FSVP does not need to address microbiological hazards that are controlled under part 113. (See 21 CFR 1.502(b)(2).)

IV. Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

15. Must an LACF processor purchase produce that was produced in compliance with 21 CFR Part 112?

No. 21 CFR part 112 applies only to certain farms and their produce. It does not apply to activities of LACF processors subject to 21 CFR part 113. For farms and their produce that would otherwise be subject to part 112, produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from part 112 (21 CFR 112.2(b)(1)). Processing in accordance with the requirements of 21 CFR part 113 are examples of processing that adequately reduces the presence of microorganisms of public health significance for purposes of this exemption. However, for the produce to qualify for the exemption from part 112, the farmer must disclose in documents accompanying the produce that the food is “not processed to adequately reduce the presence of microorganisms of public health significance” (21 CFR 112.2(b)(2)). To qualify for the exemption, the farmer must also obtain written assurance annually from the customer (e.g., the LACF operation) that performs the commercial processing that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance or that an entity subsequent to it in the food chain will do so (and in such cases, the farmer must also obtain certain additional assurances from the customer) (21 CFR 112.2(b)(3)). The compliance date for such written assurances has been extended (see 81 FR 57784 at 57786).

V. Mitigation Strategies to Protect Food Against Intentional Adulteration (IA) – 21 CFR Part 121

16. Must a manufacturer of LACF also comply with 21 CFR Part 121 – Mitigation Strategies to Protect Food Against Intentional Adulteration?

Domestic and foreign LACF manufacturers required to register with FDA (21 USC 350d) must comply with 21 CFR Part 121 unless an exemption applies to the facility. Facilities must be in compliance by the dates established by the IA final regulation.

- The IA regulation does not apply to a very small business (i.e., a business, including any subsidiaries or affiliates, averaging less than \$10,000,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in both sales of human food plus the market value of human food manufactured, processed, packed, or held without sale, e.g., held for a fee), except that the facility is required to provide for official review, upon request, documentation sufficient to show that the facility qualifies for this exemption.
- This regulation does not apply to the holding of food, except the holding of food in liquid storage tanks.
- This regulation does not apply to the packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.
- This regulation does not apply to activities of a farm that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).
- This regulation does not apply to the manufacturing, processing, packing, or holding of food for animals.

See 21 CFR 121.5 for exemptions.

VI. Sanitary Transportation of Human and Animal Food

17. Is the shipment of LACFs covered under the Sanitary Transportation of Human and Animal Food regulation?

Transportation operations for food completely enclosed by a container are not subject to the ST regulation unless the food requires temperature control for safety. LACFs packaged in hermetically sealed containers are thus not subject to this regulation.