

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

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Chapter 16: Acidified Foods

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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.

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16.1 Purpose of this Chapter

The guidance in this chapter is intended for persons who:

- Are subject to the PCHF requirements; and
- Manufacture, process, or pack acidified foods.

If you are subject to PCHF requirements and manufacture, process, or pack acidified foods, the guidance provided in this chapter is intended to explain:

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- How you can leverage procedures, practices, and processes that you establish and implement to comply with the requirements prescribed by 21 CFR 108.25 and 21 CFR part 114, and records that you establish and keep to comply with those requirements, to address corresponding requirements of the PCHF rule; and
- How you can leverage the procedures, practices, and processes that you establish and implement to comply with the requirements of the PCHF rule, and the records that you establish and keep to comply with those requirements, to address corresponding requirements of 21 CFR 108.25 and 21 CFR part 114.

This guidance is not intended for persons that manufacture, process, or pack acidified foods, but are exempt from PCHF requirements in accordance with 21 CFR 117.5(a) as a “qualified facility.” Qualified facilities that manufacture, process, or pack acidified foods remain subject to 21 CFR 108.25 and part 114 and are subject to modified requirements under 21 CFR 117.201.

16.2 Considerations to Keep in Mind If You Manufacture/Process an Acidified Food

16.2.1 Background on Specific Acidified Food Requirements

FDA has established specific CGMP requirements for thermally processed low-acid foods packaged in hermetically sealed containers (i.e., “low-acid canned foods,” or “LACF”) (21 CFR part 113; the LACF regulations²) and acidified foods (21 CFR part 114 (“part 114”). In the proposed and final rulemakings for LACF³ and acidified foods,⁴ FDA discussed the need for CGMP requirements to control *Clostridium botulinum* (*C. botulinum*). *C. botulinum* is a bacterium commonly found in soil. It can produce a nerve toxin (botulinum toxin) under anaerobic conditions such as those in canned foods. Botulinum toxin can cause botulism, a rare but serious paralytic illness that can be fatal and is considered a medical emergency. For additional information about *C. botulinum* and botulinum toxin, see Chapter 3 of this guidance and the references provided in that chapter.

Part 114 defines a scheduled process as the “process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority” (21 CFR 114.3(e)). Because the pH of acidified foods is sufficiently low to prevent the germination of spores of *C. botulinum*, acidified foods may be held at ambient temperature without a heat treatment comparable to that required in the scheduled process for LACF (41 FR 30442 at 30442; see 21 CFR 113.3(r)).

² Note that there is a partial exemption from the PCHF requirements for food subject to part 113 in 21 CFR 117.5(d).

³ Proposed rule, 41 FR 30444, July 23, 1976; final rule, 44 FR 16209, March 16, 1979.

⁴ Proposed rule, 41 FR 30457, July 23, 1976; final rule, 44 FR 16230, March 16, 1979.

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FDA also has established emergency permit control requirements, under section 404 of the FD&C Act, for acidified foods (21 CFR 108.25; the emergency permit control regulations). FDA established these requirements, in part, because of the importance of controlling the pH of acidified foods. The emergency permit control regulations are intended to ensure safe manufacturing, processing, and packing processes and to permit FDA to verify that these processes are being followed. The emergency permit control regulations require commercial processors of acidified foods to register and file with FDA information, submitted on Form FDA 2541, that includes the name of the establishment, principal place of business, 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 (21 CFR 108.25(c)(1)). The emergency permit control regulations also require commercial processors of acidified foods to provide FDA with information, submitted on Form FDA 2541e, on the scheduled processes including, as applicable, information about the product, the container type and size, pH, method of acidification, microbial preservatives critical to the scheduled process, process source, process mode, the container and container closure treatment, and details of the scheduled process (e.g., process time and temperature) for each acidified food in each container size (21 CFR 108.25(c)(2)). All plant personnel involved in acidification, pH control, heat treatment, or other critical factors of the operation must be under the operating supervision of a person who has attended a school⁵ 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 (21 CFR 108.25(f)).

16.2.2 Relationship Between the Requirements in the PCHF Rule and the Specific Acidified Food Requirements

Some requirements of the PCHF rule have corresponding requirements in the emergency permit control regulations, part 114, or both, but other requirements of the PCHF rule do not. For example:

- The requirement of the PCHF rule for process controls for biological hazards requiring a preventive control has corresponding requirements for a scheduled process for an acidified food under the emergency permit control regulations and part 114; but
- Neither the emergency permit control regulations nor part 114 requires a hazard analysis.

Likewise, some requirements in the emergency permit control regulations, part 114, or both have corresponding requirements in the PCHF rule, but other requirements in the emergency permit control regulations, part 114, or both do not. For example:

⁵ Often referred to as “Better Process Control School.”

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- The requirements in part 114 for frequent testing of pH, and recording the results of that testing, have a corresponding requirement in the PCHF rule for monitoring and for establishing and keeping records of monitoring; but
- The requirement of the emergency permit control regulations to submit the scheduled process to FDA on Form FDA 2541e has no corresponding requirement in the PCHF rule, and the requirement of part 114 for marking each container or product with an identifying code permanently visible to the naked eye has no corresponding requirement in the PCHF rule.

16.2.3 Developing a Strategy to Comply with the PCHF Rule, Emergency Permit Control Regulations, and Part 114

Sections 16.6 through 16.13 of this chapter compare the specific requirements of the emergency permit control regulations, part 114, and the PCHF rule to help you comply with all applicable requirements by explaining:

- How you can leverage procedures, practices, and processes that you establish and implement to comply with the requirements prescribed by 21 CFR 108.25 and part 114, and records that you establish and keep to comply with those requirements, to address corresponding requirements of the PCHF rule; and
- How you can leverage the procedures, practices, and processes that you establish and implement to comply with the requirements of the PCHF rule, and the records that you establish and keep to comply with those requirements, to address corresponding requirements of 21 CFR 108.25 and part 114.

Importantly, the procedures, practices, and processes that you establish and implement to comply with the requirements prescribed by 21 CFR 108.25 and part 114, and records that you establish and keep to comply with those requirements, could partially – but not fully – satisfy corresponding requirements of the PCHF rule. Likewise, the procedures, practices, and processes that you establish and implement to comply with the requirements of the PCHF rule, and the records that you establish and keep to comply with those requirements, could partially – but not fully – satisfy corresponding requirements of 21 CFR 108.25 and part 114. Sections 16.6 through 16.13 of this chapter provide details about the extent to which complying with the requirements prescribed by 21 CFR 108.25 and part 114 can address the corresponding PCHF requirements and vice versa.

In some cases, the simplest approach to complying with both sets of requirements could be to use procedures, practices, processes, or records associated with the specific acidified food requirements to address the corresponding requirements of the PCHF rule. For example, see the discussion in section 16.10.1 regarding process controls. Because process controls for acidified foods must address all parameters specified on Form FDA 2541e, a simple approach to complying with the requirement to identify and implement preventive controls that are process controls could be to complete Form FDA 2541e and include it in your food safety plan as a written process control.

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In other cases, the simplest approach to complying with both sets of requirements could be to use procedures, practices, processes, or records associated with the specific requirements of the PCHF rule to address the corresponding requirements specific to acidified foods. For examples, see the discussions in:

- Section 16.10.4 regarding the recall plan required by the PCHF rule for foods with hazards that require a preventive control and the recall procedures required by 21 CFR 108.25(e);
- Section 16.11 regarding preventive control management components required by the PCHF rule and corresponding requirements in part 114; and
- Section 16.12 regarding the recordkeeping requirements of part 117 and the corresponding recordkeeping requirements of part 114.

This chapter provides you with information to help you choose an approach for complying with the PCHF rule, emergency permit control regulations, and part 114, in a way that works best for your facility and your acidified food product.

16.2.4 You Must Comply with the Specific Acidified Food Requirements Even If There Is No Corresponding Requirement in the PCHF Rule

Appendix 16-1 in this chapter summarizes key specific acidified food requirements under the emergency permit control regulations, part 114, or both that either:

- Have no explicitly corresponding requirement under the PCHF rule; or
- Exceed the corresponding requirements of the PCHF rule.

Sections 16.6 through 16.13 of this chapter provide suggestions for how you can address some of the key specific acidified food requirements (see Appendix 16-1) by complying with the PCHF rule. For example, part 114 requires that the scheduled process for an acidified food control microorganisms of non-health significance in addition to pathogens (see 21 CFR 114.80(a)(1) and Appendix 16-1), and section 16.9 explains how your hazard analysis could identify microorganisms of non-health significance as a biological hazard requiring a preventive control, even though microorganisms of non-health significance, by themselves, are not “hazards” as that term is defined in part 117. However, sections 16.6 through 16.13 of this chapter also clarify that none of the PCHF requirements address the submission of a food canning establishment registration on Form FDA 2541 as required by 21 CFR 108.25(c)(1) or suggest any way to comply with the requirement to submit Form FDA 2541e other than the mechanism specified in 21 CFR 108.25(c)(2).

If a specific acidified food requirement exceeds the corresponding requirement of the PCHF rule, you must comply with the specific acidified food requirement. As discussed in section 16.12, part 114 requires that you keep records required by part 114 for 3 years, which exceeds the 2-year record retention requirement in part 117 for records documenting the food safety plan and implementation of the food safety plan. (See 21 CFR 114.100(e) and 21 CFR 117.315.)

16.3 Understand the Hazard Requiring a Preventive Control

The PCHF rule requires a hazard analysis to determine whether there are any hazards requiring a preventive control. (See 21 CFR 117.130(a)(1).) Part 114 includes requirements to control hazards associated with *C. botulinum* and other microorganisms of public health significance. Thus, understanding the hazards that can be controlled by complying with part 114 can help to understand which known or reasonably foreseeable (potential) hazards require a preventive control under the PCHF rule. Below, we discuss the hazards that part 114 controls, as well as the importance of controlling some microorganisms of non-health significance⁶ (which are not “hazards” as that term is defined in part 117).

When conditions are not conducive to growth of vegetative cells (e.g., when the availability of nutrients is limited), *C. botulinum* can form spores that are adapted for prolonged survival under adverse conditions (Larousse and Brown, 1997). Thermal processes using temperatures such as 212 °F (100°C) (i.e., the temperature of boiling water) or even lower (e.g., 150 °F (65.6°C) in some circumstances) can destroy the vegetative cells of *C. botulinum*, but do not destroy the spores of *C. botulinum* (see 41 FR 30442 at 30442, July 23, 1976).

When the pH of a food is 4.6 or below, spores of *C. botulinum* will not germinate and grow (41 FR 30442 at 30442). However, an acidified food can pose a risk of botulism if pH and other critical factors are not carefully controlled during processing to prevent the germination and growth of viable spores of *C. botulinum* (44 FR 16204 at 16204, March 16, 1979). When critical factors are not carefully controlled, the vegetative cells of some microorganisms of non-health significance (such as some spoilage bacteria, yeasts, and molds) can grow in an acid environment and, in so doing, cause the pH of the food to increase (Fields, Zamora, and Bradsher, 1977; Odlaug and Pflug, 1978; and Institute of Food Technologists, 2001). In addition, some spoilage microorganisms (such as *Bacillus licheniformis* (*B. licheniformis*)) produce heat-resistant, acid-tolerant spores that, when critical factors are not properly controlled, can germinate, grow, and cause the pH to increase; thermal processing that is sufficient to destroy vegetative cells of such microorganisms may not be sufficient to destroy their spores (Fields, Zamora, and Bradsher, 1977; Montville, 1982; Al Dujaili and Anderson, 1991; and Rodriguez, Cousin, and Nelson, 1992).

16.4 Terms Used in This Chapter

Section III.B in the Introduction of this guidance includes a glossary of terms that are used in this guidance but are not defined in 21 CFR 117.3. At this time, that glossary does not include all terms that are used in this chapter. See Table 16-1 for additional terms that we use in this chapter. We intend to include these terms in the glossary in the Introduction of this guidance when we update the Introduction. When we do so, we will delete Table 16-1 from this chapter.

⁶ See section 16.9 for additional discussion of microorganisms of non-health significance.

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Table 16-1 Terms Used in this Chapter

Term	What the Term Means
Emergency permit control regulations	Emergency permit control requirements in 21 CFR 108.25 for acidified foods
Part 114	Requirements in 21 CFR part 114, Acidified Foods
Potential hazard	Known or reasonably foreseeable hazard (which is defined in 21 CFR 117.3)

16.5 Quick Reference Guide

Table 16-2 is a quick reference guide to help you see at a glance the relationship between the specific acidified food requirements and corresponding PCHF requirements.

Table 16-2 Quick Reference Guide Listing the Specific Acidified Food Requirements and Corresponding PCHF Requirements

Description of Requirement	Applicable Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	Applicable Requirements in Part 117 (21 CFR)	Applicable Section in This Chapter	Applicable Chapters in This Guidance
Qualifications of personnel with responsibility for supervision or other oversight	<ul style="list-style-type: none"> • 108.25(f) • 114.10 	<ul style="list-style-type: none"> • 117.4(c) • 117.180(c)(1) 	16.6	N/A
Oversight	<ul style="list-style-type: none"> • 108.25(f) • 114.10 • 114.83 	<ul style="list-style-type: none"> • 117.126(a)(2) • 117.160(b)(1) • 117.160(c)(5) • 117.165(a)(4) • 117.170(c)(2)(ii) • 117.180(a) 	16.7	Chapter 1
Written food safety plan	N/A	117.126	16.8	Chapter 1
Hazard analysis	N/A	117.130	16.9	<ul style="list-style-type: none"> • Chapters 2, 3, and 6 • Appendix 1 • Appendix 3

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Description of Requirement	Applicable Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	Applicable Requirements in Part 117 (21 CFR)	Applicable Section in This Chapter	Applicable Chapters in This Guidance
Identifying and implementing preventive controls that are process controls for biological hazards requiring a preventive control	<ul style="list-style-type: none"> • 108.25(c)(2) • 108.25(c)(3) • 114.80(a)(1) • 114.80(a)(3) • 114.80(a)(4) 	<ul style="list-style-type: none"> • 117.126(b)(2) • 117.135(a) • 117.135(b) • 117.135(c)(1) 	16.10.1	Chapters 4 and 6
Identifying and implementing preventive controls for chemical or physical hazards requiring a preventive control	N/A	<ul style="list-style-type: none"> • 117.126(b)(2) • 117.135(a) • 117.135(b) • 117.135(c)(1) • 117.135(c)(2) 	16.10.2.1	Chapters 4, 11, 12, and 13
Identifying and implementing preventive controls that are sanitation controls	N/A	<ul style="list-style-type: none"> • 117.126(b)(2) • 117.135(a) • 117.135(b) • 117.135(c)(3) 	16.10.2.2	Chapter 10
Supply-chain controls	114.100(a)	<ul style="list-style-type: none"> • 117.126(b)(3) • 117.135(a) • 117.135(c)(4) • Subpart G 	16.10.3	Chapters 4 and 15
Recall plan	108.25(e)	<ul style="list-style-type: none"> • 117.126(b)(4) • 117.135(a) • 117.135(b) • 117.135(c)(5) • 117.139 	16.10.4	Chapters 4 and 14
Preventive control management components	<ul style="list-style-type: none"> • 108.25(c)(3)(ii) • 114.3 • 114.80(a)(2) • 114.80(a)(4) • 114.89 • 114.90 	<ul style="list-style-type: none"> • 117.126(b)(5) • 117.126(b)(6) • 117.126(b)(7) • 117.140 • 117.145 • 117.150 • 117.155 • 117.160 • 117.165 	16.11	Chapters 5 and 6

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Description of Requirement	Applicable Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	Applicable Requirements in Part 117 (21 CFR)	Applicable Section in This Chapter	Applicable Chapters in This Guidance
Records	<ul style="list-style-type: none"> • 108.25(g) • 114.100 	<ul style="list-style-type: none"> • 117.9 • 117.126(c) • 117.145(c) • 117.150(d) • 117.155(b) • 117.180(d) • 117.190(a) • 117.475(c) • Subpart F 	16.12	Chapter 6
Coding	114.80(b)	N/A	16.13	N/A

16.6 Requirements for Qualifications of Personnel with Responsibility for Supervision or Other Oversight

Part 117 includes requirements for qualifications of personnel, including supervisory personnel (see 21 CFR 117.4). Table 16-3 shows how you can leverage compliance with corresponding training requirements in 21 CFR 108.25(f) and 114.10 to address the requirement of 21 CFR 117.4(c) to provide supervisory oversight for the production of an acidified food product. Note that, in general, satisfying the training requirements of 21 CFR 117.4 would not satisfy the specialized training requirements of 21 CFR 108.25(f) and 114.10.

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Table 16-3 Qualifications of Personnel with Responsibility for Supervision or Other Oversight

Requirements in Part 117 (21 CFR)	Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Requirements in Part 117
117.4(c): Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.	108.25(f) and 114.10: All operators of processing and packaging systems 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 and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction.	Satisfactorily completing the prescribed course of instruction in a school specified in 21 CFR 108.25(f) and 114.10 provides an individual with the qualifications necessary to provide supervisory oversight for the production of an acidified food product as required by 21 CFR 117.4(c).

16.7 Requirements for Oversight

The PCHF rule requires preparation or oversight of the food safety plan, and performance or oversight of implementation of certain activities related to the food safety plan, by one or more PCQIs. (See 21 CFR 117.126(a)(2) and 117.180(a).) Table 16-4 shows how you can leverage compliance with corresponding requirements in 21 CFR 108.25(f), 114.10, and 114.83 to address these requirements of the PCHF rule as they relate to acidification.

See Appendix 16-1 in this chapter and the discussion in section 16.6 regarding the specialized training requirements of 21 CFR 108.25(f) and 114.10 for supervisory oversight of processing and packaging of acidified foods. In general, a person who satisfies the qualification requirements of the PCHF rule for a PCQI to prepare, or oversee the preparation of, the food safety plan and to conduct or oversee activities listed in 21 CFR 117.180(a) would not be qualified to supervise the processing and packaging of acidified foods unless that person also satisfies the specialized training requirements of 21 CFR 108.25(f) and 114.10.

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Table 16-4 Requirements for Oversight

Requirements in Part 117 (21 CFR)	Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Requirements in Part 117
<ul style="list-style-type: none"> • 117.126(a)(2): The food safety plan must be prepared, or its preparation overseen, by one or more preventive controls qualified individuals. • 117.180(a): One or more preventive controls qualified individuals must do or oversee certain activities related to preparation and implementation of the food safety plan: <ul style="list-style-type: none"> ○ 117.160(b)(1) (validation of preventive controls) ○ 117.160(b)(1)(i)(B)(2) (justification for a validation timeframe that exceeds the first 90 days of production) ○ 117.160(c)(5) (justification that validation is not applicable) ○ 117.165(a)(4) (review of records) ○ 117.165(a)(4)(i) (justification for a timeframe that exceeds 7 days for review of certain records) ○ 117.170(c)(2)(ii) (justification for the timeframe for completion of the reanalysis, and validation of additional preventive controls, if the timeframe exceeds 90 days after production) 	<ul style="list-style-type: none"> • 108.25(f) and 114.10: All operators of processing and packaging systems 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 and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. • 114.83 The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods. Under 114.3(e), scheduled process means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. It includes control of pH and other critical factors equivalent to the process established by a competent processing authority. 	<ul style="list-style-type: none"> • A person who satisfactorily completes the prescribed course of instruction specified in 21 CFR 108.25(f) and 114.10 could, through job experience, be qualified to conduct or oversee the following activities listed in 21 CFR 117.180(a) as they relate to acidification: <ul style="list-style-type: none"> ○ Review of records (21 CFR 117.165(a)(4); and ○ Justification for a timeframe that exceeds 7 days for review of certain records (21 CFR 117.165(a)(4)(i)) • A person who is a competent processing authority and who establishes the scheduled process in accordance with 21 CFR 114.83 could, through job experience, be qualified to conduct or oversee the following activities listed in 21 CFR 117.180(a) as they relate to acidification and thermal processing of an acidified food: <ul style="list-style-type: none"> ○ 117.160(b)(1) (validation of preventive controls) ○ 117.160(b)(1)(i)(B)(2) (justification for a validation timeframe that exceeds the first 90 days of production) ○ 117.160(c)(5) (justification that validation is not applicable) ○ 117.165(a)(4) (review of records) ○ 117.165(a)(4)(i) (justification for a timeframe that exceeds 7 days for review of certain records) ○ 117.170(c)(2)(ii) (justification for the timeframe for completion of the reanalysis, and validation of additional preventive controls, if the timeframe exceeds 90 days after production)

16.8 Requirements for a Written Food Safety Plan

The PCHF rule requires that you prepare, or have prepared, and implement a written food safety plan (see 21 CFR 117.126). Neither 21 CFR 108.25 nor part 114 has a corresponding requirement to prepare, or have prepared, and implement a written food safety plan. However, in the remainder of this chapter we explain how you can leverage procedures, practices, and processes that you establish and implement to comply with the requirements of 21 CFR 108.25 or part 114, and records that you establish and keep to comply with those requirements, to address requirements of the PCHF rule for a food safety plan.

16.9 Requirements for Hazard Analysis

Part 117 defines hazard as any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury. (See 21 CFR 117.3.) The PCHF rule includes requirements:

- To conduct a hazard analysis, which must be written regardless of its outcome (see 21 CFR 117.130(a));
- For a hazard identification that considers known or reasonably foreseeable hazards that include biological hazards, chemical hazards, and physical hazards, regardless of whether the hazard occurs naturally, is unintentionally introduced, or is intentionally introduced for purposes of economic gain (see 21 CFR 117.130(b)); and
- Applicable to the hazard evaluation (see 21 CFR 117.130(c)).

Neither 21 CFR 108.25 nor part 114 has a corresponding requirement for any requirement of the PCHF rule for hazard analysis. However, 21 CFR 108.25 and part 114 require specific controls for the biological hazard *C. botulinum*, monitoring of one of those controls (i.e., pH), and a basis for the adequacy of the process. (See 21 CFR 114.80(a)(1) and (2) and 21 CFR 108.25(c)(3)(ii), respectively.) In addition, part 114 requires thermal processing to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance. (See 21 CFR 114.80(a)(1).)

A hazard analysis that identifies and evaluates *C. botulinum* as a biological hazard requiring a preventive control can lead to appropriate preventive controls and associated preventive control management components that could address the corresponding requirements of part 114 as they relate to the biological hazard *C. botulinum*. In addition, a hazard analysis that identifies microorganisms (other than *C. botulinum*) of public health significance can lead to appropriate preventive controls and associated preventive control management components that could address the corresponding requirements of part 114 as they relate to the vegetative cells of microorganisms of public health significance other than *C. botulinum*. For example:

- As discussed in section 16.2.1, in the proposed and final rulemakings for LACF and acidified foods FDA discussed the need for CGMP requirements to control *C. botulinum*. Under part

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117, a knowledgeable person would identify *C. botulinum* as a biological hazard requiring a preventive control to inactivate vegetative cells of *C. botulinum* and to prevent toxin formation due to germination and growth from spores of *C. botulinum*. A hazard analysis could reference 21 CFR 108.25 and part 114, rather than citations to published scientific literature, as the basis for a conclusion that *C. botulinum* in shelf-stable acidified foods is a hazard requiring a preventive control.

- Part 114 requires that acidified foods be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance. (See 21 CFR 114.80(a)(1).) Under part 117, a knowledgeable person could identify pathogenic bacteria such as *Salmonella*, *Escherichia coli* (*E. coli*) O157:H7 and *Listeria monocytogenes* (*L. monocytogenes*) as hazards associated with some acidified foods because these pathogenic bacteria can be present on some of the ingredients and can be a hazard if the heat treatment is not adequate to kill vegetative cells of the pathogenic bacteria. (See Appendix 1 of this guidance and the example of the heat processing for a salsa in Chapter 6 of this guidance.)
- Part 114 requires that the scheduled process for an acidified food control microorganisms of non-health significance in addition to pathogens. (See 21 CFR 114.80(a)(1) and Appendix 16-1.) Microorganisms of non-health significance, by themselves, are not “hazards” as that term is defined in part 117. However, as discussed in section 16.3, when critical factors are not carefully controlled, the vegetative cells of some microorganisms of non-health significance (such as some spoilage bacteria) can grow in an acid environment and, in so doing, cause the pH of the food to increase. Therefore, under part 117, a knowledgeable person could identify microorganisms of non-health significance in shelf-stable acidified foods as biological hazards requiring a preventive control.
- The parameters that you submit to us on Form FDA 2541e address critical factors such as control of pH, process time and temperature, and preservatives. (See Form 2541e and 21 CFR 114.80(a)(1).) As discussed in section 16.10.1, identifying pathogenic bacteria such as *C. botulinum*, *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* as biological hazards requiring a preventive control, and identifying microorganisms of non-health significance in shelf-stable acidified foods as biological hazards requiring a preventive control, could lead to identifying the parameters that you submit to us on Form FDA 2541e as the preventive controls. As discussed in section 16.11, these parameters for process controls could lead to preventive control management components (such as monitoring pH, and verification that includes validation to establish the adequacy of the process) to address the requirement of 21 CFR 114.80(a)(2) for monitoring pH and the requirement of 21 CFR 108.25(c)(3)(ii) for adequacy of the scheduled process.⁷
- Part 114 requires that testing and examination of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination because there is a potential for recontamination with microorganisms (including pathogens and microorganisms of non-health significance that could raise the pH) if there is a loss of seam/seal integrity, especially during cooling of the sealed containers in water. (See 21 CFR 114.80(a)(4).) The hazard evaluation must consider the effect of packaging activities on the

⁷ Although not specified in part 114, preventive control management components for acidified foods generally would include monitoring the thermal process and other critical factors in addition to monitoring pH, and verification activities in addition to validation. See Section 6.16 in Chapter 6 of this for a comprehensive example of preventive control management components for an acidified food.

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safety of the finished food for the intended consumer. (See 21 CFR 117.130(c)(2)(vi).) A knowledgeable person would identify microorganisms (including pathogens and microorganisms of non-health significance that could raise the pH) that could recontaminate the food due to lack of container integrity as process-related biological hazards requiring a preventive control. As discussed in section 16.10.1, this outcome of the hazard analysis could lead to a preventive control during seaming/sealing after filling the container (i.e., applying a hermetic seal) to prevent recontamination. As discussed in section 16.11, this preventive control could lead to preventive control management components that include monitoring of seam/seal integrity to address the requirements of 21 CFR 114.80(a)(4).

For help in identifying other known or reasonably foreseeable biological, chemical, or physical hazards applicable to your product, see:

- Chapter 2 of this guidance regarding the hazard analysis;
- Chapter 3 of this guidance regarding hazards associated with the manufacturing, processing, packing, and holding of human food;
- Appendix 1 of this guidance regarding known or reasonably foreseeable (potential) hazards and
- Section 6.16 in Chapter 6 of this guidance regarding heat treatments as a process control, which provides an example of a hazard analysis for a salsa. In this example, a salsa manufacturer identified *Salmonella*, *E. coli* O157:H7, *L. monocytogenes*, and *C. botulinum* as hazards associated with the salsa because these pathogenic bacteria can be present on some of the ingredients and can be a hazard if the salsa is not properly acidified to a pH that is low enough to prevent the germination of spores of *C. botulinum* and if the heat treatment is not adequate to kill vegetative cells of the pathogenic bacteria. In addition, the salsa manufacturer consulted the scientific literature and found that sporeforming bacteria that are generally associated with spoilage (such as *Bacillus subtilis* and *B. licheniformis*) could affect the safety of an acidified food if spores that are not destroyed during the product heat treatment germinate, grow, and cause the pH to increase above 4.6.

16.10 Requirements for Preventive Controls

The PCHF rule includes requirements to identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act. (See 21 CFR 117.135(a).) Preventive controls must be written. (See 21 CFR 117.135(b).)

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16.10.1 Identifying and Implementing Preventive Controls that Are Process Controls for Biological Hazards Requiring a Preventive Control

Table 16-5 shows how you can leverage the parameters that you submit on Form FDA 2541e to address the requirements of the PCHF rule for written preventive controls that are process controls for biological hazards requiring a preventive control. For example, Form FDA 2541e requires information about pH, process time and temperature, and preservatives.⁸

See Appendix 16-1 in this chapter for key additional requirements specific to acidified foods. Table 16-5 also shows how, with some limitations, you can leverage written process controls that you identify and implement for acidification to comply with the requirements of the PCHF rule to address the corresponding requirements in part 114 and Form FDA 2541e (e.g., for control of pH, process time and temperature, and preservatives). However, the requirement in 21 CFR 108.25(c)(2) to submit Form FDA 2541e to FDA has no corresponding requirement in the PCHF rule. You must submit Form FDA 2541e to FDA as required by 21 CFR 108.25(c)(2) even if you include Form FDA 2541e in your food safety plan.

As discussed in section 16.9, one outcome of the hazard analysis could be a preventive control during seaming/sealing after filling the container (i.e., applying a hermetic seal) to prevent recontamination. Although this preventive control has no directly corresponding requirement in 21 CFR 108.25(e) or part 114, there is a related requirement specific to acidified foods. As shown in Appendix 16-1 in this chapter, part 114 requires testing and examination of containers at a frequency that is often enough to ensure that the container suitably protects the food from leakage or contamination. (See 21 CFR 114.80(a)(4).) See the discussion in section 16.11 of how the requirement of part 114 for testing and examination of containers at a frequency that is often enough to ensure that the container suitably protects the food from leakage or contamination could satisfy the requirements of the PCHF rule for monitoring of seam/seal integrity as a preventive control management component for a process control of applying a hermetic seal.

For additional help regarding the requirements of the PCHF rule for process controls for biological hazards requiring a preventive control, see:

- Chapter 4 regarding preventive controls; and
- Section 6.16 in Chapter 6 (regarding heat treatments as a process control), which provides an example of process controls for a salsa.

⁸ Note that you must include your process controls in the food safety plan that you keep onsite even though you submit them to FDA on Form FDA 2541e, because the food safety plan must be kept onsite (see 21 CFR 117.315(d)).

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Table 16-5 Identifying and Implementing Preventive Controls that Are Process Controls for Biological Hazards Requiring a Preventive Control

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
<ul style="list-style-type: none"> • Requirements to identify and implement preventive controls that are process controls: <ul style="list-style-type: none"> ○ 117.135(a) (general requirement) ○ 117.135(c)(1) Process controls. Process controls include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (i) Parameters associated with the control of the hazard; and (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control. • Requirement for written procedures for preventive controls that are process controls: <ul style="list-style-type: none"> ○ 117.126(b)(2) ○ 117.135(b) 	<ul style="list-style-type: none"> • 108.25(c)(2): Requires the submission to FDA of Form FDA 2541e. Form FDA 2541e requires, as applicable, information about the product, the container type and size, pH, method of acidification, microbial preservatives critical to the scheduled process, process source, process mode, the container and container closure treatment, and details of the scheduled process (e.g., process time and temperature), for each acidified food in each container size. • 108.25(c)(3): Requires a commercial processor engaged in processing acidified foods to process each food in conformity with at least the scheduled processes filed under 21 CFR 108.25(c)(2). • 114.80(a)(1): Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of non-health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of non-health significance (in lieu of thermal processing). • 114.80(a)(3): Lists acceptable procedures for acidification to attain acceptable equilibrium pH levels in the final food 	<ul style="list-style-type: none"> • The parameters that you establish in accordance with 21 CFR 114.80(a)(1) and submit on Form FDA 2541e could satisfy the requirement for parameters associated with control of a hazard for process controls, and applicable maximum or minimum values in 21 CFR 117.135(c)(1), as long as you include that scheduled process in the food safety plan that is signed and dated by the owner, operator, or agent in charge of the facility and kept onsite (see 21 CFR 117.310 and 117.315(c)). • Compliance with the scheduled process submitted to FDA on Form FDA 2541e could satisfy the requirements in 21 CFR 117.135(a) and (c) to implement preventive controls that are process controls for biological hazards that require a preventive control. 	<p>Complying with the PCHF requirements to identify and implement process controls, parameters associated with control of the hazard, and applicable maximum or minimum values that satisfy all requirements in 21 CFR 114.80(a)(1) and all requirements on Form FDA 2541e could satisfy all requirements of 21 CFR 108.25(c)(2) and (3) and part 114 (e.g., for control of pH, process time and temperature, and preservatives), as long as you also submit Form FDA 2541e to FDA.</p>

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16.10.2 Preventive Controls That Have No Corresponding Requirements in 21 CFR 108.25 or Part 114

As discussed in sections 16.10.2.1 and 16.10.2.2, the PCHF rule specifies some preventive control requirements that have no corresponding requirements in either 21 CFR 108.25 or part 114.

16.10.2.1 Identifying and Implementing Preventive Controls for Chemical Hazards or Physical Hazards Requiring a Preventive Control

When the hazard requiring a preventive control under part 117 is a chemical or physical hazard, neither 21 CFR 108.25 nor part 114 has a corresponding requirement to identify and implement a preventive control. Preventive controls for chemical or physical hazards could be a process control (see 21 CFR 117.135(c)(1)) or, in the case of a chemical hazard that is a food allergen hazard, a food allergen control (see 21 CFR 117.135(c)(2)).

For help in identifying and implementing preventive controls for known or reasonably foreseeable chemical and physical hazards applicable to acidified foods, see:

- Chapter 4 regarding preventive controls;
- Chapter 11 regarding food allergen controls;
- Chapter 12 regarding preventive controls for chemical hazards; and
- Chapter 13 regarding preventive controls for physical hazards.

16.10.2.2 Identifying and Implementing Preventive Controls That Are Sanitation Controls

Sanitation controls include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens, biological hazards due to employee handling, and food allergen hazards. Sanitation controls must include, as appropriate to the facility and the food, procedures, practices, and processes for the: (1) Cleanliness of food-contact surfaces, including food-contact surfaces of utensils and equipment; and (2) prevention of allergen cross-contact and cross-contamination from insanitary objects and from personnel to food, food packaging material, and other food-contact surfaces and from raw product to processed product. (See 21 CFR 117.135(c)(3).) Neither 21 CFR 108.25 nor part 114 has a corresponding requirement to identify and implement a sanitation control.

Complying with part 114 should make it unnecessary to identify and implement sanitation controls for the control of environmental pathogens (such as *L. monocytogenes* or *Salmonella*) for many acidified foods because part 114 requires thermal processing to an extent that is

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sufficient to destroy the vegetative cells of microorganisms of public health significance (see 21 CFR 114.80(a)) and because many acidified foods are packaged (e.g., by hot filling) in a way that does not expose the thermally processed food to the environment at a temperature at which environmental pathogens would survive the filling. However, as part of the hazard analysis the PCQI would evaluate whether sanitation controls for the control of environmental pathogens are necessary if a ready-to-eat acidified food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the environmental pathogen) that would significantly minimize the environmental pathogen. (See 21 CFR 117.130(c)(1)(ii).)

Sanitation controls are one way to address food allergen hazards. You determine through your hazard analysis whether food allergen hazards require sanitation controls (which can also be considered food allergen controls, because sanitation controls are procedures to protect food from allergen cross-contact).

For help in determining whether to identify and implement sanitation controls, see:

- Chapter 4 regarding preventive controls; and
- Chapter 10 regarding sanitation controls.

16.10.3 Supply-chain Controls

The PCHF rule requires that a receiving facility establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control. (See subpart G and 21 CFR 117.405(a)(1).) Supply-chain controls are not required if the receiving facility (rather than a supplier) will control a hazard requiring a preventive control. For example, supply-chain controls are not required for biological hazards that are controlled by the process controls for an acidified food.

Part 114 requires that records shall be maintained of suppliers' guarantees or certifications that verify compliance with FDA regulations and guidance documents or action levels. (See 21 CFR 114.100(a).) If your hazard analysis for a raw material or other ingredient identifies any hazards requiring a supply-chain-applied control, and your supply-chain program for that raw material or other ingredient includes sampling and testing of that raw material or other ingredient with results reported in documentation such as a Certificate of Analysis, complying with the requirements for supply-chain controls could satisfy the corresponding requirement of 21 CFR 114.100(a) for records of suppliers' guarantees or certifications. (See 21 CFR 117.410(b)(2) (which identifies sampling and testing of raw materials or other ingredients as an appropriate supplier verification activity) and 21 CFR 117.475(c)(8) (which requires documentation of sampling and testing conducted as a supplier verification activity)).

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For help in determining whether to establish and implement a supply-chain program, see:

- Chapter 4 regarding preventive controls; and
- Chapter 15 regarding a supply-chain program.

16.10.4 Recall Plan

The PCHF rule requires a recall plan for food with a hazard requiring a preventive control. (See 21 CFR 117.139.) Table 16-6 shows how you can leverage procedures, practices, and processes that you establish and implement to comply with corresponding requirements in 21 CFR 108.25(e) to address the requirements of the PCHF rule for a recall plan.

Table 16-6 also shows how, with one limitation, you can leverage a written recall plan that you establish and implement to comply with the requirements of the PCHF rule to address the corresponding requirements in 21 CFR 108.25(e) regarding recalls. However, the requirement in 21 CFR 108.25(e) for the recall procedures to include notifying FDA of any recalls has no corresponding requirement in the PCHF rule for a recall plan. Therefore, a written recall plan that you establish and implement to comply with the requirements of the PCHF rule could only satisfy all requirements of 21 CFR 108.25(e) regarding recalls if it also includes procedures for notifying FDA of any recalls.

For help regarding the recall plan, see:

- Chapter 4 regarding preventive controls; and
- Chapter 14 regarding the recall plan.

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Table 16-6 Recall Plan

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
<ul style="list-style-type: none"> • Requirements to identify and implement preventive controls: <ul style="list-style-type: none"> ○ 117.135(a) (general requirement) ○ 117.135(c)(5) (recall plan) ○ 117.139 (recall plan) • Requirement for written procedures for preventive controls: <ul style="list-style-type: none"> ○ 117.126(b)(4) ○ 117.135(b) 	<p>108.25(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 FDA of any recalls; and for implementing recall programs.</p>	<p>A written recall procedure that you establish and implement to comply with 21 CFR 108.25(e) could satisfy all requirements of the PCHF rule for a recall plan, as long as it includes procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:</p> <ul style="list-style-type: none"> • Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected food; • Notify the public about any hazard presented by the food when appropriate to protect public health; • Conduct effectiveness checks to verify that the recall is carried out; and • Appropriately dispose of recalled food—e.g., through reprocessing, reworking, diverting to a use that does not present a safety concern, or destroying the food. 	<p>A written recall plan that you establish and implement to comply with 21 CFR 117.139 could satisfy the requirements of 21 CFR 108.25(e), as long as it includes procedures for notifying FDA about any recall.</p>

16.11 Requirements for Preventive Control Management Components

With some exceptions, the preventive controls required by the PCHF rule are subject to the following preventive control management components as appropriate to ensure the

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effectiveness of the preventive controls, taking into account the nature of the preventive control and its role in the facility's food safety system:

- Monitoring in accordance with 21 CFR 117.145;
- Corrective actions and corrections in accordance with 21 CFR 117.150; and
- Verification in accordance with 21 CFR 117.155.

(See 21 CFR 117.140.) The exceptions to these requirements for preventive control management components are:

- The supply-chain program is subject to a subset of the preventive control management components (i.e., corrective actions and corrections in accordance with 21 CFR 117.150, review of records in accordance with 21 CFR 117.165(a)(4), and reanalysis in accordance with 21 CFR 117.170). (See 21 CFR 117.140(b).)
- The recall plan is not subject to the requirements for preventive control management components. (See 21 CFR 117.140(c).)

Table 16-7 lists most⁹ of the specific provisions of the PCHF rule for establishing and implementing preventive control management components, including the requirements for written procedures for the preventive control management components. Table 16-7 also lists the corresponding requirements in part 114. Table 16-7 shows how you can leverage procedures, practices, and processes that you establish and implement to comply with 21 CFR 114.80(a)(2), 114.80(a)(4), or 114.89, or that are listed in 21 CFR 114.90, to address the requirements of the PCHF rule for preventive control management components. To see how you can leverage records documenting compliance with recordkeeping requirements of part 114 to address the corresponding requirements for records documenting implementation of the preventive control management components, see Table 16-8.

Table 16-7 also shows how you can leverage the preventive control management components that you implement to satisfy the requirements of the PCHF rule to address the corresponding requirements in 21 CFR 114.80(a)(2), 114.80(a)(4), and 114.89. To see how you can leverage records documenting implementation of the preventive control management components to address corresponding recordkeeping requirements of part 114, see Table 16-8.

See also Appendix 16-1 in this chapter for key additional requirements specific to acidified foods. The emergency permit control regulations require that you provide FDA with any process and procedure information that we deem necessary to determine the adequacy of the process upon request. (See 21 CFR 108.25(c)(3)(ii).) The requirements of the PCHF rule applicable to validation of preventive controls correspond to the requirements of 21 CFR 108.25 and part 114 for the adequacy of the scheduled process, and we ordinarily will review records applicable to

⁹ See Table 16-8 for the records documenting implementation of the preventive control management components.

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process validation during inspection. However, as required by 21 CFR 108.25(c)(3)(ii) you must send us any process and procedure information that we deem necessary to determine the adequacy of the process if we ask you to do so (e.g., as a follow-up to your submission of a scheduled process on Form FDA 2541e).

For help regarding preventive control management components, see:

- Chapter 5 regarding preventive control management components; and
- Chapter 6 regarding heat treatments as a process control.

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Table 16-7 Preventive Control Management Components

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108.25 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
<ul style="list-style-type: none"> • Requirements to establish and implement preventive control management components: <ul style="list-style-type: none"> ○ 117.140 ○ 117.145 (monitoring) ○ 117.150 (corrective actions and corrections) ○ 117.155 (verification) ○ 117.160 (validation) ○ 117.165 (verification of implementation and effectiveness) ○ 117.165(a)(1) (calibration) ○ 117.165(a)(2) (product testing) ○ 117.165(a)(3) (environmental monitoring) ○ 117.165(a)(4) (review of records) • Requirement for written procedures for preventive control management components: <ul style="list-style-type: none"> ○ 117.126(b)(5) and 117.145(a) (monitoring) ○ 117.126(b)(6) and 117.150(a)(1) (corrective action procedures) ○ 117.126(b)(7) and 117.165(b) (verification) ○ 117.165(b)(1) (calibration) ○ 117.165(b)(2) (product testing) ○ 117.165(b)(3) (environmental monitoring) 	<ul style="list-style-type: none"> • 108.25(c)(3)(ii) Provide us with any process and procedure information that we deem necessary to determine the adequacy of the process • 114.3(e): Scheduled process means the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance. • 114.80(a)(2) Exercise of sufficient control, including frequent testing and recording of results, so that the finished equilibrium pH values for acidified foods are not higher than 4.6 • 114.80(a)(4) Testing and examination of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination. • 114.89 (deviations from scheduled processes) • 114.90 (methodology) 	<ul style="list-style-type: none"> • Complying with 21 CFR 114.80(a)(2) could satisfy the requirements of the PCHF rule for monitoring pH as a preventive control management component for pH control as a process control. • Complying with 21 CFR 114.80(a)(4) could satisfy the requirements of the PCHF rule for monitoring seam/seal integrity of finished product as a preventive control management component when applying a hermetic seal is a process control. • Written procedures that you establish and implement to comply with the requirements of 21 CFR 114.80(a)(2) and (a)(4) could satisfy the requirements of 21 CFR 117.126(b)(5) and 117.145(a) for written monitoring procedures. • Written procedures that you establish and implement to comply with the requirements of 21 CFR 114.89 could satisfy the requirements of 21 CFR 117.126(b)(6) and 117.150(a)(1) for written corrective action procedures as appropriate to the nature of the hazard and the nature of the preventive control. • Written procedures that you establish and implement to comply with 21 CFR 114.90 could satisfy some requirements of the PCHF rule for written procedures for preventive control management components (e.g., written procedures for monitoring or calibration of equipment). 	<ul style="list-style-type: none"> • Complying with the requirements of 21 CFR 117.145 for monitoring preventive controls for (1) pH and (2) applying a hermetic seal could satisfy the requirements of 21 CFR 114.80(a)(2) and (a)(4), respectively. • Complying with the requirements of 21 CFR 117.150 to establish and implement corrective action procedures could satisfy the requirements of 21 CFR 114.89 for deviations from scheduled processes. • Complying with the requirements of 21 CFR 117.155 and 117.160 for process validation would be consistent with the definition of “scheduled process” in 21 CFR 114.3, but you still must submit information about the adequacy of the process to FDA upon request as required by 21 CFR 108.25(c)(3)(ii).

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16.12 Requirements for Records

Subpart A of part 117 requires that food establishments establish and maintain records that document required training. (See 21 CFR 117.9.) Subparts C and G of part 117 require that you have a written food safety plan (see 21 CFR 117.126), records documenting implementation of the food safety plan (see 21 CFR 117.190), and records documenting the supply-chain program (see 21 CFR 117.475(c)).

Subpart F of part 117 includes requirements applicable to all records required by part 117. For example:

- The owner, operator, or agent in charge of the facility must sign and date the food safety plan (21 CFR 117.310);
- Part 117 allows you to use existing records, supplemented as necessary to include all required information (§ 117.330(a)); and
- Part 117 does not require that records be kept in one set of records. If existing records contain some of the required information, any new information required by the PCHF rule may be kept either separately or combined with the existing records (§ 117.330(a)).

Table 16-8 shows how you can leverage compliance with the recordkeeping requirements of 21 CFR 108.25(g) and 114.100(a) through (c) to address the recordkeeping requirements of the PCHF rule. Table 16-8 also shows how you can leverage compliance with the recordkeeping requirements of the PCHF rule to address the corresponding requirements in 21 CFR 114.100(a), (b), and (c).¹⁰

See Appendix 16-1 in this chapter for key additional requirements specific to acidified foods. Importantly:

- The regulations in 21 CFR 108.25 and part 114 each have a recordkeeping requirement that exceeds the corresponding recordkeeping requirement in part 117. Specifically, the regulations in 21 CFR 108.25 and part 114 require that you keep records required by part 114 for 3 years, which exceeds the maximum 2-year record retention requirement in part 117. (See 21 CFR 108.25(g), 114.100(e), and 117.315.)
- Part 114 requires records of distribution. (See 21 CFR 114.100(d).) Part 117 does not have a corresponding recordkeeping requirement. However, compliance with 21 CFR 114.100(d) could satisfy some requirements of 21 CFR 1.345 in part 1, subpart J (Establishment, Maintenance, and Availability of Records) for the identity of the immediate, subsequent recipients of food; likewise, compliance with the requirements of 21 CFR 1.345 in part 1, subpart J for the identity of the immediate, subsequent recipients of food could satisfy the requirements in 21 CFR 114.100(d) for records of distribution of acidified foods.

¹⁰ See also the discussions in sections 16.6 through 16.10 for limitations on whether complying with the requirements of 21 CFR 108.25 and part 114 can address the requirements of part 117 and vice versa.

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For help regarding the recordkeeping requirements of the PCHF rule for acidified foods, see section 6.16 in Chapter 6 regarding heat treatments as a process control, which provides an example of records documenting implementation of the food safety plan for a salsa.

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Table 16-8 Records

Requirements in Part 117 (21 CFR)	Corresponding Requirements in 21 CFR 108 or Part 114 (21 CFR)	How You Can Leverage Compliance with Requirements in 21 CFR 108.25 or Part 114 to Address Corresponding Requirements in the PCHF Rule	How You Can Leverage Compliance with the Requirements of the PCHF Rule to Address Corresponding Requirements of 21 CFR 108.25 and Part 114
<ul style="list-style-type: none"> • 117.9 (training) • 117.126(c): Food safety plan • 117.190(a): Implementation records, including records documenting: <ul style="list-style-type: none"> ○ Basis for not establishing a preventive control (117.136(b)) ○ Monitoring (117.145(c)) ○ Corrective actions and corrections (117.150(d)) ○ Verification (117.155(b)) ○ Supply-chain program (117.475(c)) ○ Training of PCQI) (117.180(d)) • Subpart F: <ul style="list-style-type: none"> ○ 117.301 (Applicability) ○ 117.305 (General requirements) ○ 117.310 (Food safety plan) ○ 117.315 (Record retention) ○ 117.320 (Official review) ○ 117.325 (Public disclosure) ○ 117.330 (Use of existing records) ○ 117.335 (Special requirements for written assurance) 	<ul style="list-style-type: none"> • 114.100(a): Records of examinations of raw materials, packaging materials, and finished products, and of suppliers' guarantees or certifications • 114.100(b): Processing and production records, including records of pH measurements and other critical factors intended to ensure a safe product • 114.100(c): All departures from scheduled processes having a possible bearing on public health or the safety of the food • 114.100(d): Records identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use • 108.25(g) and 114.100(e): Records shall be retained at the processing plant or other reasonably accessible location for a period of 3 years from the date of manufacture. • 108.25(f) and 114.10: All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. 	<ul style="list-style-type: none"> • Records demonstrating compliance with 21 CFR 114.100(a) could satisfy the requirements of 21 CFR 117.475(c)(8) for sampling and testing records applicable to a supply-chain program, if your supply-chain program identifies any hazards requiring a supply-chain applied control. • Records demonstrating compliance with 21 CFR 114.100(b) could satisfy: <ul style="list-style-type: none"> ○ The requirements of 21 CFR 117.145(c) for records of monitoring pH as a preventive control management component for pH control as a process control. ○ The requirements of 21 CFR 117.145(c) for records of monitoring when monitoring seam/seal integrity of finished product is a preventive control management component for the scheduled process. • Records demonstrating compliance with 21 CFR 114.100(c) could satisfy some requirements of 21 CFR 117.150(d) for records of corrective actions and corrections. 	<ul style="list-style-type: none"> • If your supply-chain program identifies any hazards requiring a supply-chain applied control, records that comply with 21 CFR 117.475(c)(8) could satisfy corresponding requirements in 21 CFR 114.100(a) for records of suppliers' guarantees or certifications. • Monitoring records that comply with 21 CFR 117.145(c) could satisfy corresponding requirements in 21 CFR 114.100(b) for records of pH measurements and other critical factors. • Corrective action records that comply with 21 CFR 117.150(d) could satisfy corresponding requirements in 21 CFR 114.100(c) for records of all departures from scheduled processes having a possible bearing on public health or the safety of the food.

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16.13 Requirements for Coding

Part 114 requires that each container or product be marked with an identifying code permanently visible to the naked eye. (See 21 CFR 114.80(b) for the complete requirements.) There is no corresponding requirement for coding in the PCHF rule. You must comply with all requirements for coding in 21 CFR 114.80(b) even though there is no corresponding requirement for coding in the PCHF rule.

16.14 References

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Appendix 16-1 Key Specific Acidified Food Requirements

The requirements of 21 CFR 108.25 and part 114 include some requirements that either have no explicitly corresponding requirement in part 117 or exceed the corresponding requirement in part 117. Appendix Table 16-1-1 lists the key additional requirements specific to acidified foods and, when applicable, resources that are available to help you comply with those additional requirements.

Appendix Table 16-1-1 Key Specific Acidified Food Requirements

Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Submit food canning establishment registration to FDA using Form FDA 2541	21 CFR 108.25(c)(1)	Registering your establishment as a food canning establishment using Form FDA 2541 (as required by 21 CFR 108.25(c)(1)) is in addition to registering your food facility using Form FDA 3537 (as required by 21 CFR Part 1, Subpart H)	<ul style="list-style-type: none"> • FDA, 2016 • FDA, 2018

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Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Submit scheduled process to FDA using Form FDA 2541e	21 CFR 108.25(c)(2)	See the discussion in section 16.10.1. Although you can leverage Form FDA 2541e to address the requirements of the PCHF rule for written process controls for biological hazards requiring a preventive control, including Form FDA 2541e in the food safety plan that you keep onsite does not affect your responsibility to submit Form FDA 2541e to FDA.	FDA, 2016
Provide FDA with information about the scheduled process and procedure upon FDA's request	21 CFR 108.25(c)(3)(ii)	See the discussion in section 16.11. The requirements of the PCHF rule applicable to validation of preventive controls correspond to the requirements of 21 CFR 108.25 and part 114 for the adequacy of the scheduled process, and we ordinarily will review records applicable to process validation during inspection. However, as required by 21 CFR 108.25(c)(3)(ii), you must send us any process and procedure information that we deem necessary to determine the adequacy of the process if we ask you to do so (e.g., as a follow-up to your submission of a scheduled process on Form FDA 2541e).	N/A

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Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Notify FDA about problems when food is in commerce	21 CFR 108.25(d) (problems include spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance)	Notifying FDA about problems when an acidified food is in commerce is in addition to your responsibility to report problems to the Reportable Food Registry (when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals)	<ul style="list-style-type: none"> • FDA, 2009 • FDA, 2010
Recall procedure that includes plans for notifying FDA of any recalls	21 CFR 108.25(e)	See the discussion in section 16.10.4. Although a plan for notifying FDA of any recalls is not required by the PCHF rule, including a plan for notifying FDA of any recalls in the written recall plan that you establish in accordance with 21 CFR 117.139 could also satisfy the requirements of 21 CFR 108.25(e) for a recall procedure.	FDA, 2003
Satisfactory completion of the prescribed course of instruction in a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification	<ul style="list-style-type: none"> • 21 CFR 108.25(f) • 21 CFR 114.10 	See the discussions in sections 16.6 and 16.7. Satisfactorily completing the prescribed course of instruction in a school specified in 21 CFR 108.25(f) and 114.10 may not provide an individual with all qualifications applicable to supervisory personnel as required by 21 CFR 117.4 or all qualifications applicable to a PCQI as required by 21 CFR 117.180(c)(1).	N/A

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Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
<p>The scheduled process for an acidified food must control microorganisms of non-health significance in addition to pathogens.</p>	<p>21 CFR 114.80(a)</p>	<p>See the discussion in sections 16.9 and 16.10.1, and 16.11. Microorganisms of non-health significance, by themselves, are not “hazards” as that term is defined in part 117. However, when critical factors are not carefully controlled, the vegetative cells of some microorganisms of non-health significance (such as some spoilage bacteria) can grow in an acid environment and, in so doing, cause the pH of the food to increase. Therefore:</p> <ul style="list-style-type: none"> • A knowledgeable person could identify microorganisms of non-health significance in shelf-stable acidified foods as biological hazards requiring a preventive control. • The preventive control could be the scheduled process that you submit to us on Form FDA 2541e. • The preventive control management components could be monitoring pH and validation that establishes the adequacy of the process. 	<p>N/A</p>
<p>Records of distribution</p>	<p>21 CFR 114.100(d)</p>	<p>Compliance with 21 CFR 114.100(d) could satisfy some requirements of 21 CFR 1.345 in part 1, subpart J (Establishment, Maintenance, and Availability of Records) for the identity of the immediate, subsequent recipients of food</p>	<p>FDA, 2012</p>

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Description of Specific Acidified Food Requirement	Applicable Regulation(s)	Comments	Resources
Record retention for 3 years	<ul style="list-style-type: none"> • 21 CFR 108.25(g) • 21 CFR 114.100(e) 	See the discussion in section 16.12. The regulations in 21 CFR 108.25 and part 114 each have a recordkeeping requirement that exceeds the corresponding recordkeeping requirement in part 117.	N/A
Coding	21 CFR 114.80(b)	See the discussion in section 16.13. Part 114 requires that each container or product be marked with an identifying code permanently visible to the naked eye; there is no corresponding requirement for coding in the PCHF rule.	N/A