DEPARTMENT OF AGRICULTURE

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

Introduction:

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the U.S. Food and Drug Administration (FDA), as the food regulatory agency of the U.S. Department of Health and Human Services, to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. On September 17, 2015, FDA published the final rule Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (PCHF rule). The Minnesota Department of Agriculture (MDA) adopts these federal regulations by reference and they are now in effect, in accordance with FDA's compliance dates, for Minnesota human food and animal feed facilities. This final rule became effective on November 16, 2015. It creates new requirements for the production of human food by registered food facilities, and revises previous requirements. Owners, operators, or agents in charge of a facility that is engaged in manufacturing/processing, packing, or holding of food for human or animal consumption in the United States, must register with FDA, unless exempt under 21 CFR 1.226 from the requirement to register.

This document focuses on Title 21 CFR Part 117 and provides a brief summary of the different components of the new regulations, including:

- Key requirements of the regulation
- Useful definitions
- Subpart-specific information – including a listing of food products and Subparts that they are subject to
- A list of exemptions to the regulation
- Training requirements
- Qualified Facilities
- A list of resources to provide further information

NOTE: Each operation is different, and your obligations under 21 CFR 117 could change based on the specifics of your operation. Review complete requirements at www.FDA.gov.

Key Requirements of 21 CFR 117:

1. Covered facilities must establish and implement a food safety system that includes an analysis of hazards and implementation of risk-based preventive controls. (21 CFR, Part 117, Subpart C)

   The rule (21 CFR 117.126) requires a written food safety plan for all covered facilities unless an exemption applies. The written plan must be prepared by (or its preparation overseen by) a "preventive controls qualified individual" and must include:

   - A hazard analysis – must consider known or reasonably foreseeable biological, chemical and physical hazards
   - Preventive controls
   - A risk-based supply chain program, if appropriate
   - A recall plan, if there are any hazards associated with the food requiring a preventive control

- Procedures for monitoring the implementation of the preventive controls
- Procedures for verifying that the preventive controls are consistently implemented and are effectively minimizing or preventing the identified hazards

2. Covered facilities must establish and implement a risk-based supply-chain program for those raw materials and other ingredients for which a hazard has been controlled before receipt (a supply-chain-applied control) (21 CFR Part 117, Subpart G).

3. Covered facilities must meet updated Current Good Manufacturing Practice (CGMP) requirements (21 CFR, Part 117, Subpart B).

Useful Definitions:

Facility – Any establishment, structure, or structures under one ownership at one general physical location, or a mobile facility traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the U.S.

Farm – defined in 1.227 of Chapter 21 CFR:

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.

The term "farm" includes operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;
(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(1) of this definition; and (iii) Manufacture/process food, provided that:
(A) All food used in such activities is consumed on that farm or another farm under the same management; or
(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:
(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);
(2) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and
(3) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the

secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraph (1)(ii) and (iii) of this definition.

Manufacturing/Processing – Making food from one or more ingredients, or creating, preparing, treating, modifying or manipulating food, including food crops or ingredients.

Packing – Placing food into a container other than a container that directly contacts the food and that the consumer receives, including incidental activities to ensure the safe or effective packing of that food such as sorting, culling, grading, and weighing or conveying.

Holding – Storage of food, including activities ensuring the safe or effective storage of a food such as fumigating food during storage, and drying/dehydrating raw agricultural commodities (when the drying/dehydrating does not create a distinct commodity, e.g., drying/dehydrating hay or alfalfa). Holding also includes activities necessary for the distribution of food such as blending of a raw agricultural commodity or breaking down pallets.

Mixed-type facility – An establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm, mixed-type facility," which is an establishment that is a farm but also conducts activities outside the farm definition that require the establishment to be registered.

Preventive Controls – Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive Controls Qualified Individual – A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified Facilities – Businesses (when including the sales by any subsidiaries, affiliates, and any entity of which the facility is a subsidiary or affiliate) with average annual sales of less than $500,000 with at least half the sales to consumers or to local retailers or restaurants or Indian reservation (within the same state or within 275 miles) or very small businesses as defined below.

Qualified Individual – A person who has the education, training, or experience (or combination there-of) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

Small businesses – A business (including any subsidiaries and affiliates) employing fewer than 500 full-time equivalent employees.

Very small businesses – A business (including any subsidiaries or affiliates) averaging less than $1,000,000 (adjusted for inflation) -- in both sales of human food plus the market value of human food

that is manufactured, processed, packed, or held without sale (e.g. held for a fee), per year during the 3-year period preceding the current calendar year.

GMP PC Regulation Overview:

Title 21 CFR Part 117 – Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Control for Human Food

The preventive controls regulation (21 CFR Part 117) is divided into seven subparts:

Subpart A – General Provisions. This subpart lists definitions and exemptions for certain foods, activities and facilities. Subpart A also includes training requirements for qualified individuals. A qualified individual is a person who has a combination of education, training, and experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to their duties.

All registered food facilities are subject to Subpart A – including seafood and juice processors

Subpart B – Current Good Manufacturing Practices. This subpart applies to all foods, activities and facilities subject to the regulation.

All registered food facilities are subject to Subpart B – including seafood and juice processors

Subpart C – Hazard Analysis and Risk-Based Preventive Controls. This subpart applies to most foods, activities and facilities. Facilities subject to Subpart C of the regulation must have and implement a Food Safety Plan (FSP). The FSP must include a written hazard analysis. If the hazard analysis reveals one or more hazards requiring a preventive control, then the firm must have and implement appropriate preventive controls. Most preventive control requirements are outlined in Subpart C, with the exception of supply chain program which is outlined in Subpart G. The hazard analysis determines which preventive control program the facility will need to include in their food safety plan.

Subpart D – Modified Requirements. This subpart outlines modified requirements for a qualified facility and for a facility that is solely engaged in the storage of refrigerated unexposed packaged foods when temperature controls are necessary to prevent pathogen growth. Subpart A exempts these facilities from the requirements in Subparts C and G.

Subpart E - Withdrawal of a Qualified Facility Exemption. This subpart only covers the circumstances and procedures regarding the withdrawal of a qualified facility exemption.

Subpart F – Requirements Applying to Records that must be Established and Maintained. This subpart outlines additional requirements for records mandated in Subparts A, C, D, and G.

Subpart G- Supply-Chain Program. This subpart outlines requirements for a supply-chain preventive control program. A facility that identifies a hazard requiring a supply-chain control must follow the requirements in Subpart G. However, it is important to realize that not all facilities will need to identify the supply-chain program as a preventive control in a food safety plan.

DEPARTMENT OF AGRICULTURE

Table 1: Examples of foods covered by 21 CFR 117 and the Subparts that apply:

Food Type	Subparts
Game Meat (elk, buffalo, etc.)	Subject to Subparts A, B, C, G, & F
Fish and Fishery Products	Subject to Subpart A (117.4 personnel training requirement), Subpart F (training record) *Exempt from Subparts C & G, subject to 21 CFR 123
Grade A Dairy Products (Ex. Milk)	Subject to Subparts A, B, C, G, & F *Also subject to Pasteurized Milk Ordinance(PMO) which is consistent with C & G
Other Dairy Products (Ex. Ice Cream)	Subject to Subparts A, B, C, G & F *Not a Grade A milk product so not subject to the Pasteurized Milk Ordinance
Eggs	Generally not subject to 21 CFR 117 *Shell eggs subject to 21 CFR 118 Egg Safety Regulation
Bakery Items (Ex. Bread)	Subject to Subparts A, B, C, G, & F
Peanut Butter	Subject to Subparts A, B, C, G, & F
100% Juice	Subject to Subpart A (117.4 personnel training requirement), Subpart F (training record) *Exempt from Subparts C & G, subject to 21 CFR 120
Low Acid Canned Foods (Ex. Canned Green Beans)	Subject to Subparts A, B, C, G, F *Subparts C & G apply to chemical & physical hazards. *Subparts C & G do not apply to microbiological hazards regulated in 21 CFR 113 *Subject to 21 CFR 108 & 113
Acidified Foods (Ex. Pickles)	Subject to Subparts A, B, C, G, F *Also subject to 21 CFR 108 & 114
Bottled Water	Subject to Subparts A, B, C, G, F

For Additional Information: Food and Feed Safety Division (FFSD)
651-201-6027 · 625 Robert Street North, Saint Paul, MN 55155-2538

	*Also subject to 21 CFR 129 Processing & Bottling of Bottled Drinking Water
Infant Formula	Subject to Subparts A, B, C, G, & F *Also subject to 21 CFR 106 Infant Formula Quality Control Procedures and 21 CFR 107 Infant Formula
Dietary Supplements (Ex. Vitamins)	Not Subject to 21 CFR 117 *Subject to 21 CFR 111 GMP's for Dietary Supplements
Alcohol (Ex. Beer, Wine, Hard Cider, Distilled Spirits)	Subject to Subparts A, B, & F *Exempt from Subparts C & G if manufacturing facility meets two conditions: 1) register with the FDA as a food facility 2) obtain a permit or register with the Secretary of Treasury with the Federal Alcohol Administration Act
Pet Food and Treats	Not Subject to 21 CFR 117. *Subject to 21 CFR 507 Preventive Controls for Animal Foods
Fruit/Veg Warehouse	If holding processed (chopped, shredded, etc.) products then subject to Subparts A, B, C, G, F Subparts C & G of this part do not apply to facilities that are solely engaged in the storage of Raw Agricultural Commodities (RAC) (other than fruits and vegetables) intended for further distribution or processing.
Multiple Foods Warehouse with unexposed packaged foods	Subject to 21 CFR 117 Subpart B, A(personnel training requirements), and F (for training records only) *Exempt form Subparts C & G because it is unexposed packaged food
Refrigerated Foods Warehouse with unexposed packaged foods	Subject to Subparts B, A (personnel training requirements), D (117.206 modified requirement) F (for training records only) *Exempt from Subparts C & G [117.7(a)-storage of unexposed packaged foods]

DEPARTMENT OF AGRICULTURE

Exemptions outlined in the regulation: 21 CFR Part 117.5 and 117.7

While all registered firms must comply with most of the regulation (21 CFR 117), Subparts C and G of the regulation do not apply to the following:

1. A Qualified Facility 117.5 (a)
2. Activities that are subject to 21 CFR Part 123 (Fish and Fishery Products) 117.5 (b)
3. Activities that are subject to 21 CFR Part 120 (Processing Juice) 117.5 (c)
4. Activities that are subject to 21 CFR Part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers). This exemption is applicable only with respect to the microbiological hazards that are regulated under part 113.117.5 (d)
5. Activities that are in compliance with 21 CFR part 111 (Dietary Supplements) 117.5 (e)
6. Activities that are subject to Section 419 of the Food, Drug, and Cosmetic Act (Standards for Produce Safety 117.5 (f)
7. Alcohol Producing Facilities 117.5 (i) (1)
8. Prepackaged food that does not constitute more than 5% of the overall sales of the facility 117.5 (i)(2)
9. Facilities that are solely engaged in the storage of raw agricultural facilities (other than fruits and vegetables) intended for further distribution or processing 117.5 (j)
10. Packing or holding of certain low-risk processed foods on a farm mixed-type facility that is a small or very small business. Twenty-three low-risk packing or holding activity/food combinations that are exempt are listed under 117.5 (g) (3)
11. Manufacturing/Processing certain low-risk foods on a farm mixed-type facility that is a small or very small business. Twenty-seven low-risk activity/food combinations that are exempt are listed under 117.5 (h) (3)
12. Facilities solely engaged in the storage of unexposed packaged foods (once they carry exposed or unpackaged foods they lose the exemption) 117.7

Training Requirements:

Companies subject to 21 CFR 117 Subpart C must ensure that their food safety system is developed and applied by an individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system (21 CFR 117.4). In addition, each individual (including temporary and seasonal personnel) engaged in (or supervising) manufacturing, processing, packing, or holding food covered by this rule must (21 CFR 117.4(b)):

- Be a qualified individual, i.e., have the education, training, or experience (or a combination of these) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
- 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.

For Additional Information: Food and Feed Safety Division (FFSD)
651-201-6027 · 625 Robert Street North, Saint Paul, MN 55155-2538

Additional qualifications for supervisory personnel: Responsibility for ensuring compliance by individuals with the requirements of this rule must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination of these) necessary to supervise subordinates in the production of clean and safe food 21 CFR 117.4(c).

Records documenting the required training in the principles of food hygiene and food safety must be established and maintained 21 CFR 117.4(d).

Qualified Facilities:

A facility that meets the definition of a "qualified facility" in part 117 is subject to CGMP requirements as well as the modified requirements described in 21 CFR 117.201. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a qualified facility. The guidance document in the link below explains how to determine whether your facility meets the definition of "qualified facility" under part 117 and how to submit Form FDA 3942a attesting to your status as a qualified facility that is subject to the modified requirements in 21 CFR 117.201. The modified requirements also include a requirement that the facility attest to certain food safety practices. See 21 CFR 117.201(a)(2).

Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm

Additional Resources:

The following resources are available to assist industry with understanding and implementation of 21 CFR 117. (Note: if unable to directly access the link from the document, copy and paste or type the address into your internet browser)

- **FSMA Final Rule for Preventive Controls for Human Food**. The following link contains information including further guidance documents and fact sheets translated into multiple languages:
  https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm

- **Frequently Asked Questions**
  http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#PC_Rules

- **FDA Food Safety Modernization Act**
  www.fda.gov/fsma

- **Food Safety Plan Builder**
  https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm539791.htm

- **Guidance for Industry: What You Need to Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide**
  https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm525201.htm

- **Submit Questions: FDA's FSMA Technical Assistance Network**
  http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

- **Illinois Institute of Technology, Food Safety Preventive Controls Alliance (FSPCA)**-

  (Recognized by the U.S. Food and Drug Administration (FDA), persons completing FSPCA Training receive a Preventive Controls Qualified Individual (PCQI) certificate. A PCQI oversees implementation of a given facility's food safety plan and other key responsibilities involved in complying with FSMA.)

  https://www.ifsh.iit.edu/fspca

- **21 CFR part 117 Guidance for Industry: Small Entity Compliance Guide**
  https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM526507.pdf

- **Registering your facility**
  https://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm2006831.htm

For Additional Information: Food and Feed Safety Division (FFSD)
651-201-6027 · 625 Robert Street North, Saint Paul, MN 55155-2538