



Wisconsin Department of Agriculture, Trade and Consumer Protection  
 Division of Food and Recreational Safety  
 PO Box 8911, Madison, WI 53708-8911  
 Phone: (608)224-4683

## WISCONSIN PREVENTIVE CONTROLS CHECKLIST

FIRM NAME		LICENSE NO.		DATE	
STREET ADDRESS		CITY		STATE	ZIP CODE
FACILITY TYPE: <input type="checkbox"/> PC FACILITY	FOOD SAFETY PLAN: <input type="checkbox"/> YES <input type="checkbox"/> NO		ISSUE DATE OF FOOD SAFETY PLAN:		
<input type="checkbox"/> QUALIFIED FACILITY	PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL(S): <input type="checkbox"/> YES <input type="checkbox"/> NO		IF MODIFIED FOOD SAFETY PLAN, ENTER NEW DATE:		

Verification items to meet the requirements for Preventive Controls under 21 CFR 117. Items marked with a double asterisk \*\* are considered a significant component of the Preventive Control Program.

### Section 1 Food Safety Plan – 21 CFR 117.126

- ☐ The facility's Food Safety Plan is documented in writing. \*\*
- ☐ The facility's Food Safety Plan is prepared or its preparation is overseen by one (1) or more Preventive Control Qualified Individuals (PCQI).
- ☐ The owner, operator or person in charge of the facility has signed and dated the Food Safety Plan upon initial completion and upon any modifications.
- ☐ Reanalysis of the facility's entire Food Safety Plan is conducted at least once every three (3) years. \*\*
- ☐ Reanalysis of the applicable portion of the facility's Food Safety Plan is conducted due to a change in a hazard; new information of a hazard: an unanticipated food safety problem; or ineffective preventive control(s). \*\* - 21 CFR 117.170
- ☐ Any reanalysis of the facility's Food Safety Plan has been performed or overseen by a PCQI.

### Section 2 Food Safety Plan Required Elements

- ☐ Facility has a written Recall Plan. (See Section 3) \*\*
- ☐ Facility has a written hazard analysis for each type of food manufactured, processed, packed, or held at the facility. (See Section 4) \*\*
- ☐ Facility has written Preventive Controls, as appropriate, for each identified hazard. (See Section 5) \*\*
- ☐ Facility has a written Supply-Chain Program, as appropriate, for each identified hazard. (See Section 6) \*\*
- ☐ Facility has written Procedures for Monitoring the implementation of the preventive control(s), as appropriate, for each identified hazard. (See Section 7). \*\*
- ☐ Facility has written Corrective Action Procedures appropriate to the nature of the hazard(s) and the preventive control(s). (See Section 8) \*\*
- ☐ Facility has written Verification Procedures appropriate to the nature of the preventive control(s). (See Section 9) \*\*

### Section 3 Recall Plan – 21 CFR 117.139

- ☐ Written procedures include how to directly notify the direct consignee of the food products being recalled, including how to return or dispose of the affected food products and assign responsible for taking those steps.
- ☐ Written procedures include how to notify the public about any hazard presented by the food products.
- ☐ Written procedures include how to conduct effectiveness checks to verify that the recall is carried out.
- ☐ Written procedures include how to appropriately dispose of product.

### Section 4 Hazard Analysis – 21 CFR 117.130

*(Similar products or similar types of production methods may be grouped together if the hazards and procedures are essentially identical.)*

- ☐ Facility has identified known or reasonably foreseeable hazards that include Biological, Chemical (including radiological and allergens) and Physical hazards. \*\*
- ☐ Facility has identified other known or reasonably foreseeable hazards, (i.e. Occurs Naturally, Unintentionally Introduced or Intentionally Introduced for purposes of economic gain). \*\*

### Section 5 Preventive Controls – 21 CFR 117.135

- ☐ Includes written preventive control(s) at critical control point(s) (CCP) for the identified hazard(s). \*\*
- ☐ Includes written preventive controls, other than those at CCPs that are also appropriate for food safety. \*\*



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Section 6

**Supply Chain Program**

**21 CFR 117 Subpart G**

- ☐ Documented that a supplier of the ingredients has a functional and written food safety program that addresses hazards to include food allergen management. \*\*
- ☐ Written program includes documentation of approved suppliers; supplier verification activities to include frequency; conducting and documenting supplier verification activities before using raw materials and other ingredients; written procedures for receiving raw materials and other ingredients; and documentation that those procedures are being followed. \*\*
- ☐ Facility has taken and documented prompt action when a determination has been made that the supplier is not controlling the hazard. \*\*

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Section 7

**Monitoring – 21 CFR 117.145**

- ☐ Written monitoring procedures including the frequency with which they are to be performed, are established, implemented and consistently performed for monitoring the preventive control(s) for the identified hazard(s). \*\*
- ☐ Monitoring records are being reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records are created.

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Section 8

**Corrective Actions – 21 CFR 117.150**

- ☐ Established and implemented written corrective action procedures that shall be taken to address the presence of a pathogen or appropriate indicator organism detected because of product testing, as appropriate. \*\*
- ☐ Established and implemented written corrective action procedures that shall be taken to address the presence of a pathogen or appropriate indicator organism detected through environmental monitoring, as appropriate. \*\*
- ☐ Established and implemented written corrective action procedures that shall be taken if preventive controls are not properly implemented for the identified hazard(s). \*\*
- ☐ Corrective action records are being reviewed, dated and signed or initialed by or under the oversight of a PCQI within seven (7) working days after the records are created.

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Section 9

**Verification and Validation – 21 CFR 117.155 and 160**

- ☐ Verification that the Preventative Control(s) is/are consistently implemented, and are effective and significantly minimizing or preventing the identified hazard(s). \*\*
- ☐ Validation that each preventive control identified and implemented is adequate to control the identified hazard(s). \*\*
- ☐ Validation has been performed or overseen by a PCQI.

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**Qualifications of Individuals – 21 CFR 117.4**

- ☐ The owner, operator or person-in-charge of the facility has ensured that all individuals who receive, handle, process and package food products are qualified to perform their assigned duties.
- ☐ Each individual has received training in the principles of food hygiene and food safety, including the importance of employee health and personnel hygiene.
- ☐ Supervisory personnel have the necessary education, training, experience or combination thereof, and ensure compliance by individuals with the requirements.
- ☐ Training records are established, maintained and retained at the facility for at least two (2) years after the date they were prepared.

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**Records – 21 CFR 117.301**

- ☐ Facility has established and is maintaining the required records documenting the implementation of the Food Safety Plan for preventive controls (e.g., monitoring, verification, and corrective actions). \*\*
- ☐ Required records are identified with the name and location of the facility or their facility code, dated and the signature or initials of the person performing the activity and on-site for review (e.g., records for metal detection or other preventive control(s) the facility may identify).
- ☐ The Food Safety Plan shall be onsite for review. \*\*
- ☐ Preventive Control records were provided onsite within 24 hours of request (e.g., monitoring, verification, and corrective actions). \*\*
- ☐ Records that support the preventive control(s) required in the facility's Food Safety Plan are retained for at least two (2) years' after the date they were created.



State of Wisconsin  
Governor Tony Evers

**Department of Agriculture, Trade and Consumer Protection**  
Bradley M. Pfaff, Secretary

## **2018-2019 Inspections Determining 21 CFR 117 Applicability and Resource List**

### **Partnering Together**

The following resources and guidance provide an educational tool to assist you in determining applicability and compliance with 21 CFR 117 of the Food Safety Modernization Act (FSMA). We look forward to working with you as we learn more about FSMA implementation with the U.S. Food and Drug Administration (FDA).

### **Key Resources**

- Key Facts about Preventive Controls for Human Food:  
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM584807.pdf>
- FSMA rules and guidance for industry:  
<https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance>
- 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>
- Federal regulation for 21 CFR 117 – Current Good Manufacturing Practice, Hazards Analysis, and Risk-Based Preventive Controls for Human Food: <https://www.ecfr.gov/cgi-bin/text-idx?SID=efd9041636f0d7e3e9b5f497cf0ba4d7&mc=true&node=pt21.2.117&rgn=div5>

### **Determining 21 CFR 117 Applicability**

The guidance below provides DATCP's current understanding of how the FDA is interpreting and applying FSMA regulations.

#### **1. Determine if your food business is required to register under the Bioterrorism Act of 2002.**

Refer to the following guidance: Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition):

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

If you are not required to register then 21 CFR 117 does not apply to you and the remainder of this document does not apply to you.

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## 2. Determine if 21 CFR 117 applies to your business.

For the previous three years did your facility average more than \$1,000,000 in sales?

### If yes, all subparts of 21 CFR 117 may apply.

- a. Refer to the Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm517412.htm>. This document contains Appendix 1: Potential Hazards for Foods and Processes. You are encouraged to use this resource when determining applicable hazards in your food safety plan. This document will likely be referenced by your regulator.

There is a Food Safety Preventive Controls Alliance (FSPCA) training course available for industry: <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>. This course is the standardized curriculum recognized by FDA. Successfully completing this course is one way to meet the requirements for a preventive controls qualified individual.

If you have a hazard analysis and critical control points (HACCP) plan that needs to convert to food safety plans, reference the attached handout for points to consider. *See table of FSP vs. HACCP plan.*

Also attached is a checklist to help you evaluate your level of preparedness for a preventive control inspection. *See Wisconsin Preventive Controls Checklist.*

### If no, you might be a qualified facility.

Refer to the following material to determine your facility's status: Guidance for Industry: Determination of Status as a Qualified Facility:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm>

If you determine that you do not meet the definition of a qualified facility, then all subparts of 21 CFR 117 may apply to you - refer to step 2a above. Otherwise continue to qualified facilities below.

### Qualified facilities means you may qualify for exemptions.

Qualified facilities are required to complete and submit an attestation with the FDA available at: <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm>. Qualified facilities may be subject to modified requirements, such as subparts A, B D, E and F of 21 CFR 117.

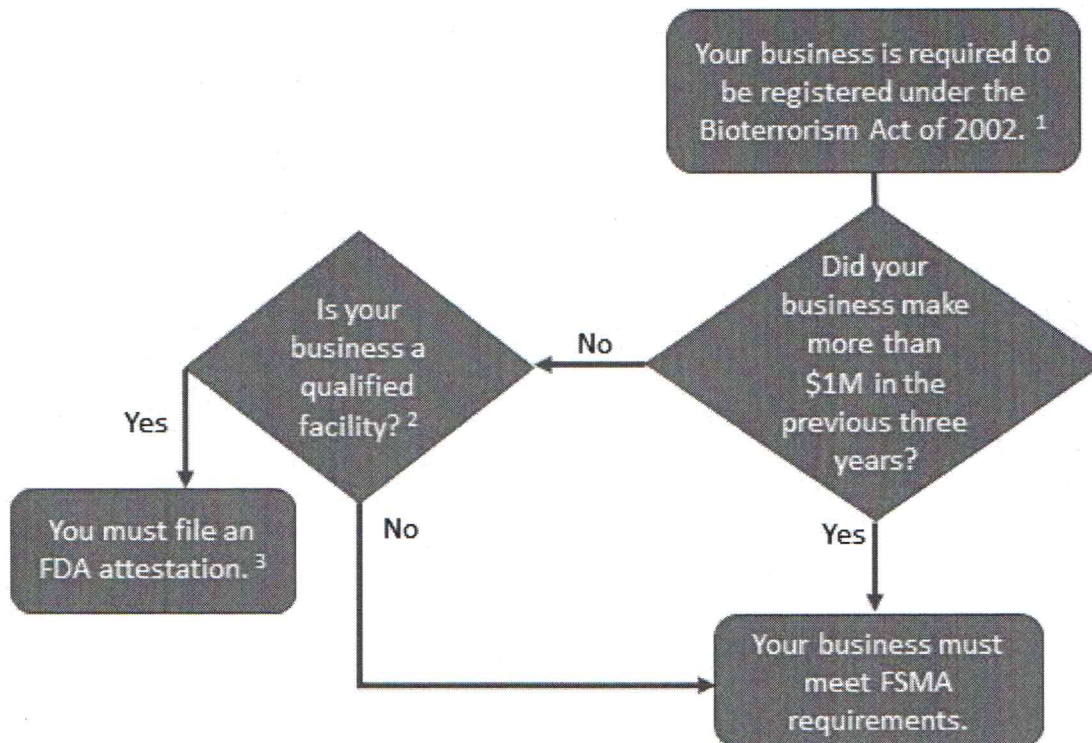
## What to Expect from DATCP

- A step-implemented regulatory approach over the next several years.
- An effort to communicate our understanding of expectations.
- A strong desire to partner with Wisconsin's food industry to achieve successful compliance with the federal rule through resource development and sharing.

Thank you for working with us as we take an educational approach for the 2018-2019 contract year. We look forward to your partnership as we continue to learn more about regulatory requirements. We encourage you to connect with your local trade organizations or academic resources who may have more resources about FSMA.

# Determining if Your Food Business Needs to Meet the Food Safety and Modernization Act Requirements

## Decision Chart



<sup>1</sup>Refer to the following guidance: Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition), available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

<sup>2</sup>Refer to the following material to determine your facility's status: Guidance for Industry: Determination of Status as a Qualified Facility, available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm496264.htm>

<sup>3</sup>Complete and submit an attestation with the FDA at <https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/QualifiedFacilityAttestation/default.htm>. Qualified facilities may be subject to modified requirements, such as subparts A, B, D, E and F of 21 CFR 117.



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dfrs\_frb\_142.doc (12/2018)