

**DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER
PROTECTION NOTICE OF PROPOSED GUIDANCE DOCUMENTS**

Pursuant to section 227.112 of the Wisconsin Statutes, the Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) is hereby accepting comments on the proposed guidance documents listed below.

Contract Inspection Preventive Controls Letter

LOCATION OF PROPOSED GUIDANCE

Proposed guidance documents may be reviewed by accessing:

https://datcp.wi.gov/Pages/About_Us/GuidanceDocuments.aspx

SUBMITTING PUBLIC COMMENTS

Public comments on proposed or adopted guidance documents may be submitted by accessing:

https://datcp.wi.gov/Pages/About_Us/GuidanceDocuments.aspx

DEADLINE FOR SUBMISSION

The comment period will run no fewer than 21 days after the publication of this document in the Administrative Register.

AGENCY PUBLICATION

The below-listed guidance documents contain statements or interpretations of law under the following applicable provisions of federal law or the applicable state statutory or administrative code provisions: Wis. Stat. ch.93.06 (11)(b)., Wis. Admin. Code, chs. 65, 70, and 71.

CERTIFICATION

Pursuant to the authority delegated to me by the Secretary, I have reviewed the below-listed guidance documents or proposed guidance documents and I certify that they comply with sections 227.10 and 227.11 of the Wisconsin Statutes. I further certify that the guidance documents or proposed guidance documents contain no standard, requirement, or threshold that is not explicitly required or explicitly permitted by a statute or a rule that has been lawfully promulgated. I further certify that the guidance documents or proposed guidance documents contain no standard, requirement, or threshold that is more restrictive than a standard, requirement, or threshold contained in the Wisconsin Statutes.



Steve Ingham

Administrator

Division of Food and Recreational Safety



Wisconsin Department of Agriculture, Trade and Consumer Protection

Division of Food and Recreational Safety

PO Box 8911, Madison, WI 53708-8911

Phone: (608) 224-4700

Fax: (608) 224-4710

GUIDANCE DOCUMENT

Guidance Document Title: Contract Inspection Preventive Controls Letter

This guidance document is based on Wis. Stat. ch. 93.06 and chapter(s) ATCP 65, 70, and 71 Wis. Admin. Code. This document is intended solely as guidance, and does not contain any mandatory requirements except where requirements found in statute or administrative rule are referenced. This guidance does not establish or affect legal rights or obligations, and is not finally determinative of any of the issues addressed.

Click or tap here to enter text.

20 (DFRS)

Steven Ingham, Ph.D. - Administrator, Division of Food and Recreational Safety

October 18, 2019

DATE

Contributors:



Wisconsin Department of Agriculture, Trade and Consumer Protection

Division of Food and Recreational Safety

PO Box 8911, Madison, WI 53708-8911

Phone: (608) 224-4720 Fax: (608) 224-4710

To: Food Processing Plants, Food Warehouses, Milk Distributors, and Dairy Plants in Wisconsin

From: Bureau of Food and Recreational Businesses, Division of Food and Recreational Safety

Date: December 10, 2018

Title: 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 RiskBased Preventive Controls for Human Food

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.



Wisconsin Department of Agriculture, Trade and Consumer Protection
Division of Food and Recreational Safety
PO Box 8911, Madison, WI 53708-8911
Phone: (608) 224-4720 Fax: (608) 224-4710

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.



Wisconsin Department of Agriculture, Trade and Consumer Protection

Division of Food and Recreational Safety

PO Box 8911, Madison, WI 53708-8911

Phone: (608) 224-4720 Fax: (608) 224-4710

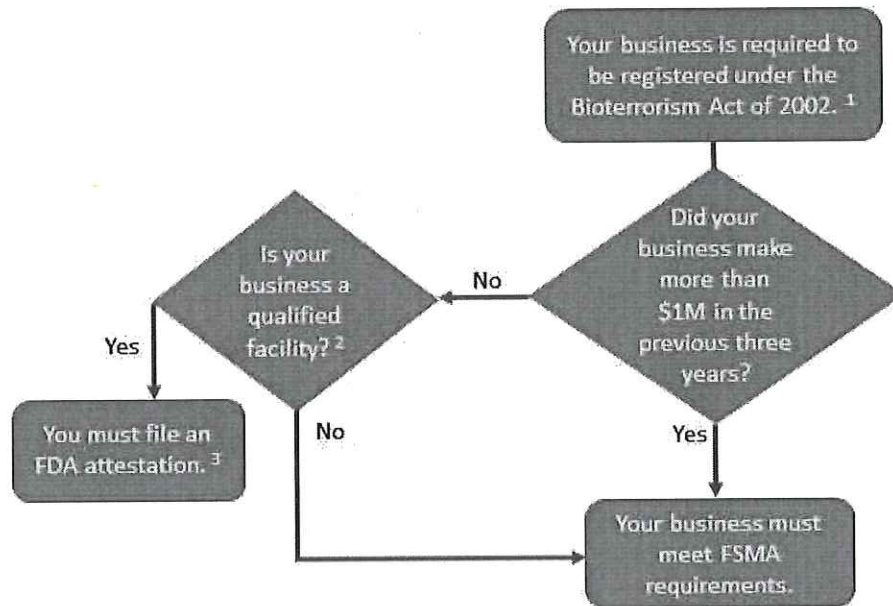
Page 2 of 3

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.



Wisconsin Department of Agriculture, Trade and Consumer Protection
Division of Food and Recreational Safety
PO Box 8911, Madison, WI 53708-8911
Phone: (608) 224-4720 Fax: (608) 224-4710

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



¹Refer 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>

²Refer 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>

³Complete 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.



Wisconsin Department of Agriculture, Trade and Consumer Protection
Division of Food and Recreational Safety
2811 Agriculture Drive
P.O. Box 8911
Madison, WI 53708
www.datcp.wisconsin.gov
dfrs_frb_142.doc (12/2018)