

**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.

Wisconsin Preventive Controls Checklist

LOCATION OF PROPOSED GUIDANCE

Proposed guidance documents may be reviewed by accessing:

[https://datcp.wi.gov/Pages/About Us/GuidanceDocuments.aspx](https://datcp.wi.gov/Pages/About%20Us/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](https://datcp.wi.gov/Pages/About%20Us/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

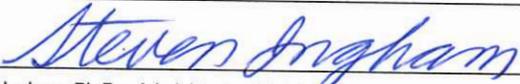
GUIDANCE DOCUMENT

Guidance Document Title: Wisconsin Preventive Controls Checklist

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.

21 (DFRS)

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	October 18, 2019
Steven Ingham, Ph.D. - Administrator, Division of Food and Recreational Safety	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)224-4683

WISCONSIN PREVENTIVE CONTROLS CHECKLIST

FIRM NAME		LICENSE NO.	DATE	
STREET ADDRESS		CITY	STATE	ZIP CODE
FACILITY TYPE: <input type="checkbox"/> PREVENTIVE CONTROLS 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 (unless otherwise noted)**

- 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 on 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.

- Facility has written Verification Procedures appropriate to the nature of the preventive control(s). (See Section 9) **

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) **

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 responsibility 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.
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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 hazards 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). **
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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 ensuring food safety. **

Section 6

Supply Chain Program
21 CFR 117 Subpart G

- Facility has 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 an identified hazard. **

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.

Section 8

Corrective Actions - 21 CFR 117.150

- Facility has 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.

Section 9

Verification and Validation - 21 CFR 117.155 and 160

- Facility has verification that the Preventive 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.

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.

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 its facility code, dated and signed or initialed by 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.