

Rule 21.1. Wholesale Food Establishment Sanitation Requirements

410 IAC 7-21.1-1 Applicability

Authority: [IC 16-42-5-5](#)

Affected: [IC 16-42-5](#)

Sec. 1. **The definitions in this rule apply throughout this rule.**

410 IAC 7-21.1-2 "Department" defined

Authority: [IC 16-42-5-5](#)

Affected: [IC 16-42-5](#)

Sec. 2. **"Department" means the Indiana department of health or its authorized representative.**

410 IAC 7-21.1-3 "Wholesale food establishment" defined

Authority: [IC 16-42-5-5](#)

Affected: [IC 15-17-5](#); [IC 15-18-1](#); [IC 16-42-11](#)

Sec. 3. (a) **"Wholesale food establishment" means any establishment within Indiana that manufactures, packages, stores, repackages, or transports human food products for distribution to another entity for resale or redistribution.**

(b) **The term does not include the following:**

(1) **A residential kitchen in a private home.**

(2) **Bed and breakfast establishments subject to [410 IAC 7-15.5](#).**

(3) **An establishment engaged solely in the harvesting, storage, or distribution of one (1) or more raw agricultural commodities, that is not ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.**

(4) **Meat and poultry processing plants subject to IC 15-17 or dairy processing plants subject to IC 15-18.**

410 IAC 7-21.1-4 Registration of a wholesale food establishment

Authority: IC 16-42-1-6; IC 16-42-5-5

Affected: IC 16-42-5

Sec. 4. (a) A wholesale food establishment that maintains a place of business in Indiana shall file with the department, on forms to be furnished by the department, a written statement of the name and address of the owner, the name of the business, the character of the business, and the business address of each place of business in Indiana.

(b) A new wholesale food establishment shall not be established in Indiana until the place of business has been registered as provided in this subsection. The department shall be notified of intent to operate at least thirty (30) days prior to beginning operations.

(c) If ownership of a registered place of business changes, the new owner shall register the place of business before operating the same.

(d) If the name of the business or the address of a registered place of business changes, the owner shall register the change.

410 IAC 7-21.1-5 Current Good Manufacturing Practices

Authority:

Affected:

Sec. 5. Wholesale food establishments shall comply with the good manufacturing practices, hazard analysis, and risk-based preventive control requirements as follows.

(a) All wholesale food establishments shall comply with the manufacturing practices, hazard analysis, and risk based preventive control requirements in 21 CFR 117 as in effect on September 17, 2015*.

(b) Wholesale food establishments that receive, buy, sell, or process molluscan shellfish shall comply with the National Shellfish Sanitation Program's Guide for the Control of Molluscan Shellfish (2023 Revision).

*This document is incorporated by reference. Copies may be obtained from the Government Publishing Office, 732 North Capitol Street, NW, Washington, DC 20401-0001, online at [INSERT LINK], or are available for review and copying at the Indiana Department of Health, 2 North Meridian Street, Indianapolis, Indiana 46204.

410 IAC 7-21.1-6 Suspension and Termination of Registration as a Wholesale Food Establishment

Authority: IC16-42-1-6; [IC 16-42-5-5](#)

Affected: [IC 16-42-5](#)

Sec. 6. (a) A wholesale food establishment shall have the registration filed under IC 16-42-1-6 temporarily suspended if they:

- (1) fail to pay a fine imposed by the department; or**
- (2) present a severe and immediate public health risk, as determined by the department, including but not limited to conditions that pose an imminent threat of foodborne illness, contamination, adulteration as set forth in IC 16-42, or environmental hazard that cannot be mitigated through on site corrective action at the time of inspection.**
- (b) A suspension issued under this subdivision is temporary and remains in effect until the department verifies that the conditions creating severe public health risk have been corrected.**
- (c) A wholesale food establishment shall have their registration terminated if they provided false or misleading information as part of their registration.**
- (d) A wholesale food establishment subject to suspension or termination under this section may request an administrative hearing.**
- (e) Any wholesale food establishment terminated under subsection (a) may submit a new registration pursuant to IC 16-42-1-6 under the following schedule:**

- (1) For the first instance of termination, ninety (90) days from their date of termination or the end of their appeal, whichever is later.**

- (2) For the second instance of termination, one hundred eighty (180) days from their date of termination or the end of their appeal, whichever is later.**

- (3) For the third instance of termination and each subsequent instance of termination, three hundred sixty-five (365) days from their date of termination or the end of their appeal, whichever is later.**

(c) A new registration under subsection (e) will not be processed if the wholesale food establishment:

- (1) has failed to correct the violation of this rule that resulted in the termination;**

(2) has failed to pay any civil penalties imposed under this rule, 410 IAC 7-23 or IC 16-42.

410 IAC 7-21.1-7 Incorporation by reference

Authority: IC 16-42-5-5

Affected: IC 16-42-5

Sec. 7. **(a) The following are hereby incorporated by reference:**

(1) 21 CFR 117 (Sept. 17, 2015 Edition).

(2) NSSP Guide for the Control of Molluscan Shellfish (2023 Revision)

(b) Federal rules and documents, which have been incorporated by reference, do not include any later amendments than those specified in the incorporated citation. Sales of the Code of Federal Regulations are handled exclusively by the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402.