

IDENTIFYING COMPLIANCE REQUIREMENTS WITH THE PREVENTIVE CONTROLS FOR HUMAN FOOD RULE FOR FACILITIES THAT MANUFACTURE, PROCESS, PACK OR HOLD FOOD FOR SALE FOR HUMAN CONSUMPTION

Is the majority (>50%) of sales of human food direct to consumer (retail)?

YES

Facility is exempt from registration with FDA, and exempt from FSMA Preventive Controls for Human Food Rule. However, the facility will still be required to comply with state food safety laws.

NOTE: If facility has registered with FDA in the past, they must cancel their registration.

NO

Does the facility make less than 1 million dollars in gross annual sales?
(See FDA's "Qualified Facility Guidance" document for detailed gross annual sales calculation and additional guidance for qualified facilities)

YES

Facility may be considered a qualified facility with exemptions from subpart C (Hazard Analysis and Risk Based Preventive Controls) and Subpart G (Supply Chain Control).

NO

Facility does not qualify for exemptions and is required to fully comply with the Preventive Controls for Human Food Rule

NEXT STEPS

Register with FDA at <http://www.fda.gov/furls>
Attest to status as a Qualified Facility by completing form FDA 3942a. See "PCHF QF Exemption Guide" and "Key Facts PCHF" document for more details.
NOTE: If a facility fails to complete the qualified facility attestation form FDA 3942a, they will be required to comply with all applicable parts of the Preventive Controls Rule.

NEXT STEPS

Facility must comply with all applicable parts of the Preventive Controls for Human Food Rule (See "Key Facts PCHF" document).
Register with FDA at <http://www.fda.gov/furls>.

Resources:

1. "Qualified Facility Guidance" <https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm499509.pdf>
2. "Key Facts PCHF" – <https://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM584807.pdf>
3. "PCHF QF Exemption Guide" – https://www.michigan.gov/documents/mdard/FSMA_PCHF_Qualified_Facility_FINAL_625063_7.pdf