

Food Safety Modernization Act

Food Facility Exemption Guidance for FSMA Preventive Controls for Human Food Rule

Does your facility manufacture, package or hold food for sale and produce less than \$1 million in gross annual sales?

If so, your facility may not be required to follow all parts of the Preventive Controls for Human Food Rule. Here are some questions and answers to help you determine if your facility is a Qualified Facility, and what steps you need to take if you qualify.

What if I don't submit the required information to FDA?

You will be required to comply with all parts of the Preventive Controls Rule. Your inspector will not be able to grant an exemption on-site.

What paperwork do I need to submit to FDA?

You must submit form FDA 3942a to FDA, confirming that sales are below 1 million dollars and that other requirements for controlling food hazards are met.

Form FDA 3942a asks for my registration number. What if I don't have one?

Facilities that manufacture, pack, and/or hold food for sale are required to register under the Bioterrorism Act of 2002 and under FSMA. Food facility registration can be completed using FDA Form 3537.

You can complete Forms FDA 3537 and FDA 3942a online at: <http://www.fda.gov/furls>

What is the deadline for submitting form FDA 3942a to FDA?

All existing food facilities attesting as a Qualified Facility are required to submit FDA Form 3942a to FDA by December 17, 2018.

How often do I have to submit paperwork to FDA?

You must renew your registration and confirm you are a Qualified Facility every two years. Renewal must take place between October 1 and December 31.

** Funding for this document was made possible, in part, by the Food and Drug Administration through the Food Protection Task Force Grant, 5R13FD004960-05. The views expressed in this publication do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices or organization imply endorsement by the United States Government.**



For more information, visit FDA's FSMA Final Rule for PCHF website at: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>

www.michigan.gov/fsma