

Preventive Controls for Human Food

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule)

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule was finalized in September 2015. Information about the rule and the implementation of the rule can be found on the [FDA web site](#).

Compliance Dates

Compliance dates for businesses are staggered based on dollar amounts of sales.

- **Very small businesses** (averaging less than \$1 million per year [adjusted for inflation]) in both annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale): Three years (September 2018), except for records to support its status as a very small business (January 1, 2016).
- **Businesses subject to the Pasteurized Milk Ordinance** (compliance dates extended to allow time for changes to the PMO safety standards that incorporate the requirements of this preventive controls rule): Three years (September 2018)
- Small businesses (a business with fewer than 500 full-time equivalent employees): Two years (September 2017)
- **All other businesses:** One year (September 2016)

Exemptions

Generally, exemptions include industries covered under other food safety regulations (low acid canned foods, seafood, fresh juice, etc.) In addition there is a **qualified exemption** for very small businesses that sell at least 50% of their product directly to the **qualified end user** and the value of all food sold is less than \$500,000 adjusted for inflation (in the preceding 3 year period). Find how the Rule defines exemptions **here**. (link to <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117.5>)

For Connecticut regulatory guidance

[If you produce dairy products, contact the Connecticut Department of Agriculture, Dairy Division](#)

Phone: 860.713.2508

Email: CTDeptAg@ct.gov

If you process foods that do not contain meat or poultry ingredients, contact [The Connecticut Department of Consumer Protection, Foods Program](#).

Phone: 860.713.6160

Email: dcp.foodandstandards@ct.gov

Do you want to read more about this?

Fact sheet

[KEY REQUIREMENTS: Final Rule on Preventive Controls for Human Food](#)

Other important links:

[FDA Food Facility Registration](#)

As a result of the requirements of the Bioterrorism Act, FDA included in FSMA a requirement that all facilities that manufacture, process, pack, or hold food for consumption in the United States must register with the FDA. The FDA also reserves the right to inspect any registered food facilities and to suspend registration under certain circumstances. Facilities must re-register every two years.

Food Safety Preventive Controls Alliance

The U.S. Food and Drug Administration is working with the Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH), who will administer the [Food Safety Preventive Controls Alliance \(FSPCA\)](#). The FSPCA is a public/private alliance consisting of representatives from the FDA, state regulatory agencies, the food industry, and academia, whose mission is to support safe food production. A standardized core curriculum, training and outreach programs are tools that the Alliance provides to assist food processing businesses that must comply with the Preventive Controls Rule, especially small and medium sized companies. In addition, the FSPCA Technical Assistance Network (TAN) has been set up to address scientific/technical questions related to FDA's Preventive Controls human food regulations.

For information about Connecticut Food Safety Preventive Controls for Human Foods (FSPCA) Courses, go **here**. (link to http://cag.uconn.edu/nutsci/nutsci/foodsafety/Home_Page/Courses_and_Workshops/HACCP_Training.php)

The FSPCA maintains a list of courses offered nationally and internationally. For this list, go **here**. (link to https://fspca.force.com/FSPCA/s/course_registration/Course_Registration_c/00B36000007edjpEAA?language=en_US)

FDA's Technical Assistance Network or TAN

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies. You may contact the TAN with questions you have about the Preventive Controls for Human Foods Rule regulations.

You may submit questions online here. (link to: <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>)

Or, you can mail your question to:

Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740