



September 2015

FDA Finalizes Food Safety Regs for Preventative Controls, Hazard Analysis

On Sept.10, 2015, the FDA announced two sets of final regulations which were mandated by the FDA Food Safety Modernization Act (FSMA) of 2011: (1) Preventative Controls and Hazard Analysis for Human Food; and (2) Preventative Controls and Hazard Analysis for Animal Food. The final regulations are scheduled to be formally published in the Federal Register Sept. 17, 2015. Click [here](#) to view a copy of the pre-publication version of the human food regulations.

The FDA is holding a series of [webinars](#) on the new regulations Sept 16, 17, and 18, 2015. Summaries and information links for both set of regulations can be found on the FDA website using these links: [Human Foods](#) and [Animal Foods](#). The following is a brief overview of the major provisions.

Human Foods

Food facilities must implement a written Food Safety Plan addressing:

- Hazard Analysis – Identification of known or reasonably foreseeable hazards
- Preventive Controls – Measures required to ensure hazards will be minimized or prevented
- Monitoring – Procedures designed to provide assurances that preventive controls are consistently performed
- Corrective Actions and Corrections – Steps to be taken to timely identify and correct a minor, isolated problem that occurs during food production
- Verification – Activities are required to ensure that preventive controls are consistently implemented and effective

The final regulations also require: (a) manufacturing and processing facilities to implement a risk-based Supply Chain Program for those raw material and other ingredients for which it has identified a hazard requiring a supply-chain applied control; (b) and a written Recall Plan.

The deadlines for compliance with the new regulations are staggered based on the size of the business. For all requirements except the Supply Chain Program, the deadlines are:

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** after publication in the Federal Register, except records to support status as a very small business are required by Jan. 1, 2016

Businesses subject to the Pasteurized Milk Ordinance: **Three years** after publication in the Federal Register

Small businesses (fewer than 500 full-time equivalent employees): **Two years** after publication in the Federal Register

All other businesses: **One year** after publication in the Federal Register

Compliance dates for the Supply Chain Program are staggered using a matrix based on the size of the business receiving the raw materials and whether or not the supplier is subject the preventative controls regulations.

Animal Foods

The final regulations for animal foods establish current good manufacturing practices (CGMPs) with requirements governing personnel, plants and grounds, sanitation, water supply and plumbing, equipment and utensils, plant operations, holding and distribution, and holding and distribution of human food byproducts for use as animal food. They also require implementation of a written food safety plan to address hazard analysis, preventative controls, monitoring, and verification, as a well as a written recall plan and a risk-based Supply Chain Program.

The deadlines for compliance with the new regulations are staggered based on the size of the business. For all requirements except the Supply Chain Program, the deadlines are as follows:

Very Small Businesses [averaging less than \$2.5 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]:

- CGMPs - **Three years** after publication in the Federal Register, except records to support status as a very small business are required by Jan. 1, 2017
- Preventative Controls – **Four years** after publication in the Federal Register

Small Businesses (a business with fewer than 500 full-time equivalent employees): **Two years** after publication in the Federal Register.

- CGMPs - **Two years** after publication in the Federal Register
- Preventative Controls – **Three years**, after publication in the Federal Register

All other businesses:

- CGMPs - **One year** after publication in the Federal Register
- Preventative Controls – **Two years** after publication in the Federal Register

Compliance dates for the Supply Chain Program are staggered using a matrix based on the size of the business receiving the raw materials and whether the supplier is subject the preventative controls regulations.

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