

FSMA AND YOUR BUSINESS

KNOWLEDGE BRIEF

FSMA Basics

Why FSMA, and Why Now?

The regulation of food for human and animal consumption has been complicated and confusing for decades. One reason is that various parts of the food industry fell under different and overlapping federal agencies, such as the U.S. Department of Agriculture, the Food and Drug Administration, the Federal Trade Commission, and others. Also, changes in existing regulations over the years further complicated matters by exempting some producers but not others, or by switching oversight from one agency to another.

While this environment of divided regulation generally seemed to work -- America's food supply is considered the safest in the world -- food safety governance has come under criticism in recent years following repeated food recalls that killed dozens of consumers, injured hundreds more, and created often ruinous economic harm to the companies involved in the contamination.

The oversight of food in the U.S. remains divided. However, Congress has directed the FDA, through FSMA, to promote the idea that preventing food contamination, rather than waiting for a problem to arise, is the key to strengthening overall food safety in the U.S.

Who is covered by FSMA?

All food facilities registered with the Food and Drug Administration (FDA) under the Food Safety Modernization Act of 2011 and as spelled out in section 415 of the FD&C Act, are required to comply with the new regulations. These facilities include domestic food companies that manufacture, process, pack, receive or hold food for human or animal consumption. Also included are foreign-based food facilities that export food into the United States for consumption or food ingredients used in the production of food for humans or animals.

Suppliers of goods or services to food manufacturers also are subject to FSMA oversight. This would include suppliers of product ingredients and such things as MRO chemicals and industrial cleaners used to maintain food production equipment.

TIP: Go to stoptlightfoodsafety.com for information on MRO chemical safety

Are Small Businesses Covered by FSMA?

FSMA regulations exempt or delay implementation for small or very small businesses. In general, that means a business that employs fewer than 500 full-time equivalent employees. A very small business is one with total sales of food of \$1,000,000 or less annually averaged over a three-year period.

Who is Exempted?

The new regulations do not cover meat processing plants regulated by the U.S. Department of Agriculture under its FSIS Inspection Services.

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FSMA also does not cover restaurants or retail grocery stores that sell food directly to consumers. Such facilities are subject to licensing or permits and oversight by state or local health agencies and thus not covered by the FDA Food Safety Modernization Act.

Various other segments of the food industry are either exempted because they are covered under a different set of regulations, or are subject to some but not all of the new regulations. These include milk processors, fish and fishery products, dietary supplements, alcoholic beverages producers, and raw agricultural commodities intended for further distribution or processing (e.g., millers). Also exempted are thermally processed items in hermetically sealed packaging.

When Does FSMA Take Effect?

For most of the food industry, the most critical date to focus on for FSMA implementation is August 2016. That's when full implementation will be in place (unless there are unforeseen delays). Smaller businesses, farms, and food or ingredient importers have later deadlines, stretching out to 2019.