

EXECUTIVE BRIEFING

FDA Food Safety Modernization Act *interpretations*

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Why FSMA?

- Globalization
 - 15 percent of U.S. food supply is imported
- Changing foods in the marketplace
 - More fresh (less processed) foods
 - Organic/Preservative free/etc
- Shifting demographics
 - Growing population (about 30%) of individuals are especially “at risk” for foodborne illness

FSMA ?

1. **Preventive controls** - comprehensive, prevention-based controls *farm-to-table*
2. **Inspection and Compliance** risk-based approaches
3. **Imported Food Safety**
4. **Response** - FDA has recall authority for all food products.
5. **Enhanced Partnerships** – Fed/State inspection

- **Preventive Controls for Human Food | Animal Food**
- **Produce Safety:** Establishes science-based standards for growing, harvesting, packing and holding produce on domestic and foreign farms
- **Foreign Supplier Verification Program:** Importers verify safety of foods equivalent to US standards
- **Third Party (auditor) Certification**
- **Sanitary Transportation of Foods**
- **Intentional Adulteration (Economic Fraud)**

FDA Food Facility Registration

Who Must Register?

- If you are a domestic or foreign facility engaged in manufacturing, processing, packing, or holding of food (even one that is only interstate)
 - unless you are exempt under 21 CFR 1.226

<https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM332460.pdf>

REGISTRATION EXEMPT

- If FDA Food Facility Registration **not** required
 - Not subject to 21 CFR 117
 - Do not require Preventative Controls
- FARMS (*must review produce safety rule*)
- Retail/Foodservice
 - >50% is sale of food products directly to consumers = EXEMPT
 - Commissary – if primary function IS to provide foods to a business = **not exempt**
- Importing foods? **Not exempt**

Internet, Mail-order Foods?

- If I supply food directly to consumers via the Internet or mail-order, am I a retail food establishment? FDA says, “Maybe”.
 - If facility primarily manufactures foods to be sold via internet or mail order then it’s a manufacturer.
 - If facility is a retail-foodservice operation normally, then it is likely to be considered retail subject to 50% rule

FSMA Preventative Controls |

Whom does this apply to? WHEN? September



FTEs

> 500
LARGE | 2016

< 500
SMALL | 2017



< Million
Sales

VERY
SMALL | 2017

FDA Registration = Yes Qualified Facilities

- *exempt from FSMA Preventative Controls rule*
- *Not exempt from having a food safety system*

Businesses (when including the sales by any subsidiaries, affiliates, and any entity of which the facility is a subsidiary or affiliate) with average annual sales of less than \$500,000 with at least half the sales to consumers or to local retailers or restaurants or Indian reservation (within the same state or within 275 miles)

or

Very small businesses (including any subsidiaries or affiliates) averaging less than \$1,000,000 (adjusted for inflation) -- in both sales of human food *plus* the market value of human food that is manufactured, processed, packed, or held without sale (e.g. held for a fee), per year during the 3-year period preceding the current calendar year.

The produce safety rule

impacts growers of fruit and vegetables intended for raw consumption. Growers will be required to adopt science-based microbial testing of and standards for water used for irrigation. The rule also elaborates on standards for manure application and for composting. *(The preventive controls rule clarifies when a farm is covered by produce safety rule and when its activities may place it under preventive controls jurisdiction.)*

Import Safety

- Importers must ensure that their foreign suppliers have adequate preventive controls in place
- FDA can rely on third parties to certify that foreign food facilities meet U.S. requirements
 - Establishing “trusted” countries re: food safety standards
- Can require mandatory certification for high-risk foods
- Voluntary qualified importer program--expedited review
- Can deny entry if FDA access for inspection is denied
- Requires food from abroad to be as safe as domestic

Many challenges

- Understanding compliance requirements
- Understanding legal culpability for non-compliant suppliers
- Global retail/foodservice foods
 - Safety
 - Allergens
 - Food fraud
- Getting assistance