

# Leveraging Irradiation to Meet FSMA Compliance

Jaymie Forrest

Chief Commercial Officer

[jforrest@scantechsciences.com](mailto:jforrest@scantechsciences.com)



# Rationale for FSMA

- Modernize our food safety system in the US
- Prevention vs. Reaction
- Mandates FDA to set new standards and make sure these standards are met in US and for importers
- Mandatory recall authority and ability to stop shipments of “suspect” food



# FSMA Key Areas of Impact

- **Preventive controls** - comprehensive, prevention-based across the food supply
- **Inspection and Compliance** - The legislation recognizes inspection is important to hold the industry accountable. FDA will apply inspection resources in a risk-based manner with innovative approaches.
- **Imported Food Safety** - FDA has new tools to ensure that imported foods meet U.S. standards and are safe. For the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.
- **Response** - For the first time, FDA has mandatory recall authority for all food products. New authorities that are also in effect: expanded administrative detention of products that are potentially in violation of the law, and suspension of a food facility's registration.
- **Enhanced Partnerships** - strengthening existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, tribal and foreign entities



# Types of Companies Impacted

- Production (farm) vs. preventive controls
- Manufacture, pack, label, or hold food – must be FDA registered facility
- Shippers, receivers, loaders and carriers who transport food in the United States by motor or rail vehicle, whether or not the food is offered for or enters interstate commerce.
- Also applies to entity outside of the United States, such as an exporter, who ships food to the United States in an international freight container by ocean-going vessel or in an air freight container, and arranges for the transfer of the intact container in the United States onto a motor vehicle or rail vehicle for transportation in U.S. commerce, if that food will be consumed or distributed in the United States.



# Who is Under Preventive Controls Requirements

- In general, facilities that manufacture, process, pack or hold food
  - Facilities required to register with FDA under sec. 415 of the FD&C Act
  - Not farms or retail food establishments
- Applies to domestic and imported food
- There are some exemptions and modified requirements for certain facilities

# Rules with Associated Opportunity or Impact

- “Preventive Controls” for Human Food
- “Preventive Controls” for Animal Food
- The “Produce Safety Rule”
- Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals
- Sanitary Transportation of Human and Animal Food
- Protect Against Intentional Adulteration Rule

# FSMA Compliance Calendar

Rule	2015	2016	2017	2018	2019	2020	2021	2022
Produce Safety	Effective Date	Jan	Large	Jan.	Ag. Water	Jan.		
			Small		Jan.	Ag. Water	Jan.	
			V. Small			Jan.	Ag. Water	Jan.
Preventive Controls Human	Sept	Sept						
		Small	Sept					
		V. Small		Sept				
Preventive Controls Animal*	Sept	GMP	PC					
		Small	GMP	PC				
		V. Small		GMP	PC			
FSVP	Effective Date	Jan	6 mo. after compliance date for supplier					

Effective Date
  Large
  Small
  V. Small
  Ag. Water

\*Animal Food rule has 1-yr staggered compliance dates for GMPs and preventive controls



# FSMA Compliance Calendar continued

Rule	2015	2016		2017	2018	2019
	Oct	Apr	May			
Intentional Adulteration			Final	Large ?		
				Small	Small ?	
					V. Small ?	
Sanitary Transportation		Final	Large June			
			Small	Small	Small June	
3 <sup>rd</sup> Party Cert.	Final					

Final
  Large
  Small
  V. Small





# Challenges for Irradiation Facility

- ❑ Establish thorough food safety program and requires collaboration between parties
- ❑ Hazard Analysis (“assess the probability that these hazards will occur in the absence of controls”)
- ❑ Get started for Sanitary Transport Act compliance; Implications from 2005:
  - ❖ **Vehicles and Transportation Equipment, Transportation Operations** –such as having established procedures for the exchange of information about temperature control, between the shipper, carrier and receiver
  - ❖ **Documentation and Records**
    - ✓ **Training:** Training of carrier personnel in sanitary transportation practices and documentation of the training.
    - ✓ **Records:** Maintenance of written procedures and records by carriers and shippers related to transportation equipment cleaning, prior cargos, and temperature control.



# Resources

- <http://www.fda.gov/fsma>
- Guidance, Fact Sheets, Presentations, recorded Webinars
- Submit questions to Food Safety Technical Assistance Network
- Online course will be develop and posted for training
- *Food Logistics* magazine articles – April edition on FSMA
- Association sponsored FSMA Workshops – GMA, United Fresh, PMA, etc.

