



TRACEGAINS WEBINAR

How FSMA Reshaped the Global Food Supply Chain



Meet
Your Moderator

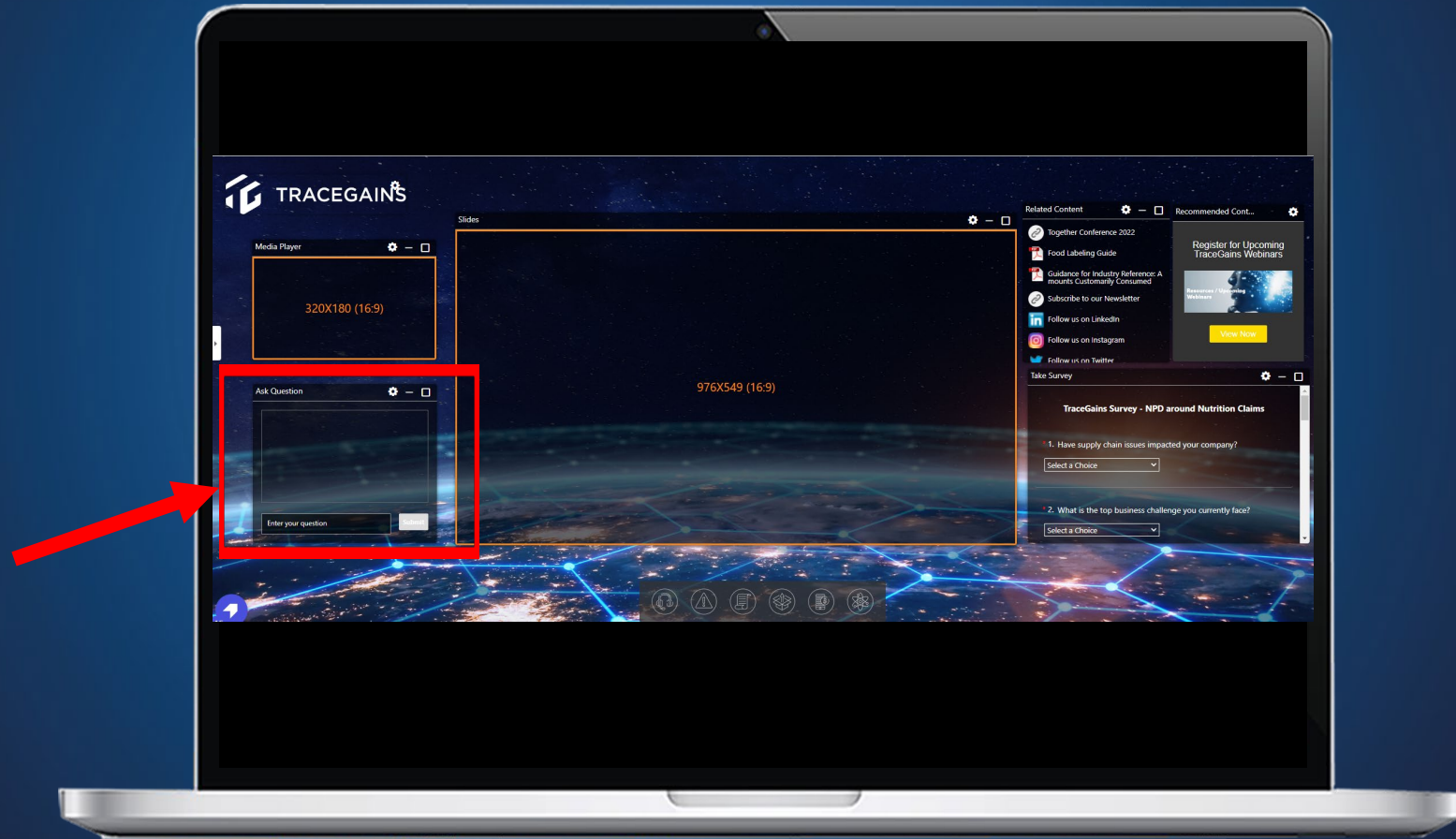


Kristen Goodale
Digital Marketing Webinar &
Podcast Specialist



Slides And Recording Will Be Shared

We want to hear from you! Please type your questions in the chat box.



About TraceGains

Together we do more



Food and Beverage ••• Dietary Supplements ••• Retail ••• Consumer Packaged Goods



Discover the Power of Networked

What Makes TraceGains Different?

On average, companies find that 80% of their suppliers are already on TraceGains Network.



Meet

Your Speakers

Brian Ravitch

Consultant | FDAImports



Justin Busch

Account Executive | TraceGains





How FSMA is Reshaped the Global Food Supply Chain.

Brian Ravitch

Senior Regulatory Advisor

Ben England and Associates LLC

Brian Ravitch

Senior Regulatory Advisor



- Extensive background in Import operations, regulatory compliance, Seafood HACCP and Preventive Controls
- Served as one of seven ORA National Program Experts in the Office of Food and Feed Operations Branch for 7 years as a headquarters' authority on import operations and inspectional techniques in the area of food and feed, he was an instructor and focal point for authoritative guidance to ORA field operations
- Subject Matter Expert instrumental in the design, development, and implementation of FSVP
- Helped write FSVP regulations and Guidance for Industry
- Designed and implemented FDA Regulator Training for FSVP
- Food Safety Preventive Controls Alliance (FSPCA) participating member of the FSVP Work Group and contributing editor of the FSVP training manual
- FSPCA FSVP Lead Instructor and PCQI

Topics to be Discussed

- Why is FSMA
- Shared responsibility among the global supply chain.
- System Recognition Agreements
- FSMA Interaction with FSVP
- FSVP Enforcement Authority
- Who must comply with FSVP
- Qualified Individual
- FSVP Exemptions
- Eight components of a FSVP program
- FSVP Verification Process
- How is FSVP enforced
- FSVP Inspection Objectives
- Inspection Priorities
- FSVP Regulatory Compliance
- 5-year Compliance Summary FSVP

Why Implement FSMA



“The FDA Food Safety Modernization Act (FSMA) is transforming the nation’s food safety system by **shifting the focus from responding** to foodborne illness **to preventing** it. Congress enacted FSMA in response to dramatic changes in the *global food system* and in our understanding of foodborne illness and its consequences, including the realization that preventable foodborne illness is both a significant public health problem and a threat to the economic well-being of the food system.”

FDA’s Associate Commissioner of Food Safety

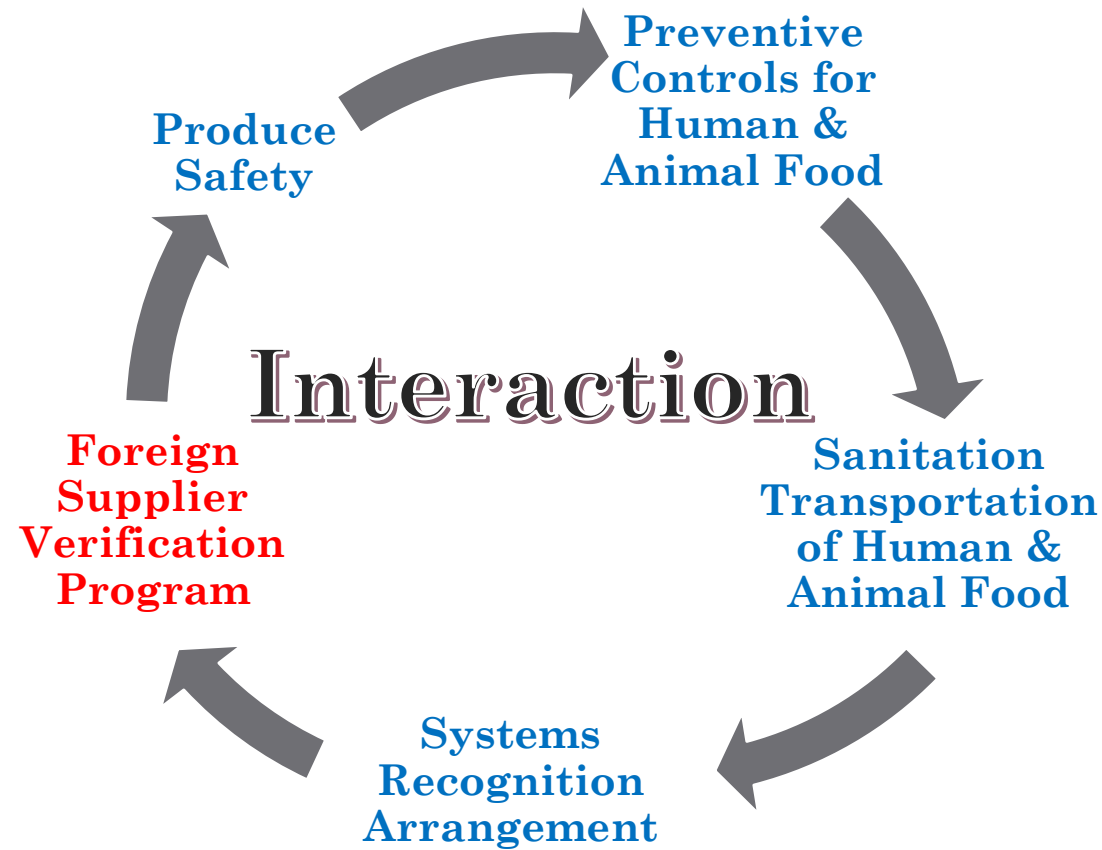
Why Implement FSMA



“About 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.”

Center for Disease Controls and Prevention

Interaction of Major FSMA Rules



Systems Recognition Agreements – An Import Tool

- FSMA allows FDA to leverage the food safety capacity of foreign governments, through arrangements and agreements
- Systems Recognition (SR) is a partnership between the U.S. Food and Drug Administration (FDA) and a foreign regulatory counterpart, in which the agencies concluded they operate comparable regulatory programs resulting in similar food safety outcomes.
- The FSVP regulation provides modified requirements for an importer of certain foods from a country officially recognized as comparable or equivalent.
- <https://www.fda.gov/food/international-cooperation-food-safety/systems-recognition-food>

FSMA Interaction and FSVP

- Shift in Importers responsibility from Reactive to Proactive
- Importers responsibility to understand food safety aspects of the foods they import
- To provide adequate assurances that:
 - Foreign suppliers produce food providing same level of public health protection as FSMA preventive controls or produce safety provisions
 - Food is not adulterated or misbranded (as related to allergen labeling)

FDA has more authority to request foreign manufacture's processing records under FSMA.



FSVP Authority

Prohibited Act. The importation or offering for importation into the United States of an article of food without the importer having an FSVP that meets the requirements of section 805 of the Federal Food, Drug, and Cosmetic Act, including the requirements of this subpart, is prohibited under section 301(zz) of the Federal Food, Drug, and Cosmetic Act.

FSVP Authority

Refusal of admission. An article of food is subject to refusal of admission under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act if it appears that the importer of that food fails to comply with this subpart with respect to that food. If there is no U.S. owner or consignee of an article of food at the time the food is offered for entry into the United States, the article of food may not be imported into the United States unless the foreign owner or consignee has appropriately designated a U.S. agent or representative as the importer in accordance with § 1.500.



FSVP Authority

Section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA) sets out the requirements for imports and exports of FDA regulated products.

*All imported products are required to meet the same standards as domestic goods.



Who must comply with FSVP?

- All importers of food both human and animal including beverages, dietary supplements, and ingredients used in producing foods, unless the food exempt.
- The FSVP Importer is the owner or consignee who resides in the United States, who at the time of entry either owns the food, purchased the food, or has agreed in writing to purchase the food.
- If no U.S. owner or consignee of the food at the time of entry, the importer is a U.S. agent or representative of the foreign owner. A signed statement of consent to serve as the importer is required.

There is no provision within the regulation for the transfer of responsibility.

Qualified Individual

- A qualified individual must develop your FSVP and perform each of the activities required under this subpart.
- A qualified individual must have the
 - education,
 - training,
 - or experience (or a combination thereof)



To perform specific activities and must be able to read and understand the language of any records that must be reviewed in performing an activity.

- Flexibility of the regulation-The qualified individual may be hired to perform specific tasks within your program.

Exemptions

- Certain juice, fish, and fishery products and ingredients used to make them, that are imported from a foreign supplier that are in compliance with in 21 CFR part 120 or part 123.
- Certain meat, poultry, and egg products subject to the requirements of the U.S. Department of Agriculture (USDA)
- Food imported for research or evaluation
- Food imported for personal consumption
- Alcoholic beverages, alcoholic beverage raw materials and ingredients used by Importer to manufacture/process an alcoholic beverage, and certain non-alcohol foods (excluding beer and wine)
- Food transshipped through the United States or imported for processing and export to other countries
- U.S. food returned

Eight Components of a FSVP Program

-
1. Conduct a hazard analysis and hazard evaluation
 2. Verification Activity- Verify suppliers procedures and processes-
 3. Review Supplier FDA compliance history
 4. Approve Supplier
 5. Take corrective actions as needed
 6. Periodic reassessment of FSVP
 7. Importer identification at entry
 8. Recordkeeping. You must have written procedures in place.

Verification Process

Two-step process:

- 1.** Verify the safety of the food by understanding the potential hazards through the use of a hazard analysis and hazard evaluation. Also include confirmation the foreign supplier is producing the food in compliance with processes and procedures providing “at least the same level of public health protection” as identified in the Risk-based Preventive Control for Human or Animal Food Rules or the Standards for Produce Safety.
- 2.** Importer must evaluate the Supplier’s food safety history.

Both are critical in the approval process of the foreign supplier.



How is FSVP Enforced?

- FSVP is enforced through inspections conducted either in person or electronically.
- The inspections consist of records review of your:
 - written procedures,
 - foreign supplier verification
 - and supporting documentation.
- Inspections hold the same regulatory authority as any other inspections.
- FDA does not enforce FSVP during the entry process.

The rule requires the Importer of Record to identify the FSVP Importer when declaring the entry to CBP. Additionally, the declaration includes an e-mail address and a “unique facility identifier” which is a *Dun & Bradstreet* DUNS number.

Objectives of FSVP Inspections

- ✓ Conduct FSVP inspections of importers of food subject to the Foreign Supplier Verification Programs for Food Importers regulation through record review.
- ✓ Document FSVP inspections and observations.
- ✓ Perform appropriate regulatory actions to prevent the importation of food by importers not in compliance with the FSVP regulation or food that appears to be in violation of the FD&C Act.

Inspection Priorities

Priority #1:

- Class 1 recalls, laboratory class 3 microbiological findings,
- Official action indicated (OAI) inspection classifications, and foodborne illness outbreaks.
- History of noncompliance include country of origin associated with noncompliance for a specific food or industry.



Inspection Priorities



Priority #2:

- High-Risk Foods Importers of high-risk foods (i.e., foods that may pose a health risk) are the second priority.

Priority #3:

Other Supply Chain Factors

- Number of different foods imported,
- Number of food foreign suppliers,
- Volume and value.

These priorities help maximize FDA's surveillance coverage

FSVP Regulatory Compliance

Regulatory Follow-Up

If adequate documentation of corrective actions from a previous inspection are not received, FDA may expedite a follow-up inspection to ensure compliance has been met.

Warning Letters

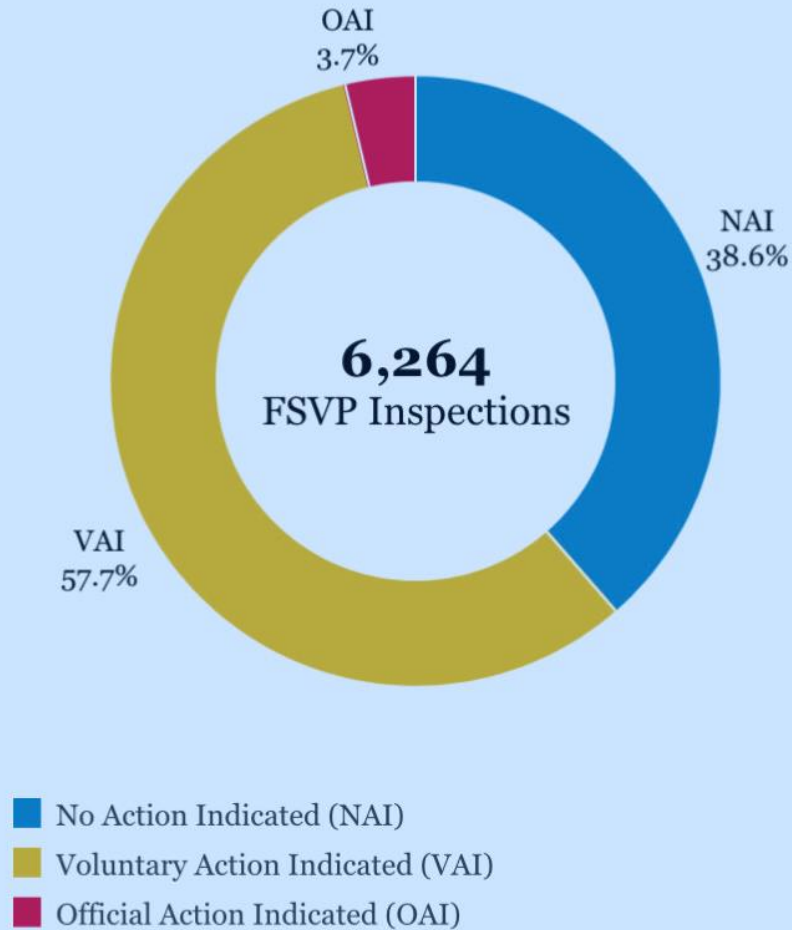
- Importers who do not take appropriate corrective actions for significant FSVP violations
- Total number issued - 173 Number issued in 2022 through August- 48

Import Alert 99-41 "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Programs (FSVP) Regulation"

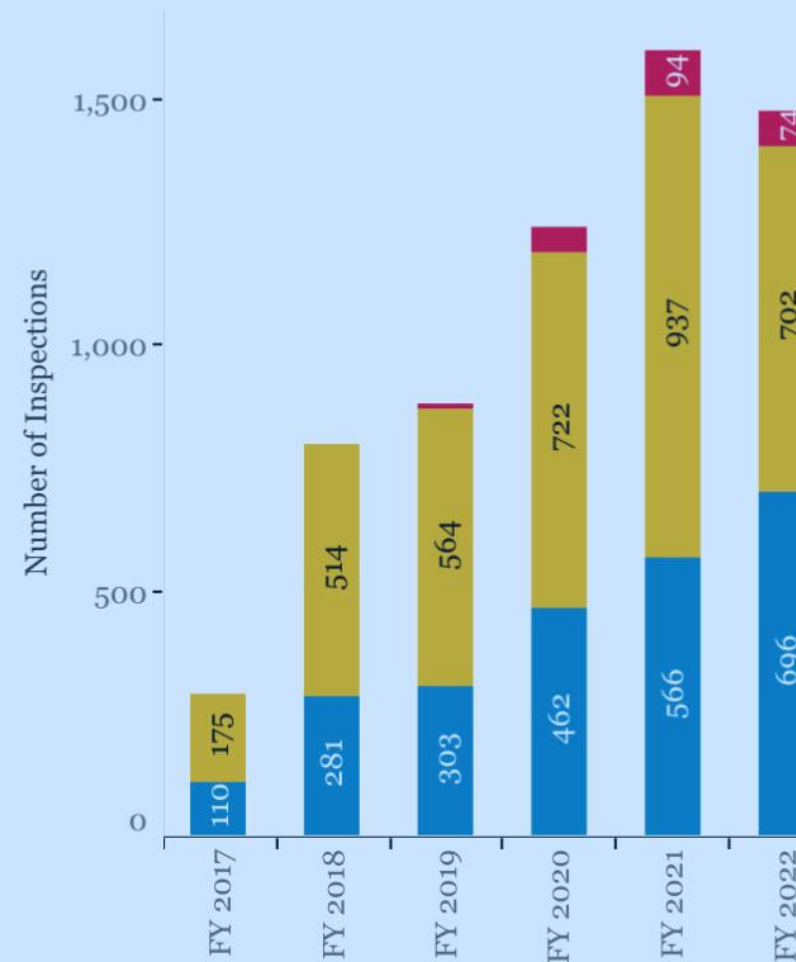
- Detention without physical examination of an article of human or animal food offered for import by the Importer that is not in compliance with the FSVP regulation.
- 37 Companies presently on Import Alert

FSVP Inspections Conducted 2017-2022

Percent of Inspections by Classification



Number of Inspections by Classification



Questions and Answers



Contact Us!

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Justin Busch

Account Executive



What did we talk about today?

- What is FSMA and why was it enacted into law in 2011
- The 7 major rules of FSMA, including FSVP and System Recognition
- FSVP: Enforcement authorities, who must comply, exemptions, and evaluation and approval of foreign supplier
- FSVP Regulatory Compliance
- Five-Year Compliance summary for FSVP
- Seven components of a successful FSVP program

How can TraceGains Help?



TraceGains Network

The global ecosystem built on networked ingredient data

56K+

Supplier Locations

425K+

Items & Ingredients

146+

Supplier Countries

3M+

Supplier, Item & Ingredient Documents

717k

Completed Standard Online Forms

53k

Counties with Customer Presence



TraceGains Product Suite

R&D / NPD TEAMS

QUALITY and REGULATORY COMPLIANCE TEAMS

Marketplace

Supplier Management

Networked Finished Goods

Formula Management

Networked Intelligence

Spec Management– Raw Materials / Spec Management – Finished Goods

Audit Management

Supplier Compliance

Quality Management

Customer Management

Explore Concept

Validate Product

Build/Manage Product

CONCEPT

TRACEGAINS C TO C SUITE

CONSUMPTION

Win a Gift Card...

Take our survey and
be entered to
win a **\$50** gift card!

Live Q&A

Type your questions
into the chat box!





Thank You

Together we do more