

FSVP and Traceability: Managing Your Supply Chain with New FDA Mandates

Coley Anderson

Director, Industry and Government Relations

Registrar Corp

Foreign Supplier Verification Program (FSVP)

Am I Required to be an FSVP Importer?

If your supplier is outside the U.S., then yes.

- FDA regulation states that **the U.S. Importer of food and beverage** shipments is considered the FSVP Importer.
- **U.S Importers may hire a third-party to act as their qualified individual** for developing and implementing an FSVP on their behalf
- For shipments that have **no U.S Importer at the time of US entry, the exporter must designate a U.S FSVP agent** to fulfill the FSVP responsibilities.



Products Exempt from FSVP

- Juice
- Seafood
- Alcoholic beverages
- USDA products (meat, dairy, etc.)

Other groups:

- Food solely for research or evaluation
- Food for personal consumption
- Food that is transshipped through the U.S.
- Food for processing and future export
- Food processed in the U.S., exported and returned

FSVP Best Practices

What is an FSVP Importer?



A designated, qualified individual should conduct all FSVP activities

Your FSVP team should obtain FSVP and PCQI training



Collect the food safety documents at the time of onboarding a supplier.
(Collect sooner than later)

Confirm who is the FSVP importer for each shipment
(IOR is not the same)



Review, assess, approve,
and sign all
FSVP plan components

*Monitor your DUNS number and know who is
designating you
as FSVP Importer*



*Confirm that you are monitoring the correct
supplier facility
(multiple facilities)*



At least two trained individuals
should have access to
your FSVP program



FSVP Best Practices Continued

Are you the FSVP importer

1. Did you agree to purchase the product before it left a foreign country?
2. Do you own it at the time of entry into the USA?

FSVP Best Practices Continued

Are you an FSVP importer ?

3. Are you the ultimate consignee?
4. Is this product imported for you and only your company?



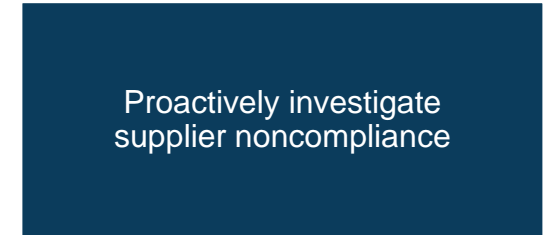
Document your monitoring of your suppliers' FDA compliance status



Automate FSVP monitoring and document renewals



Proactively investigate supplier noncompliance



Confirm third-party audits cover FSMA and relevant regulations



Understand modified FSVPs and exemptions for small businesses

Food Traceability and New FDA Mandates

Recent Outbreaks

August 2020
Leafy greens



September 2021
Parsley



December 2022
Raw oysters



Requirements for Additional Traceability Records for Certain Foods – Final Rule

- Finalized the “Food Traceability List” (FTL)
- Firms that manufacture, process, pack or hold FTL foods are subject to it
- FTL foods require additional traceability and record-keeping processes for certain entities in supply chain





Requirements for Additional Traceability Records for Certain Foods – Final Rule

- Foods that contain ingredients (in the same form) that are on the list are also subject to the requirements
- List will be updated ~ every 5 years
- Entities not subject to other FSMA rules may be subject to these new requirements
 - Restaurants
 - Retail Food Establishments

Food Traceability List – The “Usual Suspects”

Fruit

Fresh Cut	Fresh
Fruits	Melons
	Tropical tree fruits

Vegetables

Fresh Cut	Fresh
Leafy greens	Leafy greens
Vegetables (non-leafy greens)	Herbs
	Cucumbers
	Peppers
	Sprouts
	Tomatoes





Food Traceability List – The “Usual Suspects”

Seafood

Fresh	Frozen
Finfish	Finfish
Smoked finfish (refrigerated)	Smoked finfish
Crustaceans	Crustaceans
Molluscan shellfish, bivalves (exception: only consists of shucked adductor muscle)	Molluscan shellfish, bivalves (exception: only consists of shucked adductor muscle)

Food Traceability List – The “Usual Suspects”

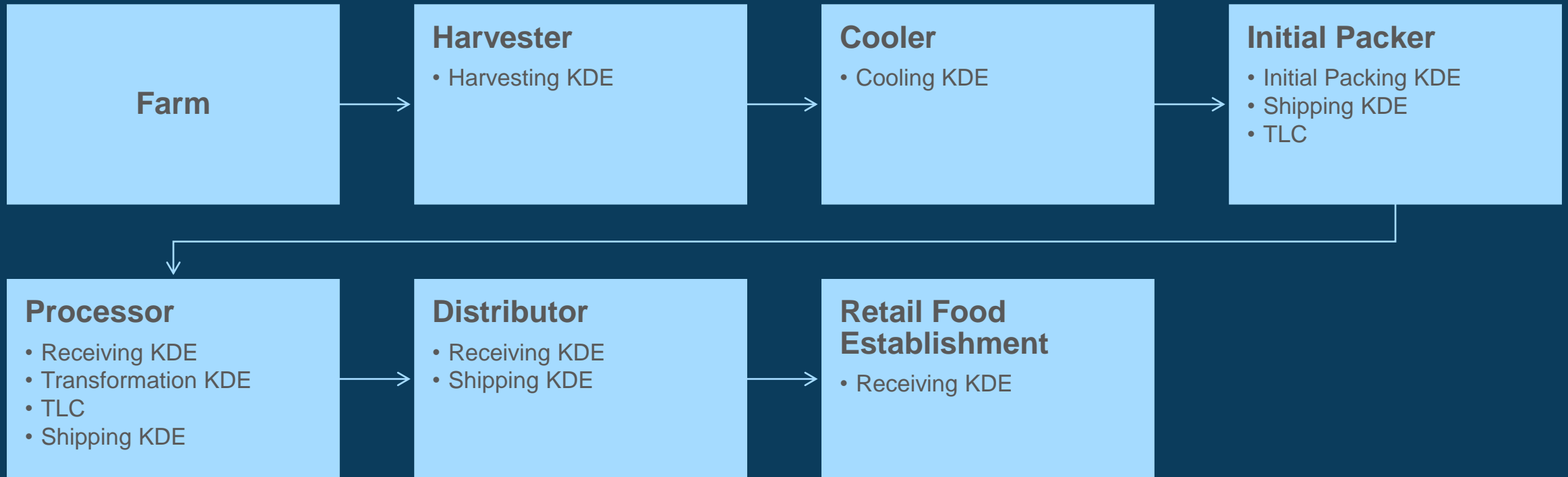
- **Fruit**
- **Vegetables**
- **Seafood**

Other High-Risk Foods

- Cheese (except hard cheese)
- Shell eggs
- Nut butters
- Ready-to-eat deli salads



Supply Chain Example: Produce



Who and What are Exempt?

Exempt Entities (Partial List)

Small produce farms with an average of \leq \$25,000 annual sales (previous 3-year period, adjusted for inflation)

Shell egg producers with $<$ 3000 laying hens at a particular farm

RAC producers (other than produce or eggs) with an average of \leq \$25,000 annual sales (previous 3-year period, adjusted for inflation using 2020 as baseline year)

Small retail and food establishments with average annual sales of \leq \$250,000 (rolling basis, adjusted for inflation using 2020 as the baseline year)

Transporters





Exempt Products (Partial List)

- **Food produced and packaged on a farm**, if packaging remains in place until the food reaches the consumer, when the labeling contains certain statements.
- **USDA regulated foods**
- **Raw bivalve molluscan shellfish** covered by the National Shellfish Sanitation Program or final equivalence determination
- **Certain commingled RAC** (partial exemption)
- **Produce that is on FDA's "rarely consumed raw" list** such as navy beans, collards, peanuts and squash.
- **Produce from farms sold or donated** directly to consumers

Exempt Due to Processing

Foods that you subject to a “kill step” (or receive after a kill step), defined as lethality processing that significantly minimizes pathogens in a food (must retain records or have written agreement)

Food that you change (or receive after a change) so that the food is no longer on the FTL (e.g., drying herbs, freezing vegetables; must maintain records)

Foods that will be subjected to a kill step or change in form by an entity other than RFE, restaurant, or consumer (requires written agreement)

Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance (e.g., thermally processed, acidified, HACCP)

Shell eggs subjected to a treatment described in 21 CFR 118.3



Mark Your Calendars

January 20, 2023

Rule became effective

January 20, 2026

Deadline for firms to be in compliance

What Should I Do Now?

Step 1

Determine if you manufacture, pack, process or hold any FTL foods

Visit FDA's FTL List for a comprehensive guide about foods that are subject to the rule:

<https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>

Step 2

Determine if any exemptions exist for your firm or your products

Visit FDA's Exemption Tool:

<https://collaboration.fda.gov/tefcv13/>

What Should I Do Now?

Step 3

Analyze your operations to determine which CTE will apply to you and which KDE you must keep

See FDA's requirements for each one

<https://www.fda.gov/media/163132/download>

Step 4

Determine which current records and codes will meet these KDE requirements and which ones will you need to obtain

Develop a process for creating sortable spreadsheet if requested by FDA

What Should I Do Now?

Step 5

Communicate with supply-chain partners and coordinate approaches to lot code assignments and record keeping

Ask trade organizations about any industry-wide approaches

Obtain any necessary written agreements (such as for a kill step)

Step 6

Investigate new technologies or strategies that might be necessary to help you comply, such as:

- Produce Traceability Initiative
<https://producetraceability.org/>
- FDA's New Era of Smarter Food Safety
<https://www.fda.gov/food/new-era-smarter-food-safety>

Questions?



registrarcorp.com

Phone: +1-757-224-0177

Fax: +1-757-224-0179

info@registrarcorp.com