



FSMA

Update

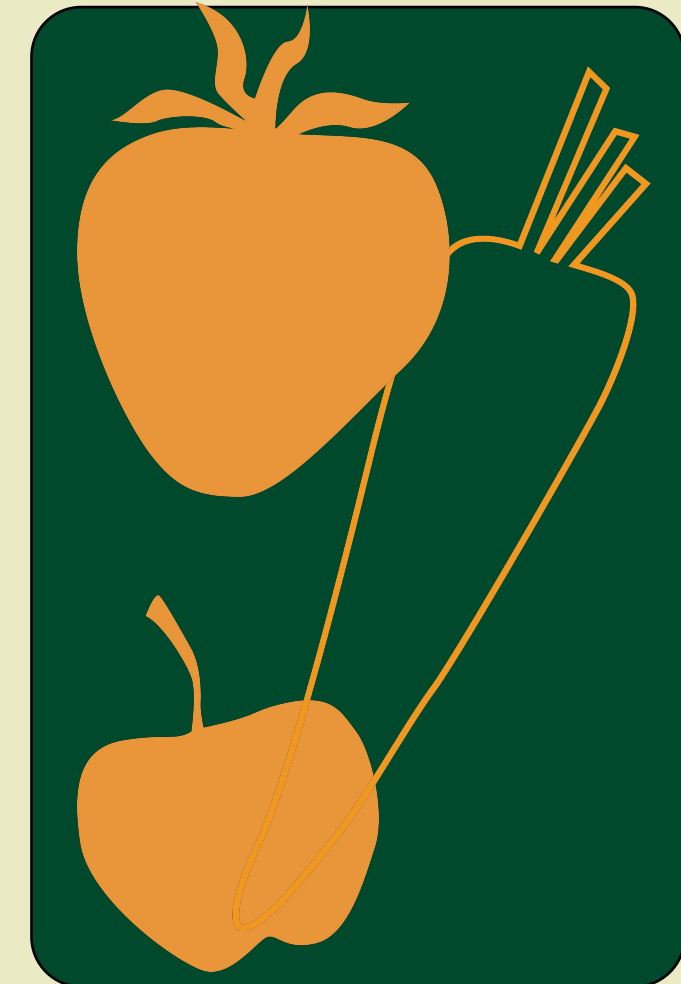
New England Vegetable and Fruit
Conference December 14, 2022

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UMassAmherst | Extension Agriculture Program



Agenda

	WHAT'S FSMA AGAIN?
	PROPOSED WATER RULE
	FINAL TRACEABILITY RULE
	INFLATION ADJUSTMENTS
	STAYING IN THE LOOP

What's FSMA Again?



- Food Safety Modernization Act
- Law passed by Congress in 2011
- Biggest amendment to the Food, Drug, and Cosmetic Act in 70 years
- Focuses on PREVENTION instead of just response
- Law gave FDA the authority to write rules
- There are several rules, covering the entire food system



What's FSMA Again?

- FSMA includes:

- Produce Safety Rule

- Preventive Controls for Human Food

- Preventive Controls for Animal Food

- Foreign Supplier Verification Programs

- Accreditation of Third-Party Auditors/Certification Bodies

- Sanitary Transportation of Human and Animal Food

- Food Traceability Rule

- Prevention of Intentional Contamination/Adulteration



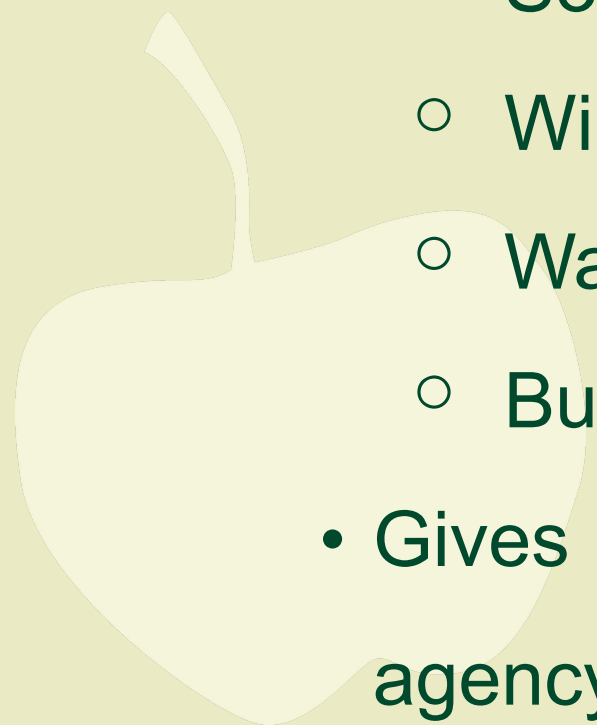
FDA FOOD SAFETY
MODERNIZATION ACT

What's FSMA Again?

•FSMA includes:

–Produce Safety Rule

- Raw agricultural commodities
- Concerned with microbial contamination, human pathogens
- Preventing contamination from:
 - Humans
 - Soil amendments
 - Wild and domestic animals
 - Water
 - Buildings, equipment, and tools
- Gives FDA authority to inspect farms (usually through state agency)

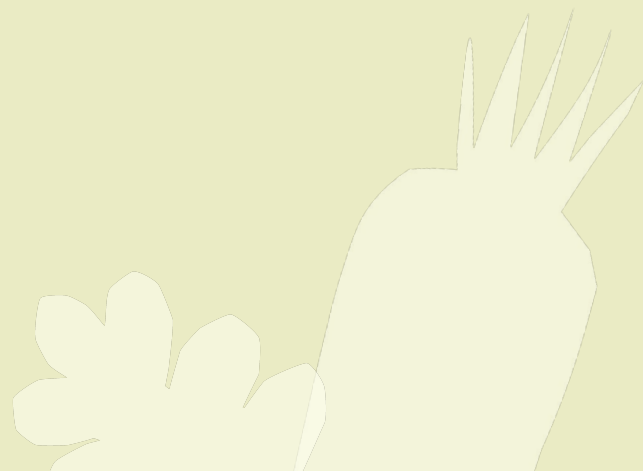


2 big changes

- Proposed Changes to WATER requirements



- New Final TRACEABILITY Rule



Subpart E - The Water Rule

§§ 112.40 – 112.50

All agricultural water must be safe and of adequate sanitary quality for its intended use.

- FDA released the proposed revisions to Subpart E on December 2, 2021
- Waiting for release of FINAL rule
- Shift from water testing as main metric for decision-making to an Agricultural Water Assessment (AgWA), looking at the whole system
- No set metric to meet, growers set standards appropriate for their own farms

Subpart E - The Water Rule

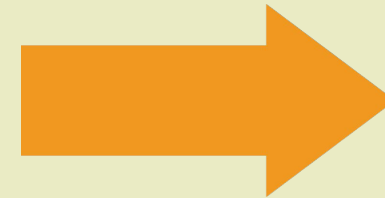
§§ 112.40 – 112.50

All agricultural water must be safe and of adequate sanitary quality for its intended use.

2015 Final

Rule

- Establish Microbial water quality profile (MWQP)
 - 20 tests for surface
 - 4 tests for ground
- Must meet standard:
 - GM 126 CFU/100 ml
 - STV 410 CFU/100 ml



2021 Proposed

Rule

- Written Agricultural Water Assessment
- Identify conditions reasonably likely to introduce hazards
- Implement mitigation measures if hazards related to animal activity

Change applies to pre-harvest water only

Subpart E - The Water Rule

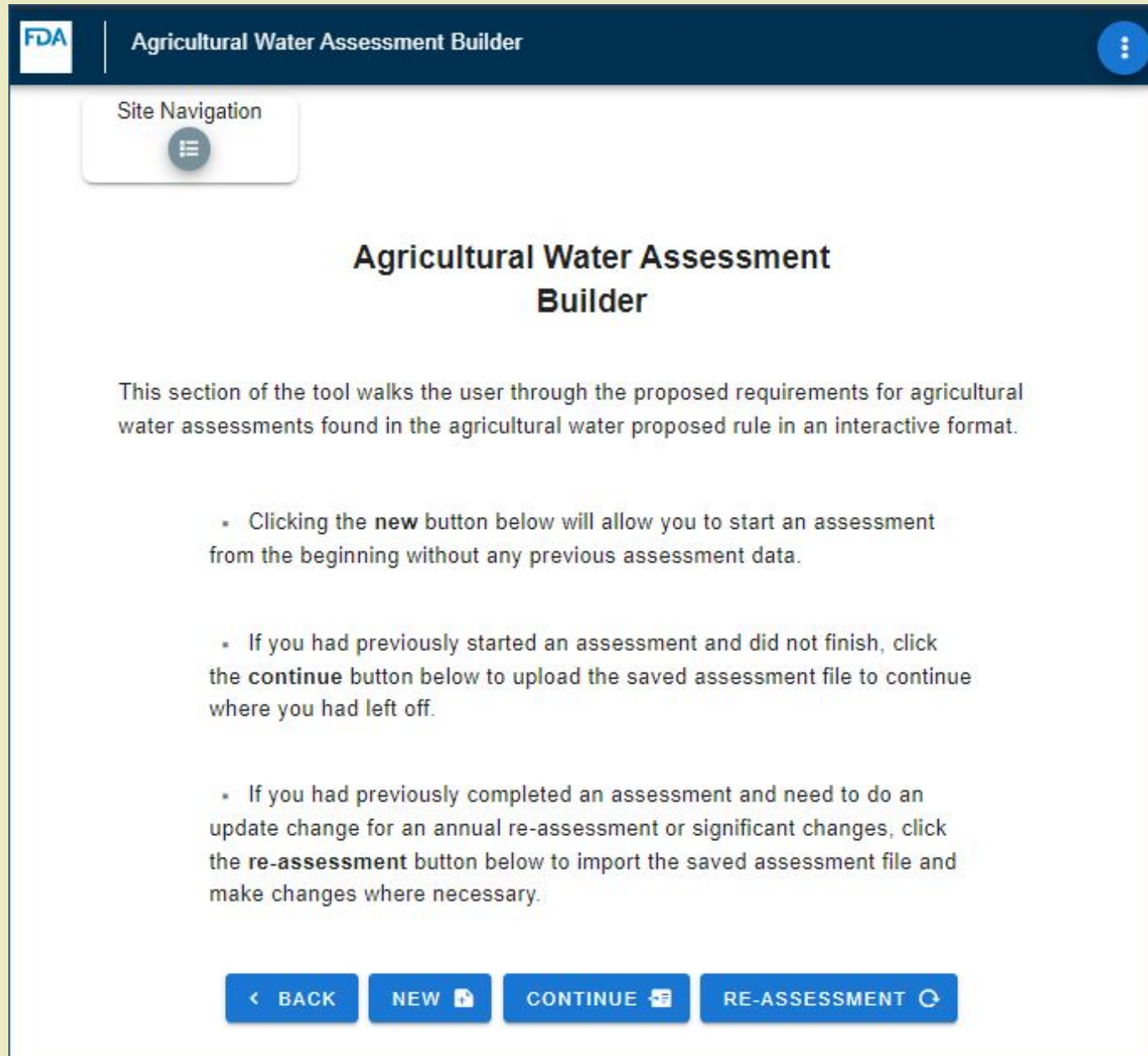
§§ 112.40 – 112.50

2021 Proposed Rule - Agricultural Water Assessment

Ag Water System	<ul style="list-style-type: none">• Source and location(surface, ground, municipal)• Water distribution system (open or closed)• Degree of protection (e.g., from other users, animals, and adjacent land uses)
Ag Water Practices	<ul style="list-style-type: none">• Type of application method (overhead, drip, furrow, flood)• Time interval between last direct application and harvest
Crop Characteristics	<ul style="list-style-type: none">• Susceptibility to surface adhesion or internalization
Environmental Conditions	<ul style="list-style-type: none">• Frequency of rain or extreme weather that might impact the agricultural water system or might damage produce• Air temperatures• Sun (UV) exposure
Other Factors	<ul style="list-style-type: none">• Includes results of water testing

Subpart E - The Water Rule

§§ 112.40 – 112.50



The screenshot shows the 'Agricultural Water Assessment Builder' web application. At the top left is the FDA logo and the title 'Agricultural Water Assessment Builder'. Below this is a 'Site Navigation' menu. The main heading is 'Agricultural Water Assessment Builder'. A paragraph explains that this section walks the user through proposed requirements for agricultural water assessments. Three bullet points provide instructions: 1) Clicking 'new' starts an assessment from the beginning. 2) Clicking 'continue' uploads a saved assessment file to resume. 3) Clicking 're-assessment' imports a saved file for updates. At the bottom are four buttons: 'BACK', 'NEW' (with a document icon), 'CONTINUE' (with a document icon), and 'RE-ASSESSMENT' (with a refresh icon).

- Use results of AgWA to determine
 - Corrective measures, e.g.:
 - re-inspect and make changes
 - Mitigation measures, e.g.:
 - make repairs
 - increase time interval
 - change application method
- Re-assess each year and when significant changes in practices or conditions

Subpart E - The Water Rule

§§ 112.40 – 112.50

No significant changes to post-harvest water requirements

- Cannot use untreated surface water
- Untreated ground water - test 4 or more times during the growing season or over the period of a year
 - 1 or more tests per year after initial year
- Public water supply - Copy of test results or current certificate of compliance

Subpart E - The Water Rule

§§ 112.40 – 112.50

FDA Enforcement and Compliance Dates for Agricultural Water Requirements

Enforcement dates for harvest and postharvest agricultural water requirements

- **January 26, 2023**, for all other businesses (>\$500K)
- January 26, 2024, for small businesses (<\$500K)
- January 26, 2025, for very small businesses (<\$250K)

Proposed compliance dates for pre-harvest agricultural water requirements

- 9 months after the effective date of a final rule for all other businesses;
- 1 year and 9 months after the effective date of a final rule for small businesses; and
- 2 years and 9 months after the effective date of a final rule for **very small businesses.**

Subpart E - The Water Rule

§§ 112.40 – 112.50

- Will be updated trainings
- PSA may require addendum training
- PSA will update current PSA GT curriculum to include major changes
- Also working on new outreach materials, including fact sheets and in-person, hands-on workshops to help growers perform an AgWA

Traceability Rule

21 CFR Part 1, Subpart
S

Requires persons who manufacture, process, pack, or hold certain foods to keep traceability records

- Final rule issued 11/21/22, effective January 20, 2023
- Compliance date in 3 years - January 20, 2026
- Applies to products on the Food Traceability List
- Faster product ID and removal
 - Prevent illnesses
 - Prevent food system disruptions

Traceability Rule

21 CFR Part 1, Subpart
S



Food Traceability List

Cheese (made from pasteurized milk), fresh soft or soft unripened

Cheese (made from pasteurized milk), soft ripened or semi-soft

Cheese (made from unpasteurized milk), other than hard cheese

Shell eggs

Nut butters

Cucumbers (fresh)

Herbs (fresh)

Leafy greens (fresh)

Leafy greens (fresh-cut)

Melons (fresh)

Peppers (fresh)

Sprouts (fresh)

Tomatoes (fresh)

Tropical tree fruits (fresh)

Fruits (fresh-cut)

Vegetables (fresh-cut)

Finfish (histamine-producing species) (fresh and frozen)

Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen)

Finfish, species not associated with histamine or ciguatoxin (fresh and frozen)

Smoked finfish (refrigerated and frozen)

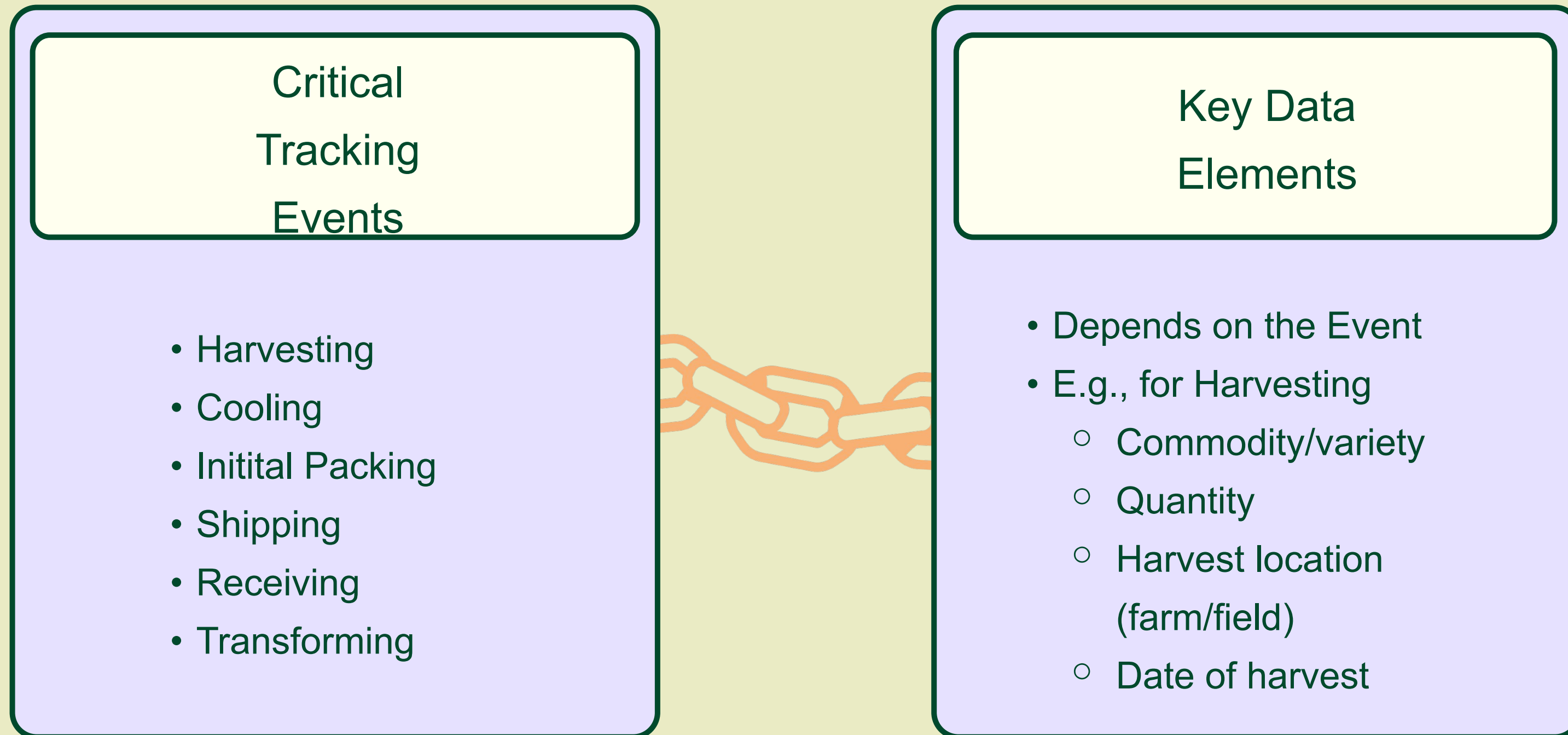
Crustaceans (fresh and frozen)

Molluscan shellfish, bivalves (fresh and frozen)

Ready-to-eat deli salads (refrigerated)

Traceability Rule

21 CFR Part 1, Subpart
S



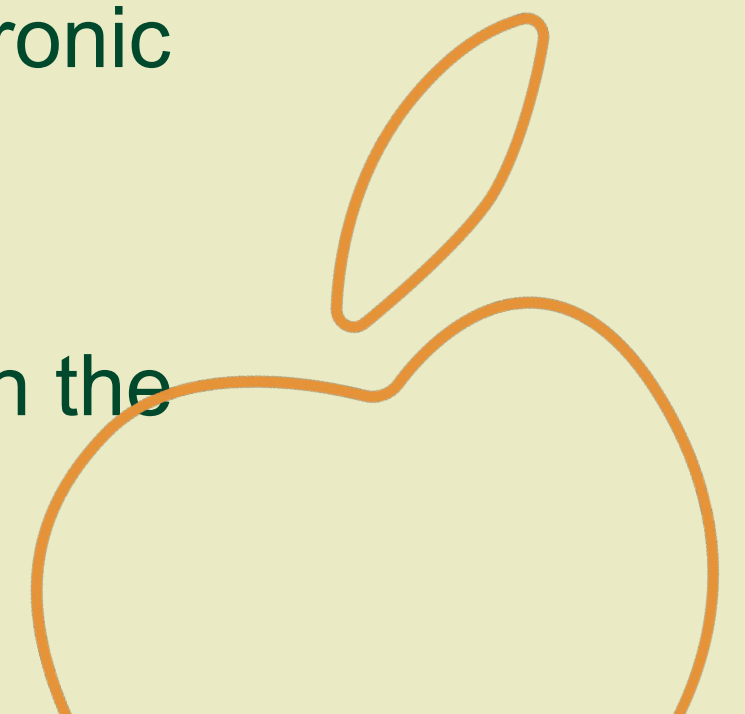
CTEs and KDEs are connected by a Traceability Lot Code

Traceability Rule

21 CFR Part 1, Subpart
S

Recordkeeping requirements

- Traceability plan
- Farm map (to field level)
- Traceability lot codes
- Electronic searchable spreadsheet
 - if annual sales under \$250,000, don't need to keep electronic spreadsheet
 - Still need to have information available for an inspector in the event of an outbreak investigation



Traceability Rule

21 CFR Part 1, Subpart
S

Exemptions include:

- Produce farms with average annual sales \leq \$25,000
- Food produced and packaged on the farm
 - Packaging must remain in place until the food reaches the consumer
 - Packaging must maintain integrity of the food and prevent subsequent contamination
 - Labeling that reaches the consumer must include farm name, address, and phone number
- Food sold directly to consumers by the farm

Traceability Rule

21 CFR Part 1, Subpart
S

Exemptions to the Food Traceability Rule

You are subject to the Food Traceability final rule, ***unless*** an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

Farms

Certain types of processing

Commingled raw agricultural commodities (RACs)

Personal consumption, holding food for specific consumers

Fishing vessels, molluscan shellfish

Other

Retail food establishments (RFEs), restaurants

FDA Exemptions Tool

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

FDA

Traceability Rule

21 CFR Part 1, Subpart
S

- Inspectors, educators need to get up to speed
- FDA - "educate before and while we regulate"
- Can ask questions/make comments to FDA
 - Contact Us/TAN
- FDA, PSA, Extension will provide trainings and tools

Inflation adjustments



Sales dollar exemptions are adjusted for inflation - PSR and Traceability Rules

- Produce Safety Rule - baseline year 2011

For Covered farm:

average 3-year value for 2018-2020: \$29,245

For Qualified Exemption:

Average 3-year value for 2018-2020: \$584,908

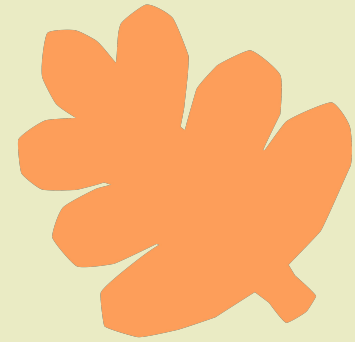
- Traceability Rule - baseline year 2020
- Recalculated annually ~April; Updated numbers on FDA's website
- If fully exempt from PSR, also exempt from Traceability

Summary

What should I do NOW??

- Test postharvest water (if using well water)
- Traceability - Check exemptions, start talking to supply chain partners, buyers
- Know your PSR exemption status (we have tools!)
 - Assume you're covered until you can prove that you're not
- Don't make any big preharvest water changes
 - run through assessment builder, take a test or two (generic E. coli)
 - Look at data collection tools re shared water sources
- Stay tuned, pay attention to Extension, Dept. of Ag, PSA, NECAFS news alerts re final water rule, upcoming trainings, etc

Resources



NECAFS

The Northeast Center to Advance Food Safety



SUBSCRIBE TO E-NEWSLETTER



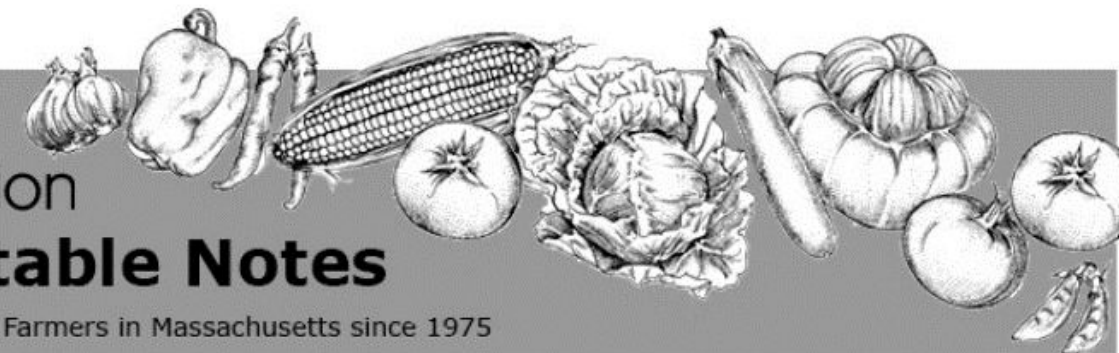
<https://www.uvm.edu/extension/necafs>

Produce Safety ALLIANCE

Sign up to receive the PSA newsletter

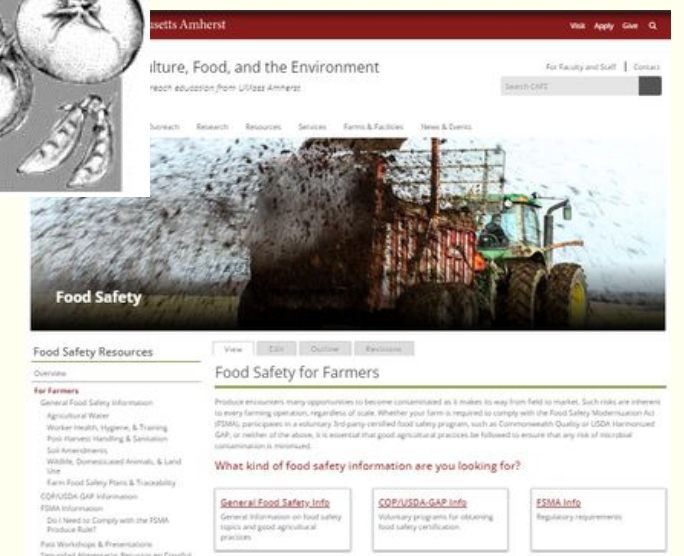
<https://cals.cornell.edu/produce-safety-alliance>

UMass Extension
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