Ed Treacy

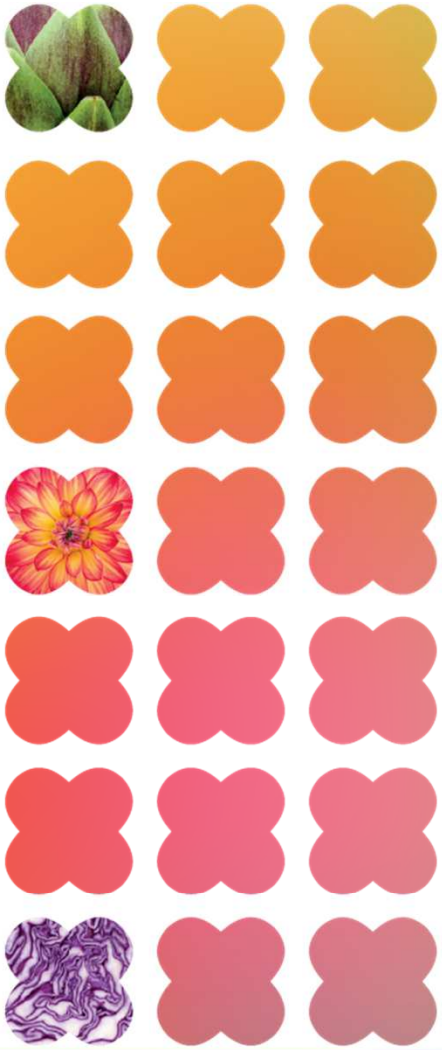
Vice President of Supply Chain and Sustainability

International Fresh Produce Association

FSMA 204 FINAL RULE

ARE YOU READY FOR FDA'S TRACEABILITY REQUIREMENTS?

June 8, 2023



FSMA 204

- US Food & Drug Administration (FDA) released the 597-page FSMA 204 Final Rule in November 2022.

70910 Federal Register / Vol. 87, No. 223 / Monday, November 21, 2022 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–AI44

Requirements for Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 20, 2023. For the applicable compliance dates, see section VI "Effective and Compliance Dates" in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this final rule, into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Katherine Vierk, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122, *Katherine.Vierk@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Rule

This final rule, which is part of FDA's implementation of FSMA (Pub. L. 111–353), establishes additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods for which the Agency has determined these additional requirements are appropriate and necessary to protect the public health in accordance with FSMA. These traceability recordkeeping requirements will help FDA rapidly and effectively identify recipients of such foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated or misbranded (with respect to allergen labeling) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination.

We are issuing this rule because Congress directed us, in FSMA, to establish recordkeeping requirements for foods we designate that would be additional to the existing traceability recordkeeping requirements in the FD&C Act and FDA regulations. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on an FTL, which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)

B. Summary of the Major Provisions of the Final Rule

The requirements of the final rule are focused on having persons who manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements) for certain critical tracking events (CTEs) in the handling of the food, consistent with the developing industry consensus approach to food tracing. The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through

FSMA 204

- US Food & Drug Administration (FDA) released the 597-page FSMA 204 Final Rule in November 2022.

- These regulations will be enforced starting on January 20, 2026.

70910 Federal Register / Vol. 87, No. 223 / Monday, November 21, 2022 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–AI44

Requirements for Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 20, 2023. For the applicable compliance dates, see section VI "Effective and Compliance Dates" in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this final rule, into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Katherine Vierk, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122, *Katherine.Vierk@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Rule

This final rule, which is part of FDA's implementation of FSMA (Pub. L. 111–353), establishes additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods for which the Agency has determined these additional requirements are appropriate and necessary to protect the public health in accordance with FSMA. These traceability recordkeeping requirements will help FDA rapidly and effectively identify recipients of such foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated or misbranded (with respect to allergen labeling) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination.

We are issuing this rule because Congress directed us, in FSMA, to establish recordkeeping requirements for foods we designate that would be additional to the existing traceability recordkeeping requirements in the FD&C Act and FDA regulations. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on an FTL, which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)

B. Summary of the Major Provisions of the Final Rule

The requirements of the final rule are focused on having persons who manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements) for certain critical tracking events (CTEs) in the handling of the food, consistent with the developing industry consensus approach to food tracing. The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through

FSMA 204

- US Food & Drug Administration (FDA) released the 597-page FSMA 204 Final Rule in November 2022.

- These regulations will be enforced starting on January 20, 2026.

- FSMA 204 applies to all fresh produce items on the Food Traceability List **(FTL),** including imported product from outside the US.

70910 Federal Register / Vol. 87, No. 223 / Monday, November 21, 2022 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–AI44

Requirements for Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 20, 2023. For the applicable compliance dates, see section VI "Effective and Compliance Dates" in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this final rule, into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Katherine Vierk, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122, *Katherine.Vierk@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Rule

This final rule, which is part of FDA's implementation of FSMA (Pub. L. 111–353), establishes additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods for which the Agency has determined these additional requirements are appropriate and necessary to protect the public health in accordance with FSMA. These traceability recordkeeping requirements will help FDA rapidly and effectively identify recipients of such foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated or misbranded (with respect to allergen labeling) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination.

We are issuing this rule because Congress directed us, in FSMA, to establish recordkeeping requirements for foods we designate that would be additional to the existing traceability recordkeeping requirements in the FD&C Act and FDA regulations. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on an FTL, which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)

B. Summary of the Major Provisions of the Final Rule

The requirements of the final rule are focused on having persons who manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements) for certain critical tracking events (CTEs) in the handling of the food, consistent with the developing industry consensus approach to food tracing. The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through

FSMA 204

- The implementation of FSMA 204 is expected to reduce traceback and trace-forward investigations from 5-6 weeks to 5-6 days

- Requires entities that Harvest, Cool, Pack, Transform, Ship and/or Receive food on the Food Traceability List, to establish and maintain records at these Critical Tracking Events **(CTE's)** containing certain information Key Data Elements **(KDE's)** and link that information a traceability lot code.

FSMA 204

- Final Rule applies to persons (not facilities) who manufacture, process, pack or hold foods that appear on the Food Traceability List **(FTL)** or foods that contain a listed food as an ingredient

Food Traceability List (FTL)

Produce Items		Non-Produce Items	
Cucumbers (fresh)	**Sprouts (fresh)**	Cheeses, other than hard cheeses	Finfish, including smoked fish (fresh and frozen)
Herbs (fresh	**Tomatoes (fresh)**	Shell eggs	Crustaceans (fresh and frozen)
Leafy greens (fresh), including fresh cut leafy greens	**Tropical tree fruits (fresh)**	Nut butter (does not include soy or seed butters)	Mollusks, bi-valves(fresh and frozen)
Melons (fresh)	**Fruits and vegetables (fresh cut)**		
Peppers (fresh)	**Ready to eat deli salads (refrigerated)**		

IFPA FSMA 204 Buyer Think Tank

- Common data and labeling requirements for all produce commodities
  - **Not just items on the FDA Food Traceability List**
- Establish minimum requirements of the rule
- Pilots to gather data to share with FDA on expectations
- Common communications with supply chain partners
- Develop milestones for implementation

Traceability Lot Codes (TLC)

- Traceability lot codes are central to the rule's operation.
- A traceability lot means a batch or lot of food that has been initially packed or transformed.
- Traceability lot codes can only be assigned at initial Packing or when the product is Transformed.

Traceability Lot Codes (TLC)

- At each Critical Tracking Event **(CTE),** entities are required to link the traceability lot code (GTIN and Lot) to the product.
  - Original Packing
  - Shipping
  - Transformation
  - Receiving

Traceability Lot Code Source

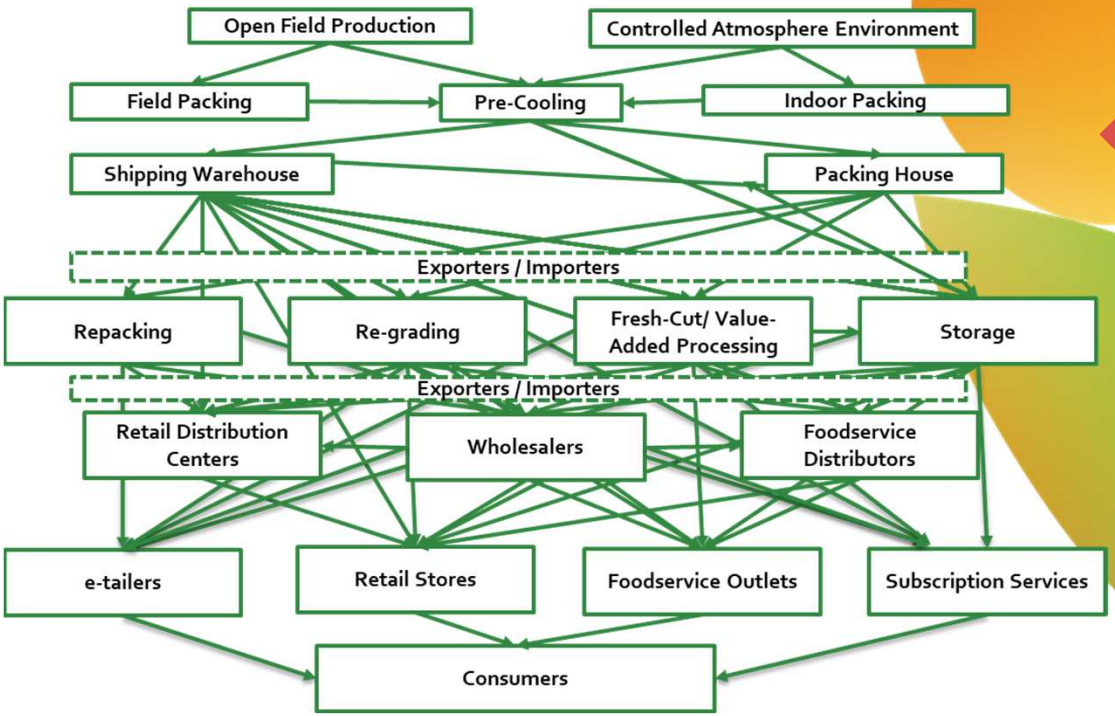
- The traceability lot code source is the place where a food was assigned a traceability lot code. It is the entity that assigned the lot code, not the person.
  - Name of Packing Facility or Ranch/Farm (field or greenhouse pack)
  - Address
  - Phone number

Traceability Lot Code Source

- The traceability lot code source must be exchanged between trading partners all the way to the store or restaurant.

Traceability Lot Code Source

- FDA will use this to contact the location the product was packed.



Traceability Lot Code Source Reference

- The traceability lot code source reference is an alternative method for providing FDA with access to the location description for the traceability lot code source.
  - FDA Food Facility Registration Number
  - GS1 Global Location Number (GLN)
  - A web address that provides FDA with the location description for the traceability lot code source for a specific lot.

What should all Packer/Shippers do?

- Implement Produce Traceability Initiative (PTI)
  https://www.producetraceability.org

- PTI will cover 90-95% of FSMA 204 requirements

- Use the PTI Harmonized Case Label

What all should Packer/Shippers do?

- Review PTI guidance documents being created for FSMA 204 implementation. ETA August 2023.

- Determine how you will accurately track and share the Traceability Lot Code (GTIN/lot) for each shipment.

- Determine if and how you will share Traceability Lot Code Source or Alternate TLC Source for every lot shipped.

What all should Packer/Shippers do?

- Determine the sources for data elements required in the electronic sortable spreadsheet.
- Update or create your Traceability Plan.
- Consider implementing electronic Advanced Shipment Notifications (ASN's)
- Pilot with your customers.

What should Packers do? FTL items only

- Determine how you will gather and store the pre-packing information
  - Harvest who/what/when/how much
  - Pre-cooling what/when/how much
  - Storage what/when/how much

What should Packers do? FTL items only

- Communicate to your growers and or harvesters they must share their data.
- Communicate to your cooling companies they must share their data.
- Communicate to your storage companies they must share their data.

What should Packers do? Non-FTL items

- Harvest, Cooling and Storage information collection and store is not required.

What should Retailers do?

What should Retailers do?

- Form a cross functional team. This is not a Produce project!
  - Store Operations
  - Distribution Management
  - Distribution Systems
  - Regulatory
  - Food Safety

What should Retailers do?

- Form a cross functional team. This is not a Produce project!
  - Store Operations
  - Distribution Management
  - Distribution Systems
  - Regulatory
  - Food Safety

- Update or create your Traceability Plan
  - D.C.'s
  - Stores

What should Retailers do?

- Communicate to your suppliers that they will have to adopt PTI.
  - FTL items
  - Non FTL items

What should Retailers do?

- Communicate to your suppliers that they will have to adopt PTI.
  - FTL items
  - Non FTL items

- Implement usage of electronic Advanced Shipment Notifications (ASNs) into your distribution centers.
  - FTL items
  - Non FTL items

What should Retailers do?

- Determine the sources for data elements required in the electronic sortable spreadsheet.

  At stores:

  - How will the stores be able to determine the list of items received that contain the FTL item being traced back by FDA?
  - How will the stores know who shipped them these items?
    - Corporate DC
    - Wholesaler
    - Direct to store (local programs)
    - Other (i.e. store to store transfer)

What should Retailers do?

- Determine the sources for data elements required in the electronic sortable spreadsheet.

  At your Distribution Centers:

  - Maintain a list of DC items for each commodity on the FTL list.
    - Whole
    - Fresh Cut
    - Prepacks (i.e. fresh shish kebob with peppers)
    - Other

What should Retailers do?

- Determine who will be responsible to create the electronic sortable spreadsheet when FDA asks for it within 24 hours.
  - At stores
  - At DC's

What should Retailers do?

- Determine who will be responsible to create the electronic sortable spreadsheet when FDA asks for it within 24 hours.
  - At stores
  - At DC's

- Plan on the FDA request coming at 4:30 PM on Friday afternoon.

What should Retailers do?

- Review PTI guidance documents being created for FSMA 204 implementation. ETA August 2023.

What should Retailers do?

- Review PTI guidance documents being created for FSMA 204 implementation. ETA August 2023.

- Pilot with your suppliers.

What should Retailers do?

- Review PTI guidance documents being created for FSMA 204 implementation. ETA August 2023.
- Pilot with your suppliers.
- Start yesterday, today is too late!

What should Retailers NOT do?

What should Retailers NOT do?

- Nothing.
  - FDA will revoke you FDA Facility Registration Number making it illegal for you to handle any fresh produce.

What should Retailers NOT do?

- Nothing.
  - FDA will revoke you FDA Facility Registration Number making it illegal for you to handle any fresh produce.
  - Make plans on running your stores and distribution centers without being able to handle or sell any Fresh Produce, not just FTL items.

What should Retailers NOT do?

- Nothing.
  - FDA will revoke you FDA Facility Registration Number making it illegal for you to handle any fresh produce.
  - Make plans on running your stores and distribution centers without being able to handle or sell any Fresh Produce, not just FTL items.
  - Find another job.

Questions?