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

<table>
<thead>
<tr>
<th>Produce Items</th>
<th>Non-Produce Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cucumbers (fresh)</td>
<td>Cheeses, other than hard cheeses</td>
</tr>
<tr>
<td>Sprouts (fresh)</td>
<td>Finfish, including smoked fish (fresh and frozen)</td>
</tr>
<tr>
<td>Herbs (fresh)</td>
<td>Shell eggs</td>
</tr>
<tr>
<td>Tomatoes (fresh)</td>
<td>Crustaceans (fresh and frozen)</td>
</tr>
<tr>
<td>Leafy greens (fresh), including fresh cut leafy greens</td>
<td>Nut butter (does not include soy or seed butters)</td>
</tr>
<tr>
<td>Tropical tree fruits (fresh)</td>
<td>Mollusks, bi-valves (fresh and frozen)</td>
</tr>
<tr>
<td>Melons (fresh)</td>
<td></td>
</tr>
<tr>
<td>Fruits and vegetables (fresh cut)</td>
<td></td>
</tr>
<tr>
<td>Peppers (fresh)</td>
<td>Ready to eat deli salads (refrigerated)</td>
</tr>
</tbody>
</table>
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.
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?
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- Form a cross functional team. This is not a Produce project!
  - Store Operations
  - Distribution Management
  - Distribution Systems
  - Regulatory
  - Food Safety
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• 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.
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• Pilot with your suppliers.
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• Pilot with your suppliers.

• Start yesterday, today is too late!
What should Retailers **NOT** do?
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• Nothing.
  – FDA will revoke your 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?